



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

Addressees at end.

16 October 2019

Dear colleague,

**UK EXIT FROM THE EUROPEAN UNION:
- SUPPLY OF MEDICINES, MEDICAL DEVICES AND CLINICAL CONSUMABLES
- MANAGEMENT OF SHORTAGES**

Purpose of letter

1. This letter explains preparations that have been made to address the risk that the UK leaves the EU on 31 October 2019 in the absence of a withdrawal agreement (a “no deal exit”), in relation to the supply of medicines, medical devices and clinical consumables.

MAIN POINTS OF ADVICE THAT ALL HEALTH AND SOCIAL CARE STAFF SHOULD FOLLOW:

Preparations have been made to reduce the risks of a “no deal” UK exit from the EU.

Pharmaceutical companies have increased their UK stock-holding of medicines. Medicines that cannot be stockpiled will be brought into the UK by air.

The NHS has increased stock-holdings of medical devices and clinical consumables in the National Distribution Centre, and will have access to dedicated shipment channels. NHS Boards will work with suppliers who deliver locally to seek to maintain supplies.

Medical supplies will be given priority for entry into the UK. Once in the UK they will be delivered in the same way as they are delivered now.

Members of the public, GPs, community pharmacies, hospitals and social care providers should not stockpile. Prescriptions should be issued as normal.

Shortages may occur, but the NHS will manage the situation and if necessary provide advice on suitable alternatives or other treatment options while supply is restored to normal levels. Advice will be issued to prescribers and pharmacists about any steps needed to respond to shortages.

Health and Social Care staff should use existing systems to report shortages.

Members of the public do not need to do anything new.



Medicines, medical devices and clinical consumables: supplier readiness

2. A “no deal” UK exit from the EU will require the UK and the EU to introduce new controls on the entry of goods from the EU into the UK. This will cause delays and very likely a slow-down in the flow of medicines and medical supplies into the UK, particularly in the busy ports of entry in the south east of England, where most imported supplies enter now.

3. Steps have therefore been taken to build stockholdings of medicines, medical devices and clinical consumables in the UK. Pharmaceutical companies supplying medicines that enter the UK from the EU have been asked to increase their UK stock holding to ensure a minimum of an additional six weeks’ of supply on top of normal levels. Reports from the UK Government and from companies suggest high levels of compliance with this request. The NHS, through National Procurement, has undertaken the same activity for supplies of medical devices and clinical consumables. Public Health England has built its stockholdings of vaccines on behalf of all the UK countries and seasonal flu vaccines, which are procured by NHS Scotland, have already been delivered and are being distributed across Scotland.

4. **Members of the public, GPs, community pharmacies, hospitals and social care providers should not stockpile.**

5. The UK Government is also making arrangements for alternative transport services to be in place if the UK leaves the EU in a “no deal” situation, and will give priority to supplies of “category 1 products”, which include medicines, medical devices and clinical consumables. The UK Government plans that these services, which will likely take the form of Roll-on Roll-off ferries, will be in place during October 2019. There is also planned to be a commercial “express freight” service that will be available to transport packages and pallets into the UK at short notice. The UK Government has further encouraged suppliers to ensure that they are ready for the new checks that will be in place at the UK Border.

6. **Once medical supplies have entered the UK, they will be delivered in the same way as they are now.**

7. Particular arrangements have been put in place by suppliers to transport into the UK by air items that cannot be stockpiled, including radioisotopes.

8. Controls have also been placed on the “parallel export” of specified medicines that are considered to be at risk of shortage. Parallel exporting is the practice of buying medicines already placed on the market in the UK in order to sell them in another country in the European Economic Area (EEA) where they are repackaged and re-labelled in accordance with the requirements of the importing country. Parallel exports can create, or exacerbate, shortages. The Medicines and Healthcare products Regulatory Agency (MHRA) will take steps to enforce these new controls. Further information on this and the list of medicines covered can be found at:

<https://www.gov.uk/government/publications/medicines-that-cannot-be-parallel-exported-from-the-uk>

Reporting and management of shortages: medicines

9. Shortages of some medicines are a regular occurrence in the NHS and there are well-established procedures in place to manage shortages.

National systems

10. The UK Government and the Devolved Administrations in Scotland, Wales and Northern Ireland are cooperating to detect, monitor and manage shortages. Supply is being monitored on a weekly cycle and issues that require attention are submitted to a **UK Medicines Shortages Response Group**. This group is clinically led on behalf of the Chief Pharmaceutical Officers and, when necessary, it commissions the Chief Medical Officers’ clinical advisory group to develop clinical advice to support the management of shortages.

11. A **Scottish Medicines Shortages Response Group** (MSRG) has also been convened and meets regularly. It involves the Scottish Government, NHS Boards, Community Pharmacy Scotland and a range of other organisations. The Scottish MSRG receives the same reports as the UK group and considers whether to adopt or adapt any UK level advice about shortages for circumstances in Scotland. It considers medicine shortages according to the classification shown at **Annex A**.

12. When necessary, the Scottish MSRG will authorise the issue of **Medicine Supply Alert Notices** (MSANs). These notices may be issued in relation to shortages at levels 2, 3 and 4. They will describe the nature of the supply issue, its priority level and expected duration and specific actions to be taken by prescribers and others. MSANs will be issued from the Scottish Government Pharmacy Policy team mail box PharmacyTeam@gov.scot and a log of MSANs will be maintained and is available via the National Services Scotland Practitioner Services website at: <https://nhsnss.org/services/practitioner/pharmacy/serious-shortage-protocol/>

13. MSANs for level 3 and 4 shortages will be issued to:

- Directors of Pharmacy;
- Medical Directors;
- Pharmacy Primary Care Leads;
- Medicines Information Pharmacists;
- Community Pharmacy Scotland;
- NHS National Procurement; and,
- The Scottish Prescribing Advisor Network.

MSANs for level 2 shortages will be issued only to Community Pharmacy Scotland and The Scottish Prescribing Advisor Network, reflecting an expectation that level 2 (and level 1) shortages will be managed through business as usual processes. We will keep this approach under review.

14. If you receive advice from the UK Government before you receive advice from the Scottish Government, **you should comply with UK Government advice that can be applied in Scotland unless and until it is replaced by Scottish Government advice.**

15. An MSAN may be supplemented by an individual **Serious Shortage Protocol (SSP)**. These protocols, which will be developed and authorised clinically, enable community pharmacists to amend prescriptions to dispense a different strength or formulation or alternative medicine in accordance with the protocol, rather than having to refer prescribing decisions back to the prescriber. These protocols will be time limited. Scottish secondary legislation enabling their use will be in place from 31 October 2019. Guidance about their operation will be issued soon.

Local systems

16. **Health and Social Care staff do not need to take any new steps to report or monitor shortages: they should use business as usual systems to report any shortages.**

17. Steps were taken during the summer of 2019 to update NHS guidance about the management of medicine shortages in primary and secondary care. Improvements have been made to surveillance, reporting, and communication systems. This guidance can be found at: <https://nhsnss.org/services/practitioner/pharmacy/serious-shortage-protocol/>

18. In primary care, shortages can be identified from various sources, including community pharmacies, GP practices, prescribing advisors and patients themselves.

19. Community pharmacists should report shortages to Community Pharmacy Scotland (CPS), who have updated their shortage reporting tool. In addition, CPS and the NHS have worked together to produce additional guidance on managing medicines shortages which sets out the processes and tools that pharmacy teams already have available in order to minimise any unnecessary additional

workload when managing shortages or dealing with a situation when the market price exceeds the reimbursement price. This is available at:

<https://www.cps.scot/media/2846/medicines-shortages-guidance-august-2019.pdf>.

20. GP practices should continue to report any shortages to their health board prescribing team. In secondary care, pharmacists should follow their health board policy for managing shortages. If appropriate, the shortage should be escalated to National Procurement, who will help resolve or escalate if there is evidence to suggest the shortage will have a significant impact.

Medicine shortages: public enquiries

21. Health Boards and others dealing with enquiries from the public about particular situations should use consistent language in offering advice. The introductory section to this letter provides the principal advice that should be issued to the public. Where enquiries are received in relation to medicines that are in shortage then the information included at **Annex B** should be issued, according to the level of seriousness of the shortage.

Management of shortages: medical devices and clinical consumables

22. NHS National Services Scotland (NSS) and the Scottish Government have made contingency plans for continued supply of medical devices and clinical consumables. This involves Scotland participating 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. All Health Boards through their Heads of Procurement have been engaging local suppliers and understanding supply routes.

23. In the event of a no deal exit, Health Boards, Primary Care providers and Social Care providers should 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 use shortage response forms to contact a triage centre being established by NSS, who will firstly attempt to resolve the supply issue within Scotland and consider the shortage according to the classification shown in **Annex C**. If necessary, according to the classification system, the triage centre will then escalate the issue to the UK-wide NSDR.

24. Health Boards and others dealing with enquiries from the public about particular situations should use consistent language in offering advice. The introductory section to this letter provides the principal advice that should be issued to the public. Where enquiries are received in relation to medical devices and clinical consumables that are in shortage then the information included at **Annex D** should be issued, according to the level of seriousness of the shortage.

We hope this information is helpful.



Dr Catherine Calderwood

Chief Medical Officer



Dr Rose Marie Parr

Chief Pharmaceutical Officer

Addressees

Chief Executives of NHS Boards
NHS Board Medical Directors
NHS Board Directors of Pharmacy
NHS Board Primary Care Lead Officers
Chief Officers of Integration Authorities
Community Pharmacy Scotland
Scottish General Practice Committee
Royal College of General Practitioners
Chair of the National Out of Hours Operations Group
Convention of Scottish Local Authorities
Health and Social Care Alliance



CLASSIFICATION OF MEDICINE SHORTAGES

LEVEL	DESCRIPTION	POTENTIAL RESPONSES
Level one (low impact)	Supply problem with a short duration (up to one month) where <u>immediately available measures are expected to be sufficient</u> and there is minimal additional management requirement.	Business as usual. Response likely to involve using the same medicine. <ul style="list-style-type: none"> Alternative strength/formulation available to meet demand, potentially from other suppliers.
Level two (medium impact)	Supply problem where <u>alternatives in the same therapeutic class are available but which may require some management such as switching to those alternatives</u> , which may include unlicensed medicines.	Business as usual. Response not likely to require a change in the class of medicine. <ul style="list-style-type: none"> Alternative strength/formulation available but clinical advice is required to help manage the switch. Alternative medicine in the same therapeutic class. Unlicensed alternatives may be used. Issuing a Medicine Supply Alert Notice.
Level three (high impact)	Supply problems where there are <u>limited or no alternatives in the same therapeutic class and which require significant management</u> , potentially including changes in clinical practice or operational direction or that have patient safety implications. Level three shortages also include level two shortages for medicines used in <u>life saving conditions</u> such as anaphylaxis or involving <u>patient groups considered as vulnerable</u> , such as neonates, paediatrics or people with learning disabilities.	Serious shortage situation. Response likely to require a change in the class of medicine. <ul style="list-style-type: none"> Alternative therapeutic class of medicine available. The use of a 'serious shortage protocol'. Additional clinical advice. Exceptional MHRA regulatory measures. Issuing a Medicine Supply Alert Notice.
Level four (critical impact)	Supply problems where there is <u>no viable therapeutic alternative</u> and where responses may also require support from outside the health system and / or which trigger the use of national resilience structures.	Very serious shortage situation. Wider burden on NHS and public sector. <ul style="list-style-type: none"> Non-medicine support provided to patients. National Resilience procedures potentially activated – including links with agencies outside NHS. Additional project management or communications support may be required. Issuing a Medicine Supply Alert Notice.

STANDARD RESPONSES TO ENQUIRIES ABOUT MEDICINE SHORTAGES

Level one

There is currently a short term issue with the supply of the medicine XXXXXX. This means that patients taking this medicine may need to be given a different strength or formulation of this medicine until the supply issue is resolved. Patients affected will be advised by their community pharmacist when they collect their prescription.

Level two

There is currently a short term issue with the supply of the medicine XXXXXX. This means that patients taking this medicine may need to be changed to a similar medicine until the supply issue is resolved. Patients affected will be advised by their doctor or community pharmacist about the change when they collect their prescription.

Level three

There is currently a supply problem with XXXXXX. This means that patients taking this medicine may need to be changed to a different medicine for a period of time or may require a change to how their condition is managed until the supply issue is resolved. Patients affected will be advised by their doctor or community pharmacist about the change when they collect their prescription.

Level four

There is a supply problem with XXXXXX. This means that patients taking this medicine will require a change to how their condition is managed. Patients affected will be contacted by their doctor about the change.

CLASSIFICATION OF MEDICAL DEVICE AND CLINICAL CONSUMABLES SHORTAGES

LEVEL	DESCRIPTION	POTENTIAL RESPONSES
Level one (low impact)	Supply problem with a short duration (up to one month) where <u>immediately available measures are expected to be sufficient</u> and there is minimal additional management requirement.	Business as usual. Response likely to involve a sharing of product within the relevant sectors. (boards or social care providers)
Level two (medium impact)	Supply problem <u>where supply from the primary supplier is not available but supply of the same product is available from another supplier but h may require some management</u> such as switching to those alternatives.	Business as usual. Response may require ordering system updates via catalogue changes. Needs management when reverting back .
Level three (high impact)	Supply problems where there are <u>limited or no alternatives in the same product category and an alternate would require significant management</u> , potentially including changes in clinical practice or operational direction or that have patient safety implications. Level three shortages also include level two shortages for medicines used in <u>life saving conditions</u> or involving <u>patient groups considered as vulnerable</u> .	Serious shortage situation. Response likely to require a change in the product type or treatment and require clinical acceptance / approval. This could be temporary or longer term. Potentially escalated to NSDR depending on clinical guidance.
Level four (critical impact)	Supply problems where there is <u>no viable clinical alternative</u> and where responses may also require support from outside the health system and / or which trigger the use of national resilience structures.	Very serious shortage situation. Wider burden on NHS and public sector. National Resilience procedures likely to be activated – including links with agencies outside NHS. Additional project management or communications support may be required. Escalated to NSDR.

STANDARD RESPONSES TO ENQUIRIES ABOUT MEDICAL DEVICES AND CLINICAL CONSUMABLE SHORTAGES

Level one

There is currently a short term issue with the supply of the product XXXXXX. This means that medical staff may need to prioritise patients / procedures to protect the supply until resolved. The board procurement staff can also attempt to request supply share from other boards to fill the supply gap until shortage is resolved.

Level two

There is currently a short term issue with the supply of the product XXXXXX. There is a potential for alternative supply which is compatible to be used in place. This may require a medical or patient procedures to be adjusted until the original supply shortage is resolved. A catalogue change will be required to manage the temporary change.

Level three

There is currently a supply problem with product XXXXXX. This means that medical and patient procedures may need to be delayed, prioritised or changed to accommodate a similar but not identical product. This substitution would require clinical acceptance and may also require other product to ensure compatibility during the period that the until the primary supply shortage is resolved. This could be further hindered by severe cold spell and high snow fall causing reduced transportation to aid supply recovery. A catalogue change will be required to manage the temporary change.

Level four

There is a supply problem with XXXXXX. There is no alternative product or supplier available. This means that medical and patient procedures would be delayed, cancelled or require prioritisation. This could be further exacerbated by seasonal flu epidemic driving increased admissions and reduced discharges.