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The Scottish Government
Riaghaltas na h-Alba

To: Chief Executives, NHS Boards
Medical Directors, NHS Board
Directors of Pharmacy, NHS Board
CC: Community Pharmacy Scotland
Scottish General Practice Committee
Royal College of General Practitioners
Royal Pharmaceutical Society
Chair of the National Out of Hours Operations Group
Health and Social Care Alliance

Action: **Please cascade to:**
GP practices
Community pharmacy contractors

17 December 2020

Dear colleague,

END OF THE EU TRANSITION PERIOD: SUPPLY OF MEDICINES, MEDICAL DEVICES AND CLINICAL CONSUMABLES

Purpose of letter

1. This letter sets out our preparations to maintain the supply of medicines, medical device and clinical consumables after the end of the EU Transition Period on the 31 December 2020.

MAIN POINTS OF ADVICE:

Preparations have been made to reduce the risks to the supply of medicines, medical devices and clinical consumables at the end of the EU Transition Period.

Pharmaceutical companies have increased their UK stock-holding of medicines and any medicines that cannot be stockpiled will be brought into the UK via a UK Government secured freight services.

The NHS has increased stock-holdings of medical devices and clinical consumables in the National Distribution Centre, for their products, and will have access to the UK's National Supply Disruption Response (NSDR) service. NHS Boards are working with suppliers who deliver locally to seek to maintain supplies.

Medicines and other medical supplies will be given priority for entry into the UK as 'category 1' goods. Once in the UK, the medicines be delivered in the same way as they are delivered now. The delivery of other medical supplies is currently being reviewed.

GP practices, community pharmacies, hospitals, social care providers and members of the public should not stockpile.

Prescriptions should be issued as normal.

Shortages are a regular occurrence and the NHS has strengthened the systems used to manage the situation.

If and when necessary we will provide advice on suitable alternatives or other treatment options during any shortages. 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 or different.

Medicines, medical devices and clinical consumables: supplier readiness

2. The end of the EU Transition Period will require the UK and the EU to introduce new controls on the entry of goods from the EU into the UK and vice versa. 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 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 UK soil on top of normal buffer levels.

4. Reports from the UK Government and from pharmaceutical companies suggest high levels of compliance with this request. The NHS, through National Procurement, has undertaken the same review for supplies in the National Distribution Centre. NHS Boards are working with their supplies to gain assurance on supplies.

5. **Members of the public, GPs, community pharmacies, hospitals and social care providers should not stockpile medicines, medical devices and clinical consumables.**

A multi-layered approach

6. As well as asking pharmaceutical companies and suppliers to increase their UK stockholding of medicines by a further six weeks stock over and above normal buffer stocks on UK soil, the UK Government has encouraged suppliers to re-route supply chains away from the short strait Channel crossings into Dover and Folkestone, including by registering and using Government procured services.

7. The UK Government has put in place arrangements for alternative Government secured transport services which will give priority to supplies of 'category 1' products, which include medicines, medical devices and clinical consumables. There is also a commercial back-up "express freight" service that will available to transport packages and pallets into the UK at short notice.

8. The UK Government has asked suppliers to ensure that they are ready for the new checks that will be in place at the UK Border.

9. **Once medicines have entered the UK, they will be delivered in the same way as they are now.**

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

Additional arrangements

11. 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. Whilst parallel exports can allow wholesalers to take advantage of currency fluctuations they 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 here.

Reporting and management of shortages: medicines

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

National systems

13. The UK Government and the Devolved Administrations in Scotland, Wales and Northern Ireland are cooperating to identify, monitor and manage shortages. Supply is being monitored on a weekly basis and issues that require attention are submitted to a UK Medicines Shortages Response Group (MSRG UK). This group is clinically led on behalf of the Chief Pharmaceutical Officers and, when necessary, it commissions clinical advice to support the management of shortages.

14. A Scottish Medicines Shortages Response Group (MSRG) considers and adapts UK-wide measures designed to mitigate any shortages that occur. A rapid review of how the medicines shortage(s) response is working in Scotland has been undertaken to ensure all the escalation and communication routes are working effectively.

15. To further support the mitigation of medicine shortages, IT reporting systems have been rolled out in hospital pharmacy departments across Scotland, initially for a period of 12 months. These systems will ensure that real-time data on both medicines stockholding and stock usage in hospitals can be captured and utilised to inform mitigating actions and procurement related distribution decisions in the event of disruption to the medicine supply chain.

16. 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. These notices will describe the nature of the supply issue, its priority level and expected duration and specific actions to be taken by prescribers and others. **Annex A** describes the

17. 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 here.

18. An MSAN may be supplemented by an individual **Serious Shortage Protocol (SSP)**. These protocols, will be developed and authorised clinically, and 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 has been in place since 31 October 2019. A review of the existing guidance about their operation is underway and will be issued soon.

Local systems

19. **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.**

20. NHS guidance on the management of medicine shortages in primary and secondary care can be found here.

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

22. Community pharmacists should report shortages to Community Pharmacy Scotland (CPS) using 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 here.

23. GP practices should continue to report any shortages to their health board prescribing team.

24. 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

25. 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.

Regulation

26. The UK Government is making sure that medicines, medical devices and clinical trials licensed or tested in the EU can continue to be imported and used in the UK by amending regulations. The Medicines and Healthcare products Regulatory Agency (MHRA) has published guidance for the end of the transition period and will continue to publish guidance post transition.

27. The EU Falsified Medicines Directive 2011/62/EU (FMD) was published to prevent the increasing risk that falsified medicines would enter the legal supply chain and reach patients. However, as of 1 January 2021, pharmacies in Great Britain (as well as wholesalers, hospitals and others handling or supplying medicines) will no longer be able to access the EU-based systems necessary to verify and decommission medicines. Please see the update and guidance provided by the UK FMD Working Group for Community Pharmacy, which also applies to hospital pharmacy. This includes some next steps that you and colleagues may need to take regarding local pharmacy systems and disconnecting them from the FMD systems.

Management of shortages: medical devices and clinical consumables

28. 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. NHS 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.

29. In the event of a no deal end of the Transition Period, Health Boards, Primary Care 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 NHS NSS for medical devices and clinical consumables 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 their current processes through their primary contacts to engage with the health triage centre being established by NHS 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.

30. 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.

Communications

31. To complement the actions taken, a public information campaign will run from week commencing 18 December 2020 for four weeks to answer concerns the public may have surrounding the wider consequences of EU Exit. The campaign will contain messaging to reassure the public that steps have been taken to ensure the continued provision of medicines and to encourage them to order prescriptions and access services as normal. The campaign will run over press, radio and digital advertising and will signpost to mygov.scot/EUExit where further information can be found.

32. We hope this information is useful in allowing you to understand the work underway and any actions you may need to take. Thank you in advance for your continued support and work on these important issues.

Dr Gregor Smith
Interim Chief Medical Officer

Alison Strath
Interim Chief Pharmaceutical Officer

Annex A

CLASSIFICATION OF MEDICINE SHORTAGES

LEVEL	DESCRIPTION	POTENTIAL RESPONSES
Level one (low impact)	Supply problem with a short duration **(up to one month**) where immediately available measures are expected to be sufficient and there is minimal additional management requirement.	Business as usual. Response likely to involve using the same medicine. • Alternative strength/formulation available to meet demand, potentially from other suppliers.
Level two (medium impact)	Supply problem where alternatives in the same therapeutic class are available but which may require some management such as switching to those alternatives, which may include unlicensed medicines.	Business as usual. Response not likely to require a change in the class of medicine. • 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 limited or no alternatives in the same therapeutic class and which require significant management, 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 life saving conditions such as anaphylaxis or involving patient groups considered as vulnerable, such as neonates, paediatrics or people with learning disabilities.	Serious shortage situation. Response likely to require a change in the class of medicine. • 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 no viable therapeutic alternative 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. • 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.

Annex B

STANDARD RESPONSES TO ENQUIRIES ABOUT MEDICINE SHORTAGES

1. 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.

2. 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.

3. 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.

4. 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.

Annex C

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 immediately available measures are expected to be sufficient 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 where supply from the primary supplier is not available but supply of the same product is available from another supplier but may require some management 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 limited or no alternatives in the same product category and an alternate would require significant management, potentially including changes in clinical practice or operational direction or that have patient safety implications.	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 no viable clinical alternative 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

1. 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.

2. 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. NDC catalogue change request will still be required to manage any change of supply even for a temporary change.

3. 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 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. NDC catalogue change request will still be required to manage any change of supply even for a temporary change.

4. 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.