

Policy for Managing Medicines Shortages in Primary and Secondary Care

1. Purpose

This policy is to ensure adherence to national best practice standards in managing medicine shortages to minimise impact on patients and NHS Fife.

2. Scope

This policy applies to all medicine shortages in Primary and Secondary Care which have the potential to create significant risk to patients.

3. References

- 3.1 NHS Scotland Best Practice Standards for Managing Medicine Shortages in Primary Care in Scotland
- 3.2 [NHS Scotland Best Practice Standards for Managing Medicine Shortages in Secondary Care in Scotland](#)

4. Definitions

- 4.1 Medicine Shortage - the total supply of an authorised medicine is inadequate to meet the current or projected demand at the patient level.
- 4.2 MSRG (SCO) - Medicines Shortage Response Group Scotland
- 4.3 MSANs - Medicine Shortage Alert Notices
- 4.4 MSNs - Medicine Supply Notifications
- 4.5 DHSC - Department of Health and Social Care
- 4.6 NP - National Procurement (National Services Scotland)
- 4.7 PSD - Purchasing, Storage and Distribution
- 4.8 FAF3 - Formulary Application Form for Unlicensed medicines/off label medicines
- 4.9 ERFC - East Region Formulary Committee
- 4.10 MSDTC - Managed Service Drug and Therapeutics Committee

5. Policy

- 5.1 The Best Practice Standards for Managing Medicines Shortages in Primary and Secondary Care must be followed within NHS Fife.
- 5.2 Pharmacy and Medicines Directorate must ensure sufficient stocks of appropriate medicines available for all patients. Pharmacy professionals should ensure that no action is taken which could exacerbate a medicines shortage within the wider NHS, for example issuing prescriptions for larger quantities or more prescriptions than normal, stockpiling medicines or ordering more stock than required to meet normal demand.
- 5.3 The Roles and Responsibilities ([Appendix 1](#)) are defined for Pharmacy, Medical Staff and Nursing.
- 5.4 Medicine shortages are identified through various channels of information, e.g. MSRG (SCO), Procurement Team, Community Pharmacy, NHS personnel, DHSC, National Procurement, Specialist Pharmacy Service (SPS), Industry, Wholesalers and Patients. All critical shortages must be escalated to NP and MSRG (SCO).
- 5.5 Once a shortage is identified a holding statement will be issued to all stakeholders informing them that local guidance is being produced and will be circulated once approved.
- 5.6 MSNs/MSANs for level 2 shortages ([Appendix 2](#)) will be managed through business-as-usual processes.
- 5.7 MSNs/MSANs for level 3 and 4 shortages ([Appendix 2](#)) will be issued through the Drug Alert cascade (SOP MM1 Dissemination of Scottish Government Medicines Directives (Drug Alerts, Drug Safety Information & Immediate / Urgent messages).
- 5.8 The Medicines Management Team (MMT) will communicate medicine shortage information to Primary and Secondary care Clinicians, Pharmacists, Nurses and AHP's following the processes laid out in the Medicines Shortages Communication checklist. ([Appendix 4](#)).
- Governance – Local guidance produced must be approved by MSDTC (Chair or Vice Chair) for approval prior to circulation. [If either Chair or Vice Chair is unavailable then approval from a Head of Pharmacy as an alternative].
- 5.9 A risk assessment should be completed for each medicine shortage by the MMT team.
- 5.10 The medicine shortage should be communicated to relevant personnel and via the appropriate routes as per ([Appendix 4](#)).

NHS Fife Director of Pharmacy and Medicines, Chief Pharmacist and Controlled Drugs Accountable Officer

Appendix 1

ROLES AND RESPONSIBILITIES

Pharmacy and Medicines Directorate

Director of Pharmacy and Medicines

Responsible for

- The overall management of medicine shortages within NHS Fife.
- Agreeing to adhere to the principles of the Best Practice Standards for Managing Medicine Shortages in Primary and Secondary Care.
- Ensuring dissemination of decisions of MSRG (SCO) and connected information to the Head of Pharmacy Medicines Supply & Quality and the Medicines Management Team.
- Ensuring level 2, 3 and 4 shortages are reported to MSRG (SCO) and NP.
- Ensuring all medicine shortages are resolved satisfactorily and any impact on patient care minimised.

Head of Pharmacy Medicines Supply & Quality

Responsible for

- Approving the use of an unlicensed medicine once a Risk Assessment and Unlicensed medicine request or FAF3 has been completed and approved by the East Region Formulary Committee.

Medicines Supply Chain Manager

Responsible for

- Acute Pharmacy team adhering to the principles of the Best Practice Standards for Managing Medicine Shortages in Secondary Care.
- Ensuring all medicine shortages are documented appropriately.
- Ensuring that no action is taken that would exacerbate a medicines shortage within the wider NHS, for example stockpiling of medicines or ordering more stock than required to meet normal demand.
- Forming and chairing a Medicine Shortage Problem Assessment Group when required in conjunction with the relevant Lead Clinical Pharmacist.

Specialist Pharmacy Technician Purchasing & Homecare

Responsible for

- Approving alternative brand/generic from suppliers.
- Local management of available stock including restricted supplies, alternative and homecare products.
- Identifying options to mitigate the effects of a medicine shortage along with the

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Clinical Pharmacist e.g. restricting stock for critical areas, sourcing an alternative medicine.

- Sourcing alternative medicines including risk assessing any alternatives and completion of the appropriate form(s) required for governance purposes, e.g. unlicensed medicine form. Co-ordinating with clinical colleagues as appropriate.
- Escalating severe and/or potential serious medicine shortages to the Director of Pharmacy and Medicines and NP for escalation to the MSRG (SCO) and DHSC.
- Updating and maintaining the Secondary Care Medicine Shortage Bulletin.
- Approving any changes to the medicine shortage log.
- Participating in all Shortage Problem Assessment Groups.

Lead Pharmacist - Medicines Utilisation & Therapeutics

Responsible for

- Forming and appointing chair of the Shortage Problem Assessment Group (PAG) along with the Medicines Supply Chain Manager.

Hospital Senior Clinical Pharmacist(s)

Responsible for

- Identifying options to mitigate the effects of a medicine shortage along with the Specialist Pharmacy Technician Purchasing & Homecare e.g. restricting stock for critical areas, sourcing an alternative medicine.
- Approving and signing of the Risk Assessment for any licensed medicine alternative.
- Discussing and communicating with medical staff the changes required.
- Completing an unlicensed or FAF3 along with medical staff.
- Completing and approving the Secondary Care Medicine Shortage Bulletin.
- Communicating with patients and their carer's as appropriate, Healthcare Professionals and any other relevant persons, e.g. finance information relating to medicine shortages and the potential impact.

Hospital Clinical Pharmacist/Pharmacy Technician

Responsible for

- Communicating with nursing and medical staff when a medicine is not available within 24 hours. Liaising with PSD for alternatives.

Dispensary/Aseptic Staff

Responsible for

- Highlighting any medicines that are not available within 24 hours to Clinical Pharmacist/Pharmacy Technician.

Purchasing Team

Responsible for

- Completing order chasing report on a weekly basis.
- Highlighting out of stock medicines from suppliers to Specialist Pharmacy Technician Purchasing & Homecare. Sourcing alternative brand/generic from suppliers.
- Highlighting any medicines that are not available with-in 24 hours that are on follow to Dispensary, Aseptic or Clinical Pharmacist/Pharmacy Technician, Specialist Pharmacy Technician Purchasing & Homecare and Specialist Pharmacy Technician Medicines Storage & Distribution.
- Updating medicine shortage spreadsheet.
- Escalating medicine shortage to NP via Knowledge Hub.
- Managing the off contract claim process in relation to medicines unavailable and currently listed on a national contract/framework.
- Adding and removing F2 notes on the pharmacy computer system.

Medicines Management Team

Responsible for

- Medicines Management Team will undertake the initial risk assessment.
- Informing the Director of Pharmacy and Medicines of severe and/or potentially serious medicine shortages for onward cascade to MSRG (SCO) and DHSC.
- Identifying options to mitigate the effects of a medicine shortage liaising with Acute Pharmacy colleagues, Consultants, and other relevant stakeholders.
- Communicating medicine shortage information affecting primary care to the Primary Care Pharmacy Teams, General Practices and Community Pharmacies.
- For Level 3 and Level 4 shortages, convene a Pharmacy & Medicines Directorate Medicine Shortage PAG to ensure actions to mitigate the effects of a medicine shortage are taken forward.
- Participating in Medicine Shortage PAGs.
- Requesting changes to the East Region Formulary (ERF) where required because of a medicine shortage.

Primary Care Pharmacy Team

Responsible for

- Adhering to the principles of the Best Practice Standards for Managing Medicine Shortages in Primary Care.
- Investigating reports of medicine shortages by liaising with community pharmacies to ensure the Medicine Shortages in Community Pharmacy: Quick Reference Guide is followed ([Appendix 3](#)).
- Supporting General Practice in managing medicine shortages.
- Utilising information on the SPS Medicines Supply Tool to manage the effects of a

- medicine shortage and minimise the impact on patients and General Practice.
- Reporting new medicine shortages to the MMT.

NHS Fife Medical Staff

Responsible for

- Discussing and approving with the clinical pharmacist changes required for prescribing and alternative licensed medicine.
- Completing an unlicensed medicine request or FAF3 along with clinical pharmacist if only option is purchasing an unlicensed medicine.
- Communicating with colleagues, medics, nursing, patients, and their carers' as appropriate.
- Participating in Medicine Shortage Problem Assessment Groups.

NHS Fife Nursing Staff

Responsible for

- Escalate to pharmacy if a patient is going to miss a dose due to shortage of medicine.
- Escalate to medical staff if a medicine is unavailable.
- Highlight at Safety Brief/Huddle if medicine is unavailable.
- Communicating with patients and their carer's as appropriate, Healthcare Professionals and any other relevant persons.
- Participating in Medicine Shortage Problem Assessment Groups.

Appendix 2

Descriptor of Shortages and Associated Management Options

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</u> such as switching to those alternatives, which may include unlicensed medicines. Level two shortages also include level one shortages that continue for more than a month.	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.
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' if the patient consents to this. Additional clinical advice. Exceptional MHRA regulatory measures. Issuing a 'Supply Disruption Alert' to the NHS via the Central Alerting System (CAS).
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.

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Appendix 3 - Medicine Shortages in Community Pharmacy: Quick Reference Guide

Medicine shortages in Community Pharmacy - Quick Reference Guide

Medicine displayed as OOS/ MCS/Discontinued" at main supplier on PC



Contact patient to clarify:

- When their current supply will run out so that timely action can be taken.

Ensure they are kept informed of action being taken to resolve the shortage. Contact supplier to ascertain:

- If "OOS/MCS/Discontinued" message is accurate.
(Sometimes these messages are displayed when the item has arrived but not been "booked in" at the depot, or is just unavailable at your primary depot).
- If possible to obtain supply from another depot.
- Duration medicine is expected to be unavailable.



If possible:

- Order via secondary/other suppliers.
- Direct to neighbouring Pharmacies known to have stock
(This may require contacting the Pharmacies to ensure a good patient journey and good customer service. If possible, where prescription(s) contain more than one item, Pharmacies should not part dispense the prescription(s) as this requires GPs to re-issue a new prescription and causes further delay to patient treatment.)
- Amendments to the medication supplied can be made by fully utilising the flexibilities to electronically endorse prescriptions where the shortage necessitates a change in the strength, dose and/or formulation substitution rather than requesting a new prescription. In addition, these flexibilities may be extended through the appropriate use of the Unscheduled Care PGD.



If none of the above have been possible an alternative product may be required:

1. If necessary, ask patient what they are using the medicine for.
2. Check [East Region Formulary](#) website for formulary alternative.
3. Check [BNF](#) and [SPS Medicines Supply Tool](#) for potentially suitable alternatives.
4. (Ensuring that these alternatives are available and do not interact with the patient's other medicines)
5. If there is a [Serious shortage protocol \(SSP\)](#) in place and if patient consents, please follow advice on SSP.



Contact GP practice with suggested alternative(s) via SBAR tool ([Appendix 8](#)) emailed to GP generic mailbox

1. Email SBAR to GP practice advising of suitable alternatives you have in stock.
2. Report to [CPS online shortage reporter](#).

Appendix 4: Medicines Shortages Communication Checklist

Pharmacy and Medicines Directorate



MEDICINES SHORTAGES COMMUNICATION CHECKLIST

1	Medicines Management Team to identify shortage from: <ul style="list-style-type: none">• Specialist Pharmacy Services• Knowledge hub
2	Save MSN/MSAN/National Patient Safety Alert in Teams channel: Fife Medicines Shortages
3	Run reports on the usage of the medication affected by shortage across primary and secondary care. <ul style="list-style-type: none">- Liaise with Specialist Pharmacy Technician for Purchasing & Homecare or Medicines Supply Chain Manager for secondary care usage.- Liaise with Senior Analyst Prescribing information for primary care usage.
4	For Level 3, Level 4 shortages, and National Patient Safety Alerts: <ul style="list-style-type: none">a. Start a Situation Report (SitRep) see (Appendix 6)b. Email shortage to relevant clinical teams and purchasing team.c. Convene a Pharmacy & Medicines Directorate Medicine Shortage Problem Assessment Group (PAG) to ensure actions to mitigate the effects of a medicine shortage are being taken forward.
5	Attendance at PAG meeting: <ul style="list-style-type: none">➤ Chair: Medicines Utilisation and Therapeutics Pharmacist➤ Specialist Pharmacy Technician – Purchasing and Homecare➤ Relevant Senior clinical pharmacist affected by shortage.➤ Managed Clinical Network (MCN) Manager for speciality.➤ Service manager, clinical leads (if complex shortage)➤ Primary Care Lead (if shortage affects primary care team)➤ MMT Admin support➤ Lead Pharmacist Public Health & Pharmacy (if shortage affects Community Pharmacy)
6	Responsibilities <ul style="list-style-type: none">➤ Chair<ul style="list-style-type: none">○ Complete the SitRep with actions from the PAG meeting.➤ Specialist Pharmacy Technician Purchasing and Homecare<ul style="list-style-type: none">○ Arrange alternate supplies as agreed in PAG meeting.➤ MMT Admin support to send out the PAG Meeting minutes (Appendix 7).

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	<ul style="list-style-type: none"> ➤ Senior Clinical Pharmacist or MCN Manager for speciality affected by shortage. <ul style="list-style-type: none"> ○ Liaise with consultants and nursing staff to draft a document aimed at addressing the shortage of medication and recommending any alternatives. ○ Complete (insert Medicine name) Shortage Communication if there are changes from the original MSN/MSAN/National Patient Safety Alert. (Appendix 5). If there are no changes, the original MSN/MSAN/National Patient Safety Alert notification to be shared across the board.
7	<p>After completion of (insert Medication name) Shortage Communication, copy to be sent to Medicines Utilisation and Therapeutics Pharmacist.</p> <ul style="list-style-type: none"> ➤ Medicines Utilisation and Therapeutics Pharmacist to send to Managed Service and Drugs Therapeutics Committee (MSDTC) fife.msdtc@nhs.scot ➤ MSDTC secretary/admin to email to MSDTC Chair and Vice Chair for approval
8	<p>Medicines Management admin team to send MSDTC approved (insert Medication name) Shortage Communication to:</p> <ul style="list-style-type: none"> ➤ Primary care teams <ul style="list-style-type: none"> ○ Primary care pharmacy communication: fife.primarycarepharmacyleads@nhs.scot ○ Primary Care admin for all GP communication: fife.primarycareadmin@nhs.scot ➤ Community pharmacy communication contact: Lead Pharmacist - Public Health & Community Pharmacy Services and Senior Pharmacist - Community Pharmacy Services Fife.fifepharmacycommpharm@nhs.scot ➤ Secondary care communication: fife.pharmacymanagedservice@nhs.scot ➤ Following should be used for shortages that have high impact as directed by Medicines Utilisation and Therapeutics Pharmacist/MMT <ul style="list-style-type: none"> ○ Stafflink communication to all hospital staff: fife.communications@nhs.scot ○ Acute huddle at VHK at 8:30 AM (liaise with person going to huddle) ○ VHK Pharmacy huddle at 9AM (liaise with person going to huddle) ○ QMH huddle: contact Pharmacy technician fife.qmhdispensary@nhs.scot ○ Mental health huddle: contact Lead Clinical Pharmacist Mental Health fife.mentalhealthpharmacy@nhs.scot ○ Non-medical prescribers contact: fife.practiceprofessionaldevelopment@nhs.scot ○ Charge nurses contact: Personal Assistant to Director of Nursing ○ All clinicians contact: Personal Assistant to Deputy Medical Director (Acute) ○ Health and Social Care Partnership (HSCP) contact: Personal Assistant to Deputy Medical Director for HSCP
9	<p>Medicines Utilisation and Therapeutics Pharmacist to retain copy of (insert Medication</p>

	name) Shortage Communication in SitRep on MS Teams Channel and when resolved saved to A drive for reference.
10	When shortage resolves for Level 3 and 4, MMT to email and update all teams

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Appendix 5: Shortage of Medication Communication Template NHS Fife

Pharmacy and Medicines Directorate



Heading: (insert Medication name) Shortage Communication

Brief introduction into medication and shortage.
MSN/MSAN to be hyperlinked or attach as Appendix.

Advice to Primary care

- Seek advice from primary care and/or specialists as needed.
- 'No action – For Information only': Specify if there is no action required by primary care team.

Advice to Secondary care

- Seek advice from secondary care and/or specialists as needed.
- No action – For Information only': Specify if there is no action required by secondary care.
- If information is same from primary care, copy/paste information here.

Clinical information

Information on alternative medicines. Provide dose equivalency information if available.

Contact

Include who to contact for further advice.

Links for further information/

Attach any relevant guidelines/links.

Appendixes – MSN or MSAN if not hyperlinked at top.

Heading and version control	Issue Date:
Authors (example antimicrobial team, MCN etc.)	MSDTC: Approved Date Review date

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Appendix 6: SitRep

Pharmacy and Medicines Shortages Sit-Rep – ENTER SHORTAGE MEDICATION

Date/Time of Sit-Rep:	Next proposed Sit-Rep:	Completed by Name/Job Title:	Contact Details:
			fife.fifemedicinesmanagement@nhs.scot

Service: Pharmacy and Medicines	
Current Level of Concern	

Area of service	Status	RAG
National position (MSN details if avail)		
Area affected (1° or 2°/Specialties)		
NHS Fife Pharmacy Stock position		
Community Pharmacy stock position (If approp)		
NHS Fife usage (No of patients if possible)		
Communications		

Actions being undertaken?
Additional Notes:

Appendix 7: PAG Meeting Minutes

Meeting:	(x Medication in Shortage) Problem Advisory Group (PAG)	Date:	
Present:		Venue:	

Item	Topic	Action / Decision / Info	Lead	Action Taken
1	Welcome and Background			
2	SitRep			
3	Next Steps			
4	AOCB			
5	Date and time of next meeting			

Appendix 8: Drug shortage memo SBAR

Patient name	
CHI	
Item	
Does another local pharmacy have (or can obtain) stock?	If yes, please specify:
Expected return date	
Does patient have a supply that will last until item is back in stock?	
Suitable alternatives	
Date	
Pharmacy	