NHS Greater Glasgow and Clyde

GUIDANCE

Guidance: Management of Medicines Shortages

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Important Note:

The online version of document is the only version that is maintained. Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

1. Purpose

To provide clear guidance for pharmacy staff across NHS Greater Glasgow & Clyde (NHSGGC) on how to identify, report, communicate, and manage medicines shortages while ensuring patient safety and continuity of care.

2. Scope

This guidance applies to all pharmacy staff working in the acute and mental health sectors within NHSGGC.

Where a medicine has been discontinued and an alternative is required, the principles described in this guidance may be applied.

Vaccine shortages are excluded and should be directed to Pharmacy Public Health (ggc.pharmacypublichealth@nhs.scot).

3. Background

Medicine supply chains are long, complex, and heavily regulated. Problems in the global medicines market mean medication shortages are occurring more frequently in many countries around the world. A medicines shortage is defined by the UK Department of Health and Social Care (DHSC) as "when supply does not meet patient demand at national level."

Please also refer to the report Medicines shortages: Solutions for empty shelves, published by the Royal College of Pharmacy.

4. Procedure

4.1 Identification and Reporting

Most supply problems within GGC are identified locally by the Pharmacy Distribution Centre (PDC), Medicines Advice (MA), or by other healthcare professionals in primary or secondary care.

Staff should verify potential shortages using:

- GGC Medicines Supply Problem page
- Specialist Pharmacy Service (SPS) Medicines Supply Tool (registration required)

If not listed, contact PDC to confirm potential shortage:

- Use PDC Customer Service portal Paragon for queries
- For urgent stock issues, use the Drug Escalation Form

4.2 Communication

- Significant shortages will be communicated by PDC or MA via email. Not all shortages will have a clinical impact or require local action, and therefore not all shortages will require email communication.
- Clinical teams should inform patients/carers if treatment may be affected, clearly communicating the reasons behind the shortage, and reassuring patients that the health board are working to ensure they experience the lowest possible impact. During significant shortages, charities or patient groups may publish information in patient-friendly language to support dissemination of information.
- Updates will be shared by PDC or MA when large-volume or critical shortages have resolved. The online supply tools listed above can also be accessed for updates.

4.3 Management Strategy Development

Advice in Medicines Supply Notifications (MSNs) or Medicine Supply Alert Notices (MSANs) sent by the DHSC or Scottish Government will be followed where possible.

Where local action is required, a strategy for the management of a medicine shortage will be developed with appropriate engagement with relevant stakeholders, for example lead pharmacist, nurse or doctor in relevant clinical areas.

Initial steps:

- PDC staff to establish stock holding and estimate the time period this will cover. PDC staff to explore alternative suppliers.
- Where no straightforward alternative exists, PDC staff to contact relevant clinical pharmacy teams or MA for advice, and/or Clinical Trials team if the medicine is an Investigational Medicinal Product (IMP).
- If a critical shortage, PDC staff, MA staff, and senior clinical pharmacist(s) to discuss and decide whether restrictions are needed to conserve stock. The Pharmacy Services executive team, senior clinicians and clinical trials pharmacists may be consulted. Details of the restrictions, along with start and review dates, will be communicated immediately to all relevant hospital staff.
- Where PDC identify a potential alternative, the relevant clinical pharmacy team must undertake a fully documented risk assessment where appropriate, e.g. for unlicensed medicines (ULMs). Where there is ambiguity over the most appropriate clinical pharmacy team, MA staff can complete the risk assessment.
- Clinical pharmacy teams to engage with Homecare if relevant.
-Pharmacy Clinical Trials team to engage with trial Sponsor(s) as appropriate.

4.4 Risk Assessment

See Appendix 2. Pharmacy staff to conduct a risk assessment where deemed necessary. Risk assessment can be completed for any alternative product, but a fully documented risk assessment **must** be undertaken where the alternative is a ULM. Please also refer to NHSGGC Unlicensed Medicines Policy and MHRA Guidance Note 14.

Risk assessment must consider:
- Estimated duration of shortage
- Usage figures and the scale of the gap in supply and demand
- Availability of alternatives
- Patient safety risks
- Practical considerations relating to ordering, supply and prescribing of medicines, e.g. restrictions on storage, required paperwork, required changes to HEPMA records.

Any clinical advice required locally should be communicated via a memo. The memo should be written by the clinical pharmacy team where the shortage falls under a specialist area, or MA where use is more widespread.

Clinical pharmacy teams (including clinical trials pharmacists, where relevant) should co-ordinate any training required as a result of the use of the alternative product in a timely manner.

4.5 Incident Reporting

- Use Datix or equivalent systems to report shortages impacting patient care.

5. Responsibilities

Pharmacy Distribution Centre (PDC)

- Monitor and manage stock levels, and respond to shortage queries placed via the Drug Escalation Form or the PDC Customer Service portal.
- Liaise with National Procurement to coordinate and manage medicines shortages and stock allocations
- Liaise with wholesalers and attempt to source an alternative product (different pack size, strength, unlicensed product etc.)
- Communicate confirmed shortages and shortage resolutions to key pharmacy personnel.
- Assess usage and potential impact in collaboration with clinical and MA teams.
- Develop shortage management strategies in collaboration with clinical and MA teams.

- Where relevant, liaise with relevant wholesaler/supplier Account Manager to communicate increased usage of chosen alternative and ensure ongoing supply.

Medicines Advice (MA)

- Assess significance of shortages and determine required actions in collaboration with PDC and clinical teams.
- Conduct risk assessments for alternative brand or unlicensed medicine using the risk assessment tool, where a shortage does not fall under a specific clinical area, and where necessary and appropriate.
- Lead communication efforts:
    - update and maintain SharePoint Supply Problems page in collaboration with primary care colleagues
    - write and/or distribute clinical advice or memo if required
    - confirm resolution of large-volume or critical medicines shortages
    - Keep records of shortages requiring local action, including decisions taken, alternatives used, and any risk minimisation measures introduced.

Individual Pharmacy Specialties/Services

- Develop shortage management strategies in collaboration with PDC and MA teams.
- Complete risk assessment for alternative or unlicensed medicine using the risk assessment tool, where a shortage clearly sits under a specific clinical area, and where necessary and appropriate.
- Write a memo where the shortage clearly sits under the specific clinical area, and where necessary and appropriate.
- Provide clinical opinion and/or consult with lead clinicians in relevant specialist area(s) to identify strategies to resolve shortages.
- Provide appropriate information regarding significant shortages to patients and carers, and engage with Homecare or trial Sponsor where required.
- Co-ordinate any training required as a result of the shortage in a timely manner.

6. Appendices

Appendix 1: Contact Details

Appendix 2: Risk Assessment Tool

Appendix 1- Contact Details for Key Personnel

Job Title	Name	Email Address	Telephone number
National Procurement	NHS National Services Scotland	nss.nhssmedicineshortages@nhs.scot	01698 794 400
Clinical Technical Services Manager – Pharmacologistics	Gayle Robertson	gayle.robertson2@nhs.scot	0141 347 8986
Specialist Purchasing Technician	Sandy Kuhse	sandy.kuhse2@nhs.scot	0141 347 8985
Pharmacy Technician – Quality Assurance	Claire McIntosh	claire.mcintosh2@nhs.scot	07891 065592
Medicines Advice General Enquiries		ggc.medsadvice@nhs.scot	0141 201 3227
Lead Pharmacist Medicines Advice	Janet West	janet.west2@nhs.scot	0141 201 3227
Senior Pharmacist Medicines Advice (Shortages)	Susan Macfie	susan.macfie@nhs.scot	0141 201 3227
Lead Pharmacist - Medicines Policy, Planning and Guidance	Ishtiaq Mohammed	ishtiaq.mohammed@nhs.scot	0141 201 3267
Lead Antimicrobials Pharmacist	Dr Lee Stewart	lee.stewart3@nhs.scot	0141 451 6263
Lead Pharmacist Public Health (vaccine enquiries)	Elaine Paton	elaine.paton2@nhs.scot	0141 201 4777
Lead Pharmacist Clinical Trials/R&I/ATMPs	Dr Samantha Carmichael	Samantha.carmichael2@nhs.scot	0141 314 0232

Appendix 2 – NHSGGC Medicines Shortages Risk Assessment Tool

This tool can be used to make decisions regarding the use of alternative products within NHSGGC during medicines shortages. Please note that this list is not exhaustive. Assessors should also use clinical judgement and consult with appropriate stakeholders

Section 1: Checklist of issues to discuss with PDC colleagues if applicable.

The estimated duration of shortage	
Usage figures and the scale of the gap in supply and demand	
The availability of suitable alternative products	
The potential risk to patients	

Section 2: Checklist of risk issues to consider.
(Please consult manufacturer's product literature (SPC, or PIL if only literature available) as a minimum. Also consider using BNF, Medusa NHS Injectable Medicines Guide, Martindale etc.)

	Current product	**Suggested replacement product**	**Comment on Significant Differences/Risks**
Generic name:			
Brand name:			
Manufacturer: Is the manufacturer of suggested replacement product reputable, i.e. provides a quality MI service and guarantees continuous supply?			

Presentation / packaging:			
Associated paperwork for alternative? e.g. ordering / monitoring /authorising use:			
Cost Are there cost implications? Drug cost, procurement, storage			
Are there prescribing implications? E.g. is there a record on HEPMA?			
Technical considerations? e.g. • how the product should or can be administered • compatibility with equipment, syringes, needle-free connectors.			

Is there an appropriate patient information leaflet or package insert available with alternative? Is the content the same as the previous product?			
Storage requirements for alternative: • Is it a fridge item? • Is product 'bulky'? • Expiry date considerations • Are there any stability issues with packing down into compliance aids?			
Does alternative require aseptic unit production?			
Any considerations on compatibility with infusion fluids and other drugs			
Volume of infusion fluid required (if applicable)			
Displacement value (if applicable)			
Excipients (may be relevant, especially in children) • alcohol • propylene glycol • sorbitol • gelatin • known allergens, e.g. sulphites, benzoates			

• Are there any specific ingredient issues to consider, e.g. is product vegan, halal, kosher?			

IV monograph: Is there a local or national monograph available? Does monograph accurately reflect the new alternative product?			
Any other issues e.g. governance			
Licensed status: Do the licensed indications of replacement match to current product? Is the new product a 'special' or unlicensed?			
Special patient groups e.g. paediatrics, pregnant patients			
Dose			
Route			
Latex free?			
Monitoring: Is additional monitoring required for alternative?			
Consider any common off-label uses, and any implications			
Consider any notable contra-indications / cautions and any implications			

Section 2: Summary of Risks Identified

Summary of Risk Assessment:

Difference Identified	Potential Risk(s)	Potential Impact (Negligible to Extreme)	Likelihood of Occurrence (Rare to Almost Certain)	Risk Rating (Low to Very High)

Assessors should discuss identified risks with appropriate specialties and stakeholders and refer to appropriate section of the NHSGGC Medicines Shortages Guidance document.