# Guidance For The Management Of Medicine Shortages Within NHS Grampian

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<th>Co-ordinators:</th>
<th>Consultation Group:</th>
<th>Approver:</th>
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<tr>
<td>Principal Pharmacist</td>
<td>Lead Pharmacists</td>
<td>Grampian Area Drug and Therapeutics Committee</td>
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<tr>
<td>(Supply), Aberdeen Royal Infirmary</td>
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<th>Identifier:</th>
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<tr>
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**Executive Sign-Off**

This document has been endorsed by the Director of Pharmacy and Medicines Management

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Across NHS Boards | Organisation Wide | Directorate | Clinical Service Sub Department Area

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Lead Author/Co-ordinator: Principal Pharmacist (Supply), Aberdeen Royal Infirmary

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Document application: NHS Grampian

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Organisational: Chief Executive/Lead Officers and Management Teams across NHSG and HSCPs

Corporate: Senior Managers

Departmental: Heads of Service/Clinical Leads

Area: Line Managers

Hospital/Interface services: Assistant General Managers, Group Clinical Directors and clinical leads

Operational Management Unit: Unit Operational Managers and service managers

Guidance statement: It is the responsibility of all staff to ensure that they are working to the most up to date and relevant policies, protocols procedures.

Review: This guidance will be reviewed in three years or sooner if current treatment recommendations change.
Responsibilities for review of this document: Principal Pharmacist (Supply), Aberdeen Royal Infirmary

Physical location of the original of this document: Pharmacy and Medicines Directorate

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* Changes marked should detail the section(s) of the document that have been amended, i.e. page number and section heading.
Guidance For The Management Of Medicine Shortages Within NHS Grampian

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Guidance For The Management Of Medicine Shortages Within NHS Grampian

1. Introduction

This guidance is to ensure that medicine shortages are managed efficiently and the impact on patients and NHS Grampian is minimised.

1.1 Scope

This guidance applies to all medicine shortages (except blood products) which have the potential to create significant risk to patients and services. For blood products refer to the NHS Grampian Protocol for the Management of Blood and Blood Products during a Period of Shortage.

1.2 Objectives

- Detail how medicines shortages are identified within the Health Board.
- Outline the roles and responsibilities of Pharmacy and Dispensing Practice personnel in reporting shortages and how shortage information is communicated.
- To signpost the relevant escalation procedures relating to medicines shortages within NHS Grampian.
- Define the roles of the groups which will coordinate, assess, develop and implement a NHS Grampian management strategy in response to a significant shortage.
- To provide details on how medicines shortage related incidents are recorded.

1.3 Definitions

- Medicine Shortage – the total supply of a medicine, vaccine or prescribable product approved and recommended for use, is inadequate to meet the current or projected demand at the patient level.

- Medicine Stockout - the complete absence of the medicine, vaccine or prescribable product at the point of service delivery to the patient.

1.4 Background

Medicines shortages are occurring in the UK and globally for a variety of reasons posing a significant ongoing challenge for the NHS. Although some shortages are easily resolved, others have the potential to create significant risk to patients. This guidance is designed to provide advice on managing medicines shortages to minimise the impact on patients.
1.5 Identification, Reporting and Communication of a Medicine Shortage

Medicine shortages are identified through various channels of information (e.g. procurement teams, clinical interest groups, pharmacists, NHS personnel, Department of Health, NHS Scotland National Procurement, pharmaceutical industry, wholesalers and patients) so the sharing of information across sectors regarding shortages is increasingly important.

Where shortages are identified, a schematic outlining the process for handling shortages is provided in Appendix 1. A categorisation tool is provided in Appendix 2 and a risk assessment tool is provided in Appendix 3.

1.5.1 NHS Grampian Hospitals and Clinics

This section applies to all those areas that receive supplies procured by and sent out from the Pharmacy Acute Distribution Service including all acute hospitals, (ARI, RACH, RCH, DGH and Woodend), community hospitals, GMED and NHS Grampian clinics.

Clinical pharmacy technicians or pharmacists in each service will be the main conduit for any communications regarding shortages between clinical services and Pharmacy in the first instance. Where significant risks are identified (e.g. a significant impact on patient care or where there is an impact on care across healthcare sectors), the shortage must be escalated through the pathway in Appendix 4. In order to support appropriate escalation and reduce duplication of reporting it is expected that Pharmacy Acute Distribution Service managers will be the focus of reporting to the NHS Grampian dedicated email address nhsg.PMSG@nhs.net.

The Acute Service Pharmacy Team and Medicines Management Team within the Pharmacy and Medicines Directorate will work with both National Procurement and the Scottish Government’s Medicines Shortages Response Group (MSRG) and other stakeholders as appropriate to resolve shortages as quickly as possible and communicate up to date information.

At all times, whether in a period of shortage or not, medicines should only be transferred between NHS Grampian sites or to non NHS Grampian sites with the authorisation of the Acute Pharmacy Distribution Service (extension 53227 or 01224 553227).

1.5.2 Primary Care Settings

Medicines are procured through community pharmacies, dispensing doctor practices and through direct order, e.g. PECOS for some products for use in General Practices, e.g. dressings.

Community pharmacies already have a route of reporting shortages to the national trade body Community Pharmacy Scotland (CPS). This route of reporting has historically focussed in providing information to facilitate discussions between CPS and National Services Scotland around changes to reimbursement as shortages
often lead to price rises. However, this process has been revised to provide additional information to National Services Scotland for use in the national response processes to medicine shortages via the MSRG.

Where shortages are identified in Primary Care settings and cannot be managed through normal supply routes the issue should be escalated through practice pharmacists to HSCP Lead Pharmacists who will report via the NHS Grampian dedicated email address nhsG_PMSG@nhs.net. This focussed approach to escalation through the pharmacy team is to avoid multiple reporting and ensure that where clinicians are reporting shortages to a member of the pharmacy team there is an opportunity for direct feedback where shortages are already known about/being responded to.

Where the HSCP Pharmacy Leads and Clinical Leads identify significant risks (e.g. a significant impact on patient care or where there is an impact on care across healthcare sectors), the shortage must be escalated through the pathway in Appendix 4.

2. Pharmacy Medicines Shortages Group (PMSG)

The Pharmacy Medicines Shortages Group (PMSG) will act as a focus for the management of shortages responses where the shortage can no longer be managed within the sector or where pan Grampian actions are required.

PMSG will:

1) Act as the route of escalation for medicines shortages which are difficult to manage within an individual healthcare sector, requiring a coordinated Pharmacy response across NHS Grampian.

2) The group will work with Pharmacy colleagues across NHS Grampian and national contacts within National Procurement and the Scottish Practice Pharmacy and Prescribing Advisers Association (SP3AA) to resolve shortages minimising the need for further escalation. Examples of the activities to be undertaken in managing a shortage will include:

   a) Maintain a log of identified medicines shortages under PMSG management (including resolution information).

   b) Assess the significance of shortage/urgency required regarding alternative stock/advice and classify a shortage using the categories in Appendix 2.

   c) Source and risk assess alternative medicines (e.g. alternative pack size, strength, unlicensed product) using the risk assessment tool (Appendix 3) to record the impact of identified medicines shortages within NHS Grampian.

   d) Communicate confirmed medicines shortages to key pharmacy personnel and wider stakeholders through established routes.

   e) Collaborate with key departments on management of specific medicines shortage when required.

   f) Where further escalation is required, e.g. to manage limited stocks of medicines, prioritise use of limited stocks to particular patient groups or where significant clinical or patient impacts are envisaged the PMSG will activate the Medicines Advisory Group.
3. **Medicines Advisory Group (MAG)**

The Medicines Advisory Group, where activated by the PMSG, will lead the organisational response to Level 3 or 4 medicines shortages deemed by PMSG to require senior organisational oversight.

MAG will:

a) Appoint Expert Working Groups (EWG) and support the chairs in the EWG formation where necessary to provide expert clinical advice relating to the medicine shortage and patient treatment.

b) Prioritise the use of restricted medicines resources taking into account the expert recommendations from the Expert Working Groups and information provided through the Pharmacy Medicines Shortages Group.

c) Manage the organisational service response to Level 3 or 4 medicines shortages. This will include the modification, addition or cessation of clinical services if appropriate.

d) Coordinate any multiagency involvement (e.g. police, SAS) through the civil contingencies route where required.

e) Escalation and liaison if required to Scottish Government.

4 **Recording**

All Level 4 shortages, as categorised by the PMSG, will be recorded on Datix by PMSG. Further documentation systems may be developed for serious shortages by the Pharmacy Medicines Shortages Group (PMSG), Expert Working Groups (EWG) and the Medicines Advisory Group (MAG).

Any assessments, analyses and response plans developed will be recorded in the log of shortages managed by PMSG.

5 **References**


**Appendices**

Appendix 1: Process For Managing Medicine Shortages  
Appendix 2: Shortage Classification Categories  
Appendix 3: Medicines Shortages Risk Assessment Tool  
Appendix 4: Pathway For Escalating Medicines Shortages In NHS Grampian  
Appendix 5: PMSG Terms Of Reference  
Appendix 6: MAG Terms Of Reference  
Appendix 7: EWG Terms Of Reference

(Adapted from Fox ER, McLaughlin MM. ASHP guidelines on managing drug product shortages. *Am J Health Syst Pharm* 2018; 75(21):1742-1750)
Appendix 1: Drug Shortage Identified

Drug Shortage Identified

Operational Assessment
1. Validate details of shortage
2. Determine stock in hand
3. Determine supply from predetermined alternative sources
4. Determine purchase history and/or true use history
5. Estimate time to impact on the healthcare organisation
6. Determine supply of alternative drug products

(Typically done by pharmacy)

Therapeutic Assessment
1. Identify primary patient population affected
2. Identify therapeutic alternatives

(May be done by pharmacists or interdisciplinary team)

Shortage Impact Analysis
Estimate impact on patient care
1. Therapeutic differences
2. Prescribing processes
3. Distribution processes
4. Administration processes
5. Financial ramifications

(May be done by pharmacy or interdisciplinary team)

Establish Final Response Plan

Communicate
1. Shortage
2. Effective date
3. Identified therapeutic alternative
4. Temporary guidelines
5. Temporary Procedures
6. End of shortage / return to BAU

Implement
1. Information system changes
2. Technological changes (i.e. bar coding)
3. Stock control system changes
4. New procedures
5. Return to BAU when appropriate
## Appendix 2: Shortage Classification Categories

<table>
<thead>
<tr>
<th>LEVEL</th>
<th>DESCRIPTION</th>
<th>POTENTIAL RESPONSES</th>
</tr>
</thead>
</table>
| 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. |
Appendix 3: Risk Assessment Tool

NHSG Medicines Shortages Risk Assessment Tool

This risk assessment tool is for use to inform recommendations on alternative products made within NHSG PMSG in the face of a medicines shortage. (Please note that this list is not exhaustive and assessors should also use their clinical judgement and consult with appropriate stakeholders).

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

<table>
<thead>
<tr>
<th>The estimated duration of shortage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usage figures and the scale of the gap in supply and demand</td>
</tr>
<tr>
<td>The availability of suitable alternative products</td>
</tr>
<tr>
<td>The potential risk to patients</td>
</tr>
</tbody>
</table>

Section 2: Checklist of risk issues to consider.
(Please note, as a minimum, the manufacturer’s SPC should be consulted. Other useful sources of info include the BNF and IV monographs for injectable preparations)

<table>
<thead>
<tr>
<th>Risk</th>
<th>Current Product</th>
<th>Suggested Replacement Product</th>
<th>Comment on significant differences in risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic name:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brand name:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturer:</td>
<td></td>
<td></td>
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<tr>
<td>Is the manufacturer of suggested replacement product reputable, i.e. provides a quality MI service and guarantees continuous supply?</td>
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</table>

<table>
<thead>
<tr>
<th>Produced by the...</th>
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<tbody>
<tr>
<td>Manufacturer’s...</td>
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<tr>
<td>Product...</td>
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</tbody>
</table>
## NHSG Medicines Shortages Risk Assessment Tool (Continued)

<table>
<thead>
<tr>
<th>Presentation/packaging:</th>
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<tbody>
<tr>
<td>Is the new presentation / packaging appropriate?</td>
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<table>
<thead>
<tr>
<th>Associated paperwork for alternative?</th>
<th></th>
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<tbody>
<tr>
<td>E.g. ordering/monitoring/authorising use?</td>
<td></td>
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<table>
<thead>
<tr>
<th>Cost</th>
<th></th>
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<tbody>
<tr>
<td>Are there cost implications? Drug cost, procurement, storage</td>
<td></td>
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<table>
<thead>
<tr>
<th>Technical issues with alternative that should be considered?</th>
<th></th>
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<tbody>
<tr>
<td>E.g.</td>
<td></td>
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<tr>
<td>• How the product should or can be administered</td>
<td></td>
</tr>
<tr>
<td>• Compatibility with equipment, syringes, needle-free connectors</td>
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| Is there an appropriate patient information leaflet or package insert available with alternative? Is the content the same as the previous product? |  |

<table>
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<tr>
<th>Storage requirements for alternative:</th>
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<tr>
<td>• Is it a fridge item? If so, does the manufacturer have fridge stability data that are comparable to the current product?</td>
<td></td>
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<tr>
<td>• Is the product ‘bulky’?</td>
<td></td>
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<tr>
<td>• Expiry date considerations</td>
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<tr>
<td>• Are there any stability issues with packaging down into compliance aids?</td>
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</tbody>
</table>

| Does alternative require aseptic unit productions? |  |

| Any considerations on compatibility of alternative with infusion fluids and other drugs |  |

| Volume of infusion fluid required for alternative if applicable |  |

| Displacement value of alternative if applicable |  |

<table>
<thead>
<tr>
<th>Excipients considerations for current product vs alternative (may be relevant, especially in children)</th>
<th></th>
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<tbody>
<tr>
<td>• Alcohol</td>
<td></td>
</tr>
<tr>
<td>• Propylene glycol</td>
<td></td>
</tr>
<tr>
<td>• Sorbitol</td>
<td></td>
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<tr>
<td>• Gelatine</td>
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</table>

| Questions | | | |
|------------|-------------------------------|
| Other known allergens such as sulphites and benzoates should also be considered | | | |
| Are there any specific ingredients issues to consider e.g. Is product 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 indication of replacement match to current product? Is the new product a ‘special’ or unlicensed? | | | |
| Special patient groups e.g. paediatrics, pregnant patients | | | |
| Dose | | | |
| Route | | | |
| Is the alternative 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. | | | |
Summary of Risk Assessment:

<table>
<thead>
<tr>
<th>Difference Identified</th>
<th>Risk(s)</th>
<th>Potential Impact (Negligible to extreme)</th>
<th>Likelihood of Occurrence (Rare to Almost Certain)</th>
<th>Risk Rating (Low to Very High)</th>
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Appendix 4: Pathway for Escalating Medicines Shortages in NHS Grampian

Validated Shortage Identified

Can the Shortage be managed locally with minimal impact across NHS Grampian?

Yes → Manage Locally

No → Escalate to the PMSG (Pharmacy Medicines Shortages Group)

Can the PMSG manage through collaboration across healthcare sectors in NHS Grampian without significant impact on service delivery or risk to patients?

Yes → Manage Locally with PMSG support and collaboration across sectors

No → PMSG requests activation of the MAG to lead organisational response including agreement of explicit rationing strategies

Expert Working Group (EWG) set up to provide expert clinical advice where required

MAG continues to lead the organisational response until stock supply no longer requires explicit rationing
Appendix 5: PMSG Terms of Reference

TERMS OF REFERENCE FOR THE PHARMACY MEDICINES SHORTAGES GROUP (PMSG)

1. Title
Pharmacy Medicines Shortages Group (PMSG).

2. Accountable to
Director of Pharmacy

3. Objective(s)

a) Act as the route of escalation for medicines shortages which are difficult to manage within an individual healthcare sector, requiring a coordinated Pharmacy response across NHS Grampian.

b) The group will work with Pharmacy colleagues across NHS Grampian and national contacts within National Procurement and SPAA to resolve shortages minimising the need for further escalation. Examples of the activities to be undertaken in managing a shortage will include:

- Maintain a log of identified medicines shortages under PMSG management (including resolution info).
- Assess the significance of shortage/urgency required regarding alternative stock/advice.
- Source and risk assess alternative medicines (alternative pack size, strength, unlicensed product etc) using the risk assessment tool (Appendix 2) to record the impact of identified medicines shortages within NHS Grampian.
- Communicate confirmed medicines shortages to key pharmacy personnel and wider stakeholders through established routes.
- Collaborate with key departments on management of specific medicines shortage when required.
- Where further escalation is required to manage limited stocks of medicines PMSG will:
  - Contact the Chair of MAG to activate the group (if the group is currently inactive).
  - Support MAG to form and coordinate multidisciplinary short life working groups to manage medicines shortages as required.
  - Brief MAG and Expert Working Groups (EWGs) with summary information regarding their progress to obtain supplies.
  - Liaise with National Procurement and Scottish Medicines Shortages Response Group.
4. Membership Roles and Responsibilities

<table>
<thead>
<tr>
<th>Member</th>
<th>Role and Responsibility</th>
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<tbody>
<tr>
<td>Principal Pharmacist Medicines Management</td>
<td>Coordinator of the Pharmacy response across the HSCP.</td>
</tr>
<tr>
<td>Principal Pharmacist (Supply) [Chair]</td>
<td>Manages the Acute Pharmacy response.</td>
</tr>
<tr>
<td>Pharmaceutical Services Improvement and Development Manager</td>
<td>Coordinator for contractor services response.</td>
</tr>
<tr>
<td>Lead Pharmacist Medicines Information</td>
<td>Provision of information to NHS Grampian clinicians and to support the response</td>
</tr>
<tr>
<td>Lead Pharmacy Technician Distribution</td>
<td>Manages Procurement and Distribution in Acute.</td>
</tr>
<tr>
<td>CHP Lead Pharmacist rep</td>
<td>Liaison within HSCP’s</td>
</tr>
<tr>
<td>Principal Pharmacist Mental Health &amp; Learning Disability Services</td>
<td>Manages the Mental Health &amp; Learning Disability Pharmacy response</td>
</tr>
</tbody>
</table>

5. Confidentiality

Information considered by the Pharmacy Medicines Shortages Group may be of a commercially confidential nature. It is vital that members understand their responsibility to treat as confidential, information that is identified to them as such.

Individuals must not breach this duty of confidence by disclosing, or using in an unauthorised manner, confidential information, or providing access to such information by unauthorised individuals or organisations. Information considered to be confidential may, however, be required to be disclosed by law, by court of competent authority, by a requirement of a regulatory body or under the Freedom of Information (Scotland) Act 2002.

6. Managing Conflicts of Interests

If any member of the group has a relevant declaration of interest with products or companies under discussion by the group (original or alternative), this should be communicated to the chair. The Chair is responsible for the decision on how the potential conflict will be managed.
7. **Decision Making**

Decisions and advice agreed by the group will be recorded in an action log, and communicated appropriately. A quorum for decision making will be the Chair plus three other members.

8. **Frequency and Location of Meetings**

The frequency and location of meetings will be determined by the group, as required. Meetings may be organised by teleconference, video conference or in person as required.

9. **Papers**

Relevant papers will be distributed prior to each meeting wherever possible.

10. **Lifespan**

The Pharmacy Medicines Shortages Group will be stood up and down as required in response to shortages. This will be communicated to the Medicines Advisory Group as required.
Appendix 6: MAG Terms of Reference

TERMS OF REFERENCE FOR MEDICINES ADVISORY GROUP

1. Title
Medicines Advisory Group

2. Accountable to
Chief Executive NHS Grampian

3. Objective(s)
   a) Lead the organisational response to Level 3 or 4 medicines shortages which require senior organisational oversight.
   b) Prioritise the use of restricted medicines resources taking into account the expert recommendations from the Expert Working Groups (EWG) and information provided through the Pharmacy Medicines Shortages Group.
   c) Appoint the Chairs of Short Life Working Groups and support the chairs in the EWG formation where necessary.
   d) Manage the organisational service response to severe medicines shortages. This will include the modification, addition or cessation of clinical services if appropriate.
   e) Coordinate any multiagency involvement (e.g. police, SAS) through the civil contingencies route.
   f) Escalation and liaison if required to Scottish Government.
### 4. Membership Roles and Responsibilities

<table>
<thead>
<tr>
<th>Core Members</th>
<th>Role and Responsibility</th>
</tr>
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<tbody>
<tr>
<td>Director of Pharmacy</td>
<td>Professional leadership and management of the NHS Grampian Pharmacy response.</td>
</tr>
<tr>
<td>Director of Nursing</td>
<td>Professional leadership and management of the NHS Grampian Nursing response.</td>
</tr>
<tr>
<td>Medical Director</td>
<td>Professional leadership and management of the NHS Grampian Medical response.</td>
</tr>
<tr>
<td>HSCP Clinical Lead(s)</td>
<td>Leadership and management of the HSCPs response.</td>
</tr>
<tr>
<td>Chair PMSG</td>
<td>Coordinate PMSG activity with MAG and update MAG regarding shortages using local and national information.</td>
</tr>
<tr>
<td>Consultant in Public Health Medicine</td>
<td>Leadership and management of the NHS Grampian Health Protection response.</td>
</tr>
<tr>
<td>Patient Representative</td>
<td>Ensure the NHS Grampian response to medicines shortages is patient centred.</td>
</tr>
<tr>
<td>Director of Finance</td>
<td>Lead the NHS Grampian corporate financial response taking in to account the financial impact of medicines shortages.</td>
</tr>
<tr>
<td>Head of Corporate Communications</td>
<td>Lead, manage and advise on the corporate communication strategy in response to shortages.</td>
</tr>
<tr>
<td>Head of Civil Contingencies</td>
<td>Provide expertise, leadership and guidance to minimise the impact of shortages by utilising Civil Contingency measures where necessary.</td>
</tr>
</tbody>
</table>

Deputies acceptable and encouraged. Secretarial and administrative support is essential for meeting management and recording of minutes.

Chair will be either the Director of Pharmacy, Director of Nursing or Medical Director.

### 5. Confidentiality

Information considered by the Medicines Advisory Group may be of a commercially confidential nature. It is vital that members understand their responsibility to treat as confidential, information that is identified to them as such.

Individuals must not breach this duty of confidence by disclosing, or using in an unauthorised manner, confidential information, or providing access to such information by unauthorised individuals or organisations. Information considered to be confidential may, however, be required to be disclosed by law, by court of competent authority, by a requirement of a regulatory body or under the Freedom of Information (Scotland) Act 2002.
6. Managing Conflicts of Interests

If any member of the group has a relevant declaration of interest with products or companies under discussion by the group, this should be communicated to the chair.

The Chair is responsible for the decision on how the potential conflict will be managed.

7. Decision Making

Decisions and advice agreed by the group will be recorded in the minutes of each meeting, and communicated appropriately.

8. Frequency and Location of Meetings

The frequency and location of meetings will be determined by the group, as required. Teleconference or video conferencing facilities will be made available for members unable to attend in person.

9. Papers

Relevant papers will be distributed prior to each meeting wherever possible.

10. Lifespan

The need for the MAG will be reviewed at the MAG meetings with a recommendation made to PMSG when it should be stood down.
Appendix 7: EWG Terms of Reference

TERMS OF REFERENCE FOR MEDICINES SHORTAGE EXPERT WORKING GROUPS

1. **Title**

Medicines Shortages Expert Working Groups

2. **Accountable to**

Medicines Action Group

3. **Objective(s)**

   a) Consider information provided by PMSG and assess the impact on patient care.

   b) Work closely with national specialist groups to ensure best practice is followed.

   c) Access the relevant expertise and make recommendations for prioritisation and allocation of remaining stocks, consider alternative therapies and place restriction on access to stocks if required.

   d) Inform clinical and service leads of the shortage(s), the implications and management actions for onward cascade and the need for feedback to the group.

   e) Issues for further escalation should be communicated to MAG. This may include the following:

      1) Where there is likely to be a moderate, major or extreme impact on patient care (e.g. withdrawal of treatment)

      2) There is the risk of a moderate, major, extreme financial or service impact

      3) Issues arising in sensitive patient groups (e.g. paediatrics, maternity).

   f) Establish a recording system to support retrospective analysis of the incident.

   g) Ensure neighbouring boards and dependent services (e.g. Orkney and Shetland) are considered in meetings and communicated appropriately.

   h) Ensure MAG and PMSG are updated regarding progress.
4. Membership Roles and Responsibilities

Membership and the chairmanship will be determined by the type, scope and scale of the shortage and may require to be flexible and adaptive.

<table>
<thead>
<tr>
<th>Core Members</th>
<th>Role and Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead Consultants/Deputy</td>
<td>Provide clinical expertise to support the response and coordinate with consultant colleagues as necessary</td>
</tr>
<tr>
<td>Nurse Specialists</td>
<td>Provide clinical expertise to support the response and liaise with nurse colleagues as necessary</td>
</tr>
<tr>
<td>GP( clinical lead or those with Special Interest)</td>
<td>Provide clinical expertise to support the response and coordinate with GP colleagues as necessary</td>
</tr>
<tr>
<td>Clinical Pharmacist</td>
<td>Provide clinical expertise to support the response and liaise with hospital pharmacy colleagues as necessary</td>
</tr>
<tr>
<td>Pharmacy CHP Lead (rep)</td>
<td>Support the response and liaison within HSCP’s</td>
</tr>
<tr>
<td>Others as necessary</td>
<td></td>
</tr>
</tbody>
</table>

Secretarial and administrative support is essential for meeting management and recording of minutes.

5. Confidentiality

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6. Managing Conflicts of Interests

If any member of the group has a relevant declaration of interest with products or companies under discussion by the group, this should be communicated to the chair. The Chair is responsible for the decision on how the potential conflict will be managed.
7. **Decision Making**

Decisions and advice agreed by the group will be recorded in the minutes of each meeting, and communicated appropriately.

8. **Frequency and Location of Meetings**

The frequency and location of meetings will be determined by the group, as required. Teleconference or video conferencing facilities will be made available for members unable to attend in person.

9. **Papers**

Relevant papers will be distributed prior to each meeting wherever possible.

10. **Lifespan**

The need for the Expert Working Group will be reviewed at the meetings.