


**Guidance For The Management Of Medicine Shortages Within NHS
Grampian**

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| Co-ordinators: Principal Pharmacist (Supply), Aberdeen Royal Infirmary Lead Pharmacist, Medicines Management | Consultation Group: See page 5 | Approver: Grampian Area Drug and Therapeutics Committee |
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This document has been endorsed by the Director of Pharmacy and Medicines
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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

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| | | Section 3. Minor update to wording. | Page 5 |
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Guidance For The Management Of Medicine Shortages Within NHS Grampian

| Contents | Page No |
|---|---------|
| 1. Introduction | 2 |
| 1.1 Scope | 2 |
| 1.2 Objectives | 2 |
| 1.3 Definitions | 2 |
| 1.4 Background | 2 |
| 1.5 Identification, Reporting and Communication of a Medicine Shortage..... | 3 |
| 1.5.1 NHS Grampian Hospitals and Clinics | 3 |
| 1.5.2 Primary Care Settings | 3 |
| 2. Pharmacy Medicines Shortages Group (PMSG) | 4 |
| 3. Medicines Advisory Group (MAG) | 5 |
| 4. Recording of level 4 shortages | 5 |
| 5. References | 5 |
| 6. Consultation Group..... | 5 |
| Appendix 1 - Pathway For Escalating Medicines Shortages In NHS Grampian | 6 |
| Appendix 2 - PMSG Management Of Drug Shortage Flow Chart | 7 |
| Appendix 3 – Shortage Classification Categories For Use By PMSG | 8 |
| Appendix 4 - NHS Grampian PMSG Medicines Shortages Risk Assessment Tool..... | 9 |
| Appendix 5 - PMSG Terms Of Reference | 12 |
| Appendix 6 - MAG Terms of Reference | 15 |
| Appendix 7 - EWG Terms of Reference | 18 |

Guidance For The Management Of Medicine Shortages Within NHS Grampian

1. Introduction

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

1.1 Scope

This guidance applies to all medicine and prescribable product shortages (except blood products) which have the potential to create significant risk to patients and services.

1.2 Objectives

- Detail how medicines shortages can be identified within the Health Board.
- Outline the roles and responsibilities of hospital, primary care, community pharmacy and dispensing practice personnel in reporting shortages.
- Outline the roles and responsibilities for communicating shortage information.
- 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 – Total or partial shortage of a medicine, vaccine or prescribable product approved and recommended for use – resulting in a supply which is inadequate to meet the current or projected demand at the patient level.

1.4 Background

Medicines shortages are occurring in the UK and globally for a variety of reasons and pose significant ongoing challenges 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. Specialist Pharmacist Service (SPS), 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 imperative. All information relating to shortages should be from an appropriate and validated resource.

Where shortages are identified, a schematic outlining the process for handling shortages is provided in [Appendix 1](#) and [Appendix 2](#). A categorisation tool is provided in [Appendix 3](#) and a risk assessment tool is provided in [Appendix 4](#).

1.5.1 NHS Grampian Hospitals and Clinics

This section applies to all areas that receive supplies procured by and supplied from the Pharmacy Acute Distribution Service including: all acute hospitals, (Aberdeen Royal Infirmary, Royal Aberdeen Children's Hospital, Royal Cornhill Hospital, Doctor Grays Hospital and Woodend Hospital), 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 Acute Distribution Service 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 1](#). 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 gram.pmsg@nhs.scot.

The Acute Service Pharmacy Team and Medicines Management Team within the Pharmacy and Medicines Directorate will work with National Procurement, the Scottish Government and other stakeholders as appropriate to manage 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 such as dressings for use in General Practices / CTAC / Community Nursing teams.

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 on providing information to facilitate discussions between CPS and National Services Scotland (NSS) around changes to reimbursement as shortages often lead to price rises. However, this process has been revised to provide additional information to NSS for use in the national response processes to medicine shortages via the Medicines Shortages Response Group (MSRG).

Where shortages are identified in Primary Care settings and cannot be managed through normal supply routes, the issue should be escalated to HSCP Lead Pharmacists (through primary care pharmacy teams where possible) who will report via the NHS Grampian dedicated email address gram.pmsg@nhs.scot or by contacting the Lead Pharmacist Medicines Management or the Principal Pharmacist (Supply). This focussed approach to escalation through the pharmacy team is to avoid multiple reports 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 Lead Pharmacists investigate and 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 1](#).

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 (NP) and other relevant stakeholders to manage shortages, minimising the need for further escalation. Examples of the activities to be undertaken in managing a shortage will include:
 - a) Notes are kept of PMSG meetings relating to identified medicines shortages (including actions and resolution information).
 - b) Assess the significance of shortage/urgency required regarding alternative stock/advice and classify a shortage using the categories in [Appendix 3](#).
 - c) Source and risk assess alternative medicines (e.g. alternative pack size, strength, unlicensed product) using the risk assessment tool ([Appendix 4](#)) to record the impact of identified medicines shortages within NHS Grampian.
 - d) Communicate confirmed medicines shortages to all relevant 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 (MAG).

3. Medicines Advisory Group (MAG)

The MAG, 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 PMSG.
- 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) Escalate and liaise if required with Scottish Government.

4 Recording of level 4 shortages

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 PMSG, EWG or the MAG.

Any assessments, analyses and response plans developed will be recorded by PMSG.

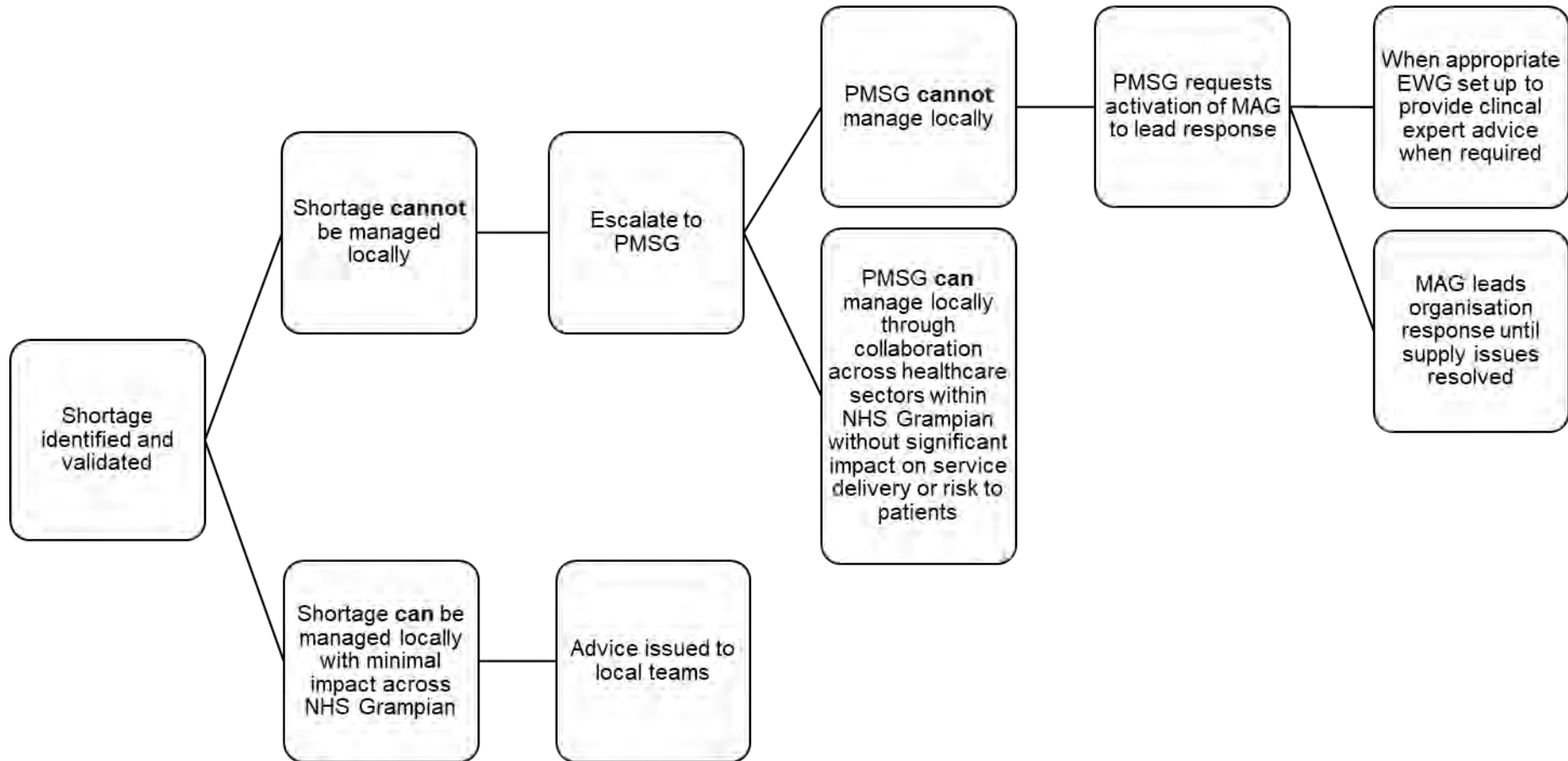
5 References

[NHS Scotland Best Practice Standards for Managing Medicine Shortages in Secondary Care in Scotland.](#)

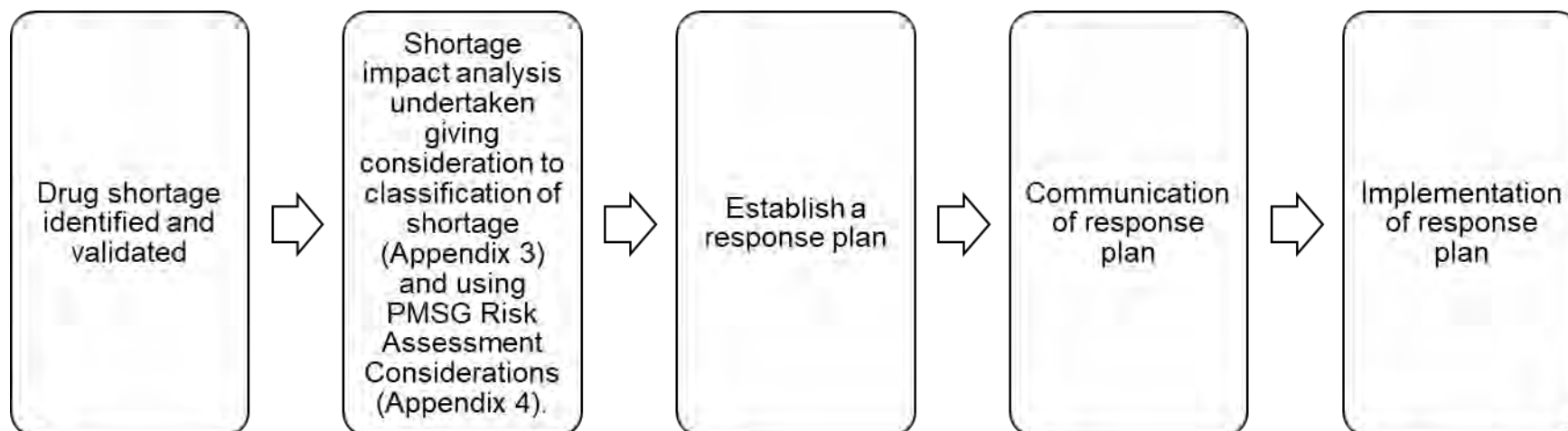
6. Consultation Group

| | |
|---------------------|--|
| Rebecca Anderson | Medicines Information Pharmacist, ARI |
| Donna Beedie | Lead Pharmacy Technician, Distribution, ARI |
| Lesley Coyle | Associate Director of Pharmacy, NHS Grampian |
| Alison Davie | HSCP Lead Pharmacist, Aberdeen City |
| Elaine Neil | HSCP Lead Pharmacist, Aberdeenshire |
| Elizabeth Robertson | HSCP Lead Pharmacist, Aberdeen City |
| Alexander Thomson | Associate Director of Pharmacy, NHS Grampian |

Appendix 1 - Pathway For Escalating Medicines Shortages In NHS Grampian



Appendix 2 - PMSG Management Of Drug Shortage Flow Chart



Appendix 3 – Shortage Classification Categories For Use By PMSG

These classifications should be used as a guide, with ultimate decisions for classification sitting with the PMSG.

| Level | Description | Potential Responses |
|----------------------------------|---|---|
| One (low impact) | Likely to carry low risk and management options should result in patients being maintained on the same licensed medicine. | Business as usual. Response likely to involve using the same medicine with alternative strength/formulation available to meet demand, potentially from other suppliers. |
| Two (medium impact) | Greater risk to patients/health providers than Level 1 issues but considered safe to be implemented at sub-regional level without further escalation. These issues will require more intense management options such as using therapeutic alternatives, unlicensed specials, unlicensed imports or alternative strengths or formulations. | Business as usual. Response not likely to require a change in the class of medicine. Use of 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. National Alert Issued. |
| Three (high impact) | These supply issues will be more critical, with potential change in clinical practice or patient safety implications that require clinical or operational direction to the system. They will be expected to generate public and clinician concern. The response will be nationally coordinated and guided. | Serious shortage situation. Response likely to require a change in the class of medicine. Use of a 'serious shortage protocol'. Additional clinical advice required. Exceptional MHRA regulatory measures. National Alert Issued. |
| Four (critical impact) | These supply issues will require additional support from outside the health system and will trigger the use of dedicated national processes and procedures in order to provide additional support for the management of the shortage. | Very serious shortage situation with 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. National Alert Issued. |

Appendix 4 - NHS Grampian PMSG Medicines Shortages Risk Assessment Tool

The checklist below is to be used by PMSG as the basis for information collation to allow a robust risk assessment discussion to take place in relation to a shortage and suitable alternatives.

When used by PMSG a copy of any assessment should be retained by the group for governance purposes.

| Details of shortage | |
|--|--|
| Medication(s) affected (including strength, form, manufacturer etc). | |
| Official documentation relating to shortage (to validate shortage) e.g. Medicine Supply Tool, MSAN, MSN, and NP updates. | |

| Operational Assessment | |
|---|--|
| Anticipated duration of shortage / re-supply dates provided. | |
| Stock in hand. Will this cover duration of supply issues? Consider historic usage data | |
| Stock levels of potential alternatives and therefore ability to support any uplift in demand. | |

| Therapeutic Assessment | Notes (including comments on any risks/ mitigations identified) |
|---|--|
| Current use of medication including both licensed and unlicensed indications, specialities, patient numbers. | |
| Potential alternatives both within and out with medication class (including drug class, dose, route of admin etc). | |
| Are any potential alternatives off-label, unlicensed or special manufacture products? For 'special' products is there indicative timescales for order/supply? | |
| Is engagement with specialists required to support with alternative considerations, and if so who? | |
| Are any special patient groups impacted e.g. paediatrics, pregnant patients? | |
| Do any potential alternatives have excipients which should be considered relevant (e.g. alcohol, propylene glycol, sorbitol, gelatine)? | |
| Do any potential alternatives contain known allergens (e.g. sulphites, benzoates, latex)? | |
| Are there any additional monitoring requirements associated with alternatives? | |
| Technical issues with alternative e.g. alternative route of administration, compatibility with equipment, aseptic preparation? | |

| | |
|---|--|
| Communication Assessment | |
| Who would require official communication/notification relating to shortage e.g. primary care, community pharmacists, acute teams, patients? | |

| | |
|---------------------------------|--|
| Other Considerations | |
| What are the cost implications? | |
| Governance considerations | |

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 other relevant stakeholders to resolve shortages, minimising the need for further escalation. Examples of the activities to be undertaken in managing a shortage will include:
 - Maintenance of 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 4](#)) 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 Medicines Advisory Group (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 (NP) and Scottish Medicines Shortages Response Group.

4. Membership Roles and Responsibilities

| Member | Role and Responsibility |
|---|--|
| Lead Pharmacist Medicines Management | Coordinator of the pharmacy response across primary care and community pharmacy. |
| Principal Pharmacist (Supply) [Chair] | Manages the Acute Pharmacy response. |
| Pharmaceutical Services Improvement and Development Manager | Coordinator for contractor services response. |
| Lead Pharmacist Medicines Information | Provision of information to NHS Grampian clinicians and to support the response. |
| Lead Pharmacy Technician Distribution | Manages Procurement and Distribution in Acute. |
| HSCP Lead Pharmacist representative | Liaison within HSCP's. |
| Principal Pharmacist Mental Health & Learning Disability Services (if required) | Manages the Mental Health & Learning Disability Pharmacy response. |

5. Confidentiality

Information considered by the PMSG 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.

9. Papers

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

10. Lifespan

The PMSG will be stood up and down as required in response to shortages. This will be communicated to the MAG 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

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

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.

| Core Members | Role and Responsibility |
|---|---|
| Lead Consultants/Deputy | Provide clinical expertise to support the response and coordinate with consultant colleagues as necessary. |
| Nurse Specialists | Provide clinical expertise to support the response and liaise with nurse colleagues as necessary. |
| GP (clinical lead or those with Special Interest) | Provide clinical expertise to support the response and coordinate with GP colleagues as necessary. |
| Clinical Pharmacist | Provide clinical expertise to support the response and liaise with hospital pharmacy colleagues as necessary. |
| HSCP Lead Pharmacist (representative) | Support the response and liaison within HSCP's. |
| Others as necessary | |

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

5. Confidentiality

Information considered by the Expert Working 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 Expert Working Group will be reviewed at the meetings.