# Introduction

Shortages of medicines have become increasingly common-often occurring without advance notification and the identification of a shortage can be incidental. It is therefore imperative that the Pharmacy has a co-ordinated approach for appropriately managing and communicating those shortages considered critical in order to minimise the impact on patient safety.

# Scope

For the purpose of this document, a critical medicine shortage is defined as: a *[Insert Trust]* formulary- approved medicine where supplies are at high risk of becoming (or have already become) exhausted and there is no direct therapeutic alternative (including unlicensed or off-label use). In addition, an interruption of supply would be considered by any one of the teams described below to compromise therapeutic care of a patient.

This SOP outlines the responsibilities of the pharmacy team for deciding a critical medicine shortage management (contingency) plan where a critical shortage is identified and the communication pathway for ensuring all relevant staff members are made aware.

# Responsibilities

**Chief Pharmacist**

To ensure there are processes in place to identify, manage and communicate medicines shortages.

**Pharmacy Clinical Governance (CG) Team *[change title as appropriate according to local management]***

In conjunction with the Procurement team, to monitor and track medicines shortages and assign a Designated Pharmacist (see below) for those shortages they deem to be critical.

In liaison with the Designated Pharmacist, to consider suitable therapeutic alternative(s) if existing stock, is or is likely to be exhausted before the shortage is resolved. Where a non-formulary, off-label or unlicensed medicine(s) are considered the only alternative, the ***[CG team]*** will seek the relevant formulary and/or Drug and Therapeutics Committee (DTC) approvals.

To review and where appropriate disseminate Medicines Supply Shortage *memos* to the relevant pharmacy and dispensary teams by *attaching it to a medicine shortage supply notification e-mail message (appendix 1). This message will detail instructions to be followed by relevant team members.*Where a supply shortage requires Trust-wide communication, the ***[CG team]*** will lead on this.

To respond to any national shortage communications received from the Commercial Medicines Unit (CMU) and liaise with the CMU on any emerging national medicine shortages.

**Designated Medicine Shortage Pharmacist or Designated Pharmacist (DP)**

For the purposes of this SOP, the Designated Medicine Shortage Pharmacist is the pharmacist taking the lead for co-ordinating and communicating a response from the relevant clinical area(s) regarding the preferred option for managing a critical medicine shortage and liaising with the procurement and ***[CG teams].*** This will include identifying and managing any risks associated with the shortage particularly where alternative agents are used.

They will be one of the ***[Insert Trust Pharmacists]*,** their assigned deputy(s), clinical practitioner ***and/or the Intravenous Medicines Safety Pharmacist (where the critical shortage involves a parenteral medicine)*** and will be assigned by the ***[CG team]*.**

To appropriately act upon instructions from any medicines supply shortage communications received.

**Pharmacy Procurement**

The pharmacy procurement team are responsible for investigating and providing procurement information on critical medicine shortages and purchasing alternatives as follows:

* Gathering advance intelligence on risks to interruptions of medicines supply
* Liaising with the Designated Pharmacist and ***[CG team]*** to determine the potential medicines affected by a shortages that could become critical
* Maintaining an up-to-date list of all medicines shortages, highlighting medicine shortages that are considered critical
* Disseminating the shortage list to principal pharmacists and clinical practitioners on a weekly basis
* Providing Trust-wide usage of medicines where there is a critical supply shortage
* Sourcing and purchasing alternative medicines as advised by the Designated Pharmacist and ***[CG team]*** where required
* Providing usage data and current stock levels in pharmacy and at ward level
* Monitoring for when normal supplies are expected resume
* Advising the ***[CG team]*** when the critical stock shortage can be de-escalated i.e. when normal supply has resumed and stock levels are replenished
* Informing the Commercial Medicines Unit of any critical supply shortages
* Identifying any pack size changes and informing pharmacy stores and Ward Medicines Management teams to make relevant adjustments to stock levels where necessary (which takes into account any changes in pack size)

Where stock has been exhausted and there is an immediate need to supply, the procurement team will arrange an urgent supply from a reputable wholesaler or local Trust as agreed by Designated Pharmacist and ***[CG team]***.

**Dispensary**

The dispensary leads for ***[Insert Hospital dispensaries]*** (inpatient and outpatient) are responsible for informing their dispensary teams of the contingency plan for managing medicines shortages as detailed in the critical supply notification email message. If required, the dispensary leads will arrange for paper copies of memos to be disseminated to affected ward/clinical areas.

Where a member of an inpatient or outpatient dispensary team identifies a stock shortage, they should contact the procurement team to notify them of the shortage and obtain advice.

**Pharmacy Stores and Ward Medicines Management teams**

Where the contingency plan includes conserving stock of the medicine affected by the shortage, the pharmacy stores team and or Ward Medicines Management teams will be responsible for concentrating stock to identified clinical areas or to pharmacy as per instructions provided by the procurement team. This may include taking account of any changes in pack sizes and adjusting quantity of whole packs stocked in clinical areas accordingly.

Once normal supplies resume, reverse previous stock adjustments are made in response to the shortage. The stores team will be responsible for replenishing stock to normal levels.

**EPMA (Digital Medicines) Team *(Include if an EPMA system is in use)***

Will make any amendments required where feasible to the EPMA system to assist with the management and communication of a critical medicine shortage.

# Procedure

1. **Identifying a critical medicine shortage**

The procurement team in conjunction with the ***[CG team]*** will monitor and track all medicine shortages known to them by reviewing the stock shortage report. Where a shortage has been identified and not included in the report, the procurement team should be contacted (by ***[Insert Trust communication method]*** to investigate.

A medicine shortage will be deemed critical where procurement and ***[CG team]*** agree (in conjunction with the relevant clinical pharmacy team) that a contingency plan (see below) needs to be instigated. The existing stockholding, usage data, available alternative agents and indication(s) the medicine is used to treat will inform these teams on whether the shortage is critical.

Where medicines shortage is deemed to be critical, a Designated Pharmacist (DP) will be assigned to co-ordinate a contingency plan (see below).

 **2. Agreement of a critical medicine shortage management (contingency) plan**

Once a critical medicine shortage is identified, the procurement team are to provide the ***[CG team]***, Designated Pharmacist and the ***Intravenous Medicine Safety Pharmacist (where appropriate)*** with:

* a usage report which identifies the areas that the affected medicine is supplied to and quantity supplied over a given timeframe (usually 1 year)
* usage data with expected timeline until all current stock in pharmacy is exhausted
* stock holding at ward level
* expected timeframe of the stock shortage
* provide details of suggested alternative options and availability where appropriate (e.g. alternative presentations, strengths, vial sizes of the same drug and unlicensed options)

Based on this information and clinical need a decision, with the Designated Pharmacist and **Intravenous Medicine Safety Pharmacist (where appropriate)**, will be made to either:

1. manage stock shortage with existing stock levels
2. substitute with an alternative licensed formulary medicine
3. substitute with an alternative licensed non-formulary medicine
4. substitute with an alternative unlicensed/off-label formulary medicine
5. substitute with an alternative unlicensed/off-label non-formulary medicine

The ***[CG team]*** will co-ordinate the required approvals (e.g. Quality Assurance, ***[Trusts therapeutics committee]*** for unlicensed use and where necessary, *facilitate electronic profiling of new medicines (e.g. JAC).*

**3. Communication Pathway for Management of Critical Medicine Shortage (appendix 3)**

Once a critical medicine shortage has been identified as requiring a contingency plan, the communication pathway for informing relevant teams will depend on the impact of the shortage and the chosen strategy to manage it. In liaison with the ***[CG team]*,** the Designated Pharmacist will notify teams of the stock shortage according to one of the following assigned levels of communication:

* Level 1: Medicine shortage predicted to have no impact on clinical practice, pharmacy internal communication required only e.g. Short-term, limited supply problem managed by conserving stock levels. Designated Pharmacist to inform the Pharmacy Department by ***[Insert Trust communication method] (\*see appendix 1 for example)*** to: Pharmacy detailing the management strategy.
* Level 2: Medicine shortage affects discrete clinical areas and deemed as having minimal impact on clinical practice/administration (e.g. change of product or packaging). Designated Pharmacist to ***[Insert Trust communication media]******(\*\*see appendix 2 for example)******[Insert Trust communication method] (\*see appendix 1 for example)*** to the relevant clinical lead(s) working within the affected clinical areas and/or request dispensary or stores to distribute paper copies to the affected clinical areas.
* Level 3: Medicine shortage affects discrete clinical areas and deemed to have significant impact on clinical practice (e.g. change to total amount of drug per vial, change to strength). Designated Pharmacist to ***[Insert Trust communication media]******(\*\*see appendix 2 for example)******[Insert Trust communication method] (\*see appendix 1 for example)***to the relevant clinical lead(s) working within the affected clinical areas. The designated pharmacist must have assurance that the message has been received and clearly understood and if they deem necessary, paper copies of the memo to be distributed to the affected clinical areas. Where any changes to EPMA prescription profiles are necessary, the EPMA team must be contacted.
* Level 4: Medicine shortage affects a number of clinical areas (e.g. change of therapy for a commonly used medicine such as IV cyclizine) and Trust-wide communication required. Designated Pharmacist to send Medicines Supply Shortage memo to the Pharmacy Department and a member of the ***[CG team]*** will send communication via the ***[Insert Chief Medical and Nursing leads as per Trust management]*** as supported by the Drug & Therapeutics Committee.

Level 2 and 3 ***[communication media]*** will need review and approval by the ***[CG team].***

\*see Appendix 1: The medicine supply shortage email notification message should as a minimum, include:

* Clear subject heading of the medicine affected
* Main areas affected
* Course of action to be followed and who is responsible
* Where a memo is attached, to request it is brought to the attention of relevant staff that may not routinely have access to email
* Expected date of return of stock
* That a follow up message will be sent once there is confirmation that stock levels have been replenished
* Additional measures to be put in place to mitigate against any identified risks.
* Where appropriate, advise that Clinical Pharmacists or Pharmacy Technicians covering any affected ward speak directly with the nurse in charge of the relevant ward for additional confirmation that they are aware of the shortage and contingency plan.

\*\*clinical leads will be dependent on the number of areas affected. For level 2, this will usually need to include the ward manager and matron and for level 3 shortages, Heads of Nursing and Clinical Directors may also need to be included.

Where stock is required to be mobilised, the procurement team will liaise with the relevant teams (Pharmacy Stores, Dispensary) and where supply is for a critical medicine that has been exhausted, the procurement team will liaise with the wholesaler or external Trust to arrange an urgent delivery. If the delivery is expected to be out of hours, this is to be handed over to the resident or on call pharmacist on duty.

Any stock shortages expected to impact on supplies out of hours, the Designated Pharmacist is to remind the weekend teams and on call pharmacists.

The procurement team are to inform the ***[CG team]*** and Designated Pharmacist when the shortage has been resolved and stock levels has been replenished.

**4. De-escalating a critical medicine shortage**

Once a contingency plan has been invoked, it will be reviewed by the ***[CG team]*** and procurement team periodically until there is confidence that the supply will not be interrupted for at least 8 weeks. At this stage, the contingency plan is to be de-escalated. This is to be achieved by the relevant teams involved in managing the shortage, reversing any measures that were implemented as part of the contingency plan. This will be co-ordinated and communicated by the Designated Pharmacist and the ***[CG team]*** who will advise of the required actions that are to be taken. This will include how to use any surplus supplies of a substitute procured as a result of the shortage to avoid wastage.

## Reference Documents

***[Insert local Trust documents]***

<http://www.rpharms.com/support-pdfs/managing-medicines-shortages-in-secondary-care.pdf>

<http://www.pharmaceutical-journal.com/download?ac=1066420>

## Revisions and Reasons

Nil

**Appendix 1: Example email notification – for amendment according to each shortage scenario**

|  |  |
| --- | --- |
| Level of Shortage | Subject heading |
| 1 | Medicine Supply Shortage of [Name of Medicine] – for information |
| 2 & 3 | Medicine Supply Shortage of [Name of Medicine] – Memo attached |
| 4 | Please read: Medicine Supply Shortage of [name of medicine] - Memo attached |

Dear All,

There is a shortage in the supply of [name of medicine], where supplies of medicines are expected to be affected until [insert month/year].

Level 1 (delete): This email notification is for information only. Arrangements have been made to conserve stock until normal supplies are expected to resume. The main clinical areas affected are:

Level 2&3 (delete): Please find attached a memo detailing actions to be taken to manage the shortage until normal supplies have resumed. The main clinical areas affected are:

Please forward ensure that staff who do not routinely have access to emails and need to be aware of the shortage are informed.

A confirmation email will be sent once normal stock levels of the affected medicine have been replenished.

In the meantime, please do not hesitate in contacting me for further advice.

Kind regards,

[name, designation and contact details]

**Appendix 2: Example Supply Shortage communication Template**

**Memo [Trust Logo]**

**[Directorate]**

**To: xxx**

**From: xxx**

**Date: xx**

**Re: Supply Shortage of Medicine XXX**

**Author: ext/bleep: Date:**

**Approved by:**

**Appendix 3: Summary of Communication Strategy for a Critical Medicine supply Shortage**

|  |  |  |  |
| --- | --- | --- | --- |
| **Level** | **Description** | **Communication from:** | **Communication to** |
| 1 | Pharmacy Only | DP | Pharmacy Department |
| 2 | Discrete Clinical Areas – minimal impact on clinical practice/administration | DP  | Affected Clinical Leads: Memo required  |
| 3 | Discrete Clinical Areas – significant impact on clinical practice/administration | DP | Affected Clinical Leads: Memo required detailing contingency plan |
| 4 | Trust-wide | ***[CG team]*** | Pharmacy DepartmentTrust Wide Memo detailing contingency plan  |