



## **Best Practice Standards for managing medicines shortages in NHS hospitals**

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# **The first stop for professional medicines advice**

# Best Practice Standards for managing medicines shortages in NHS hospitals

## Purpose of the document

Best Practice Standards for managing Medicines Shortages in Secondary Care first published by the Royal Pharmaceutical Society in 2012 has been reviewed and updated. The document outlines best practice standards for managing Medicine Shortages in NHS hospitals and can be adapted and used to develop local policies and Standard Operating Procedures or where regional or other collaborative working is in operation, within STP footprints, for example.

Note. The principles apply to the whole of the NHS but the implementation will need to reflect differing local organisational structures in England, Scotland, Wales and N. Ireland

## Introduction

Medicine supply issues can arise for a variety of different reasons including issues with the supply of active pharmaceutical ingredients, in-process manufacturing issues, batch failures, and distribution/logistic issues. Globalisation of the pharmaceutical industry means that the manufacture of individual medicines is frequently limited to just one or two sites worldwide. Production schedules are planned months in advance and this together with the adoption of "just in time" manufacture and inventory control, means that manufacturing volumes are matched exactly to predicted demand. Unanticipated surges in demand can't quickly be matched by increased production.

Medicine shortages have always been a problem for the NHS, however more recently there have been an increasing number of more significant critical shortages, which are very challenging and problematic to manage. The Department of Health and Social Care (DHSC) and NHS England Commercial Medicines Unit (CMU) are working together to mitigate and minimise the impact of the shortages on the NHS, in addition to the work undertaken regionally and locally in NHS Trusts to reduce the risk of medicine supply issues affecting patients.

All too often the first pharmacy teams know of a shortage is when a product they've ordered isn't delivered as expected and they then have little information about possible causes or how long the shortage may last. Early identification of a potential shortage by the pharmacy is important but there is also ample anecdotal evidence that hasty, ill-considered action such as panic buying by a very few pharmacy teams can quickly turn a short term disruption in a local supply chain into a much longer term shortage for all. The appropriate response to what seems likely to be a short term interruption to local supply may be the wrong response to what looks as if it may be the first sign of a longer term shortage affecting the whole NHS supply chain. At the time a local stock outage or the risk of an imminent outage becomes apparent, it's important that a senior member of the pharmacy procurement team assesses and then decides how to react. It is therefore very important that hospitals do not respond to supply issues in isolation or by stockpiling; instead they should ensure they are working with their regional leads, which will be able to raise awareness with the national teams who will then formulate a management plan for the whole NHS. These standards described within this document are designed to provide advice to help NHS hospital pharmacy teams manage medicines shortages, to encourage efficiency and cross boundary working to minimise the impact on patients.

## Responsibilities

### National responsibilities

The Principal Pharmacist at the NHS England Commercial Medicines Unit and the Department of Health and Social Care (England) Medicines Supply Team are responsible for engaging with suppliers, assessing the risks posed by shortages, seeking alternative suppliers/medicines and sharing information with NHS trusts directly and through regional medicines procurement specialists (RMPS). This includes active engagement with suppliers to prevent shortages occurring. Also work with UK Medicines Information teams (UKMI), national clinical leads and Clinical Reference Groups when significant issues occur including liaison with the network of Medication Safety Officers, CCGs and Community Pharmacy contractors.

### Regional responsibilities

In acute care, RMPS are responsible for engaging with CMU and DHSC, providing local information and context to shortage management. Where a risk assessment supports further work on a potentially long term and/or critical shortage, RMPS will facilitate CMU/DHSC communications to and from Trust pharmacy teams to ensure that any required actions and information are communicated effectively. This may include advice to restrict use if rationing and reservation of limited stock for the neediest patients is required across regions.

Where a shortage leads to the need to use imported medicines, Regional Quality Control is responsible for assessing and advising on the quality of the imported medicine and provides the required approval for clinical use.

## Overarching Principles of best practice for Local Management of Medicines Shortages in NHS

### Hospitals

1. Where there is insufficient stock to meet the needs of patients, hospitals should work collaboratively to ensure that priority is given to patients with the greatest clinical need; this may necessitate managed sharing of stock between hospitals and collaboration across regions.
2. Hospitals should collaborate to minimise duplication of effort on risk assessment of impact of shortages, procurement alternatives and production of clinical advice, for example.
3. Information on shortages may originate from many sources including other trusts, manufactures and suppliers, regional procurement specialists, the NHS Commercial Medicine Unit, DHSC Medicines Supply Team and MHRA. On-going work aims to collate key information about shortages and their management on the Specialist Pharmacy Services Website (SPS) [www.sps.nhs.uk](http://www.sps.nhs.uk)
4. At the time a local stock outage or the risk of an imminent outage first becomes apparent, it's important that a senior member of the pharmacy procurement team is involved in deciding how to react. No action should be taken until clear as possible understanding of the nature and cause of the problem. The appropriate response to a short term interruption to local supply may be the wrong response to a potentially longer term shortage affecting the whole NHS supply chain.
5. Whilst the guiding principle must be that the right medicine should be available to all patients, in the right presentation at all times, pharmacy professionals should ensure that no local action such as local stockpiling which could exacerbate a medicines shortage within the wider NHS is taken.

## Standards for NHS Hospital Trusts

1. The Director of Pharmacy/Chief Pharmacist in each Trust is responsible for taking a leadership role in ensuring that there are strategies, procedures and sufficient staff resource in place for effective management of medicines shortages within their organisation.
2. A designated senior pharmacist or technician should take 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 Clinical teams. This will include identifying and managing any risks associated with the shortage particularly where alternative agents are used.
3. On all aspects of formulating the local response to a medicine stock outage or shortage, the Chief Pharmacist or designated lead pharmacist/technician should work closely with the regional medicines procurement specialist.
4. All Trusts should have an up-to-date written standard operating policy (SOP) for managing medicines shortages. This should include 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 including primary care medicines management teams, where relevant.
5. The SOP should include an internal and external communication plans which should be reviewed regularly to ensure they are fit for purpose. The aim of the plan is to ensure that all hospital staff involved in the supply chain and affected patients are fully informed of the situation. Effective communication may include written, verbal and electronic methods and one single method should not be relied upon. Where electronic prescribing systems are in use then notifications can be configured to alert and guide prescribers to alternative products with associated dosage and administration guidance. It is critical that patient/carers are counselled when a medicine shortage is likely to delay or compromise care or leads to a change in their medication. Where there are financial consequences in managing a shortage internal communications should involve financial teams.
6. When a shortage is identified, a risk assessment should be conducted to evaluate the potential effect of the shortage. The risk assessment should take account of :-
  - The apparent root cause of the initial stock outage
  - Estimated duration of the outage: is it really a potential long-term- NHS-wide shortage or a temporary interruption to the local supply chain only
  - Usage figures and scale of the gap between current supply and average demand
  - Availability of suitable alternative products
  - Potential risk to patients of continued unavailability
7. The Specialist Pharmacy Services (SPS) Website is being developed as a source of verified information about medicines shortages and their management. A mechanism through which information can be collected and validated is also being developed. Chief Pharmacists should support this development and implementation of this.

8. Not all temporary outages will become long term shortages and not all shortages will require further action. Where the initial assessment supports further work on a potentially long term/critical shortage, the designated pharmacist/technician should establish stock on hand within the entire organisation and estimate how long it is likely to last. It is essential that this includes stock used by Homecare and any 3<sup>rd</sup> party contractors such as Outpatient services. In addition the issue must be escalated to regional medicines procurement specialist (RMPS) at the earliest opportunity. The RMPS will liaise directly with CMU and DHSC and facilitate system-wide communication and information sharing about the problem and potential solutions to it.
9. Collaborative working across organisations (e.g. regional) ensures that limited stock can be prioritised and shared according to clinical need. RMPS will support and co-ordinate this when required.
10. Where limited stock leads to restriction of use, then there should be engagement at individual Trust level with relevant clinical stakeholders to agree and support implementation of management strategies. Typically liaison with Medical/Clinical Directors, Clinical Speciality leads, Senior Nurse Management and Clinical Pharmacy teams will be required to ensure patient safety and prevent medication errors if substitute therapies are required.
11. Where a suitable alternative medicine is available, i.e. same drug alternative supplier, different drug or imported medicine, then a fully documented risk assessment should be carried out under the guidance of the Chief Pharmacist or the designated pharmacist or their deputy. Where the alternative is an unlicensed medicine, Trusts should risk assess the product in line with relevant local and national professional and regulatory guidance. The regional QA pharmacist, appropriate medicines information staff and clinicians should be involved in risk assessment and drafting advice for management of long term and critical shortages
12. Once the risk assessment and management plan has been completed they should be communicated to all relevant hospital staff including those on shifts and on call Pharmacy teams.
13. The management plan should be reviewed periodically, If/once supply of the affected product has returned and there is confidence that the supply will not be interrupted for at least 8 weeks, the contingency plan should be de-escalated by the relevant teams involved in managing the shortage taking into account the need to avoid wastage of any surplus supplies of an alternative therapy/product procured as a result of the shortage
14. All medicines shortages believed to have significant patient safety implications should be recorded on a medicines incident reporting system e.g. Datix. Any lessons learned should be communicated around the Trust and shared with the RMPS.
15. Ideally, Chief Pharmacists should keep a log of shortages to include details of the shortage, decisions taken, alternatives used and any safeguards or permanent changes to practice that were introduced in response.
16. A sample Standard Operational Procedure (SOP) is included in Appendix 1 for Trusts to adapt according to local need.

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## Appendix 1



Stock Shortage SOP  
draft sample.docx



NHS Specialist Pharmacy Service  
[www.sps.nhs.uk](http://www.sps.nhs.uk)