

## **Best Practice Standards for Managing Medicines Shortages in Secondary Care in Scotland**

### **Introduction**

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. These standards are designed to provide advice to NHS Scotland hospitals in managing medicines shortages to minimise the impact on patients and the NHS.

### **Overarching Principles**

1. Whilst the guiding principle must be that appropriate medicines should be available for all patients, pharmacy professionals should ensure that no action is taken within a hospital which could exacerbate a medicines shortage within the wider NHS, for example stockpiling medicines or ordering more stock than required to meet normal demand.
2. Where there is insufficient stock to meet the needs of all patients, Health Boards should work collaboratively to ensure that priority is given to patients with the greatest clinical need; this may necessitate sharing stock between hospitals and Health Board areas.
3. Health Boards should seek to work on a collaborative basis to minimise duplication of effort, for example on risk assessments, procurement alternatives and production of clinical advice.
4. Whoever provides the initial information on a medicine shortage, be it the Department of Health, NHS National Procurement or the pharmaceutical industry, this should be provided in a timely manner, with as much supporting information as possible, to allow hospitals to take appropriate action to mitigate any effects on patient safety.

### **Standards for NHS Scotland Hospitals**

1. The Director of Pharmacy in each Health Board 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 Board.
2. All Health Boards should have an up to date, written policy for managing medicines shortages.
3. When a shortage is identified, a risk assessment should be conducted to evaluate the potential effect of the shortage. This assessment should be documented and take account of:

- The estimated duration of the shortage
  - Usage figures and the scale of the gap in supply and demand
  - The availability of suitable alternative products
  - The potential risk to patients
4. There should be engagement with relevant clinical stakeholders to agree and support implementation of management strategies, for example lead pharmacist, nurse or doctor for the speciality(s) that use the medicine in short supply.
  5. Not all shortages will require further action, but where the risk assessment supports further work on a long term/ critical shortage, the pharmacy should establish their stock holding within the organisation and estimate the time period this will cover. In order to manage this stock appropriately it may be advisable to hold the limited stock in a single area. Where the medicine is supplied through homecare, engagement with homecare providers may be required.
  6. Where limited stock leads to a restriction being placed on the use of a medicine, then this restriction should be discussed and agreed with an appropriate senior doctor in the Health Board (e.g. Medical Director, Clinical Director, Lead Speciality Clinician) with start and review dates, and should be communicated immediately to all relevant hospital staff. Communication of these restrictions is essential for ensuring patient safety and preventing medication errors.
  7. Where a potential alternative medicine is available, then a fully documented risk assessment of the alternative should be undertaken. If the alternative medicine involves the use/manufacture of an unlicensed product, then Boards should follow the guidance in MHRA Guidance Note 14.
  8. Hospitals should review their internal and external communications plans on a regular basis to ensure they are fit for purpose. The aim of the plan is to ensure that all hospital staff involved in the supply chain, including those on shift work, where appropriate, are made fully aware of the situation. There are a range of possible communication routes including daily patient safety huddles. Where relevant, information should be passed to the Area Drug and Therapeutic Committee and primary care lead(s).
  9. If any training or clinical advice is necessary as a result of the use of the alternative medicine, then this should be co-ordinated in a prompt and effective manner.
  10. Patients/carers should be consulted when a medicine shortage is likely to delay or compromise care or where it leads to a change in medication regimen.
  11. All medicines shortages have the potential to affect patient safety; consideration should therefore be given to the recording of such incidents through incident reporting systems (e.g. Datix).
  12. The resolution of a medicines shortage should be communicated to relevant hospital staff and consideration should be given to lessons learned and future actions.
  13. Health Boards should keep a log of shortages to include details of the shortage, decisions taken, alternatives used and any new safeguards which have been introduced.