

Notification and management of medicines shortages

Best Practice Guidelines



Foreword

Every day millions of NHS patients rely on medicines supplied by the pharmaceutical industry. Thanks to the hard work of all those in the supply chain – manufacturers, wholesalers and pharmacists – patients receive the medicines they require. Sometimes, there are minor supply problems, often unnoticed by patients and clinicians. Occasionally, despite the best efforts of all those concerned, supply problems can affect patients. The Department of Health (DH) and the generics industry are committed to working together to tackle these problems.

This is why the DH and the British Generic Manufacturers Association (BGMA) have produced these best practice guidelines, which are designed to help minimise the impact of any medicine shortage. They recommend that companies communicate with the DH as soon as possible about impending shortages that are likely to have an impact on patient care. This early exchange of information will enable the DH and the industry to work together to explore the options for managing the shortage and will allow time to make contingency arrangements where necessary.

Companies are encouraged to nominate a member of staff to have overall responsibility for supply issues, and to act as a contact point. The DH also has a nominated contact point, and an electronic mailbox has been set up to facilitate communication.

We hope that companies will choose to adopt these guidelines and we look forward to continuing to work together in ensuring that patients get the best possible treatment in the NHS.



ANDY BURNHAM
Minister of State
Department of Health



WARWICK SMITH
Director, BGMA

Introduction

Medicines shortages have become increasingly common over the last few years. There are many reasons why a medicine might go out of stock.

These include:

- Manufacturing problems
- Supply/demand imbalance
- Raw material problems
- Regulatory problems.

Each supply problem has its own characteristics and has to be dealt with on an individual basis.

The Department of Health (DH), the NHS Purchasing and Supply Agency (PASA) and the Medicines and Healthcare products Regulatory Agency (MHRA) have worked with companies to help resolve shortages by:

- Expediting regulatory procedures for products deemed critical
- Working with companies to manage supply of existing stocks
- Identifying and liaising with other manufacturers to increase production of the product concerned and/or alternative medicines
- Identifying sources of product from abroad, and expediting import for individual patient use
- Identifying NHS manufacturing units with capacity and ability to meet demand
- Advising and facilitating communication with the NHS.

It is important that all stakeholders work together to ensure that a shortage of a product does not cause problems for patients and prescribers. The DH and the British Generic Manufacturers Association (BGMA) have therefore drawn up best practice guidelines, which are designed to ensure best practice in the management of supply problems.

These guidelines are voluntary, and complement the statutory requirement to inform the Licensing Authority of any disruptions in supply under European Medicines Legislation (Directive 2001/83/EC, as amended) – see paragraph 5 of these Guidelines.

Best Practice Guidelines

1. Notification of shortages to the DH

It is not always possible for companies to predict when a product shortage might occur. However, the more warning that the DH has of a shortage, the better it is able to help manage the situation effectively.

With generic products, a shortage of one company's product might not necessarily lead to a supply problem in the marketplace, as other companies may be able to meet demand.

Companies should notify the DH if they find themselves heading towards a product shortage that is likely to impact on patient care. In deciding whether to notify the DH of a potential problem, companies should take into account:

- Their share of the market for the product concerned
- The number of companies manufacturing the product
- The nature of the problem (e.g. raw material problems could have a widespread effect)
- Whether the medicine is the only treatment available for certain patient groups
- Whether the product has a limited market and has been largely superseded by different medicines
- The likely duration of the shortage.

Information supplied to the DH will be treated as 'in-confidence' and the DH will not take any action which might jeopardise the commercial business of a company. The DH will not approach competitors or other stakeholders unless otherwise agreed by the company concerned.

In addition to informing the DH, companies who are supplying products under contract to PASA should inform them immediately of any inability to supply.

2. Management of shortages

Companies should take steps towards minimising the effect of any supply problem. To this end, if they have not already done so, companies should develop internal procedures for identifying, avoiding and dealing with potential shortages.

When, after consideration of the criteria set out previously, a company reports a shortage or potential shortage to the DH, both parties should come to an agreement on the criticality of the product and reach an understanding of the supply problem and an overview of the UK supply position.

Companies and the DH should then work together to develop and agree appropriate strategies for dealing with the particular problem. The full participation and co-operation of companies in this process is essential.

3. Communication strategy

In the event of a shortage, companies need to decide whether communication with the NHS is necessary, and if so, what format it should take.

This might include:

- Medical/pharmaceutical journals (e.g. The Pharmaceutical Journal)
- The National Electronic Library for Medicines
- Healthcare professionals
- Patient organisations.

These communication plans should be shared with the DH.

4. Contact points within companies and the DH

Each company should nominate a person, and a designated deputy, as a contact point for supply issues. He/she should be sufficiently senior to have an overview of the supply situation for any particular product, or should be able to direct enquiries to the appropriate person.

Information required by the DH in the event of a medicine shortage is set out at the end of these guidelines. Telephone, fax and e-mail contact details within the DH are also included. There is a dedicated DH mailbox to deal with notifications of shortages of generic medicines.

5. European Medicines Legislation

Articles 23a and 81 of Directive 2001/83/EC (as amended) relate directly to the supply of medicines, and require marketing authorisation holders – within the limits of their responsibilities – to maintain appropriate and continued supplies of their products, and to notify the Licensing Authority if a product is not going to be available, either temporarily or permanently. The legislation requires two months' notice in all but exceptional circumstances.

In addition to this requirement, companies should ensure that the DH is notified as soon as possible of any potential shortages that are likely to have an impact on patient care.

Reporting shortages to the DH

Information required

Company details

- Company name
- Name of contact within company
- Contact telephone number
- Contact fax number
- Contact e-mail address

Product details

- Product name and presentation
- Licensed/unlicensed uses
- Other companies affected (supplied)
- Names of alternative manufacturers (if known)

Reason for shortage

Expected duration of shortage

Steps taken/planned to address shortage

Date of notification to DH/MHRA

See over for contact details.

Contact Details

Department of Health

F.A.O. Mrs Isabelle Izzard
Principal Pharmacist
Medicines, Pharmacy and Industry Group
456D Skipton House
80 London Road
London SE1 6LH

Tel: 020 7972 2913
Fax: 020 7972 2932
E-mail: isabelle.izzard@dh.gsi.gov.uk
Mailbox: Genericmedicineshortages@dh.gsi.gov.uk

In addition, for products affecting secondary care contract items:

NHS Purchasing and Supply Agency

F.A.O. Howard Stokoe
Principal Pharmacist
Premier House
60 Caversham Road
Reading RG1 7EB

Tel: 0118 980 8850
Fax: 0118 980 8853
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Copies can also be downloaded from

www.dh.gov.uk/medicinesupply

www.britishgenerics.co.uk