

Gateway reference number 18605

Best Practice for Ensuring the Efficient Supply and Distribution of Medicines to Patients

Introduction

Patients can suffer distress and inconvenience if supplies of medicines are disrupted. Increased demand for UK stock can occur for a number of reasons including from parallel trade of branded medicines and can cause difficulties in managing the supply chain. Organisations representing the various parts of the supply chain, regulators and government are committed to working collaboratively to ensure that patients can continue to obtain medicines quickly and conveniently from the pharmacy or dispensing doctor dispensary of their choice.

This guidance has been developed following detailed consideration of the current problems by a group representing the different parts of the supply chain. There is separate guidance available for managing difficulties due to manufacturing or regulatory issues. Effective implementation of this best practice guidance is an essential part of improving the efficiency of supply to patients and reducing the burden caused by the current supply problems. Medicines should be supplied in a timely manner. The aim of all parties should be that, under normal circumstances, pharmacies should receive medicines within 24 hours. The government and the organisations representing the various parts of the supply chain will continue to review the situation and take appropriate action as necessary. This guidance is relevant to marketing authorisation holders, manufacturers, wholesalers, dispensing doctors, pharmacists and prescribers.

There is an existing framework in legislation to control the appropriate and continued supply of medicines to patients in the UK. Both manufacturers and wholesalers licensed to trade in the UK have a legal duty¹ to ensure that UK patient needs are met and pharmacists and dispensing doctors have ethical obligations to ensure the needs of patients are always put first. More information on the key legal and ethical obligations on different parts of the supply chain can be found in the separate guidance note, “Trading Medicines for Human Use: Shortages and Supply Chain Obligations” (published in November 2009 and revised in January 2013). It is available on the DH website at

www.dh.gov.uk/health/2013/01/medicines-human-use/

A list of key affected products and guidance on contingency arrangements can be found on the PSNC Website (www.psn.org.uk/brandedshortages).

¹ Article 81 of European Directive 2001/83, requires the maintenance of appropriate and continued supply of medicinal products by marketing authorisation holders and distributors. This is implemented in UK legislation by the Human Medicines Regulations 2012 (SI 2012/1916).

Manufacturers

Manufacturers should have robust supply arrangements in place that ensure medicines are distributed to pharmacies and dispensing doctors in an efficient and timely way.

Care should be taken to ensure that sufficient stock is put into the UK market to meet UK patients' needs. Manufacturers should make best endeavour to fill all UK orders, in a timely and prompt fashion. In planning stock holdings, manufacturers should hold a reasonable volume of buffer stock to ensure continuity where there are fluctuations in demand, for example if there is a sudden reduction in parallel import availability in the UK or where there are time lags or reliability issues with the data used to forecast demand.

Quotas are one of the tools being used to try to ensure fair distribution of medicines when out of the ordinary demand exceeds available supply. However, any allocation of quotas must be flexible enough to cope with reasonable fluctuations in demand. Where quotas are used, manufacturers should ensure that they are set equitably.

Manufacturers should maintain regular phone or “face to face” contact with their wholesaler customers and/or distributor/agent to monitor products identified as in short supply in order to ensure both parties have a good understanding of the supply and demand for particular products. To facilitate communication, each manufacturer should nominate a person as a contact point for wholesalers and/or distributor/agent in the event of supply chain problems.

Manufacturers should have contingency arrangements in place to supply product where stock is exhausted at wholesalers, pharmacies or doctors' dispensaries. These arrangements may include the direct shipment of stock to pharmacies or doctors' dispensaries or joint working with wholesalers to ensure supply through the normal wholesaling channel.

Manufacturers should, where appropriate, make available and advertise a dedicated supply shortages phone helpline, which has sufficient capacity and is adequately resourced with appropriately trained personnel. It is essential that these arrangements are communicated to pharmacies and doctors' dispensaries; some manufacturers have successfully used their sales force to support raising awareness of contingency arrangements. Best practice is for details of individual supply problems and related contingency arrangements to be flagged to dispensing staff at the point of order, for example through electronic ordering systems.

In exceptional circumstances, manufacturers may find it necessary to verify that their supply and contingency arrangements will be used for genuine UK patient needs and in doing so should be able to utilise reasonable verification processes. This could be done in a number of ways including asking for confirmation that there is an urgent patient need or for the reason why there is an unusual demand for the product. Routine checking of proof of prescription

is rarely acceptable because of the need to safeguard patient confidentiality and the associated administrative burden. Nonetheless, where there still remains doubt regarding patient need, manufacturers may choose to check (possibly through independent third party auditors) a prescription to establish that the demand is genuine. Manufacturers who require this type of verification need to be sensitive to the workload implications for dispensers who are dealing with many companies and the dispensers' responsibilities to comply with the Data Protection Act and other relevant legislation and professional/NHS guidance and assurances (in particular, the NHS Information Governance Toolkit) with regard to patient data displayed on a prescription. As part of this, dispensers should completely obscure all patient data and prescriber details. This should include any barcodes, which could be used to obtain confidential information. In tandem, manufacturers should have appropriate organizational and technical security measures in place to protect any personal data that they obtain inadvertently via this route from unauthorised or unlawful processing and accidental loss.

Manufacturers should, where appropriate, undertake customer audits or surveys to assess the performance of supply arrangements and as a means of identifying areas to target improvement work.

Wholesalers

All wholesalers have a key role in working with manufacturers to ensure the efficient and timely supply of medicines to pharmacies and doctors' dispensaries.

Wholesalers should schedule regular communication with branded manufacturers to ensure both parties have a good understanding of the supply and demand for particular products so that patients receive the medicines they need. Close working has proven to help identify problems. To facilitate communication, each wholesaler has named supply chain contacts for manufacturers in the event of problems.

A wholesaler should use best endeavours to put in place measures and controls that ensure the equitable distribution of available medicines amongst all pharmacies and doctors' dispensaries.

To ensure equity in geographic distribution of available stock, it is important for wholesalers to co-ordinate orders centrally as well as at depot level.

Quotas are one of the tools being used to try to ensure fair distribution of medicines between pharmacies and doctors' dispensaries when out of the ordinary demand exceeds available supply.

Where a depot's stock of a product has been exhausted, incoming deliveries to replenish supplies should be given priority status to meet patient need over routine deliveries of other products. This will help ensure the stock is available for order by pharmacies and doctors' dispensaries as soon as possible.

It is essential that wholesalers communicate with pharmacies and doctors' dispensaries, clearly, consistently and in a timely way. If a product cannot be delivered as requested, wherever possible, the dispenser should be provided with details of any contingency supply arrangements, where these are known. The reason an order cannot be met should be made clear to the pharmacy/doctor dispensary.

This guidance applies to all wholesalers who buy and sell prescription medicines not only BAPW members.

Pharmacies and Doctors' Dispensaries

All pharmacies and doctors' dispensaries should have contingency arrangements in place to source supply where stock is unobtainable from wholesalers. These arrangements should be documented and made available to all relevant staff, including locums.

Where stock is unavailable from a wholesaler, reasonable steps should be taken to obtain the medicines in question. For pharmacies, this may include having reciprocal arrangements with neighbouring pharmacies when required to meet urgent patient needs, and the use of manufacturers' contingency order arrangements.

Pharmacies and doctors' dispensaries should have easy access to a current contact list for manufacturers and should designate a member of the pharmacy/dispensary team as lead on procurement.

A range of resources including the list of medicines that have been reported nationally as being difficult to obtain and a summary of key manufacturers contingency arrangements can be found on the PSNC website:
www.psnc.org.uk/brandedshortages

Additional 'next patient' stock should be kept to a reasonable level.

Where a manufacturer requests prescription specific information, dispensers will need to consider how they ensure they continue to comply with their responsibilities within the Data Protection Act and other relevant legislation and professional/NHS guidance and assurances (in particular, the NHS Information Governance Toolkit) with regard to patient data displayed on a prescription. As part of this, dispensers should completely obscure all patient data and prescriber details. This should include any barcodes, which could be used to obtain confidential information.

Pharmacy and general practice staff should advise patients to request their prescription in good time. This is particularly important for patients taking medicines with a significant clinical consequence to missing any doses (e.g. anti-psychotics, anti-epileptics, anti-cancer, etc).

Where appropriate, pharmacies and doctors' dispensaries should discuss the problems of stock availability direct with local practices.

Support in sourcing branded medicines is available from the PSNC Information Team (01296 432823) and the NPA Information Department (01727 858687).

Prescribers

Prescribers should be flexible in their approach and response to difficulties experienced by their patients. This may include the consideration of a change in medication, though such choice may not be possible or appropriate if patients are to receive optimal therapy. Any such decision should take into consideration the clinical history of the patient, consider the therapeutic equivalence of the medicines and be taken in consultation with the patient. Co-operation with other professionals to minimise the effects of supply problems is essential.

Prescribers and general practice staff should advise patients to request their prescription in good time. This is particularly important for patients taking medicines with a significant clinical consequence to missing any doses (e.g. anti-psychotics, anti-epileptics, anti-cancer etc).

This document has been endorsed by the following organisations:

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|  | Association of the British Pharmaceutical Industry |
|  | British Association of Pharmaceutical Wholesalers |
|  | British Medical Association |
|  | Department of Health |
|  | Dispensing Doctors' Association |
|  | Ethical Medicines Industry Group |
|  | General Pharmaceutical Council |
|  | Medicines and Healthcare products Regulatory Agency |
|  | National Pharmacy Association |
|  | Pharmaceutical Services Negotiating Committee |
|  | Royal Pharmaceutical Society |

Updated: January 2013