



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 duty 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 December 2010). It is available on the DH website at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_122741

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

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