

**Canadian Generic Pharmaceutical
Association (CGPA)**



**Best Practices Guidelines for the
Prevention, Notification and Management of
Drug Shortages**

Introduction

Every day millions of Canadian 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 supply issues, most often unnoticed by patients and physicians. The key objective of the Canadian Generic Pharmaceutical industry is to provide adequate supply of quality, affordable medicines for Canadian patients through their health care professionals. Occasionally, despite the best efforts of all those concerned, supply problems can affect patients. Any disruption in supply is of serious concern to us.

This is why CGPA has produced this best practice guideline which is designed to help prevent, manage and notify drug shortages – hopefully with the ultimate goal of Canadians always getting the drugs they need.

The discussion in this guideline is divided into 3 parts: preventing drug shortages whenever possible, notifying stakeholders of current and anticipated drug shortages and managing the drug shortage issue.

We encourage companies to implement these best practices guidelines and we look forward to continuing to work together in ensuring that patients get the best possible treatment.

Discussion

Manufacturers actively manage the supply chain as much as possible. The Canadian supply chain for pharmaceuticals is very complex so it is often difficult to identify true shortages.

What is very obvious is that each supply problem has its own reasons and characteristics and has to be solved on an individual basis.

There may be a number of complex contributing factors that may cause supply disruptions. They can be generally grouped into 4 categories: Production factors, Regulatory factors, Supply Chain factors and Market factors.

1. Production Factors:

- The manufacturing of pharmaceuticals is highly complex, regarding significant lead times and the demand for specific products is subject to significant fluctuations
- There are shortages in the availability of certain active pharmaceutical ingredients (API) at prices and/or quantities necessary to meet Canadian market demands
- There are unexpected surges in market demand for particular products
- Manufacturers are increasingly manufacturing for a global market. Therefore production decisions for products and marketplaces have become increasingly complex
- There are significant challenges in the production process resulting from capacity bottlenecks, especially considering international production is the standard

2. Regulatory Issues:

- There are increasing and changing regulatory requirements from Health Canada and other agencies
- There are lengthy backlogs in review performance that affect the supply of product in the marketplace

3. Supply Chain Issues:

- The manufacturer sells product to self distributing pharmacy chains and wholesalers. These buyers take title to the product. The manufacturer often cannot re-distribute product between buyers once title transfers have taken place. Manufacturers do not possess information about inventory levels of the products at the buyers' level.
- There are excess inventory purchases within the supply chain in anticipation of product listing, legal (patent) or price changes. Buyer behaviour can affect supply for other buyers, especially hoarding practices when faced with possible supply chain issues or shortage lists

4. Market Issues:

- The provinces continue to implement broad and restrictive pricing policies for listing multi-source generics on to their formularies. Manufacturers have confirmed that these decreasing pricing policies continue to challenge manufacturers in decisions whether or not to continue manufacturing and supply. Provinces have granted only variable degrees or no ability and/or success to be able to negotiate price increases (i.e. to adjust for API cost inflation) or to get exceptions to the fixed and broadly applied pricing levels. Companies need to constantly rationalize the profitability of products within their product lines
- Differing provincial pricing regulations also result in a Canadian market place where the price of the same product will differ from region to region and there is significant product movement by buyers in order to maximize profitability

What is being done to prevent drug shortages?

Generic manufacturers are:

- Increasing resources and investing in new systems, personnel and equipment and facilities
- Prioritizing production to shifting market demands
- Heavily allocating additional resources (financial and personnel) to Quality Control and Quality Assurance Operations to ensure continued compliance with all regulatory agencies
- Focussing on delivering highest service levels possible
- Working with health care professionals to prioritize products deemed critical and medically necessary
- Implementing practises at the wholesaler level which will provide more transparency in the movement of product throughout the supply chain

- Companies should take steps towards minimising the effect of any supply problem. To this end, companies should develop internal procedures for identifying and making business decisions to prevent actual and potential shortages
- Working with Health Canada to reduce the generic approval backlog and bring products to market in the most efficient and timely manner

How will Generic Companies Notify all stakeholders about Drug Shortages?

CGPA member companies have committed to posting their drug shortages on www.drugshortages.ca (available in English and French).

It is not always possible for companies to predict when a product shortage might occur. However, the more warning of a shortage, the better is the ability 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 will communicate if they find themselves heading towards any product shortage or anticipated/allocated supply issue that is likely to impact on patient care. In deciding whether to notify a current or anticipated shortage, companies will 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 product could or is deemed medically necessary because there are only few alternative therapies available
- 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
- The possibility of hoarding behaviour by stakeholders

1. Communication Strategy:

In the event of a shortage, companies need to decide what communication is necessary and if so, what format it should take. Companies are encouraged to over-communicate in order to alleviate the real anxiety felt by stakeholders when they hear of a current or anticipated drug shortage and consider how they would need regular communications to manage or plan actions.

This communications list will include:

- Healthcare professionals

- Patient organizations
- Federal Government
- Provincial Governments
- Supply Chain partners

2. Contact Points within Companies:

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.

Communicating Shortages

Information required:

Date:

Company Details:

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

Product Details:

- Product name, strength and dosage form

If possible:

- Expected duration of shortage
- Steps taken/planned to address shortage
- Status of shortage – Anticipated Shortage/Allocated Supply
 - No ability to supply

How will generic companies manage a drug shortage situation?

In the event of an anticipated shortage or an actual shortage situation, manufacturers will develop, implement and communicate a specific drug shortage work plan to address how the distribution of any remaining product will be prioritized (as medically necessary) and allocated. The company should ensure that the shortage work plan addresses and minimizes hoarding behaviour that would exacerbate the shortage

The entire industry (generic and brand) should address the shortage situation by identifying alternate sources of supply. These include other manufacturers of the product already approved, other manufacturers of product which potentially could be fast-tracked for approval or potential alternate supply of non-Canadian labelled lots of product. All alternate sources of

supply should be discussed with Health Canada to determine how to best mitigate shortage difficulties.

In summary, no generic manufacturer wants to be in a position where they are not able to provide supply of their product. This guideline is intended to help the generic manufacturer to prevent a drug shortage, to notify in the unavoidable case of a current or anticipated drug shortage and to manage a shortage situation to minimize the effect of the shortage on Canadians.

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