

## **National Pharmaceutical Drug Shortages**

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**CFMS**  
Canadian Federation  
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**FEMC**

Fédération des étudiants et des  
étudiantes en médecine du Canada

## **Background**

There is growing awareness among health care providers and patients alike of a shortage of prescription drugs in Canada. While the problem of drug shortages is not new, the recent frequency and duration of these shortages have sparked alarm among clinicians in North America. (1) This phenomenon is especially noted in generic injectable drugs, which was brought to the attention of the public after the halt of production at Sandoz Canada. Sandoz Canada, the sole supplier of multiple injectable drugs in Canada and the U.S., abruptly slowed or halted production following an unfavourable FDA inspection in 2012. (2) However, the Sandoz drug shortage is not isolated. There have been recent reports of shortages encompassing a variety of drug classes: generic antidepressants, antiemetics, chemotherapeutic agents, and antibiotics have also been implicated. (2,3) In fact, these drug shortages were reported by over 90% of pharmacists dating back to a 2010 survey by the Canadian Pharmacists Association. (3) Recent years have seen limited access to pharmaceutical products essential to patient care in both the inpatient and outpatient setting. At the time of publication of this document, upwards of 500 pharmaceutical products were listed in short supply.(4)

### **Impact on Patient Care**

The downstream effects of drug shortages are multifaceted and potentially life threatening. In the U.S., drug shortages have been reported by virtually all surveyed hospitals in 2011, with 82% reporting the need to delay patient treatment as a result. Medication errors, and patient deaths have since been linked to shortages of necessary pharmaceutical drugs. (5) In Canada, the majority of pharmacists believe that their patients are adversely affected by these shortages due to disruptions in continuity of care, the use of less effective alternatives, and loss in adherence to medications. (3)

The Canadian Pharmacists Association, Canadian Medical Association, and Canadian Society of Hospital Pharmacists surveyed their members in October 2012 and found that patient well-being was being negatively affected by drug shortages. (6) At that time, physician and pharmacist respondents reported that patient care was compromised in up to 20% of patients due to delayed access to medication, use of a less effective alternative, or drug formulation, or increased risk of an adverse effect or safety incident. Furthermore, 20% of physicians also reported that a patient in their care had clinically deteriorated as a result. Patient care was further compromised by placing increased demands on providers' time in sourcing medications, instead of looking after other patients. (6)

In addition, multiple national organizations have urged for action on drug shortages, including the Canadian Epilepsy Alliance (7), The Canadian Cancer Society (8), and The Arthritis Society of Canada. (9)

### **The Multi-Stakeholder Steering Committee on Drug Shortages (MSCC)**

In 2012, Health Canada and Alberta Health launched the Multi-Stakeholder Steering Committee on Drug Shortages (MSSC). Their aim was to focus on the prevention, notification and communication, and mitigation and crisis management of drug shortages. (10)

In September 2013, the MSSC published a toolkit for understanding Canada's drug shortages. (11) Multiple points in the drug supply chain were identified as potential areas where a drug shortage could be attributed. These include:

#### **MANUFACTURING**

- Non-compliance with standard manufacturing processes resulting in product recalls
- Non-compliance of foreign suppliers
- Single source foreign suppliers
- Changes in manufacturing procedures
- Global economic trends that lead to discontinuance of non-profitable products, downsizing product portfolios, and addition of new products that limits the capacity to manufacture existing products
- Unanticipated increases in demand
- Differing international regulatory requirements that make importing of foreign products during a shortage more challenging

#### **PROCUREMENT AND DISTRIBUTION**

- Sole suppliers
- Inventory management practices that result in incapability of handling unexpected increases in demand

#### **FRONT LINE DELIVERY**

- Inventory management at the levels of pharmacies, regional health authorities, and drug wholesalers
- Stockpiling which limits ability to reallocate inventory when needed, and leads to inaccurate estimates of total stock available
- Limited drug supply movement between community pharmacy supply chain and regional health authorities that prevents re-allocation of stock during a shortage

The House of Commons Standing Committee on Health identified sole contract sourcing as the most avoidable cause of drug shortages. (12) Sole contract sourcing often exists as a mechanism to incentivize suppliers to offer the best possible discounts in exchange for committed purchasing. (13) Taking into account the fiscal pressures of increased Canadian healthcare and pharmaceutical spending, it is understandable how Canada has become increasingly reliant sole contract sourcing.

### **Drivers of Current Drug Shortages**

A clear consensus on the drivers contributing to these pharmaceutical drug shortages has yet to emerge. As shortages in the raw material of drugs accounts for less than 10% of cited shortages, these shortages seem largely supplier-driven.

Failure of quality management directly resulted in 56% of the injectable drugs shortages reported in the U.S. in 2011. (14) The serious health and safety violations documented in the FDA inspections that led to the injectable drug shortage in 2011 indicate that closure of these manufacturing facilities is not due to overzealous regulation, but actual gaps in quality management. (5) In fact, many point further upstream towards economic factors, particularly the inability of current market incentives to reward quality of drugs. (14,15)

The pharmaceutical drug industry does not adhere to traditional models of supply and demand. Ideal market conditions include freedom of suppliers to enter and exit the market, the inability of suppliers to influence prices, and perfect information. Many drugs have only one sole supplier, and there are therefore little or few viable therapeutic substitutions available for these drugs if they become in short supply. Furthermore, the demand for a drug remains stable due to clinical need, regardless of the price or supply of these drugs. (1) Yet, there are few information systems in place to help buyers make purchasing decisions based on quality. In the case of sterile injectable drugs, where there is little margin for error, it may become more profitable to refocus manufacturing on other drug products that do not require as much vigilance and costs when quality becomes compromised. (14) This strategy may be even more pronounced in the generic industry, as the profit margin for generic drug manufacturing is relatively low at the outset. (2)

There is also evidence that another driver of drug shortages is the lack of structures in place to forewarn and prepare for drug shortages. Sandoz Canada provided very little warning of their decision to halt or stop production on many necessary drugs of which it was the sole supplier. (2) Furthermore, manufacturers rarely explain why a shortage exists and do not offer details into their decisions to alter production of a drug. This may partially be explained by the competitive market place in which pharmaceutical products are sold. There is no law or policy requiring prior

notification of impending drug shortages from companies who choose to discontinue crucial drugs, and whether such regulation will be effective in this competitive market is unknown.

### **Action to date**

The pharmaceutical industry launched the website [www.drugshortages.ca](http://www.drugshortages.ca), serving as a resource for drug shortage information. Manufacturers voluntarily update the website with actual or potential pharmaceutical shortages, and identify available alternatives. This could serve as a valuable resource for health care providers, though the impact this has made on delivery of patient care is uncertain at this time.

The National Pharmaceutical Strategy is an initiative undertaken in 2004 by the federal/provincial/territorial governments with five areas of focus: costing models for catastrophic drug coverage, expensive drugs for rare diseases, the establishment of a common national formulary, real-world drug safety and effectiveness, and pricing and purchasing strategies. (16) In 2012, the Standing Senate Committee on Social Affairs, Science and Technology published a review of the 2004 Health Accord. (17) The committee found that progress in those domains was mixed and that collaboration between the federal and provincial and territorial governments had slowed since 2006. There were disparities in the provision of pharmacare across the country, stressing the need for governments to work together to develop a national pharmacare program that reflected universal and equitable access. The committee stressed that improved safety and appropriate use of pharmaceuticals, cost control for value for money and sustainability, and a national formulary remain key priorities.

### **Principles**

- 1. All Canadians should have the ability access medical care, including access to pharmaceutical drugs**
- 2. Pharmaceutical drugs in Canada should be safe, effective, and delivered to the highest standard of care**
- 3. The federal, provincial, and territorial governments are accountable to shaping the necessary policies that will create fiscally sustainable and accessible health care that is effective for Canadians.**

## Recommendations

### **1. We urge the Government of Canada to consider the challenge of pharmaceutical drug shortages as a federal priority.**

Prime Minister Stephen Harper of the Conservative Party of Canada argued that the drug shortage problem was caused by the fact that “[c]ertain provinces have undertaken to sole-source certain critical medications”, and thus dissolved federal action in the matter. (2) However, this fails to recognize that provinces are incentivized to sole contract source to keep procurement costs at a minimum. In fact, sole-source contracting is outlined as a good procurement principle as outlined by the World Health Organization, but only when accompanied by effective monitoring and enforcement. (13) We are concerned that this attitude therefore undermines federal responsibility to regulate pharmaceutical suppliers to ensure that they provide safe and effective products. Furthermore, the universality of these drug shortages across Canada demonstrates that this is a topic that requires federal attention.

It is critical that policy changes are introduced to minimize both the occurrence and impact of future drug shortages. Changes to policies such as requiring companies to report impending drug shortages could ensure better preparation. Changes to policies incentivising quality in the manufacturing process of these drugs could encourage companies to re-invest in quality management instead of refocusing on other drugs with more profitable margins.

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