

## Position Statement on Prescription Drug Shortages in Canada

The escalation in shortages of prescription drugs in the past few years and the ongoing disruptions to supply experienced in Canada and globally are matters of grave concern to the Canadian Medical Association (CMA) and its members. Drug shortages are having a detrimental impact on the delivery of patient care and treatment and the availability of health care services across the country.

CMA has advocated for a thorough examination of the drug supply system to identify points where we in Canada can influence supply problems. Solutions will have to involve the various players in the drug supply chain, from manufacturers through to healthcare providers and levels of government.

### Background

Drug shortages are not a problem confined to Canada. In the United States the number of drug shortages from 2006 to 2010 grew by more than 200 per cent.<sup>1</sup> In 2011, 251 shortages were reported to the FDA.<sup>2</sup> Canada has not had an accurate record of the number of drugs in short supply over past years but in April 2013 253 drugs were listed on the industry sponsored Canadian Drug Shortage Website.<sup>3</sup> Factors that influence the occurrence of a drug shortage can occur at any stage of the drug supply chain and any disruptions can ripple through the system.

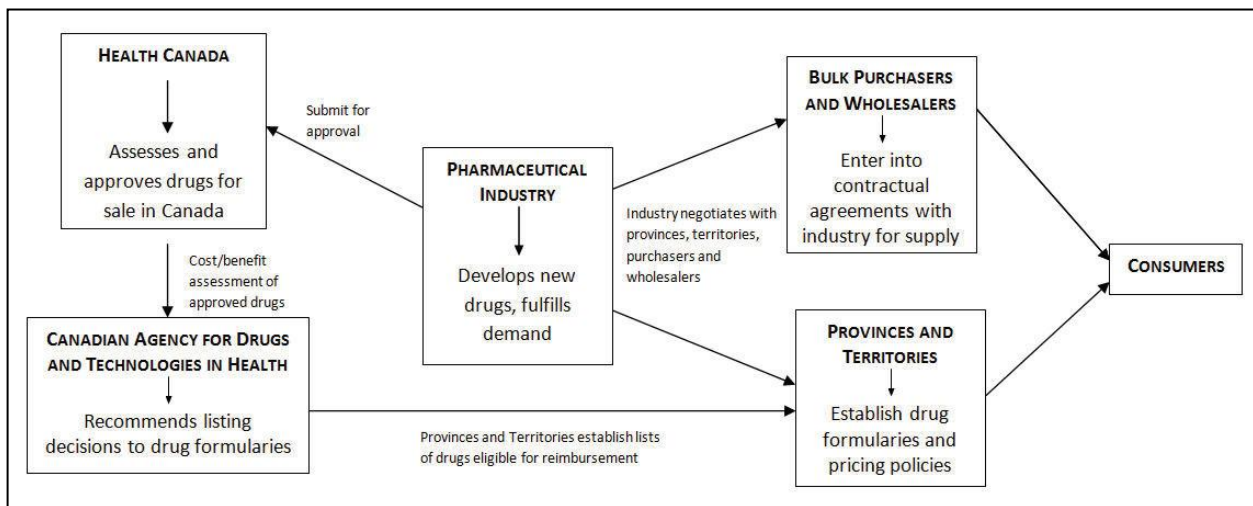


Figure 1 Drug supply chain in Canada<sup>4</sup>

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There are many causes that can lead to a drug shortage. Disruptions in the supply of an active or key ingredient contribute to drug shortages and this is exacerbated when the active ingredient is produced by a single raw material supplier. If the supplier is unable to meet demand than all manufacturers relying on that supply become vulnerable to disruptions. The sourcing of raw materials from outside of North America, primarily China and India, whose safety and regulatory standards may not be stringently enforced can result in regulatory authorities closing down facilities thereby impacting supply of active ingredients or necessitating a lengthy search for a new supplier.

Additional manufacturing issues contributing to shortages can include complex manufacturing processes like those used to make sterile injectables, changes in product formulations, problems in the production process or regulatory enforcement of good manufacturing processes, limited capacity, an unexpected surge in demand, regulatory delays in product approvals and business decisions.<sup>5</sup>

Shortages may also be due to factors outside the manufacturers control such as various interruptions in the normal delivery of medicines through the pharmacy supply chain and distribution network<sup>6</sup>. Just in time inventory management practices can lead to a reduction of available drug inventories. In addition procurement strategies that lead to sole source contracts for bulk purchases has been identified as the single most avoidable cause of drug shortages.<sup>7</sup>

### **Health Consequences**

Disruptions in the supply of medications have the potential to impact patient care, patient health and the efficiency of the overall health care system.

Among the impacts of drug shortages are:

- delays in access to needed medication;
- delays or disruptions to clinical treatment;
- delayed or cancelled surgeries,
- loss of therapeutic effectiveness when an appropriate alternate therapy is not available;
- increased risk of side effects;
- increased non-compliance when changes in medication make it confusing and harder to comply with a new medication regime particularly for those on long term therapy.<sup>8</sup>

Any and all of these situations can result in a disruption to clinical stability and deterioration, particularly in patients with complex problems. Drug substitution can also result in unintended consequences. In 2010 an Institute of Safe Medication Practices survey of 1800 US health professionals revealed that in one year drug shortages caused over 1000 incidents involving negative side effects or medical errors.<sup>9</sup> In many instances shortages can lead to an increase in the use of the health care system, be it in physician or emergency room visits or treatments.

A CMA survey of physicians in September 2012 found that 66% of respondents indicated that drug shortages have gotten worse since 2010 and 64% stated that the shortages have had consequences for their patients or practice. Similarly, the results of the 2012 Canadian Pharmacists Association (CPhA) survey of pharmacists found that over 91% of pharmacists indicated that patients had been inconvenienced by shortages and 51% indicated that patients' care had been compromised.<sup>10</sup>

Drug shortages also have an impact on the practices of physicians and pharmacists. Sixty seven percent of the respondents to the CMA survey stated that drug shortages do have an impact on their practice most notably by increasing time spent on research or consultation with health professional colleagues to source alternative medicine, increase in length of patient visits due to medication substitution concerns, and increase in time spent on forms such as insurance claims. Seventy six percent of hospital pharmacists and 76 percent of community pharmacists also report an impact on their workload and practice.<sup>11</sup>

## Recommendations

Since as early as 2005, the CMA has supported a comprehensive strategy and adequately resourced system for monitoring domestic drug supply. In response to a Health Canada consultation in October 2005 on a report entitled “Developing a Drug Supply Network” CMA recommended that Canada needs such a system to identify shortages and respond quickly to remedy them, and to ensure that policy and regulatory decisions are founded on accurate and reliable knowledge.

In March 2011 this position was reinforced in communication with the Government of Canada stating that Canada needs a sustainable, adequately resourced process to identify shortages, rapidly communicate them to health professionals and respond quickly to resolve them.

- 1. The Canadian Medical Association supports an investigation into the underlying causes of prescription drug shortages in Canada.**
- 2. The Canadian Medical Association recommends the creation of a monitoring unit to track drug production disruptions in Canada and abroad.**

The communication of information to health professionals once a shortage occurs, or is expected, is critical to their ability to make patient centered decisions and provide continuity of optimum care. CMA has participated on a Multi Stakeholder Working Group on Drug Shortages that has had the pharmaceutical industry and health professional organizations working together to establish a national drug shortage reporting website. CMA provided key input on the needs of needs of physicians to ensure that information required to provide optimum care when managing a drug shortage such as product information including name, manufacturer, formulation, strength, package size, expected duration of shortage, notification that shortage is resolved as well as automatic alerts and search and sort functionality was included on the website.

The establishment of the Canadian drug shortage website marks an improvement in the management of drug shortages but significant issues remain. Of great concern are drugs that are ‘single sourced’. When there are shortages of single sourced medications there are no clear substitutes. Related to this are the unintended consequences of sole sourcing products from one manufacturer to secure a lower price. This introduces a vulnerability to the marketplace if the sole supplier experiences production disruptions. The 2011 production stoppage at a Sandoz facility in Quebec due to regulatory compliance issues and a subsequent fire in the plant resulted in a scramble to find alternate sources of many essential medications. The CMA supports the development of strategies at the provincial/territorial and federal level to discourage single source purchasing decisions. The inclusion of incentives or penalties for guaranteed supplies, or a contingency plan for supply disruptions should be inserted into purchase contracts. We must be extremely careful not to exacerbate supply problems while trying to address cost issues.

- 3. The Canadian Medical Association calls for a review of the supply processes in place for drugs and equipment considered essential for medical practice.**
- 4. The Canadian Medical Association supports strategies to discourage single-source purchasing decisions for prescription medications.**

Advance notice, by manufacturers to Health Canada, of expected drug shortages can provide a window of opportunity for the manufacturer and regulators to work together to resolve production problems or identify alternate supply. We are encouraged by recent initiatives by Health Canada to collect information on planned discontinuances from manufacturers.

**5. The Canadian Medical Association calls for the establishment of a legislative framework requiring pharmaceutical companies to provide advance notice of production stoppages and any forecast disruptions in the drug supply.**

Because of the complexity of the drug supply system, to effectively identify the situations that lead to drug shortages and find Canadian based solutions that can decrease the incidence of shortages or mitigate their impact requires the involvement and cooperation of all players in the process. CMA has consistently asked the government of Canada to work with the provinces and territories, the private sector and health professionals to address this potentially dangerous threat to the lives of Canadian patients.

**6. The CMA supports the provinces and territories in their efforts to prevent drug shortages.**

We are heartened by actions of Health Canada in 2012 to bring together representatives of industry, federal, provincial and territorial governments and health professional associations in a Multi Stakeholder Steering Committee on Drug Shortages to respond to the need for the mitigation of drug shortages. We trust that processes can be put in place and supported by key players to allow Canada to respond in a coordinated, transparent and accountable fashion to future or actual drug shortages.

**Conclusions**

Drug Shortages represent an ongoing worry for physicians. The impact on patients, health professionals and the health care system can be significant. Substantial progress has been made since 2011 in terms of gathering and sharing drug shortage information and improving our understanding of the drug supply processes but much still remains to be done. Although complex and challenging, ongoing attention to the issue is required to ensure that Canadians can count on a secure supply of medication into the future.

The CMA will continue to represent the best interests of patients and physicians to ensure that Canada's health care system delivers on patient-centered care.

## References

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<sup>1</sup> DRUG SHORTAGES FDA's Ability to Respond Should be Strengthened, Statement of Marcie Cross, Director, Health Care, United States Government Accountability Office, Testimony before the Committee on Health, Education, Labor, and Pensions, U.S. Senate, December 15, 2011.

<sup>2</sup> FDA is asking the public to send in ideas for combatting drug shortages, FDA Voice, Feb. 13, 2013, U.S. Food and Drug Administration, available at <http://blogs.fda.gov/fdavoice/index.php/tag/drug-shortages/> (accessed 2013 April 2).

<sup>3</sup> Canadian Drug Shortages Database available at <http://www.drugshortages.ca/drugshortages.asp> (accessed 2013 April 5).

<sup>4</sup> Drug Supply In Canada: A Multi-stakeholder Responsibility, Report of the Standing Committee on Health, 41<sup>st</sup> Parliament, First session, June 2012.

<sup>5</sup> Drug Supply Disruptions, Environmental Scan, Canadian Agency for Drugs and Technologies in Health, Issue 17, March 2011.

<sup>6</sup> Canadian Drug Shortages Database available at <http://www.drugshortages.ca/drugshortages.asp> (accessed 2013 April 5).

<sup>7</sup> Drug Supply In Canada: A Multi-stakeholder Responsibility, Report of the Standing Committee on Health, 41<sup>st</sup> Parliament, First session, June 2012.

<sup>8</sup> Prescription Drug Shortages, E Panel Survey, Canadian Medical Association, December 2010.

<sup>9</sup> Drug Shortages, Recommendations of the Working Group on Drug Shortages, Ordre des Pharmaciens du Québec, March 2012.

<sup>10</sup> Impact of Drug Shortages, Member survey, Canadian Pharmacists Association, October 2012.

<sup>11</sup> BACKGROUNDER - DRUG SHORTAGES SURVEY, Canadian Pharmacists Association, Canadian Society of Hospital Pharmacists, Canadian Medical Association, January 2013, available at [http://www.cma.ca/multimedia/CMA/Content/Images/Inside\\_cma/Media\\_Release/2013/Backgrounder-Drug-shortages\\_en.pdf](http://www.cma.ca/multimedia/CMA/Content/Images/Inside_cma/Media_Release/2013/Backgrounder-Drug-shortages_en.pdf) ( assessed 2013 April 2).