Drug Shortages in Health Care Institutions: Perspectives in Early 2014

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INTRODUCTION

The year 2012 was marked by an unprecedented number of drug shortages in Canada. This crisis was due in particular to the publication, in November 2011, of a warning letter from the US Food and Drug Administration (FDA) to Novartis International AG for its Boucherville plant, which was managed by Sandoz Canada.1,2 Although Sandoz was not the only drug manufacturer with shortages for some products, the wide range of single-source generic parenteral products affected by this crisis led to a high level of uncertainty in the Canadian health care sector. Since the publication of our most recent analysis of the Canadian drug shortage situation,3 the FDA has issued at least one other warning letter, this time to Apotex, a Canadian generic manufacturer.4

In 2012, our research group evaluated the impact of drug shortages in 5 Quebec teaching hospitals and highlighted administrative costs of at least Can$0.5 million to manage these shortages, mainly at the level of individual pharmacies.5 Barthélém y and others6 also published a case study of the management of drug shortages in hospitals, illustrating the challenges for pharmacists and the risks for patients.

In response to this crisis, many stakeholders (including the Standing Committee on Health, the Royal College of Physicians and Surgeons of Canada, the Ordre des pharmaciens du Québec, the Canadian Pharmacists Association, and the group purchasing organization SigmaSante) came together in 2012 and made a set of recommendations to various levels of government, buying groups, supply chains, the pharmaceutical industry, and individual pharmacists.7 Surprisingly, only one-third of the 30 recommendations had been implemented 1 year later.7

In June 2013, a Member of Parliament from the New Democratic Party of Canada proposed a private member’s bill on the mandatory disclosure of drug shortages in Canada,8 but this bill was defeated at second reading in February 2014. In September 2013, Health Canada published a drug-shortage protocol and tool kit, based on the work of the Multi-Stakeholder Steering Committee on Drug Shortages.9 In its Appendix B, the protocol establishes a guide for drug-shortage notification and communication and lists the key relevant fields to be completed by drug manufacturers in the Canadian drug shortage database (www.drugshortages.ca). Pharmacists and various stakeholders, such as the Canadian Society of Hospital Pharmacists and group purchasing organizations, found this database to be incomplete and requested the addition of key data (e.g., number of similar commercialized products, links to other relevant information sources). Disappointingly, it took more than 24 months after initial consultations for these key data to be added as fields on the website for complete update by the manufacturers. Before then, these key data were available only on a website known as “FridayPM”. The FridayPM website, a voluntary, pharmacist-initiated tool launched in early 2011, was closed in August 2014, as drug manufacturers are now allowed by some group purchasing organizations to declare their drug shortages only on the Canadian drug shortage platform.

DESCRIPTION OF THE PROGRAM

The Pharmacy Practice Research Unit of the Centre hospitalier universitaire Sainte-Justine has been gathering data on drug shortages since 2006.10-16 For these reports, drug shortage data were extracted from the pharmacist-initiated website (FridayPM). Here, we provide an update on the situation for the period September 1, 2012, to August 30, 2013. For this analysis, data from the 12-month period in 2012–2013 were compared with data from 2006 to 2012.

EVALUATION OF THE PROGRAM

A total of 497 drug shortages were reported in the 12-month period in 2012–2013, which represents a 54% decrease from the 1081 drug shortages reported in a corresponding period in 2011–2012. Before 2011, the annual numbers of drug shortages were 493 in 2006, 400 in 2007, 441 in 2008, 679 in 2009, and 429 in 2010.

The average duration of drug shortages has increased, with a mean (± standard deviation) of 168 ± 153 days (range 15–710
days), compared with 141 ± 116 days (range 1–775 days) for 2011–2012, 103 ± 85 days (range 8–363 days) for 2010–2011, and 108 ± 130 days (range 5–1623 days) for 2006–2010. Shortages of parenteral formulations have increased over the years, representing 33% of drug shortages in 2011–2012 and 36% in 2012–2013. In terms of duration, shortages of parenteral formulations represented 37% of the total number of drug-shortage days in 2011–2012 and 47% in 2012–2013.

The number of manufacturers involved in drug shortages declined to 38 manufacturers in 2012–2013, compared with 58 in 2011–2012, 41 in 2010–2011, and 70 over the period 2006–2010. Most of the drug shortages in 2012–2013 involved generic drug manufacturers, which accounted for 85% of the total number of drug shortages and 87% of the total number of drug-shortage days. The main manufacturers involved were, in decreasing proportion of total number of shortages, Apotex (16%), Teva (15%), Pharmascience (15%), Baxter (10%), Sandoz (9%), and Hospira (9%).

Most therapeutic classes were affected by shortages in 2012–2013. In decreasing order of the number of drug shortages, drug classes affected were central nervous system agents (AHFS drug classification 28:00), accounting for 23% of affected products; cardiovascular drugs (24:00), 13%; anti-infective agents (08:00), 11%; skin and mucous membrane agents (84:00), 6%; hormones and synthetic substitutes (68:00), 5%; gastrointestinal drugs (56:00), 4%; antineoplastic drugs (10:00), 3%; and all other classes (35%).

Besides the decrease in drug shortages for the period from September 2012 to August 2013, this update indicates an increase in the proportion of parenteral formulations among the drugs that were in shortage and an increase in the shortages involving generic manufacturers. The same 6 generic drug manufacturers were mainly involved, representing 74% of the total number of drug shortages.

**IMPLICATIONS AND SIGNIFICANCE FOR PRACTICE**

Should we be reassured that fewer drugs were in shortage in 2013? Perhaps. However, at the same time, the safety of the drug supply chain is being questioned, not only because of drug shortages but also in relation to the safety of drug manufacturing in Asia and other overseas locations. In France, the Académie nationale de pharmacie has recognized that one of the causes of drug shortages is the lack of quality of some imported raw materials. In addition, issues of dishonesty with regulatory authorities have been reported in the press. For example, in May 2013, the generic manufacturer Ranbaxy pleaded guilty to 7 federal criminal counts of selling adulterated drugs with intent to defraud, failing to report that its drugs did not meet specifications, and making intentionally false statements to the government. The grey market is also becoming an issue in Canada, and Sandoz is again facing manufacturing and distribution challenges and has almost 50 products on allocation. Drug shortages represent a complex problem with many potential solutions. At the hospital level, pharmacists could alleviate the effects of drug shortages by revising inventory levels and maintaining a safe buffer of 60 days’ worth of critical drugs. Having a buffer stock would make a difference if there is a pandemic, a local catastrophe, or just typical back-orders, as has been the case over the past 7 years in Canada. We also need to better understand this complex problem and evaluate the effects of interventions (or the absence of interventions) by provincial and national authorities.

**References**

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