

Canadian drug shortage: recent history of a mystery

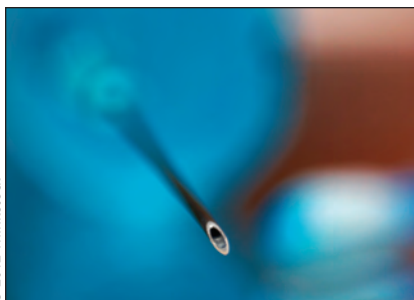
That's right, doctor. There's no prochlorperazine anywhere in Kingston. But you can prescribe [expensive brand name]." The community pharmacist was responding to my baffled query back in November 2010. I couldn't believe my ears. That drug had been around for decades. How could it be missing?

My first thought — which is shared by other doctors — was: Is the pharmaceutical industry letting generics disappear to favour pricier alternatives?¹ Eventually, we might give up ordering these drugs, then manufacturers could stop production, legitimately claiming that no one wanted them.

Concern about the availability of these drugs and for our patients prompted nine of us at the Kingston Regional Cancer Centre to write to the federal and provincial ministers of health on Dec. 16, 2010.² The Ontario minister replied a week later insisting that it was not the fault of new rules governing generic pricing, passed in June. The federal minister did not reply until 16 weeks later. Minister Leona Aglukkaq said the government's role is to assure the safety of drugs; it has no role in supply. But the patent law is federal, as is the Canada Health Act, with its pillar of access, so her stance did not make sense. Later, when the heat was turned up, she endorsed fast-tracking and released emergency stocks.

During the long wait for Aglukkaq's disappointing reply, the Canadian Pharmacists Association released its 2010 survey showing that up to 98% of pharmacists were dealing with shortages up to 10 times a shift.³ Most missing drugs were generic. A Canadian Medical Association survey indicated that 75% of physicians had also been affected.¹ When generics go missing it's the working poor who suffer. Ten percent of Canadians don't fill prescriptions because they can't afford to.⁴

We began probing the causes of the problem. Industry insisted that they lay offshore: paucity of raw materials, competition from rising affluence in develop-



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ing nations, manufacturing slowdowns to maintain standards, government interference. But a dearth of raw materials cannot explain why generics are most affected. Foreign affluence could squeeze supplies, but it seems a reason to ultimately increase production.

Despite our best efforts, few in media or government seemed interested. Cluster reports emerged, centred around specific shortages: antidepressants, anesthetics, anticonvulsants, antiemetics, antibiotics. Yet, all were part of a larger problem.

By August, in an attempt to track and share this information, I launched www.canadadrugshortage.com. Soon, Aglukkaq announced that as of Sept. 30, 2011, drug companies should *voluntarily* declare forthcoming shortages at a single site. Industry response was slow and incomplete: two sites began in December 2011, but they are less reliable than two, nonprofit sites that have long served pharmacists: (<http://en.vendredipm.ca/> and http://druginfo.usask.ca/healthcare_professional/drug_shortages.php).

By contrast, President Barack Obama, issued an Executive Order in October 2011 *requiring* pharmaceutical companies to declare shortages six months in advance or face heavy penalties.

My website attracted a few concerned people who suggested other possible causes, such as the "monopsony" (single-buyer) effect of large buyers such as the American Group Purchasing Organizations.^{5,6}

On Nov. 24, 2011, Liberal health critic, Dr. Hedy Fry convened a roundtable meeting with representatives from the medical and pharmacist professions,

and brand-name and generic industry. There were no concrete results.

Everything changed in early 2012 with the February slowdown and March fire at Sandoz's Boucherville plant. The potential loss of 800 jobs and the threat to 90% of Canada's injectable generics spawned much media coverage. The country woke up, as if the problem had not been raging for two years. In a four-hour emergency debate in the House of Commons on March 12, Aglukkaq blamed Sandoz for not warning in advance and she chided the provinces for failing to diversify supply chains. But Health Canada approves drugs; surely Health Canada knows which drugs are vulnerable because of single suppliers.

Two days later, a New Democratic Party motion to *mandate* advance reporting of shortages passed unanimously in the House of Commons, and Health Canada began fast-tracking applications for substitutes. The Standing Committee on Health is now examining the matter. Media interest has already begun to wane, as if these anodyne, stop-gap measures were the solution.

But Boucherville is merely the tip of a gigantic, international iceberg. The problem continues not only for injectables, but for all generics sold at all pharmacies, whether manufactured in Canada or abroad. We need the federal government, Health Canada, and perhaps the ministries of industry, finance, and foreign affairs to help locate and address causes inside and outside the country.

Unless we identify the real causes of this problem among the many hypotheses, we will lurch from crisis to crisis for a long time to come.

First we diagnose, then we treat.

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For references, see Appendix 1, available at www.cmaj.ca/lookup/suppl/doi:10.1503/cmaj.120527/-/DC1.

CMAJ 2012. DOI:10.1503/cmaj.120527