ECONOMIC NOTE

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Ideas for a More Prosperous Nation

How Can We Prevent Prescription Drug Shortages?

by **Yanick Labrie**

The shortage of injectable drugs that Canada has been experiencing in recent months is an ongoing headache for health professionals and hospital administrators. Many surgeries had to be postponed recently and clinical treatments had to be suspended due to certain essential drugs, in particular painkillers and anaesthetics, being out of stock.[1] The phenomenon has become so serious that last March, the House of Commons Standing Committee on Health called in the main participants and specialists in the pharmaceutical field for special hearings in order to take stock of the situation.[2]

While the production difficulties of generic manufacturer Sandoz have made headlines these past several months, drug shortages are not a new phenomenon. However, certain ill-advised public policies in the pharmaceutical sector have in all likelihood contributed to their increased frequency over the past few years.

The unintended consequences of price caps

In Canada, the prices of prescription drugs, whether patented or generic, are heavily regulated by government authorities. The prices of new drugs are fixed upon their arrival onto the market by the Patented Medicine Prices Review Board, a federal organization, based on average prices observed in seven industrialized countries.[3] The prices of generic drugs, on the other hand, are regulated by provincial governments, almost all of which set a cap. This price cap varies as a percentage—from 25% to 45% depending on the province—of the price of patented drugs belonging to the same therapeutic class (see Table 1).

The government of Ontario was the first, in the early 1990s, to adopt a price cap, which it has been lowering ever since, for generic drugs. The last reform implemented in 2010 stipulates that the prices of generic drugs can no longer exceed 25% of the reference patented drug price.[4] Other provinces have followed suit and imposed similar maximum prices in recent years. Quebec has adopted a policy according to which all manufacturers of generics must match the best prevailing Canadian price for their products if they want the province to include them on the formulary of products covered by drug insurance plans.

What the provinces are hoping to achieve with these price-cap policies is to bring the cost of drug insurance plans under control. But although they may be motivated by laudable intentions, these policies do not necessarily ensure good results. Indeed, the multiplication of cases of drug shortages observed in recent years coincides with provincial governments' continued lowering of maximum prices. According to data from RAMQ, the number of notices of prescription drug supply disruptions in Quebec has risen considerably over the last five years, from 33 in 2006 to 207 in 2010 (see Figure 1).

Policies that artificially lower prices end up making the production of certain prescription drugs simply unprofitable. In the long run, this situation has the effect

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Table 1 ► Price caps for generic drugs in the Canadian provinces (July 2012)

Province	Price cap for generic drugs (as a % of patented drug prices)
British Columbia	35%
Alberta	35%
Saskatchewan	35%
Manitoba	25% (lowest prevailing Canadian price)
Ontario	25%
Quebec	25% (lowest prevailing Canadian price)
New Brunswick	40%
Prince Edward Island	No price cap
Nova Scotia	35%
Newfoundland and Labrador	45%

Source: Benefit Partners, *Generic drug pricing reforms*, April 2012, p. 3.

of pressuring several pharmaceutical companies to abandon the production of drugs whose profit margins are too small and reallocate their resources to the production of others offering better prospects of profitability. It is therefore not an accident that current shortages include a higher proportion of drugs whose manufacturing processes are more complex and expensive, and whose profit margins are accordingly slim.[5]

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Furthermore, the regulation of prices has the effect of discouraging pharmaceutical investment and the entry of new drugs onto the market.[6] Studies have shown that the marketing of generic drugs is more often successful in countries where no price caps exist.[7] International data also show that price controls can actually lead to higher prices.[8]

Price-cap policies for prescription drugs, and the unintended consequences that result from them, are not limited to Canada. In the United States, a recent study showed that the modification of policies in 2005 aimed at lowering prices for the public Medicare insurance plan contributed to the shortages of injectable drugs experienced by that country in recent years.[9] Drugs intended for patients covered by this program were much more likely to be in short supply than other drugs, due to the maximum prices imposed by the U.S. government, which greatly reduced their profitability.

The risk of single supplier procurement contracts

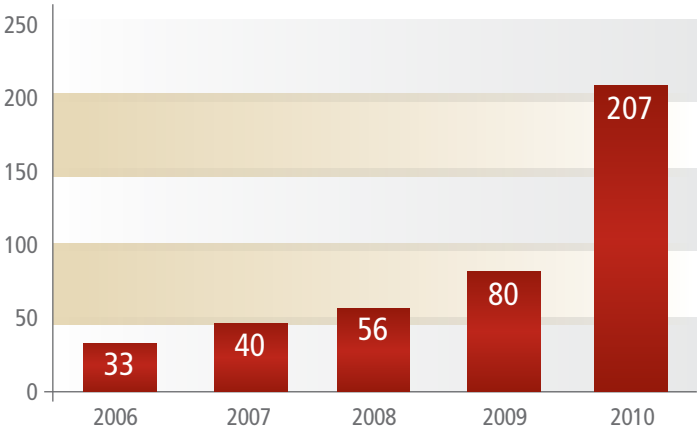
The problem of shortages is also amplified by certain procurement practices used by hospital networks that favour the awarding of exclusive contracts to a single supplier. In particular, this is the case for injectable drugs.

Since hospitals are large purchasers of prescription drugs, they generally get their supplies through group purchasing organizations, which allows them to obtain better prices. These organizations succeed in reducing costs by buying in bulk through a competitive tendering process open to all interested prescription drug suppliers. For each drug, a procurement contract is signed, often with a single supplier[10] —the winning bidder—and generally for a period of three years.

While this procurement strategy produces savings in the short term, it has an increased risk of leading to shortages by encouraging numerous potential suppliers to exit the market, often to the point where only a single supplier is willing to provide the drug at the negotiated price.[11] Indeed, excessive use of this procurement method is in all likelihood one of the reasons Sandoz, the company blamed for the recent shortages of injectable drugs, became the sole supplier of a multitude of crucial generic products.[12]

At the international level, the dangers of resorting to a single supplier are increasingly recognized, the practice having been called into question in several countries. Criticisms have been raised in New Zealand, where the adoption of this kind of procurement process by PHARMAC, a public corporation, entailed an increase in the number of pharmaceutical products subject to shortages.[13] Australia opted for a more prudent strategy and now divides its procurement contracts for drugs and vaccines among several suppliers, with the explicit goal of preventing shortages. In Belgium, generic drug manufacturers having all decided to stop participating in the competitive tendering process, the single supplier policy was abandoned.[14]

Figure 1 ► Number of notices of supply disruptions for prescription drugs in Quebec (2006 to 2010)



Source: Comité sur les ruptures d'approvisionnement en médicaments, *Les ruptures d'approvisionnement en médicaments,* 2011, p. 13.

Long approval delays

Long delays in approving new innovative drugs are another factor that can lead to supply difficulties.[15] As underlined in a recent report from the Canadian Agency for Drugs and Technologies in Health, "The backlog of new drug applications awaiting regulatory approval, that could be potential alternatives to drugs in short supply, can also contribute to drug shortages."[16]

Before hoping to be able to market a new drug, all pharmaceutical manufacturers must first receive the approval of Health Canada. This organization examines the drug in order to ensure that it conforms to established safety and quality standards. This process normally takes several years. According to a recent report, delays in receiving Health Canada's approval are significantly longer than such delays are in the United States or in Europe.[17]

Once approved, manufacturers that want their products included on the formularies of reimbursable drugs of the provinces' various public insurance plans must submit a request for each of them. Whether the request is accepted or rejected, the process often requires over a year. On average, barely 23% of the new drugs approved by Health Canada from 2004 to 2010 can be found on these lists of reimbursable products covered by the provincial drug insurance plans as of January 2012.[18]

Other regulatory requirements help to exacerbate the phenomenon of prescription drug shortages. One notable example is the new policy on Notifiable Changes requests made by pharmaceutical companies that want to improve the quality of a drug or the efficiency of their manufacturing procedure. Before September 2009, changes could be carried out by a manufacturer if it had not heard otherwise from Health Canada within 90 days of its submission of a request. Manufacturers are now obliged to wait until Health Canada has finished reviewing and has approved their requests before implementing any changes.[19]

According to a recent report from the Auditor General of Canada, Health Canada very rarely completes its reviews of Notifiable Change requests in less than three months. In 2010, barely 14% of requests were treated within this target time frame. Reviews of these change requests take an average of 250 days, nearly three times longer than the standard set by the organisation.[20]

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Surmounting these administrative and regulatory obstacles therefore entails not only an extremely long wait, but also a costly one. The decision to adopt a new, large-scale production technology becomes even more risky, and the profitability of the investment uncertain, in a context of price caps and changing regulatory standards.

Barriers to the importation of medications

By all accounts, the extended delays and high costs faced by manufacturers that wish to obtain approval from Health Canada for their prescription drugs makes many foreign pharmaceutical companies reluctant to launch their products on the Canadian market.

The most promising approach for getting around this problem would be to set up a process of collaboration between Health Canada and foreign regulatory agencies. For example, the federal government could sign agreements with other countries whereby drugs already approved in those countries could be subject to an accelerated approval process and marketed more rapidly on Canadian soil, and vice versa.

Currently, Health Canada only exceptionally allows the importation of alternate drugs that are not authorized for sale and distribution on the Canadian market, when the

urgency of the situation demands it.[21] Recently, Health Canada reacted to the shortage of injectable drugs by accelerating the authorization of equivalent drugs that it had not approved.[22]

Why does Health Canada only apply this accelerated approval process in times of crisis? There is no reason to believe that similar drugs produced and approved in other industrialized countries could not be purchased and marketed rapidly in Canada. This strategy would not only decrease the drawbacks for patients, but by increasing competition, it would also encourage Canadian manufacturers to invest more in order to avoid supply disruptions. The risk of shortages would therefore greatly diminish.

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Conclusion

The federal and provincial governments must revisit their policies regarding the management of prescription drugs, because they hinder production and entail abnormally long approval delays. Indeed, we are missing our target if, by trying to ensure that drugs are safe and sold at low prices, we create shortages and keep many patients from having access to those drugs in a timely fashion.

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