Canada's New Generic Pricing Policy: A Reasoned Approach to a Challenging Problem

Nouvelle politique canadienne d'établissement des prix des médicaments génériques : démarche raisonnée face à un problème difficile

AIDAN HOLLIS, PhD
Professor, Department of Economics, University of Calgary
Calgary, AB

PAUL GROOTENDORST, PhD
Associate Professor, Leslie Dan Faculty of Pharmacy, University of Toronto
Toronto, ON

Abstract
Alberta, quickly followed by other Canadian provinces, has introduced a new pricing model for generic drugs, in which prices are inversely related to the number of generic manufacturers of the drug. This paper examines the rationale for the new policy.

Résumé
L'Alberta, rapidement suivie par d'autres provinces canadiennes, a mis en place un modèle d'établissement des prix pour les médicaments génériques, modèle dans lequel les prix sont inversement liés au nombre de manufacturiers du médicament générique. Cet article étudie les fondements de cette nouvelle politique.

The Canadian Generic Manufacturing Association recently announced a new three-year agreement with the provinces and territories to establish pricing policies for generic drugs (Canadian Generic Pharmaceutical Association 2014a; Ontario Ministry of Health and Long-Term Care 2014). The proposed policies are novel within Canada, and follow the recommendations made in academic papers (Cambourieu et al. 2013; Hollis 2009; Hollis and Grootendorst 2014). The expected savings to payers are some $3.8 billion over three years (Canadian Generic Pharmaceutical Association 2014a).

The new agreement is in a contested area of drug policy in Canada, with some experts recommending tendering (Law 2013) and others reduced regulatory interference (Skinner and Rovere 2010). The starting point is, however, the status quo, which has received considerable criticism (Competition Bureau 2010; Patented Medicine Prices Review Board 2011). In the status quo system, the provinces set the prices that they pay for generic drugs dispensed to public drug plan beneficiaries, typically at a fixed percentage of the brand price. And most provinces regulate generic drug prices paid by private drug plans. Over the past seven years, the provinces have reduced prices from as high as 70% of the price of the brand drug, down to as low as 18% for some generics.

If the goal is to reduce spending, why stop at 18%? How low can prices go? The provinces are walking a tightrope. On the one side, they risk paying excessive prices for generic drugs. On the other, they risk losing generic entry, in which case they pay even higher prices. The challenge is aggravated by a pricing policy in which every generic drug is supposed to be priced at the same fraction of the brand price. The problem is that not all generic drugs are the same.

In some cases, there may be a dozen manufacturers – domestic and foreign – competing in the market. In this situation, it makes sense to beat the price down as far as possible.

In other cases, there is a single generic manufacturer in the market, who risks a substantial patent infringement liability. In these situations, the manufacturer will enter only if the price is well above the cost of production and distribution; a substantial cushion is required to make it worth bearing a significant risk. It is important to note that the parties to litigation cannot reliably predict how courts will rule. For example, in the set of decisions between Apotex and Sanofi over the validity of a patent regarding Plavix: Sanofi won in PM(NOC) cases in Federal Court, Federal Court of Appeal and Supreme Court cases; Apotex then sought to impeach the patent with the benefit of a full trial including discovery, and was successful in the Federal Court; Sanofi appealed and was successful. Apotex has discontinued its application to the Supreme Court.

In yet other cases, there is only a single generic manufacturer of an old drug with quite limited volume of sales. Here the manufacturer may find it not worthwhile to invest in maintaining spare capacity to ensure security of supply if the price is too low.

It is also evident that some generic drugs are relatively expensive to manufacture, and others are less costly. Reimbursement policy should reflect this.

The case of the cardiovascular drug ramipril is illustrative. When the generic company Apotex started selling ramipril in 2006, it generated very substantial savings for provincial

and private insurers, which purchased ramipril at the generic price, instead of the higher brand price. Apotex was immediately sued by Sanofi, the patentee, which alleged infringement and damages on lost sales valued at the full brand price. The Federal Court found Apotex non-infringing. Sanofi appealed, and lost, and then appealed to the Supreme Court, which ultimately declined to hear the appeal in 2012 (Sanofi-Aventis Canada Inc v Apotex Inc, January 3, 2012 [SCC Case No. 34600]). There was probably a big sigh of relief at Apotex, which was liable for hundreds of millions of dollars, much more than the amount it had earned from selling the drug. In 2006, had Apotex faced today's pricing environment, in which provinces refuse to allow higher prices to a generic facing patent infringement risk, it might instead have avoided entering the market until all the relevant patents had expired in 2020, 14 years after actual generic entry. The extra cost to Canadians of no generic entry is estimated at over $8 billion (Canadian Generic Pharmaceutical Association 2014b).

In some markets, the combination of small market volumes and low prices deters entry. For example, "Cuprimine" has been off patent for many years, but on the Ontario formulary, there are no listed interchangeable drugs: the profits from selling a low-volume generic drug at a low price are not enough to make it worth even going through the regulatory process. Similarly, in other markets, the risk of patent infringement may deter generic entry given a low generic price. In other cases, generic firms may find it more attractive to settle a patent dispute with the patentee, resulting in delayed entry, rather than entering at risk. The inevitable result is that the provinces will continue to pay the full brand price for an extended period.

Fortunately, there is a sensible solution to this problem. Prices should reflect the number of generic firms willing to sell. When there is only one generic firm, the reimbursed price should be relatively high – perhaps 75% of the brand. And if more generic firms are willing to enter, prices should fall to reflect this. Such a mechanism could automatically generate very low prices for high-volume competitive drugs – with no need for the drug plan to figure out the lowest feasible price. And, importantly, it would produce higher prices to stimulate generic entry in those situations where that is the only way to obtain competition at all. Essentially, the design of the scheme is such that it imitates competitive pricing. If only one firm enters, then the price stays high; if many firms enter, the price drops much lower. Firms will be attracted to enter provided that the post-entry price is greater than their average costs of production, with the result that the price is driven towards the average cost of production. The implementation of this system by the provinces should generate substantial savings (Cambourieu et al. 2013; Canadian Generic Pharmaceutical Association 2014a; Hollis 2009; Hollis and Grootendorst 2014).

Alberta's latest pricing model reflects this approach (ABC Benefits Corporation 2014). Introduced in April 2014, the current pricing policy for new generic drugs starts at 70% of the brand price if there is only one generic entrant, and falls to 50%, 25% and, then, 18% for markets with two, three and four generic entrants, respectively. The 70% pricing lasts for, at most, one year, after which, 50% pricing applies. More recently, the provinces and territories

have reached an agreement with the Canadian Generic Manufacturing Association similar to the Alberta model (Canadian Generic Pharmaceutical Association 2014a). Ontario has proposed new regulations along this line (Ontario Ministry of Health and Long-Term Care 2014). This is one of the rare situations in which a proposal made by academics was implemented by policy makers. The expected savings to all payers from the agreement is claimed to be approximately $3.8 billion over three years.

We have some reservations about the details of the agreement, which sets the lowest price at 18% of the brand, well above the cost of production for many important drugs. This will leave considerable profits available to be split between manufacturers and pharmacies. There should be additional lower price tiers that would be effective when more than four manufacturers are willing to enter. However, the agreement creates many benefits. First, it is national, which will eliminate the substantial price variations between provinces. Second, it is designed to ensure that private payers get the same prices as the public plans. Third, it creates stability and some predictability in the generic market, as the agreement is for three years. And fourth, it meaningfully relates prices to costs through firms' willingness to enter.

While it is still too early to assess the effectiveness of this scheme in practice, it is at least an effort to create pricing flexibility in a way that reflects costs and the importance of stimulating generic entry. This scheme deserves careful attention and a review once it has been fully implemented, and indeed, the provinces have committed to undertake a review within three years (Ontario Ministry of Health and Long-Term Care 2014).

Correspondence may be directed to: Aidan Hollis, Department of Economics, University of Calgary, 2500 University Drive, Calgary, AB T2N 1N4; tel: (403) 220-5861; e-mail: ahollis@ucalgary.ca.

References

ABC Benefits Corporation. 2014. *ADBL – Updated Price Policy*. Retrieved March 15, 2014. <https://www.ab.bluecross.ca/dbl/pdfs/dbl_sec1_prpol.pdf>.

Cambourieu, C., P. Grootendorst, A. Hollis and M. Pomey. 2013. "Generic Drug Pricing Policy in Quebec." Retrieved March 15, 2014. <http://www.csbe.gouv.qc.ca/fileadmin/www/2013/Medicaments/CSBE_Generic_Drug_Pricing_Policy_Quebec.pdf>.

Canadian Generic Pharmaceutical Association. 2014a. "Canadians to Save $3.8-Billion through Unprecedented Three-Year Pan-Canadian Agreement on Generic Prescription Medicines." Retrieved November 10, 2014. <http://www.canadiangenerics.ca/en/news/docs/10.16.14CoF-CGPAAgreementRelease_FINAL.pdf>.

Canadian Generic Pharmaceutical Association. 2014b. "The Value of Generic Prescription Medicines: Are You Taking Full Advantage?" Retrieved November 8, 2014. <http://www.canadiangenerics.ca/en/advocacy/value_of_gpm_f.asp>.

Competition Bureau. 2010. "Benefiting from Generic Drug Competition in Canada: The Way Forward." Retrieved November 10, 2014. <http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/02753.html>.

Hollis, A. 2009. "Generic Drug Pricing and Procurement: A Policy for Alberta." Retrieved October 13, 2014. <http://www.policyschool.ucalgary.ca/sites/default/files/research/hollis-online-feb-09.pdf>.

Hollis, A. and P. Grootendorst. 2014. "A Comparison of Mechanisms for Setting Generic Drug Prices." Retrieved March 15, 2014. <http://individual.utoronto.ca/grootendorst/pdf/generic-pricing-approaches-2014-03-11-web.pdf>.

Law, M.R. 2013. "Money Left on the Table: Generic Drug Prices in Canada." *Healthcare Policy* 8(3): 17–25. <http://www.longwoods.com/content/23208>.

Ontario Ministry of Health and Long-Term Care. 2014. "Proposed Regulation Amendments to Establish a Pricing Framework for Certain Generic Products on the Ontario Drug Benefit (ODB) Formulary." Retrieved November 14, 2014. <http://www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/notices/exec_office_20141105.pdf>.

Patented Medicine Prices Review Board. 2011. "Generic Drugs in Canada: International Price Comparisons and Potential Cost Savings." Retrieved November 10, 2014. <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=870>.

Skinner, B. and M. Rovere. 2010. "Canada's Drug Price Paradox, 2010." Retrieved March 15, 2014. <https://www.ab.bluecross.ca/dbl/pdfs/dbl_sec1_prpol.pdf>.