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**Title:** Ontario's plunging price-caps on generics: deeper dives may drown some drugs.

## **Author names and affiliations:**

**Aslam Anis** (<u>aslam.anis@ubc.ca</u>) is a Professor of Health Economics in the School of Population and Public Health, University of British Columbia

**Stephanie Harvard** (<a href="mailto:harvards@interchange.ubc.ca">harvards@interchange.ubc.ca</a>) is a Medical Writer and Researcher in the School of Population and Public Health, University of British Columbia

**Carlo Marra** (<u>cmarra@exchange.ubc.ca</u>) is an Associate Professor in the Faculty of Pharmaceutical Sciences, University of British Columbia.

## **Corresponding Author:**

Aslam H. Anis

@St. Paul's - Tel: 604 806 8712, Fax: 604 806 8778 @UBC - Tel: 604 822 5550, Fax: 604 822 4494

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In April 2010, the Ontario government announced another reduction in the maximum price of generic drugs permitted under the Ontario Drug Benefit (ODB) program and is now demanding that generic drugs be sold for no more than 25% of the brand-name product's price. This represents a 50% drop from the maximum price set out in Ontario's 2006 policy<sup>2</sup> and the third modification to the original '75/90' regulations adopted in 1993, which stipulated that the first generic to enter the market must not be priced at more than 75% of the cost of the branded product, any subsequent generics at no more than 90% of the cost of the first generic. Other provinces are following Ontario in setting new price-caps to lower the cost of generic drugs. In July 2010, the British Columbia government changed its maximum price of generics to 35% of the brand-name price. As Quebec's policy requires generic companies to match their lowest price in Canada, prices there will be the same as in Ontario.

While the new price-caps may be effective at reducing generic drug prices compared to previous years, it is unknown whether these regulations can achieve their ultimate goal-the *lowest possible* prices for generics. Economists will tell you that free competition is the best motivator in a market with many suppliers and buyers. Nonetheless, various pricing regulations have been implemented in Europe and Canada. While one study concluded that the average price of generics is higher in European nations that adopt a free-market approach, it also identified France and the Netherlands, two highly regulated markets, as having among the highest-priced generics in Europe, behind only Germany.<sup>6</sup> France uses a price-cap that requires generics to be 40% less than the branded product, while the Netherlands uses a 'maximum price' system based on average prices in neighboring countries.

The high price of generics in France and the Netherlands is consistent with evidence that pricing regulations result in a clustering of prices around the maximum allowable levels with little price dispersion. Previously, we compared drug prices in the periods before and after the introduction of Ontario's 70/90 regulations and found that in both periods the price of generic drugs fell as the number of generics entering the market increased.<sup>3</sup> However, the magnitude of decrease in prices was significantly lower after the introduction of the 70/90 regulations than before. A review of the effects of European pricing regulations similarly suggests that price-caps and maximum price systems result in higher-priced generics than would exist without regulation, while the entry of new generic competitors into regulated markets lowers generic drug prices paid by pharmacies, though not prices paid by government drug plans.<sup>7</sup> There is growing awareness that the same situation exists in Canada.

In 2007, the Competition Bureau of Canada issued a report concluding that while pharmacy invoice prices consistently reflect maximum prices allowed under provincial drug plans, net pharmacy prices are anywhere from 20-60% of invoice prices after factoring in pharmacy 'professional allowances'.<sup>8</sup> These findings are the driving force behind Ontario's move to disallow professional allowances, yet there is no evidence this will reduce the price of generics. Professional allowances are simply a reflection of the fact that manufacturers can offer more competitive prices than they offer the government.

The tendering process in Canada, by which competitive bidding determines not the sole provider of a drug but the price point at which all generic manufacturers may sell their product, keeps bids artificially high by removing manufacturers' incentive to compete. Price-cap regulations then set a ceiling price, which manufacturers have no incentive to undercut. Instead, generic manufacturers compete at the pharmacy level, while regulations prevent savings resulting from competition from being passed on to third-party payers. Banning professional allowances means generic manufacturers must compete on attributes outside of cost, such as product range and other value-added services, which will have unknown effects on utilization, but will not promote prices below the established ceiling.

As provincial governments do not have any information about generic drug manufacturers' 'bottom line', price-caps, i.e., ceilings, have been set arbitrarily- and adjusted haphazardly- in relation to the price of the branded product. This practice is risky, as not only do arbitrary price-caps keep the price of some generics higher than would be observed without regulation, they may actually threaten the viability of generics that are already competitively priced. In Ontario, the price of some generics could conceivably go lower than 25% of the brand price in the absence of regulation; still some generics may not be profitable at this price point and manufacturers will lose the incentive to produce them. Furthermore, with the relative price-caps set lower, closer to generic manufacturers' bottom-line, brand-name pharmaceutical companies gain undue power over generic companies. At the time of genericization, brand-name companies might strategically "limit price", i.e., lower their price to the level where the generic price falls below cost, keeping generic manufacturers from ever entering the market.

Instead of experimenting with different price-caps every few years without evidence regarding their potential effects, the provinces may be advised to allow generic manufacturers to compete directly as a means of reducing generic drug prices. As an international comparison of generic drug prices indicates<sup>10</sup>, the lowest generic drug prices in the world are seen in the United States, where there is free competition between generics. Many of the same forces thought to contribute to low US prices already exist in Canada, such as the presence of large chain pharmacies and mass merchandisers such as Wal-Mart, Superstore, Costco, etc., the immense buying power of which can effectively compel generic manufacturers to compete on price. Yet in Canada, where the combined buying power of the provinces would be substantial, regulation prohibits such competition from taking place and generic prices here are five times higher than in the US.<sup>10</sup> While academia continues to study the comparative effects of regulation and competition on drug pricing, Canadian policy-makers should take notice of international trends and use the evidence that is already available to inform pricing policies around generic drugs.

## REFERENCES

- 1. Blackwell T. Ontario unveils new rules for generic drugs. The National Post, April 7, 2010. .
- Silversides A. Pharmacies receiving massive rebates from generic drug-makers. CMAJ 2006 Aug 15;175(4):342.
- 3. Anis AH, Guh DP, Woolcott J. Lowering generic drug prices: Less regulation equals more competition. Med Care 2003 Jan;41(1):135-41.
- 4. Coyne T, Fowlie J. Generic drug deal to drop annual costs by \$380 million. The Vancouver Sun, July 9, 2010. .
- 5. Marotte B. Generic drug battle moves to quebec. The Globe and MailJune 29, 2010. .
- 6. Simoens S. International comparison of generic medicine prices. Curr Med Res Opin 2007 Nov;23(11):2647-54.
- 7. Puig-Junoy J. Impact of European pharmaceutical price regulation on generic price competition: A review. Pharmacoeconomics 2010 Aug 1;28(8):649-63.
- 8. Competition Bureau of Canada. Canadian generic drug sector study.; 2007.
- 9. Bulfone L. High prices for generics in Australia more competition might help. Aust Health Rev 2009 May;33(2):200-14.
- 10. Danzon PM, Furukawa MF. International prices and availability of pharmaceuticals in 2005. Health Aff (Millwood) 2008 Jan-Feb;27(1):221-33.