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Title

Pan-Canadian Medicine Overpricing: A Six-Country Study of Generic Medicine Cost Control

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Authorship Statement

JN, RB, and AA conceived the study, designed the methodologies, collected and analyzed the data, and wrote the manuscript. All three authors contributed to all stages of the project and approved the final version of the manuscript. RB wrote the first draft of the manuscript. AA is the guarantor for the project.

Abstract

Background

On April 1, 2013, Canada's Council of the Federation (a body of Canada's provincial and territorial Premiers) launched a pan-Canadian pricing scheme to improve the affordability of six generic medicines (amlodipine, atorvastatin, omeprazole, rabeprazole, ramipril, and venlafaxine) that represent about 20% of publicly funded generic drug spending. The Council set a price ceiling on these drugs at 18% of the equivalent innovator medicine's price, which the Council predicted would result in an estimated savings of up to \$100 million for government drug plans.

Methods

To test whether the Council's price ceiling will result in generic drug prices comparable to other countries, we obtained data on the pan-provincial reimbursement prices of the six medicines, and compared them with prices in the United States, the United Kingdom, Germany, Sweden, and New Zealand.

Results

In 69 pairwise comparisons of the newly reduced prices on these generic products, we found that 80 percent (55 of 69) were still more expensive in Canada than in the five other countries studied. While the Council's new approach reduces the cost of generic medicines, even with this imposed price ceiling, Canadians continue to overpay for generic medicines.

Interpretation

We conclude that much more money could be saved, were it not for the fact that the Council's approach is inferior to that of other countries. We suggest the Council of the Federation better harness competition or negotiation by returning to its initial but unfulfilled plan of instituting a national competitive bidding process for generic medicines.

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Introduction

On 1 April 2013, Canada's provincial and territorial governments achieved a breakthrough in lowering the price of six hitherto costly generic medicines. Under the auspices of Canada's Council of the Federation, the Premiers of all the provinces and Territories (except Quebec) agreed to peg the reimbursement price of amlodipine, atorvastatin, omeprazole, rabeprazole, ramipril and venlafaxine at 18% of the price of the original innovator's product. These six medicines represent about 20% of Canada's publicly funded generic drug spending, and with its new price ceiling, the Council expects to save up to \$100 million for public drug plans.

Price ceilings have long been a common way of regulating drug prices in Canada. They have always been set by governmental fiat at arbitrary levels, but never as low as 18% as an *ex factory* or supply-side price, and politicians have never made them national in scope (a single authority, Blue Cross Alberta, is coordinating the national effort). The Council's fiat, therefore, represents an experiment of considerable importance in improving health system affordability and the equitable access to essential medicines for Canadian patients.

Canada's Patented Medicines Regulations require application submissions to include price comparisons from peer nations, but no such comparisons are mandated for national pricing schemes for generic drugs. In this study, we set out to make such a comparison and to examine whether the Council's new initiative is resulting in medicine prices that compare with other developing countries. Simply put, where the Council favored a governmental fiat to impose a price ceiling on all vendors of the six post-patent medicines under its control, other countries flexibly make use of competition or negotiation on a case-by-case basis for individual medicines or vendors. We compare the prices that governments obtained under these differing models, and discuss the implications for Canadian drug policy. Price comparisons of this nature have been carried out in academic venues as well as government ones, typically finding the Canadian prices to be higher.

Methods

We obtained the prices for medicines regulated under the Council's reimbursement price ceiling. We selected markets of varying size from similarly wealthy countries: (i) the United Kingdom's National Health Service and (ii) Germany's Deutsches Institut fuer Medizinische Dokumentation und Information (DIMDI), which have pharmaceutical

markets larger than Canada's; (iii) the United States' Federal Supply Schedule Service , which caters mainly to aboriginals and national security personnel and which has a comparable market size to Canada of about 23 million , and; (iv) New Zealand's PHARMAC and (v) Sweden's Tandvårds-och läkemedelsförmånsverket (Dental and Pharmaceutical Benefits Agency) , which compare in size to individual Canadian provinces. While previous peer-reviewed studies on this topic used only one or two peer nations as comparators , we chose to apply similar methods but expand the dataset using the aforementioned five countries in order to have broader validity. For the purpose of clarity, we have organized some of the strengths and limitations of our comparison choices in Table 1.

As the Council launched its prices in April 2013, we accessed price databases of the foreign buyers' in that same month. For countries that approve the same generic drug at more than one price (Sweden, USA, Germany), the price of the cheapest approved supplier was chosen. Comparisons were based on identical product strengths and formulations, except tablets and capsules were considered interchangeable. As in other studies , foreign currency prices were converted using the Bank of Canada 10-year currency converter for April 1, 2013 into US dollars per unit for calculating the price ratio.

Results

It was possible to obtain direct comparisons for all six generic drugs on the Council's list, with some lacunae. For rabeprazole, which remains under patent in much of the world, the only country having a generic comparator was the United Kingdom. Likewise, some doses (e.g., amlodipine 2.5mg) were not available to one or more foreign buyers. All data are summarized in Figure 1 and Table 2 with more detail in the excel web supplement S1.

With few exceptions, Canadian drug prices are markedly higher than those in the other countries—and this remains true even after the large price reductions mandated by the Council of the Federation. This result is consistent with other studies that have demonstrated that Canadians are paying much more for generic drugs than peer nations . Our overall result across all medicines and strengths is that Canada continues to be more expensive than foreign generics by a median price ratio of 2.13 (0.30 - 21.71). In 69 pairwise comparisons of these generic products with their equivalents in the other countries studied, only 14 of 69 (20 percent) were cheaper in Canada. The German prices were closest to the new Canadian ones on these particular products; but even after its dramatic cost reductions, Canada's prices were still higher in half of the comparisons. In contrast, Canada's new prices were most significantly higher relative to the US and Sweden. The

publicly available data from Sweden and the US are the consumer price, which normally would be higher than the reimbursement price taking into account a profit margin or overhead for the end distributor, meaning that the reimbursement price would be (conservatively speaking) below that the data presented here and compared relative to the Canadian reimbursement formulary, likely resulting in an even wider margin than the one reported here.

Thus, the prices agreed to by the Council are generally much higher than in foreign countries. This even holds true in the few situations where Canadian generics companies supply the product. For example, the United States and New Zealand both purchase amlodipine and venlafaxine from Apotex, a Canadian generics firm, at deep discounts (86-91% and 53-94%, respectively) compared to the Council's in-Canada price.

Interpretation

The results of our study suggest that while Canadians can expect significant price reductions in generic medicines when compared to the price of the original innovator's version, these savings are more modest than they potentially could be. Even with the Council's unprecedentedly deep price reductions of 1 April 2013, Canadian patients still pay more for generic medicines overall than patients in any of the other countries included in our analysis. Fully 5 of the 6 medicines in the Council's initiative are cheaper in some or all of the foreign countries we studied.

That Canada's generic drugs are priced above international norms has been noted in previous studies . Ontario, the largest province, introduced generic price ceilings by fiat at 25% of the equivalent innovator product for public procurement and at 50% for private procurement in July 2010. Law, Ystma and Morgan found that despite these price reductions, Ontarians still overpaid for generic medicines compared to other countries . The same would be true of other Canadian provinces, having prices of 25 – 40% of the innovator product .

What accounts for Canada's excessive generics prices relative to the foreign countries in this study? It is not possible to ascribe that result to the market size or the wealth of those foreign countries. In our study, New Zealand, Sweden, Germany, the UK and the USA vary considerably in market size, and are similarly wealthy as Canada—but all obtain better generics prices. We propose that the price differences are better explained by the procurement strategies of the various countries.

The Council's decision to set the maximum price for these post-patent medicines at an arbitrary 18% of the equivalent innovator's product was not its original plan. Rather, the Council first proposed in August 2010 "to establish a provincial-territorial purchasing alliance to consolidate public sector procurement of common drugs" . Later, the Council decided that the purchasing alliance would "initiate a national competitive bidding process by Fall 2012 that would result in lower prices taking effect by April 1, 2013 ."

However, the proposal to use competitive bidding—or what is commonly called drug tendering—never came to fruition when the provinces could not agree on an underlying alliance for bulk purchasing . So instead, the Council decided, with hurried consultation, on the very different approach of imposing a single, national, price ceiling by fiat at 18%. The Council offered no rationale for that arbitrary percentage, and has not stated when, how, or even if the percentage will be revised in the future, to adapt to changing market conditions.

The Canadian approach is very unusual. None of the foreign countries in this study uses a single, arbitrary price ceiling to set medicine prices, and all prefer competition or negotiation to varying extents. The most liberalized is New Zealand, where the public health system competitively tenders to procure from a single preferred vendor of a product at the best price . Many developing countries also use some form of tendering (there are many variants) to buy drugs on the international market . In the USA, federal government programs (except Medicare) can procure a given product from multiple vendors, but each vendor negotiates its own government-approved maximum price that is tailored to its particular economic and political situation . Likewise in Sweden, the public health system also procures from multiple vendors, with the difference that each vendor proposes a price that the government accepts or rejects, without negotiation . Only the UK and Germany operate a sort of fiat pricing like Canada, in that a maximum reimbursement price is set that binds all vendors, but with the important differences that there is no arbitrary price ceiling applying to all medicines, and prices are revised at short intervals (e.g., quarterly or monthly) based on negotiations with vendors and market trends .

Thus the Council's arbitrary price ceiling, while it saves some money, is still suboptimal, and undoubtedly more could be saved under an alternative system, be it single source tendering such as New Zealand uses, or flexible price ceilings set in manner of Germany, Sweden, the United Kingdom or the United States. Should the Council continue to revise and/or add to the list of post-patent drugs with price ceilings, it could consider introducing routine international price comparisons to

inform its price ceilings, similar to this study or those carried out by the Patented Medicines Prices Review Board . Alternatively, a single source tendering process could be an even more powerful alternative that has been gaining support by observers . These are just two of many promising policy alternatives that have been proposed over the years for introducing more competition into Canada's pricing of generics and/or for bringing down Canada's generic prices down to a level that is more typical amongst its peers nations . Why the Council rejected these options is unknown, although it appears that aggressive, often inaccurate lobbying by Canada's generic drug industry may have played a part.

In a report commissioned by the Canadian Generic Pharmaceutical Association , Professors Hollis and Grootendorst offer three principal arguments against tendering and other forms of competition. First, they argue, but without citing evidence, that Canadian-style price ceilings already result in "generic drug reimbursement prices ... comparable to prices paid elsewhere." Second, they argue that tendering would make drug supplies dependent on a single supplier, and increase the risk of drug shortages if that supplier fails to meet demand. Third, they argue that lower generics prices would make it unaffordable for generics companies to sue and overturn invalid patents that would otherwise force buyers into paying even higher prices because of an unusual Canadian law that "links" the innovator medicine's patent status to obtaining marketing approval for generics .

None of these arguments is convincing. As we show in this study, even at the Council's unprecedentedly low 18% price ceiling, generics prices in Canada are not comparable to other countries, but usually remain higher, often by a vast margin. The dangers of drug shortages can be greatly mitigated by simply continuing to use multiple suppliers as Germany, Sweden, the United Kingdom and the United States do, and not single suppliers as New Zealand does (although we were unable to find credible, published reports of New Zealand experiencing drug shortages). Finally, rather than pay generics companies elevated prices as bounty for suing and invalidating patents, it would be cheaper (basically, free) for Canada's Parliament to amend its unusual law, especially the controversial linkage between the innovator medicine's patent status and generic medicines' marketing approval. None of the other countries in this study have patent linkage laws, except the United States, where that system is better tailored and coexists with cheaper generics than Canada .

The Council plans to report in 2014 on the progress of its generic drug pricing scheme. That report will show some money was saved—but the principal conclusion of this study is that much more could be

saved, were it not for the fact that the Council's approach is inferior to that of other countries' that better harness competition or negotiation. Since no arbitrary price ceiling, whether at the 18% level or any other, can possibly be optimal for all generic medicines, we recommend that the Council of the Federation refrain from any such fiat, and return to its original but unfulfilled plan to "initiate a national competitive bidding process" . This approach is more likely to restrain Canadian drug prices, and to avoid the politically difficult appearance of Canadian generic companies offering better prices to foreign countries than in the home market. Such improvements, perhaps imbued with best practices borrowed from foreign countries, would save far more than the \$100 million that the Council expects to save from its well-intentioned, but misguided efforts.

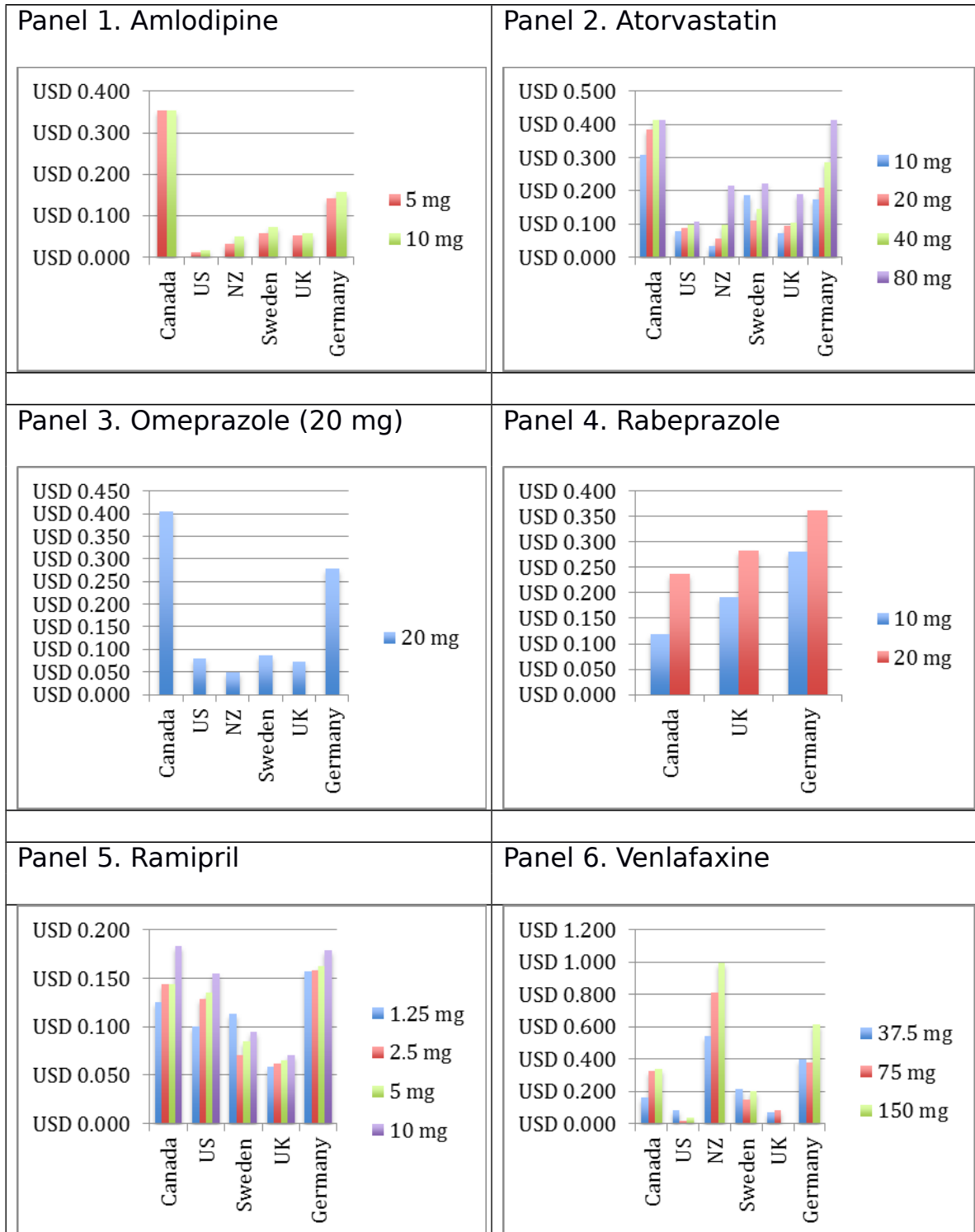
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None to mention

References

Figure Legends

Figure 1. Prices of the six pharmaceuticals targeted by the Council relative to four other nations



Tables

Table 1. Strengths and weaknesses of choices in peer nations for comparison

Country	Data	Pro	Con	Ref
USA	Veterans Administration	<ul style="list-style-type: none"> - Comparable size to pan-Canadian market (federal public sector only) - Competitive negotiation by multiple vendors for price ceiling 	<ul style="list-style-type: none"> - Consumer price data, not supplier price data 	
New Zealand	PHARMAC	<ul style="list-style-type: none"> - Comparable market size to individual provinces - Formulary price data 	<ul style="list-style-type: none"> - Smaller than pan-Canadian market - Single source tendering 	
Sweden	TLV	<ul style="list-style-type: none"> - Comparable market size to individual provinces - Competitive negotiation by multiple vendors for price ceiling 	<ul style="list-style-type: none"> - Consumer price data, not supplier price data - Smaller than pan-Canadian market 	
UK	PSNC	<ul style="list-style-type: none"> - Reimbursement formulary price data - Reimbursement price set for all vendors but revised quarterly by product and strength 	<ul style="list-style-type: none"> - Larger than pan-Canadian market size 	
Germany	DIMDI	<ul style="list-style-type: none"> - Reimbursement formulary price data - Reimbursement price set for all vendors but revised monthly 	<ul style="list-style-type: none"> - Larger than pan-Canadian market size 	

		by product and strength		
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Table 2. Canada-to-foreign price ratio comparison in US dollars per unit

Drug	Canada	USA			New Zealand			Sweden			UK	
	Price	Price	Supplier	Ratio	Price	Supplier	Ratio	Price	Supplier	Ratio	Price	Supplier
Amlodipine 5mg 10mg	\$0.238	\$0.012	Exelan	20.6	\$0.03	Apotex	7.52	\$0.057	Actavis	4.18	\$0.05	Various
	\$0.353	\$0.016	"	7 21.7 1	2 \$0.05 0	"	7.12	\$0.074	Orion	4.79	3 \$0.05 8	"
Atorvastatin 10mg 20mg 40mg 80mg	\$0.309	\$0.078	Watson	3.97	\$0.03	Pfizer	9.24	\$0.187	KRKA	1.65	\$0.07	Various
	\$0.386	\$0.088	"	4.39	3	"	6.98	\$0.111	Sve	3.49	2	"
	\$0.415	\$0.097	"	4.28	\$0.05	"	4.27	\$0.144	Actavis	2.87	\$0.09	"
	\$0.415	\$0.106	"	3.90	5	"	1.93	\$0.221	"	1.87	3	"
					\$0.09 7 \$0.21 5				Teva Swe		\$0.10 5 \$0.19 0	
Omeprazole 20mg	\$0.405	\$0.080	Kremer s	5.04	\$0.05 0	Mylan	8.08	\$0.086	Pensa Ph	4.71	0.073	Various
Rabeprazole 10mg 20mg	\$0.118 \$0.237	- -	Not listed "	- -	- -	Not listed "	- -	- -	Not listed "	- -	\$0.19 3 \$0.28 4	Various "
Ramipril 1.25mg 2.5mg 5mg 10mg	\$0.125	\$0.100	Golden	1.25	-	Not	-	\$0.114	Sandoz	1.10	\$0.05	Various
	\$0.145	\$0.129	St	1.13	-	listed	-	\$0.071	Teva Swe	2.05	9	"
	\$0.145	\$0.136	"	1.07	-	"	-	\$0.084	Sandoz	1.71	\$0.06	"
	\$0.183	\$0.155	"	1.18	-	"	-	\$0.095	Actavis	1.92	1	"
			"			"					\$0.06 6 \$0.07 1	
Venlafaxine 37.5mg ER 75mg ER 150mg ER	\$0.162	\$0.084	Apotex	1.93	\$0.54	Arrow	0.30	\$0.217	Actavis	0.75	\$0.06	Various
	\$0.323	\$0.019	"	16.7	0	"	0.40	\$0.149	Sandoz	2.17	9	"
	\$0.341	\$0.040	"	1 8.60	\$0.81 0 \$0.99 8	"	0.34	\$0.204	Bluefish	1.67	\$0.08 4 -	Not listed