Consequences of over-regulating the prices of new drugs in Canada

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SUMMARY

Introduction
Canada's federal government is in the end-stages of a process for implementing changes to the rules used by the Patented Medicine Prices Review Board (PMRPB) to regulate the prices of new medicines. Two of the stated purposes for the PMPRB regulatory changes are to significantly lower the cost of prescription drugs and to provide faster access to new drugs that are safe and effective.

Objective
To examine whether the evidence supports the government's assumption that it can preserve the availability of new medicines for Canadian patients while further depressing the prices of patented drugs.

Data and Method
Using data from the PMPRB and the Organisation for Economic Co-operation and Development (OECD), a multi-variable linear regression analysis was conducted to test the statistical relationship between the number of new drug launches (dependent variable) across 31 OECD countries and three independent variables: the market price level for patented drugs, the per capita GDP and the total market size (population) in each country.

Results
Market price level was the only one of the three independent variables that was a statistically significant predictor of the number of new drug launches ($P < .05$, at 95% CI). The analysis confirms that lower priced markets experienced fewer new drug launches, and vice versa, that higher priced markets tended to experience more new drug launches (Coefficient = .283).

Conclusions
The analysis strongly suggests that any regulatory change that further depresses prices runs the risk of reducing the availability of new medicines for Canadian patients. There is no evidence-based justification for expanding the scope or complexity of existing price regulations for patented drugs. Policy-makers should reject the PMPRB's proposed regulatory changes. They are unnecessary and will almost certainly reduce access to new medicines for Canadian patients.

Introduction

Canada's federal government is in the end-stages of a process for implementing changes to the rules used by the Patented Medicine Prices Review Board (PMRPB) to regulate the prices of new medicines.[1,2,3]

The stated purposes for the PMPRB regulatory changes are as follows:

> "The Government of Canada is firmly committed to… taking action to significantly **lower the cost of prescription drugs**; [*and to*] provide **faster access to new drugs** that are safe and effective... This important work includes **reducing the cost of patented drugs through the modernization of the pricing framework under the Patented Medicine Prices Review Board** (PMRPB)."[4]

The purpose of this paper is to examine whether the evidence supports the government's assumption that it can preserve the availability of new medicines for Canadian patients while further depressing the prices of patented drugs.

Analysis

Canadian prices for patented drugs are already well below comparable countries.

The most accurate data source available for Canadian and international prices for patented drugs sold in Canada is the PMPRB. The Patent Act along with the Patented Medicines Regulations require patentees to annually file information pertaining to the sale of their drug products in Canada. PMPRB staff reviews pricing information on an ongoing basis until patents have expired. In accordance with the Act and the Regulations, patentees must report publicly available prices of their patented drug products in seven foreign comparator countries ("PMPRB7") including: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States. The prices reported to the PMPRB are at the manufacturer's level (ex factory) and exclude wholesale and retail price markups, pharmacy fees, etc.[5]

[1] PMPRB (2016). PMPRB Guidelines Modernization: Discussion Paper. June 2016. Ottawa: Patented Medicine Prices Review Board. http://www.pmprb-cepmb.gc.ca/en/news-and-events/consultations/current-major-consultations/rethinking-the-guidelines/discussion-paper.

[2] Health Canada (2017). Protecting Canadians from Excessive Drug Prices: Consulting on Proposed Amendments to the Patented Medicines Regulations. May 2017. Ottawa: Government of Canada. https://www.canada.ca/en/health-canada/programs/consultation-regulations-patented-medicine/document.html.

[3] Health Canada (Dec 1, 2017). News release: Government of Canada Proposes Regulatory Changes to Lower the Cost of Patented Drugs. https://www.newswire.ca/news-releases/government-of-canada-proposes-regulatory-changes-to-lower-the-cost-of-patented-drugs-661335603.html.

[4] Health Canada (2017). Protecting Canadians from Excessive Drug Prices: Consulting on Proposed Amendments to the Patented Medicines Regulations. Page 3. Abbreviated.

[5] PMPRB (2017). 2016 Annual Report. Ottawa: Patented Medicine Prices Review Board. http://www.pmprb-cepmb.gc.ca/reporting/annual-reports.

PMPRB uses the Median International Price (MIP) as the threshold to determine whether Canadian prices are excessive. Data published in the PMPRB's annual reports from 2007 to 2016 confirm that, adjusted for the market exchange rates (MER) of currencies, median international prices have been higher than Canadian prices for the last 10 years, as much as 25 per cent (ratio 1.25) higher in 2016. [Table 1, Chart 1][6]

When the PMPRB used the mean (or average) prices, and adjusted currencies at purchasing power parities (PPP), international prices for patented drugs were 51 per cent (ratio 1.51) higher than Canadian prices in 2016, and the gap has widened from 4 per cent (ratio 1.04) higher in 2007. [Table 1, Chart 1]

Arbitrarily depressing prices further could affect the availability of new medicines.

Using data published by the PMPRB and the Organisation for Economic Co-operation and Development (OECD), a multi-variable linear regression analysis was conducted to test the statistical relationship between the number of new drug launches (dependent variable) across 31 OECD countries and three independent variables: the associated price level for patented drugs, the per capita GDP and the total market size (population) in each country.

New drug launches were defined by the PMPRB according to each country's percentage share of the 210 new active substances (NASs) that were launched between 2009 and 2014 in Canada and the PMPRB7, current to the 4th quarter of 2015. The data reported by the PMPRB are sourced from a secondary non-PMPRB external private-sector data provider cited by the PMPRB as the IMS AG MIDAS™ database.[7]

The foreign-to-Canada price ratios for patented drugs in the 31 OECD countries were as reported by the PMPRB in Figure 10 of its 2015 Annual Report, which was also sourced from IMS AG MIDAS™ database.[8]

Per capita GDP was defined by the OECD at 2015 $US PPP, and population was current to the most recent common data year

[6] PMPRB (2017). 2016 Annual Report. Table 13. Average Foreign-to-Canadian Price Ratios, Multilateral Comparisons, 2016. Previous years' corresponding data obtained from PMPRB 2007 to 2015 Annual Reports.

[7] PMPRB (2017). Meds Entry Watch, 2015. Appendix, Figure I.1 Share of NASs launched by OECD country, Q4-2015. Based on the non-PMPRB external data source: MIDAS™ database, IMS AG. http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1307&lang=en.

[8] PMPRB (2016). 2015 Annual Report. Figure 10. Average Foreign-to-Canadian Price Ratios, Patented Drugs, OECD, 2015. Based on the non-PMPRB external data source: MIDAS™ database, IMS AG. ***NOTE: The price ratios reported in MIDAS™ for the 31 OECD countries differ from the price ratios reported by PMPRB for Canada and the PMPRB7 countries. The MIDAS™ total market sales and volumes data are estimated based on a sample which varies by country. Prices are also calculated from aggregate sales and volumes. Nevertheless, MIDAS™ is the only source of data that allows for a comparison of market price levels across 31 OECD countries, and so this analysis relies on the secondary data reported by PMPRB.***

available when the analysis was conducted (2013 for all except Greece 2012).[9]

The results of the analysis show that the market price level was the only one of the three independent variables (price, GDP and population) that was a statistically significant predictor of the number of new drug launches ($P < .05$, at 95% *CI*). The analysis confirms that lower priced markets experienced fewer new drug launches, and vice versa, that higher priced markets tended to experience more new drug launches (*Coefficient* = .283). [See Table 2, Chart 2]

Other research confirms the limitations of price regulation.

There is a consensus among most economists that government price controls are generally ineffective at achieving their intended purpose, and tend to distort the allocation of resources, and thereby produce inequitable social outcomes.[10] Price ceilings rarely control overall expenditure levels, and typically cause shortages.

For example, a study of pharmaceutical price regulation in the European Union found that limiting the rise of pharmaceutical prices did not control the rise of pharmaceutical expenditures because of the volume effect of utilization.[11]

Other evidence suggests price regulation depresses R&D and the discovery of new drugs. This, in turn, affects health outcomes and can lead to higher expenditures on other forms of medical care.[12,13]

There is also specific evidence to suggest that price regulation can delay launch of new drugs, with several studies showing that more regulated, lower-price markets experienced the longest delays in launching new medications.

A 2005 study analyzed the effect of price regulation on delays in launch of new drugs in 25 major markets, including 85 new chemical entities (NCEs) launched between 1994 and 1998. The study found that countries with lower expected prices had fewer launches and longer launch delays,

[9] OECD (2017). Gross domestic product (GDP) (indicator). (Accessed on 12 October 2017). Population (indicator). (Accessed on 23 October 2017). Organisation for Economic Co-operation and Development.

[10] Alston, Richard & Kearl, J & Vaughan, Michael. (1992). Is There a Consensus Among Economists in the 1990s? *American Economic Review*. 82. 203-09.

[11] Monique F. Mrazek (2002). Comparative Approaches to Pharmaceutical Price Regulation in the European Union. *Croatian Medical Journal*, 2002; 43:453-461.

[12] Daniel P. Kessler (2004). The Effects of Pharmaceutical Price Controls on the Cost and Quality of Medical Care: A Review of the Empirical Literature. Stanford University, Hoover Institution, and the National Bureau of Economic Research.

[13] Robert B. Helms (2004). The economics of price regulation and innovation. *Managed Care*. 2004 Jun; 13(6 Suppl): 10-2; discussion 12-3, 41-2.

controlling for per capita income and other country and firm characteristics.[14]

A 2007 study found that price controls had a statistically and quantitatively important effect on the extent and timing of the launch of new drugs, with companies being less likely to introduce products in price-controlled markets.[15]

A 2008 study compared pharmaceutical spending, availability, use, and prices in twelve countries including Canada in 2005. The researchers found that, based on the full universe of drugs launched in 1995 to 2005 in these 12 major markets, countries where drugs can be launched without requiring government approval of the price had the shortest average launch lag and the highest percentage of new drugs available.[16]

A 2011 study used a multi-variable regression analysis to examine the delay for drug product launches in 20 major pharmaceutical markets for new molecules from 14 different therapeutic classes. Controlling for other factors, the researchers found a correlation between median delays and the prices. The findings suggest that delay is longer in lower-priced markets.[17,18]

Conclusion

An objective analysis of the PMPRB's own published data strongly suggests that any regulatory change that further depresses prices runs the risk of reducing the availability of new medicines for Canadian patients. There is no evidence-based justification for expanding the scope or complexity of existing price regulations for patented drugs. Policy-makers should reject the PMPRB's proposed regulatory changes. They are unnecessary and will almost certainly reduce access to new medicines for Canadian patients.

[14] Patricia M. Danzon, Y. Richard Wang and Liang Wang (2005). The impact of price regulation on the launch delay of new drugs – evidence from twenty-five major markets in the 1990s. *Health Economics*, 14: 269–292 (2005).

[15] Margaret K. Kyle (2007). Pharmaceutical Price Controls and Entry Strategies. *Review of Economics and Statistics*, Volume 89 | Issue 1 | February 2007 p.88-99.

[16] Patricia M. Danzon and Michael F. Furukawa (2008). International Prices And Availability Of Pharmaceuticals In 2005. *Health Affairs* 27, no. 1 (2008): 221–233; 10.1377/hlthaff.27.1.221.

[17] Joan Costa-i-Font, Nebibe Varol, Alistair McGuire (2011). Does price regulation affect the adoption of new pharmaceuticals? The Centre for Economic Policy Research. http://voxeu.org/article/does-price-regulation-affect-adoption-new-pharmaceuticals.

[18] Nebibe Varol & Joan Costa-i-Font & Alistair McGuire (2011). Explaining Early Adoption of New Medicines: Regulation, Innovation and Scale. CESifo Working Paper Series 3459, CESifo Group Munich.

Author

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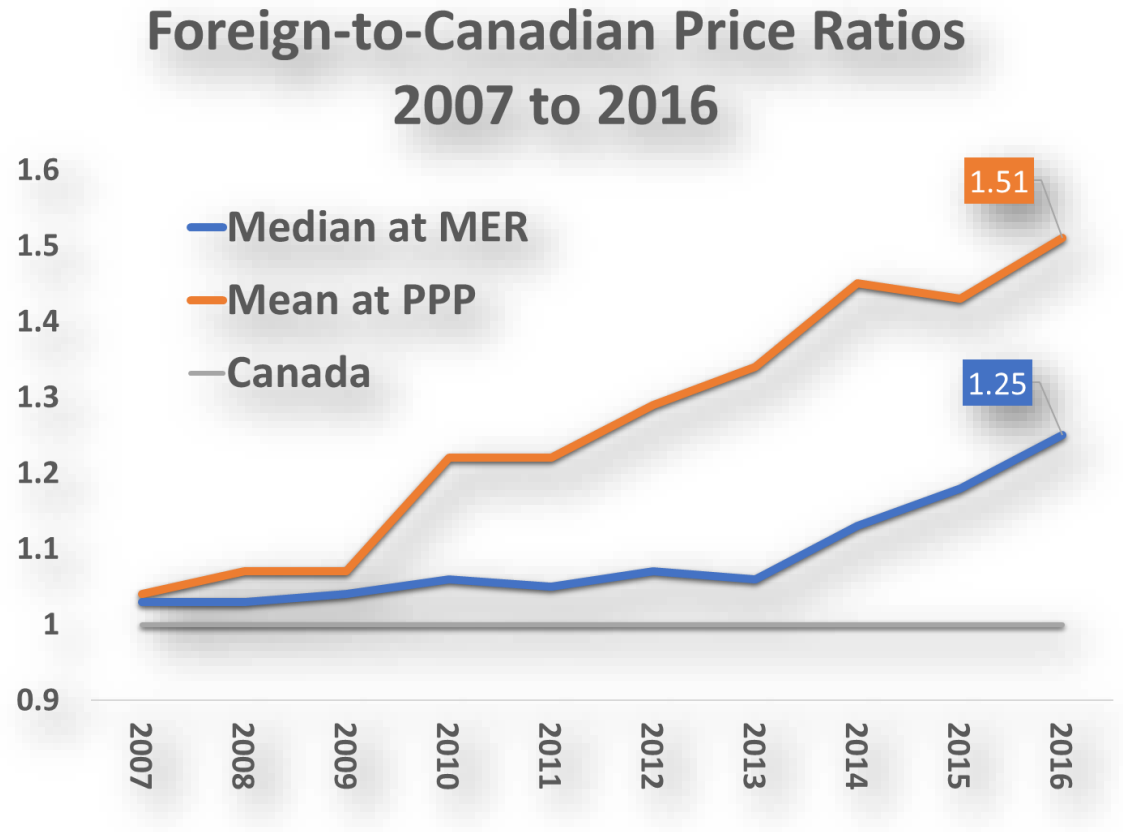
Charts and Data Tables

Table 1 [*back*]. Foreign-to-Canadian prices compared at market exchange rates (MER) and purchasing power parities (PPP), PMPRB7 countries, 2007 to 2016.[19]

Year	Median at MER	Mean at PPP
2007	1.03	1.04
2008	1.03	1.07
2009	1.04	1.07
2010	1.06	1.22
2011	1.05	1.22
2012	1.07	1.29
2013	1.06	1.34
2014	1.13	1.45
2015	1.18	1.43
2016	1.25	1.51

[19] PMPRB (2017). 2016 Annual Report. Table 13. Average Foreign-to-Canadian Price Ratios, Multilateral Comparisons, 2016. Previous years' corresponding data obtained from PMPRB 2007 to 2015 Annual Reports.

Chart 1 [*back*]. Foreign-to-Canadian prices compared at market exchange rates (MER) and purchasing power parities (PPP), PMPRB7 countries, 2007 to 2016.[20]



[20] PMPRB (2017). 2016 Annual Report. Table 13. Average Foreign-to-Canadian Price Ratios, Multilateral Comparisons, 2016. Previous years' corresponding data obtained from PMPRB 2007 to 2015 Annual Reports.

Table 2 [*back*]. Analysis of the statistical relationship of new drug launches to prices, GDP and population.[21,22,23,24]

Regression Data

	% of NAS Launched	Foreign-to-Canada Price Ratio	GDP per capita $US PPP	Population (millions)
Australia	40%	0.79	$46,894.40	23.1
Austria	61%	0.88	$50,108.90	8.5
Belgium	45%	0.78	$45,861.40	11.2
Canada	**61%**	**1.00**	**$44,205.00**	**35.2**
Chile	28%	0.86	$23,210.90	17.6
Czechia	37%	0.62	$34,058.30	10.5
Estonia	21%	0.64	$29,130.70	1.3
Finland	55%	0.82	$42,281.90	5.4
France	45%	0.78	$41,199.20	63.8
Germany	69%	0.99	$48,170.00	80.6
Greece	22%	0.65	$26,450.00	11.1
Hungary	39%	0.75	$26,699.10	9.9
Ireland	45%	0.83	$70,146.40	4.6
Italy	57%	0.81	$37,407.10	60.2
Japan	38%	0.91	$40,737.30	127.3
Luxembourg	23%	0.74	$103,769.80	0.5
Mexico	38%	1.07	$17,894.20	118.4
Netherlands	36%	0.75	$50,077.60	16.8
New Zealand	13%	0.89	$37,724.80	4.4
Norway	56%	0.73	$62,038.20	5.1
Poland	38%	0.72	$26,528.50	38.5
Portugal	49%	0.69	$29,738.10	10.5
Slovakia	48%	0.73	$29,995.30	5.4
Slovenia	42%	0.72	$32,189.20	2.1
South Korea	33%	0.50	$34,421.50	50.2
Spain	52%	0.78	$34,867.40	46.6
Sweden	60%	0.89	$48,037.80	9.6
Switzerland	49%	0.99	$63,291.50	8.1
Turkey	21%	0.38	$24,324.20	76.1
United Kingdom	62%	0.82	$42,136.90	63.2
United States	84%	2.57	$56,420.40	316.5

[21] PMPRB (2017). Meds Entry Watch, 2015. Appendix, Figure I.1 Share of NASs launched by OECD country, Q4-2015. Ottawa: Patented Medicine Prices Review Board.

[22] PMPRB (2016). 2015 Annual Report. FIGURE 10. Average Foreign-to-Canadian Price Ratios, Patented Drugs, OECD, 2015. Based on the non-PMPRB external data source: MIDAS™ database, 2005-2015, IMS AG.

[23] OECD (2017), Gross domestic product (GDP) (indicator). OECD 35, Gross domestic product (GDP) at market prices 2015, expenditure based, per capita US dollars at PPP. doi: 10.1787/dc2f7aec-en (Accessed on 12 October 2017). Organisation for Economic Co-operation and Development. https://data.oecd.org/gdp/gross-domestic-product-gdp.htm.

[24] OECD (2017), Population (indicator). doi: 10.1787/d434f82b-en (Accessed on 23 October 2017). Organisation for Economic Co-operation and Development. https://data.oecd.org/pop/population.htm.

Table 2: cont'd.

Summary Output

Regression Statistics

Multiple R	0.601
R Square	0.361
Adjusted R Square	0.290
Standard Error	0.134
Observations	31

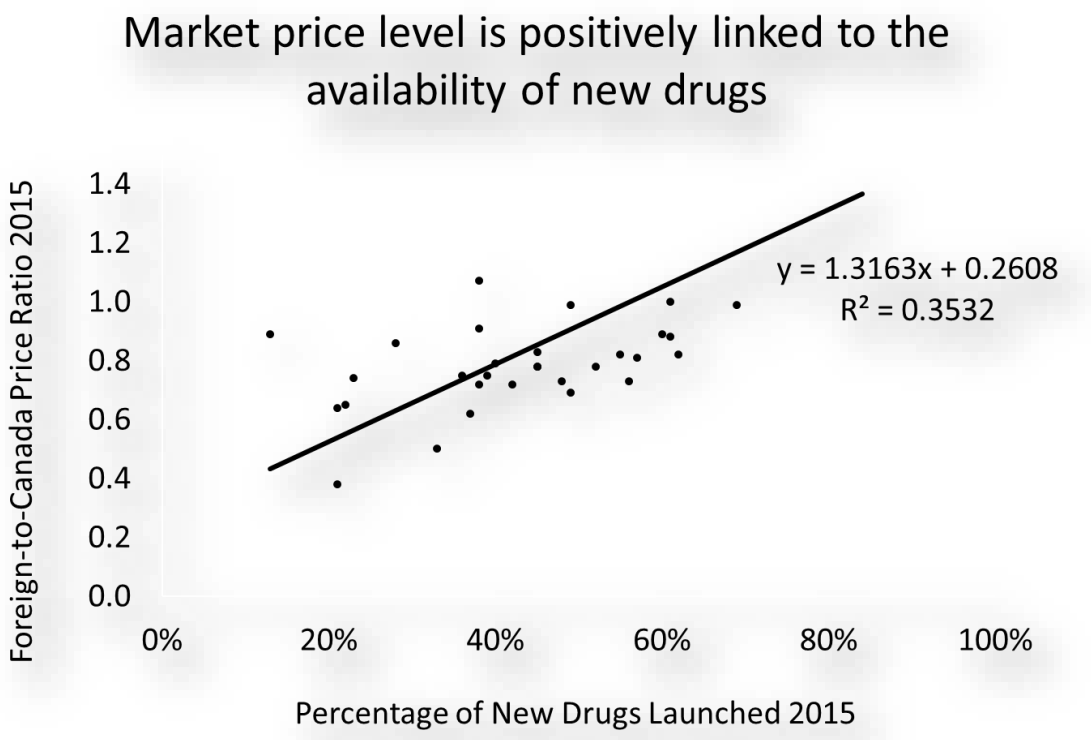
ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	3	0.272	0.091	5.093	0.006
Residual	27	0.481	0.018		
Total	30	0.754			

Predictors of the Number of New Drugs Launched

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	0.181	0.088	2.050	0.050	0.000	0.361	0.000	0.361
PRICE	0.283	0.129	2.186	0.038	0.017	0.549	0.017	0.549
GDP	0.000	0.000	0.430	0.671	0.000	0.000	0.000	0.000
POP	0.000	0.001	-0.216	0.831	-0.002	0.001	-0.002	0.001

Chart 2 [*back*]. Scatter-plot of the statistical correlation between the market price level for patented drugs and the percentage of new drugs launched in 31 OECD countries, 2015.[25,26]



[25] PMPRB (2016). 2015 Annual Report. FIGURE 10. Average Foreign-to-Canadian Price Ratios, Patented Drugs, OECD, 2015.

[26] PMPRB (2017). Meds Entry Watch, 2015. Appendix, Figure I.1 Share of NASs launched by OECD country, Q4-2015. Ottawa: Patented Medicine Prices Review Board.