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Protecting Canadians from Excessive Regulation

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Submitted to the PMPRB Draft Guidelines Consultation by Canadian Health Policy Institute (CHPI).

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RE: Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements): SOR/2019-298. Canada Gazette, Part II, Volume 153, Number 17. Registration: SOR/2019-298, August 8, 2019. PATENT ACT: P.C. 2019-1197 August 7, 2019.

About the Author

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About CHPI

Launched in 2012, Canadian Health Policy Institute Inc. (CHPI) is a private-sector research enterprise and the publisher of Canadian Health Policy (CHP) Journal. CHP Journal features the work of CHPI affiliated researchers and external independent authors. The Journal is focused on health economics and policy issues affecting patient access to innovative medical goods and services and the cost related issues of sustainability and value for money for taxpayers. Our published research is subject to formal review and critique by CHP editorial staff, CHPI affiliated researchers and independent external experts in health economics and health policy. The Institute and the Journal are funded by sales of articles and subscriptions to readers. We set articles free (or at reduced prices) if the research and publishing costs are recovered through sponsorship. Some of the research referenced in this submission was published through CHPI's Access to Innovative Medicines research program. This program is partly sponsored by several innovative pharmaceutical companies.[1] Dr. Skinner chairs this research program. CHPI also offers expert consulting services to non-profit, corporate and government clients for non-published research projects through its policy intelligence unit (PolicyIntel).

[1] CHPI Programs: https://www.canadianhealthpolicy.com/pages/programs.html.

Preface

CHPI submits this discussion paper to support the PMPRB Draft Guidelines Consultation regarding the pending implementation of the Amendments to the Patented Medicines Regulations. CHPI has published research and conducted analyses that are relevant to the Amendments and the Guidelines. The paper references this evidence and other research to present a critical examination of the changes. It concludes by recommending revisions and alternative approaches to reconciling the issues related to the prices of patented medicines in Canada. The submission directly addresses the Consultation and by extension the Government of Canada.

Overview

The Amendments and Guidelines have important health and economic implications. The changes go beyond what is necessary to fulfill the PMPRB mandate. The new regulatory factors and methods are not suitable for use as regulatory tools. The economic impact of the changes has been underestimated and risks serious unintended consequences. Several of the rationales for the Amendments are based on faulty assumptions that undermine the legitimacy of the Guidelines. Substantial revisions to the Amendments and Guidelines are required to remedy these problems. It is recommended that the Government of Canada suspend the implementation of the new regulations to allow for a full re-examination of the Guidelines versus alternative approaches. In the absence of a suspension (and in the interim period), the PMPRB should apply a long-run societal welfare maximization perspective to the Guidelines and revise the new regulatory factors and criteria accordingly. The PMPRB should also revise the group of countries used for external reference pricing and change the method for determining international benchmarks.

Excessive Regulation

The previous regulatory regime.

Previously the PMPRB regulated the manufacturer's ex-factory gross (list) price. Net prices were not regulated. Price ceilings were set primarily using External Price Referencing and benchmarked to the PMPRB7 group of countries which had balanced representation from higher priced and lower priced markets. Pharmacoeconomic and market size factors were not used by the PMPRB in price regulation.

External price referencing.

The Guidelines benchmark the Maximum List Price (MLP) to the Median International Price (MIP) of the PMPRB11, which is overrepresented by lower priced markets. The exclusion of higher priced markets and the inclusion of additional lower priced markets biases the MIP downward [TABLE 1]. Further, the selection of external price referencing countries was arbitrary. The inclusion criteria (similarity re: price controls, GDP per capita, population and market entry of new products) were inconsistently applied:

- Switzerland regulates the prices of publicly reimbursed patented medicines using external price referencing, yet it was excluded as a reference country by the PMPRB. Germany does not regulate market entry prices and only applies external price referencing and pharmacoeconomic evaluation as tools to support negotiations for public reimbursement. Yet Germany was included as a reference country by the PMPRB.
- Comparing GDP per capita to Canada, the US is 26% higher, Norway is 35% higher and Switzerland is 39% higher. Yet the US and Switzerland were excluded, while Norway was included as a reference country [TABLE 2].

- Comparing the latest population data (2017) for OECD countries [TABLE 2] shows Canada 36,447,341, Sweden 9,995,153, Switzerland 8,419,550 and Norway 5,258,317. Yet Switzerland was excluded, while Sweden and Norway were included as reference countries. The United States population (324,076,293) is 9 times larger than Canada, but Canada's population is 7 times greater than Norway. Yet the US was excluded, while Norway was included.
- PMPRB data [TABLE 3] show that the US has the highest degree of commonality with Canada regarding the entry of new drug products. Of the 128 new active substances (NAS) launched in Canada between 2009 and 2014, 123 were also launched in the US. The same data show that of the 128 NAS launched in Canada, 91 were also launched in Switzerland, which is higher than the 76 NAS launched in France.[2] Yet France was included as a reference country by the PMPRB while the US and Switzerland were excluded.

Pharmacoeconomic factors are incompatible with use in regulation.

Pharmacoeconomic analysis is used in Canada and other countries to inform reimbursement negotiations. But it is unsuitable for use in regulation because it is based on data, metrics and methods for which there are no agreed standards and which at best produce subjective, assumption-dependent estimations. It should not be used to calculate market-wide price ceilings that are definitive, prescriptive and legally enforceable. There are well-known conceptual and technical problems and limitations associated with pharmacoeconomic analysis.[3,4,5] The Guidelines have not resolved these problems.

For example, the pharmacoeconomic price (PEP) formula is derived from the Pharmacoeconomic Value Threshold (PVT), which is known elsewhere as the cost-effectiveness (CE) threshold. There is no international standard or consensus regarding the appropriate CE threshold. In fact, the CE threshold in the Guidelines is far below thresholds in the PMPRB11 countries. A 2018 study reviewed the CE thresholds in 17 countries including 8 of the PMPRB11 [TABLE 4]. CE thresholds ranged from 102% of per capita GDP in Sweden up to 391% of per capita GDP in Belgium. On average CE thresholds were 215% of per capita GDP.[6] By contrast, the Guidelines will use a CE threshold of CA$60,000, which is approximately 100% of Canada's GDP per capita in 2018 of CA$60,555.[7]

Also, the PVT is derived from the Quality Adjusted Life Year (QALY). Again, there is no international consensus regarding the appropriate value of a QALY. QALY is a weighted numerical value which is assigned to various potential health conditions. The values are subjectively determined based on responses from public and expert opinion surveys, using a variety of methods of which there is no standard because each are vulnerable to significant limitations. The simplest method asks respondents to weight the importance of health conditions on a scale from zero (death) to one (perfect health). Other methods ask people to choose between alternatives involving a trade-off between quantity and quality of life; or to weight improving the life expectancy of people with full health vs improving the health

[2] PMPRB (2017). Meds Entry Watch, 2015. Figure A1.5 Comparison of the number of NASs available in Canada with those launched in PMPRB7, Q4-2015. Ottawa: Patented Medicine Prices Review Board.
[3] George A. Diamond, Sanjay Kaul (2009). Cost, Effectiveness, and Cost-Effectiveness. Circ Cardiovasc Qual Outcomes. 2009;2:49-54.
[4] Hill SR, Mitchell AS, Henry DA. Problems with the interpretation of pharmacoeconomic analyses: a review of submissions to the Australian Pharmaceutical Benefits Scheme. JAMA. 2000 Apr 26;283(16):2116–21. doi: http://dx.doi.org/10.1001/jama.283.16.2116 PMID: 10791503
[5] Pettitt D, Raza S, Naughton B, Roscoe A, Ramakrishnan A, Ali A, Davies B, Dopson S, Hollander G, Smith JA, Brindley DA (2016). The limitations of QALY: a literature review. J Stem Cell Res Ther 6: 4.
[6] David Cameron, Jasper Ubels and Fredrik Norström (2018). On what basis are medical cost-effectiveness thresholds set? Clashing opinions and an absence of data: a systematic review. GLOBAL HEALTH ACTION, 2018. VOL. 11, 1447828. https://doi.org/10.1080/16549716.2018.1447828.
[7] Calculated from Statistics Canada GDP (income-based, Q3 2018) and population data (July 1, 2018). CA$2,244,092,000,000/37,058,856 =CA$60,555.

expectancy of people with an illness/disability; or to choose between no treatment and the risk of a treatment with two possible outcomes, one worse and the other better than no treatment. Such methods are not objectively scientific and are susceptible to ethical problems, knowledge limitations and potential bias.[8]

The Guidelines are more extreme than other drug pricing regimes in the PMPRB11.

The scope and severity of the new Guidelines goes beyond the norms for drug pricing regimes in the PMPRB11 countries. Prices in the private market are not typically regulated. Public reimbursement prices are not typically regulated but are negotiated between pharmaceutical manufacturers and public payers whose decisions are guided by external price referencing and pharmacoeconomic evaluation. Where price ceilings are specified, they typically reference list prices. Net prices are typically confidential. Reference countries are typically chosen based on geographic proximity and market similarities like product availability. The external price referencing benchmark metric most commonly used is the average of the comparator countries, not the median.[9,10,11]

Unintended Consequences

Impact on prices.

The Regulatory Impact Analysis Statement (RIAS) published in the Canada Gazette II (CG2)[12] estimated that the updated schedule of comparator countries (PMPRB11) would reduce the prices of new high-priority medicines by 4.5%, while prices of other medicines are expected to be reduced by 3.5%. [CG2 p. 5968] It also calculated that the new price regulatory factors are expected to reduce the prices of new high-priority medicines by a further 40% on average. [CG2 p.5967] The RIAS further calculated that requiring patentees to report price and revenues net of all price adjustments is expected to reduce the prices of new drugs by 7.7%. In total, this represents a severe reduction of approximately 52% from the current price level. [CG2 p.5969] The impact is likely to be much larger. A recent study examined the Guidelines and applied them to a hypothetical new medication for a rare disorder. The case study demonstrated that the changes in the Guidelines will impose regulated price ceilings that could be 45-84% below existing levels.[13]

Price linked to new drug launches in 31 OECD countries.

The RIAS stated that "prices do not appear to be an important determinant of medicine launch sequencing." [CG2 p.5992] However, a 2018 study of 31 countries using data from the PMPRB and the Organisation for Economic Co-operation and Development (OECD) tested the statistical relationship

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[8] Bjarne Robberstad (2005). QALYs vs DALYs vs LYs gained: What are the differences, and what difference do they make for health care priority setting? *Norsk Epidemiologi* 2005; **15** (2): 183-191.
[9] Valérie Paris, Annalisa Belloni (2013). OECD Health Working Papers No. 63. Value in Pharmaceutical Pricing. https://dx.doi.org/10.1787/5k43jc9v6knx-en.
[10] Cecile Remuzat, Duccio Urbinati, Olfa Mzoughi, Emna El Hammi, Wael Belgaied and Mondher Toumi. Overview of external reference pricing systems in Europe. Journal of Market Access & Health Policy 2015, 3: 27675 - http://dx.doi.org/10.3402/jmahp.v3.27675
[11] Martin Wenzl, Valérie Paris (2018). Pharmaceutical Reimbursement and Pricing in Germany. OECD. June 2018. https://www.oecd.org/health/health-systems/Pharmaceutical-Reimbursement-and-Pricing-in-Germany.pdf
[12] Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements): SOR/2019-298. Canada Gazette, Part II, Volume 153, Number 17. Registration: SOR/2019-298, August 8, 2019. PATENT ACT: P.C. 2019-1197 August 7, 2019.
[13] Rawson, Nigel SB; Lawrence, Donna (2020). New Patented Medicine Regulations in Canada: Updated Case Study of a Manufacturer's Decision-Making about a Regulatory Submission for a Rare Disorder Treatment. *Canadian Health Policy*, January 2020.

between the number of new drug launches and the market price level for patented drugs, the per capita GDP and the total market size (population) in each country. 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. 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.[14]

The findings are consistent with other research on the issue. A 2019 study conducted for the European commission showed that manufacturers adopt launch sequencing strategies to mitigate downward price spiral, delaying the launch of new products in low-price countries or in countries with highly regulated prices. Within the EU, this has led to reduced availability of medicines in countries with lower prices.[15] Research out of the University of Pennsylvania analyzed the effect of price on the launch of new drugs in 25 countries finding that manufacturers delay or forego launching in markets where prices are visible to external price referencing and regulation reduces prices below levels expected from local market characteristics.[16]

Price linked to the number of industry-funded clinical trials in 31 OECD countries.

The RIAS stated that, "The link between high domestic prices and industry investment has not been demonstrated." [CG2 p.5992] However, a 2019 study of 31 OECD countries tested for statistical correlations between the geographic distribution of industry-funded clinical trials and variation in drug price levels, controlling for differences in GDP and market size. A multi-variable regression analysis showed that price-level was a statistically significant predictor of the number of industry-funded clinical trials. The same study also showed that according to PMPRB data the decline of spending on R&D in Canada coincides in time with a deteriorating Canadian price level relative to competing markets in the PMPRB7 countries.[17]

Availability of new drugs linked to lower healthcare costs.

Higher total healthcare costs are to be expected if the availability of innovative pharmaceutical treatment technologies is negatively impacted by the Regulations. Access to new drugs is linked to lower healthcare costs in Canada. A 2019 study compared the availability of various medical resources and government health expenditure across the healthcare systems in the 10 provinces; and tested for statistical correlations between the variables. Regression analysis showed that higher availability of new drugs was correlated with lower overall health expenditures.[18] The findings are consistent with a separate systematic literature review which found 68 studies published in peer-reviewed academic journals from 1990 to 2018 confirming that greater use of innovative pharmaceuticals is empirically associated with treatment efficiencies and net societal health and economic benefits.[19]

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[14] Skinner, Brett J. Consequences of over-regulating the prices of new drugs in Canada. *Canadian Health Policy*, March 27, 2018. https://www.canadianhealthpolicy.com/products/consequences-of-over-regulating-the-prices-of-new-drugs-in-canada.html.

[15] Panos Kanavos, Anna-Maria Fontrier, Jennifer Gill, Olina Efthymiadou (2019). Does external reference pricing deliver what it promises? Evidence on its impact at national level. The European Journal of Health Economics..

[16] Danzon, P. M., Wang, R., & Wang, L. (2004). The Impact of Price Regulation on the Launch Delay of New Drugs—Evidence From Twenty-Five Major Markets in the 1990s. Health Economics, 14 (3), 269-292.

[17] Skinner, Brett J. Patented drug prices and clinical trials in 31 OECD countries 2017: implications for Canada's PMPRB. *Canadian Health Policy*, August 2019. https://www.canadianhealthpolicy.com/products/patented-drug-prices-and-clinical-trials-in-31-oecd-countries-2017--implications-for-canada---s-pmprb-.html.

[18] Canadian Health Policy Institute (CHPI). Medical resources and spending across provincial healthcare systems in Canada. *Canadian Health Policy*, July 2019. https://www.canadianhealthpolicy.com/products/medical-resources-and-spending-across-provincial-healthcare-systems-in-canada-.html.

[19] Canadian Health Policy Institute (CHPI). Evidence that innovative medicines improve health and economic outcomes: focused literature review. *Canadian Health Policy*, April 2019. https://www.canadianhealthpolicy.com/products/evidence-that-innovative-medicines-improve-health-and-economic-outcomes--focused-literature-review-.html.

Illegitimate Rationale

Spending on patented medicines is affordable and sustainable.

The RIAS stated that, "Innovative medicines, including those that are subject to patent protection, help prevent and cure disease as well as save lives. But Canadians are not getting the value for money they deserve relative to total medicine spending, which has increased from 8.5% of the total health care expenditures in 1977 to about 16% today." [CG2 p.5948]

The statistics cited in the RIAS are based on data from the Canadian Institute for Health information (CIHI) for total drugs and related spending, which is not equivalent to direct spending on patented medicines. CIHI drugs spending statistics cannot be used to justify the Amendments to the Patented Medicines Regulations. The actual costs attributable directly to patented drugs are only a fraction of the total "drugs" costs published by CIHI.

In 2017 CIHI reported $38.2 billion was spent on all "drugs" and $32.3 billion on "prescribed drugs". According to PMPRB, the total direct cost from gross national sales of patented drugs was $16.8 billion in 2017, which accounts for 44% of the "drugs" total reported by CIHI for the same year. CIHI defines "drugs" expenditure much differently than PMPRB. The data reported by CIHI encompasses total national expenditure at final prices (manufacturer prices, plus wholesale and retail price markups, pharmacy fees and sales taxes) on patented and non-patented (off-patent brands and generics) drugs, prescribed and non-prescribed drugs, personal health supplies, administrative costs of public drug plans, and spending by pharmaceutical companies on drug research. By contrast, the data reported by PMPRB includes total national manufacturer sales of patented drugs at manufacturer (*ex factory*) gross 'list' prices.[20]

Contextual analysis of the proper data sources reveals a very different story from the narrative used to justify the Amendments. Every aggregate measure confirms that spending on patented medicines in Canada is both affordable and sustainable and has been for a long time.

Gross sales of patented drugs ($16.8 billion in 2017) accounted for only 6.9% of the $243.4 billion reported by CIHI for total health spending in Canada in 2017. Patented drugs accounted for a smaller percentage of total health spending in 2017 (6.9%) than in the year 2001 (7.1%), a 17-year period of near zero average annual relative cost growth. Accounting for public drug plan rebates, the net national cost of patented drugs was only 6.0% of total health spending in 2017.[21]

Gross sales of patented drugs have accounted for less than 1% of GDP for the last 28 years. Patented drug sales were the same percentage of GDP in 2017 (0.78%) as in 2003 (0.78%), a 15-year period of zero average annual growth relative to GDP. Accounting for public drug plan rebates, the net national cost of patented drugs was only 0.68% of GDP in 2017.[22]

High-cost drugs were specifically cited as an affordability challenge for public and private payers. The RIAS stated, "Between 2007 and 2017, the average annual cost of treatment for the top 10 selling patented medicines in Canada increased by 800% and the number of medicines in Canada with annual per-patient treatment costs of at least $10,000 swelled from 20 to 135. These high-cost medicines now account for

[20] Canadian Health Policy Institute (CHPI). Facts about the cost of patented drugs in Canada: 2018 Edition. *Canadian Health Policy*, February 2019. https://www.canadianhealthpolicy.com/products/facts-about-the-cost-of-patented-drugs-in-canada--2018-edition-.html

[21] See previous note.

[22] See previous note.

40% of new patented medicines coming under the PMPRB's jurisdiction every year. Fully 30% of public and private insurer spending is allocated to these medicines, which cover less than 2% of beneficiaries." [CG2 p.5954, 5952]

Again, contextual analysis of PMPRB data contradicts the cost crisis rationale for the regulations. PMPRB defines high-cost patented drugs as medicines with annual treatment costs of more than $10,000. According to PMPRB there were 144 patented medicines defined as high-cost drugs in 2017 accounting for $6.3 Billion in gross sales, which is only 0.29% of GDP and 2.6% of total health expenditures in 2017. Gross national sales of high-cost patented drugs have accounted for less than 0.35% of GDP and less than 3% of total health expenditures for the last 12 years. Accounting for a national average rebate of 30% applied to the public drug plan share of sales, net national spending on high-cost patented drugs was only $5.5 Billion representing 0.26% of GDP and 2.3% of total health expenditures in 2017.[23]

Regulating net prices to undermine price discrimination.

The RIAS cited price discrimination as the rationale for regulating net prices, "In Canada and other developed countries, it is common practice for medicine manufacturers to negotiate confidential rebates and discounts off public list prices in exchange for having their products reimbursed by public and private insurers. This empowers manufacturers to price-discriminate between buyers based on their perceived countervailing power and ability to pay." [CG2 p.5952]

The PMPRB mandate is to protect consumers from excessive pricing, not to protect commercial and institutional payers from price discrimination. In addition, using regulation to undermine price discrimination is misguided for several reasons.

In Canada price discrimination between public payers is already mitigated by the Pan-Canadian Pharmaceutical Alliance (PCPA). The PCPA conducts joint price negotiations with pharmaceutical manufacturers on behalf of all Provincial and Territorial public drug plans and cancer care agencies, plus the Federal Non-Insured Health Benefits, Correctional Services of Canada and Veterans Affairs Canada. The purpose of the PCPA is to leverage the monopsony bargaining power of all provincial and federal public drug plans and to achieve uniform pricing and reimbursement conditions for public payers.

Also, price discrimination (or differentiation) can maximize societal welfare. Research has shown that differential pricing across countries increases both consumer and producer welfare, relative to charging a uniform price across all countries. Research also suggests that domestic price discrimination between payers improves long-run societal welfare more than uniform pricing.[24,25,26]

Indeed, price discrimination between public and private payers in Canada has probably increased long-run societal welfare. Ontario's Auditor General reported that the province's public drug plan received rebates of close to 30% on its total expenditure for brand name drugs in the fiscal year 2016/17.[27] While private payers are free to negotiate rebates with manufacturers, there is little evidence that they obtain rebates as large as those reported for public payers. However, private drug plans cover economically secure

[23] See previous note.
[24] Patricia M. Danzon (2018). Differential Pricing of Pharmaceuticals: Theory, Evidence and Emerging Issues. PharmacoEconomics. https://doi.org/10.1007/s40273-018-0696-4.
[25] Patricia Danzon, Adrian Towse, Jorge Mestre-Ferrandiz (2015). Value-Based Differential Pricing: Efficient Prices for Drugs in a Global Context. Health Economics 24: 294–301 (2015).
[26] Lichtenberg, Frank R., Pharmaceutical Price Discrimination and Social Welfare. Capitalism and Society, Vol. 5, Issue 1, Article 2, 2010. Available at SSRN: https://ssrn.com/abstract=2208666.
[27] Office of the Auditor General of Ontario. Annual Report 2017. Section 3.09 Ontario Public Drug Programs. Page 491.

populations, whereas public drug plans serve economically vulnerable populations. The higher prices charged to private payers subsidize the lower prices negotiated with public payers. Price discrimination therefore makes it possible for public payers to cover more drugs for more vulnerable people than they would otherwise be able to afford within tax-funded budget constraints. It achieves this without reducing utilization among privately insured populations, who are early adopters of new drugs and thereby fund future innovation. Importantly, differential pricing has likely increased the availability of new drugs in Canada. The potential to obtain higher prices in the private market encourages pharmaceutical manufacturers to launch new drug products in Canada earlier than would otherwise occur with uniform prices set at public market levels.

The fact that public payers have more bargaining (countervailing) power than private payers does not justify the regulation of net prices. Private insurers have significant bargaining power relative to pharmaceutical manufacturers. In fact, research has shown spending by private insurers attributable to the ex-factory list prices of patented drugs is as sustainable as other components of privately insured extended health benefits in Canada.[28] High-cost drugs can cause affordability challenges within some individual drug plans, but this occurs mainly as a result of insufficient risk pooling. Many employer-sponsored drug plans essentially self-insure their employee population, utilizing the insurer merely for administrative services only. Industry-wide risk pooling is a solution and the Canadian Life and Health Insurance Association (CLHIA) offers such a scheme. Government could make it mandatory for all employer-sponsored drug plans to participate. This approach would be more legitimate than using the PMPRB as a cost manager for private sector drug plans.

Narrow regulatory perspective.

The Guidelines Working Group indicated in its final report that it was prevented from applying a societal perspective to the Guidelines.[29] According to the RIAS, "the policy intent is for the PMPRB to adopt the perspective of the public health care system and favour a supply-side cost-effectiveness threshold in estimating opportunity cost." [CG2 p.5955]

The Guidelines should reflect the long-run societal perspective.[30]Public policy should maximize societal welfare over the long-run. Governments should consider the net benefits to society from spending more or less on healthcare versus other items in the government budget; and from spending more or less on pharmaceuticals versus other medical and non-medical items within the health budget.[31] Net societal benefits should include the potential costs avoided for healthcare and informal care, plus health-related productivity gains (or losses avoided) that are attributable to the reduction of mortality and morbidity; and the implicit value of future health gains from funding innovation in the current period.

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[28] Skinner, Brett J (2014). Private health insurance costs in Canada: Testing the insurance industry's claims about the sustainability of drug plans. *Canadian Health Policy*, March 31, 2014. https://www.canadianhealthpolicy.com/products/private-health-insurance-costs-in-canada.html

[29] Working Group to Inform the Patented Medicine Prices Review Board (PMPRB) Steering Committee on Modernization of Price Review Process Guidelines. Final Report. March 2019. S.5.2, p.43.

[30] Johannesson, M. et al. (2009), Why should economic evaluations of medical innovation have a societal perspective? *OHE Briefing*, No. 51, Office of Health Economics, London.

[31] Research has shown that billions of dollars in healthcare expenditures are potentially being squandered annually on non-medical expenses without any demonstrable benefits for patients. In 2015, over $33 billion was spent by Fed-Prov-Terr health ministries on things other than the direct costs of providing hospital and clinical medical services, and pharmaceuticals in Canada. Canadian Health Policy Institute (2017). Costs without benefits for patients? Non-medical spending in Canada's public health system. 2017 Health System Metrics Report. *Canadian Health Policy*, November 15, 2017. https://www.canadianhealthpolicy.com/products/costs-without-benefits-for-patients--non-medical-spending-in-canada---s-public-health-system.html

Recommendations

Assuming the Regulations and Guidelines will be implemented on July 1, 2020 the following interim actions are recommended to the PMPRB:

1. The Guidelines should be revised to adopt a long-run societal welfare maximization perspective and a demand-side approach to setting cost-effectiveness thresholds and other pharmacoeconomic and market size metrics.
2. Cost-effectiveness thresholds and other pharmacoeconomic and market size metrics should be indexed to changes in GDP per capita and the CPI to prevent artificial deflation in real values.
3. Restore the post-market MLP CPI-adjustment factor.
4. Revise the group of reference countries to include the United States and Switzerland comprising the PMPRB13. The PMPRB11 is over-represented by lower priced markets making it unbalanced and biased as a regulatory metric.
5. Revise the MLP for first-in-class patented drugs without therapeutic alternatives: Set the interim MLP (iMLP) at launch to the lower of the Average International Price (AIP) of the PMPRB13 (restore the US and Switzerland) and the Highest International Price (HIP) of the PMPRB12 (excluding the US). The iMLP should be recalculated annually until the earlier of 3 years from the date of the introduction of the patented medicine in Canada; or the date when the patentee has filed international price information for at least 7 of the PMPRB13 countries. At the end of the interim period, the MLP should replace the iMLP. The post-market MLP should be indexed to the CPI but never exceed the higher of the AIP of the PMPRB13 and the HIP of the PMPRB12 and the HIP of the domestic therapeutic class (dTC).
6. Revise the MLP for patented drugs with therapeutic alternatives: Set the MLP to the higher of the AIP of the PMPRB13 and the HIP of the PMPRB12 and the HIP of the dTC.

Assuming it is open to considering changes to the Regulations, the following policy actions are recommended to the Government of Canada:

1. Short-term: Postpone and then repeal the Regulations and related Guidelines affecting net prices. Pharmacoeconomics are not suitable for use in regulation. Net prices are best determined by payers through negotiation with manufacturers.
2. Long-term: Limit the function of the PMPRB to researching publicly available data on domestic and international list prices on behalf of public payers. Price regulation is redundant given the existence of the PCPA and health technology assessment agencies like CADTH and INESSS. Public payers already leverage monopsony bargaining power and pharmacoeconomic evaluation to negotiate deeply rebated prices that are affordable and sustainable. Private payers exercise bargaining power that is proportional to pharmaceutical manufacturers and have patented drug expenses that are as sustainably insurable as the other components of extended health benefits plans.

TABLE 1. AVERAGE FOREIGN-TO-CANADIAN PRICE RATIOS PMPRB7 v PMPRB11

PMPRB7	2014		2015		2016		2017
United States	2.21	United States	2.57	United States	2.91	United States	3.21
Switzerland	0.98	Germany	0.99	Switzerland	1.06	Switzerland	1.06
Germany	0.96	Switzerland	0.99	Germany	1.00	Germany	0.97
Sweden	0.87	Sweden	0.89	Sweden	0.89	Sweden	0.86
Italy	0.73	United Kingdom	0.82	United Kingdom	0.84	Italy	0.85
France	0.72	Italy	0.81	Italy	0.83	United Kingdom	0.83
United Kingdom	0.72	France	0.78	France	0.78	France	0.76
Canada	1.00	Canada	1.00	Canada	1.00	Canada	1.00

PMPRB11	2014		2015		2016		2017
~~United States~~	~~2.21~~	~~United States~~	~~2.57~~	~~United States~~	~~2.91~~	~~United States~~	~~3.21~~
Japan	1.04	Germany	0.99	~~Switzerland~~	~~1.06~~	~~Switzerland~~	~~1.06~~
~~Switzerland~~	~~0.98~~	~~Switzerland~~	~~0.99~~	Germany	1.00	Germany	0.97
Germany	0.96	Japan	0.91	Japan	0.92	Japan	0.92
Sweden	0.87	Sweden	0.89	Sweden	0.89	Sweden	0.86
Australia	0.80	United Kingdom	0.82	United Kingdom	0.84	Italy	0.85
Spain	0.73	Italy	0.81	Italy	0.83	United Kingdom	0.83
Italy	0.73	Australia	0.79	Belgium	0.80	Spain	0.80
France	0.72	Belgium	0.78	Spain	0.80	Netherlands	0.80
Belgium	0.72	Spain	0.78	Netherlands	0.79	Belgium	0.79
United Kingdom	0.72	France	0.78	Australia	0.78	Norway	0.78
Norway	0.69	Netherlands	0.75	France	0.78	France	0.76
Netherlands	0.66	Norway	0.73	Norway	0.75	Australia	0.74
Canada	1.00	Canada	1.00	Canada	1.00	Canada	1.00

NOTE: MIP highlighted. SOURCE: PMPRB Annual Reports 2014-2017, Figures 10,10,13,21 respectively. Based on IQVIA data.

TABLE 2. 2018 GDP PER CAPITA, US$ PPP; 2017 POPULATION

	GDP		POP
Switzerland	$69,358	United States	324,076,293
Norway	$67,614	Japan	126,932,772
United States	$62,853	Germany	82,521,653
Netherlands	$57,564	France	66,804,121
Germany	$54,457	United Kingdom	65,844,142
Sweden	$53,808	Italy	60,589,445
Australia	$53,663	Spain	46,528,024
Belgium	$52,282	Canada	36,447,341
Canada	$50,076	Australia	24,598,933
United Kingdom	$46,885	Netherlands	17,081,507
France	$46,242	Belgium	11,351,727
Italy	$42,798	Sweden	9,995,153
Japan	$41,502	Switzerland	8,419,550
Spain	$40,542	Norway	5,258,317

SOURCE: OECD.Stat (2020).

TABLE 3. NAS LAUNCHED IN CANADA ALSO AVAILABLE IN FOREIGN MARKET, 2009-14.

	NAS LAUNCHED
Canada	128
United States	123
Germany	111
United Kingdom	105
Sweden	103
Italy	94
Switzerland	91
France	76

SOURCE: PMPRB NPDUIS MEDS ENTRY WATCH 2015, FIG: A1.5.

TABLE 4. COST EFFECTIVENESS THRESHOLDS, GDP PER CAPITA, CE:GDP RATIO, 8 PMPRB11 COUNTRIES (2015 US$ PPP).

	CE US$	GDP US$	CE/GDP
Belgium	$180,653	$46,213	3.91
Norway	$173,971	$60,357	2.88
Netherlands	$132,340	$50,302	2.63
Japan	$83,938	$40,406	2.08
United States	$100,000	$56,770	1.76
United Kingdom	$65,871	$42,522	1.55
Australia	$63,096	$47,351	1.33
Sweden	$50,173	$48,975	1.02
Average	$106,255	$49,112	2.15

SOURCES: CE: Cameron et al (2018); GDP: OECD.Stat (2020).

Brett Skinner

From: PMPRB Consultations / Consultations CEPMB <PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca>
Sent: Tuesday, February 11, 2020 2:32 PM
To: Brett Skinner
Subject: Automatic reply: CHPI Submission to the PMPRB Draft Guidelines Consultation

French content follows | Le contenu français suit l'anglais

Hello,

Thank you for your interest in the PMPRB Guidelines Consultation process, we confirm the receipt of your email. The feedback you provided will be considered in the development of the PMPRB Guidelines.

In the meantime, you can follow us on Twitter for regular updates on our consultation process and get more information on the PMPRB Draft Guidelines at the resources below:

- PMPRB Draft guidelines
- Consultation Background – PMPRB Draft Guidelines PMPRB consultation
- PMPRB Consultation website

Have a great day,

PMPRB Consultation Team

Bonjour,

Merci de l'intérêt que vous portez au processus de consultation sur les Lignes directrices du CEPMB, nous accusons réception de votre courriel. Les commentaires que vous avez fournis seront pris en compte dans l'élaboration des lignes directrices du CEPMB.

Dans l'intervalle, vous pouvez nous suivre sur Twitter pour des mises à jour régulières sur notre processus de consultation et obtenir de plus amples renseignements sur les Lignes directrices provisoires du CEPMB aux liens suivants :

- Lignes directrices provisoires du CEPMB
- Document d'information – Consultation sur les Lignes directrices provisoires du CEPMB
- Site Web de la consultation du CEPMB

Bonne journée,

L'équipe des consultations du CEPMB

Brett Skinner

From: Brett Skinner <brett.skinner@canadianhealthpolicy.com>
Sent: Monday, April 6, 2020 12:56 PM
To: 'Patty.Hajdu@parl.gc.ca'; 'hcminister.ministresc@canada.ca'
Cc: 'info@mattjeneroux.ca'; 'Matt.Jeneroux@parl.gc.ca'
Subject: PMPRB censoring its draft guidelines consultation
Attachments: Automatic reply: CHPI Submission to the PMPRB Draft Guidelines Consultation ; CHPI PMPRB Draft Guidelines Consultation FEB 2020 .pdf

To: The Honourable Patty Hajdu, Minister of Health, Government of Canada
Re: https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines.html#submissions

Minister,

As you know, the Patented Medicines Prices Review Board (PMPRB) recently conducted a public consultation regarding the pending implementation of new draft regulatory guidelines. According to the website (hyper link shown above) "Extensive feedback was received and all written submissions are now available on the PMPRB website.". However, as of April 6, 2020 this website has not posted a submission made by the Canadian Health Policy Institute (CHPI). The attached Outlook email file is the email reply from the PMPRB acknowledging receipt of our submission and is proof that the PMPRB Draft Guidelines Consultation received CHPI's submission before the deadline. I am expressing my serious concern that the PMPRB has censored its public consultation by excluding CHPI's submission from the list of posted submissions on the consultation website. This action by the PMPRB consultation is a violation of the democratic process that such a consultation is supposed to represent. It is also inconsistent with the government's commitment to evidence based policy making. CHPI will be publicizing the fact that the PMPRB has excluded our submission. On behalf of CHPI I am requesting that the PMPRB consultation website be updated to include our submission. In the meantime, I have attached a PDF of CHPI's submission document for your consideration.

Brett J Skinner, Ph.D.
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