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Introduction

Canadian Health Policy Institute (CHPI) has published research that is relevant to the PMPRB Consultation on new Draft Guidelines. CHPI referenced the research, as well as a substantial body of evidence from the broader peer reviewed literature to support earlier submissions. The purpose of this submission is to make the government aware of limitations associated with the guidelines that have not been resolved.

PMPRB11 reference countries selection bias

The new reference countries are not an objective comparator group. The inclusion criteria specified by the PMPRB required reference countries to be similar to Canada on the basis of GDP per capita, population, and market entry of new products. The data shown below suggest that the PMPRB11 countries are skewed by selection bias.

EXHIBIT 1 shows data sourced from the Organization for Economic Cooperation and Development (OECD) for GDP per capita denominated in US dollars at purchasing power parity (PPP) for each of the seven current and six new reference countries to Canada. Average income varies widely across current and former PMPRB reference countries. This makes it nearly impossible to exclude any of the former reference countries based on differences or similarities related to GDP per capita. Notice that, in 2020 GDP per capita in the United States ($63,415) and Norway ($63,293) was 32% higher than Canadian GDP per capita ($48,091). Yet the US was excluded, while Norway was included as a reference country.

EXHIBIT 1. Population 2019 and GDP per capita US $ PPP 2020, PMPRB14

	POP	GDP PC
AUS	25,357,553	$51,743
BEL	11,455,519	$52,063
CAN	37,317,904	$48,091
FRA	67,177,636	$46,537
GER	83,019,213	$53,812
ITA	59,816,673	$41,492
JPN	126,443,180	$40,150
NLD	17,282,163	$59,335
NOR	5,328,212	$63,293
SPA	46,937,060	$38,335
SWE	10,230,185	$54,848
SWI	8,544,527	$71,298
UK	66,647,112	$44,929
USA	327,170,529	$63,415

Data: OECD

Inconsistencies in the application of the population criteria are also obvious. Comparing the most recent population data from the OECD [**EXHIBIT 1**] shows Canada at 37.3 million, Sweden at 10.2 million, Switzerland at 8.5 million, and Norway at 5.3 million. Yet Switzerland was excluded, while Sweden and Norway were included as reference countries. The United States population (327.1 million) 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 [EXHIBIT 2] show that the US has the highest degree of commonality with Canada regarding the market entry of new drug products.[1] 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. Yet France was included as a reference country by the PMPRB while the US and Switzerland were excluded.

EXHIBIT 2. New drug launches matching products launched in Canada, 2009 to 2014

	NAS LAUNCHED
CAN	128
USA	123
GER	111
UK	105
SWE	103
ITA	94
SWI	91
FRA	76

Data: PMPRB, NPDUIS

'Excessive' price metric is unreliable

PMPRB metrics are prone to spurious results. Research has shown that the median international price (MIP) fluctuates depending on the composition of the group of reference countries, prices data sample, currency values and exchange rate standardization, the timeframe, etc..[2] The highest international price (HIP) is a more stable 'excessive pricing' benchmark because it would be anchored to a constant comparator, usually the United States, and would therefore also reflect a real-world market equilibrium price in the country that is most similar to Canada.

Basing international comparisons on list prices also reduces the reliability of the MIP benchmark. Federal and provincial courts have affirmed that net prices are legally protected confidential business information, and that the regulation of net prices goes beyond the mandate of the PMPRB which is to prevent excessive prices.[3] PMPRB is left to analyze the cost of drugs at the manufacturer's list price level. However, list prices do not reflect rebates negotiated between manufacturers and public and private payers. Rebates can vary widely across jurisdictions, and actual prices paid can differ substantially from the manufacturer's list prices. The lack of real-world data reduces confidence in the accuracy of international price comparisons. Using the highest international list price as the benchmark for 'excessive' pricing minimizes the risk of a supply disruption from a price ceiling being imposed based on inaccurate metrics that vary too far from Canada's natural market equilibrium price.

It has been part of the PMPRB's process for 35 years to reward innovative developers with a higher price for drugs considered to be breakthroughs or substantial improvements. This incentive is no longer part of the PMPRB's assessment. PMPRB will now regard medicines that extend and/or improve the quality of lives the same as drugs for minor ailments. This is another reason why the MIP should be replaced with the HIP.

The MIP is an arbitrary metric selected purposely to produce lower price ceilings in Canada, and it is not consistent with the PMPRB mandate to prevent excessive pricing. The HIP is more consistent with a common-sense understanding of an 'excessive' price threshold.

More fundamentally, regardless of the metric used, PMPRB comparisons of nominal price differences are not very meaningful because they do not reflect the actual affordability of patented medicines across countries. The prices of patented medicines tend to follow variation in average income across countries, other factors held constant.[4, 5, 6] Prices might be higher in wealthier countries, but account for a lower percentage of average income.

Potential for abuse of process

Another potential problem with the guidelines is the provision allowing 'excessive' price investigations to be prompted by a complaint initiated by any person without any requirement for evidence. This makes initiation of an investigation a

completely subjective and arbitrary process open to abuse from misinformed or deliberately malicious complainants, Industry critics, or commercial competitors.

Also, regular assessments can be imposed and prices re-benchmarked annually, and the PMPRB may change what leads to an investigation every year. So, developers will have to assess whether their price is likely to lead to an investigation at launch and during the patent. This lack of certainty will lead to developers delaying bringing new medicines to Canada or not bringing them at all.

Conclusions

The new guidelines introduced a high degree of uncertainty regarding the Canadian market that did not previously exist, and probably have already discouraged new drug launches in Canada, and disincentivized clinical R&D investment.[7] CHPI's assessment is that the guidelines are based on flawed methods and metrics and should be repealed. Moreover, there is no practical need for the regulations. List prices of patented medicines in Canada are not excessive. Patented medicines have accounted for a stable, small percentage of national health expenditures (NHEX) and gross domestic product (GDP) for more than 30 years, and Canadian prices for patented medicines fall in the middle of prices in comparable countries, and appropriately reflect the country's GDP per capita.[8,9] The PMPRB's function is redundant. Several other agencies are involved in regulating the efficacy and price of new drugs, including Health Canada, CADTH, INESSS, and the PCPA which negotiates prices that are well below the list prices permitted by the PMPRB.

About the Authors

Dr. Brett Skinner is CEO of the Canadian Health Policy Institute (CHPI), and the Editor of CHPI's online journal *Canadian Health Policy*. He was previously Executive Director Health and Economic Policy at Innovative Medicines Canada (2013 to 2017). Dr. Skinner has a B.A. and M.A. from the University of Windsor, and a Ph.D. from Western University (London), where he has lectured in both the Faculty of Health Sciences and the Department of Political Science.

Dr. Nigel Rawson is a pharmacoepidemiologist and pharmaceutical policy researcher based in Saskatoon, Saskatchewan. Educated in the United Kingdom, he holds an M.Sc. in statistics and a Ph.D. in pharmacoepidemiology. Dr. Rawson has performed epidemiologic studies of the use of drugs and their outcomes for over 40 years and published more than 140 book chapters and articles in peer-reviewed journals. He held academic research positions in the United Kingdom until the end of 1989 and subsequently held professorships at the University of Saskatchewan and Memorial University of Newfoundland in Canada.

Notes

[1] 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.

[2] Skinner, Brett (2021). Prices for Patented Medicines in Canada and 13 Other Countries: Testing the PMPRB's Narrative Justification for Amending the Regulations. *Canadian Health Policy*, August 2021. www.canadianhealthpolicy.com

[3] Innovative Medicines Canada v. Canada (Attorney General). Federal Court Decisions Database. 2020-06-29. 2020 FC 725. T-1465-19; and Merck Canada Inc. et al v Canada (Attorney General), Quebec Superior Court file 500-17-109270-192.

[4] Patricia M. Danzon (2018). Differential Pricing of Pharmaceuticals: Theory, Evidence and Emerging Issues. PharmacoEconomics. https://doi.org/10.1007/s40273-018-0696-4.

[5] 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).

[6] 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.

[7] Rawson, Nigel SB (2022). Effect of amended Patented Medicine Regulations on industry decisions to launch new drugs in Canada. Canadian Health Policy, JUL 2022. ISSN 2562-9492, https://doi.org/10.54194/ZJIH9721, www.canadianhealthpolicy.com.

[8] Canadian Health Policy Institute (CHPI) (2022). Patented Medicines Expenditure in Canada 1990–2020. 7th Edition. Canadian Health Policy, JUN 2022. ISSN 2562-9492, https://doi.org/10.54194/CZXJ1621, www.canadianhealthpolicy.com.

[9] Skinner, Brett (2021). Prices for Patented Medicines in Canada and 13 Other Countries: Testing the PMPRB's Narrative Justification for Amending the Regulations. *Canadian Health Policy*, August 2021. www.canadianhealthpolicy.com