

SUBMISSION FOR CONSULTATION ON PMPRB'S 2020 DRAFT GUIDELINES



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Introduction

The Canadian Health Coalition (CHC) is a non-profit organization that has been working for over forty years to protect, improve and expand public health care in Canada. We are made up of health care workers, unions, community organizations, faith-based organizations, seniors and academics, as well as affiliated coalitions in the provinces and one territory.

The CHC participated in the consultations on the PMPRB's 2019 Draft Guidelines. We [expressed our support](#) for the Guidelines, which would operationalize the amended *Patented Medicines Regulations*. These new regulations were set to come into effect on July 1st, 2020. Regrettably, the implementation of the amendments has been delayed yet again, this time until January 2021.

The CHC is calling on the government to prevent further delays in the implementation of the new PMPRB regulations. These regulations will significantly reduce the prices of patented medicines in Canada and lay the foundation for a universal, public pharmacare program. This essential new program would ensure that everyone in Canada can access their prescription medication. The need for this program has never been more urgent given that millions of Canadians have lost their jobs and their employer-sponsored drug plans during the COVID-19 pandemic.

The CHC is disappointed with the watered-down 2020 version of the PMPRB's Draft Guidelines. The PMPRB has made several concessions to the pharmaceutical industry that will result in higher drug costs for Canadians. This will prevent the PMPRB from effectively fulfilling its mandate of preventing pharmaceutical companies from charging consumers excessive prices. We therefore urge the PMPRB to abandon these amendments and return to the 2019 version of the Guidelines.

Rising Drug Costs in Canada

Robust PMPRB guidelines are needed to curtail Canada's rapidly rising drug costs. Canada currently spends more on prescription medication than on physicians.¹ Our spending on medication per capita is higher than all other OECD countries except for the United States and Switzerland. Among OECD countries, Canada pays the third highest prices for patented medicines.² Since 2006, the number of patented medicines in Canada that cost over \$10 000 per year has more than tripled. In 2017, these medicines accounted for over 40% of patented medicine sales compared to 7.6% in 2006.³ In 2017, Canadians with drug costs of \$10 000 or more represented 2% of beneficiaries but accounted for more than one-third of public drug spending.⁴

Given these high drug costs, many Canadians cannot afford to take their medication as prescribed. In 2016, nearly one million Canadians had to choose between food and heat and

¹ Canadian Institute for Health Information. National Health Expenditure Database - 2019.

² Patented Medicine Prices Review Board. Annual Report 2017, Figure 21, p.42.

³ Patented Medicine Prices Review Board. Annual Report 2017, p.30.

⁴ Canadian Institute for Health Information. Prescribed Drug Spending in Canada, 2018: A Focus on Public Drug Programs, p.5.

buying their medication.⁵ Among eleven high-income countries, Canada has the second highest rate of cost-related non-adherence.⁶

Instead of improving price protections for consumers, the 2020 version of the PMPRB's Guidelines contains several concessions to industry.

Exemptions from Category 1 price controls

The new Guidelines define high cost treatments as having an annual treatment cost of 150% of GDP per capita. The previous version of the Guidelines set high cost treatments as having an annual treatment cost greater than 50% of GDP per capita. The PMPRB offers no rationale for this change.

Under the new Guidelines, market size adjustments will apply to medicines with sales of \$50 million. The previous version of the Guidelines applied market size adjustments to medicines with sales of \$25 million annually. Again, the PMPRB offers no rationale for this change.

These changes will exempt more new patented medications from the stronger price controls that apply to Category 1 medications. This will increase the cost of prescription drugs for government plans and individuals.

In making these changes, the PMPRB appears to have relied at least in part on the views of patient groups advocating for drugs for rare diseases. The PMPRB did not consider the fact that many of these groups receive funding from pharmaceutical companies, which may have influenced their views. The PMPRB feels that prices should not discourage the introduction of medicines for rare diseases. Although pharmaceutical companies often claim that they will not market drugs in Canada if prices are too low, there is virtually no evidence to support this. Finally, the PMPRB cites its desire to adopt a risk-based approach in determining what percentage of new drugs should fall into Category 1. The PMPRB chose a figure of 25% without providing any rationale for this choice.

Recommendation: These changes should not be made to the Guidelines unless the PMPRB can provide a compelling rationale for why they are necessary.

Prices set at the highest cost of treatment

In two instances, the new Guidelines will allow companies to set prices for new patented medicines at the level of the highest cost of treatment. The first instance is when the patentee has not filed international price information for the PMPRB11 countries. In that case, the interim Maximum List Price is set by the top of the domestic Therapeutic Class Comparison in the

⁵ Law M et al. The consequences of patient charges for prescription drugs in Canada: a cross-sectional survey. *CMAJ Open*. 6:1, E63-E70 (2018).

⁶ Morgan S & Lee A. Cost-related non-adherence to prescribed medicines among older adults: a cross-sectional analysis of a survey in 11 developed countries. *BMJ Open*. 7:e014287 (2017).

comparator medicines (typically medicines in the same therapeutic class). In the second instance, the Maximum List Price for Grandfathered and Line Extension medicines could be set at the highest international price for the PMPRB11 countries for which the patentee has provided information.

There is no reason to allow companies to set prices at the maximum of either the therapeutic class or the international price. In the first case, the assumption is that the new patented medicine has the best benefit-to-harm ratio of drugs in the class. This assumption is not based on any comparative evaluation. In the second case, the Maximum List Price for Grandfathered and Line Extension medicines in Canada could be based on the price in a country that has, on average, higher prices than in Canada.

The CHC is not convinced by the PMPRB's rationale for these changes as stated in the Backgrounder document. If the patentee believes that its new medicine "within a class [has] differing levels of therapeutic benefit", then it should be up to the patentee to submit convincing evidence from randomized clinical trials to demonstrate the new medicine's benefit. The PMPRB's explanation that the use of the highest international price for Grandfathered and Line Extension medicines is a "concession" to industry is troublesome. Retaining the median international price for this group of medicines could equally be justified as a concession to consumers and payers.

The PMPRB believes that the impact of its proposed change will not be that significant because "list prices are not reflective of true net prices paid by a large segment of the Canadian market." This rationale may apply to new patented medicines, but what is the evidence that it applies to Grandfathered and Line Extension medicines? The PMPRB should produce hard figures rather than relying on speculation.

Recommendation: Canadian prices should be set at the median of the price in the therapeutic class and the median of the international price.

Patented biosimilars and generic medicines

The 2019 version of the Guidelines made no special provision for biosimilars. Consequently, patentees of these medicines would be required to file price information with the PMPRB and could fall into either Category I or Category II. According to the new version of the Guidelines, an investigation into the price of patented biosimilars and patented generic medicines will only be initiated if there is a complaint about their price. In that case, these medicines will be deemed to be Category II medicines.

In making this change, the PMPRB has assumed that the context is the same for all patented biosimilars and generics. This ignores the situation where the company making the originator has withdrawn the product from the market and a single biosimilar or the generic is the only version available.

Recommendation: In situations where a patented biosimilar or patented generic is the only version of a drug that is available, the PMPRB should treat the price of these products in the same manner that it treats the prices of all other patented medicines.

Therapeutic Criteria Levels 1 and 2

A Therapeutic Criteria Level 1 medicine is a patented medicine that is “the first medicine to be sold in Canada that effectively treats a particular illness or effectively addresses a particular indication in a clinically impactful manner”. A Therapeutic Criteria Level II medicine is a patented medicine that “provides a considerable improvement in therapeutic effect, relative to other medicines sold in Canada, in a clinically impactful manner.”

The terms “effectively” and “considerable improvement” are subjective and may not be interpreted rigorously and consistently.

Recommendation: The guidelines need to include a set of criteria that will be used to determine whether medicines offer “effective” treatment and “considerable improvement”.

Disclosure of Therapeutic Criteria Levels of Category 1 medicines

According to the PMPRB’s Backgrounder document, the Maximum Rebated Price calculation will be a function of the Therapeutic Criteria Level assigned to the patented medicine and the applicable Pharmacoeconomic Value threshold and corresponding price floor. The Therapeutic Criteria Level is the assessment of the therapeutic value of a Category I medicine compared to existing medicines. The Backgrounder document states that Therapeutic Criteria Level “will be known only to the PMPRB and the patentee” (p.14).

The therapeutic value of new Category 1 medicines should not be confidential. This information is relied on by researchers to assess the value of industry research, by clinical practice guideline developers, and by physicians who prescribe the medications. The evaluation of therapeutic value is an undertaking of the PMPRB. It should be publicly available, even if it could help other jurisdictions estimate the confidential price rebate given in Canada.

Recommendation: The Therapeutic Criteria Level of Category 1 medicines must be publicly available.

Pharmacoeconomic Value Thresholds

In the 2019 Guidelines, Category I medicines that were required to report a cost-utility analysis had a maximum rebated price ceiling based on the level at which the patented medicine’s Incremental Cost-Effectiveness Ratio would equate to the Pharmacoeconomic Value threshold of \$60,000 per Quality-Adjusted-Life-Year (QALY). The maximum rebated price for drugs for rare diseases was set at 50% above this level. In the new Guidelines, this has been changed to between \$150,000 to \$200,000 per QALY, depending on the therapeutic criteria level.

The PMPRB cites cost effectiveness thresholds in different countries, but these figures are highly variable. No figures are given for Japan. The PMPRB has chosen figures that are near the upper range used in the United Kingdom for Highly Specialized Technologies. The PMPRB has not offered any rationale for this choice.

Recommendation: The PMPRB should return to its position in the 2019 Guidelines, setting the Pharmacoeconomic Value threshold at \$60,000 per QALY.

Conclusion

The CHC strongly supports the amendments to the *Patented Medicines Regulations* and urges the government to implement them immediately to make patented medicines more affordable for Canadians. The CHC is disappointed that the new 2020 version of the PMPRB's Guidelines includes several concessions to the pharmaceutical industry and to patient groups funded by industry. These concessions will increase the costs of patented medicines for Canadians and make pharmacare more expensive. The CHC therefore urges the PMPRB to abandon these changes and return to the 2019 version of the Guidelines. This will allow the PMPRB to more effectively fulfill its mandate of preventing pharmaceutical companies from charging consumers excessive prices and will reduce the cost of a universal, public pharmacare program.