

**Patented Medicines Prices Review Board (PMPRB)
June 2020 Draft Guidelines**

Submission of the Canadian Union of Public Employees

July 2020

The Canadian Union of Public Employees

The Canadian Union of Public Employees (CUPE) is Canada's largest union, with 700,000 members across the country, who work in health care, emergency services, education, early learning and child care, municipalities, social services, libraries, utilities, communications, transportation, and the airline industry.

We want to thank the Patented Medicines Prices Review Board (PMPRB) for welcoming our participation in the consultation session that took place in Ottawa in December 2019 to comment on the November 2019 Draft Guidelines. CUPE is grateful for the ongoing opportunity to provide feedback to the PMPRB, this time regarding the June 2020 Draft Guidelines, which operationalize the amended *Patented Medicines Regulations* (Regulations). However, CUPE is very concerned the June 2020 Guidelines compromise the capacity of the PMPRB to achieve the dual objectives of reducing the prices of patented medicines and protecting patients in Canada to the greatest extent possible.

CUPE is disappointed the federal government issued an Order-in-Council delaying the date the Regulations would come into force from July 1, 2020 to January 1, 2021.

In its final report, *A Prescription for Canada: Achieving Pharmacare for All*, the Advisory Council on the Implementation of National Pharmacare recommended "the federal government advance efforts to strengthen the Patented Medicines Regulations to lower the prices of patented drugs for all payers."¹ The postponement of the enforcement date of the Regulations stalls the long-awaited and recommended reforms, further prolonging the wait by patients for protection against patented drug prices that are among the highest in the world.

In our January 2020 written submission to the PMPRB, CUPE expressed its support for the November 2019 Guidelines and amended Regulations. The reforms proposed in the Guidelines would have made patented medicines more affordable, while benefitting everyone by improving access to prescription drugs and therefore, the health of the population. The modernization of the Guidelines and Regulations lay the foundation for the creation of a national, public, universal, single payer, and comprehensive pharmacare plan, which will ensure equitable access to medications for everyone from coast to coast to coast. This is critical given that Canada remains the only OECD country with a public health care system that does not include coverage for prescription drugs outside of hospitals.

The November 2019 Guidelines and Regulations were consistent with the legislative purpose of ensuring pharmaceutical companies do not abuse their statutory monopoly by charging excessive prices for patented medicines.² This purpose is upheld by the Supreme Court of Canada which noted in 2011 that the role of the PMPRB is to protect consumers from excessively priced patented drugs during the monopoly period.³ In June 2020, Justice Manson of the Federal Court again found the function of the Regulations is to modernize the Board and to lower patented medicine prices to protect consumers from abusive drug pricing.⁴

¹ Government of Canada, "A Prescription for Canada: Achieving Pharmacare for All," June 2019, <https://www.canada.ca/content/dam/hc-sc/images/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharmacare/final-report/final-report.pdf>.

² *Innovative Medicines Canada v. Canada (Attorney General)*, 2020 FC T-1465-19 at para. 77, <https://decisions.fct-cf.gc.ca/fc-cf/decisions/en/item/481803/index.do>.

³ *Ibid.*, at para. 79.

⁴ *Ibid.*, at para. 104.

CUPE is therefore concerned with the significant changes reflected in the June 2020 Draft Guidelines. Critically, the changes will restrict the Guidelines from achieving their full potential to help lower the cost of patented medications, and to protect patients by ensuring medications are available to everyone at prices they can afford. The June 2020 Guideline changes reflect a series of significant concessions to Innovative Medicines Canada, the pharmaceutical industry, and their supporters. For CUPE, patient interests, rather than the profit motive of pharmaceutical patentees should drive pharmaceutical policy in Canada. Instead, the June 2020 Guideline changes greatly favour the profit motives of pharmaceutical companies over peoples' health and financial interests. They will also undermine price reductions for patented medicines that would otherwise serve as an essential building block for national pharmacare.

Federal Court Challenge on Amended *Patented Medicines Regulations*

As noted above, the amended Regulations were recently reviewed by a Judge of the Federal Court. The Regulations altered the previous patented medicines pricing regime through the inclusion of pharmacoeconomic assessments in setting maximum drug prices, changing the basket of comparator countries, and requiring patentees to report rebates and discounts provided to third parties in addition to public list prices. In the review of the Regulations brought forward by Innovative Medicines Canada and 16 pharmaceutical companies, Justice Manson ruled that provisions related to the use of pharmacoeconomic factors and the reconstitution of the PMPRB11 basket of comparator countries falls within the mandate of the PMPRB as set out in the *Patent Act*.

However, Justice Manson struck down the provision requiring patentees to report rebated or discounted drug prices to third parties, as falling outside the scope of the government's regulation-making authority contained in the *Patent Act*. CUPE believes the federal government should appeal this decision by the deadline of September 29, 2020. We believe the decision does not give sufficient latitude to the power of the Governor-in-Council to proclaim regulations which are consistent with the purpose of the PMPRB, namely, to protect consumers from excessively priced drugs.

As a result of this ruling, when the amended Regulations come into effect in January 2021, "subsection 4(4) of the Patented Medicines Regulations in their current form will remain in effect."⁵

This is highly unfortunate for patients. In Canada and internationally, confidential drug pricing that involves rebates and discounted prices of patented medications contributes to escalating drug prices. Confidential pricing conceals the actual market price of a drug and enables pharmaceutical companies to unfairly inflate public list prices as a standard to negotiate with third parties. It also allows pharmaceutical companies to price-discriminate between third parties and to continue to increase the difference between the public list prices reported to the PMPRB and actual market prices for a drug.

The requirement to report rebated or discounted drug prices, in addition to the public list price, is common sense. It would allow the PMPRB to have more complete and rigorous information upon which to calculate the ceiling price of a new drug, and to better evaluate whether a drug is excessively priced throughout the statutory monopoly period.

⁵ Government of Canada, "PMPRB Draft Guidelines," July 8, 2020, <https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines.html>.

Section 2: Maximum List Price (MLP) Test – International Price Comparison

Under the November 2019 Guidelines, the Maximum List Price (MLP) would be “set by the lower of the Median International Price (MIP) for the PMPRB11 comparator countries and the domestic Therapeutic Class Comparison (“dTCC”), subject to a floor set by the Lowest International Price (LIP) in the PMPRB11.”⁶

The June 2020 Guidelines change how the MLP is set by applying “the HIP [Highest International Price] test to Grandfathered medicines.”⁷ This proposal will not benefit patients, or federal or provincial health care budgets. The PMPRB even acknowledges this change is a “concession to patentees.”⁸ This change will allow companies to set prices for new patented medicines at the level of the highest cost of treatment when the patentee has not filed international pricing information for the PMPRB 11 countries, or when the MLP for grandfathered and Line Extension medicines is set at the highest international price for the PMPRB11 countries for which the patentee has provided information.

Recommendation

CUPE does not support the June 2020 revisions regarding the use of the HIP for Grandfathered patented medicines and their Line Extensions. We recommend that the PMPRB set prices at the MIP of the PMPRB11 basket of comparator countries, or the median price of the therapeutic class as originally proposed in the November 2019 Guidelines.

CUPE does not find the rationale for the Guideline changes offered by the PMPRB compelling. It is also very troubling that the PMPRB acknowledges the changes made are a direct “concession” to pharmaceutical companies. The PMPRB suggests the impact of the change will not be overly significant because “list prices are not reflective of true net prices paid by a large segment of the Canadian market and the true impact on the net revenue will thus be less than the nominal impact on the list price.”⁹ While this rationale may apply to new patented medicines, the PMPRB relies on speculation rather than rigorous evidence to show it applies to Grandfathered and Line Extension medicines.

Section 3: Classifying a Patented Medicine as Category I

Compared to the November 2019 Guidelines, the June 2020 Guidelines increase the market size threshold from \$25 to \$50 million in annual revenues and increase the treatment cost from 50% to 150% of GDP per capita.¹⁰ The PMPRB states these changes align with its intent to adopt a risk-based approach with approximately 25% of new drugs triggering the Category I criteria. It also states the changes are warranted “in order for its risk-based approach to be administratively feasible for PMPRB Staff and patentees.”¹¹

Recommendation

CUPE does not support the June 2020 Guideline changes made to the thresholds used to classify Category I medicines, and we recommend that neither of these measures be adopted.

⁶ Ibid.

⁷ Ibid.

⁸ Ibid.

⁹ Ibid.

¹⁰ Ibid.

¹¹ Ibid.

The rationale offered by the PMPRB to explain these changes is not compelling. Both these changes will increase the exemption for new patented medicines from stronger price controls that apply to Category I medicines thereby increasing the cost of prescription drugs for public and private drug plans, and individuals who lack prescription drug coverage. The 25% threshold for Category I medicines appears arbitrary and was not mentioned in either the Canada Gazette with respect to the amendments to the Regulations, or the November 2019 Guidelines. It may seem reasonable for the PMPRB to take administrative feasibility into consideration. However, it should not impede the agency's capacity to fulfill its mandate as a regulator, especially since the agency has received additional funding to increase its capacity to enforce and administer the new Regulations.

Section 4: Pharmacoeconomic Value (PV) Threshold & Accounting for Therapeutic Comparators – High Cost Medicines

Under the November 2019 Guidelines, Category I medicines that were “required to report cost-utility analysis would have a maximum rebated price (MRP) ceiling based on the level at which the patented medicine's incremental Cost-Effectiveness Ratio (“ICER”) would equate to the Pharmacoeconomic Value (PV) threshold of \$60,000 per Quality-Adjusted-Life-Year (QALY).”¹²

Moreover, “[f]or patented medicines for rare diseases...the MRP would be set at 50% above the level at which the ICER would equate to the PV threshold of \$60,000 QALY.”¹³

In the June 2020 Guidelines, the PV threshold has been changed to between \$150,000 to \$200,000 per QALY depending on the therapeutic criteria level of a drug.

Recommendation

CUPE does not support the June 2020 Guideline changes made to the PV threshold for high cost medicines, and we recommend that it be set at the \$60,000/QALY threshold originally established in the November 2019 Guidelines.

In explaining the changes to the Guidelines, the PMPRB refers to the PV thresholds used in other countries, such as the United Kingdom, the Netherlands, Norway, and Japan, but these figures are highly variable, and no figure is provided for Japan. In addition, the PMPRB seems to rely on figures near the upper range of the threshold used in the United Kingdom for Highly Specialized Technologies, while not offering a compelling rationale for this choice.

Section 6: Confidentiality of Maximum Rebated Price (MRP)

The June 2020 Guidelines indicate that the Therapeutic Criteria Level (TCL) of a patented medicine (i.e., the assessment of a therapeutic value of a Category I medicine compared to already existing medicines) “will be known only to the PMPRB and the patentee.”¹⁴ The TCL used to calculate the MRP of a Category I drug will therefore not be made public under the revised Guidelines.

Recommendation

¹² Ibid.

¹³ Ibid.

¹⁴ Ibid.

CUPE is deeply troubled by the significant concession the PMPRB has made to the pharmaceutical industry in the June 2020 Guidelines with respect to transparency requirements and public reporting. For CUPE, public transparency must be at the core of the amended Regulations and Guidelines. We therefore recommend the PMPRB make the TCL of Category I medicines publicly available, as was required under the November 2019 Guidelines.

It is unacceptable to keep the TCL of new Category I medicines confidential. This information is required by analysts to assess the value of industry research, experts who develop clinical practice guidelines, and physicians who prescribe the drugs.

Section 7: Regulatory Review of Patented Biosimilars and Generics

Under the November 2019 Guidelines, there were no special provisions for biosimilar medicines. As a result, patentees would have been “required to file price information with the PMPRB and could fall into either Category I or II.”¹⁵ In the June 2020 Guidelines, patented biosimilars and generic medicines “will only be subject to investigation if a complaint is received by the PMPRB,” at which point it will be deemed a Category II medicine.¹⁶ The Board explains it “is of the view that a strong case can be made that expanding the scope of exempt patented medicines beyond the strict regulatory definition for administrative purposes is consistent with a risk-based approach to regulating ceiling prices.”¹⁷

Recommendation

CUPE recommends that, in situations where a patented biosimilar or generic medicine is the only available version of a drug (i.e., when the original reference product is no longer available), the price of these drugs should be subject to the same scrutiny by the PMPRB as all other patented medicines.

CUPE supports savings to our health care system and drug plans that can be made through the increased use of biosimilar and generic medicines. The PMPRB is assuming that the context for all patented biosimilars and generics is the same. This assumption overlooks instances when the company producing the original reference product withdraws the product, leaving only a single biosimilar or generic version available on the market.

Conclusion

On behalf of CUPE’s 700,000 members, we respectfully submit that the recommendations outlined above be made to the June 2020 Guidelines by the PMPRB before their adoption. The role of the PMPRB is to protect patients in Canada from excessively priced patented drugs during the monopoly period. We are therefore highly troubled that the changes reflected in the June 2020 Draft Guidelines provide major concessions to pharmaceutical companies and their supporters, thereby compromising the capacity of the PMPRB to achieve the dual objectives of reducing the prices of patented medicines and protecting patients to the greatest extent possible.

By making the changes CUPE recommends, we can ensure that the PMPRB fully exercises its authority as a regulator, that the profit-making interests of pharmaceutical companies aren’t prioritized over those of patients, and that we take a necessary step towards establishing the measures Canada needs to implement a national, public, universal, single payer, and

¹⁵ Ibid.

¹⁶ Ibid.

¹⁷ Ibid.

comprehensive pharmacare plan, which will help to make prescription drugs even more affordable for everyone.

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