Canadian Labour Congress

Submission

on the

PMPRB Draft Guidelines 2020

July 14, 2020

Canadian Labour Congress

The Canadian Labour Congress (CLC) is Canada's largest central labour body. The CLC brings together over 55 national and international unions. It spans public and private sector unions, and includes 12 provincial and territorial federations of labour, and over 100 local labour councils. The CLC represents 3 million unionized workers in every part of Canada.

We are grateful for the opportunity to provide comments on the 2020 Draft Guidelines. We also want to acknowledge and thank the Patented Medicines Price Review Board (PMPRB) for its work on the amended Patented Medicines Regulations (Regulations) and the Draft Guidelines. The research and webinars the PMPRB has provided to explain the impact of the amended Regulations on R&D investments, drug shortages, clinical trials and new medicine launches in Canada have been tremendously informative and helpful.

The CLC was very pleased to see the federal government bring in the amended Regulations in August 2019. This is an important first step to the implementation of a national public pharmacare plan that would create a more comprehensive, affordable and accessible public healthcare system that benefits everyone in Canada. Canada is still the only developed country with a publicly-funded health care system that does not cover prescription drugs outside of hospitals. The current patchwork public and private prescription drug approach is misaligned with our public healthcare system or medicare, and is unfair to every Canadian across the country. And, without a national single-payer universal pharmacare plan, Canada lacks the ability to leverage national buying power of prescription drugs, and to negotiate lower prices for new drug therapies.

The CLC agrees strongly with recommendation 59 in the final report *A Prescription for Canada: Achieving Pharmacare for All* by the Advisory Council on the Implementation of Pharmacare. This recommendation calls on the federal government to implement the amended Regulations to make universal public pharmacare more sustainable, including the requirement for pharmaceutical patentees to report to PMPRB the discounted or rebated prices that public and private insurers in Canada are actually paying in addition to the list prices.

The CLC is disappointed with the postponement of the coming-into-force date of the amended Regulations to January 1, 2021 from July 1, 2020. This six-month delay further prolongs an unfair drug pricing system that for the last three decades has resulted in Canadian consumers paying some of the highest drug prices in the world.

The pharmaceutical global business model, in tandem with the current Canadian Regulations and Guidelines, excessively favours patentees. The current environment and practices, until the amended Regulations come into force, continues to deliver billions of dollars in annual profits for pharmaceutical patentees in Canada.

Pharmaceutical patentees' gains are Canadian consumers' losses. The negative impact of this excessive burden inflicted on Canadians for the last 33 years has been:

- excessive drug prices during the statutory monopoly period;
- the failure of Innovative Medicines Canada (IMC) members to meet their agreement of investing 10% of sales in research and development (R&D) per year; and
- the introduction of a vast majority of new drugs that only provide no, slight or only moderate improvement compared to existing medicines.

Between 2010 and 2018, of the total of 811 new medicines introduced by patentees, the vast majority offered slight to no improvement compared to existing medicines (672 or 83%). A minority delivered moderate improvement (98 or 12%) or substantial improvement (22 or 3%), and only a fraction represented breakthrough medicines (19 or 2%). Over these eight years, 95% of new medicines introduced offered no, slight and moderate improvements, but represented 98% of sales.

Clearly, the profit motive drives what new medicines pharmaceutical patentees introduce in Canada, with little to no regard for the negative impact on Canadians.

Impact of COVID-19 Pandemic

Before the COVID-19 pandemic, about 7.5 million people – roughly one in five Canadians – either did not have prescription drug insurance, or did not have adequate insurance to cover their medication needs. Almost one million people in Canada cut back on food or home heating, or borrow money in order to pay for their prescription drugs. The pandemic has exacerbated this situation, with millions of workers with private drug coverage at risk of losing access to needed medications simply because they have lost their jobs.

The coming into force of the amended Regulations is even more important and urgent now. The amended Regulations are a critical step in ensuring a better and stronger public healthcare infrastructure that will give Canadians better protection to face future adversities.

Upon the coming into force of the amended Regulations, the PMPRB will have additional tools to more vigorously fulfil its dual mandate of:

- ensuring that prices charged by patentees for patented medicines sold in Canada are not excessive; and
- reporting on pharmaceutical trends of all medicines and on R&D spending by pharmaceutical patentees.

During this COVID-19 period, federal public service workers and public services, including public healthcare, have been lauded for their quick actions to support and keep individuals and businesses afloat. With the amended Regulations, the PMPRB is strongly poised to be a substantial contributor in Canada's efforts to building a more equitable and strong post-pandemic future. It is even more important now that the new Guidelines are robust in order to operationalize the amended Regulations to its fullest extent. The new Guidelines cannot and must not be a series of compromises and concessions to the IMC, pharmaceutical patentees and their supporters.

This is the time for the PMPRB as a regulator to stay the course and fully exercise its consumer protection powers for people across Canada.

Federal Court Challenge of Amended Regulations

The intransigence of the IMC and its members toward the amended Regulations and the consultations of the Draft Guidelines is not unexpected. Opposition to the Regulations took the form of a challenge, by the IMC and 16 pharmaceutical companies, of the amended Regulations before the Federal Court of Appeal. The Canadian Organization for Rare Disorders (CORD) was granted intervener status in this challenge. The IMC and its co-applicants took issue with three aspects of the amendments to the Regulations.

The Federal Court decision was released on June 29, 2020. The Federal Court ruled that the provisions in the amended Regulations relating to use of pharmacoeconomic factors and the PMPRB11 basket of countries for international comparison in price assessments is within the mandate of the PMPRB, as set out in the *Patent Act*.

However, the CLC is disappointed that the Federal Court struck down the part of the amended Regulations requiring patentees to report the rebated or discounted drug prices to third parties, in addition to the current requirement of only reporting the public list prices. Confidential pricing that involves rebates and discounted prices of pharmaceutical drugs is a key driver to skyrocketing drug prices, in Canada and internationally. Confidential pricing obfuscates the true market price of a drug and permits pharmaceutical companies to unfairly set inflated public list prices as a benchmark to negotiate with third parties. This allows pharmaceutical companies to price-discriminate between third parties based on their perceived power and ability to pay, and to continue increasing the discrepancy between the public list prices reported to the PMPRB, and the actual market prices.

It is only common sense that reporting discounted or rebated drug prices in addition to the status quo of reporting public list prices will enable PMPRB to have more complete and accurate information to determine the ceiling price of a new drug. It will also allow the PMPRB to better assess excessive pricing of the drug throughout the statutory monopoly period.

Classifying a Patented Medicine as Category I

The thresholds for classifying Category I medicines were increased in the Draft Guidelines 2020 compared to Draft Guidelines 2019.

Draft Guidelines 2020	Draft Guidelines 2019
1. 12-month treatment cost greater than 50% of Gross Domestic Product (GDP) per capita (≈$30,000 per capita)	1. 12-month treatment cost greater than 150% of Gross Domestic Product (GDP) per capita (≈$90,000 per capita)
2. An estimated or actual market size (revenue) exceeds annual Market Size Threshold, initially set at $25 million.	2. An estimated or actual market size (revenue) exceeds annual Market Size Threshold, initially set at $50 million.

Lower thresholds would allow the PMPRB to better scrutinize more patented medicines. The rationale offered by PMPRB for these increases were:

- that this is in line with the intent of moving to a risk-based approach at an approximate threshold of 25% of new medicines triggering the Category I criteria; and
- that the higher thresholds were more administratively feasible for PMPRB staff and patentees in terms of its risk-based approach.

The PMPRB rationale is not compelling here. The intended threshold of 25% of new medicines seems arbitrary, and was not mentioned in either the Canada Gazette with regards to the amendments to the Regulations or in the 2019 Draft Guidelines.

Although administrative feasibility is a consideration, it should not interfere with the PMPRB robustly fulfilling its mandate as a regulator. In addition, the PMPRB has been given additional resources, starting in 2018-19 onwards, through the budgetary process to increase the organization's capacity to support the expected increase in enforcement-related activities, and administering the new price regulatory factors.

The CLC does not agree with the increased thresholds to classify Category I medicines.

Therapeutic Criteria Level for Maximum Rebated Price (MRP) Calculation – Category I

The four therapeutic criteria levels used in the calculation of the MRP in Category I medicines will not be made public under the new 2020 Draft Guidelines. The amended Regulations and Draft Guidelines must, as one of its principles, provide transparency to the public. The CLC urges the PMPRB to make the Therapeutic Criteria Level (TCL) for patented Category I medicines public.

Patented Biosimilar and Generic Medicines

The CLC is supportive of savings in the healthcare system through the increased use of biosimilar and generic medicines.

The 2020 Draft Guidelines deem biosimilar and generic medicines to be at low risk of excessive pricing. Under the newest Draft Guidelines, patented biosimilar 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.

There may be a situation where the original reference product is no longer available in the market, and the patented biosimilar or generic medicine is the only one available. In this event, the CLC recommends that the patented biosimilar or generic medicine be subject to scrutiny by the PMPRB, as are other patented medicines.

Grandfathered Patented Medicines and their Line Extensions

As a concession to the patentees, the PMPRB has proposed that the list price ceiling of Grandfathered patented medicines be set as the lower of the Highest International Price (HIP) for the PMPRB11 countries, and the price ceiling under the previous Guidelines. Further, the Maximum List Price (MLP) of Line Extensions of Grandfathered medicines (i.e., new strengths and dosage forms) will also be set by the HIP.

The newest proposal is a shift from the 2019 Draft Guidelines, where the MLP was 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." The international Therapeutic Class Comparison ("iTCC") will be used to set the MLP, should the patentee fail to file international prices by the end of the three-year interim period.

The PMPRB's own analysis of the impact of using the MIP for Grandfathered medicines is that it "may be less significant than claimed by certain stakeholders who oppose it." This suggests that the PMPRB was on track with the proposal in the 2019 Draft Guidelines to use the MIP to set the MLP.

The CLC does not support the use of the HIP as proposed in the 2020 Draft Guidelines for grandfathered patented medicines and line extensions. The CLC recommends the application of either the MIP of the PMPRB11 basket of comparative countries, or the median of the dTCC and iTCC in the 2020 Draft Guidelines as a more reasonable and fair approach.

Pharmacoeconomic Value (PV) Threshold

In the 2019 Draft Guidelines, the Pharmacoeconomic Value (PV) threshold of $60,000 per Quality-Adjusted-Life-Year (QALY) was used. The proposal in the 2020 Draft Guidelines has raised the PV thresholds to between $150,000 and $200,000/QALY. There are variable descriptions of the PV thresholds used by other countries in the PMPRB 2020 Guidelines backgrounder, such as the United Kingdom, the Netherlands and Japan. In addition, some public insurers have previously recommended PV thresholds of $100,000/QALY and $120,000/QALY for medicines that are therapeutically superior, or even higher thresholds for medicines that are potentially curative. The PMPRB does not provide a compelling rationale for increasing the PV thresholds so drastically to $150,000 to $200,000/QALY from $60,000/QALY.

In the absence of a compelling rationale, the CLC recommends that the PV threshold be set at the original $60,000/QALY.

All of which is respectfully submitted,

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