

Canadian Labour Congress Submission for the PMPRB Draft Guidelines Consultation

January 30, 2020



Introduction

The Canadian Labour Congress (CLC) brings together Canada's national and international unions along with the provincial and territorial federations of labour and 130 district labour councils. The CLC is the largest labour organization in Canada representing three million unionized workers in virtually all sectors of the economy, in all occupations.

The CLC is appreciative of this opportunity to provide a submission on the draft PMPRB Guidelines to implement amendments to the *Patented Medicines Regulations*.

The amended *Patented Medicines Regulations* is very important and critical steps towards a national single-payer universal pharmacare plan in Canada. Canada is the only developed country with a publicly-funded health care system that does not cover prescription drugs outside of hospitals. Without a national single-payer universal pharmacare plan, Canada lacks the ability to leverage national buying power of medicines, and to negotiate lower prices for new drug therapies.

The CLC is especially encouraged by the fact that the policy intent of the amended Regulations is for the PMPRB to "adopt the perspective of the public health care system" which provides greater alignment with the adoption and implementation of a national single-payer universal pharmacare plan.

The federal government cannot stop at just the amended *Regulations* for more affordable drug pricing because it is not enough. The amendments to the *Regulations* are expected to save an average of \$1.32 billion per year on patented drug costs. Just as it cannot stop at relying solely on the pan-Canadian Pharmaceutical Alliance (pCPA), working with the provincial/territorial to negotiate lower prices for brand name and generic drugs in Canada in order to achieve greater value for publicly-funded drug programs and patients. The pCPA reported that after eight years since it was

established, overall annual savings was \$1.98 billion in 2018. With regards to excessively high drug pricing, pCPA has stated on public record that “Current industry pricing and models are not aligned with payer expectations for value-for-money, quality of evidence, and cost-effectiveness.”

A national single-payer universal pharmacare plan in Canada is the most effective way to substantially lower high prescription drug prices. The existing patchwork of public and private drug system continues to deliver very high drug prices, is extremely costly, and provides inequitable access and coverage for people across Canada.

According to the Advisory Council on the Implementation of National Pharmacare report, fully implemented universal, single-payer, public pharmacare will cost the government \$15.3 billion by 2027, and will reflect a total savings to the system of \$5 billion. Fully implemented universal, single-payer, public pharmacare will reduce the cost of prescription drugs for employers and businesses by \$16.6 billion, and for families by \$6.4 billion. In practical terms, for each year, universal, single-payer, public pharmacare, on average, would put money back in the pockets of businesses \$750 for each employee, and \$350 for each family. Not only are there huge annual net savings, access and coverage will be equitable for everyone regardless of their income, age, residence or their employment status.

A national single-payer universal pharmacare plan will be delivered like medicare in Canada to provide system-wide improvement to health care in Canada.

The CLC was very pleased to see the federal government bring in the amended *Patented Medicines Regulations* as an important first step to the implementation of a national single-payer universal pharmacare plan.

The amendments to the *Regulations* were much needed since the establishment of the

PMPRB more than thirty years ago. Labour's perspective has been that the previous *Patented Medicines Regulations* did not serve Canadian interests as well as it could. In the last three decades, the landscape has also shifted greatly from the advancement of pharmaceutical therapies, to the many patent expirations of lucrative drugs leading to much greater generic competition.

As a result, today, Canadian drug prices are the third highest among OECD countries. At the same time, Innovative Medicines Canada members continue to renege on their agreement with the government and Canadians of investing 10% of annual sales to pharmaceutical research and development (R&D). In fact, in 2017 the R&D investment was at its lowest point over the last three decades. This loss of R&D investment over the last three decades has cost Canadians and Canada dearly. With this in mind, it was outrageous that five major pharmaceutical companies filed suit in a Canadian court challenging the constitutionality of amended *Regulations*: the Canadian arms of U.S.-based Merck & Co and Johnson & Johnson's Janssen Inc, Germany's Bayer AG and Boehringer Ingelheim, and France's Servier Inc.

From labour's perspective, we welcome the amended *Regulations* intent to address the excessively high pricing of new patented medicines. The CLC is supportive of the revised schedule of comparator countries, the new PMPRB11 that comprise of countries with similar consumer protection priorities, economic wealth and marketed medicines as Canada. The exclusion of the United States and Switzerland as comparator countries is much welcomed as they have very high drug prices that over inflated the price ceiling. We are also in support of the additional factors in section 85 that include pharmaeconomic value, the market size and both the gross domestic product (GDP) and per capita GDP factors. Below, we have provided, some specific comments on the draft Guidelines.

PMPRB draft Guidelines 2019

Ad-hoc Audits

IV. Filing Requirements Pertaining to Price Review (page 9)

Paragraph 27

Staff may conduct ad-hoc audits to verify the accuracy of the information required for filings by the patentee including domestic and foreign pricing, revenue and patent information.

The draft Guidelines do not elaborate on the ad-hoc audit process. The CLC would like the PMPRB to provide details of how these ad-hoc audits would be implemented, and what is in place to ensure adequate “checks and balances” in the process to assure public confidence in the integrity of patentees’ filing requirements.

Categories of New Patented Medicines

V. Price Review Process (page 13)

Paragraph 48

The draft Guidelines classifies new patented medicines into two categories: Category I and Category II, where previous to the amended *Regulations* there were four categories.

Category I patented medicines are deemed to be at highest risk of excessive pricing relative to Category II ones. The CLC supports the new risk-based approach using this categorization.

However, it is very useful to also keep the previous four categories of new patented medicines of: breakthrough, substantial improvement, moderate improvement, and slight or no improvement. These four categories accessibly show consumers

information on the therapeutic improvement of new patented medicines. Between 2010 and 2017, 95% of new patented drugs introduced offered moderate, slight or no improvement. This information provides a perspective not reflected in the new categorization of the amended *Regulations*.

Reassessment and Investigations

VI. Reassessment, VII Investigations (pages 16–19)

Paragraphs 62-79

The criteria set out in sections VI and VII for reassessment and investigations is clear. However, what is less clear is the implementation process:

- Are the measures in the reassessment and investigation implementation processes part of an on-going system that pro-actively monitors, or reactively monitors by responding only when PMPRB is made aware that at least one of the criterion listed in this section (paragraph 63) arises?
- How will PMPRB staff know if and when one of the criterion for reassessment or an investigation is triggered?
- What measures are taken to ensure the integrity of the reassessment and the investigation implementation process?

The implementation of the amended *Regulations* will only be successful with a robust system for timely and adequate level of reassessments and investigations.

Hearings

X. Excessive Price Hearing Process and Remedies, XI Failure to File Hearing (pages 22-23)

Paragraphs 88-94

The hearing processes and remedies must be robustly implemented. After the hearing, the PMPRB must ensure that it fully enforces the remedy determined for patentees found to sell or have sold a patented medicine at an excessive price, and orders to patentees in breach of reporting requirements of the Act and Regulation.

Guidelines Modernization and Evaluation Process (GMEP)

Backgrounder PMPRB Draft Guidelines Consultation (page 13)

How and when will the PMPRB monitor and report on the impact of the new Regulations and Guidelines and whether they are working as intended?

Section 25

We are pleased to see that the PMPRB is embarking on developing and conducting an extensive GMEP to monitor the impact of the new Guidelines. The CLC would like to be consulted on the detailed GMEP proposal.

For accountability and transparency, we support making the first and subsequent GMEP reports publicly available.

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