Comments Regarding the Patented Medicine Prices Review Board's Final Guidelines Issued on October 23, 2020

Submitted to the
House of Commons Standing Committee on Health (HESA)

November 2, 2020

Introduction

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 present our comments to the House of Commons Standing Committee on Health (HESA) in regards to the study on the Patented Medicine Prices Review Board's (PMPRB) Final Guidelines released on October 23, 2020.

The CLC was very pleased to see the federal government bring in the amended *Patented Medicines Regulations* in August 2019, and PMPRB the Final Guidelines on October 23, 2020. The non-binding Final Guidelines give effect to the amended *Patented Medicines Regulations* which come into force on January 1, 2021.

This is an important first step to the implementation of a national single-payer pharmacare plan that would create a more comprehensive, affordable and accessible public healthcare system for everyone in Canada. Canada is the still the only developed country with a publicly-funded health care system that does not cover prescription drugs outside of hospitals. In a survey, released on October 29, 2020, almost nine in ten Canadians indicated they support universal pharmacare.[1]

The current patchwork of public and private prescription drugs system 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

[1] Angus Reid Institute. October 29, 2020. Access for all: Near universal support for a pharmacare plan covering Canadians' prescription drug costs. Accessed 30 October 2020: http://angusreid.org/pharmacare-2020/

the ability to leverage national buying power of prescription drugs, and to negotiate lower prices for new drug therapies.

Universal single-payer pharmacare was clearly supported by HESA in their report to the government in 2018 *Pharmacare Now: Prescription Medicine Coverage for All Canadians*, and a year later by the Advisory Council on the Implementation of Pharmacare in their final report *A Prescription for Canada: Achieving Pharmacare for All*.

The CLC concurs with HESA where its report states: "Though Canada has some effective mechanisms in place to manage the costs of prescription drugs, including the pan-Canadian Pharmaceutical Alliance, the Canadian Agency for Drugs and Technologies in Health and the Patented Medicine Prices Review Board, the Committee heard that these bodies are not equipped to meet changes in the global drug market."[2]

We also strongly agree with recommendation 59 in the final report *A Prescription for Canada: Achieving Pharmacare for All* by the Advisory Council on the Implementation of Pharmacare.[3] This recommendation calls on the federal government to implement the amended *Patented Medicines Regulations* to make universal single-payer pharmacare more sustainable, including the requirement for pharmaceutical patentees to report to the PMPRB, the discounted or rebated prices that public and private insurers in Canada are actually paying in addition to the list prices.

[2] *HESA. 2018. Pharmacare Now: Prescription Medicine Coverage for All Canadians.* Accessed 2 November 2020: https://www.ourcommons.ca/DocumentViewer/en/42-1/HESA/report-14/page-18
[3] Advisory Council on the Implementation of Pharmacare. 2019. *A Prescription for Canada: Achieving Pharmacare for All*. Accessed 2 November 2020: https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharmacare/final-report.html

Federal Court Challenge of Amended Regulations

The intransigence of the Innovative medicines Canada (IMC) and its members toward the amended *Patented Medicines Regulations* and the Final Guidelines is not unexpected. Among their many intransigent actions was 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] had intervener status in this challenge. The IMC and its co-applicants took issue with three aspects of the amendments to the amended *Patented Medicines Regulations*.

The Federal Court decision was released on June 29, 2020. The Federal Court ruled that the provisions in the amended *Patented Medicines 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 very disappointed that the Federal Court struck down the part of the amended *Patented Medicines 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 any transparency of the true market price of a drug and amply permits pharmaceutical companies to unfairly set overly inflated public list prices as a benchmark to negotiate down 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.

The intransigence of the IMC and its members as well as patient groups continued with their push to have HESA study the Final Guidelines. The PMPRB released the Final Guidelines on October 23, 2020 after a long five-year consultative process, involving

mainly these parties. Over this time, unions were not afforded the same access to the development work and discussions. But, Canada's unions understand the prominence of prescription drugs in both private and public spending. It was very important for us to contribute to the process of modernizing Canada's pricing framework for patented medicines, and to better enable the PMPRB to regulate excessive drug prices to protect Canadians. Over this consultative period, unions made submissions on the amendment *Patented Medicines Regulations,* Draft Guidelines 2019 and Draft Guidelines 2020.

The Final Guidelines were based on input from the consultation on Draft Guidelines 2020. The Draft Guidelines 2020 was filled with a series of compromises, acquiescing concessions to the IMC, pharmaceutical patentees and their supporters.

Yet, when the Final Guidelines was released, Canada's unions were supportive as an important step towards universal single-payer pharmacare. This was a conciliatory position—even though we did not win everything that we wanted in the Final Guidelines—to facilitate a way forward on fairer and better regulatory framework that benefits all Canadians.

Amended Patented Medicines Regulations and Final Guidelines Needed

The CLC is disappointed with the delay in the coming into force date of the amended *Patented Medicines Regulations* that has been postponed to January 1, 2021 from July 1, 2020. This one-half year delay further prolongs an unfair drug pricing system of the last three decades that has Canadian consumers paying dearly for it.

In 1987, Canada enacted Bill C-22, its medicine patent regime to strengthen patent protection that would incentivize research and development (R&D) by ensuring Canadian drug prices were in keeping with other high R&D countries such as the U.S. and Switzerland. At the same time, the PMPRB was created as a consumer protection

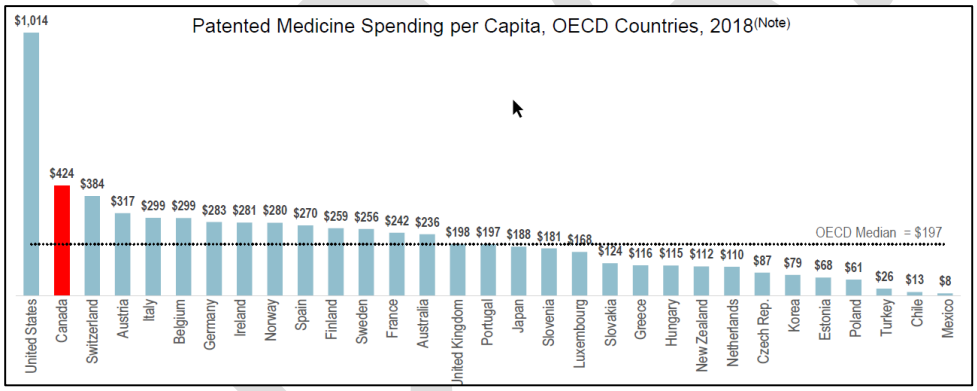
pillar “to ensure that patentees did not abuse their newly strengthened patent rights by charging consumers excessive prices during the statutory monopoly period.”[4]

Pharmaceutical global business models in tandem with the current Canadian *Regulations* and Guidelines excessively favour patentees. The current environment and practices, until the amended *Patented Medicines Regulations* come into force, continue to deliver stratospheric profits in the billions annually for pharmaceutical patentees in Canada. Pharmaceutical patentees’ ample gains are Canadian consumers’ immense losses.

The colossal failure of the *Patent Act* policy objectives has inflicted an interminable burden on all Canadians for the last 30 years as follows:

1. Canada has the second highest spending on patented medicines per capita among OECD countries behind the U.S. (see Figure 1)

Figure 1



Note: (i) Patented medicines were identified based on patents in Canada, for which sales were extracted for other countries. (ii) Spending data for Greece, Chile, Estonia, Luxembourg and Mexico include only retail sales. and exclude hospital sales. (iii) Includes only countries for which data are available.

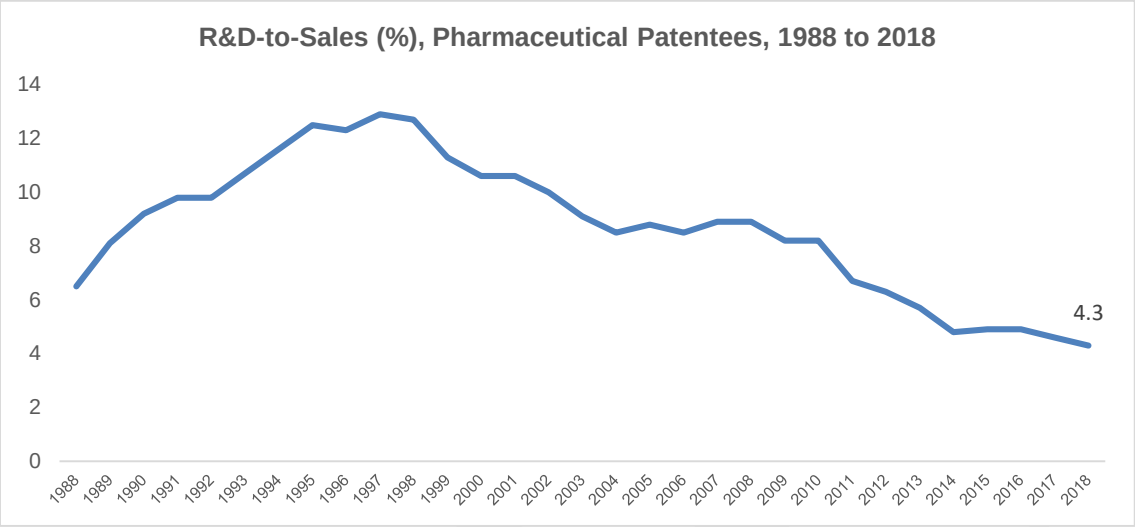
Source: PMPRB, 2020

2. Member companies of Innovative Medicines Canada (IMC) continual reneging on their agreement of investing 10% of sales in research and development (R&D) per

[4] PMPRB Guidelines Modernization – Discussion Paper – June 2016. Accessed 28 October 2020: http://www.pmprb-cepmb.gc.ca/en/news-and-events/consultations/current-major-consultations/rethinking-the-guidelines/discussion-paper

year in exchange for strengthened drug patent protection increased since 1987[5]. (see Figure 2)

Figure 2



Source: PMPRB, 2020

3. Over nine in ten new drugs introduced offers no, slight or only moderate improvement compared to existing medicines. Between 2010 and 2018, 95% of new medicines introduced offered no, slight and moderate improvements, but represented 98% of sales. Over these eight years, of the total 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%). Clearly, the profit motive drives what new medicines pharmaceutical patentees introduce in Canada, with little to no regard for the negative impact on Canadians.[6]

The coming into force of the purpose of the amended *Patented Medicines Regulations* and the Final Guidelines is critical to changing these disastrous outcomes for

[5] Regulatory Impact Assessment Statement (RIAS) of the *Patented Medicines Regulations*, 1988, published in the Canada Gazette, Part II, Vol. 122, No. 20 – SOR/DORS/88-474.
[6] PMPRB Annual Report 2018. Accessed 30 October 2020: https://www.canada.ca/en/patented-medicine-prices-review/services/reports-studies/annual-report-2018.html

Canadians. The amended *Patented Medicines Regulations* will better equip the PMPRB with the regulatory tools and information reporting authorities it needs to effectively protect Canadians from excessively priced patented medicines. The changes will be "more closely aligned with prices in like-minded countries, more reflective of their value to Canadian consumers and more informed by the affordability constraints of the Canadian economy."[7] These amendments will also save Canadians $13.2 billion over ten years.

Impact of COVID-19 Pandemic

Before the COVID-19 pandemic, about 7.5 million people - one in five Canadians either did not have prescription drug insurance or did not have adequate insurance to cover their prescription drug 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. Today, massive layoffs triggered by the COVID-19 pandemic have left hundreds of thousands more at-risk of losing their workplace drug benefits. The fact is that seven out of ten Canadians consider improving prescription drug access and affordability a high priority issue for their government representatives to tackle.[8]

The pandemic has shone a light on the essential importance of a strong public health and healthcare system. That is why the coming into force of the amended *Patented Medicines Regulations* and the Final Guidelines is even more importance and urgent now. These two instruments are critical and timely 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 *Patented Medicines Regulations*, the PMPRB will have additional tools to more vigorously fulfil its dual mandate of:

[7] Accessed 30 Oct. 2020: http://www.gazette.gc.ca/rp-pr/p2/2019/2019-08-21/html/sor-dors298-eng.html
8 Angus Reid. October 29, 2020. Access for all: Near universal support for a pharmacare plan covering Canadians' prescription drug costs. Accessed 2 November 2020: http://angusreid.org/pharmacare-2020/

- 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 pandemic, 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 *Patented Medicines Regulations*, the PMPRB is strongly poised to be a substantial contributor in Canada's efforts to building back a more equitable and strong future, post-pandemic. It is even more important now that the new Final Guidelines are robust in order to operationalize the amended *Patented Medicines Regulations* to its fullest extent. This is the time for PMPRB as a regulator to stay the course and fully exercise its consumer protection powers for people across Canada.

Conclusion

For over 30 years, Canadians have borne the burden of the failed policy mandate of the *Patent Act*. On January 1, 2021, Canadians will not only bring in the New Year, they will also see the amended *Patented Medicines Regulations* and the Final Guidelines come into force. This modernized regulatory framework will serve all Canadians better and strengthen our collective ability to contribute to recovery.

Of course, Canada's unions would have preferred that the Final Guidelines:

- enabled a higher threshold of new medicines triggering the Category I criteria;
- provided more transparency by making the Therapeutic Criteria Level (TCL) for patented Category I medicines public; and
- did not deem new vaccines a Category II medicine but a Category 1 medicine that would receive more vigorous scrutiny.

For the good of all Canadians in these unprecedented times, it is of utmost importance that we move forward in facilitating the coming into force of the amended *Patent Medicines Regulations* and the Final Guidelines on January 1, 2021.

Canada's unions also want to recognize and thank the PMPRB for all the work on the new Final Guidelines. The webinars and documents the PMPRB has provided to allay the fears of the impact of the amended Regulations on access to prescription drugs, drug launches and clinical trials in Canada is based on credible and unbiased research from Canada and internationally. The PMPRB's research shows that many countries with lower patented drug prices than Canada does not result in:

- fewer new medicines being launched;
- fewer clinical trials;
- drug shortages; and
- lower R&D investments.

In fact, despite the very low R&D investments by pharmaceutical patentees, Canada has a sizable number of clinical trials underway, few of which are funded by patentees.

Finally, the pandemic has shown us that timeliness in policy responses is critical, and delays have severe and costly outcomes. People all across Canada are struggling and there is a lot of uncertainty to deal with during the pandemic. There is a role and a great responsibility among those who can bring change and forge a path forward to act in the very best interest of everyone across the country. Coming into force of the amended Patent Medicines Regulations and the Final Guidelines is one of these paths that cannot be further delayed.

lgf:ea:COPE*225