Submission

of the

Canadian Union of Public Employees

Patented Medicines Prices Review Board (PMPRB)

July 1, 2021, Guidelines

August 2021

1375 St. Laurent Blvd
Ottawa, ON K1G 0Z7
613-237-1590

cupe.ca

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 the ongoing opportunities to provide feedback to the PMPRB, this time regarding the decision to delay the coming-into-force date of the Regulations Amending the Patented Medicines Regulations ("Regulations") an additional six months, from July 1, 2021 to January 1, 2022.

CUPE is deeply disappointed the federal government is delaying the date the Amended Regulations would come into force for a third time, eighteen months later than the original coming-into-force date of July 1, 2020.

The 2019 Guidelines and amended Patented Medicines Regulations are important and necessary steps towards affordable patented medicines, the implementation of a national, public, universal, single payer, and comprehensive pharmacare plan in Canada and a universal, not-for-profit public health care system.

Delays preventing people in Canada from accessing affordable medicines

Health Canada's rationale for the three delays is because "additional time is required for patentees to prepare for and comply with the changes introduced in the Amending Regulations."[1]

Health Canada concludes "that the resulting increased costs these Regulations would impose on consumers will be low."[2] The *Regulations amending the Regulations Amending the Patented Medicines Regulations* notes: "This extension will result in a small possibility of higher cost for Canadian payers. It was originally estimated that payers would save a total of $8.8 billion [present value] (PV) over 10 years from lower patented medicine spending as a result of the Amending Regulations. Delaying the coming-into-force by another six months may impact some of these savings, but Health Canada anticipates that most of these savings will continue to occur as originally estimated."[3]

CUPE is concerned these delays will impact affordable patented medicines for people in Canada, many who are experiencing financial hardship due to the COVID-19 pandemic. Even before the pandemic, 25 per cent of households could not afford prescription medication because of high costs. Up to 4 million people in Canada don't have drug coverage.

[1] Regulations amending the Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), No. 3: SOR/2021-162, Canada Gazette, Part II, Volume 155, Number 14 https://gazette.gc.ca/rp-pr/p2/2021/2021-07-07/html/sor-dors162-eng.html.
[2] Ibid.
[3] Ibid.

Since the start of the pandemic, millions of people have lost their jobs or are working reduced hours. Statistics Canada reports, "The number of long-term unemployed workers rose sharply in September and October [2020] as a result of the initial lockdowns. As of January 2021, 512,000 workers were experiencing long-term unemployment, about 27% of all unemployed people."[4] In a July update, Statistics Canada reported that despite the recent increases in employment, "the number of employed Canadians who worked less than half their usual hours remained 341,000 higher than before the start of the pandemic."[5]

Job loss means many people have lost their coverage for prescription medication or have an even lower income to afford prescription medication. Being unable to afford medication has a significant impact on people's individual health as well as our health care system. A further delay in the PMPRB guidelines means that people in Canada continue to pay some of the highest prices for medicines around the world.

The PMPRB Draft Guidelines

The PMPRB framework proposed in November 2019, would have better regulated and protected people in Canada against excessive drug prices. Since prescription medications are an essential component of patient care, CUPE supports the reforms proposed in the 2019 Draft Guidelines, which would operationalize the amended Regulations.

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.

The proposed 2019 changes are essential to promoting better health care and improving health outcomes for the population.

As outlined in CUPE's July 2020 Submission, CUPE continues to be concerned with the significant changes reflected in the June 2020 Draft Guidelines. The June 2020 Guideline changes reflect a series of significant concessions to Innovative Medicines Canada, the pharmaceutical industry, and their supporters. 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.

These concessions include a change to how the Maximum List Price (MLP) is set by applying "the HIP [Highest International Price] test to Grandfathered medicines."[6] This proposal will not benefit patients,

[4] COVID-19 in Canada: A One-year Update on Social and Economic Impacts, Statistics Canada, March 11, 2021, https://www150.statcan.gc.ca/n1/pub/11-631-x/11-631-x2021001-eng.htm.
[5] Canadian Economic Dashboard and COVID-19, Monthly update, July 15, 2021 https://www150.statcan.gc.ca/n1/pub/71-607-x/71-607-x2020009-eng.htm.
[6] Government of Canada, "PMPRB Draft Guidelines," July 8, 2020, https://www.canada.ca/en/patentedmedicine-prices-review/services/consultations/draft-guidelines.html.

or federal or provincial/territorial health care budgets. The PMPRB even acknowledges this change is a "concession to patentees."[7] 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 PMPRB11 or Schedule Countries, or when the MLP for grandfathered and Line Extension medicines is set at the highest international price for the PMPRB11 or Schedule Countries for which the patentee has provided information.

CUPE notes the proposed amendment to change reference of the PMPRB11 to the "Schedule Countries" in the July 1, 2021, Guidelines.

CUPE is still troubled by the increase to the market size threshold used to classify Category 1 medicines, increase to the Pharmoacoeconmic Value threshold from $60,000 to between $150,000 to$ 200,000 per Quality-Adjusted-Life Year and other changes outlined in CUPE's July 2020 submission.

For CUPE, patient interests, rather than the profit motive of pharmaceutical patentees should drive pharmaceutical policy in Canada. Instead, several significant 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

On June 29, 2020, the amended Regulations were reviewed by a Judge of the Federal Court. 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.

On September 10, 2020, Innovative Medicines Canada and the 16 pharmaceutical companies filed a Notice of Appeal to ask the Federal Court of Appeal to declare the provisions related to the use of pharmacoeconomic factors and the reconstitution of the PMPRB11 basket of comparator countries "void and of no force and effect" because they are outside of the powers of the Patent Act.[8] The appeal even asks for the cost of this appeal to be awarded to Innovative Medicines Canada and the 16 pharmaceutical companies.[9]

[7] Ibid.

[8] Federal Court of Appeal, Notice of Appeal A-215-20, <https://www.smartbiggar.ca/docs/default-source/rx/a-215-20_notice-of-appeal.pdf?sfvrsn=d6a6744b_2>

[9] Ibid.

On September 21, the federal government filed a Notice of Cross-Appeal arguing that the judge erred in making his ruling that the provision requiring patentees to report rebated or discounted drug prices to third parties was outside the PMPRB's mandate.[10]

We support the federal government's Notice of Cross-Appeal as we believe the June 29, 2020 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.

Prices of patented medicines and investment in research and development

The PMPRB's regulatory mandate is to protect people in Canada "against excessive prices of patented medicines." For nearly 35 years, the existing framework used by the PMPRB to regulate the cost of drugs has failed to adequately protect people in Canada from inflated prices for patented medicines. As a result, people in Canada have been forced to unfairly pay some of the highest drug prices in the world.

Individuals, provincial and territorial governments, and work-based health insurance plans have all struggled to cover the exorbitant costs, leaving many people unable to fill their prescriptions or to take medications as prescribed by their doctor. This negatively affects the health of Canadians and increases costs to our health care system. Even workers with employer-sponsored benefit plans face significant barriers to accessing needed medicines due to cost. The burden of paying for excessively priced patented drugs has been transferred onto workers' shoulders through increasing insurance premiums, copayments and deductibles, the lowering of annual or plan maximums, and a reduction in drugs eligible for coverage.

The absence of strong pricing regulations has generated massive profits for pharmaceutical companies. This has not been returned to people in Canada in the form of investments in research and development (R&D), or industry-related jobs.[11] While the share of sales for high-cost patented medicines has risen exponentially over the past decade, pharmaceutical companies have abandoned their commitment to invest 10% of sales in R&D during periods of market exclusivity.[12]

The industry's claim that high prices and large profits are necessary to promote pharmaceutical innovation are untrue; there is no relationship between the price of drugs, company profits, and R&D investments. The absence of national pricing regulations in relation to R&D investments in Canada has clearly been a policy failure.[13] In fact, the pharmaceutical industry could do much more to make their

[10] Federal Court of Appeal, Notice of Cross-Appeal A-215-20, <https://www.smartbiggar.ca/docs/default-source/rx/a-215-20_notice-of-cross-appeal.pdf?sfvrsn=d6d7f8b4_2>

[11] Marc-André Gagnon, "Commentaires Quant Aux Modifications Proposées au Règlement sur les Médicaments Brevetés: Comment Trouver L'équilibre Néecesaire contre les Prix Excessifs Dans un Secteur Pharmaceutique en Mutation," Submission to Health Canada, June 22, 2017.

[12] Patented Medicines Prices Review Board, "PMPRB Draft Guidelines Consultation," December 10, 2019, https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/presentationdec10-en.pdf

[13] Marc-André Gagnon, "Commentaires Quant Aux Modifications Proposées au Règlement sur les Médicaments Brevetés: Comment Trouver L'équilibre Néecesaire contre les Prix Excessifs Dans un Secteur Pharmaceutique en Mutation," Submission to Health Canada, June 22, 2017.

R&D activities more efficient, which would allow more "drugs to be developed per dollar of R&D spending – offering to offset revenue declines that might affect the flow of new drugs."[14] The PMPRB's own research shows that, "Most of Canada's peer countries enjoy far greater levels of R&D investment despite having considerably lower drug pricing," including Belgium, Sweden, France, the United Kingdom, and the Netherlands.[15] According to Industry Canada, "Canada ranks low on the global corporate priority for R&D investment, despite having the 8th largest global [pharmaceutical] market."[16]

In 2019, brand-name drug companies spent only 3.9% of their Canadian revenues on R&D in Canada.[17] This is half the percentage of what pharmaceutical companies were investing of sales into R&D in 2008 (at 8% of their Canadian revenues). The percentage of sales invested in R&D has continued to decline under the 10% threshold, which it has not met for nearly 20 years.[18]

For too long, pharmaceutical companies have benefited from Canada's weak regulatory environment and failed to uphold their end of the bargain at the expense of Canada's health care system and the people who live here.

Conclusion: The need for national, public, universal, single payer, and comprehensive pharmacare

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."[19] 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.

The federal government has repeatedly promised to implement a pharmacare program. In the Minister of Health Mandate Letter, Prime Minister Justin Trudeau outlines the implementation of national

[14] Richard G. Frank, "Drug Companies Exaggerate – Controlling Drug Prices Won't Threaten Innovation," The Hill, November 13, 2019, https://thehill.com/opinion/healthcare/470266-drug-companies-exaggerate-controlling-drugprices-wont-threaten-innovation

[15] Patented Medicines Prices Review Board, "PMPRB Draft Guidelines Consultation," December 10, 2019, https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/presentationdec10-en.pdf.

[16] Industry Canada, "Canada's Pharmaceutical Industry and Prospects," Government of Canada, 2013, https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/vwapj/PharmaProfileFeb2014_Eng.pdf/$file/PharmaProfileFeb2014_Eng.pdf.

[17] Annual Report 2019, Patented Medicine Prices Review Board, https://www.canada.ca/en/patented-medicine-prices-review/services/annual-reports/annual-report-2019.html

[18] The Pharma Letter, "Canada's R&D Based Drugmakers not Reaching 10% of Research-to-Sales Ratio Commitment," (December 3, 2018), https://www.thepharmaletter.com/article/canada-s-r-d-based-drugmakersnot-reaching-10-research-to-sales-ratio-commitment. This calculated added with percentage of sales from Annual Report 2019 and 2018, Patented Medicine Prices Review Board, https://www.canada.ca/en/patented-medicine-prices-review/services/annual-reports.html.

[19] 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/publicengagement/external-advisory-bodies/implementation-national-pharmacare/final-report/final-report.pdf.

universal pharmacare.[20] The Minister of Health Supplementary Mandate Letter from January 15, 2021, calls on the Minister to "accelerate steps to achieve a national, universal pharmacare program, including establishing the Canada Drug Agency and implementing both a national formulary to keep drug prices low and a rare-disease strategy to help families save money on high-cost drugs."[21]

Despite these clear mandates, there was no new funding for pharmacare in the federal government's Budget 2021 and it only noted the funding for $500 million for rare diseases announced in Budget 2019.

Canada is the only country in the world with a system of universal health care that doesn't include coverage for prescription drugs. Our current patchwork system of 100 public and over 100,000 private drug plans is fragmented, expensive, and unable to provide everyone with the medications they need. The federal government must do more than simply prevent excessive drug pricing. It must also ensure fair and equitable access to prescription medications for everyone.

A national, public, universal, single payer, and comprehensive pharmacare plan will ensure everyone can access medicines based on need, not an ability to pay. It will also maximize the therapeutic value of every dollar spent by increasing our bargaining power with companies that have a monopoly over patented drugs. Until then, regardless of the PMPRB's regulatory reforms, people in Canada will continue to face barriers to accessing needed medicines, while continuing to pay too much for prescription drugs.

On behalf of CUPE's 700,000 members, we recommend that the November 2019 Guidelines be adopted immediately with minor changes (as outlined in CUPE's February 2020 submission). The latest coming-into-force date of July 1, 2021 has already passed and therefore there needs to be immediate implementation of the Amending Regulations so that people in Canada can access more, affordable patented medicines as soon as possible.

EL/sc/cope491
August 5, 2021

[20] Minister of Health Mandate Letter, Office of the Prime Minister, December 13, 2019, https://pm.gc.ca/en/mandate-letters/2019/12/13/minister-health-mandate-letter.
[21] Minister of Health Supplementary Mandate Letter, January 15, 2021, Office of the Prime Minister, https://pm.gc.ca/en/mandate-letters/2021/01/15/minister-health-supplementary-mandate-letter