

Canadian Union of Public Employees

**Submission to the Patented Medicines Prices Review Board (PMPRB)
On Changes to the PMPRB Draft Guidelines**

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CUPE

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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. We thank you for the opportunity to comment on the PMPRB Draft Guidelines, which follows two years of extensive consultations with patient groups, academic experts, industry and other public stakeholders. The Guidelines and amended *Patented Medicines Regulations* are important and necessary steps towards the implementation of a national, public, universal, single payer, and comprehensive pharmacare plan in Canada.

The PMPRB Draft Guidelines

For over 30 years, the existing framework used by the PMPRB to regulate the cost of drugs has failed to adequately protect Canadians from inflated prices for patented medicines. As a result, Canadians 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 Canadians in the form of investments in research and development (R&D), or industry-related jobs.¹ 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.² In 2017, brand-name drug companies spent only 4.6% of their Canadian revenues on R&D in Canada, "marking the 15th consecutive year they...failed to meet the 10% threshold," without having to face any consequences.³ 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.

¹ Marc-André Gagnon, "Commentaires Quant Aux Modifications Proposées au Règlement sur les Médicaments Brevetés: Comment Trouver L'équilibre Nécessaire contre les Prix Excessifs Dans un Secteur Pharmaceutique en Mutation," Submission to Health Canada, June 22, 2017.

² Patented Medicines Prices Review Board, "PMPRB Draft Guidelines Consultation," December 10, 2019, <https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/presentation-dec10-en.pdf>.

³ The Pharma Letter, "Canada's R&D Based Drugmakers not Reaching 10% of Research-to-Sales Ratio Commitment," (December 3, 2018), <https://www.thepharmalatter.com/article/canada-s-r-d-based-drugmakers-not-reaching-10-research-to-sales-ratio-commitment>.

Since 2010, the pan-Canadian Pharmaceutical Alliance (pCPA) has negotiated price agreements for over 200 patented drugs, and price reductions for over 60 generic drugs covered by existing provincial, territorial, and federal public drug plans. The pCPA estimates overall annualized savings of \$1.98 billion. However, in a recent submission to the House of Commons, the pCPA states that it “remains very concerned that the prices achieved through negotiation remains largely unfair, excessive and not cost-effective and that pCPA needs collaborative federal support to manage.”⁴ Although existing public drug plans currently possess the capacity to jointly negotiate lower drug prices, in the absence of a stronger national drug pricing framework, they are still struggling to pay high drug costs, which reduces accessibility for Canadian patients.

The new PMPRB framework will better regulate and protect Canadians against excessive drug prices. Since prescription medications are an essential component of patient care, CUPE supports the reforms proposed in the Draft Guidelines. These changes are essential to promoting better health care and improving health outcomes for the population. CUPE is also pleased that the PMPRB’s monitoring and evaluation reporting will be made publicly available.

However, because “regulations alone cannot make medicines affordable to patients,” Canada must do more to ensure fair and equitable access to prescription medicines based on need, not an ability to pay.⁵ This can only be accomplished through a system of universal drug coverage, like we see in New Zealand and Australia. CUPE views the PMPRB regulatory changes as an essential building block towards implementing the national, public, universal, single payer, and comprehensive pharmacare plan we need across our country.

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, Canadians will continue to face barriers to accessing needed medicines, while continuing to pay too much for prescription drugs.

⁴ pan-Canadian Pharmaceutical Alliance, “Brief to House of Commons’ Standing Committee on Barriers to Access Treatment and Drugs for Canadians Affected by Rare Diseases and Disorders,” December 7, 2018, <https://www.ourcommons.ca/Content/Committee/421/HESA/Brief/BR10275853/br-external/PanCanadianPharmaceuticalAlliance-e.pdf>.

⁵ Steve Morgan, “We Need Innovation in our Drug Price Regulations,” *Policy Options*, May 30, 2019, <https://policyoptions.irpp.org/magazines/may-2019/we-need-innovation-in-our-drug-price-regulations/>.

The Impacts of the Guideline Changes

The pharmaceutical industry has warned, and some patient groups have expressed concern, that the new Guidelines will delay or prevent new medications from entering the Canadian market. At the public consultation on the Draft Guidelines that took place on December 10, 2019, PMPRB staff assured concerned stakeholders that while the new Guidelines will change how the PMPRB operates, the changes it proposes are not intended to reduce the availability of new drugs in Canada.

CUPE believes the Guidelines will not prevent new, evidence-based drugs that provide a therapeutic improvement from entering the Canadian market. Pharmaceutical companies will still earn sufficient profits on patented drugs even when prices are set at levels that are more affordable. Research shows that price regulations are not solely responsible for the extent to which new drugs are launched around the world. Cockburn et al. (2016) show that other factors also influence access to new drugs, including:

- The size and demographic features of a given market;
- The presence of substitute treatments that limit demand to a level that does not justify the cost of a new drug; and
- Local regulatory practices that block the approval of new drugs.⁶

Kanavos et al. (2017) illustrate that drug launches are also impacted by a country's GDP, the amount a country spends on public health care, and the amount of money a country spends on health care as a proportion of GDP.⁷ The fear that Canada's new pricing regulations will suddenly restrict new drugs from entering the country are therefore not supported by recent research.

High-quality drugs that substantially advance patient or public health, address a significant unmet medical need, and are approved by regulatory agencies such as the U.S. Food and Drug Administration (FDA), are launched widely around the world.⁸ In countries where new drugs are not launched, this may not be the result of price controls but a consequence of advances in technology that render the drugs obsolete, or a lack of important complementary technologies or health care resources. Launches of new drugs that are not approved by a regulatory body, such as the FDA, occur more slowly and are less extensive. However, this outcome is expected if significant risks are associated with a new drug, or in cases where the drug may not provide a therapeutic advancement over an existing medication that is available at a fraction of the cost.⁹

⁶ Iain Cockburn, Jean O. Lanjouw, and Mark Schankerman, "Patents and the Global Diffusion of New Drugs," *American Economic Review* 106, no. 1 (January 2016): 136-164.

⁷ Panos Kanavos, Anna-Maria Fontrier, Jennifer Gill, Olina Efthymiadou, and Nicola Boekstein, "The Impact of External Reference Pricing Within and Across Countries," 2017, <http://www.lse.ac.uk/business-and-consultancy/consulting/assets/documents/the-impact-of-external-reference-pricing-within-and-across-countries.pdf>.

⁸ Ibid.

⁹ Ibid.

Therefore, the PMPRB's new drug pricing guidelines should not have a negative impact on the availability of patented medicines in Canada.

Orphan or rare diseases are conditions that affect 5 or less people in 10,000. Orphan drug policies are designed to provide incentives to companies to develop new drugs for rare diseases; to create regulatory pathways to get new drugs for rare diseases to market more quickly; and to help make new drugs for rare diseases more affordable for patients, usually through public funding for a medication. In a study that compared how often and how quickly drugs for rare diseases are approved and marketed in Australia, which has an orphan drug policy, and Canada, which does not have an orphan drug policy, researchers found that Canadians do not suffer a disadvantage compared to Australians, in accessing new drugs.¹⁰ "The 2 countries approved the same proportion of drugs and showed no difference in the delay in approving the products nor in the time spent in the regulatory review process."¹¹ The study concludes that Canada is as attractive a market for drugs for rare diseases as comparable countries, even in the absence of an orphan drug policy. Compared to Canada, Australia has median drug prices that are lower than the OECD median price. Therefore, the capacity of Canada to access new drugs in a timely manner is not likely to be hindered by reductions in drug prices. Patients should be able to maintain access to new drugs when they enter the market with minimal access barriers.

The pharmaceutical industry has warned, and some patient groups are worried, that the new Guidelines will fail to incentivize industry investments in R&D, thereby reducing drug innovation. 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.¹² According to Industry Canada, "Canada ranks low on the global corporate priority for R&D investment, despite having the 8th largest global [pharmaceutical] market."¹³ It adds,

Closures of Canadian R&D facilities by MNEs [Multinational Enterprises] are occurring because these facilities were engaged in therapeutic areas that are no longer areas of global corporate focus or as the result of outsourcing and in-licensing to minimize costs and risks associated with in-house product development. Moreover, MNEs are consolidating research centres to clusters located closer to company headquarters, or are located in attractive geographic

¹⁰ Joel Lexchin and Nicholas Moroz, "Does an Orphan Drug Policy Make a Difference in Access? A Comparison of Canada and Australia," *International Journal of Health Services*, (November 6, 2019): 1-13, <https://journals.sagepub.com/doi/pdf/10.1177/0020731419886526>.

¹¹ Ibid.

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/presentation-dec10-en.pdf>.

¹³ 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](https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/vwapj/PharmaProfileFeb2014_Eng.pdf/$file/PharmaProfileFeb2014_Eng.pdf).

markets. Conditions of attractive markets include investment infrastructure and government incentives such as taxation.¹⁴

Other factors that have also affected R&D investments in Canada include the 2008 financial crisis and other economic downturns.¹⁵ Since these findings suggest the ability of Canada to attract and sustain higher levels of R&D activity have been attributed to factors other than drug prices or drug pricing regulations, CUPE believes that R&D investments in Canada will not be negatively impacted by the Guideline changes.

As noted above, pharmaceutical companies are already failing to meet their commitment to invest 10% of sales in R&D in Canada. 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.¹⁶ In fact, the pharmaceutical industry could do much more to make their 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."¹⁷

Questions for Clarification

CUPE requests that the PMPRB provide answers to the following questions to ensure all procedures undertaken by the PMPRB under the new Guidelines are predictable and transparent to the public, as well as all other relevant stakeholders:

- 1) One way to regulate prices will be based on anticipated market size. How will the market size be assessed?
- 2) What will happen when a manufacturer doesn't trigger a pharmacoeconomic analysis of a new drug via the Canadian Agency for Drugs and Technologies in Health (CADTH) or the Institut national d'excellence en santé et services sociaux (INESSS)? Will the PMPRB commission the required studies from other sources?
- 3) The list price for a drug can be adjusted by the Consumer Price Index (CPI). Under what circumstances is this likely to happen?
- 4) The PMPRB will evaluate the maximum prices for patented drugs in relation to a new basket of 11 countries, the size of market share, and the pharmacoeconomic value of a drug. Will the therapeutic advancement of a drug also be factored into these evaluations?

¹⁴ Ibid.

¹⁵ Ibid.

¹⁶ Marc-André Gagnon, "Commentaires Quant Aux Modifications Proposées au Règlement sur les Médicaments Brevetés: Comment Trouver L'équilibre Nécessaire contre les Prix Excessifs Dans un Secteur Pharmaceutique en Mutation," Submission to Health Canada, June 22, 2017.

¹⁷ 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-drug-prices-wont-threaten-innovation>.

- 5) The PMPRB will make every reasonable effort to assist patentees in understanding the guidelines and their application. Will the PMPRB also actively assist other groups in understanding the guidelines, such as consumer and patient groups?
- 6) The new Guidelines state, “Price reviews are normally conducted by Staff using the methods and tests set out in these Guidelines based on the information filed by the patentees or obtained by Staff from relevant outside sources such as public formularies.”¹⁸ What does the term “normally” mean? Will there be other ways of conducting price reviews? If so, what are the methods and tests that will be used?
- 7) For non-grandfathered patented medicines, a reassessment may be conducted if a Category 1 patented medicine’s cost-utility analysis is updated. Will the cost utility analysis be produced by CADTH, INESSS, or another organization?

Recommendation

In order to strengthen the Draft Guidelines, CUPE recommends the PMPRB make the following change:

- The new Guidelines state, “Ad hoc audits of patentee filings, including pricing, revenue and patent information, may be conducted by Staff.”¹⁹ We recommend that the language regarding ad hoc audits in this section be strengthened, by changing the word “may” to “shall,” to regularly ensure pharmaceutical companies are complying with the new reforms.

Conclusion

On behalf of CUPE’s 700,000 members, we recommend that the Guidelines be adopted with minor changes. Namely, the inclusion of responses within the Guidelines to the questions listed above to increase procedural transparency, as well as terms that will strengthen the language related to ad hoc audits to ensure pharmaceutical companies comply with the new reforms. By making these positive changes, we can lower the costs of patented medicines, and improve accessibility and the health of Canadians. These important steps will also serve as an essential building block towards implementing a national, public, universal, single payer, and comprehensive pharmacare plan, which will make prescription drugs even more affordable, improve public health outcomes, and decrease costs to our health care system.

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¹⁸ Ibid.

¹⁹ Patented Medicines Prices Review Board, “PMPRB Guidelines 2019,” <https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/draft-guidelines-en.pdf>.