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Submission to: House of Commons Standing Committee on Health (HESA)
Study on the Patented Medicine Prices Review Board's Final Guidelines

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PDCI Market Access is a Canadian pharmaceutical pricing, reimbursement, and health economics consultancy with core expertise in pharmaceutical pricing, health technology assessment (HTA), clinical and pharmacoeconomic evaluations and modelling. Since 1996, PDCI has provided its advice and expertise to Canadian and global pharmaceutical manufacturers to help navigate the complexities of Canadian pricing and market access landscape with the goal of achieving timely access to the market.

The purpose of this submission is to assist the Health Committee with its review of the PMPRB guidelines. It is not the intent of this submission to advocate on behalf of the pharmaceutical industry, but rather to provide objective, evidence-based information on the likely impacts of the PMPRB's new guidelines.

Since 2016, when discussions regarding potential PMPRB price reforms began, PDCI has conducted impact analyses of the PMPRB price reforms. Based on these analyses, combined with our decades of PMPRB experience, we conclude that the October 23rd, 2020 final Guidelines are not fit-for purpose.

More specifically, the PMPRB 2020 Guidelines will:

- Make some patented medicines commercially unviable in the Canadian market.
- Delay access to innovative new medicines for Canadian patients
- Reduce the number of clinical trials conducted in Canada, impacting Canadian researchers and patients
- Duplicate the role and impede the effectiveness of the pan Canadian Pharmaceutical Alliance (pCPA) that is mandated to negotiate drug prices on behalf of the provinces
- Improperly rely on health economics as a crude price setting mechanism, rather than its intended role to inform value-for-money price negotiations

Recommendation

Health Canada should delay the implementation of PMPRB price reforms until more appropriate, practical, and balanced Guidelines can be developed. Ideally, this would involve changes to the new Patented Medicines Regulations due to come into force on January 1, 2021. However, in the absence of that Regulatory change, the reform process must be paused to allow for meaningful consultation.

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Background

Prior to the 1987 changes in the Patent Act, the Canadian pharmaceutical industry was relatively small, and pharmaceutical companies faced "compulsory licensing" whereby generic copies of patented drugs could be imported and sold in exchange for a royalty paid by the generic manufacturer to the patentee.

In the 30 years since the introduction of patent protection, the industry in Canada has grown to over 34,000 high-quality, well-paying jobs, and an economic footprint of over $ 3 billion, annually. Over this same period, Canadian society has seen many advances in biotechnology, and Canadians have benefited from these advances – we are living longer, more productive, and higher quality lives.

Now, we are entering a new era of technological advancement that will bring us stem cell, gene and cell therapies, immuno-oncology therapeutics, and new vaccines that hold the promise of cures for many more diseases, including rare diseases. In order to ensure that Canadians continue to benefit from advances in health technology, our regulatory policies must evolve to enable and support timely access to these state-of-the-art biologic treatments.

Government Rationale for Reform

In this context of the emergence of revolutionary biotechnologies, the Canadian government has announced its intention to implement new regulatory policies aimed at providing more timely access to the latest medicines, while improving the affordability of prescription drugs. This package of reforms includes Health Canada regulatory review of drugs and devices (R2D2) and PMPRB Regulatory reform. The R2D2 initiatives are focused on broad goals of making the regulatory process more efficient, supporting timely access to therapeutic products, and building better linkages within the health care system as a whole. In contrast, the sole goal of the regulatory changes to the PMPRB is solely to reduce prices of medicines in Canada.

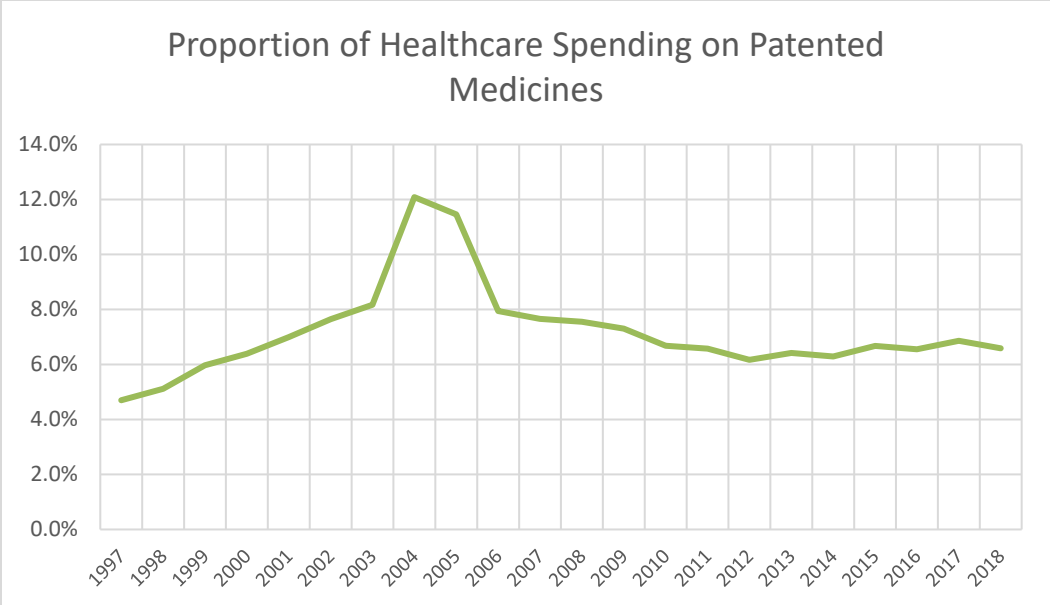
While this might seem like a worthy endeavour at first glance, a closer examination of this rationale and potential unintended consequences of these changes tell a very different story. The rationale provided to support the changes is that Canadian drug prices are among the highest in the world,

and spending on drugs is growing uncontrollably. While it is true that Canadian drug prices as reported by PMPRB over the past several years tend toward the higher end of the OECD countries, the prices reported are well below US prices, even when accounting for deep discounts offered to US Federal government payers, and are within the range of the median of the other 6 current PMPRB reference countries.

In addition, the analysis used to support that Canadian prices are high relative to other jurisdictions is based on list prices. This reporting does not account for a cumulative $ 2 billion in rebates paid to Provincial, Territorial, and Federal jurisdictions as the result of price rebates and other benefits negotiated between patentees and the pan-Canadian Pharmaceutical Alliance (pCPA).

The claim that Canadian drug prices are growing at an alarming pace is not borne out by data from PMPRB Annual Reports. As shown in Figure 1, below, the proportion of total Canadian healthcare spending on patented medicines has decreased steadily since reaching a high of 12.1% in 2004. In fact, the proportion of healthcare dollars spent on medicines in 2018 is at its lowest point (6.6%) since 2000.

Figure 1: Proportion of Healthcare Spending on Patented Medicines[1,2]



[1] PMPRB Annual Reports available online at: http://www.pmprb-cepmb.gc.ca/en/reporting/annual-reports
[2] CIHI National Health Expenditure Trends 1975 to 2019 online at: https://www.cihi.ca/en/national-health-expenditure-trends-1975-to-2019

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Impacts on Patient Access to New Medicines

The price reductions imposed by the new PMPRB Guidelines are impactful and highly complex and create such uncertainty that they put a chill on future launches of innovative medicines in Canada. Introduction of new medicines may be delayed or cancelled outright, meaning patients will not have timely access to the best therapies. Importantly, delays and cancellations of Canadian launches will also mean fewer clinical trials in Canada. Manufacturers generally do not conduct clinical trials in countries where there is any doubt that the drug can be marketed in that market.

A recent analysis conducted by PDCI of Health Canada's clinical trials database shows a significant reduction in clinical trial activity beginning in late 2019 and continuing through Q1 2020, likely in reaction to uncertainty related to the ongoing PMPRB Guidelines consultation.

This is not unexpected, given a recently published systematic literature review[3] of studies aimed at measuring the impact of price level or regulation on R&D, pharmaceutical innovation and patient access to medicines reported that the majority of relevant studies demonstrated a significant negative impact between drug price controls and patient access.

These unintended consequences of the new Regulations and Guidelines arise because of PMPRB's single-minded focus on reducing prices without regard for the broader stated Health Canada reform goals of providing more timely access to the latest medicines.

Need for Meaningful Consultation

Even though Health Canada and PMPRB Staff have been engaged in consultation on the new Regulations and Guideline changes since 2016, it has been consultation in name only and anything but broadly collaborative. Many stakeholders, particularly patient groups and representatives of the pharmaceutical industry, feel that their extensive feedback submitted during these consultations has been disregarded and is not reflected in the final Regulations and Guidelines.

[3] Yanick Labrie. Is there any evidence that regulating pharmaceutical prices negatively affects R&D or access to new medicines? A systematic literature review. *Canadian Health Policy* June 2020

The PMPRB's own published Consultation Policy[4] promises meaningful public impact and an open and transparent decision-making process. Further, the policy states that effective consultations are based on integrity and mutual respect and are undertaken with the objective of ensuring the Board takes into consideration the views of all stakeholders in making policy decisions. Finally, the policy establishes guiding principles for consultations, stating that they should build relationships and trust.

Unfortunately, the PMPRB has failed to live up to its promise of meaningful consultation, focusing instead on defending a predetermined outcome (the 2020 Guidelines) showing complete disdain for considering any alternatives that would moderate drug pricing while avoiding the negative impacts to Canadian patients and the Canadian health care system.

Conclusion

New PMPRB Guidelines should be developed from a blank slate. The Guideline development process should involve bilateral industry and PMPRB technical working groups tasked to develop policy solutions that will provide a balance of cost savings and appropriate timely patient access.

Additionally, a multi-stakeholder working group, including robust patient representation should be established to carefully analyze the expected impact of any changes on drug prices and patient access to innovation

[4] PMPRB Consultation Policy