



VIA EMAIL: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

June 21, 2021

Patented Medicine Prices Review Board
Standard Life Centre, Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

Subject: Life Sciences Ontario submission to PMPRB GMEP consultation

On behalf of Life Sciences Ontario (LSO), thank you for the opportunity to provide feedback on the PMPRB's proposed Guideline Monitoring and Evaluation Plan (GMEP).

From the outset of the PMPRB reform process, LSO has actively monitored developments related to the revisions and responsibly engaged on this issue out of concern for the potential impacts of the new rules on Ontario's and Canada's diverse life sciences ecosystems. As a science-based organization that supports evidence-based policymaking, LSO has also commissioned several studies to help evaluate the impacts of the PMPRB changes. Two in particular are worthwhile referencing here:

- A June 2020 report by IQVIA found that Canada has already started to see a decline in new medicine launches.¹ In 2019, the year the reforms were adopted, Canada only benefitted from access to 13 globally launched medicines, when we should have had closer to 30 based on historical trends. These numbers are based on commercial launches rather than Health Canada approvals – the former is a better indicator of the actual number of medicines available to Canadians.
- A January 2021 Research Etc. survey of 43 pharmaceutical leaders found that more than a third have already delayed bringing new treatments to Canada, and nearly all anticipate that the new rules will drive further decisions to delay or not bring new treatments to Canada and reduce industry investments in research, clinical trials, and innovation.²

¹ IQVIA, June 22, 2020, New Medicine Launches: Canada in a Global Context: <https://lifesciencesontario.ca/canada-may-be-losing-its-status-as-a-top-global-destination-for-new-medicine-launches/>

² Research Etc, January 21, 2021, Health Canada Pricing Reform Research Report: <https://lifesciencesontario.ca/wp-content/uploads/2021/01/Impact-of-Health-Canada-Pricing-Reform-FINAL-Report-Jan-21-2021.pdf>

Despite these and other data showing that the PMPRB changes have already affected decisions on new medicines and research, the PMPRB has consistently denied that the new rules will impact the access environment for new health technologies or the life sciences ecosystem that supports their development. Instead, the PMPRB frequently used select and unreferenced information to support its positions.³

Moreover, despite the PMPRB's multi-year consultation process on the reforms, very little has changed in terms of how the PMPRB intends to implement the new rules, and the impacts will be far greater than what the quasi-judicial agency forecasts. One obvious methodological error in the PMPRB's forecasts is the use of a 7% discount rate, which is several times higher than the actual rate of inflation or interest. This means the PMPRB dramatically understates the forecasted impacts of the changes. The analysis also fails completely to consider the impact of "no launch" decisions.

The PMPRB's strategy to downplay the impacts of the reforms was most recently exemplified by the release of its 2021 communications plan, obtained through an access to information request.⁴ As a quasi-judicial regulatory agency with a duty to implement government policies in a neutral and objective manner, the PMPRB's recent behaviour – namely, engaging in a *de facto* lobbying campaign aimed at Members of Parliament and other stakeholders, and designed to counter opposing views and shore up support for its reforms – is unacceptable. The PMPRB has maligned patients who need medicines and denigrated its regulated sector, calling into question its capacity to responsibly serve as a neutral, independent, quasi-judicial tribunal.

In this context, LSO has serious reservations regarding the PMPRB's capacity to monitor the impacts of its own regulations in a neutral and unbiased manner. LSO strongly recommends that this key auditing role be undertaken by an independent third-party with expertise in policy, regulatory and program evaluation.

LSO would also like to reiterate our recommendation for the government to delay the July 1, 2021 implementation date for the PMPRB regulation changes. This is a request that has been echoed by numerous other stakeholders, including most recently by the province of Ontario.⁵ Now is not the time to be experimenting with novel regulations, untried and untested anywhere else in the world, as our country continues its battle against, and efforts to recover from, the COVID-19 pandemic.

³ Two examples: On November 23, 2020, PMPRB Chair Dr. Mitchell Levine said to the House of Commons Health Committee that the United Kingdom spends the same amount as Canada on medicines with twice the population. Neither of those figures is accurate. On March 26, 2021, @PMPRB_CEPMB tweeted "1 in 10 Canadians had to forego filling prescriptions in the past year for reasons related to cost." There is no source, and all of the literature related to cost-related non-adherence has different results.

⁴ PMPRB communications plan, February 9, 2021:

<https://www.dropbox.com/s/eusxuabcq26uqt9/PMPRB%20ATIP%20Disclosure.pdf?dl=0>

⁵ Hill Times Research, Ontario and Quebec push back on PMPRB rule changes, June 2, 2021:

<https://hilltimesresearch.ca/ontario-and-quebec-push-back-on-pmprb-rule-changes/>

Delaying the implementation of the regulations will greatly support our sector's response to the crisis while also providing additional time to explore alternative approaches to price regulation. It is also inadvisable to move forward on the reforms given the current lack of legal clarity over their constitutional and administrative law validity, issues that continue to be contested in Canadian courts. Notably, the government of Quebec has weighed in on the constitutional case to request that the changes be declared *ultra vires* of federal jurisdiction.⁶

Thank you for the opportunity to provide input.

Sincerely,



Jason Field
President & CEO
Life Sciences Ontario
jason.field@lifesciencesontario.ca

Life Sciences Ontario (LSO)

LSO is a not-for-profit organization that represents and promotes Ontario's vibrant and diverse life sciences sector. Members of LSO include life sciences companies, entrepreneurs, members of academia, and service providers from many different areas of the life sciences ecosystem, including biopharmaceuticals, agriculture, agri-food, the bioeconomy, medical devices, animal health, environmental technologies, and more. Ultimately, our mission is to encourage commercial success throughout this diverse sector by collaborating with governments, academia, industry and other life sciences organizations in Ontario and across Canada.

⁶ Hill Times Research, Ontario and Quebec push back on PMPRB rule changes, June 2, 2021: <https://hilltimesresearch.ca/ontario-and-quebec-push-back-on-pmprb-rule-changes/>