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August 31, 2021

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

Subject: Merck's input on PMPRB's July 2021 notice on proposed Guidelines changes

On behalf of Merck Canada Inc. (Merck), thank you for the opportunity to provide comments on the PMPRB's proposed Guidelines changes. Our submission aims to complement those made by our industry associations, Innovative Medicines Canada and BIOTECanada.

We want to start by noting that our participation in this consultation is not intended and should not be interpreted as supporting the amendments to the *Patented Medicines Regulations* or the PMPRB's Guidelines. Merck continues to have grave concerns about the practicality and legality of the amended Regulations, which are the subject of ongoing legal challenges, and which have most recently been challenged by the province of Quebec as being outside the scope of the federal government's jurisdiction.[1]

We were extremely disappointed that the PMPRB proposed major and unexpected changes to its Guidelines immediately following the federal government's decision to delay the implementation of the regulations. These Guidelines changes, which include earlier and steeper enforcement of public list price reductions for Grandfathered medicines, go directly against the government's intention of providing a reprieve from the pricing reforms to help our sector address the COVID-19 pandemic.

This submission outlines our more specific concerns with the Guidelines changes, which include: (1) Lack of mandate and rationale; (2) Major impact on Grandfathered medicines; (3) Destabilizing the industry at a critical time; (4) Undermining Canadian governments' goal of growing the life sciences sector; and (5) Insufficient and inappropriate consultation.

1. Lack of mandate and rationale

There was no mandate for the PMPRB to suddenly change the price test for Grandfathered medicines from the highest international price (HIP) to the median international price (MIP). The PMPRB claims that the changes were related to the government's decision to delay the regulations but there is no link between the two. In fact, as indicated above, the changes undermine the government's decision to delay the implementation of the regulations to allow

[1] 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/

the sector to continue to focus efforts on the pandemic. Specifically, Merck is currently developing an antiviral therapy against COVID-19 and is conducting phase 3 studies, including trials taking place in Quebec and Ontario.

However, instead of being able to focus efforts on addressing the pandemic, which has now entered its fourth wave, patentees have been forced to review and analyze new rules with limited information and on a compressed timeline.

In addition, the PMPRB has provided no rationale in the consultation documents to support its contention that all prices above the median are, by that nature, excessive due to abuse of patent monopoly. A departure from the current rules requires a reasonable justification, as recently outlined by the Federal Court of Appeal in the Alexion case.[2] The court clearly stated that the PMPRB's mandate is restricted to ensuring medicines are not excessively priced. The proposed Guidelines changes go beyond this mandate.

2. Major impact on Grandfathered medicines

The PMPRB indicated in its "Frequently Asked Questions" document that the changes will decrease prices of grandfathered medicines on average by 10%. However, no detailed impact assessment was provided, the latest changes were never considered in Health Canada's regulatory analysis (RIAS and Cost Benefit Analysis) and the PMPRB's calculation appears to be a non-weighted average impact across all Grandfathered medicines.

The impact is likely to be much greater than what the PMPRB is stating based on a weighted analysis of impact for Grandfathered medicines. For instance, a high-level review of the impacts of a move to the median of the PMPRB11 can be found in this Poster Presentation from the CADTH Symposium 2020, showing **a weighted average price reduction of 28% for list prices**.[3] While the latest changes would regulate down to the median of the old basket of countries (PMPRB7) and not the PMPRB11, we anticipate the impact to be much closer to what this study is showing than what the PMPRB is stating.

Finally, price decreases for Grandfathered medicines will occur much sooner than anticipated by patentees. Through technical changes to the Guidelines, the PMPRB is now proposing to essentially reverse its position in October 2020 and reaffirmed in April 2021 to provide a one-year transition period for Grandfathered medicines from the coming into force of the new regulations. Specifically, the PMPRB is proposing to unilaterally force down the prices of these medicines within a compressed transition period of six months instead of one year.

[2] Alexion Pharmaceuticals v. Canada (Attorney General), 2021 FCA 157: https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/500849/index.do

[3] https://virtualsymposium.cadth.ca/2020/07/27/impact-of-patented-medicine-prices-review-board-new-reference-countries-on-drug-prices-in-canada-a-comparison-of-current-and-anticipated-list-prices-for-top-drugs-in-the-country/

3. Destabilizing the industry at a critical time

The proposed changes were completely unexpected. In fact, the PMPRB had previously rejected the idea of applying the HIP price test to Grandfathered medicines in the context of the 2020 Guidelines consultations. Companies cannot successfully carry out their operations in a continuously changing pricing regulatory environment. They need predictability and stability to operate optimally and guide their long-term planning. It should also be stressed that the latest changes add another layer of complexity and uncertainty over the Canadian pharmaceutical and vaccines market. These changes are additive to the new regulatory framework, which still includes uncertain economic factors (market size and pharmacoeconomic factors) and the lower-priced country comparisons.

If these changes go forward, the new price test for Grandfathered medicines will severely undercut a broad section of the health system, including drug developers, generics, pharmacists and pharmacies, distributers and wholesalers. This will increase the risks of drug shortages, at a very critical time for our health system.

4. Undermining Canadian governments' goal of growing the life sciences sector

The pandemic has shown the importance of building a strong domestic life sciences sector to protect our health and our economy. Canadian governments, including most notably the federal government, Québec and Ontario, are taking measures to attract increased investments in health research and biomanufacturing.

However, the Guidelines changes will undermine these efforts. In particular, the changes run counter to the goal of Canada's Biomanufacturing and Life Sciences Strategy, which is to grow a strong, competitive life sciences sector.[4] They will also jeopardize the strategy's fifth pillar, which is "Enabling Innovation by Ensuring World Class Regulation" in order to "make Canada a more attractive destination for leading life sciences firms to establish and grow."

5. Insufficient and inappropriate consultation

The Guidelines changes were introduced by the PMPRB with limited consultation in the middle of the summer and which overlapped with the federal election.

More specifically, the consultation documents failed to clearly lay out and explain the changes and the PMPRB did not hold webinars or information sessions to help clarify them and respond to stakeholders' questions. In addition, the federal election now prevents the PMPRB from providing further information to coherently help explain the changes.

Conclusion

Given the important concerns outlined in this submission, we urge the PMPRB to refrain from moving forward with the proposed changes to the pricing test and compliance timeline for Grandfathered medicines. Instead, we recommend that the time provided by the regulatory

[4] https://www.canada.ca/en/innovation-science-economic-development/news/2021/07/the-government-of-canada-announces-biomanufacturing-and-life-sciences-strategy.html

delay be used to revisit all of the pricing reforms to ensure they do not undermine the federal government's key goals of improving access to medicines, good governance, growing Canada's biomanufacturing capacity and life sciences sector and pandemic preparedness.

We also think that a more comprehensive review of the PMPRB is warranted to ensure it is acting within the scope of its mandate and regulating the sector in a neutral and impartial manner. Recent actions by the PMPRB have led us to believe that this may not be the case, as most clearly evidenced by its February 2021 communications plan,[5] which signalled the agency's highly negative views against the sector it is responsible of regulating in a fair manner.

We thank you for the opportunity to provide our comments. Please do not hesitate to contact me should you have any questions about this submission.

Sincerely,

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[5] PMPRB Communications Plan, February 2021:
https://www.dropbox.com/s/eusxuabcq26uqt9/PMPRB%20ATIP%20Disclosure.pdf?dl=0