August 31, 2021

Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Dear PMPRB Board Members,

Subject: Notice and Comment – July 2021 Proposed Changes to PMPRB Guidelines

On behalf of Life Sciences Ontario (LSO), thank you for the opportunity to provide feedback on the PMPRB's proposed Guidelines changes to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions.

LSO has actively engaged on the PMPRB reforms since they were first introduced out of concern for the potential impacts of the new rules on Canada's diverse life sciences ecosystem. It goes without saying that Canada's life sciences sector has been at the forefront of Canada's response to the COVID-19 pandemic and has been at the centre of Canadian and global efforts to develop vaccines, treatments, and other solutions needed to stem the tide of this crisis. Moving forward, the life sciences sector also has an important role in driving our country's economic recovery and building up our resilience in the face of future health challenges.

In this context, LSO remains deeply concerned about the PMPRB's continued onslaught against the life sciences sector – the latest being its intention to implement an unreasonable and unsubstatiated change to price tests and to reduce compliance timelines for Grandfathered medicines.

In particular, our key concerns regarding the latest PMPRB proposals include:

1. **No rationale** is provided for the proposal to change the price test for Grandfathered medicines from the highest international price (HIP) to the median international price (MIP). The consultation document states that these changes "are believed to be an appropriate response to the most recent six-month extension in the coming-into-force date of the Regulations, to January 1, 2022". However, it is difficult to understand what the connection to the delay is or why it would be an appropriate response. In addition, the changes appears to exceed the PMPRB's mandate, which is restricted to the regulation of patent abuse and excessive pricing according to the Federal Court of Appeal

in the recent Alexion decision.[1] Specifically, the PMPRB has not provided a reasonable justification to explain why the changes are required to ensure medicines are not priced excessively as a function of abuse of monopoly, just by virtue of being higher than the median of the comparator countries. The PMPRB appears to have once again grounded its proposal in a consumer protection mandate, which the court has confirmed it does not have.

2. **Significant impact on Grandfathered medicines** is expected given the change in price test. Specifically, the "Frequently Asked Questions" document issued by the PMPRB as part of this consultation indicates that the changes are anticipated to result in list price reductions of 10% on average for Grandathered medicines and that 51% of these medicines will be affected. First, this is a major impact that could drive drug shortages if medicines are pulled from the market. Given this is an average, we can expect some medicines to be affected more than others and face much steeper reductions than 10%. Second, the PMPRB has not shared any details, including its calculations, to support and explain this data. There are many outstanding questions, including: is the 10% reduction an average across all Grandfathered medicines or is it limited to the 51% of medicines that will be impacted? Is it a weighted average by volume of sales? A more detailed impact assessment is required to be shared with patentees. It would be reckless to proceed without understanding the full impacts of the proposed changes, especially at a time where the federal government has committed to stengthen the sector as part of its overall pandemic preparedness effort and through its recently announced Biomanufacturing and Life Sciences Strategy (more on this strategy below).

3. **The compliance timeline** for Grandfathered medicines has effectively been reduced from twelve months to six months following the coming into force of the new pricing regulations in January 1, 2022. This goes directly against the government's rationale for delaying the implementation of the new pricing regulations by six months, namely to free up bandwidth for life sciences companies so that they can focus their attention and resources on responding to the COVID-19 crisis, which is far from over.

4. The proposed changes serve as an **additional and uneccessary deterrent to the Canadian market for life sciences companies**, at a time when federal and provinicial governments are actively trying to create a more attractive business and policy environment for companies. Companies need predictability and stability in order to operate and guide their long-term planning, and this unexpected change will further reduce Canada's attractiveness as a place to do business. This proposal demonstrates that a broad range of the PMPRB's regulatory activites are subjective, unpredictable and unreasonable, and these challenges are not limited to the new economic factors.

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

5. **The consultation is inappropriate and short**. A change of this magnitude requires more extensive and meaningful consultation – not a short six-week window in the middle of summer, while many stakeholders are away, and with a federal election campaign underway. As well, the PMPRB has not held any information sessions or webinars to explain its proposals. Very limited information was provided as part of the PMPRB's consultation document and the "Frequently Asked Questions" document.

In sum, the proposed changes are uneccessary, inappropriate, and harmful to Canada's life sciences ecosystem and our collective efforts to recover and build back better from the pandemic. They will undermine the federal government's goal of growing the sector through the recently announced federal **Biomanufacturing and Life Sciences Strategy**. Specifically, the PMPRB's changes will undermine the 5th pillar and priority of this strategy, which is focused on "enabling innovation by ensuring world class regulation" of health products.

We therefore strongly encourage the PMPRB to recall the present consultation and take the time to assess the extent of its impacts on life sciences companies. We need to avoid further damage to our life sciences ecosystem from the PMPRB. Our sector's ability to continue to contribute to Canada's rescue, recovery, and health system resilience efforts depend on it.

Sincerely,

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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.