



July 18, 2022

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

Dear PMPRB Board Members,

Subject: Notice and Comment - PMPRB Price Review Approach During the Interim Period following publication of Amendments to the Patented Medicines Regulations

On behalf of Life Sciences Ontario (LSO), thank you for the opportunity to provide feedback on the PMPRB's proposed transitional approach regarding its Guidelines.

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. We are pleased that the most contentious aspects of the reforms (i.e., the economic factors and confidential rebates provisions) have been removed from the regulations; however, we remain concerned about the implementation of the proposed basket-of-countries provision at a time when Canada's access to medicines is declining.

Recent [research](#) commissioned by Life Sciences Ontario from IQVIA showed that the number of new drugs launched in Canada has declined significantly in recent years, which represents a departure from trends seen globally. Meanwhile, the median time to launch has more than doubled between 2020 and 2021 from 1 to 2.1 years. The PMPRB has a role to play in ensuring clarity, certainty and fairness, recognizing that Canada represents just about 2% of the global market for pharmaceuticals. All stakeholders have a role in ensuring Canada can attract research and new medicine launches as we rebuild from the pandemic, reversing the uncertainty that has been the hallmark of the PMPRB changes since 2017.

In this context, we are pleased to provide the following general recommendations and considerations with respect to the PMPRB's approach for the interim period and beyond:

- **Establish working groups and review case studies:** The PMPRB's approach in the interim guidelines provides a step towards clarity, but there has been significant uncertainty over the past few months. Very little information or notice was given about the PMPRB's planned approach, which has disrupted business planning for many life sciences companies. Moving forward, LSO recommends that PMPRB work more closely with industry on its permanent guidelines approach. In this context, with respect to the development of the final guidelines, LSO recommends establishing working groups that

include PMPRB and industry representatives to foster closer dialogue and work through any potential issues and case studies (both hypothetical and building on real-world cases), collaboratively.

- **Regulating within the clarified mandate to regulate for patent abuse:** Recent appellate-level decisions have clarified that the PMPRB’s mandate is to prevent abuse of patent rather than determine reasonable pricing of pharmaceuticals. Whatever approach the PMPRB moves forward with for the interim and final guidelines, it should be aligned with this clarified mandate.
- **Align with broader government priorities:** A new context has emerged since the COVID-19 pandemic. Recognizing the gaps in Canada’s health and innovation ecosystem, governments across Canada, including the Ontario government, have taken an all hands on deck approach to closing those gaps by growing the life sciences sector. At the federal level, the Government of Canada announced its intention to implement a Biomanufacturing and Life Sciences Strategy (BLSS). Importantly, the fifth pillar of the strategy has made creating ‘world class regulation’ for our sector a priority. The PMPRB’s interim and final guidelines should be closely aligned with the spirit and intent of the BLSS and related national priorities.
- **Introduce grandfathering for on-market medicines:** To preserve alignment with the BLSS and ensure a more predictable market for life sciences companies, LSO recommends introducing true grandfathering for all medicines launched prior to the finalization of the new PMPRB Guidelines. Medicines already on market that will be launched before these Guidelines are finalized should not be subject to the new pricing regime, as this could lead to unnecessary uncertainty related to launching at risk, operational challenges, and supply disruptions – this at a time when Canada’s access to medicines is already on the decline.

Thank you for your consideration.

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.