August 21, 2023

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

Dear PMPRB Board Members,

Subject: Notice and Comment - Amendment to the Interim Guidance re: New Medicines

Dear PMPRB Board Members,

On behalf of Life Sciences Ontario (LSO), thank you for the opportunity to comment on the PMPRB's proposed update to the approach for conducting interim price reviews on new medicines, pending the development of new guidelines.

The present submission aims to provide forward looking considerations to support the development of both the PMPRB's interim and final guidelines approaches.

As a not-for-profit organization that represents and promotes Ontario's vibrant and diverse life sciences sector, LSO has monitoried, engaged and researched the proposed changes to the PMPRB since amended regulations were first tabled in 2017.

In this context, we are well positioned to shine light on some of the challenges that have emerged as a result of previous proposals from the PMPRB on our members, the broader life sciences ecosystem and patients.

As a science-based organization, LSO believes in evidence-based policymaking, and for this reason we have undertaken and supported research on the reforms over the past several years.

Most recently, in 2022, LSO commissioned research from IQVIA – a global leader in health data and analytics – to examine new medicine launches in Canada to see whether and to what extent the new rules are having an impact. The data showed that the number of new drugs launched in Canada (i.e., not just submitted to Health Canada for approval but actually sold in Canada) declined steadily after the reforms were first conceived back in 2016, whereas global launches increased on average.

From 2017-2021, there were an average of 34 annual new medicine launches globally but an average of just 20 per year in Canada.[1] IQVIA is a respected authority on drug launch information. Its data is based on real-time sales figures and is used by governments the world over, including the Government of Canada.

The decline in new medicine launches in Canada is unsurprising, given that the PMPRB's original approach included layer upon layer of price-cutting mechanisms that would have resulted in significant price reductions for some treatments, including for cancer and other critical illnesses.

Under these conditions, there would be few incentives for companies to bring their medicines to Canada. Data that we commissioned from a third-party research organization which surveyed leaders in the pharmaceutical sector explains further how and why the proposals are so problematic to the sector.[2]

The PMPRB has an important 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 the eventual final guidelines.

- **Establish working groups and review case studies:** LSO recommends that PMPRB work more closely with industry on its permanent guidelines approach, including by 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.
- **Work within the PMPRB's mandate:** Recent legal 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 and jurisdictional 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, including bolstering our strained health system by ensuring access to innovative research, medicines and vaccines.

- The PMPRB's approach should also align with and support the federal government's rare disease drug strategy, which aims to increase access to orphan medicines and spur R&D in rare diseases.
- Finally, emerging and established provincial life sciences strategies are making important strides in boosting our sector. In Ontario, for example, our government's strategy relies upon a federal regulatory system that provides clarity and certainty for long-term research and commercial decisions, and the PMPRB Guidelines continue to be an important factor in this context.

Thank you for the opportunity to provide our input.

Sincerely,

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[1] Life Sciences Ontario commissioned research from IQVIA (2022), Is Canada Losing its status as a priority medicine launch Country: https://lifesciencesontario.ca/is-canada-losing-its-status-as-a-priority-medicine-launch-country-preview_id6648preview_nonce0772186744previewtrue/

[2] Research Etc. (2021) Health Canada Pricing Reform Research Report, https://lifesciencesontario.ca/new-survey-data-federal-drug-pricing-regulations-are-already-stopping-what-canadians-wantaccess-to-new-medicines-as-soon-as-possible/