

December 20, 2023

Patented Medicines Prices Review Board
Box L40 Standard Life Canada
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Subject – Feedback on Scoping paper for the consultations on the Board’s Guidelines

Dear PMPRB Board Members,

On behalf of Life Sciences Ontario (LSO), thank you for providing the opportunity to provide feedback on the PMPRB’s first phase of consultations on its new Guidelines.

LSO is a fully member funded not-for-profit organization dedicated to championing Ontario’s dynamic life sciences sector. Our focus is on advocating for public policies that support the growth and advancement of the sector. We collaborate with government, academia, industry, and other life sciences organizations in Ontario and across Canada to promote and encourage commercial success throughout the sector. Unlike most industry associations, LSO is unique, as we represent the entire life sciences ecosystem in Ontario, ranging from academic institutions, service providers and SMEs to large companies.

LSO has been actively monitoring and engaging with the PMPRB on its proposed changes since their introduction in 2017. From the outset, our focus has been on advocating for public policies that support the growth and advancement of the life sciences sector. Importantly, 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.¹ 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. Looking at this year, as of August 2023, Canada witnessed only about nine new medicine launches, when we should have experienced double that number.²

Unfortunately, the decline in new medicine launches in Canada is unsurprising, and largely supports the results of an earlier 2021 survey of 46 life sciences executives (from both Canadian affiliates and global companies, as well as both large and small companies), which found that

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 IQVIA PharmaFocus Update Briefings, October 2023

98% of respondents reported that the proposed PMPRB changes would negatively impact their overall business plans, including product launches, investments, employment, and clinical trials.³

Clearly, the rising uncertainty surrounding the regulatory changes over the past several years has deteriorated Canada's access to new medicines and research investments, which inhibits both innovation and economic development. While it's hard to quantify the absence of something like investments, we know without a doubt that we have lost opportunities due to this ongoing uncertainty.

Moving forward, the PMPRB has an important role to play in supporting Canada's ability to attract life sciences investments and new medicine launches, recognizing that Canada represents about 2% of the global market for pharmaceuticals. In this context, we are pleased to provide the following general recommendations and considerations with respect to the PMPRB's approach for the 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 situations), collaboratively.
- **Establish clear and predictable rules:** Clear, fair, and effective guidelines will contribute to regulatory certainty and support new medicine launches and ongoing innovation and investment in the life sciences sector. LSO recommends that the PMPRB collaborates with industry experts in drafting these rules to ensure they are practical and conducive to the dynamic needs of the life sciences sector.
- **Work within the PMPRB's mandate:** Recent legal decisions have clarified that the PMPRB's mandate is to prevent abuse of patent through excessive pricing rather than determine reasonable pricing of pharmaceuticals. Whatever approach the PMPRB moves forward with for the final guidelines, it should be aligned with this clarified mandate, recognizing that there are other stakeholders within the system who contribute to managing affordability.
- **Align with broader government and jurisdictional priorities:** The PMPRB's final guidelines should be closely aligned with the spirit and intent of federal and provincial life sciences growth strategies and related national initiatives and priorities, including bolstering our strained healthcare system and supporting the federal rare disease drug strategy by ensuring access to innovative research, medicines and vaccines.

We would like to once again thank the PMPRB board and staff for the opportunity to provide LSO's perspectives on the development of the new guidelines. The life sciences sector is Canada's greatest untapped potential, but we must acknowledge the complexity of the sector. The intricate web of challenges and opportunities demands a comprehensive strategy. We continue to stress the importance of the whole-of-government approach. Ongoing engagement

³ Research Etc. (2021) Health Canada Pricing Reform Research Report, <https://lifesciencesontario.ca/new-survey-data-federal-drug-pricing-regulations-are-already-stopping-what-canadians-want-access-to-new-medicines-as-soon-as-possible/>

with stakeholders is a necessary step in creating a viable life sciences sector in Canada and ensuring that Canadians have access to new medicines in a timely manner.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Field", is enclosed in a light grey rectangular box.

Dr. Jason Field
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