September 11, 2024

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

Subject: Feedback on Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations

Dear PMPRB Board Members,

On behalf of Life Sciences Ontario (LSO), thank you for the opportunity to provide feedback on the above-noted consultation.

As a not-for-profit organization that represents and promotes Ontario's vibrant and diverse life sciences sector, LSO has monitored, engaged and researched the proposed changes to the PMPRB since the reform process began in 2017. In this context, we are well positioned to shine light on some of the challenges and opportunities that impact 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 and have shared the findings with the PMPRB and other stakeholders.

For example, in 2022, LSO commissioned 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.[1] From 2017-2021, there were an average of 34 annual new medicine launches globally but an average of just 20 per year in 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 have been 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 were so problematic to the sector.[2]

These examples illustrate the impacts of the PMPRB's pricing policies on access to innovation and life sciences investment, and the importance of ensuring clarity, certainty and fairness, recognizing that Canada represents just about 2% of the global market for pharmaceuticals.

Our members consistently raise concerns that the PMPRB's approach to price regulation may create uncertainty, making Canada a less attractive market for launching new medicines compared to peer countries. This could have long-term consequences for our healthcare system, patients, and the life sciences ecosystem.

In this context, we are pleased to provide the following general recommendations and considerations that should be considered with respect to the PMPRB's approach on updated guidelines.

1) **Provide certainty by reserving in-depth reviews for "outliers," and avoid applying the new guidelines retroactively:** Intellectual property rights are a critical pillar of our knowledge-based society and a key driver of life sciences research, development and commercialization. In this context, triggers for in-depth reviews to consider whether a price may be "excessive" need to be reserved for rare cases (i.e., prices above the Highest International Price in the new basket of comparator countries). The updated basket of countries cannot be applied to medicines that are currently on the market which were commercialized under a different regulatory framework, as prices for those medicines, even if some are above the new highest international price, cannot be considered a case of patent abuse. It would also be a massive administrative and economic drag on key parts of our pharmaceutical supply chain if the new guidelines were applied retroactively.
2) **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.
3) **Align with broader government and jurisdictional priorities:** The PMPRB's Discussion Guide states that addressing issues outside its statutory authority would limit its ability to establish transparent, predictable and procedurally fair Guidelines. However, updated Guidelines and the PMPRB's execution of its mandate do not occur in a vacuum. As noted above and in our research, the PMPRB's regulatory role has a direct and indirect influence on key decisions on whether and when to invest in research and commercialization of new medicines. In this context, we still strongly believe that the PMPRB's guidelines approach must be aligned with ongoing federal and provinical life sciences priorities and initiatives, including:
    - The federal government's efforts to support life sciences growth and create 'world class regulation' for our sector through the fifth pillar of the Biomanufacturing and Life Sciences Strategy
    - The federal government's rare disease drug strategy, which aims to increase access to orphan medicines and spur R&D in rare diseases
    - Emerging and established provincial life sciences strategies. For example, Ontario's strategy relies on 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.

4) **Review or consider the impact of price reviews:** Previous guidelines consultations included an impact report as a key element, such as the Guidelines Monitoring and Evaluation Plan. LSO recommends that the PMPRB consider a monitoring plan undertaken by an independent third-party with expertise in policy, regulatory and program evaluation to support alignment with broader government and jurisdictional priorities.

In sum, the ability to attract new medicines, clinical trials, foster collaborations with international pharmaceutical companies, and encourage investment in early-stage biotech companies is crucial to maintaining Canada's standing as a hub for life sciences innovation.

Moving forward, we encourage the PMPRB to ensure that the guidelines reforms consider these important aspects and take steps to mitigate any unintended consequences on Canada's life sciences industry.

Thank you for the opportunity to provide our insights and input.

Sincerely,

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About Life Sciences Ontario

Life Sciences Ontario (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, LSO's 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.

REFERENCES:

[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/