March 18th, 2025

Patented Medicine Prices Review Board (PMPRB)
Box L40
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
K1P 1C1

Subject: Feedback on Administrative Process for Excessive Price Hearing Recommendation

Dear PMPRB Board Members,

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

LSO is a member-funded, not-for-profit organization that represents and promotes Ontario's vibrant and diverse life sciences sector. LSO's mission is to foster commercial success for Ontario's life sciences sector through advocacy and education, and to promote the industry locally, nationally and internationally.

Canada's life sciences sector is among the most-research intensive sectors in the country, and a key driver of Canada's economic growth and competitiveness. Ontario alone is currently home to one of the largest life sciences clusters in North America. The sector supports a thriving research and innovation ecosystem, contributes over $58 billion to Ontario's GDP, and provides approximately 200,000 jobs, direct and indirect, in the province.[i]

As an organization committed to championing Ontario's life sciences sector, LSO has monitored, engaged, and researched the proposed changes to the PMPRB since the reform process began in 2017. In doing so, we have consistently supported evidence-based policymaking and shared our findings with the PMPRB, all levels of government, and our stakeholders.

Given the increasing political tension between Canada and our neighbouring ally, the U.S., it is crucial for Canada to reassess its political landscape in order to attract more investments, bring in companies, and create jobs, ultimately fostering greater self-sufficiency as a country. 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.[ii] From 2017-2021,

Life Sciences Ontario
162 Cumberland Street, Suite 310
Toronto, Ontario M5R 3N5
E: admin@lifesciencesontario.ca
www.lifesciencesontario.ca

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 largely linked to the PMPRB reforms, which aimed to lower drug prices but inadvertently created significant uncertainty for pharmaceutical companies. The original regulatory approach included multiple layers of price-cutting mechanisms that would have led to substantial price reductions, particularly for treatments for cancer and other serious illnesses. Pharmaceutical companies are hesitant to launch new drugs in Canada due to uncertainty about how the PMPRB will enforce new pricing regulations. This uncertainty has led companies to delay or reconsider introducing innovative medicines in the country.[iii]

The newly proposed administrative process for excessive price hearings under the PMPRB is a complex system that could introduce significant uncertainty and unpredictability for pharmaceutical companies. From an industry perspective, the reliance on a two-step review process – beginning with an initial or annual review, followed by an in-depth review for high-risk drugs – raises concerns. While the guidelines are designed to help identify which medicines are at greater risk of being priced excessively, the lack of clarity about how drugs will be selected for further review can result in delays and raises questions about whether global leadership will consider Canada for new launches. Additionally, the administrative burden imposed by the hearings can be a deterrent for companies. If a product faces an in-depth review and potentially lengthy hearing process, it creates a risk that will lead some companies to delay launches in Canada or avoid it altogether.

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. The risk of an unpredictable review process will not only contribute to delays in market entry, but also prevent patients from accessing critical, life-changing therapies. Moreover, if Canada is seen as a less favourable market for new launches due to regulatory uncertainty, pharmaceutical companies may prioritize other markets over Canada, further exacerbating the delay in access to life saving treatments.

For Canada to remain an attractive market for pharmaceutical investment, there needs to be an alignment between the goals of fast access to medication and a clear and predictable pricing environment. This alignment is critical given the ongoing trade war between Canada and the U.S.. The ongoing trade war has created uncertainty in cross-border business, particularly for critical industries like pharmaceuticals, which depend on strong trade relationships and regulatory alignment between neighbouring countries. Given the current state of international trade relations and heightened competition for investment, Canada's regulatory unpredictability risks

placing it at a disadvantage compared to markets that offer clearer, more stable pricing frameworks.

Considering these circumstances, aligning all levels of government on regulatory matters is crucial for fostering a predictable and competitive environment. Ontario Premier Doug Ford's commitment to accelerating the delivery of medicines to patients is an important step in the right direction. If the PMPRB's pricing reviews can be aligned with the provincial commitment to fast-tracking access to medicines, there is an opportunity to balance affordability with innovation. Moreover, in a time when international trade relations are under unprecedented strain, it is crucial that Canada strengthens its regulatory credibility to maintain its competitiveness in the global market. Aligning federal and provincial policies, and providing a clear, transparent and predicable environment will be key to keeping Canada competitive.

In this context, LSO is pleased to provide the following general recommendations and considerations that should be considered with respect to the administrative process on excessive price hearing.

1) **Provide certainty by reserving in-depth reviews for "outliers," and avoid applying 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 proposed administrative process for excessive price hearings is a significant shift in direction. However, as we've noted, this process adds another layer of uncertainty and unpredictability. 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. With the added pressures of the ongoing trade war, we strongly believe that the PMPRB's guidelines approach must be aligned with ongoing federal and provincial life sciences priorities and initiatives, including:

a. 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.[iv]
b. The federal government's rare disease strategy, which aims to increase access to orphan medicines and spur R&D in rare diseases.[v]
c. 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.

LSO strongly encourages the PMPRB to consider the recommendations outlined above to create a more predictable and balanced regulatory environment. By providing greater certainty, collaborating with industry stakeholders, aligning with broader government priorities, and considering the broader impacts of these reforms, Canada will attract investment, foster innovation, encourage investment in early-stage biotech companies and ensure timely access to life-saving medications for patients. If these concerns remain unaddressed, Canada risks further declines in life sciences investment, compounding the challenges of the ongoing trade war with the U.S.. This would delay access to critical, life-changing therapies and could result in long-term economic consequences, such as reduced global investments and a diminished role in global innovation.

We encourage the PMPRB to ensure that a holistic approach considers these important aspects and takes the necessary steps to mitigate any intended consequences on Canada's life sciences industry.

Thank you for the opportunity to provide our insights.

Sincerely,

Life Sciences Ontario
162 Cumberland Street, Suite 310
Toronto, Ontario M5R 3N5
E: admin@lifesciencesontario.ca
www.lifesciencesontario.ca

Jason Field
President & CEO
Life Sciences Ontario
C: (647) 821-3392
jason.field@lifesciencesontario.ca

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[i] https://lifesciencesontario.ca/accelerating-prosperity-the-life-sciences-sector-in-ontario/

[ii] 1Life 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/

[iii] Nigel Rawson and Brett Skinner, "Uncertainty about PMPRB price regulations will deter new drug launches in Canada," *Canadian Health Policy Journal, September 7, 2022*: ps://canadianhealthpolicy.com/opnions/on-going-uncertainty-about-prices-will-deter-new-drug-launches-in-canada/).

[iv] Innovation, Science and Economic Development Canada. "*Canada's Biomanufacturing and Life Sciences Strategy."* Innovation, Sciences and Economic Development Canada. http://ised-isde.canada.ca/cite/biomanufacturing/en/canadas-biomanufacturing-and-life-sciences-strategy.

[v] Health Canada. "*Strategy for Drugs for Rare Diseases."* Government of Canada. http:// www.canada.ca/en/health-canada/services/health-care-systems/national-pharmacare/strategy-drugs-rare-diseases.html.