**2022 Proposed Updates to the PMPRB Guidelines Consultation:**
**LEO Pharma Inc. Submission**

Dermatology
beyond the skin

**LEO Pharma Inc**
3389 Steeles Avenue East
Suite 110
Toronto, ON
M2H 3S8

Main +1 905 886 9822
+1 800 668 7234
(toll-free, Canada only)

www.leo-pharma.ca

November 29th, 2022

Submitted via the PMPRB Website: Consultation Submission Portal

Dear PMPRB Board Members,

Thank you for the opportunity to provide input on the proposed changes to the Patented Medicine Prices Review Board (PMPRB) guidelines (the Draft Guidelines) following the recent publication of the amendments to the *Patent Medicines Regulations*. This submission builds on our previous submissions throughout this process and is complementary to that of Innovative Medicines Canada (IMC).

LEO Pharma A/S is a global leader in medical dermatology with a mission of helping people achieve healthy skin. The company is based in Denmark and is privately owned by the LEO foundation, focusing on advancing science in Dermatology. LEO Pharma has a robust R&D pipeline, a wide range of therapies and a pioneering spirit. Globally, LEO Pharma invests 23% of revenue in R&D. LEO Pharma actively promotes growth in innovation and collaboration in the Canadian life science sector.

While we support health system reform that leads to improved health outcomes for patients and sustainability of the health system, the adoption of a completely different approach to determining excessive pricing in the PMPRB guidelines introduces great uncertainty for existing and new innovative medicines. As such, we urge PMPRB to suspend their current proposed changes to the guidelines and collaborate with rights holders in developing clearly defined guidelines by establishing a more robust consultation process in 2023. LEO Pharma has identified the following challenges and strongly urge PMPRB to consider the following:

1) **The proposed Draft Guidelines are inconsistent with the mandate of the PMPRB to regulate excessive pricing.**
The Draft Guidelines appear to be in favor of regulating pharmaceutical prices downward, which should be an area of exclusive provincial jurisdiction. This is misaligned to the recent appellate court decisions that have constrained the role of the PMPRB within its proper constitutional and legislative limits. Moreover, the introduction of Median International Price (MIP) as investigation criteria is inconsistent with controlling patent abuse in accordance with section 85 of the Patent Act.

2) **The proposed Draft Guidelines lack clarity and predictability.**
The PMPRB guidelines must exhibit a predictable set of rules in determining excessive pricing; the current proposed changes are based on a series of

Dermatology
beyond the skin

arbitrary investigation triggers which drive an open-ended approach that provides an unbalanced amount of power in favor of the Board staff in determining when an investigation will be triggered. These broad, open-ended powers that permit Board staff to trigger investigations and recommend hearings based on their own perceptions do not provide a sufficient level of clarity to allow companies to perform the robust pricing analysis that is required to determine likely compliance requirements and before launching a medicine in Canada.

We foresee this creating significant challenges in the launch of new medicines in Canada, both in terms of understanding what price will be considered 'non-excessive' at launch and what prices will be acceptable throughout the life cycle of the product. Moreover, moving away from the previous voluntary compliance system will likely result in a less predictable, more litigious and administratively onerous system; all of which will likely result in fewer clinical trials and delay or prevent drug launches in Canada, ultimately impacting future access to new medicines for Canadian patients.

Moreover, the Draft Guidelines currently would allow the PMPRB to inappropriately force ceiling prices downward over time through annual price reviews. As such, we ask that PMPRB provide greater clarity in the application of consumer price index (CPI), the implications and impact of new indications for existing products and the international pricing provisions (i.e., impact of perpetual re-benching as international prices fluctuate).

3) **No therapeutic differentiation or recognition of innovation.**
The newly proposed "investigation criteria" approach which utilizes the domestic therapeutic class comparison (dTCC) to lower prices below the PMPRB 11 median removes any recognition of innovation or differentiation between therapeutic improvement, especially considering that new innovative medicines may be compared to generic drugs, whose prices are set and managed by other, non-PMPRB related mechanisms. The lack of recognition for innovation may have several unintended consequences including, but not limited to 1) decrease in competition in a given therapeutic class, thereby limiting the ability of payers to negotiate the best price 2) difficulties/deterrence in conducting clinical trials at Canadian sites and 3) decreased investments in new, innovative medicines in Canada, ultimately resulting in fewer options for patients.

Thank you for considering our input on the proposed changes to the Patented Medicine Prices Review Board (PMPRB) guidelines. We are hopeful that PMPRB will consider these concerns and make the changes necessary to prioritize access to innovative medicines in Canada.

Sincerely,

**Jill Archibald**
President and CEO, LEO Pharma Canada