2024 PMPRB Consultation: Discussion Guide on the Board's Guidelines
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

September 6, 2024

Submitted via the PMPRB Website: Consultation Portal

Dear PMPRB Board Members,

Thank you for the opportunity to provide input on the Discussion Guide on the Board's Guidelines. This submission builds on our previous submissions throughout this process and complements the perspectives 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 16% of revenue in R&D. LEO Pharma actively promotes growth in innovation and collaboration in the Canadian life science sector.

In relation to the topics and questions outlined in the Discussion Guide, LEO Pharma would like to express the following sentiments:

Topic 1: Price level within the PMPRB11 to be used in the initial and post-initial price review.

Consistent with our previous submission, LEO Pharma recommends adopting the Highest International Price (HIP) as this threshold is consistent with an excessive pricing standard and therefore, is in alignment with the PMPRB's mandate.

Clear and predictable PMPRB Guidelines are crucial for informed pricing, launch timelines, and investment decisions in Canada. The proposed annual post-initial price review introduces unpredictability akin to price control, which conflicts with the PMPRB mandate with regards to excessive pricing and patent abuse. LEO Pharma suggests routine compliance monitoring with the CPI-adjusted price benchmark established at a medicine's introduction, without annual re-benchmarking.

Topic 2: The length of time Staff should wait, following the implementation of the Guidelines, to determine whether the IPC identification criteria for an Existing medicine is met.

The PMPRB should proceed with option 3, the three-year transition period, to allow patentees and stakeholders in the broader complex supply chain ecosystem adequate time to make the necessary adjustments to come into compliance.

Dermatology
beyond the skin

Topic 3: In-depth review based on CPI increase criteria.

Per the *Patent Act,* Consumer Price Index (CPI) adjustments are permitted and as such, the New Guidelines must allow an adjustment of price over time. However, the interplay between the annual price reviews and CPI-adjustment was unclear in the discussion guide and specific IMC queries with regards to this were not answered at the August 13th, 2024, webinar. More technical details regarding the relationship between annual price reviews and allowable CPI-adjustments are required prior to choosing an appropriate option.

Topic 4: individuals/groups permitted to submit a complaint.

Option 1 (limiting complaints to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts) is the most appropriate path forward as it keeps the eligibility for complaints narrow and consistent with s.86(2) of the Patent Act.

Topic 5: expanding the list of products that would only be subject to an in-depth review following a complaint to include biosimilars and/or vaccines
and
Topic 6: Use of clinical evidence to contextualize the degree of similarity of comparators identified for the TCC.

There is currently insufficient detail in the discussion guide to provide the PMPRB with thoughtful input on these 2 topics. LEO Pharma requests that the PMPRB address the outstanding queries conveyed in the IMC submission to help patentees formulate well-informed feedback.

Topic 7: Future role of HDAP.

There is currently insufficient detail in the discussion guide to provide the PMPRB with thoughtful input on the future role of HDAP. Without further detail on how the scientific review process is envisioned to operate and the implications on the determination of excessive price, it is premature to comment on what role, if any, HDAP may or may not have.

In closing, we commend the PMPRB for its efforts in developing the discussion guide and encourage the PMPRB to engage in direct dialogue with IMC during the consultation process to support the development of fundamentally sound Guidelines. As a global leader in medical dermatology, PMPRB Guidelines play a critical role in our operations as it informs pricing decisions, launch timelines, and investment decisions in Canada. We are confident that through meaningful dialogue and careful analysis, we can achieve a set of predictable and clear Guidelines that benefit patients and ensure that Canadian patients can continue to access the medicines they need.

Thank you for considering our input on the Discussion Guide on the Board's guidelines.

Sincerely,

Jill Archibald

Electronically signed by: Jill Archibald
Reason: I'm an approver
Date: Sep 6, 2024 13:45 EDT

Jill Archibald
President and CEO, LEO Pharma Canada

LEO Pharma_PMPRB Discussion Guide Consultation Submission_Sept 2024_FINAL

Final Audit Report 2024-09-06

Created:	2024-09-06
By:	Patricia Lam (PALLA@leo-pharma.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA1ylkKbJIiyP3dmXqldqbXE56hsSD-A_e

"LEO Pharma_PMPRB Discussion Guide Consultation Submission_Sept 2024_FINAL" History

Document created by Patricia Lam (PALLA@leo-pharma.com)
2024-09-06 - 3:32:19 PM GMT- IP address: 69.159.41.186

Document emailed to Jill Archibald (JIARC@leo-pharma.com) for signature
2024-09-06 - 3:32:59 PM GMT

Jill Archibald (JIARC@leo-pharma.com) authenticated with Adobe Acrobat Sign.
Challenge: The user completed the signing ceremony.
2024-09-06 - 5:45:23 PM GMT

Document e-signed by Jill Archibald (JIARC@leo-pharma.com)
Signing reason: I'm an approver
Signature Date: 2024-09-06 - 5:45:24 PM GMT - Time Source: server- IP address: 76.68.53.133

Agreement completed.
2024-09-06 - 5:45:24 PM GMT