

**2023 PMPRB Consultation: Amendment to the Interim Guidance re: New Medicines  
LEO Pharma Inc. Submission**



● **Dermatology**  
beyond the skin

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August 21<sup>st</sup>, 2023

Submitted via the PMPRB Website: [Consultation Submission Portal](#)

Dear PMPRB Board Members,

Thank you for the opportunity to provide input on the proposed update to the approach for conducting interim price reviews on new medicines, pending the development of new guidelines. 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.

In response to the proposed amendments to the interim guidance, LEO Pharma would like to express the following concerns:

1. The current interim guidance lacks clarity regarding the allowable CPI adjustments under the interim guidance for all medicines. As CPI is specifically referenced in the *Patent Act*, LEO Pharma requests that PMPRB continue to update its *CPI-Based Price-Adjustment Factors for Patented Drug Products* and provide greater clarity that a price increase alone within the range of CPI for 2023 and ongoing, will not cause a product to be “under review” or trigger an investigation.
2. Moreover, the PMPRB has not clearly defined the price ceiling that will be used for determining compliance for Existing Medicines for the 2023 reporting period (i.e., N-ATP measured against the 2023 N-NEAP calculated using the 2023 CPI % posted on the PMPRB website). LEO Pharma requests that PMPRB provide clarity on the 2023 price ceiling to ensure rights holders are informed well in advance of the H2 reporting deadline.



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3. The interim guidance appears to encourage price points of New Medicines that are inappropriate when placed in the context of the PMPRB's mandate. The "below median" price point used in determining whether a product be "considered as reviewed" in the interim guidance is inconsistent with PMPRB's *excessive price* mandate and recent court decisions.
  
4. Based on the proposed updates to the interim guidance, a product will be established as "reviewed" or "under review" dependent on whether the price is above or below the MIP of the PMPRB11 basket of countries. However, there is still inherent unpredictability with this approach as there is no assurance of impact and consequences once the draft Guidelines are published. To provide further predictability, LEO Pharma proposes that a statement, in addition to the "*no retrospective calculation of revenues*", be published that the PMPRB staff will not reassess or re-benchmark New Medicines, provided its list price does not increase by more than CPI.

Thank you for considering our input on the proposed amendment to the interim guidance. We are hopeful that PMPRB will consider these concerns and make the changes necessary to ensure that the guidelines are clear, predictable, and implementable.

Sincerely,

*Jill Archibald*  
Electronically signed by:  
Jill Archibald  
Reason: I'm an approver  
Date: Aug 16, 2023  
11:24 EDT

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







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Final Audit Report

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