2025 PMPRB Consultation: PMPRB Draft Guidelines
LEO Pharma Inc. Submission

Dermatology beyond the skin

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Submitted via the PMPRB Website: Consultation Portal

Dear PMPRB Board Members,

Thank you for the opportunity to provide input on the Draft Guidelines for PMPRB Staff. 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 company dedicated to advancing the standard of care for the benefit of people with skin conditions, their families and society. The company is based in Denmark and is majority owned by the LEO Foundation, with a focus on advancing science in dermatology. Through our unmatched passion, expertise, scientific partnerships and more than 115 years' experience in medical dermatology, LEO pharma is dedicated to transforming innovative ideas into more effective and easier-to-use medicines that meet unmet needs of people living with, and suffering from skin conditions.

LEO Pharma would like to express the following sentiments as it relates to the Draft Guidelines for PMPRB staff:

International Price Referencing

LEO Pharma believes that the PMPRB has taken a judicious approach in anchoring to the highest international median (HIP). As written in our previous submission, LEO Pharma sees the HIP as the threshold that is most consistent with an excessive pricing standard – as such, it is imperative that the HIP is maintained in the Final Guidelines.

Annual Price Reviews

The proposal of annual price reviews introduces arbitrary price reductions as a result of yearly re-benchmarking of international prices. This approach lacks predictability where rights holders may not be able to determine an allowable price throughout the product life cycle. LEO Pharma requests the PMPRB consider routine compliance monitoring with the CPI-adjusted price benchmark established at a medicine's introduction, without annual re-benchmarking.

Moreover, fluctuations in exchange rates also introduces a factor of unpredictability. LEO Pharma suggests that the PMPRB include reasonable buffers or tolerance factors to ensure changes in exchange rates do not result in unnecessary regulatory burden when domestic prices are otherwise stable.

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Existing Products and Transition Period

LEO Pharma requests that the PMPRB incorporate an exemption for existing products, and their line extensions (i.e., medicines with a first sale reported prior to July 1, 2022), in the Final Guidelines. Existing products were already deemed compliant and therefore non-excessive with the applicable legislation and Guidelines, given that the amended Regulations did not change the excessive price factors under the *Patent Act*. Existing products should not be subject to investigations under the new Guidelines provided their pricing remains stable, with CPI allowable adjustments.

PMPRB has proposed a transition period of one year. LEO Pharma requests that the PMPRB implement a three-year transition period for existing products to allow sufficient time for rights holders to come into compliance and for other stakeholders in the Canadian pharmaceutical supply chain (e.g., pharmacists, distributors, and generic manufacturers) to adjust to the new policy environment.

Complaints Process

Under the current Draft Guidelines, complaints automatically result in in-depth reviews with no mechanism to prevent arbitrary complaints that result in unnecessary review burden. LEO Pharma suggests the PMPRB establish a reasonable complaints resolution mechanism that anchors to validating complaints against the HIP standard and resolve complaints where pricing is at or below the HIP, without the need for an in-depth review. Moreover, to ensure consistency with s.86(2) of the *Patent Act*, eligibility for complaints should be restricted to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts – it should not include for-profit commercial insurance companies and their associations.

In-depth Reviews

LEO Pharma is unclear on the practicality of the proposed in-depth review process. The introduction of therapeutic comparability tiers appears to rely on subjective decisions made by PMPRB staff. This introduces uncertainty for rights holders throughout the in-depth review process as there is no way for a rights holder to predict the outcome of an in-depth review. LEO Pharma suggests that the PMPRB work together with technical working groups to identify a clearer path forward.

Moreover, clarity is needed regarding the date to which excess revenue calculations is applied. More specifically, LEO Pharma suggests written clarity that excess revenue calculations will not be retroactive to the time of product launch, but rather will only apply to the period in which a complaint is received, or an in-depth review is initiated.

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. In closing, we ask that the PMPRB consider our input above and continue to work with technical working groups to develop a set of even clearer and more predictable Final Guidelines.

Thank you for your consideration of our submission.

Sincerely,

Jill Archibald

Electronically signed by: Jill Archibald
Reason: I'm the author
Date: Mar 5, 2025 14:30 EST

Jill Archibald
President and CEO, LEO Pharma Canada

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