



Submission to the PMPRB Interim Approach Consultation LEO Pharma Inc.

● Dermatology
beyond the skin

July 18th, 2022

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

Dear PMPRB Board Members,

Thank you for the opportunity to provide input on the PMPRB's Price Review Approach During the Interim Period following publication of Amendments to the Patented Medicines Regulations Guidelines (*Notice and Comment – June 30, 2022*). 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 A/S 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, we have continuously expressed significant fundamental concerns in our previous four consultation submissions. In addition to the recommendations we have previously made, we strongly urge PMPRB to consider the following:

- 1) **Provide patentees with clear direction on when we must come into compliance (i.e., transition period) after the final Guidelines are published.** We believe that a full twelve-month (two reporting periods) transition period, consistent to the transition period PMPRB previously committed to on April 16, 2021, would be required following the finalization of the new Guidelines to allow us to modify our business plans to the new regime. With no visibility into the nature of the new Guidelines during the "interim period", our interpretation currently is that the "interim period" is separate from that of the "transition period" and would appreciate PMPRB's confirmation on this front.

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- 2) **Provide additional information on what constitutes as the “non-excessive average price (NEAP)” applicable during the interim period.** While the Interim approach states that the PMPRB “*will not conduct a price review of any new patented medicines or open any investigations in respect of them until the new guidelines come into effect*”, this does not provide sufficient guidance as to what price will be considered ‘non-excessive’ during this period. This uncertainty should be addressed in the Interim Approach by stating that manufacturers will not be required to pay back any inadvertent excess revenues accrued during the interim period.
- 3) **Increases in list prices of existing patented medicines should be allowed without triggering an investigation during the Interim Period.** As proposed in the Interim Guidance, PMPRB has decided to take a “status quo” approach to carrying out its regulatory mandate. With such an intent, the PMPRB should allow list prices of existing patented medicines to increase (according to the CPI-Adjustment Methodology) without triggering an investigation during the Interim Period. This consideration should also apply in the event that the Interim Period extends beyond December 2022.
- 4) **The new Guidelines should be grounded in the mandate of the PMPRB.** The PMPRB’s mandate is to ensure that prices are non-excessive in the context of patent abuse, as confirmed by recent court decisions (see e.g., *Innovative Medicines Canada v Canada (AG)*, 2020 FC 725, appeal under reserve in Court File No. A-215-20.), and to continue to consider all the factors laid out in the Regulations. As a company devoted to growth and innovation, we believe that innovation and the life sciences sector are key drivers of economic growth, improved health outcomes, and long-term health system sustainability. By introducing uncertainty, even in these interim measures, the R&D ecosystem in Canada continues to erode, diminishing the health and economic benefits that result from it.

Thank you for considering our input on the PMPRB’s Price Review Approach published in Notice and Comment (June 30, 2022). We look forward to the outcomes of this consultation as well as further discussions on the PMPRB’s new permanent Guidelines in the Fall of 2022.

Sincerely,

Jill Archibald
President and CEO, LEO Pharma Canada