



Submission to PMPRB Guidelines Consultation LEO Pharma Inc.

• Dermatology
beyond the skin

LEO Pharma Inc.
123 Commerce Valley
Drive East
Suite 400
Thornhill, ON L3T 7W8

Phone 905.886.9822
Fax 905.886.6622

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Dear PMPRB Board Members,

Thank you for the opportunity to provide input on the PMPRB's draft Guidelines regarding the implementation of the newly amended *Patented Medicines Regulations*. Our submission is complementary to that of Innovative Medicines Canada (IMC) and the Danish Life Science Forum.

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. LEO Pharma Canada has approximately 100 Canadian employees and invested 14% of our Canadian revenue in development activities in Canada alone. Globally, LEO Pharma invests 25% of revenue in R&D. LEO Pharma actively promotes growth in innovation and collaboration in life science in Canada. LEO Innovation Lab (iLabs), is an example of how LEO is fostering growth in life sciences. LEO iLabs develops digital solutions for patients with skin conditions with an aim to go beyond medicinal interventions. LEO Innovation Lab invests and partners with startups in Canada and beyond, to foster innovation and creativity in apps, web platforms, wearables, virtual reality, artificial intelligence, tele-medicine and other advance technologies. LEO Pharma also invests in LEO Open Innovation, a collaborative space created to explore research with the goal of finding next-generation treatments. Open Innovation allows any organization insights and access to LEO Pharma's research tools to test their molecules for free. Open Innovation has recently launched in Canada, with events held in both British Columbia and Ontario.

While we support health system reform that leads to improved health outcomes for patients and sustainability of the health system, the PMPRB's draft Guidelines published in November 2019 pose fundamental concerns with its regulatory approach and operational feasibility.

In the light of above, LEO Pharma would like to extend the following recommendations to support a more functional pricing framework.

1) Employ economic factors in exceptional cases only

The new economic factors proposed by the draft Guideline are fundamentally flawed and do not yield reliable prediction of allowable prices for new medicines.



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The use of QALYs to assess cost-effectiveness has limitations and does not fully capture all dimensions of health value.¹ PMPRB proposes to source pharmacoeconomic analysis from two Health Technology Assessment (HTA) bodies in Canada, namely Canadian Agency for Drugs and Technologies in Health (CADTH) and Institut national d'excellence en santé et services sociaux (INESSS).

It is important to note that CADTH and INESSS often have widely differing assessments of economic value of medicines due to different perspectives and methods they employ in their analyses. The analyses conducted by the two agencies can also diverge greatly from the analysis submitted by the patentees, demonstrating how subjective and wide of a range a medicine's QALY values can be. In addition, the economic models at CADTH and INESSS take the perspective of a publicly funded health care payer and /or a broader societal perspective. These models are unlikely to be relevant for medicines that are predominantly reimbursed through the private payer system. Therefore, the use of pharmacoeconomic factors will lead to arbitrary decisions about the net price for a new medicine in Canada.

The market size adjustment is also unreasonable and represents revenue control as opposed to price regulation, which is beyond the PMPRB's jurisdiction. The way PMPRB anticipates using units to calculate the annual revenue is also significantly flawed and poses challenges in cases where free-goods penalize patentees as they are incorporated into PMPRB's market size calculation.

For the above reasons, we strongly recommend using the new economic factors in exceptional circumstances only. For instance, they can be employed as a supplementary tool by PMPRB during the hearing or investigation process to assess potential price excessiveness.

2) Grandfather existing products completely or commit to a fair and reasonable transition

Based on the PMPRB proposed draft Guidelines, no products are truly "grandfathered". Grandfathering entails exempting existing products from a new law or regulation. Existing medicines should not be held to any of the new rules in the draft Guidelines, which is a fair and reasonable expectation given that business decisions have been made based upon patentee compliance with the current PMPRB regime.

While we believe in complete grandfathering of existing products, we are open to discussing more reasonable transition measures. According to the published case studies by PMPRB in December 2018, the forecasted medicine price reductions range from 40-70%². Any company or industry would agree that this level of revenue decline is not acceptable nor sustainable. At a minimum, a more gradual transition for existing products is required.

We propose that the existing products are exempt from the new rules in 2021. In the event that "grandfathered" products are subjected to new pricing rules, we propose a gradual phased reduction scheme with set maximum annual price reduction limits (i.e. x% negative list price impact) until the total price reduction requirement is reached. This type of transition measure is much more fair, practical and manageable.

¹ Knapp, M. "Economic outcomes and levers: impacts for individuals and society" *Int Psychogeriatr*. 2007 Jun;19(3):483-95, <https://www.ncbi.nlm.nih.gov/pubmed/17391570>

² PMPRB Guidelines Modernization case studies: <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1419>



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3) Set up industry working groups to demonstrate how PMPRB will operationalize the regulations

The draft Guideline presents lack of clarity and insufficient information to predict allowable ceiling prices for current and future products. The sheer volume of questions and concerns raised by the industry representatives, patient organizations and provincial governments in the last two months since the publication of the draft Guidelines signals that there is significant uncertainty and confusion as to how to operationalize the new rules. This unpredictability impedes pricing and launch decisions at the global level for the Canadian market.

On top of the significant uncertainty posed by the PMPRB draft Guidelines, the financial impact to the industry is assessed to be \$41.8 billion NPV over 10 years, in contrast to Health Canada's cost-benefit analysis (CBA) calculation of \$8.8 billion.³

This level of dramatic negative revenue impact is simply unsustainable. A recent Life Science Ontario survey confirmed that the proposed draft Guidelines will have a negative impact on product launches, commercialization and supply of products in the Canadian market. Furthermore, compassionate access programs, patient support programs, clinical trial investments in Canada will be compromised.⁴

We therefore request you to set up industry working groups as soon as possible and run extensive case studies to demonstrate the workability of the new regulations to ensure they do not lead to excessive and unsustainable price reductions.

Closing Thoughts

Thank you for considering our input on the PMPRB's draft Guidelines and we look forward to working with you on an alternative approach that is consistent with PMPRB's core principles (sustainability, predictability, consistency, functionality, and fairness) and achieves the goal of more affordable medicines while minimizing the impact on patient access and innovation in Canada.

Sincerely,

Kristian Fick
President
LEO Pharma Inc., Canada

³ PDCI : Impact Analysis of the Draft PMPRB Excessive Price Guidelines. 2020 Feb. http://www.pdci.ca/wp-content/uploads/2020/02/PDCI-PMPRB-Impact-Assessment-February-2020_Final.pdf

⁴ Life Science Ontario (LSO): Impact of PMPRB Pricing Changes- Final Research Report. 2020 Jan <https://lifesciencesontario.ca/wp-content/uploads/2020/02/Research-Etc.-PMPRB-Survey-02-03-20.pdf>

