Submission to PMPRB Guidelines Consultation
LEO Pharma Inc.

Dermatology
beyond the skin

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Dear PMPRB Board Members,

Thank you for the opportunity to provide input on the PMPRB's June 2020 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, as well as LEO Pharma's earlier consultation submission on PMPRB's November 2019 draft Guidelines.

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 June 2020 continue to pose fundamental concerns with its regulatory approach and operational feasibility.

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

Dermatology beyond the skin

1) Grandfather existing products completely or commit to a reasonable and efficient transition

Based on the June 2020 PMPRB proposed draft Guidelines, no products are truly "grandfathered". As also noted in the previous submission[1], grandfathering entails exempting existing products from a new law or regulation. We maintain the position that while we believe in complete grandfathering of existing products, we are open to discussing more reasonable and efficient transition measures with sufficient extension period in order to allow patentees to focus on pandemic crisis management and recovery efforts at this time.

In addition, we propose that PMPRB apply the lower of the highest international price ceiling and the current highest compliant list price rather than the current non-excessive average price (NEAP) for Existing products. Current list prices that are compliant with current NEAP are more appropriate references to determine Maximum List Prices. Furthermore, employing list prices over NEAP will be more efficient use of resources for both patentees and PMPRB staffs as it will reduce patentee's reporting burden as well as time spent by PMPRB staffs to re-calculate the NEAP during the transition time. Most importantly, the recommended transition measures will ensure there are no unwarranted price increases during the transition period.

2) Reconsider the use of economic factors

The proposed economic factors in the June 2020 draft Guidelines continue to be highly arbitrary and unreasonable, and present significant uncertainty and disincentives to future innovative product launches in Canada.
As noted in the previous submission[1], the use of pharmacoeconomic (PE) values or QALYs to assess cost-effectiveness has limitations and does not fully capture all dimensions of health value.[2] The two Health Technology assessment (HTA) bodies PMPRB proposes to source PE analysis from, namely Canadian Agency for Drugs and Technologies in Health (CADTH) and Institut national d'excellence en santé et services sociaux (INESSS), often have widely differing assessments of economic value due to different perspectives and methods they utilize and vast ICUR ranges. In fact, CADTH's latest Guidelines for the Economic Evaluation specified that "the perspective should be that of

[1] LEO Pharma Inc. "Submission to PMPRB Guidelines Consultation" PMPRB Guidelines 2019 submission. 2020 Feb 14. https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/submission-received/2020_02_Guideline%20Consultation%20Submission_LEO%20Pharma%20Canada.pdf

[2] 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

the publicly funded health care payer". [3] Therefore, it would be highly unjust and inappropriate to generate a single point ICUR estimate based on a single-payer PE assessment framework and set a single national regulated price ceiling for a mixed payer system which include both public and private markets.

In addition, the proposed market size factor presents compounding price reduction via use of Maximum Rebated Price (MRP) and Maximum Rebated Price Adjusted (MRP(A)) concepts. This approach is unreasonable and poses a revenue control mechanism as opposed to price regulation, which is beyond the PMPRB's jurisdiction.

For the above reasons, we strongly recommend PMPRB to reconsider the use of economic factors and work together with technical working groups to come up with an alternative solution that is more fair, reasonable and reflective of the current mixed private and public payer system in Canada.

3) PMPRB staff should not have excessive discretion

The section 94 of the June 2020 draft Guidelines states that "the tests and ceilings used during the investigation may differ from the initial thresholds that led to the triggering of the investigation. In such cases, the investigation ceilings (as opposed to the triggering ceilings) will be used to calculate potential excess revenue." This gives PMPRB staff improper discretion to change price tests and ceilings as they see fit. PMPRB has provided no rationale for this extensive and unprecedented staff power. We recommend the rules stay consistent for Guidelines on triggers and investigations in alignment with the PMPRB's core principles (sustainability, predictability, consistency, functionality, and fairness).

In addition, while we appreciate the recognition of therapeutic improvements in the June 2020 draft Guidelines, we respectfully propose that Human Drug Advisory Panel (HDAP) expert committee continue to have a primary role in therapeutic improvement level assessments over PMPRB staff, who may not necessarily have the scientific and/or clinical expertise to effectively perform such analyses. We further propose that the therapeutic category level assessments include clinician and patient input for more comprehensive review.

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

The June 2020 draft Guidelines are excessively complex and present information gaps. Many of the questions and concerns raised by various stakeholder groups during the initial November 2019 draft Guidelines consultation period remain unaddressed and there continues to be significant uncertainty

[3] CADTH. "Guidelines for the Economic Evaluation of Health Technologies: Canada." 2019 Sept;4th Ed, : https://www.cadth.ca/sites/default/files/pdf/cp0008-guidelines-for-economic-evaluation-of-health-technologies.pdf

and confusion as to how to predict allowable ceiling price for new products and operationalize the new rules. This unpredictability poses great hurdles for pricing and launch decisions at the global level for the Canadian market. Most importantly, the Federal Court decision invalidating third-party rebates reporting suggests that a reconsideration is required with respect to the Guidelines.

As noted in our earlier submission[1], we recommend that PMPRB set up industry working group as soon as possible to run extensive case studies to demonstrate the workability of the new regulations.

We also propose that PMPRB consult on the yet to be released Online Help Tool, which will replace the current Patentee Guide to Reporting as this portal will contain critical information for patentee compliance.

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