Submission to the PMPRB Guidelines Amendment Consultation
LEO Pharma Inc.

Dermatology
beyond the skin

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Via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Dear PMPRB Board Members,

Thank you for the opportunity to provide input on the PMPRB's proposed amendments to the new PMPRB Guidelines (*Notice and Comment- January 15, 2021*) resulting from the six months delay of the *Regulations Amending the Patented Medicines Regulation* from January 1, 2021 to July 1, 2021. Our submission is complementary to that of Innovative Medicines Canada (IMC), as well as LEO Pharma's earlier consultation submissions on PMPRB's November 2019 draft Guidelines[1] and June 2020 draft Guidelines.[2]

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 the Canadian life science sector. LEO Pharma 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. It is unfortunate that such initiatives are becoming

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

[2] LEO Pharma Inc. "Submission to PMPRB Guidelines Consultation". Aug 2020 https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/submission-received/june2020/June%202020%20submission_LEO%20Pharma%20Inc_EN.pdf

unsustainable from a global perspective, with the increasingly unpredictable Canadian environment.

While we support health system reform that leads to improved health outcomes for patients and sustainability of the health system, we have expressed significant fundamental concerns in our previous two submissions during the PMPRB draft Guidelines Consultation periods with regards to PMPRB's approach to reform and implementation therein. In addition to the recommendations we have made in the previous submissions, we strongly suggest that the PMPRB reconsider its January 15, 2021 proposal to limit the Guidelines transition period to six months, as opposed to the originally proposed twelve months in the final Guidelines.

The final PMPRB Guidelines published in Oct 2020 provided twelve months of transition from the effective date of the amended *Patented medicines Regulations* for patentees to bring the existing and "Gap" medicines into compliance with the new regime. By proposing to reduce the transition time to six months without providing any rationale, the PMPRB is displaying inconsistency in its approach and guidance in operationalizing the Regulations.

The federal government clearly stated its intent in delaying the Regulations by six months in *Regulatory Impact Analysis Statement (RIAS)*[3]: the delay was to provide the industry with additional time to prepare for the new reporting obligations, familiarize with the PMPRB's Final Guidelines and operationalize the Amending Regulations, acknowledging the fact that is a challenging time for all stakeholders involved with the COVID-19 pandemic. The PMPRB's proposal to reduce the Guidelines transition period to six months is highly inconsistent with the objective of the government and counterproductive for all parties involved.

A *minimum* of two reporting periods is required for the patentees to manage the significant administrative burden. This includes understanding and implementation of the new Regulations, coordinating processes to meet individual provincial public formulary requirements and timelines to update the prices, and coordinating with other stakeholders including wholesalers and distributors. With the additional challenges brought forth by the COVID-19 global pandemic, a more reasonable transition period timeline would greatly benefit all stakeholders.

Thank you for considering our input on the PMPRB's proposals published in Notice and Comment (January 15, 2021) and we look forward to working with you on a more reasonable transition timeline that is consistent with PMPRB's core principles (sustainability, predictability, consistency, functionality, and fairness) and achieving the goal of more affordable medicines while minimizing the impact on patient access and innovation in Canada.

[3] RIAS Canada Gazette, Part 2, Volume 155, Number 2: Regulations amending the Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), No. 2

Sincerely,

Gonçalo Goya
President
LEO Pharma Inc., Canada

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