Submission to 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- July 15, 2021*) resulting from the six months delay of the *Regulations Amending the Patented Medicines Regulation* from July 1, 2021 to January 1, 2022. 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 submissions on PMPRB's November 2019 draft Guidelines[1], June 2020 draft Guidelines[2] as well as January 2021 Notice and Comment.[3]

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 invests 21% of revenue in R&D globally and has approximately 110 employees within Canada. The company actively promotes growth in innovation and collaboration in life science in Canada through numerous initiatives. LEO Innovation Lab (iLabs) is an example of how LEO works to foster growth in life sciences. LEO iLabs was created to develop digital solutions for patients with skin conditions, and foster innovation 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-

[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

[3] LEO Pharma Inc. "Submission to PMPRB Guidelines Amendment Consultation". Feb 2021. https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/definition-of-gap-medicines/submissions/2021NC_LEO%20Pharma%20Canada.pdf

generation treatments. Open Innovation allows any organization to access and gain insights to LEO Pharma's research tools to test their molecules for free. Open Innovation has recently launched in Canada, with events held in British Columbia and Ontario; a similar event is planned for September 2021 in Quebec. On top of that, LEO Pharma continues to invest in clinical trial sites in Canada to support Canadian patients.

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 three consultation submissions. In addition to the recommendations we have previously made, we would like to strongly urge PMPRB to consider the following recommendations to reverse the July 15, 2021 proposal without delay.

1) Maintain the Highest International Price (HIP) test for Grandfathered Medicines and Line Extensions as published in the Final Guidelines October 23, 2020

On July 15, 2021, the PMPRB has proposed to change the international price tests for Grandfathered medicines and their line extensions, from the Highest International Price (HIP) test based on the PMPRB 11 countries to Median International Price (MIP) test based on the PMPRB 7 countries.

IMC has previously shared a case study[4] that shows how benchmarking existing products to the median international prices can stifle innovation by compromising regulatory fairness and predictability. The case specifically illustrated an example where the new innovative product was going to be priced significantly lower than the generic price of an older product due to proposed median international pricing. IMC remarked this presents a pricing regime that is inconsistent with PMPRB's mandate as a safeguard against patent abuse and excessive pricing since it forces the patented medicine's price well below comparable generics.

It is important to note that after the 2020 Guideline consultation, the PMPRB has concluded: "the Board has decided to apply the [highest international price (HIP)] test to Grandfathered medicines as a concession to patentees whose expectations may have been raised by [Health Canada's Cost Benefit Analysis (CBA)] and in recognition of the impact of changing the schedule of comparator countries." [5]

[4] "IMC Response to PMPRB Draft Guidelines". Feb 2020. 2020_02_Guideline Consultation Submission_Innovative Medicines Canada.pdf

[5] "Patentees, the biosimilar industry, distributors, industry consultants and some patients and patient groups argue that the MIP should be replaced by the Highest International Price (HIP) for Grandfathered medicines and make a number of points in support of that position." PMPRB also expressly acknowledged that the CBA assumes maximum list price (MLP) ceilings are generally closer to the "highest" of the PMRPB11 for Grandfathered products. PMPRB, June 19, 2020, Backgrounder.

It is highly concerning that the PMPRB has provided no clear rationale behind the proposed change that completely undermines a series of stakeholder consultations held in good faith over the last few years. This is inconsistent with the PMPRB's own commitment to transparency and accountability.

This is an arbitrary and unreasonable change that will not only negatively impact the patentees and the Canadian pharmaceutical supply chain in the short term, but also create an atmosphere of high unpredictability that will impede product launch and investment decisions at the global level for the Canadian market in the long term.

PMPRB's own analysis indicates that this change will bring significant and immediate new negative impacts for patentees' existing products and line extensions.[6]

We propose that PMPRB maintain the HIP test for all Grandfathered medicines and Line Extensions as consistent with the Final Guidelines published in October 2020.

2) A Minimum of Two Reporting Periods (Twelve Months) or More is Required for Effective Transition

The PMPRB has also proposed maintaining the compliance date for Grandfathered and Line Extensions effective July 1, 2022 despite the significant proposed changes, and the delay of the coming into force of Regulations Amending the Patented medicines Regulations from July 1, 2021 to January 1, 2022. This translates into a mere six-month transition time.

The final PMPRB Guidelines published in October 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. On April 16, 2021, the Board published a decision which confirmed two reporting periods for compliance purposes after a Notice and Comment consultation period.

Again, 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 PMPRB's timeline for implementation is misaligned with the federal government's intent to give additional time for patentees to prepare for and comply with the changes introduced in the Amending regulation in consideration of the impact of the third wave of the COVID-19 pandemic and the ongoing pandemic response efforts.[7] Reducing the Guidelines transition period to six months is

[6] Based on its own internal analysis, PMPRB advised IMC that the July 15, 2021 proposal will nearly double the estimated savings to 9% from the previous estimate of 5%.

[7] See quote above on rationale for regulatory delay. Canada Gazette, Part II, Volume 155, Number 14 (June 24, 2021). https://gazette.gc.ca/rp-pr/p2/2021/2021-07-07/html/sor-dors162-eng.html.

inconsistent with and counterproductive to this objective and will substantially increase the administrative burden and cost for all stakeholders involved.

Amidst the growing uncertainty and often confusion with yet another consultation on proposed changes to PMPRB's new Guidelines (most recently the July 15, 2021 proposed amendments) which leaves patentees less than 4 months to obtain clarity on the Final Guidelines, a minimum of two reporting periods or more is required for the patentees to manage the significant administrative burdens as the patentees will have to adhere to individual provincial payer processes and timelines, as well as coordinate with other stakeholders such as wholesalers and distributors.

Closing Thoughts

The proposed amendments made by PMPRB on July 15, 2021 are misaligned with the Biomanufacturing and Life Sciences Strategy announced July 28, 2021 by the federal government, which focuses on increased collaboration, growth initiatives and removal of barriers that can hinder innovation to build a strong life sciences sector in Canada.[8]

We strongly urge PMPRB to consider our recommendations above and reverse the proposed changes to be consistent with the federal government's intent in delaying the *Regulations Amending the Patented Medicines Regulation* and the Life Sciences Policy, as well as the PMPRB's core principles of sustainability, predictability, consistency, functionality, and fairness. This balanced and collaborative approach will achieve the goal of more affordable medicines while minimizing the impact on patient access and innovation in Canada.

Sincerely,

Goncalo Goya
President & CEO
LEO Pharma Inc., Canada

[8] Innovation, Science and Economic Development Canada (ISED) July 2021 Biomanufacturing and Life Sciences Strategy