**Danish Life Sciences Forum**

**Notice and Comment - PMPRB Price Review Approach During the Interim Period following publication of Amendments to the *Patented Medicines Regulations***

The Danish Life Sciences Forum (DLSF) was formalized in 2018 as a way for Danish life sciences companies to collaborate around shared opportunities and challenges in the Canadian market, for the benefit of patients everywhere. With the support of the Danish Trade Council acting as the forum secretariat, the group consists of Novo Nordisk Canada Inc., LEO Pharma Canada Inc., Lundbeck Canada Inc. and ALK – all foundation-owned companies with a long-term mission to find cures in their therapeutic areas. Our mission is to leverage Danish and Canadian life sciences best practices to advance health, innovation and the Canadian economy.

July 18, 2022

Dear Professor Bourassa Forcier,

Thank you for the opportunity to comment on the proposed approach to price reviews by the PMPRB during the current interim period following the recent publication of the amendments to the *Patient Medicines Regulations*. This submission builds on our previous submissions throughout this process and is intended to be complementary to the input of Innovative Medicines Canada, of which we are members.

As Danish foundation-owned companies, we operate on a mandate to deliver wide-ranging health and socioeconomic benefits to society at large. We believe that a lot of good can be achieved through better and more affordable access to treatments for patients, and we fully support health system reform that leads to improved patient health outcomes or addresses healthcare sustainability in a holistic and collaborative way.

The PMPRB has put forward an interim approach to regulating non-excessive prices during a time when there are new regulations but no accompanying guidelines for patentees. We believe that it is incorrect to characterize the proposal as a 'status quo' approach, as this proposal still creates considerable business uncertainty and the unintended potential for increasing disputes in the future. These changes come at a difficult time, as Canada and the rest of the world

continue to battle the economic and health effects of the COVID-19 pandemic. It is therefore important to ensure that even these interim measures are designed to minimize uncertainty now but also into the future.

It is within this perspective that the following comments are framed. We trust that these suggestions will help enable business continuity while still ensuring prices of medicines in Canada are appropriate within the mandate of the PMPRB.

**New medicines without a Non-Excessive Average Price (NEAP) prior to July 1, 2022, or during the 'interim period' have no guidance as to what constitutes a 'non-excessive' price.**

While the proposal stipulates that "*[t]he 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 still leaves manufacturers with no guidance as to what price will be considered 'non-excessive' during this period. The proposal should therefore further elaborate this point and state that manufacturers will not be required to pay back any inadvertent excess revenues accrued during the interim period due to the lack of guidance. This would include medicines with a first sale prior to July 1, 2022 but which do not yet have a NEAP, and those with a first sale after July 2022, but before the implementation of the new guidelines.

**New medicines should be allowed a reasonable transition time to bring prices in line with the new guidelines.**

Given the uncertainty for new medicines launched during the interim period, if a price is determined to be 'excessive' under the future guidelines, manufacturers should be given at least 12 months (two reporting periods) to bring the price to a 'non-excessive' level, with no penalties. This concept should also be applied to all existing medicines once the new guidelines are implemented.

Going forward, it is important that the new guidelines be grounded in the mandate of the PMPRB, which 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. 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.

**List prices of existing patented medicines should be allowed to increase without triggering an investigation during the Interim Period.**

In the intent of applying a "status quo" approach, the PMPRB should allow list prices of existing patented medicines to increase without triggering an investigation during the Interim Period, in accordance with the CPI-Adjustment Methodology. This particularly applies in the event where the Interim Period would be extended beyond December 2022.

We hope that with this finalization of the Regulatory reform, we can restart the conversation on the goals of the Health and Biosciences Economic Strategy Table, to double the size of the sector by 2025. We have all learned the importance of this sector to Canada and the world over the past two years, and the Danish Life Sciences Forum companies are ready to support the federal government to achieve this important objective. For this to happen, we urge the PMPRB to take the time necessary to carefully consider its approach to the new guidelines, as they will have far-reaching impacts on access to medicines for vulnerable Canadians and the health of our economic future.

We thank you for considering our input on this issue.

Sincerely,

Jill Archibald
President and CEO
LEO Pharma Canada

Béatrice Clerc
President
Novo Nordisk Canada

Michal Juul Sørensen
Vice President & General Manager
Lundbeck Canada

Andrew Desbarats
General Manager
ALK-Abelló Pharmaceuticals Inc.