November 6, 2020

Standing Committee on Health (HESA)
Sixth Floor, 131 Queen Street
House of Commons
Ottawa ON K1A 0A6
Canada

Subject: Danish Life Sciences Forum submission to HESA study on PMPRB changes

Dear Honourable Members,

On behalf of the Danish Life Sciences Forum (DLSF), thank you for the opportunity to provide our input on the House of Commons Standing Committee on Health's study on the Patented Medicine Prices Review Board (PMPRB) reforms. This is an important and timely study on the future of Canadian healthcare, and we commend your efforts to foster dialogue on this critical matter.

As background on our group, DLSF members are foundation-owned companies, each operating on a mandate to deliver wide-ranging health and socioeconomic benefits to society at large. Collectively, our group believes 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.

However, we believe the recent changes to the PMPRB regulations and associated guidelines run contrary to these objectives and will lead to unintended, adverse consequences for patients and the wider Canadian economy. There is already significant independent evidence demonstrating that the proposed PMPRB changes are limiting access to new medicines,[1] clinical trials,[2] and investments in health research in Canada.[3] The changes also 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.

In this context, we would like to use this opportunity to draw attention to the aspect of the PMPRB regulations requiring immediate change: the proposed use of economic factors and maximum rebated price (MRP) requirements to regulate medicine prices.

[1] https://lifesciencesontario.ca/wp-content/uploads/2020/06/EN_LSO_Global-Launch-Benchmarking_Webinar-June22-20_Final.pdf
[2] https://www.canadianhealthpolicy.com/products/clinical-trials-in-canada-decrease--a-sign-of-uncertainty-regarding-changes-to-the-pmprb-.html
[3] https://lifesciencesontario.ca/wp-content/uploads/2020/02/Research-Etc.-PMPRB-Survey-02-03-20.pdf

There continues to be a tremendous amount of uncertainty associated with the use of economic factors as part of price regulation. There is broad consensus that these factors are creating significant confusion and uncertainty regarding the acceptable net price for a new therapy in Canada. If companies have no reasonable way of knowing at what price they can legally sell their products, it will be functionally impossible to make a clear business case for commercializing new medicines and vaccines in Canada. Unfortunately, unlike patients and payers in other countries, this could cause unnecessary delays and deprive many Canadians from accessing potentially life-saving and life-improving innovations.

The use of these factors remains a key aspect of the PMPRB's Final Guidelines, although their application has been temporarily and partially suspended pending the outcome of an ongoing judicial review. Nevertheless, this approach creates commercial uncertainty, which is an obstacle to the deployment of new medicines and vaccines in Canada.

The final guidelines are also extremely complicated, difficult to understand, and contain missing pieces of information that companies need to make pricing decisions. Moreover, PMPRB bureaucratic staff have given themselves exceptional powers to use whatever price tests and ceilings they believe they need in the context of an investigation, which may be even more punitive than those that were initially used and which triggered the investigation in the first place. It is extremely important to address this to avoid further dissuading companies from commercializing new medicines in Canada, to the detriment of patients and Canada's health system.

Final thoughts

Innovation and life sciences growth are key drivers of improved health outcomes, long-term health system sustainability and economic growth. By introducing uncertainty and reducing incentives for continued industry investments in research and innovation, it is hard to imagine how Canada can continue to enjoy its current benefits from a thriving R&D ecosystem and the numerous health and economic benefits that result from it.

In fact, Canada has an important opportunity to restart the conversation on how to achieve the ambitious goals of the Health and Biosciences Economic Strategy Table to double the size of the sector by 2025. The DLSF stands ready to support the federal government to achieve this important objective, which will help support the Canadian economy and health system in the face of the ongoing pandemic and future health crises.

However, for this to happen, **we strongly recommend the removal of the proposed economic factors from the *Patented Medicines Regulations*, which are the most challenging aspect of the reforms.**

On behalf of the Danish Life Sciences Forum, thank you for considering our input.

Sincerely,

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Novo Nordisk Canada Inc.

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ABOUT THE DANISH LIFE SCIENCES FORUM

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., and Lundbeck Canada – 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.