



Danish Life Sciences Forum
Submission to 2020 PMPRB Guidelines Consultation

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.

August 4, 2020

Dear PMPRB Board Members,

Thank you for the opportunity to provide input on the PMPRB’s revised draft guidelines document, which outlines how the PMPRB intends to implement the August 21, 2019 amendments to the *Patented Medicines Regulations*.

This submission builds on our group’s previous feedback to date¹, and is intended to be complementary to the input of Innovative Medicines Canada, of which our respective companies are also members.

As foundation-owned companies, we each operate 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 new Canadian pharmaceutical pricing rules run contrary to these objectives and will adversely impact the health and well-being of Canadians and the wider Canadian economy. There is already significant evidence demonstrating that the proposed PMPRB changes are decreasing access to new medicines,² clinical trials,³ and investments in health research in Canada.⁴ The changes also come at a difficult time, as Canada and the rest of the world continues to battle the economic and health effects of the COVID-19 pandemic.

¹ DLSF submission to previous PMPRB guidelines consultation: https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/submission-received/2020_02_Guideline%20Consultation%20Submission_Danish%20Life%20Sciences%20Forum.pdf

² https://lifesciencesontario.ca/wp-content/uploads/2020/06/EN_LSO_Global-Launch-Benchmarking_Webinar-June22-20_Final.pdf

³ <https://www.canadianhealthpolicy.com/products/clinical-trials-in-canada-decrease--a-sign-of-uncertainty-regarding-changes-to-the-pmprb-.html>

⁴ <https://lifesciencesontario.ca/wp-content/uploads/2020/02/Research-Etc.-PMPRB-Survey-02-03-20.pdf>

In this context, we would like to use this opportunity to make the following recommendations with regard to the revised PMPRB draft guidelines:

1. **Reconsider the economic factors and maximum rebated price (MRP) requirements:**

There continues to be a tremendous amount of uncertainty associated with the use of economic factors as part of price regulation, which are not adequately addressed by the revised guidelines. The proposed thresholds remain arbitrary and will continue to impact many vital chronic diseases including conditions such as diabetes, mental health and dermatological disorders. For instance, the use of pharmacoeconomic value (cost-effectiveness criteria) to set the MRP is subjective and does not fully capture all dimensions of health value.⁵ Meanwhile, the market size adjustment remains arbitrary and represents revenue control as opposed to price regulation, as well as a disincentive for companies to bring innovative products to Canada that meet a high unmet medical need. This goes beyond the PMPRB's mandate of protecting Canadians from excessive medicine prices, and negatively impacts some of the most innovative and beneficial medicines.

Furthermore, the economic factors create significant confusion and uncertainty about 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 very difficult to make a clear business case for commercializing new medicines and vaccines in Canada. Unfortunately, this reform will cause unintended consequences including unnecessary delays and deprive many Canadians from accessing potentially life-saving and life-improving innovations.

The recent federal court decision to invalidate the use of confidential rebates in the calculation of the MRP reinforces the need to revisit the entire concept of regulating the price level below the public price.

2. **Address the unprecedented levels of complexity in the current proposal:** The 2020 draft guidelines are significantly more complicated than the 2019 guidelines, with many additional steps and points of uncertainty that companies must navigate through if they want to commercialize their medicines in Canada. The new guidelines are missing important information that companies need to make pricing decisions. For instance, price floors have been added, but how will companies know what price floor will apply to their products if the therapeutic criteria level is not known ahead of time?

There are also concerns about the proposed use of the top of the domestic Therapeutic Class Comparison Test (dTCC) to set the interim maximum list price (iMLP) when a product is yet to launch in any of the PMPRB11 countries. In some cases, innovative medicines may have value beyond available treatments, meaning that these innovations

⁵ 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>

would be unfairly penalized through the application of just the dTCC. Furthermore, when the eventual median international list price (MIP) becomes apparent and is higher than the iMLP, there are no ways to adjust pricing upward by more than the lagging consumer price index (CPI). In this particular scenario, the iMLP will set the course for the pricing trajectory in Canada and will be below the lowest PMPRB11 prices, which is contradictory to the spirit of the regulation. An alternative solution could be to provide a grace period for Patentees to price liberally until at least one or more of the PMPRB11 countries have launched.

Rather than adding additional hurdles to an already complicated process, we recommend that the PMPRB only move forward with regulatory changes that are clear and are simple to implement and administer.

3. **Significant discretion afforded to PMPRB staff:** Under the new draft guidelines, PMPRB 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. This combined power of judge, jury, and prosecutor provides no effective recourse for patentees outside a hearing, which should be a last resort. Unfortunately, this will further dissuade companies from launching new medicines in Canada, to the detriment of patients and Canada's health system.

Furthermore, excessive discretion is provided to PMPRB staff with regard to determining therapeutic criteria levels. It is unlikely that the PMPRB staff have the clinical expertise needed to assess therapeutic improvement. In this context, the Human Drug Advisory Panel (HDAP) expert committee should have a much more prominent role in these important assessments.

Closing thoughts

Innovation and life sciences growth are key drivers of economic growth, improved health outcomes, and long-term health system sustainability. By introducing uncertainty and reducing incentives for continued industry investments in research and innovation, Canada will no longer benefit 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 the PMPRB must take the time necessary to carefully reconsider its current approach with its far-reaching and unintended consequences, and directly address the

many concerns repeatedly voiced by stakeholders from multiple sectors throughout the PMRPB reform process. In particular, we strongly recommend the removal of the proposed economic factors, which are the main source of uncertainty for companies, and which are impossible to effectively implement in the context of the recent federal court ruling on the disclosure and calculation of confidential rebates.

On behalf of the Danish Life Sciences Forum, thank you for considering our input on the PMPRB's 2020 Draft Guidelines.

Sincerely,



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