

Submission to PMPRB Guidelines Consultation Danish Life Sciences Forum

The Danish Life Sciences Forum (DLSF) was formalized in 2018 as a way for Danish pharmaceutical affiliates to collaborate around 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 Inc. – all foundation-owned companies with a long-term mission to find cures in their therapeutic areas. The mission of the DLSF is to share the life sciences sector’s experience in Denmark and globally through engagement with public and private sector stakeholders in Canada. Our vision is to leverage Danish-Canadian life sciences best practices to advance health, innovation and the Canadian economy.

February 14, 2020

Dear PMPRB Board Members,

Thank you for the opportunity to provide input on the PMPRB’s Draft Guidelines regarding the implementation of the newly amended *Patented Medicines Regulations*. Our submission aims to provide a Danish life sciences perspective on the new price control regime for patented medicines in Canada and is complementary to the individual submissions made by our Canadian affiliates and Innovative Medicines Canada.

As foundation-owned companies, we each operate on a mandate to deliver wide-ranging societal and economic benefits to deliver health, innovation and economic 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. We fully support health system reform that leads to improved health outcomes for patients while also ensuring the sustainability of the health system, and we want to contribute to policy-makers’ efforts in this area.

Based on our knowledge and experiences gathered in countries across the world, we would like to share our concern that some of the specific tools being proposed to lower medicine prices in Canada under the recent amendments to the *Patented Medicines Regulations* and Draft Guidelines have significant adverse implications for patients, health systems, and health innovation – in Canada and globally. The magnitude of these implications has prompted our collective response as global leaders of Denmark’s largest biopharmaceutical companies – LEO Pharma, Lundbeck, and Novo Nordisk.

We respectfully offer the following recommendations to help inform and contribute to a more functional pricing framework:

1) Use economic factors in exceptional circumstances only

The new economic factors are an ill-suited, excessive, and unnecessary tool to achieve the desired result of improving the affordability of and access to medicines in Canada.

The proposed use of pharmacoeconomic factors as part of price regulation is of particular concern. The use of QALYs to assess cost-effectiveness/cost-utility has been shown to have its limitations and does not fully capture all dimensions of health value.¹ Using these subjective cost-effectiveness analyses to set the Maximum Rebated Price, across all payers, rather than as recommendations to facilitate reimbursement will jeopardize the access environment for patented medicines in Canada. No other country in the world uses these tools in the manner that the PMPRB intends to use them. A similar approach was contemplated by the United Kingdom a few years ago but was subsequently abandoned due to the inherent limitations of these tools.

The pharmacoeconomic factors will lead to arbitrary decisions about the acceptable net price for a new therapy in Canada. This approach will force many companies, including DLSF members, to make difficult decisions about whether to prioritize Canada as a first-tier launch country for new treatments. This could cause unnecessary delays and deprive many Canadians from accessing life-saving and life-improving innovations. The market size adjustment is also arbitrary and represents revenue control as opposed to price regulation, which is beyond the PMPRB's jurisdiction.

For these reasons, we recommend using the new economic factors in exceptional circumstances only (e.g. as part of a hearing). This type of approach will add clarity to the pricing process, reduce the compliance burden on companies, make the process easier and more resource-efficient for the PMPRB to administer, and ultimately ensure Canada continues to be a priority launch country for new medicines. It will also allow more time to review the concept of a fixed ICER threshold, which the PMPRB has noted is still in an “embryonic state.”²

2) Demonstrate how the PMPRB will operationalize the regulations

We recommend the PMPRB resolve and change confusing operational issues before implementing the new pricing system as there continues to be significant ambiguity about how it will work in practice. A country's pharmaceutical pricing policy is a significant factor in launch sequencing of new medicines at the global level. As the Draft Guidelines currently stand, there is a lack of clarity and the necessary information to predict allowable ceiling prices for current and future products required to properly assess the impact. This uncertainty inhibits our pricing and launch decisions at the global level for the Canadian market.

¹ 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>

² PMPRB Guidelines Consultation Backgrounder: <https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/backgrounder-draft-guidelines-en.pdf>

In December 2018, the PMPRB published case studies that forecasted medicine price reductions in the magnitude of 40-70%, which significantly exceeds Health Canada's target of 10%.³ While we understand the pressures confronting the Canadian health care system, this level of impact is unsustainable and will impact our ability to innovate and bring new treatments to Canadians.

Lower prices combined with high uncertainty creates unfavourable market conditions. We are already seeing that the reforms are impacting companies' business plans in Canada. A recent Life Sciences Ontario survey of Canadian and global pharmaceutical and life sciences leaders revealed unanimity on the negative impacts of the reforms, with some companies already taking decisions to delay new medicine launches in Canada. As well, nearly all companies are anticipating significant job losses and reduced access to investments in clinical research, patient support programs, and compassionate access programs – all vital means by which patients have better and early access to new treatments.⁴

The lack of transparency in operationalizing the Guidelines moves away from PMPRB's own principles of sustainability, predictability, consistency, functionality, and fairness. For this reason and the reasons above, we encourage you to set up industry working groups as soon as possible and run extensive case studies to demonstrate the workability of the new regulations. This will provide companies with greater clarity about the new pricing system and ensure it does not lead to excessive and unsustainable price reductions through the cumulative impact of the numerous changes being proposed.

3) Consider the long-term implications

We recommend that the PMPRB take a more strategic and long-term view to pricing and its implications. Patented medicines represent just 6% of total health care spending.⁵ Limiting patients' access to innovative treatments may reduce drug expenditures, but it will not lead to meaningful overall healthcare system savings.

With the recent focus on the cost of medicines, the value and improved outcomes that innovative medicines have delivered for patients has been overlooked. For example, between 2000 and 2009, 73% of the increase in life expectancy was due to new medicines.⁶ In addition, innovative medicines add value to the healthcare system by reducing hospitalizations and other costly complications of disease. In fact, studies have shown that every dollar spent on

³ PMPRB Guidelines Modernization case studies: <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1419>

⁴ Research Etc., February 3, 2020, Impact of PMPRB Pricing Changes Final Research Report: <https://lifesciencesontario.ca/wp-content/uploads/2020/02/Research-Etc.-PMPRB-Survey-02-03-20.pdf>

⁵ Canadian Health Policy Institute (CHPI). Facts about the cost of patented drugs in Canada: 2018 Edition. Canadian Health Policy, February 2019. www.canadianhealthpolicy.com.

⁶ Lichtenberg, F. R., Pharmaceutical innovation and longevity growth in 30 developing and high-income countries, 2000–2009. 2014. Health Policy and Technology 3, pp. 36-58

medications results in two dollars of offsetting health and societal benefits.⁷ It also appears that there are no incentives for innovation in the Draft Guidelines. 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, to the detriment of the knowledge economy.

It is also worth noting that the argument that other countries are able to maintain innovation with lower prices is misguided, as most other countries, including Denmark, provide significant offsetting incentives for the life sciences sector, including supportive policies, competitive periods of market exclusivity, and subsidies. In Denmark's case, our tradition of foundation-owned companies also creates unique "pull factors" that attract and retain long-term investment and ensure R&D stays in the country.⁸ Unfortunately, many of these conditions are not present in Canada, and the investment climate is becoming more difficult and unpredictable as a result of the reforms. Moving forward, we strongly encourage PMPRB Board Members to consider the long-term implications of these reforms and take steps to mitigate any potential negative impacts to patients and Canada's innovation ecosystem.


Closing thoughts

In sum, there is enough flexibility in the interpretation of the amended regulations and Draft Guidelines to develop a more functional and pragmatic price regulation system that achieves the goal of more affordable medicines, while limiting the negative impacts on patient access and innovation. We encourage you to adopt an alternative approach that is more predictable and easier to implement and administer. On behalf of the Danish Life Sciences Forum, thank you for considering our input on the PMPRB's Draft Guidelines.

Sincerely,



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⁷ Conference Board of Canada, Reducing the Health Care and Societal Costs of Disease: The Role of Pharmaceuticals, 2013: <https://www.conferenceboard.ca/e-library/abstract.aspx?did=5598>

⁸ <https://www.labiotech.eu/interviews/denmark-biotech-industry-bio-europe/>