Danish Life Sciences Forum
Notice and Comment – On the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions

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 – 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.

August 30, 2021

Thank you for the opportunity to comment on the Patented Medicine Prices Review Board (PMPRB)'s proposed amendments to the new PMPRB Guidelines. Our input builds on our group's feedback to date and provides a Danish life sciences perspective on the new price control regime for patented medicines in Canada. It is intended to be complementary to that of our trade association, 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 in Canada that leads to improved patient health outcomes and addresses healthcare sustainability in a holistic and collaborative way.

The DLSF welcomes the federal government's recent announcement of a biomanufacturing and life science strategy. The strategy will provide opportunities for increased cooperation and for further collaboration to build a stronger life sciences sector in Canada and has the potential to make Canada an attractive and competitive jurisdiction globally. However, achieving this objective will require not only growth initiatives, but also the removal of growth barriers that hinder innovation and the adoption of promising innovations in the health care system.

In that regard, the DLSF is convinced that the three proposed amendments to the new PMPRB Guidelines will stifle life sciences growth objectives, while impacting the availability of new

medicines, increasing drug shortages, and negatively impacting clinical trials in Canada. The uncertainty created by a new pricing test and change to the transition period at this point in the process conveys instability in the Canadian pharmaceutical pricing environment to international stakeholders. Moreover, these changes are at odds with the federal government's stated policy objective to delay the implementation date of the amended PMPRB Regulations until January 2022 to support the response to COVID-19.

We believe that these proposed amendments will have significant adverse implications for patients, health systems, and health innovation. These proposals are also misaligned with the federal government's commitment to a more collaborative relationship to preserve and bolster the Canadian life sciences environment. Local market and regulatory conditions play a significant role in attracting the industry investment required to achieve a strong, innovative life sciences sector.

We believe the proposed changes will make Canada an unsustainable market relative to other jurisdictions. We would like to work with the federal government as a partner 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.

In Denmark, the life sciences sector is viewed as a direct contributor to the wealth of the nation, the health of its citizens, and a source of revenue for government. This "health is wealth" mentality has contributed to Denmark's growth into a global life sciences powerhouse. Denmark is currently number two in the world for developing biotechnology and number one in Europe in the number of clinical trials per capita.[1]

A major driving force behind Denmark's success in this area has been a long-standing tradition for public-private partnerships, based in part on the trust of the constituency for such arrangements, and a willingness from government to use private sector expertise when developing policies to fuel their long-term strategies. Denmark recently unveiled a new 2021-23 strategy for the Danish life science industry, composed of 38 new initiatives across seven domains. Developed together with industry partners, the initiatives aim to improve conditions for research and development, the use of health data, securing a highly skilled workforce and delivering on international partnerships and market access for the benefit of patients, healthcare system sustainability and the economy.

The strategy leverages a whole-of-government approach (including the Ministry of Industry Business and Financial Affairs, Ministry of Health, Ministry of Foreign Affairs, and the Ministry of Higher Education and Science). The Danish Medicines Agency also plays a key role with a focus on innovative strategies for purchasing and procurement. Emphasis has been placed on initiatives targeting chronic disease and inequity in health.

[1] Claudius, B. (2021, June 10). *Amgen: Denmark - a preferred location for clinical trials and research*. Invest In Denmark. https://investindk.com/insights/amgen-denmark-a-preferred-location-for-clinical-trials-and-research

The DLSF recommends that the federal government engage with the Canadian life science industry on a more meaningful level and take steps to remove unnecessary regulatory barriers across the entire value chain of the industry, including research, regulatory approval, pricing, evaluations, and funding decisions. The government should also work with industry to find the best solutions to addressing its dual objectives of improving medication affordability while growing the life science industry.

We would also welcome the opportunity to bring together senior representatives from the Canadian and Danish governments and life sciences industry to share best practices. It is only through meaningful engagement and broad collaboration that Canada will succeed in developing a strong and competitive life science sector that meets the needs of the patients it serves.

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

Sincerely,

Béatrice Clerc
President
Novo Nordisk Canada

Gonçalo Goya
President & CEO
LEO Pharma Canada

Michal Juul Sørensen
VP and General Manager
Lundbeck Canada