CONSIDERATIONS FOR NATIONAL PHARMACARE: REFLECTIONS FROM DENMARK AND CANADA ON ACHIEVING HEALTH AND ECONOMIC GROWTH

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Submission by:

The Danish Life Sciences Forum*

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*The Danish Life Sciences Forum (DLSF) consists of the Danish Trade Council, a division of Denmark's Ministry of Foreign Affairs, and the Canadian affiliates of three of the foremost foundation-owned life sciences companies in Denmark: LEO Pharma, Lundbeck, and Novo Nordisk. Formalized in 2018, the alliance is committed to engaging with public and private sector stakeholders in Canada to help ensure that the life sciences industry delivers improved health outcomes while continuing to be an important local source of jobs and economic growth long-term.

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EXECUTIVE SUMMARY

The DLSF is committed to improving the health of Canadians with chronic diseases, ensuring access to medications, and fostering a collaborative life sciences ecosystem that drives local research and innovation. Moreover, the Ministries of Health of Denmark and Canada are proud to share a Memorandum of Understanding on five key areas of collaboration, including: health systems strengthening, life sciences innovation, and non-communicable disease prevention. With this, the DLSF is pleased to share its perspectives on national pharmacare as currently articulated in Bill C-64, as it may limit medication availability, restrict patient and clinician choice, plateau economic growth, and stifle innovation.

In this report, we summarize the life sciences ecosystems and pharmaceutical markets in Denmark and Canada. We then consider the potential long-term impacts of national pharmacare in Canada as currently articulated in Bill-C-64.

The DLSF strongly supports efforts to improve healthcare and ensure adequate supply of medical products to Canadians. Drawing from best practices and learnings in both Denmark and Canada, and taking into consideration the differences that exist in the ecosystems between both countries, the DLSF would suggest the following:

1) A fill-the-gap model to provide health benefits to the uninsured or underinsured via a comprehensive drug formulary.

2) For the benefit of the patients, avoid sole-supplier agreements for a given medication or a class of drugs and protect the operation of private insurance drug plans. These private plans provide faster and broader coverage of prescription medications for Canadians compared to public plans.

3) Support the existing dual Private-Public drug insurance system. In an environment where the Canadian demand for healthcare continues to increase, it enables a sustainable healthcare system where the drug budget spending is shared between private and public drug insurance plans and where provinces can continue to strike favourable pricing agreements with manufacturers and access highly-cost effective innovative and life-saving treatments.

4) Create a multidisciplinary Life Sciences Council to build collaboration amongst government, academia, and industry such that we may drive the sector toward better patient outcomes and economic prosperity through innovation, together.

1.0 THE DANISH CONTEXT: LIFE SCIENCES ECOSYSTEM & PHARMACEUTICAL MARKET

Denmark's government plays a crucial role in creating a business-friendly environment for pharmaceutical companies, driven by its forward-looking life sciences strategy.[1] Periodically updated, this strategy emphasizes innovation, talent acquisition, and a transparent regulatory framework that balances health outcomes with economic growth.[2] Central to this is the Life Sciences Council, comprising 20 representatives from industry, government, academia, and patient groups, which advises on national policies.[3]

Denmark's life sciences ecosystem thrives on public-private partnerships, which are instrumental in advancing research, attracting international investment, and addressing complex health challenges, such as mental health and chronic diseases. The government supports these collaborations through funding and strategic initiatives, fostering cross-sectoral collaborative synergies.[4] Life sciences accounts for 19% of Danish exports; the sector is one of the largest employers in the country and contributes significantly to the Danish economy.[5]

As a result of the regulatory framework established by the European Medicines Agency and the strong tradition for public-private partnerships and the resulting environment of trust in Denmark, the Danish Medicines Agency (DMA) ensures that the regulatory framework supports innovation while maintaining high safety and efficacy standards. Known for its transparency and efficiency, the DMA works closely with companies to accelerate the approval process, with timelines for new products ranging from 12 to 18 months. Denmark's alignment with EU regulations further facilitates market access across Europe.[6]

2.0 THE CANADIAN CONTEXT: LIFE SCIENCES ECOSYSTEM & PHARMACEUTICAL MARKET

Canada's strong scientific research foundation offers a reliable setting for developing and implementing medical advancements.[7] Federal funding supports health research and development in academia, while companies benefit from tax incentives and direct funding to promote local R&D and workforce growth.[8] The Canadian government's significant investment through the Biomanufacturing and Life Sciences Strategy is promising for addressing future health crises and economic growth. It can, however, be argued that it remains largely reactive in its nature and therefore overlooks the sector's great potential for improving treatment of chronic and rare conditions.

Despite strong research support, bringing new drugs to market remains a challenge. Launching a pharmaceutical product in Canada involves a lengthy, multi-phase process. Regulatory approval by Health Canada takes 7 to 12 months. Public payer reimbursement can take a further 24 months or more following approval by Health Canada due to the health technology assessment and pricing negotiations with the pan-Canadian Pharmaceutical Alliance (pCPA).[9] Regulatory reforms uncertainties (*e.g.* Patented Medicine Prices Review Board process changes) over the last several years have further complicated and delayed this process compared to other countries.[10]

The Canadian life sciences ecosystem could benefit from a more open and engaging collaboration between public and private actors. In the absence of a coherent, proactive, and synergistic life sciences ecosystem, drug pricing becomes a critical factor on which business cycles hinge. Further regulatory changes, including a potential national drug formulary, could introduce additional challenges for businesses navigating this complex environment.

3.0 PERSPECTIVES ON NATIONAL PHARMACARE

3.1 ACCESS TO BEST MEDICINES

Equitable access to innovative medicines is a crucial concern for patients in both Canada and Denmark.[11, 12] Ensuring that all individuals can access the latest treatments regardless of socioeconomic status or location is key to improving health outcomes and reducing disparities.[13]

The centralized approval system through the European Medicines Agency initially allows for shorter wait times for new medicines to be introduced in Denmark.[14] The Danish Medicines Agency then evaluates the cost-effectiveness of treatments, making them available to the public.[15] Most prescription medicines are subsidized at the point of sale, ensuring equitable access to treatment options for all. The percentage of subsidy (ranging from 50% to 100%) depends on the total cost of a patient's annual medications, increasing with higher expenses.[16] Doctors may prescribe specific brands at no additional cost to patients, following an approval for exemptions. Consumers have the freedom to purchase brand name products, covering only the price difference to the most cost-effective product. This allows for a high level of flexibility and freedom for patients.[17]

The Danish government has undertaken additional measures to target special populations to ensure effective illness management over time. For example, antipsychotic medication is provided free of charge for 15 years post diagnosis of schizophrenia.[18] Despite good coverage, Danish patient groups have raised concerns about the speed at which new innovations become accessible.[19] This highlights the need to further streamline regulatory processes and strengthen public-private partnerships to enhance access.

In Canada, prescription drug access is shared between federal, provincial, and private insurance plans. To varying degrees, provinces provide coverage for seniors, low-income individuals, and those living with chronic conditions.[20] Though these plans aim to reduce access disparities, differences in formularies and eligibility criteria create inequities across regions.[21] Currently, 97.2% of Canadians have access to drug coverage through private insurance via their employers and/or public plans. Private insurance typically covers a broader range of drugs, including many innovative medicines not covered by public plans.[22] Additionally, the time to coverage is much shorter: on average, private plans in Canada historically took 152 days to cover new drugs compared to 473 days for public plans.[9]

Provinces already manage drug coverage tailored to their populations' needs, maintaining a balance between public and private payers.[23] Canadians benefit from a dual system that combines public and private insurance options, offering flexibility and comprehensive coverage.[22] Introducing a national pharmacare plan as outlined in Bill C-64 would not necessarily improve existing provincial or regional plans, but could in fact complicate service delivery, add bureaucracy, and limit treatment options without providing additional value for most patients.[23] Reduced competition amongst drug products could force patients to switch therapies (*e.g.* preferred brand to generic or a completely different compound), potentially impacting health outcomes and quality of life.[23]

A one-size-fits-all pharmacare plan risks making products less accessible for certain patient groups. Government efforts could benefit from focusing on creating a comprehensive public formulary for the uninsured and under-insured, while allowing those with adequate private coverage to maintain their current plans. Healthcare decisions should prioritize clinical evidence and individual patient needs as determined by highly qualified medical professionals; public cost savings should not limit best possible care.

3.2 HEALTH SYSTEM SUSTAINABILITY

Pharmaceutical budgeting in Denmark is managed at both state and regional levels.[24] Drug pricing in Denmark is largely market-driven: pharmaceutical companies submit their prices fortnightly to the DMA, which apply uniformly across all pharmacies in the country. The auction system encourages competitive pricing and balances public affordability with private profitability, but can lead to cost variability, which may inconvenience consumers.[25]

That said, there is ongoing debate about whether medicine prices in Denmark are too low compared to other Nordic countries.[26, 27] While pharmaceutical companies face pricing challenges, Denmark's substantial investment in research and innovation, accounting for over 2.9% of its GDP,[28] creates favourable conditions for the pharmaceutical industry, enabling growth despite pricing pressures.[4]

In contrast, Canada's multi-payer prescription drug system is mixed, with over 100 public and 100,000 private plans.[29] Proponents of national pharmacare in Canada argue that it would lower pharmaceutical expenditures for insurers and individuals by streamlining access to medications.[23] Yet, Canada already has such a mechanism through unified negotiating with manufacturers via pCPA.[23] By April 2024, the pCPA had achieved annual savings of $3.89 billion on brand name and generic drugs,[30] demonstrating that significant cost reductions can be achieved without implementing a national pharmacare program.

National pharmacare could foreseeably reduce access to medicines for privately insured Canadians while increasing taxpayer expenses.[31] Calculations by the Parliamentary Budget Officer (PBO) assumed additional discounts on drugs due to united bargaining.[32] However, the PBO may not recognize that current competitive pricing for provinces is made possible because pharmaceutical manufacturers are able to balance returns between public and private markets. If the private market is undermined, the government may lose negotiating power, resulting in less favourable pricing and higher taxpayer costs.

The plan as currently articulated in Bill C-64 would result in an additional $11.2 billion in federal spending in its first year, rising to $13.4 billion by 2027.[32] While national pharmacare is positioned to improve equity in accessing prescription drugs, the required incremental cost could limit resources for other critical healthcare areas (*e.g.* mental health services, seniors care, or infrastructure improvements).

Focusing on allocating resources to fill the existing coverage gaps, similar to the national dental care program, could prove to be a more efficient and fiscally responsible approach than national pharmacare.

3.3 CONTINUOUS INNOVATION

Incremental innovation in pharmaceuticals allows physicians to tailor treatments to individual patient needs with greater precision. Drugs within the same therapeutic class may vary in molecule structure, dosing, half-life, side effects, and interactions.[23] These differences offer more targeted care options. Additionally, incremental innovation fosters price competition, leading to cost savings when multiple drugs are available in the same class.[23] The future of pharmacare will be characterized by greater personalization via pharmacogenetics and rapid development as a result of artificial intelligence-enabled drug discovery.[33] Canada's pharmacare could benefit from enabling this breadth, precision, and dynamicity.

Beyond better health outcomes, pharmaceutical innovation drives economic growth. A decline in new drug development could lead to job losses in the sector, reduced biotech investment, and weakened academic partnerships,[34] culminating in stifled scientific advancement in Canada.

Canada is an important trading partner for Denmark, but lengthy regulatory processes often lead Danish life sciences companies to prioritize other markets.[35] Additional barriers in this market could impact the vibrancy of Canada's life sciences ecosystem. For instance, reduced incentive for investment would impact clinical trial activity. As a result, Canadian patients may experience a lower standard of care due to reduced access to new and improved treatment options compared to other countries.

While sole tendering can lead to cost savings and administrative efficiencies, it also poses risks, including restricted medication access, limited supplies, poorer health outcomes, fewer treatment options, and reduced innovation.[23]

The DLSF encourages Canadian policymakers to ensure the right balance between controlling drug costs and fostering an environment that facilitates pharmaceutical innovation to ensure comprehensive and effective healthcare for all Canadians.

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