VIA EMAIL: hpsdpdcorr-corrdgppsdp@hc-sc.gc.ca

March 7, 2024

Director, Policy and Data Division
Health Product Shortage Directorate
Health Canada
200 Tunney's Pasture Driveway
Ottawa ON K1A 0K9

Subject: Consultation on proposed amendments to regulations to address health product shortages in Canada

On behalf of Life Sciences Ontario (LSO), thank you for the opportunity to provide input on the proposed amendments to regulations to address health product shortages in Canada.

LSO is a not-for-profit organization that represents and promotes Ontario's vibrant and diverse life sciences sector. Dozens of LSO members are drug and medical device industry stakeholders, researchers and academics, so we are well positioned to respond to this consultation and would welcome an opportunity to expand further on our recommendations in the coming months.

Canada's life sciences sector is among the most research-intensive sectors in the country. Ontario alone is currently home to one of the largest life sciences clusters in North America. The sector supports a thriving research and innovation ecosystem, contributes $58 billion to Ontario's GDP, and provides 190,000 direct and indirect jobs in the province.[1]

However, there is widespread consensus that the sector is not achieving its full potential. Despite our country's strengths and investments in science and research, we still lack a sufficiently robust life sciences manufacturing base or the type of homegrown billion-dollar biotech success stories that we see in other jurisdictions. A robust life sciences manufacturing base in Canada along with regulatory measures to prevent and mitigate the impacts of drug and medical device shortages and discontinuations are both key to ensuring timely access to treatments and positive health outcomes for Canadian patients.

Canada is now facing an unprecedented threat to our economy and sovereignty by the US federal government which would seriously impact health product shortages if delivered on. Industry and government collaboration to prevent and mitigate the impacts of health product

[1] https://lifesciencesontario.ca/accelerating-prosperity-the-life-sciences-sector-in-ontario/

Life Sciences Ontario
162 Cumberland Street, Suite 310
Toronto, Ontario M5R 3N5
Tel: 416-426-7293 Email: admin@lifesciencesontario.ca
www.lifesciencesontario.ca

shortages are more important now than ever before, and the proposed amendments to the regulations should be developed with this issue top of mind.

In this context, the amendments to regulations to address health product shortages in Canada should be considered based on a thorough examination of three key themes: (a) consider the threat of US tariffs on health product shortages and supply chain disruptions; (b) consider the impact on industry and the investment required for compliance; (c) address health product shortages as one part of a broader strategy.

Each of these themes are discussed in more detail, below.

A) Consider and prepare for the threat of US tariffs on health product shortages and supply chain disruptions

Companies may need to reevaluate their manufacturing and distribution strategies to mitigate tariff impacts. In the short term, US healthcare providers and patients could face supply shortages, longer lead times, and rising costs due to reliance on Canadian medical products. In the long term, manufacturers may explore relocating production to non-tariffed regions, introducing regulatory, logistical, and operational challenges. Canadian-based manufacturers could experience declining exports, reduced revenues, and potential job losses as their competitiveness weakens. Meanwhile, US pharmaceutical firms reliant on Canadian suppliers may be forced to secure alternative sources, further complicating supply chain logistics and increasing costs.

Canadian stakeholders have come together to prepare for these challenges. Notably, LSO is a member of the newly launched Life Sciences Tariff Taskforce and the Ontario Business & Trade Leadership Coalition (OBTLC). The Life Sciences Tariff Taskforce is a strategic partnership that will focus on identifying trade-related impacts specific to our sector, creating strategies for the evolving landscape, and building a network of stakeholders across the ecosystem—from innovative startups to established industry leaders and academic institutions.[2] The Ontario Business & Trade Leadership Coalition (OBTLC), Representing leaders from Ontario's most trade-dependent sectors, was formed to tackle the challenges posed by rising international protectionism and the threat of U.S. tariffs.[3]

Increased tariffs could disrupt drug manufacturing and distribution, leading to potential shortages and delays in patient access to medicines. Hospitals, pharmacies, and healthcare providers may struggle to secure adequate supplies, which could compromise patient health outcomes and broader healthcare efforts. A reliable and efficient supply chain is essential to ensuring timely access to medicines. Trade barriers threaten the stability of the supply chain,

[2] https://www.linkedin.com/posts/life-sciences-ontario_ontariolifesciences-innovation-collaborativeleadership-activity-7300262033852116993-GUsW/

[3] https://occ.ca/events/ontario-business-trade-leadership-coalition/

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increasing risks of drug shortages and potentially threatening the health and lives of many Canadians and Americans.

B) Consider the impact on industry and the investment required for compliance

Overall, while the proposed regulations aim to address critical issues related to drug and medical device shortages, they also impose significant responsibilities on pharmaceutical companies. The industry will need to adapt to these changes by investing in infrastructure, technology, and strategic planning to ensure compliance and that they continue to meet the healthcare needs of Canadians.

- **Operational Costs:** The mandate to maintain safety stocks for select drugs will require substantial investment in inventory management and storage facilities which could increase operational costs for pharmaceutical companies.
- **Resource Allocation:** Developing and maintaining comprehensive shortage prevention and mitigation plans will demand additional resources and strategic planning. Companies will need to invest in robust supply chain management systems and collaborate closely with suppliers and distributors.
- **Data Management:** The requirement for drug importers and wholesalers to report surges in demand to the Minister of Health necessitates real-time data collection and reporting mechanisms, which could be resource-intensive.
- **Regulatory Flexibility:** The ability of the Minister of Health to expand the scope of drugs subject to shortage regulations and extend expiration dates in certain circumstances provides needed flexibility in managing supply issues. This can allow for more adaptive responses to unforeseen shortages.
- **Exceptional Importation Frameworks:** Updating the exceptional importation frameworks to be used in a broader range of circumstances will allow for quicker access to necessary drugs and medical devices during shortages, ensuring that patient care is not compromised.
- **Transparency and Accountability:** Enhancing the regulatory frameworks for reporting drug and medical device shortages and discontinuations will improve transparency and accountability. This can help build trust and confidence with healthcare providers and patients, but it also requires efficient data management systems to be implemented effectively.

(c) Address health product shortages as one part of a broader strategy

Timely and consistent access to innovative medicines is essential for improving the health outcomes and productivity of Canadians. However, Canada falls behind other comparative countries in timelines for public reimbursement and in the variety of medicines reimbursed. For example, only 11% of new cancer medicines are publicly reimbursed in Canada compared to 74%

in the EU and 90% in the US with Canadians waiting more than twice as long to get access to these treatments.[4]

To support the timely and consistent access of new medicines and vaccines, the government should coordinate with its departments and agencies on the major initiatives at the federal level related to pharmaceutical policy that are already happening, such as Health Canada regulatory modernization, Canada's Drug Agency's mandate, National Strategy for Drugs for Rare Diseases, and National Pharmacare, to name a few, and work together with provinces/territories as well as patients, civil society, health system leaders and the private sector. This will not only provide better health outcomes for Canadians but will also build resilience and protect Canada's life sciences ecosystem.

Due to the complexity of this policy environment, the federal government should look at these issues beyond their individual mandates and goals and adopt a whole-of-government approach to pharmaceutical policy, including the proposed amendments to these regulations.

Thank you for considering our input. Please do not hesitate to reach out to me if you require clarification or have any additional questions regarding the recommendations made in this submission.

Sincerely,

Jason Field
President & CEO
Life Sciences Ontario
C: (647) 821-3392; jason.field@lifesciencesontario.ca

About Life Sciences Ontario

Life Sciences Ontario (LSO) is a not-for-profit organization that represents and promotes Ontario's vibrant and diverse life sciences sector. Members of LSO include life sciences companies, entrepreneurs, members of academia, and service providers from many different areas of the life sciences ecosystem, including biopharmaceuticals, agriculture, agri-food, the bioeconomy, medical devices, animal health, environmental technologies, and more. Ultimately, LSO's mission is to encourage commercial success throughout this diverse sector by collaborating with governments, academia, industry and other life sciences organizations in Ontario and across Canada.

[4] Skinner B., Canadian Health Policy Institute, 2023: https://www.canadianhealthpolicy.com/product/new-cancer-drugs-in-canada-2012-to-2021-an-economic-analysis-of-cost-benefit-availability-and-public-insurance-coverage/ *NOTE: This statistic relates to cancer medicines approved between 2016 and 2020 in at least one of the US, EU and/or Canada.*