March 3, 2026

Debra Haltrecht
Acting Executive Director
Office of Legislative and Regulatory Modernization
Policy, Planning and International Affairs Directorate
Health Products and Food Branch
Health Canada
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sent via email: lrm.consultations-mlr@hc-sc.gc.ca

Re. Canada Gazette, Part I, Volume 159, Number 51: Order Providing for Reliance on Decisions of, or Documents Produced by, Foreign Regulatory Authorities in Respect of Certain Drugs

Dear Ms. Haltrecht,

On behalf of the two hundred member companies of BIOTECanada, I am writing you about Health Canada's *Order Providing for Reliance on Decisions of Foreign Regulatory Authorities*. BIOTECanada strongly supports this proposal as demonstration of Health Canada's commitment to advancing and improving access to medicines and red tape reduction.

BIOTECanada is the national association for Canada's biotech industry representing a mix of large multinational pharmaceutical companies, early-stage biotech companies of varying sizes, vaccine companies, drug discovery and accelerator organizations, research centers, universities, and investors. The implementation of a reliance order in Canada will build on investments made in the healthcare sector and further enable the collaborative regulatory authority relationship established during the pandemic and over the past years to support access to emerging technologies, an affordable healthcare system and the growth of Canada's biotech ecosystem more broadly.

During the pandemic, the federal government recognized the strategic importance of developing a robust and diverse life sciences and biomanufacturing sector. Correspondingly, the government developed the Biomanufacturing and Life Sciences Strategy (BMLSS) led by both ISED and Health Canada. The work Health Canada undertook during the pandemic strategy has helped establish vital new global

partnerships with other respected global regulators which enabled Canada to respond accordingly with rapid access to medicines and vaccines in a global health crisis. This achievement signals a new level of momentum and opportunity as Canada seeks to build capacity and maintain the health and security of Canadians.

BIOTECanada welcomes Health Canada's proposal to leverage foreign regulatory authority decisions as part of the Red Tape Review initiative and recognizes this as a meaningful step toward improving timely access to medicines for Canadians.

We recognize the importance of balancing regulatory efficiency with the maintenance of robust safety and quality standards for Canadians. As a national organization representing Canada's life sciences sector, BIOTECanada is committed to supporting Health Canada throughout the regulatory development process, including engagement during the Gazette II consultation period and the development of implementation guidance.

Canada's regulatory system continues to face significant pressures from increasing submission complexity, resource constraints, and persistent approval delays. Implementing a robust reliance framework is essential to reducing duplicative work, accelerating access to innovative medicines, and aligning Canada with leading global regulatory practices. In order to fully realize the benefits of the Order and the reliance pathway BIOTECanada suggests the following improvements:

- **Broaden the Scope/IbR List:** We acknowledge Health Canada' proposal to initiate reliance with pediatric indications. We encourage timely expansion of the framework, specifically the Incorporated by Reference (IbR) List (pertaining to eligible drug classes), and any potential piloting, to other areas of high unmet patient need, early application to backlog products, and progression to broader application. The scope of drugs eligible for reliance should reflect the needs of the Canadian healthcare system with priority for access to innovative medicines. Additionally, a transparent and responsive IbR List, developed with stakeholder input, will be essential to ensuring equitable and predictable implementation.

- **Expedite Timelines:** Timelines for review under the pathway are not stated. We would propose a timeline between 60 to 110 days, similar or quicker than the IRP Procedure of UK's MHRA[1]. This creates a viable incentive for utilization and retaining timelines that are comparable/competitive with other jurisdictions. This is particularly important given that a fee reduction is not currently contemplated for submissions managed through this mechanism.

[1] (https://www.gov.uk/government/publications/international-recognition-procedure/international-recognition-procedure)

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- **Detailed Implementation Guidance:** We urge Health Canada to better define the operational details of reliance, ideally prior to or concurrent with publication in the Canada Gazette Part II, or at minimum within 180 days of the Order coming into force. Success of the Order depends on timely, detailed, and clear implementation guidance. Industry requires certainty regarding submission procedures, documentation expectation, difference assessments, and post-market obligations.

Further, we acknowledge Health Canada's sovereign mandate to protect the health and safety of patients. Nevertheless, we respectfully urge Health Canada to leverage learnings from the implementation of the Foreign Reliance Ministerial Order to systematically identify instances in which its regulatory requirements differ substantively from those of other trusted regulatory authorities. Where such differences do not materially enhance patient protection, Health Canada should pursue global regulatory harmonization.

The attached document provides BIOTECanada's input on behalf of the diverse biotechnology ecosystem.

Sincerely,

Wendy Zatylny
President and CEO
BIOTECanada

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