September 12, 2026

Input into Health Canada's consultation on a proposed pilot approach to prioritize certain generic drug submissions involving domestic manufacturing within the review queue

As its mission, the Best Medicines Coalition (BMC) seeks timely access to a comprehensive range of medically necessary, safe, and effective drugs and related treatments, informed by patient-driven evidence and values, and delivered equitably and affordably to all patients in Canada. BMC therefore supports measures that advance this mission, including efforts to prioritize generic drug submissions involving Canadian manufacturing, and further asserts that protecting access to medications and related treatments is essential.

BMC supports taking steps that strengthen safe and timely access while also increasing Canada's pharmaceutical sovereignty. As patients in Canada have seen, global changes and supply chain pressures can put Canada's drug supply at risk. Strengthening domestic capacity can help reduce these vulnerabilities and provide greater security and predictability for patients. Fostering domestic manufacturing, where appropriate, is one way to support this objective.

BMC understands pharmaceutical sovereignty not as complete domestic self-sufficiency, but as Canada's ability to ensure reliable, timely and equitable access to medicines through a resilient combination of strategic domestic capacity and diversified, dependable international supply chains. Domestic manufacturing is an important tool for strengthening supply resilience, but should not become a substitute for assessing actual supply vulnerability and the potential impact of disruptions on patients.

Accordingly, BMC recommends that the pilot also evaluate whether additional supply-security and patient-impact considerations should inform future review-sequencing decisions alongside domestic manufacturing. These could include the diversification or concentration of supply, vulnerability to shortage, availability of alternative treatments, and the potential consequences for patients if supply is disrupted. Health Canada's Critical and Vulnerable Drug List already assesses medicines according to clinical criticality and vulnerability to shortage; over time, BMC encourages Health Canada to consider how this type of evidence could help inform review sequencing.

In addition to encouraging Canadian manufacturing, the proposed pilot provides an opportunity to reduce review timelines and improve access for Canadian patients.

BMC recognizes that earlier initiation of a regulatory review does not, on its own, guarantee earlier patient access. Regulatory authorization is one step in the pathway to access, and medicines must still become available in the Canadian market and move through applicable pricing, listing, procurement and reimbursement processes. Nevertheless, reducing avoidable regulatory delays can remove an important barrier. BMC therefore hopes that earlier review will translate into earlier and more reliable

availability for patients, and encourages Health Canada to evaluate the pilot not only in terms of review-queue performance, but also its ultimate contribution to timely patient access.

As BMC told the House of Commons Standing Committee on Health, BMC supports “Investing in domestic capacity where it is strategically critical, including biologics, advanced therapeutics, and clinical trial supply.”

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About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of 33 patient organizations. The BMC seeks timely access to a comprehensive range of medically necessary, safe, and effective drugs and related treatments, informed by patient-driven evidence and values, and delivered equitably and affordably to all patients in Canada. The BMC's areas of interest include drug approval, assessment, and reimbursement, as well as patient safety and supply issues. As an important aspect of its work, the BMC strives to ensure that Canadian patients have a voice and are meaningful participants in health policy development, specifically regarding pharmaceutical care. The BMC's core activities include issue education, consensus-based position development, and advocacy, making certain that patient-driven positions are communicated to decision makers and other stakeholders. The BMC was formed in 2002 as a grassroots alliance of patient advocates. In 2012, the BMC was registered under the federal Not-for-profit Corporations Act and operates under the direction of a Board of Directors composed of representatives of member organizations and elected annually.

Asthma Canada
Brain Tumour Foundation of Canada
Canadian Arthritis Patient Alliance
Canadian Breast Cancer Network
Canadian Cancer Survivor Network
Canadian Council of the Blind
Canadian Cystic Fibrosis Treatment Society
Canadian Epilepsy Alliance
Canadian Hemophilia Society
Canadian PKU & Allied Disorders
Canadian Skin Patient Alliance
Canadian Spondyloarthritis Association
CanCertainty
Crohn's and Colitis Canada
Cystic Fibrosis Canada
Eczema Society of Canada
Family Alliance on Severe Mental Illnesses
Fighting Blindness Canada
Health Coalition of Alberta
Huntington Society of Canada
Kidney Cancer Canada
Lung Health Foundation
Lymphoma Canada
Medicines Access Coalition – BC
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