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Health Canada
Health Product Shortage Directorate
200 Tunney's Pasture Driveway
Ottawa ON K1A 0K9

Proposed drug shortage regulation amendments and critical and vulnerable drug list

Introduction:

The Best Medicines Coalition (BMC), a national alliance of 32 patient organizations, welcomes the opportunity to provide input on proposed ***Food and Drug Regulation Amendments related to drug shortages and discontinuations*** and on the draft ***Critical and Vulnerable Drug List***. The position points included in this submission represent areas of consensus among BMC member organizations.

The BMC acknowledges the dedicated work by Health Canada officials, in cooperation with stakeholders, to identify, monitor and mitigate supply issues including shortages. The BMC welcomes efforts to engage patient voices, including the February 19, 2025 presentation to BMC member organizations on the current framework and proposed improvements. The BMC looks forward to further discussions with Health Canada on these topics and ongoing opportunities to share patient perspectives.

Overview:

- Canada's drug supply is fragile and the reality of prolonged and intermittent shortages and discontinuations of drugs, vaccines, and other treatments is a challenge both to individual patient care and outcomes and to health care system efficiency and effectiveness.
- Strategies to improve the availability and accessibility of drugs and other health products are critically important to patients. The goals of improved prevention and management of shortages, along with improvements in how these issues are communicated to patients, professionals, and other supply chain players, warrants prioritization.
- Patient needs must be front and centre in all discussions and decision-making related to drug supply, and importantly patients and the organizations that represent them must be actively involved in all stages of this process, alongside other stakeholders.

Position points:

1. Proposed Food and Drugs Act amendments regarding shortages and discontinuations

- The BMC supports additional tools, such as the measures enabled by the proposed regulations, to prevent adverse health outcomes due to a drug or medical device shortage, including to improve rapid response, detection and intervention for potential shortages, minimization of impact and restoration of supply

Improved patient communications

- We encourage Health Canada, and all jurisdictions and supply chain stakeholders, to strengthen efforts to communicate on all aspects of drug supply, including current and potential drug shortages, and measures being undertaken to address broad supply issues and individual shortages proactively and transparently.
- Specifically, the BMC supports further efforts to improve targeted communications on anticipated and current shortages to patients. Transparent, and proactive approaches to communication are critical to patient communities and individual patients, including available information about nature of shortage and anticipated duration and how alternatives will be accessed and reimbursed. Importantly, Patients must be informed of shortages as early as possible to avoid gaps in treatment, especially important for those with difficult to treat conditions. Last minute notification leaves the patient, pharmacy and prescriber having to scramble to identify and source an appropriate alternative, a difficult and lengthy process with potentially serious implications.
- Updates on shortages must also be communicated to relevant patient organizations allowing these groups to take a more proactive approach to informing their patient communities about shortages, options, and alternatives.
- Importantly, processes are needed to enable early warning of shortages, perhaps providing portals for early reporting and notification. A sentinel network to signal critical shortages as experienced on the frontlines warrants consideration.
- Improved data collection and information systems are integral to enable timely identification and greater understanding of the nature and extent of anticipated and current supply issues. Robust data collection and sharing across all health care systems is necessary to the development of effective solutions.

Broaden scope beyond limited definition of drugs

- We urge Health Canada to broaden the scope of its work on shortages and discontinuations to encompass a broader range of medically necessary treatments. This would include medicinal food, medical formulas and medically necessary supplements which are not assigned Drug Information Numbers and are not considered drugs as narrowly defined by Health Canada. For some patients, including many with rare diseases, these prescribed "medicines" are the only available therapy, and a shortage or other disruption of supply can have critical implications.

2. *Draft Critical and Vulnerable Drug List*

- The BMC acknowledges the rigour applied to develop the draft Critical and Vulnerable Drug List, including reviews of international lists and validation processes. It is noted that the project team employed a multidisciplinary approach to assess clinical importance of drugs and vulnerability to shortages, consulting with clinicians, policy makers and industry stakeholders.
- The BMC recommends adopting processes for incorporating patient perspectives into the framework, including consultations with patient organizations and individual patients, along with other stakeholders and clinicians.



About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of 32 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 comprised of representatives of member organizations and elected annually.



- Alliance for Access to Psychiatric Medications
- 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
- Fighting Blindness Canada
- Health Coalition of Alberta
- Huntington Society of Canada
- Kidney Cancer Canada
- Lung Health Foundation
- Lymphoma Canada
- Medical Cannabis Canada
- Medicines Access Coalition – BC
- Migraine Canada
- Millions Missing Canada
- Ovarian Cancer Canada
- Parkinson Canada
- Platelet Disorder Support Association
- Psoriasis Canada
- the cancer collaborative