



## **Drug Supply: Improving access to drugs and other health products in Canada**

Submitted: August 31, 2023

### ***Introduction:***

The Best Medicines Coalition (BMC), a national alliance of 30 patient organizations, welcomes the opportunity to provide input to Health Canada as it considers measures to improve access to drugs and other health products in Canada. This submission was developed with the participation of BMC member organizations and represents a compilation of positions and themes discussed and shared. The BMC looks forward to further discussion and consultation on these issues with Health Canada and the Drug Shortages Task Force.

### ***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. At any given time, a sizable percentage of all drugs and related treatments are in short or no supply. These shortages are often related to components or finished products sourced elsewhere and are difficult to mitigate, sometimes with life threatening implications.
- Health Canada, in cooperation with other jurisdictions and departments, currently works diligently to identify, monitor, and mitigate drug shortages. The *Multi-Stakeholder Steering Committee – Drug Shortages*, co-chaired by Health Canada and a rotating provincial/territorial partner, provides an effective framework for cooperation and information sharing between officials and various stakeholders, including the BMC.
- Building on these efforts, the development of a long-term strategy to improve the availability and accessibility of drugs and other health products is 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. There must be meaningful patient engagement and representation on all working groups and advisory bodies to ensure valuable input into solutions that meet patient care needs and preferences.

### ***Improved Communications and Transparency:***

- We encourage the federal government, 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.

- More open, transparent, and proactive approaches to communication are critical to patient communities, including in alleviating some of the stress and anxiety associated with not knowing whether a needed medication is in short supply and how and when the situation might be resolved. Transparent and clear communications should not be limited to whether there is a shortage but must also incorporate available information about the duration of the shortage, the nature of the shortage, what alternatives are available during the shortage and how those alternatives will be accessed and reimbursed.
- Patients must be informed of shortages as early as possible to avoid gaps in treatment. Situations where patients arrive at a pharmacy to pick up a medication and are only then informed of a shortage must be avoided. Such 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 at any time but especially during holiday periods.
- Pharmacies currently have practices for contacting and informing customers/patients about promotions or other updates and these systems must be utilized for current or anticipated shortages. For example, an email could be sent to a patient and prescriber with relevant information prompting all parties to work together to develop a plan in advance of a critical need. Importantly, alert systems must be standardized and mandatory.
- 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.

#### ***Agile Regulatory Toolbox:***

- The development of effective and proactive policy frameworks and regulations to address drug supply disruptions must be pursued and given immediate priority. Drug supply challenges are a critical national health issue and patients expect the federal government to take a leadership role in developing solutions and using all avenues available under its authority to ensure a safe and consistent supply of medications. Canadians need a regulatory framework that enables officials to prevent shortages and protect patient safety to the greatest extent possible.
- The premise that approval to market a drug includes an obligation to ensure a consistent supply of that drug is of paramount importance to patients and must be explored. For example, Health Canada is encouraged to consider using its Notice of Compliance with Conditions regulatory provision to require license holders to be responsible for continuity of supply, especially in circumstances with few other suppliers or therapeutic alternatives.
- Specific efforts must be made to protect Canada's drug supply internationally. Global supply challenges may continue to prompt actions by United States law makers to pursue bulk importation of drugs meant for Canadians with critical implications for patients here. This is not viable, especially in the long term, and would put patients on both side of the border at risk. Measures, including robust production policies, to expand Canada's domestic manufacturing capacity to increase supply of critical drugs and vaccines and safeguard against exportation must be considered and pursued.
- A process for the development of a vulnerable drug list must be initiated and pursued. This list would include what would be considered mainstay medications where there are not alternatives, across all conditions. Essentially, such a list would focus on situations where there would be critical or life-threatening implications should a shortage occur and would identify or categorize impact or level of risk. Criteria for inclusion in the list should be developed in partnership with all stakeholders, including patients, supply chain players, pharmacists, and prescribers.

### ***Greater supply chain visibility:***

- It is necessary to build on current manufacturer reporting processes to capture frontline experiences at pharmacy, clinical and patient levels, ensuring that systems have a high level of accuracy and are up to date. More rigorous surveillance is needed to capture shortages as experienced by those who prescribe and dispense, and by patients. It is commonly reported that patients are informed at the pharmacy that a medication is not available but the shortage has not been captured through the tracking system. The current manufacturer reporting process has value but does not sufficiently reflect disruptions and impact on patient care.
- 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.

### ***Enhanced response to supply and demand***

- Discontinuations, including where a long-standing and relied upon drug is no longer made available by a manufacturer, are a critical patient care issue. Pricing frameworks, including for generic drugs, are cited as among the many factors leading to a manufacturer decision to no longer supply a drug in Canada.
- All policy makers are encouraged to ensure that all regulatory frameworks or pricing agreements do not have the unintended consequence of limiting availability of drugs. Market diversity must be encouraged and incentivized to ensure that there are options from more than one manufacturer in cases of stoppage because of a contamination issue, for example, or discontinuations. Options such as streamlining pathways and creating incentives must be considered to ensure that patients in Canada have access to the same diversity of medications that are available elsewhere.
- In addition, mechanisms are needed to ensure that those who rely on a specific medication can access supply if there are new demands on that supply. For example, during the COVID-19 pandemic several medications were re-directed from existing patients to those with other needs causing disruptions for patients who relied on those medications.



## About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of 30 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 involve issue education, 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 Association of Psoriasis Patients  
 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 Psoriasis Network  
 Canadian Skin Patient Alliance  
 Canadian Spondyloarthritis Association

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 Medical Cannabis Canada  
 Medicines Access Coalition – BC  
 Migraine Canada  
 Millions Missing Canada  
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