



March 12, 2021

Biomanufacturing Strategy: Collaboration informed by patients to meet patient needs

Introduction

The Best Medicines Coalition (BMC), a national alliance of patient organizations together representing millions of patients, welcomes the opportunity to provide input to the Department of Industry, Science and Export Development's consultation on the consideration of a biomanufacturing strategy for Canada.

The BMC's focus is on ensuring that all Canadians have access to the medicines they need when they are needed, including vaccines. We provide recommendations regarding selected issues within the context of regulations and programs related to pharmaceutical care for Canadians, including drug price regulations, review, assessment and reimbursement of drugs, strategies to support patients with rare diseases, and broad pharmaceutical care reform. Importantly, the BMC is involved in drug supply issues, particularly regarding ongoing and intermittent shortages, and is an active participant in the Multi-Stakeholder Steering Committee on Drug Shortages, convened by Health Canada in concert with provincial/territorial governments.

Overview:

Canada has long experienced drug supply issues which are ongoing and often with critical implications. As the COVID-19 pandemic has unfolded, these challenges have been brought sharply into focus. The need for expeditious access to new and emerging vaccines, drugs and personal protective equipment has become both necessary and apparent at all levels of government, and indeed by Canadians at large.

We support and applaud the government's focus on enhancing and expanding the domestic biomanufacturing sector to produce life-saving vaccines and therapeutic drugs at a scale that could meet the needs of Canadians. Our organization will support government strategies that enable more, faster, and sustainable access to existing or new and innovative medicines. Importantly, we believe that enabling and sustaining the best possible patient care and outcomes should be a fundamental objective of a biomanufacturing strategy. Recommendations are listed below, followed by discussion.

Recommendations:

- Establish sustainable patient care as a fundamental goal
- Formalize and embed sustained patient access holistically
- Pan-Canadian collaboration to build supply capacity and efficiency
- Collaborative, inclusive and transparent governance

Core considerations:

- **Establish sustainable patient care as a fundamental goal.** While there are a multitude of positive implications of an expanded and robust biomanufacturing sector, we believe that improving and sustaining patient care and optimizing patient health outcomes must be adopted and entrenched as the objective. Ultimately, Canadian patients need access to necessary medicines and domestic manufacturing must be expanded to enable these needs to be met. Policy options must be considered and pursued through the lens of expanding the domestic footprint of biomanufacturing, to increase supply and access to drugs and vaccines.
- **Formalize and embed sustained patient access holistically.** Any biomanufacturing strategy intended on providing supplies of drugs and vaccines for Canadians should be part of a holistic approach to ensuring sustained access to necessary medications for Canadian patients. As such, the strategy must reach across departmental lines to a whole-of-government approach to ensure that individual government initiatives are aligned with overarching objectives. The federal government should instill this focus on access in other initiatives that impact Canadian's access to drugs, such as the government's pricing reform agenda, the government's rare drugs strategy, the proposed development of the Canadian Drug Agency, as well as in the development of any model of national pharmacare.
- **Pan-Canadian collaboration to build supply capacity and efficiency.** Governments across Canada have been increasingly working together and collaborating over the past decade to purchase medical supplies in bulk, including pharmaceutical drugs and vaccines, to both enable supply and sustainable prices for those supplies. Governments should collaborate to assess how they can work together with the tools available to both federal, provincial and territorial governments to not just ensure there is domestic supply of drugs for Canadians, but that the drugs and vaccines efficiently and effectively move through the supply chain, from the manufacturer to the patient.
- **Collaborative, inclusive and transparent governance.** As consultation, strategy development, policies and implementation move forward, delivery frameworks and related governance must reflect the diversity of stakeholders that can meaningfully contribute in defining values, needs and objectives. Patients and the organizations that represent them must have an integral role as this moves forward through formal representation in governance and through consultative processes. Given the importance of Canada's drug and vaccine supplies both in pandemic scenarios and ongoing, policy and implementation frameworks must be transparent and accountable to Canadians. We call for the co-development of this biomanufacturing strategy to include patient representatives.



About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of patient organizations, together representing millions of patients, with a shared goal of equitable, timely and consistent access for all Canadians to safe and effective medicines that improve patient outcomes. 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, consensus building, 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.



Alliance for Access to Psychiatric Medications
 Arthritis Consumer Experts
 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 Spondylitis Association
 CanCertainty
 Crohn's and Colitis Canada
 Cystic Fibrosis Canada
 Fighting Blindness Canada
 Health Coalition of Alberta
 Huntington Society of Canada
 Kidney Cancer Canada
 Lymphoma Canada
 Medical Cannabis Canada
 Medicines Access Coalition – BC
 Millions Missing Canada
 Ovarian Cancer Canada
 Parkinson Canada