BEST MEDICINES COALITION

Submission to the Standing Committee on Finance: Priorities for the 2021 Federal Budget

Best Medicines Coalition

August 7, 2020

Priorities for the 2021 Federal Budget

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 Standing Committee on Finance as part of its pre-budget consultation with an emphasis on COVID-19 pandemic recovery. This submission was informed by position documents developed in consultation with BMC's member organizations. Statements and recommendations expressed here reflect areas of consensus among the organizations listed at the end of this document.

Summary of recommendations:

The BMC's focus is on ensuring that all Canadians have access to the medicines they need when they are needed. We provide recommendations regarding selected issues within the context of COVID-19: drug price regulations, drug supply challenges, pharmaceutical care policies and financial needs in the not-for-profit/charitable sector.

1. ***Drug price regulations (Patented Medicines Price Review Board)***
   - Given the COVID-19 challenges ahead, Canada needs pharmaceutical pricing rules which achieve two goals:
     - Improve the affordability of medicines.
     - Encourage, not deter, the introduction of new medicines and vaccines plus clinical trials in Canada sponsored by drug developers.
   - We call for phased implementation of the pending Patented Medicines Regulations:
     - Apply the new basket of comparator countries to bring down prices as soon as possible.
     - Defer proposed new economic factors to a second stage, while monitoring and evaluating.
   - We call on the Government of Canada to state publicly what its goal for drug price reductions is. Is it to the median of OECD countries or lower? If lower, we fear problems with patient access to new therapies and clinical trials.

2. ***Drug supply and shortages***
   - The Government of Canada needs to adopt more proactive approaches to communicating drug supply and shortages and measures to address them. In addition, effective and proactive policy responses to drug supply and shortages regarding COVID-19 and otherwise, must be pursued.
   - We recommend to Parliament that the new powers for the Health Minister in the Food and Drug Act governing drug supplies should be extended past their September expiry date and made permanent. In addition, measures to expand Canada's pharmaceutical manufacturing capacity must be taken to safeguard against critical shortages moving forward.

3. ***Comprehensive pharmaceutical policy reform***
   - COVID-19 has exposed significant health care deliver challenges, including pharmaceutical care. Policy reform must move forward to address the most critical disparities and inequities and ensure a comprehensive range of medicines are available to all. Every patient needs drug insurance to address the +20% of drug spending which comes out of the pockets of patients.
   - Streamlining infrastructure, such as the proposed Canada Drug Agency (CDA), is imperative to eliminating waste and redundancy, and reduce wait times for patient access to new therapies. The CDA must not be an additional layer, but a modernization instrument, with appropriate governance including patient representation, established by statutory law and subject to Parliamentary oversight and interventions, unlike too many parts of the status quo.

4. ***Support for health sector not-for-profits and charities***
   - COVID-19 has had devastating financial impacts, including on patient organizations within the not-for-profits and charity sector as they face increased demands from patient communities.
   - We support targeted financial assistance and further measures to ensure that patient organizations, both not-for-profits and registered charities, can continue to fulfil their missions.

Pre-budget considerations: Issues and discussion

1. Drug price regulations (Patented Medicine Price Review Board)

Canadians need rules which improve affordability of medicines, bringing prices in line with appropriate international comparators. Equally important, especially in the COVID-19 environment, regulations must encourage, not deter, new medicines or clinical trials in Canada sponsored by drug developers. Regulatory processes must be made accountable, transparent, and inclusive.

BMC has participated in consultations regarding modernizing pharmaceutical pricing regulations, including on pending regulations and PMPRB staff guidelines. While there are positive elements, concerns remain and, therefore, the regulations and guidelines should not proceed as presented.

Primary areas of concern are:

- Initial signs of negative impact on patient access
- Price reductions beyond and below original intent
- Inequitable distribution of affordability gains
- Lacking transparency, accountability, and meaningful patient engagement

Recommendations to move forward:

Evidence-based decisions. The path forward must be informed by current, credible, and comprehensive evidence, including on initial impacts on critical markers, namely introductions of new medicines and initiation of clinical trials sponsored by drug developers (Phase 2, 3 & 4 trials). Work must begin on gathering appropriate data. The framework for data collection and analysis must be developed in cooperation with patient representatives and all stakeholders and conducted independently.

Appropriate pricing and phased implementation. Price reduction goals must be carefully reviewed to ensure measures are appropriate and necessary. In addition, the regulations and guidelines must be evaluated from the lens of all patients, regardless of how they access medicines, with special consideration of whether status quo of negotiated rebates is equitable to all patients. Implementation should be in phases to quickly achieve affordability goals while permitting all of us to understand potential negative impacts on access to new medicines and relevant clinical trials. Specifically, a first phase would apply the new basket of comparator countries to bring down prices as soon as possible for all patients, leaving new economic factors to a second phase after data collection, analysis, and public discussion.

Rigorous evaluation. Transparency and accountability must be strengthened with the goal of ensuring health outcomes and patient care do not suffer as regulations and guidelines are applied. Monitoring and evaluation must be transparent and rigorous including analysis of real savings and costs related to possible treatment delays in the short or long term, with mechanisms in place to trigger adjustments. Patients must be involved in determining these factors. Importantly, public reporting must be entrenched, such as in the Patented Medicine Prices Review Board Annual Report, and made public in a timelier manner than current PMPRB practice. (The 2018 report was just published/tabled DATE.) An external audit would be appropriate to provide Canadians with confidence in our federal pricing regulator.

Collaborative engagement. A holistic and value-based approach to patient engagement must be adopted, with opportunities for input and involvement embedded in PMPRB's structure and throughout its processes. Specifically, patients should be represented on the Board and included on the Human Drug Advisory Panel, and a formal patient advisory body should be established.

5. Drug supply and shortages

Drug supply challenges are long standing in Canada, and the pandemic has prompted shortages related to COVID-19 treatment and supply chain disruptions. We have concerns about increasing number of reported drug shortages. Prior to March 2020, the government's drug shortage website listed approximately five new shortages per day, and since then new shortages have spiked to up to 16 daily.

In late 2019/early 2020 and as recently as July 2020, momentum has been building in the United States to seek bulk importation of Canadian drugs, primarily to take advantage of lower prices here. The United States federal government and various states have introduced rules to enable bulk importation, an increasingly serious threat in the current pandemic. Emergency COVID-19 legislation approved by Parliament included new powers for the Health Minister to require information disclosure and make orders to protect drug supplies. These new powers are set to expire in September but should be made permanent.

The federal government, primarily through Health Canada, has been working to identify and address current and anticipated shortages. The BMC participates in the *Multi-Stakeholder Steering Committee – Drug Shortages*, co-chaired by Health Canada, through which much of this important work is shared.

We encourage the federal government to strengthen efforts to communicate more openly on current and potential drug shortages and measures to address broad supply issues and individual shortages. We support further measures to protect our drug supply. COVID-19 has highlighted that we are dangerously dependent on global supply chains for critical medical supplies and necessary medicines. We support policies to address this, including measures to facilitate increased domestic manufacturing, especially of those medicines considered critical.

6. Comprehensive pharmaceutical reform

The BMC has been actively involved in providing advice on reform of Canada's pharmaceutical care framework, including consulting with the Advisory Council on the Implementation of National Pharmacare. As a core position, while universal drug coverage through a single payer system may be a worthy long-term goal, we support a phased approach to reform, levelling up public programs to address inequities and prioritizing addressing the most critical disparities in the system. Every Canadian needs insurance for prescription drugs.

While this pandemic has shifted priorities, addressing system-wide challenges is more important than ever. We support the federal government resourcing and moving forward with policy reform aimed at providing better care to all Canadian patients. This must begin with building a more efficient and effective infrastructure. The proposed Canada Drug Agency (CDA) has potential to drive positive reform and deliver integration and efficiencies while providing more timely access to necessary medications, including breakthrough therapies.

Establishment of the CDA is an excellent opportunity to address the current policy and program delivery labyrinth by eliminating duplication, waste, and redundancy. Importantly, the CDA must not be an additional layer, but an instrument for modernization and effectiveness. To ensure transparency and accountability, we recommend that the CDA be established by statutory law, subject to Parliamentary oversight, the Access to Information Act, Auditor General of Canada scrutiny, and interventions by an Ombudsman-type office. Enshrinement of the patient voice within governance is an important and powerful tool to ensure that patient expertise and values are recognized and drive policy and decision-making, and should be entrenched in all organizations involved in drug review, approval, evaluation, and negotiation, and resourced appropriately. This includes Health Canada, Canadian Agency for Drugs and Technologies in Health, Patented Medicine Prices Review Board, and pan-Canadian Pharmaceutical Alliance.

7. Support for health sector not-for-profits and charities

The COVID-19 crisis has been financially devastating for our member organizations, including not-for-profits and registered charities, as they work to continue supporting patient communities. During this time, BMC patient organization members face a dual challenge: (a) increased demands from patients, many with complex and difficult to treat conditions, for information and services to navigate care; and (b) a crisis of financing and revenue declines due to the economic shutdown. We commend the federal government's efforts to date to support this sector and support and welcome further measures to ensure that patient organizations, both not-for-profits and registered charities, can fulfil their missions.

BEST MEDICINES COALITION

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, planning 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
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 Mental Health Association
Canadian PKU & Allied Disorders
Canadian Psoriasis Network
Canadian Skin Patient Alliance
Canadian Spondylitis Association
Crohn's and Colitis Canada
Cystic Fibrosis Canada
Fighting Blindness Canada
Health Coalition of Alberta
Huntington Society of Canada
Kidney Cancer Canada
Lymphoma Canada
Medicines Access Coalition - BC
Millions Missing Canada
Ovarian Cancer Canada
Parkinson Canada