



May 7, 2020

Members of the Standing Committee on Health
Sixth Floor, 131 Queen Street
House of Commons
Ottawa ON K1A 0A6
Canada

Subject: Study on the Canadian Response to the Outbreak of the Coronavirus

Dear Honourable Members,

In the context of the House of Commons Standing Committee on Health's ongoing deliberations on the COVID-19 pandemic, on behalf of the Best Medicines Coalition (BMC) – a national alliance of 27 Canadian patient organizations representing millions of patients across the country – I am writing to provide recommendations for how the federal government can further support patient communities at this time.

The COVID-19 crisis has been particularly devastating for our member organizations, including not-for-profits and registered charities, as they work to support their patient communities. During this time, Best Medicines Coalition member organizations 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 downturn. We commend the federal government's efforts to support this sector and welcome further measures to ensure that patient organizations can fulfil their missions.

While health care system and patient care challenges are considerable, our focus as a coalition remains ensuring that all Canadians have access to the medicines they need. As such, we wish to provide you with perspectives and recommendations regarding two significant issues within the context of COVID-19, namely drug supply challenges and barriers to patient access to new therapeutics and vaccines in Canada.

1) Maintain strong drug shortage mitigation; adopt proactive consultation and communication

Drug supply challenges are long standing in Canada, and COVID-19 has prompted specific shortages related to treatments and supply chain disruptions. The patient community has very real concerns about the increasing number of reported drug shortages across the country.

According to the Canadian Pharmacists Association, in the months leading up to March 2020, the government's mandatory drug shortage website had been listing approximately five new shortages per day. However, we have seen that number spike significantly in the past few weeks, up to 16 reported new drug shortages per day, and that was during the week of March 31-April 7 – nearly a month ago.¹ These shortages affect a broad number of medications used for a variety of different diseases and indications, not just COVID-19.

In addition, over the past year, intensifying in late 2019 and early 2020, there has been momentum building in the United States to look at bulk importation of Canadian supplies of prescription drugs, primarily to take advantage of lower prices here in Canada. In fact, the United States federal government and various states have introduced enabling legislation, rules and plans to permit bulk importation. This is an increasingly threat in the current pandemic. The omnibus legislation approved by Parliament to deal initially with COVID-19 included new powers for the Health Minister to make orders to protect drug supplies. These new powers are helpful safeguards which should be extended past their September expiry date and made permanent.

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The federal government, primarily through Health Canada with the involvement of other departments, has been working tirelessly to identify, monitor and proactively address current and anticipated drug shortages. We fully commend Health Canada's efforts to protect Canadians, working to ensure that all patients can get the drugs they need. The BMC participates in the *Multi-Stakeholder Steering Committee – Drug Shortages*, co-chaired by Health Canada, through which much of this important work is reviewed and discussed on weekly conference calls. This committee is an exemplar for information sharing and cooperation among stakeholders.

However, the real threat of drug shortages continues to be challenging for patients and the health system to manage, and it has a very real impact on patient care. It is important to support patient communities, and to alleviate much of the stress and anxiety associated with not knowing whether a needed medication is in short supply. We encourage the federal government to strengthen efforts to proactively and transparently communicate on this topic, including current and potential drug shortages emerging because of COVID-19, or other reasons, and measures being undertaken to address broad supply issues and individual shortages.

Part of the broader Canadian response to the COVID-19 emergency led to specific measures to secure our drug supply. In March, we witnessed a Canada-wide set of limits on prescriptions to a 30-day refill supply, down from the typical 90-day supply for drugs for chronic, stable conditions. It is recognized that rationing access to drugs may be necessary if there is a real threat of shortage but perhaps would not be justified for medicines that are in normal supply. The unintended consequence of applying this policy to all medicines has been to expose patients to extra costs for dispensing fees, in some cases, and necessitating additional visits to pharmacies by those who have a need to isolate and/or receive additional home deliveries. These additional interactions are of particular concern for high-risk groups such as the elderly and those who are immunocompromised. It would be appropriate for the federal government to lead in involving all stakeholders, including the patient community, in examining and understanding the implications of this policy, including perhaps developing evidence-based criteria for setting, easing or lifting the 30-day limit on prescription refills, especially if there turn out to be additional waves of COVID-19 infections.

In this context, we recommend that Canadian governments and regulators adopt proactive approaches to communicating drug supply and shortages issues and measures to address them. In order to achieve this, health systems and their partners should engage with patient communities, including the Best Medicines Coalition and its member organizations, in order to inform policy responses to drug shortages regarding COVID-19 and otherwise. We also recommend 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.

2) Remove barriers to new therapeutic and vaccine introductions in Canada

The COVID-19 infections increased the need for patients to have access to therapeutics that can help them manage their conditions and avoid unnecessary hospitalizations and even death. In this respect, the federal government's August 2019 amendments to the *Patented Medicines Regulations*, which change how the Patented Medicine Prices Review Board (PMPRB) regulates medicine prices in Canada, represents a significant new barrier to the introduction of new therapeutics and vaccines in Canada.

Since the amendments were first proposed by Health Canada in 2017, patient communities, along with hundreds of other stakeholders, have repeatedly communicated concerns about the potential impacts of the reforms on patient access to new medicines and there are indications that these concerns have unfortunately been validated. Evidence suggests that the regulations have negatively impacted decisions by pharmaceutical companies on whether to withdraw or launch new medicines or invest in Canada.

In terms of new medicine launches, the percentage of new medicines approved in Canada before or within a year after approval in the United States decreased substantially from an average between 2013 and 2016 of 55.4% to 15.6% in 2019.ⁱⁱ Meanwhile, the number of clinical trials registered by Health Canada between November 2019 and mid-March 2020 fell by 52% compared to the average number registered during the same period in the previous six years.ⁱⁱⁱ

There are concerns that the lack of therapeutic alternatives coming to Canada as a result of the PMPRB changes will only further exacerbate drug supply issues noted above.

In addition, the COVID-19 emergency measures have made it impossible for the PMPRB or other stakeholders – especially patient organizations – to effectively consult and discuss the changes and their unfolding impacts in advance of their formal coming-into-force on July 1, 2020. In this context, we have called on the federal government to pause implementation of the PMPRB regulations.

In the context of the COVID-19 emergency, the Best Medicines Coalition recommends that the government pause the implementation of the regulations regarding the PMPRB and provide public notification to this effect in order to ensure there is time to appropriately consult all stakeholders, including patient representatives, on these changes. The government needs to be open to recalibrating its regulatory approach in the face of growing evidence of drug supply issues, reductions in clinical research and decisions to withdraw, delay or not launch new medicines in Canada.

Final remarks

The federal government has an important opportunity to address the current challenges patients face during this unprecedented public health emergency. We strongly encourage you to consider these recommendations as part of the government's response to the crisis. We appreciate the opportunity to provide our input into this important process and we welcome the opportunity to provide oral testimony on any of the above recommendations.

Yours sincerely,



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CC: Alexandre Jacques, Clerk of the Committee

ⁱ <https://www.pharmacists.ca/news-events/news/pharmacists-see-spikes-in-drug-shortages-during-pandemic>

ⁱⁱ Rawson N., *Fewer new drug approvals in Canada: early indications of unintended consequences from new patented medicines regulations*, Canadian Health Policy Institute, March 2020: https://www.canadianhealthpolicy.com/products/fewer-new-drug-approvals-in-canada-early-indications-of-unintended-consequences-from-new-pmprb-regs.html?buy_type=

ⁱⁱⁱ Rawson N., *Clinical Trials in Canada Decrease: A Sign of Uncertainty Regarding Changes to the PMPRB?*, Canadian Health Policy Institute, April 2020: https://www.canadianhealthpolicy.com/products/clinical-trials-in-canada-decrease--a-sign-of-uncertainty-regarding-changes-to-the-pmprb-.html?buy_type=



About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of patient organizations 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
 Arthritis Consumer Experts
 Asthma Canada
 Better Pharmacare Coalition
 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 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
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