



August 10, 2020

The Honourable Patty Hajdu, P.C. M.P.
Minister of Health
70 Colombine Driveway
Tunney's Pasture
Ottawa, Ontario K1A 0K9
Via email: hcmister.ministresc@canada.ca

Dear Minister Hajdu,

I am contacting you on behalf of the Best Medicines Coalition (BMC) as follow up to our June 19, 2020 letter about the Patented Medicines Regulations and government policy related to drug prices. Building on our previous letter, now that the time has ended for written submissions on only the revised draft Guidelines BMC wants to take this opportunity to express our ideas on ways to move forward immediately to achieve lower drug prices and related policies.

I reiterate our support for improving affordability of medicines and bringing prices in line with appropriate international comparators. It is also of equal or greater importance that Government regulations and/or Guidelines of the Patented Medicine Price Review Board (PMPRB) do not deter the introductions of new medicines or prevent clinical trials sponsored by drug developers from being conducted in Canada. Governance for regulating prices must be accountable, transparent, and inclusive.

It is in the spirit of these goals of affordability, patient access and better governance that we reviewed the revised draft Guidelines presented by PMPRB. We asked the fundamental question: How will patient care be impacted? As we stated in our August 4, 2020 submission to the PMPRB (attached), there are positive elements in this most recent version of the draft Guidelines, but significant concerns remain and, therefore, BMC asks that the Government and PMPRB not proceed with the Regulations and Guidelines fully, as presented.

Again, the core issue is impact on patients. The Regulations and draft Guidelines apply new comparator countries and also new economic factors which together, by all accounts, will deliver reductions beyond the government's original intent. We understand that Government intent was to be at the OECD median of drug prices, which is an anticipated reduction of approximately 20 per cent. As such, we are concerned about patient care repercussions with fewer new medicines made available in Canada and a decrease in industry-sponsored clinical trials which often provide early access for patient volunteers to promising new therapies. Early signals indicate a drop off in launches of new drugs compared to other developed countries.

We also note that the Regulations and Guidelines, as proposed, would entrench the status quo, a price negotiation and rebate system, which only allows some payers (governments and private insurers) to fully realize lower prices but not other payors, namely patients who pay out-of-pocket. This approach excludes those patients and is inequitable to them. Lastly, the framework (Regulations and Guidelines) as presented lacks transparency, accountability, and meaningful patient engagement.

These issues are made particularly critical given the realities of the COVID-19 pandemic crisis which has brought into sharp focus our two needs: access to new treatments and vaccines as soon as possible and affordability. With this in mind:

- *We call on the Government of Canada to state publicly and precisely its specific goal for drug price reductions. Is the federal goal to lower drugs prices by regulation either at or below the OECD median and, if below, how far below?*

and

- *We call on the Government of Canada to bring down prices as soon as possible, by applying the new basket of comparator countries first – not later than January 1, 2021 - and deferring the new economic factors until a second stage, to be determined based on monitoring and evaluating.*

We look forward to your response on these requests and welcome any opportunity to discuss our perspectives.

Looking ahead, as we stated in our June 19, 2020 letter, holistic policy approaches to pharmaceutical pricing warrant a more fulsome and inclusive consultative discussions. Importantly, the path forward must be informed by current, credible, and comprehensive evidence, including on initial impacts on critical markers, with the framework for data collection and analysis developed in cooperation with patient representatives and all stakeholders and conducted independently and impartially.

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. Importantly, public reporting must be entrenched, and an external audit would be appropriate to provide Canadians with confidence in our federal pricing regulator. Providing the PMPRB annual report for 2018 in the summer of 2020 does not meet that standard. We should all be seeing the 2019 report by now. As with other public bodies, a value-based approach to patient engagement must be adopted. In the case of PMPRB, patients should be represented on the PMPRB Board and included on the PMPRB Human Drug Advisory Panel, and a formal patient advisory body to PMPRB should be established.

Again, we look forward to your response to our requests about price reduction goals and approaches to move quickly to achieve increased affordability. In addition, we wish to engage in meaningful and productive discussions on policy approaches to pharmaceutical pricing and related issues, and request opportunities to do so.

Sincerely,



John Adams
Chair, Best Medicines Coalition

Encl.

cc. Sabina Saini, Chief of Staff, Health Minister's Office (sabina.Saini@canada.ca)
 Kathryn Nowers, Director of Policy, Health Minister's Office (kathryn.nowers@canada.ca)

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