June 19, 2020

The Honourable Patty Hajdu, P.C. M.P.
Minister of Health
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Tunney's Pasture
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Ottawa, Ontario K1A 0K9

Dear Minister Hajdu,

I wanted to send you a note on behalf of the patient communities that the Best Medicines Coalition (BMC) represents to thank you and your government for delaying the implementation of the Patented Medicine Prices Review Board (PMPRB) regulations. It is encouraging that Health Canada is receptive to stakeholders' concerns and has demonstrated considerable flexibility in its approach during this unprecedented COVID-19 crisis. The Best Medicines Coalition has been asking the government to pause and reflect on these regulations. Again, thank you.

I also want to reiterate that the Best Medicines Coalition is aligned with the government on the need to improve the affordability of medicines in Canada. Patients and their families live with a significant burden of prescription drug costs which can cause personal and financial stress in addition to living with health conditions or disability. We can and should secure access to medicines at more affordable prices, and there are many proven ways to accomplish this.

At the same time and of equal importance, BMC believes that patients need more timely access to new drugs which meet unmet needs. Canada has seen challenges in this regard and we believe there must be confidence, based on best available evidence, that the new regulations will not exacerbate these challenges. Regulations must not discourage rapid introduction of a comprehensive range of medicines and vaccines to Canadians. This includes access to clinical trials as they provide willing patients early access to promising new therapies, and medical research investments. Quite simply, Canadians need an effective, balanced, and fair framework of regulations whose primary goal must be sustaining and improving the health and wellbeing of current and future patients.

In this context, we hope that you will use this period – until January 1, 2021 – to fully consult and consider fundamental aspects in the amended regulations that act as barriers for patient access to new medicines. We believe there are indications these barriers will continue to exist if the policies embedded in the regulations are not recalibrated prior to implementation. Specifically, we request that you consider the following as you move forward in the coming weeks and months:

1. Government reconsideration of regulatory policy approaches
2. Government consultations with stakeholders
3. PMPRB, as an independent quasi-judicial tribunal, intentions to consult with stakeholders

These issues are discussed in turn, below.

1. Government Policy Reconsideration Including Phased Implementation and Impact Monitoring

Patient communities in Canada support efforts to lower drug prices. However, we question fundamental aspects of the government's policy underlying the regulations and strongly urge you to re-examine the impacts on patients of the proposed regulatory regime. For example, it could be worthwhile to explore phasing in aspects of the regulations to meet the goal of increasing affordability without additional measures which may have unintended negative impact on patient access to new medications.

It is worthwhile to consider whether the need for the new economic factors is necessary as part of the regulations, especially given that the changed list of comparator countries will in itself provide price reductions that will satisfy the goal of improving medication affordability. We note that these policies are also being implemented during a time of great upheaval in the economy and social systems, and it is necessary to consider how all these pieces will work together in our "new normal".

The new economic factors appear to be causing the most uncertainty and potential adverse impacts on our most vulnerable communities, and at the very least, could be suspended for potential implementation later on (if the desired cost savings are not achieved), while other elements of the regulations move forward as planned. We strongly believe that when there is not reasonable certainty that aspects of the new regulations will have a positive impact on patient care and health system efficiency, value and sustainability, which is the case here, then these elements must be revisited.

The broad regulation of the safety, efficacy, quality, patents and pricing of pharmaceuticals must be efficient and effective. The use of cost-effectiveness factors should not duplicate or prolong the work of others in the system or create overlapping mandates, as the new economic factors risk doing. It has not been made clear how PMPRB's application of cost effectiveness factors will include patient perspectives, as is done by the Canadian Agency for Drugs and Technologies in Health (CADTH) in its Common Drug Review and pan-Canadian Oncology Drug Review, by the Institut national d'excellence en santé et en services sociaux (INESSS) in Quebec, by the BC government in its Your Voice process or by the Ontario government through its Ontario Health Technology Advisory Committee. Decisions about the value of health technologies are never based on numbers alone and patients' perspectives in these decisions are essential to achieving better patient care.

Moving forward first with the change in comparator countries would also allow Canadians to better consider the effects and outcomes of this major reduction in prices on its own. As in good medical practice, a prescribing clinician should implement one treatment or change at a time, to understand the impacts of each new medical intervention on the patient. Moving forward with both major changes (comparator countries and the new economic factors) will make it impossible to assess the impacts of each change, and risks "over-medicating" the already challenged pharmaceutical system in Canada. Put simply, these regulations do too much at the same time.

2. Government to Consult Substantively, Transparently and Appropriately with Patients and other Stakeholders

Our second consideration is for the Government of Canada to undertake consultations that are aligned with the Government's longstanding goal of substantive, transparent and accountable consultations. These consultations should not be limited to how the policies in the regulations will be administered and implemented through the PMPRB's own guidelines. It would be appropriate that Health Canada undertake its own consultations focused on holistic policy concerns about the regulatory framework including the new economic factors, with particular focus on patient impacts. Based on the experience to date, patients are concerned that their perspectives will not be sufficiently heard or considered by the PMPRB.

We also note concerns about the quality of the department's Gender-Based Analysis Plus, which has become a core government policy. From our experience, the plain truth is that the burden of caring for patients, including children and elders, falls more greatly on women than men, something the department's analysis did not consider, likely because it assumed (incorrectly) that the policy would have no impact on access to new medicines, which we believe is incorrect. Lack of access to new medicines will lead to a disproportionate negative burden on women. In addition, people living with disabilities often live with chronic health conditions and an analysis could and should be done of likely impacts on this vulnerable population.

One opportunity to expand the level of review and analysis of the regulations would be to ask for a parliamentary committee to examine the PMPRB reforms in a holistic way, and in a democratic manner

allowing for incorporation of a range of perspectives. Moving the implementation date back by six months would allow for an external parliamentary review, which could be used to better inform government policy and regulations. Different perspectives including those of patients with lived experiences should be enabled to present.

3. PMPRB to Consult Substantively, Transparently and Appropriately with Patients and Other Stakeholders

We look forward to participating in the written consultation and any other opportunities on the second version of PMPRB draft guidelines, and are hopeful that working together we can improve the quality of this consultation and address the gaps in consultations to date, which we have outlined for your reference in Appendix A. Many patients have different experiences and concerns about how these changes might impact them and their families. We are optimistic that the delay of savings for patients and their families resulting from earlier failures of process can be addressed and we look forward to continuing to bring the voices of patients to this discussion.

In this context, I encourage you, as Minister, to do whatever you can to conduct transparent, substantive, and patient- and citizen-centered consultations in a way that addresses the above-noted issues and to help guide PMPRB go do likewise within its mandate.

We look forward to reviewing and participating in the PMPRB draft guidelines consultation and we look forward to fulsome consultation on government policy approaches and options in the coming months.

I will keep you posted on our activities, and please do not hesitate to stay in contact with me as these consultations move forward.

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)

Appendix A: ***Issues with PMPRB consultations to date***

- 2016 PMPRB Consultation Paper entitled *Rethinking the Guidelines* committed to "Engage Stakeholders and Gather Expert Input" through a "Public Policy Hearing – invite stakeholders to appear before the Board and make representations in support of their written submissions" - this was to happen in the Fall 2016/Winter 2017, and did not happen.
- The PMPRB has a longstanding tradition of publishing all of the submissions that it receives on the guidelines. In March 2020, it noted three submissions were received but they will be considered "confidential," with no explanation for this change in policy. We are very hopeful that the submissions for this next round of guidelines consultation will all be made public and, if there is a divergence from longstanding practice, that there be a published reason for such a change that can be open for scrutiny and public consideration, in line with your mandate and government policy on openness and transparency.
- The PMPRB's March 2020 Public Forum to discuss the draft guidelines was cancelled because of COVID-19. Notably, there are many government activities that are able to continue to take place, including parliamentary committees, the House of Commons and the legal system through videoconferencing systems. There was no substantive explanation for cancelling this opportunity to engage. The Health Minister should encourage the PMPRB to hold a Public Forum, virtual if necessary, to be scheduled as soon as feasible once PMPRB has received the fresh round of written submissions and all submissions are published on its website.
- There was no public presentation by the PMPRB on the draft guidelines in French regarding its approach, despite this issue being raised during the English briefing earlier this year. As a result, we are concerned that the patients that we represent whose first language is French may have been penalized in not being adequately briefed on the government's positions to allow meaningful participation and engagement in both languages.
- The patient representatives on both the PMPRB Steering Committee and its Technical Working Group in 2018 and 2019 raised significant concerns about how the consultations were conducted, how their contributions were treated and even personal character attacks. The PMPRB needs to significantly improve how it engages and consults with patients and patient organizations.
- Finally, the PMPRB's 2018 Annual Report has not yet been made public, which is a statutory requirement; we are now more than a year after this report is normally tabled in the House of Commons. We are concerned as patients that we do not have the appropriate and up-to-date data required to provide input on all of these consultations, when reports like this are not made available to Parliament and the public.

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
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