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Patented Medicine Prices Review Board
Standard Life Centre, Box L40
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Ottawa, ON K1P 1C1
submitted electronically to pmprb.consultations.cepmb@pmprb-cepmb.gc.ca

Re: Notice and Comment – On the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions

Dear Board Members,

Once again, we are grateful for PMPRB's efforts to maintain engagements with patients, stakeholders, and the public about the ongoing changes with the Guidelines. Many of our previous submissions continue to provide salient points that the Board should (re)consider. Our efforts to submit input to date include, but are not limited to, our collaboration with the Alliance for Safe Biologic Medicines for the Draft Guidelines 2019,[1] the Draft Guidelines 2020,[2] and feedback on the Guideline Monitoring and Evaluation Plan 2021.[3] I will reference applicable sections throughout this letter and have attached them for your convenience.

As I have mentioned in a letter to the Prime Minister[4] and in our feedback to GMEP,[3] I was one of only three patient representatives on the PMPRB Steering Committee on Modernization of Price Review Process Guidelines 2018-2019. At the time, I sat as both the CEO of the Gastrointestinal Society and the Chair of the Best Medicines Coalition. I repeatedly voiced the patient perspective with the PMPRB reforms. Sadly, patient representatives were nothing more than a checkmark in the Steering Committee deliberations and the PMPRB is wrongly characterizing us as distributors of disinformation, with the recent PMPRB internal communications plan. I strongly encourage PMPRB to reconsider our concerns on its **clearly demonstrated adversarial culture toward patients** and to acknowledge its appalling actions toward patient communities. We are respectfully representing the patients who need the medications on which the PMPRB is attempting to implement excessive controls that could affect the supply chain.

The PMPRB's Consultation Policy outlines service standards such as "identify[ing] in advance what information will be needed to support the consultation process and how this will be shared with stakeholders," as well as "identify[ing] evaluation and feedback mechanisms."[5] While we, along with many others, would greatly benefit from further information on this consultation topic, i.e., a town hall where meaningful conversations can take place, and more time to provide feedback considering the summer season, fourth wave of COVID-19, and a federal election, I hope all our input receive the genuine and conscientious response we long deserve.

The Elephant(s) in the Room

Before I delve into some of the issues in the proposed changes to the comparator countries and international price tests for Grandfathered medicines and their line extensions, I must first address larger factors beyond PMPRB's control that I am sure are of concern to you as well.

As you know, there are several court decisions regarding PMPRB's amendments. Appeals are still pending on the decisions of the Federal Court in *Innovative Medicines Canada v Canada (Attorney General)* and the Quebec Superior Court in *Merck, Janssen, Servier, Boehringer Ingelheim, Bayer, Theratechnologies, Avir Pharma c. Procureur Général du Canada et Procureur Général Du Québec.*[6] In a unanimous decision of the Federal Court of Appeal in *Alexion Pharmaceuticals Inc. v Canada (Attorney General),* the Court made significant criticisms on PMPRB's departure from its mandate of controlling patent abuse under the *Patent Act* and lack of transparency in its application of the Guidelines.[7]

Even parliamentary democracy expert, Professor Donald J. Savoie, declared that "legislation and regulations establish the perimeters within which public servants must operate... [and] accordingly, public servants are not free to improvise when they produce a communications plan or launch a strategic plan as PMPRB did for the 2015-2018 period."[8] There is a growing body of precedent and case law detailing PMPRB's jurisdiction and

statutory limits as a regulator, including examples of its arbitrary and inconsistent application of price tests without legally acceptable reasons and attempts in expanding as a consumer protection agency.

Despite these glaring concerns and the well-known and anticipated snap election (which is now underway), PMPRB proceeded to make additional changes in this consultation period.

As the Honourable Judge David W. Stratas proclaimed in the *Alexion* decision, "Administrators cannot put themselves in a position where they are not accountable." Evidently, Health Canada must conduct an **external review** of PMPRB's operations and policies to ensure that it stays within its **statutory limits** and to prevent future legal challenges. PMPRB must **put on hold the proposed changes in this consultation, the amendments in the 2020 Guidelines that do not conflict with court decisions,** and refrain from making **any further changes** and additions until these legal challenges end.

Issues with the Proposed Guidelines

The PMPRB proposed amendments to the price tests and schedule for Grandfathered medicines. However, there is no definition of specific dates of application. PMPRB needs to clarify this to provide some knowledge on its anticipated impacts. We also support the submission from the Medicine Access Coalition – BC, of which we are a member. In that joint submission, we suggest that PMPRB should provide examples of real-world applications with low, medium, and high impact cases. It is unclear what an average of 10% decline in public list prices (which, as you know, is not the price public drug plans pay), affecting 51% of medicines, could mean for Canadians' access to medicine. From initial estimates, the new international price tests might indicate that some drugs that public drug plans have already approved and provide coverage for can have an 80-90% decrease in price while others may have none, resulting in an average reduction of 10%.

The new price test of lowering the ceiling of the Maximum List Price (MLP) from the Highest International Price (HIP) to the Median International Price (MIP) for Grandfathered and Line Extension medicines will result in more price reductions. The PMPRB is also looking to compare these prices to the new PMPRB11, which will also lower prices. Of greater concern is that these medicines have been on the market for years, with existing agreements with public drug plans, pharmacies, and more. It is also unclear how far PMPRB will go to apply these price tests retroactively. With these uncertainties, manufacturers may no longer make their medicines available in Canada. This will result in Canadians losing access to important treatments they need to live and have a good quality of life.

Real Consequences

As we detailed in our *Impact Report*,[9] the PMPRB changes, including those they propose in this consultation period, are significantly decreasing Canada's attractiveness as a priority jurisdiction for regulatory approval of new medicines. A recent study conducted by the Canadian Health Policy Institute reiterates this point, as it found that from 2015 to 2020, there was a decline of 22% in manufacturer-funded late phase clinical trials whereas, by comparison, the rate of decline in the US was 11%.[10] It is worth repeating, again from our *Impact Report*, that in accordance with the Declaration of Helsinki,[11] at the end of a clinical trial manufacturers are ethically bound to provide study patients with the study drug (if effective) at no cost until reimbursement is available. This means that manufacturers are less likely to conduct clinical trials in countries where reimbursement is unlikely and there is insufficient certainty as to whether they will achieve an acceptable price or reimbursement level.

Moving Forward

With significant legal and political factors and more uncertainties with the proposed amendments, I recommend that the Board put a hold on any reforms and refrain from making additional changes to the Guidelines. The actions of the PMPRB must reflect its legal mandate while working toward an approach that embraces innovation and research and development in Canada. With the recent court decisions and PMPRB's breach of neutrality, Health Canada must conduct an **external review** of PMPRB's operations and policies to ensure that it stays within its **statutory limits** and to prevent future legal challenges. With all the other bodies in Canada addressing health technology assessment and further negotiating price reductions, and with the upcoming transition to the Canada Drug Agency, it may also be worth a huge pause so we can all consider PMPRB's significance or value for Canada's drug pathway. It seems to me that the PMPRB is a costly redundancy for Canada.

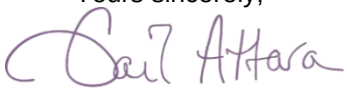
In response to the Draft Guidelines 2019, we co-authored a submission[1] with the Alliance for Safe Biologic Medicines. Here, we reiterated the endeavors of Health Canada's former Director of Scientific & Regulatory Affairs for Consumer Health Products, Kristin Willemsen, regarding the importance of the federal government's vision for

Canada to become a global leader in innovation and growing the life sciences sector by 2025. At the time of its writing in February 2020, we hardly had any clue about the full extent of the tragedies of the COVID-19 pandemic that lay before us. If the past year taught us anything, it is that we desperately need a robust life sciences strategy to protect the health and wellbeing of Canadians.

We encourage the Board to consider input from the Medicine Access Coalition – BC, of which we are members, and that of other patient associations and coalitions, as collectively we provide a comprehensive evaluation of the proposed changes in this consultation period. What you do as Board members will affect patients' lives for long into the future. Please, tread carefully with our lives.

As always, we welcome further opportunities to discuss our concerns with the Board.

Yours sincerely,



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1 Alliance for Safe Biologics Medicines and Gastrointestinal Society Submission to the PMPRB Draft Guidelines. 2020-02-14. Available at: https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/submission-received/2020_02_Guideline%20Consultation%20Submission_Alliance%20for%20Safe%20Biologic%20Medicines.pdf.

2 GI Society and CSIR Provide Input to PMPRB Consultations. Gastrointestinal Society page. 2020-08-06. Available at: https://badgut.org/pmprb-input-2020/.

3 *Feedback to the PMPRB Guideline Monitoring and Evaluation Plan (GMEP) 2021* Gastrointestinal Society. 2021-02-21. Available at: https://badgut.org/wp-content/uploads/2021-06-21-GI-Society-Feedback-to-the-PMPRB-GMEP.pdf.

4 *Letter to the Right Honourable Prime Minister Justin Trudeau.* Gastrointestinal Society. 2021-06-16 Available at: https://badgut.org/wp-content/uploads/2021-06-16-GI-Society-letter-to-Prime-Minister-Trudeau-re-PMPRB.pdf

5 Government of Canada. Consultation Policy page. 2018-04-19. Available at: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1028&lang=en.

6 The Federal Court delivered a decision on 2020-06-29, and is currently on appeal for judicial review. See application *Innovative Medicines Canada et al. v. AGC*, Court File No. T-1419-21. The Quebec Superior Court delivered its decision on 2020-12-18. See *Merck et al. v. Attorney General of Canada*, Court File No. 500-17-109270-192.

7 *Alexion Pharmaceuticals Inc. v Canada (Attorney General),* Court File No. A-237-19. Available at: https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/500849/index.do.

8 Savoie DJ. Machinery of Government Issues with respect to the Patented Medicine Prices Review Board. 2021-06-07. Available at: http://www.raredisorders.ca/content/uploads/Savoie-DJ-re-PMPRB-and-Duty-of-Neutrality-June-7-2021.pdf.

9 *Patented Medicine Prices Review Board Changes and Their Impact on Canadians IMPACT REPORT* Gastrointestinal Society. 2020-12. Available at: https://badgut.org/wp-content/uploads/PMPRB-Impact-Report-2021.pdf

10 Rawson NSB. Clinical Trials in Canada: Worrying Signs Remain Despite PMPRB's Superficial Response. *Canadian Health Policy.* 2021-03. ISSN 2562-9492. Available at: https://www.canadianhealthpolicy.com/products/clinical-trials-in-canada--worrying-signs-remain-despite-pmprb---s-superficial-response.html.

11 World Medical Association. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects page. Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.