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Patented Medicine Prices Review Board
Standard Life Centre, Box L40
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submitted electronically to PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Dear Board Members,

Re: Feedback to the PMPRB Guideline Monitoring and Evaluation Plan (GMEP) 2021

Thank you for the opportunity to provide input. In light of recent publications of internal documents from the PMPRB through Access to Information Privacy requests, I sincerely hope that Board Members and PMPRB staff take the time to fully **listen**, **acknowledge**, and **engage** with patients and patient organizations on their valid concerns about the PMPRB reforms and the Guideline Monitoring and Evaluation Plan (GMEP). With all due respect, the misconduct in these documents, gaps in appropriate and transparent reporting of information, as well as the input we provide below, are symptoms of a fundamental issue: the **competency** of leadership in the PMPRB in upholding its mandate **fairly** and **responsibly**.

Public Engagement Guidelines

It may be wise to review Health Canada and the Public Health Agency of Canada Guidelines on Public Engagement[1] as well as the roles and responsibilities of Board Members[2] to ensure that the PMPRB provides fair and appropriate consultation for public stakeholders, including patients and patient organizations. The Guidelines define public engagement as, “Planned two-way discussions with individuals, organizations, or groups, external to the Government of Canada, designed to gather input, clarify information and foster understanding among those interested and affected by an issue, decision, or action and to better inform HC and PHAC's decision-making.” PMPRB Roles and Responsibilities for Board Members also highlight that members must demonstrate, “people values - maintaining respect, fairness and courtesy in dealings with citizens and other public office holders.” Our experience with the PMPRB consultations to date demonstrates a total disregard for this essential democratic step.

As one of the only three patient representatives on the PMPRB Steering Committee on Modernization of Price Review Process Guidelines 2018-2019,[3] and as an active patient representative in many health technology and drug review processes, including the PMPRB, the belittling of patients and patient organizations must stop. We have suffered outrageous disrespect and defamation from government officials within the PMPRB and the recent evidence gathered via the Access to Information and Privacy (ATIP) requests further validate this point.

Let me be clear. This behaviour from the PMPRB toward patients and patient organizations is not new. PMPRB Executive Director, Doug Clark, spoke with CBC reporter, Kelly Crowe,[4] who, on November 24, 2018, characterized Doug Clark as a “frustrated bureaucrat” and quoted him, “You've got public and private payers on one side and industry and patient groups on the other, and views can be quite polarized. Patient groups are aligned with industry on most of the issues.” He also said, “There's not a lot of daylight between their two positions.” If the reporter had contacted patient groups for comment, she would have discovered that this is simply not true! More importantly, as the presumed neutral ED, *Doug Clark should have listened to us*, and then he would have known that we have very real concerns about the PMPRB changes for valid reasons.

Dr. Mitchell Levine, in a recent response letter to the Best Medicines Coalition, claimed full responsibility for the development and approval of the $56,000 Communications Plan.[5] I find it extremely defamatory to allow the specific labelling of the Best Medicines Coalition, the Canadian Organization for Rare Disorders, and an entire community of patients living with cystic fibrosis as culprits of “*aggressive* public relation strategies” and that these patients “aim to strike fear in people.” Identifying patient organizations as a category is already more than sufficient, but to target specific patient communities radically changes the nature of the communications plan. I cannot comprehend why this is warranted for patient organizations.

Recently, the Canadian Organization for Rare Disorders (CORD) requested parliamentary democracy expert Professor Donald J. Savoie to review the PMPRB Communications Plan from a machinery of government perspective.[6] It is clear from that report, as well as from patient advocates requesting independent investigations, that the **PMPRB has breached the duty of neutrality** that applies more extensively to independent tribunals, which need to always act impartially and fairly.

Patient Input

There are no patient representatives in PMPRB's technical experts committee for the GMEP and information on members is exclusively available by request. Note that the technical advisors were only mentioned once, on the last page, throughout the GMEP document. They also did not provide any information behind the recruitment process for these subject matter "experts", including approval criteria, so stakeholders and the public have no knowledge as to why PMPRB appointed them and the duration and scope of their role. PMPRB has not communicated whether they will seek patient input specifically and give weight to their feedback in the same manner as its planned series of outreach sessions with intergovernmental partners and private payers. In fact, several of the individuals on the technical committee have come out strongly against patient views. For example, Sharon Batt, the first member on the technical advisors list, has consistently proclaimed that patient organizations who receive funding from industry are merely mouthpieces, stating in an opinion piece that, "many patient groups are given little choice but to take the conditions placed on them by Big Pharma funders, or face closure."[7] Yet, later in that article, she also claims that "pharmaceutical giants are ***sometimes able*** to buy additional lobbying influence through their conditional funding of under-resourced patient groups." This kind of bias of a "technical expert" is beyond outrageous. **Who is looking out for patient needs?**

Conflict of Interest

I question PMPRB's rationale and the value of implementing an evaluation process that is only a self-assessment tool. On page 8, the PMPRB adds to this by "monitor[ing] how its own review processes are lining up with the processes for the HTA assessment, price negotiation and positive reimbursement decisions." I invite you to enlighten me as to how PMPRB will address its conflict of interest and exercise impartiality and neutrality with GMEP. I strongly encourage the use of methods (i.e., quantitative bias analysis techniques) to prevent and/or mitigate bias in data collection. If these are already in practice, PMPRB should make them publicly available.

External Review

The PMPRB admits that there are many challenges in implementing an evaluation plan of this "unparalleled scale and scope," and they recognize that "trends in the pharmaceutical market are driven by multiple variables, many of which are difficult to quantify (page 2)." PMPRB staff communicated similar sentiments in a webinar on May 31, constantly stating the "limitations of PMPRB to identify and establish causality of access." As a result, I strongly suggest that an **independent** body, which includes patient representatives, should be the primary inspector of the PMPRB reforms to ensure that it is an accurate, complete, and impartial evaluation process. Access to medicines is not a trivial matter and warrants the highest level of competence and integrity.

Review Period

The PMPRB should revise the GMEP review period to begin from December 2017, which is when the Canada Gazette Part I published the proposal to amend the *Patented Medicines Regulations.*[8] It would be negligent to not consider the impacts of this announcement on the availability of globally-launched medicines coming to Canada, clinical trials, and patient supports in the country; especially with consideration of the years-long deliberations behind these reforms.

Inaccuracies

As I stated above, the PMPRB needs to publicize its methodology and references for its publications. There are several statistics or facts in the document that do not have any references and, upon further investigation, their data appears to be selective and exaggerated. For instance, on page 9, it states that "drugs are now the second largest component of [health] spending, ahead of physicians." This conflicts with data from the Canadian Institute for Health Information (CIHI) in its 2019 report, which found that while hospitals, drugs, and physicians make up for the majority of health spending, expenditures on drugs are growing at the slowest rate (1.8%) compared to hospitals (2%) and physicians (3.5%). PMPRB's data is even more questionable since drug expenditures combines spending on prescribed and non-prescribed products, which includes generic and over-the-counter drugs.[9]

PMPRB Impact Report

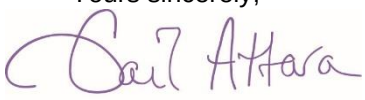
In December 2020, we released our heavily-referenced report, ***Patented Medicine Prices Review Board: Report on the Changes and Their Impact on Canadians* (*PMPRB Impact Report*)**. This is available on our English and French websites. In it, we discuss some of the unintended consequences associated with the PMPRB changes and we encourage GMEP to include them in their metrics. Some of these are impacts to clinical trial activities as well as patient support and compassionate access programs, which include specialty pharmacy services, infusion services (if applicable), nurse support and self-care training (e.g., subcutaneous injections) reimbursement coordination, co-pay assistance, compassionate access for patients with no drug insurance, and more.

In the Medicine Access Coalition-BC submission (we are members) on the updated PMPRB draft Guidelines,[10] under section 5, we list several indicators and measures, which we encourage PMPRB to include in its GMEP.

Conclusion

The GMEP displays crucial gaps and inconsistencies that PMPRB must address. As a result, and with regard to the targeting of patient communities and organizations, I am not confident in the ability of the PMPRB to carry out its operations impartially and responsibly. We strongly recommend an independent evaluation of the PMPRB changes instead. The GMEP could proceed, but merely as a complementary self-assessment tool and it should not function as a basis to justify the need for future adjustments to PMPRB. We welcome opportunities to discuss the PMPRB reforms and GMEP with Board Members.

Yours sincerely,



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