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June 16, 2021

The Right Honourable Justin Trudeau, P.C., M.P.
Prime Minister of Canada
80 Wellington Street
Ottawa, ON K1A 0A2
submitted electronically to pm@pm.gc.ca

Dear Prime Minister,

Our access to medicines, including new innovations, is changing on July 1, 2021, due to reforms by the Patented Medicine Prices Review Board (PMPRB). These changes are of utmost concern to us, and with the ongoing pandemic and court challenges against the PMPRB, we strongly advise the federal government to **halt these reforms immediately**. On behalf of the Gastrointestinal Society, I am also gravely concerned about the treatment toward, and value of, patients' voices within the PMPRB as well as our ability to participate in Canada's democratic process.

To establish my specific role in this process, I was one of only three patient representatives on the PMPRB Steering Committee on Modernization of Price Review Process Guidelines 2018-2019.[1] Sadly, patient representatives were nothing more than a checkmark to the PMPRB. We also suffered outrageous disrespect from government officials, which I will explain later.

PMPRB Impact Report

To clarify what the PMPRB amended Regulations and Guidelines mean for Canadians, we wrote the ***Patented Medicine Prices Review Board: Report on the Changes and Their Impact on Canadians* (*PMPRB Impact Report*)**. This heavily-referenced report is available on our English https://badgut.org/pmprb-impact-report/ and French https://badgut.org/cepmb-rapport-impact/?lang=fr websites and is attached.

As you are no doubt aware, the PMPRB, a federal quasi-judicial agency and regulator, has been around since 1987 with a mandate to set the maximum prices at which patented drugs can be sold in Canada. We are the only country in the world that regulates the maximum prices of drugs. However, the drug pricing world has changed since the 80s and several tough measures to further reduce and manage drug costs have emerged. Thus, after the PMPRB sets a maximum price, Canada and its provinces and territories have other bodies and pricing mechanisms that further push the price of a medicine lower. These include the pan-Canadian Pharmaceutical Alliance (pCPA), through which Canadian governments negotiate lower drug prices, and policies and tools used by public and private drug plans to reduce the prices of medicines.

Every year, the PMPRB enforces ceiling prices that have led to the collection of millions of dollars in excess revenues to the Government of Canada.[2] Meanwhile, the pCPA, a joint provincial/territorial/federal body, achieved $2.58 billion in additional annual savings through their joint negotiation on product listing agreements with manufacturers and generic price reductions in 2019, a figure that is likely much higher today.[3] With the pCPA and other medicine review processes available in our modern drug regulation ecosystem, many have questioned the continued relevance of the PMPRB. Clearly, there is no need for the PMPRB to overhaul its processes when other agencies and governments already further mitigate prices!

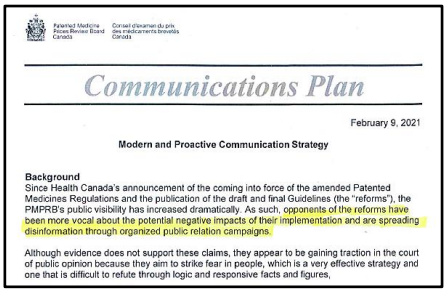
PMPRB reforms include updating the list of comparator countries for the retail public prices of drugs as well as new economic factors that import health technology assessments into regulating sale prices, which has never been done in any other country. While we have concerns about the new comparator countries (see our Impact Report for more information), at least there is some predictability in terms of how they would operate.
However, the PMPRB isn't stopping there and is also creating a new and complex process that will affect which new medicines will be available for our population. This new process is partly on hold due to ongoing litigation on the PMPRB Regulations in the Federal Court and the Court of Appeal of Quebec.[4] The Quebec government recently intervened in the latter litigation, arguing that the amendments to the PMPRB Regulations should be declared invalid as they fall outside of federal jurisdiction.

Canada only represents close to 2% of the global market for medicines.[2] When the government forces the price of a medicine too low, it might no longer be viable for the companies to sell that medicine in Canada. This includes both new and existing drugs, which could disappear from the Canadian market, so they will no longer be available, even if you have a private drug plan. Unfortunately, pricing ambiguity has already begun impacting drug manufacturers, who are not bringing new drugs to Canada.

According to government guidelines on public engagement, a fair and appropriate consultation with government includes, "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".[5] Our experience with the PMPRB consultations to date demonstrates a disregard for this essential democratic step. These consultations have been stacked with "experts" that support the PMPRB's regulatory expansion and have not allowed active engagement (the webinars include questions that only the moderators can see, with no opportunity for dialogue).

PMPRB's Campaign Against Patients

On February 9, 2021, *using public funding*, the PMPRB**,** created a **$56,000 Communications Plan** to influence public opinion on the impact of its reforms set for implementation on July 1**.** Through an Access to Information and Privacy request, the Member of Parliament for Calgary Shepard, Tom Kmiec, obtained and shared this document on May 21.[6]



Patented Medicine Prices Review Board Canada | Conseil d'examen du prix des médicaments brevetés Canada

Communications Plan

February 9, 2021

Modern and Proactive Communication Strategy

Background
Since Health Canada's announcement of the coming into force of the amended Patented Medicines Regulations and the publication of the draft and final Guidelines (the "reforms"), the PMPRB's public visibility has increased dramatically. As such, opponents of the reforms have been more vocal about the potential negative impacts of their implementation and are spreading disinformation through organized public relation campaigns.

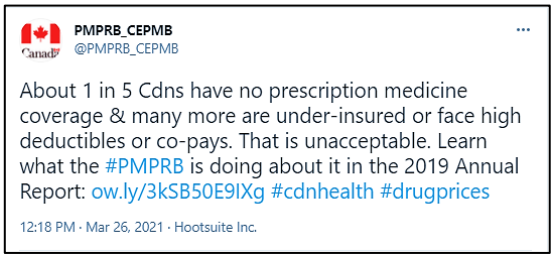
Although evidence does not support these claims, they appear to be gaining traction in the court of public opinion because they aim to strike fear in people, which is a very effective strategy and one that is difficult to refute through logic and responsive facts and figures,

The public relations campaign further accuses patient communities and patient organizations of spreading disinformation on PMPRB reforms. The PMPRB has dedicated resources to actively delegitimize and belittle the voices of millions of Canadians that it claims to support and protect. Instead of engaging with us to address our pressing concerns on access to lifesaving and life-prolonging medicines, PMPRB responded by identifying patients with cystic fibrosis, the Canadian Organization for Rare Disorders, and the Best Medicines Coalition for the promotion of "aggressive public relation strategies." With lives on the line every minute, PMPRB is engaging in **shameful** and **grossly unethical** practices.

Unfortunately, this behaviour from the PMPRB toward patients and patient organizations is not new. During the steering committee deliberations, PMPRB Executive Director, Doug Clark, spoke with CBC reporter, Kelly Crowe,[7] 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 said. "There's not a lot of daylight between their two positions." This is simply not the case!

The most troubling aspect of PMPRB's Communications Plan is that it accuses us of "disseminating disinformation" and further falsely claims that those of us who are raising valid and critical questions about the reforms are spreading baseless claims that "aim to strike fear in people." This is simply not true, and it is a disingenuous comment on the tireless efforts we put in so we can accurately and appropriately represent patients' perspectives in consultations, policy and patient input submissions, meetings with decision-makers, and more. We do this without compensation on behalf of the acutely and chronically sick patients who we serve.

I have yet to see exactly what PMPRB claims as disinformation. Yet, the PMPRB uses questionable data, some of which are selective and exaggerated, to support claims they have made in reports, webinars, and social media. For instance, on March 26, 2021,[8,9] PMPRB's Twitter account posted the following:



PMPRB_CEPMB
@PMPRB_CEPMB

About 1 in 5 Cdns have no prescription medicine coverage & many more are under-insured or face high deductibles or co-pays. That is unacceptable. Learn what the #PMPRB is doing about it in the 2019 Annual Report: ow.ly/3kSB50E9IXg #cdnhealth #drugprices

12:18 PM · Mar 26, 2021 · Hootsuite Inc.

PMPRB_CEPMB
@PMPRB_CEPMB

1 in 10 Canadians had to forgo filling prescriptions in the past year for reasons related to cost. That is unacceptable. Learn what the #PMPRB is doing about it in the 2019 Annual Report: ow.ly/5Uaj50E9KS9 #cdnhealth #drugprices

12:53 PM · Mar 26, 2021 · Hootsuite Inc.

These posts reference a variety of secondary sources, leading back to a report conducted by the Conference Board of Canada, from which the PMPRB has deceitfully represented the "1 in 5" and "1 in 10" statistics. They are simply incorrect, or the very "disinformation" that the PMPRB ascribes to patient groups! The facts show instead that "4.1 million Canadians are not enrolled for either public or private coverage, despite being eligible… [and that only] 5.2% of the population is not eligible for a public plan or enrolled in a private plan."[10,11] Some individuals on Twitter questioned the reason and nature of these tweets, with one likening its tone to "political campaign statements." I find this disinformation by a Canadian regulator to be outrageous.

The PMPRB is also seeking to review the impact of the pricing reforms through their Guideline Monitoring and Evaluation Plan (GMEP).[12] **How can a federal quasi-judicial regulator exercise impartiality while playing the judge, jury, and executioner of its own reforms, which the PMPRB itself has been advocating for since at least 2015?**

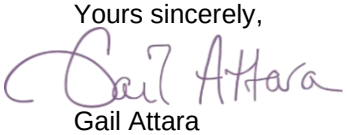
On May 31, 2021, MP Tom Kmiec obtained another ATIP[13] that displayed internal emails among executives within the PMPRB. It revealed PMPRB's biases toward the pharmaceutical industry, with one Director stating that, "Industry has been sucking Canada for decades." This contempt for the industry contributes to the growing distrust that patients have in the PMPRB, which should be acting in a neutral and impartial way when making decisions on prices of medicines given it is a quasi-judicial body. The PMPRB's decisions have repercussions on access to medicines, and ultimately, the health of patients.[14]

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.[15] 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. Our experience with the PMPRB establishes that the February 2021 plan is just the latest in a long record of inappropriate, unethical, and potentially illegal behaviour by the PMPRB.

$56,000 may be a drop in the bucket for PMPRB's $17.8 million budget,[2] which they estimate to double with the reforms,[16] but for patient advocates and patient groups, this ongoing conduct has forced us to divert our scarce resources to standing up to the PMPRB and its unethical and inappropriate advocacy to expand its regulatory empire. Perhaps they are not aware, but 60% of health charities experienced significant losses in funding for their programs and services due to the COVID-19 pandemic. Most are experiencing unsustainable increases in demand with decreased staff and resource capacity.[17] I simply do not have the bandwidth nor the desire to spread fake news about the PMPRB reforms. What I will raise awareness on are the evidence-based concerns – and the human cost – of the impending PMPRB changes.

Again, I sincerely hope you take the time to read our report and consider **stopping** or at least **postponing the PMPRB reforms** until further investigation takes place.

Yours sincerely,



Gail Attara
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Attachment: PMPRB Impact Report 2020

cc: Honourable Patty Hajdu, M.P., Minister of Health
Katie Telford, Chief of Staff, Office of the Prime Minister
Ben Chin, Senior Advisor, Office of the Prime Minister
Marci Surkes, Executive Director of Policy & Cabinet Affairs, Office of the Prime Minister
Matt Stickney, Executive Director of Operations, Office of the Prime Minister
Rick Theis, Director of COVID-19 Response, Office of the Prime Minister
Cameron Ahmad, Director of Communications, Office of the Prime Minister
Sabina Saini, Chief of Staff, Health Canada, Minister's Office
Kathryn Nowers, Director of Policy, Health Canada, Minister's Office
Thierry Bélair, Director of Communications, Health Canada, Minister's Office

References

1 Government of Canada. Patented Medicine Prices Review Board (PMPRB) Terms of Reference for Steering Committee on Modernization of Price Review Process Guidelines. 2018-06-29. Available at: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1377&lang=en.

2 Government of Canada. PMPRB Annual Report 2019. Available at: https://www.canada.ca/en/patented-medicine-prices-review/services/annual-reports/annual-report-2019.html.

3 pCPA – Strategic Revitalization Summary. Available at: https://www.pcpacanada.ca/forms-and-publications.

4 The Federal Court delivered a decision on June 29, 2020, 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 December 18, 2020 and is currently being appealed to the Court of Appel of Quebec. See *Merck et al. v. Attorney General of Canada*, Court File No. 500-17-109270-192.

5 Government of Canada. Health Canada and the Public Health Agency of Canada – Guidelines on public engagement. 2019-11-21. https://www.canada.ca/en/health-canada/services/publications/health-system-services/health-canada-public-health-agency-canada-guidelines-public-engagement.html

6 Tom Kmiec Twitter Account. 2021-05-21. Available at: https://twitter.com/tomkmiec/status/1395851080441999364?s=20.

7 Crowe K. Canada has found the key to lowering drug prices, but it won't be used any time soon. CBC News. 2018-11-26. Available at: https://www.cbc.ca/news/health/canada-drug-price-patented-medicine-pharmaceutical-industry-pmprb-1.4919200.

8 PMPRB Twitter Account. 2021-03-26. Available at: https://twitter.com/PMPRB_CEPMB/status/1375527518242021381?s=20.

9 PMPRB Twitter Account. 2021-03-26. Available at: https://twitter.com/PMPRB_CEPMB/status/1375536390763655170?s=20.

10 Dinh T and Sutherland G. Understanding the Gap: A Pan-Canadian Analysis of Prescription Drug Insurance Coverage. Conference Board of Canada. 2017-12-07. Available at: https://www.conferenceboard.ca/e-library/abstract.aspx?did=9326.

11 These estimates are prior to the implementation of OHIP+. With OHIP+, they estimate that the population of uninsured Canadians will drop to about 1.8 percent.

12 Government of Canada. Consultation on the Guideline Monitoring and Evaluation Plan. 2021-05-31. Available at: https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/consultation-guideline-monitoring-evaluation-plan.html.

13 Tom Kmiec Twitter Account. 2021-05-31. Available at: https://twitter.com/tomkmiec/status/1399499855920349192?s=20.

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15 Canadian Organization for Rare Disorders. Webinar 3 Bringing Home the 5% Solution. 2021-06-10. Available at: https://www.youtube.com/watch?v=FSnx0fFkF90.

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17 New Study: Ongoing Impacts of the COVID-19 Crisis on the Charitable Sector. Imagine Canada. Available at: https://imaginecanada.ca/en/360/ongoing-impacts-covid-19-crisis-charitable-sector.