Canadian Organization for Rare Disorders

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June 6, 2019

The Right Honourable Justin Trudeau, PC, MP
Prime Minister of Canada
80 Wellington St.
Ottawa, Ontario K1A 0A2

Ginette Petitpas Taylor
Minister of Health
Brooke Claxton Building, Tunney's Pasture
Ottawa, Ontario K1A 0K9

Dear Prime Minister Trudeau and Health Minister Petitpas Taylor:

Subject: Nobody is listening

On behalf of the Canadian Organization for Rare Disorders (CORD), which represents over 100 rare disease patient groups and hundreds of thousands of patients and their families, I am writing to you once again TO STOP proposed regulatory changes for the Patented Medicine Prices Review Board (PMPRB) until there has been REAL engagement with patients and other stakeholders.

WHY IS NOBODY IS LISTENING?

I hope that the bluntness of this language gets your attention in a way that we have not been able to achieve with all of our previous evidence-based feedback through the "so-called" consultation process, the nuanced letters to you and other government representatives, and the "politically correct" public statements made through conferences, forums, interviews, and posted documents. However, there is too much at stake for us to remain polite any longer.

While I agree that there is much room for improvement in terms of how medicines are adopted and funded in Canada, the proposed PMPRB changes will be disastrous for Canadians with rare disorders and more common conditions who depend on medicines to survive. Three points in particular need to be emphasized:

1. **No meaningful consultations have been held**: The consultations have been among the worst if not THE worst in my experience. They have been one-sided throughout, with respectful questions from experts including patients and academics being met with obstinance, non-answers and ad hominem character attacks. It is clear that Health Canada and the PMPRB were acutely focused on ramming through a pre-determined approach, regardless of input received from stakeholders, including patients – the very people the proposed reform is supposed to be helping.
2. **Misrepresenting the Dodge report to justify the reform:** Health Canada's reference to the Dodge Report to support the regulatory changes is disingenuous. It is a prime example of selective reading to support the positions your officials are looking to justify. The federal government never even publicly released the report. We feel compelled to put the Dodge Report on our website so that all Canadians can review the analysis themselves.
3. **Ignoring patient groups' concerns regarding access environment for medicines**: There has been no analysis conducted on the proposed changes to evaluate its impact on patient access despite over 100 patient groups calling for this. The government has simply chosen to ignore the number one priority for patients.

1. No <u>meaningful</u> consultations have been held

Health Canada indicates it has held information sessions and that it has received considerable stakeholder input. I have no doubt that you have received significant input given the level and extent of stakeholder discontent and concerns about the proposal. However, I see no evidence, contrary to statements in Health Canada's communications that it is "taking the time required to carefully consider the comments received during consultations."

Based on the recent Forward Regulatory Plan 2019-2021: Regulations Amending the Patented Medicines Regulations (Regulatory Plan), it is clear that the regulation package that Health Canada intends to publish in Canada Gazette 2 (CG2) remains virtually identical to the one originally published in Canada Gazette 1 (CG1). No substantive changes have been made to the proposal since it was first presented to stakeholders in June 2017. REALLY? Did the federal government do such comprehensive research and analysis prior to CG1 that there was NOTHING to improve?

While there have been opportunities for stakeholders to provide input, these do not count as consultations if none of the concerns raised by stakeholders have been addressed or reflected in the final regulations. It is also extremely frustrating that the federal government has not responded to specific issues raised by our organization and other patient groups.

As a member of the Steering Committee on the Implementation of the PMPRB Guidelines (SC), I have experienced first-hand the disingenuousness of the SC "consultation" process. Members of the SC, including myself, have repeatedly raised concerns about the procedural integrity of the process, most importantly, the need for an independent chair (not the executive members of the PMPRB), publicly available minutes from the meetings, and an opportunity to arrive at conclusions and to make recommendations as mandated by the SC Terms of Reference. Our role throughout the process has been limited to providing comments that were largely ignored or dismissed. Our input was restricted to responding to sets of questions pre-determined by the PMPRB executive staff. The requests by SC members to develop and consider alternative pathways to achieving the goals of "non-excessive" pricing and "sustainability of drug budgets" were denied as "out of scope" with no rationale.

In summary, all "consultations" to date have been a box-checking exercise, and nothing more.

2. Misrepresenting the Dodge report to justify the reform

Health Canada has repeatedly cited an excerpt from the conclusion of the Dodge report that "there is no reason not to proceed" with the regulatory proposal. However, this is a misleading statement taken out of context.

The report's conclusion is entirely inconsistent with the analysis found in the body of the report, where Mr. Dodge and Mr. Blomqvist flag many of our concerns related to the lack of transparency and stakeholder engagement, question the use of pharmacoeconomic analysis by the PMPRB, and articulate the problems and deficiencies associated with the cost-benefit analysis (CBA). The report notes that economic factors can be used by reimbursement systems but have never been used at the regulatory level to apply across an entire health system with no guarantee of timely funding.

Indeed, with regard to the CBA, there is no doubt that Mr. Dodge and Mr. Blomqvist would have flagged even more serious concerns about whether the CBA appropriately assessed the impact of the regulatory changes had the economists had the opportunity to review the PMPRB case studies produced subsequently, showing price reductions of 40-70%.

Contrary to the government's publicly touted interpretation, the Dodge report cannot be used to confirm the government's choice of economic factors nor the conclusion of no harm to timely patient access. The misappropriation of Dodge only serves to heighten our distrust and fear. Verily, it is telling that the government has not publicly released the Dodge report as part of this "consultation" process. Why not? This speaks again to the lack of transparency that has plagued this whole process to date.

3. Ignoring patient groups' concerns regarding access environment for medicines

The Canadian government and particularly Health Canada have completely forgotten about the people it should be serving and helping: Canadian patients. There will be delayed access or, worse, no access to new medicines as a result of these changes, and this will harm patients. As acknowledged in recent letters from Health Canada, there are many factors that affect the availability of medicines and pricing is one of them.

No one at Health Canada or PMPRB has yet explained to patients how a 40-70% price decrease on price, as anticipated by the PMPRB, will not affect the availability of medicines in this country. Citing a Meds Entry Watch study does not in any way address our fears. We have repeatedly called for an informed analysis by the government on how the broader access system will be affected. To date, Health Canada has not acknowledged the price decrease projection by the PMPRB, nor has it conducted a reanalysis of the impact of the reform on patient access to medicines based on this new projection. And if it has, it was not shared with patients.

Your letter cites lower drug prices in other global jurisdictions as a justification to move forward with PMPRB reform. However, you neglect to mention that none of the countries mentioned use price regulation and cost effectiveness thresholds as a way to achieve lower prices across the entire population. In fact, the idea was explored and has since been abandoned by the UK and other jurisdictions.

CORD absolutely supports fair drug pricing in Canada, for all payers, including public and private drug plans and individual consumers. But if "fair pricing" compared to other countries is the goal, then the proposed reference basket of similar countries is reasonable and sufficient. What is deeply concerning is the proposed economic factors that will create significant confusion and uncertainty in the Canadian marketplace and have a profound impact on patient access to medicines, especially for those patients with severe, life-threatening conditions where alternative therapies are not available. This is truly a matter of life and death for many patients. The federal government needs to take the time to rethink its approach and properly consult with stakeholders.

Final consideration

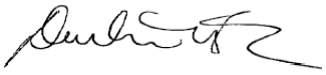
In summary, we do not support your proposed pricing reform and are extremely disappointed about the lack of engagement and meaningful consultations that has plagued the entire process. If the federal government was truly interested in listening to patients, it would have taken the time to engage with us on less risky approaches to ensuring that Canadians have sustainable and cost-effective access to life-saving therapies.

CORD and our 100 patient organizations are fully committed to ensuring Canadians know what is happening and will continue to oppose changes that will further reduce already hampered access to the medicines we need to

survive and be well. We urge your government to demonstrate leadership by establishing a constructive dialogue among all stakeholders that will build trust and lead to optimal drug pricing and drug access for Canadian patients.

As always, I welcome the opportunity to discuss these important matters with you in person.

Sincerely,



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