Canadian Organization for Rare Disorders

November 6, 2020

Standing Committee on Health
Sixth Floor, 131 Queen Street
House of Commons
Ottawa ON K1A 0A6

Subject: Study on the Patented Medicine Prices Review Board (PMPRB) Reforms

Honourable Members of the Standing Committee on Health:

The Canadian Organization for Rare Disorders (CORD) is the national voice for the nearly 3 million Canadians affected by rare diseases. This brief focuses on three fundamental questions:

1. Have Health Canada and the PMPRB meaningfully addressed the concerns raised by CORD through its written feedback and working group participation since 2017?
2. Do the final guidelines provide a fair, transparent, and evidence-based pathway for patients and developers to be certain as to the impact of guideline changes on access to new therapies?
3. Have Health Canada and the PMPRB provided forums for open and meaningful dialogue to exchange perspectives, to address stakeholder concerns, and most importantly, to jointly explore and co-create mutually beneficial solutions?

Our very short answer to all of these questions is an emphatic “NO!” In fact, not even close.

Health Canada and the PMPRB have failed to adequately address our original concerns or to meet our expectations for revision. Our fundamental concerns and expectations have not changed. In fact, many of the revisions adopted in the final guidelines were modest. And some changes have resulted in even greater uncertainty, for example,

- how innovation will be assessed
- how the therapeutic value category will be assigned
- pricing at market entry, and pricing adjustments

CORD, in addition to other patient organizations, clinicians and developers critiqued the draft “rare disease drugs” pathway as superficial and irrelevant, calling for more a targeted, nuanced, and adaptive approach relevant to emerging and future innovative therapies. In response, the PMPRB eliminated all references to rare disease drugs EXCEPT when premising the need for pricing reform on the false narrative that rare disease drug prices are driving drug spending increases and the price index, with highly selective and biased data. They failed to reflect and show the evidence in totality, which demonstrates that rare disease drugs represent only a very small fraction (< 3%) of drug spending.

By dumping drugs for rare diseases into the same pricing guidelines as drugs for common conditions, PMPRB has unilaterally ignored all other federal and provincial authorities that have designated processes.

Health Canada has defined a regulatory approach for rare and orphan drugs that acknowledge the unique challenges of small patient populations, those with severe, progressive, or life-threatening conditions, and high unmet need, that is, no effective therapy for 95% of rare conditions.

Compared to other disease areas, Canadians with rare diseases continue to face unique challenges, including substantial barriers to accessing needed treatments. We recognize that every country struggles to meet the challenges of providing access to innovative treatments that by their definition are outside the norm. Every jurisdiction has been challenged with adaptive and novel clinical trial designs, regulatory review and approval, post-market data collection, pricing review, health technology assessment, product negotiation processes, and funding/financing frameworks that were never designed for drugs for rare disease drugs and highly targeted patient populations (aka precision therapies) as well as “one-time” administration cell and gene therapies with lifetime benefits.

There is no doubt that these innovations are also much more expensive than traditional medicines. In a previous generation, stagnated drug programs with capped drug budgets struggled to accommodate biologic medicines with higher costs but that significantly improved health and societal outcomes. But Canada has erected more barriers and offered less flexibility than most other developed countries. And now Canada has introduced a new seemingly insurmountable barrier that constitutes a full-stop to entry of innovative therapies in the form of the changes to the *Patented Medicines Regulations*.

Since the changes were first proposed in 2017, CORD and other stakeholders have consistently raised concerns and put forward thoughtful alternative proposals for how to address the federal government’s medicine affordability objectives without harming the access environment for new medicines. Unfortunately, these concerns have largely fallen on deaf ears.

From the outset of the PMPRB reform process, our position has been clear: we support improving affordability of rare disease medicines while simultaneously assuring appropriate and timely access. Other jurisdictions, like England, Scotland, Germany, and Lithuania, have evolved separate or adapted frameworks for rare diseases that recognize these dual objectives.

In contrast,[1] Canada has chosen to manage capped drug budgets by using health technology assessment (HTA) to slow down negotiations toward reimbursement. But at least there was the recognition that pharmacoeconomic analyses did not truly reflect the health value of the medicine[2].

Now, the PMPRB proposes to co-opt the HTA process and to set, without negotiations, arbitrary, nonevidence-based pre-defined maximum regulated prices.

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[1] Nicod E, Whittal A, Drummond M et al. Are supplemental appraisal/reimbursement processes needed for rare disease treatments? An international comparison of country approachesOrphanet Journal of Rare Diseases (2020) 15:189 https://doi.org/10.1186/s13023-020-01462-0

[2] Chambers A, Silver M et a. Orphan Drugs Offer Larger Health Gains but Less Favorable Cost-effectiveness than Non-orphan Drugs J Gen InternMed DOI: 10.1007/s11606-020-05805-2

We have consistently warned that the new pricing framework would unduly and unreasonably limit access to life-saving and life-improving medicines for patients with rare disorders, who are already disadvantaged under our current, complex system.

We were initially very hopeful in 2018 when PMPRB set up a Steering Committee to advise on guidelines for the implementation of the proposed regulatory changes. Unfortunately, we all learned that the guidelines were already written and there was little interest in receiving advice and even less interest in any meaningful change to the guidelines. Indeed, our suspicions were substantiated when "Recommendations Report" ostensibly from the Steering Committee were written entirely by the PMPRB staff; the Steering Committee was told that they were not to make recommendations nor would they have and any opportunity to read the recommendations before they were tabled. Moreover, the first draft guidelines that were made public in December 2019 were mostly unchanged from the initial draft that was presented to the so-called Steering Committee in June 2018.

That pattern of non-listening continued this past summer, with tightly controlled forums, no open dialogue between staff/board and stakeholders, and no opportunity to deliberate on alternative approaches to pricing. The PMPRB promised to make "significant changes" to its initial proposed implementation plan in light of significant stakeholder concerns about the impacts of the new pricing system on patient access to needed medicines; however the final guidelines offer only modest changes that do nothing to reduce the uncertainty in the process, including the arbitrariness of the "ceiling" prices and the absolute control of the PMPRB staff to determine therapeutic value of new therapies. In fact, the final guidelines have made it worse by introducing more restrictive thresholds for treatments that may have more uncertain data, such as rare disease treatments given the small population they treat and therefore the smaller clinical trials. In sum, the guidelines do nothing to ensure that new rare disease treatments will continue to come to Canada.

Given the lack of meaningful two-way dialogue or consultation with the PMPRB on the proposed guidelines, CORD felt compelled to spearhead a parallel consultation to foster open discourse and consideration of alternative pathways to appropriate drug pricing. We invited patients, clinicians, researchers, academics, economists, industry representatives, and unassailable Canadian and global health policy experts, to deliberate among themselves and with the attendees how the PMPRB changes will impact Canadian patients. We also invited the PMPRB to participate, attend and otherwise engage in our webinars.

We provide the following high-level summaries of these webinars of what was heard to help situation our recommendations.

1. **The PMPRB changes are having a significant negative impact on new drug launches in Canada**

The PMPRB changes would require steep price reductions for many new medicines entering Canada. It is expected that the price for many specialized medicines, including those for rare diseases and oncology treatments, will have to be reduced in many cases by over 50% compared to today's list prices. Price reductions of this magnitude are unsustainable and will

have a substantial impact on companies' commercial activities in Canada and may lead to reduced or no access to some of the newest, often life-saving, medicines for patients.

The PMPRB chose to present analyses of highly selected indirect data to bolster their contention that there is no relationship between drug price, drug launches, and clinical trials. In contrast, we curated real-world data documenting the number of new drug launches and the number of clinical trials since the announcement of the PMPRB regulatory changes.

This harsh reality is already playing out, with examples of pending drugs put on hold, extended indications withdrawn, and Canadian priority for launches being reassessed. Recent IQVIA research on global medicine launches showed that there has already been a sharp drop in the number of new medicines commercialized in Canada since the PMPRB changes were first introduced, whereas new medicine launches in other countries have been increasing.

Even looking at developer submissions to Health Canada, we are falling behind. As we provided in our submissions on the guidelines, we have updated and attached a list of medicines approved by the USFDA versus submissions to Canada's regulator, finding that since the *Patented Medicines Regulations* were published on August 22, 2019, only 17 out of 56 medicines *already* approved in the US have even been submitted for review by Health Canada as of November 6, 2020.

You will see that dozens of medicines now available just south of the border that Canadians are missing out on include treatments for Parkinson's disease, cystic fibrosis, many cancers (lymphoma, bladder, GIST, cholangiocarcinoma, breast, lung), sickle cell disease, epilepsy, Duchenne muscular dystrophy, schizophrenia, cardiovascular disease, Cushing's disease, Neurofibromatosis type 1, and HIV.

2. **Patients are and will continue to die and suffer considerable harm because of the reforms**

Sadly, Canadians have and are dying because of the PMPRB changes. The impact of the PMPRB changes was displayed tragically by the death of Chantelle Lindsay, a 23-year-old Nova Scotia woman with cystic fibrosis. Chantelle died while waiting for "Trikafta," a new therapy that may have saved her life. While there is no "proof" that Chantelle would have survived with the therapy, it is irrefutable that patients just like Chantelle are alive with Tikafta. It is also irrefutable that the manufacturer has declined to launch Trikafta because of the strict PMPRB pricing controls. During the course of our consultations, dozens of other patients have stepped forward to share their stories of denied or delayed access to a new life-altering or life-saving therapy.

Clinicians have expressed their frustration in losing access to valuable clinical trials or therapies. They have been informed that promising treatments already available in other jurisdictions, including some with meaningful survival benefits, will not be brought to Canada for at least 2-3 additional years as a result of the reforms or may not come here at all.

3. **The new draft guidelines continue to perpetuate uncertainty**.

Among the most alarming concerns in the updated draft guidelines is the provision for PMPRB staff to arbitrarily modify price tests, resulting in high uncertainty around the application of the economic factors. They have offered no reliable or externally validated examples or case studies to demonstrate how the new system would work. Therefore, despite some changes to the final guidelines, the high uncertainty and threat of lower ceiling prices continue to affect companies' decisions to launch new medicines and invest in health research in Canada. We also heard from experienced economists and senior industry staff that the PMPRB's new guidelines are also even more complex and unclear than the 2019 draft. As a result, they are feverishly doing their own analyses, developing their own test cases, and reporting to their international offices that they cannot justify launching a new medicine in Canada until "others" have "tested the waters."

4. **The use of subjective pharmacoeconomic analyses by a price regulator puts the agency in the role of single-handedly determining the value of a patient's life**

The guidelines for the application of the pharmacoeconomic factor in the price regulations gives the agency the unfettered power to determine the price of any new therapy and therefore the value of the life of the patient, including those with rare diseases, cancer, and other serious illnesses, who rely on access. In a great departure from today, pharmacoeconomic analyses will be used by the PMPRB to set maximum regulated prices instead of serving as the basis for negotiation between the manufacturer and the public payer. The PMPRB staff will also single-handedly apply other factors (including therapeutic innovation, total sales, and total budget impact) without transparent, evidence-based, standardized procedures and without, counsel from or accountability to external experts and external stakeholders. By handing powers over to a regulator to set maximum prices, the federal government is giving the PMPRB the right to determine the value of a patient's life. The PMPRB's mandate is to ensure that prices of patented medicines sold to Canadians are not excessive, not to assign value on a patient's life. It is important to ensure that the PMPRB's new framework does not replace the role of individual drug plans in making decisions about which drugs they will cover or negotiate on behalf of those plans. In fact, as we heard from one patient advocate who participated in our webinars, the PMPRB changes prevent individuals from purchasing their own medicines or insurance to access new treatments by keeping these medicines off of the Canadian market.

5. **The PMPRB continues to use misleading figures to justify the need for the reforms**

The PMPRB continues to use misleading support points and case-studies to justify its position. For instance, during its most recent Public Webinar on the PMRPB Guidelines, the PMPRB said "Canada is an outlier in not using HTA systemically at the regulatory level." This is blatantly false. No other country uses subjective pharmacoeconomic anlyses to set maximum price thresholds as a requirement for sales.

Moreover, the PMPRB continues to use alarmist language to convey the idea that Canada is paying too much for rare disease treatments and conflates drug spending categories to support its position. For instance, in the case of drugs for rare diseases, the PMPRB lumps

together oncology medicines with those with true orphan indications to generate larger number to help justify the need for the reforms. In reality, in 2019, non-oncology rare disease treatments represented just 1.9% of the total Canadian medications bill (covering both the public and private markets) based on their list prices (i.e., not considering the substantial value obtained by public drug plans from negotiated rebates).

Evidence-based estimates indicate that percentage might increase to just 6% by 2025. That trajectory does not suggest that costs are "out-of-control" or threaten to overwhelm public drug plan budgets. Even today, the PMPRB's own data shows Canada underspends on a per-capita basis for rare disease treatments. It's CORD's patients and members who ultimately pay the price when this misinformation is propagated and used to justify flawed policy decision-making.

6. **VERY IMPORTANT: Whither Canada's Rare Disease Drug Strategy?**

In the February 2019 Federal Budget, the Canadian government committed $1 billion for the first two years of a national Rare Disease Drug Strategy to be put in place in 2022-23, with $500 million to be added annually. Moreover, in September 2020, in the Speech from the Throne, the government further committed to a Canadian Rare Disease Strategy, essential to the success of a rare disease drug program. In October 2020, CORD began a series of multi-stakeholder consultations premised on these federal commitments and building on other federal and/or provincial-territorial announced initiatives specific to rare disease drugs, namely: Nov 2018 P/T Supplemental (Managed Access) Process for specialty/rare disease drugs and June 2019 call for a distinct rare disease strategy in proposed National Pharmacare. The first three publicly broadcast consultations have each engaged 150-200 participants from all sectors, attesting to widespread interest and priority.

On November 6th, Webinar 3 in CORD's Rare Drug Strategy Consultation, a multi-stakeholder panel considered the potential impact of the PMPRB revised guidelines on entry and access of rare disease therapies, using "real" case examples. Panelists agreed that the PMPRB changes, while theoretically intended to lower drug prices and make drugs more accessible, had an obverse real-world effect of so severely restricting Canadian prices relative to international norms that many innovative and rare therapies are not being launched in Canada. There is the genuine possibility that Canada could build the "best" rare disease drug strategy in the world, but no innovative drugs will be available because of the high uncertainty created by the PMPRB changes.

Panelists deliberated on alternatives to the PMPRB approach that could better meet the Triple Aim of "timely appropriate patient access," "optimal, sustainable healthcare expenditure," and "non-excessive industry compensation that incentivizes launching new therapies and future R&D." There are many viable alternatives that must be explored and considered in the context of Canadian principles and goal of patient-centred care.

As patients, we believe it is critically important to stop, recognize what is already happening as a result of the reforms and consider viable alternative processes to ensure Canadians have sustainable and cost-effective access to prescription medicines.

We cannot not wait until after the changes have come into effect in 2021 to assess impacts on access. Health Canada and PMPRB's willful negligence regarding the impacts of the reforms is inexcusable and patients will suffer and even die as a result. If Canada's goal is to achieve non-excessive prices in line with those of comparable countries, we should examine the processes used in other countries that do not harm patients. There are many ways of achieving drug cost savings while minimizing the impacts on the availability of new medicines for Canadian patients that need them.

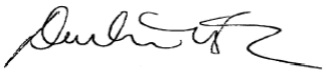
If the goal is to save billions of dollars through reduced medicine prices in Canada, as stated by Health Canada and PMPRB officials, this is achievable through the implementation of the new 11-country basket comparison. The economic factors, the most problematic aspect of the reforms, need to be removed or delayed until a proper assessment of their potential impacts on patient access to medicines has been made.

Moving forward, Health Canada and the PMPRB should explore the impact of its pricing policies on patients' lives and build polices to support drugs getting to Canadian patients. The PMPRB should also act less like a punitive body and more like a "public good" agency. It should collaborate with patients, clinicians, payers, and other stakeholders to arrive at pricing guidelines that work for all.

Please consider these important points in conducting your study and making your recommendations that will hopefully help mitigate the very real negative impacts of PMPRB reform on the thousands of Canadian patients who are literally in the fight for their lives.

I would welcome an opportunity to appear at your committee in the coming weeks to provide further information regarding CORD's perspectives on this issue.

Sincerely,



Durhane Wong-Rieger, PhD
President & CEO
durhane@raredisorders.ca

Encl.

Drug Name	Active Ingredient	FDA Approval Date	Submitted to HC?	Treatment / Use
Veklury	remdesivir	22-Oct-20	Yes	FDA: To treat COVID-19; HC: Antivirals for systemic use
Inmazeb	atoltivimab, maftivimab, and odesivimab-ebgn	14-Oct-20	No	To treat ebola virus
Gavreto	pralsetinib	04-Sep-20	No	To treat non-small lung cancer
Enspryng	satralizumab-mwge	14-Aug-20	No	To treat neuromyelitis optica spectrum disorder
Viltepso	viltolarsen	12-Aug-20	No	To treat Duchenne muscular dystrophy
Olinvyk	oliceridine	07-Aug-20	No	To manage acute pain in certain adults
Evrysdi	risdiplam	07-Aug-20	No	To treat spinal muscular atrophy
Lampit	nifurtimox	06-Aug-20	No	To treat Chagas disease in certain pediatric patients younger than age 18
Blenrep	belantamab mafodotin-blmf)	05-Aug-20	No	To treat multiple myeloma
Monjuvi	tafasitamab-cxix	31-Jul-20	No	To treat relapsed or refractory diffuse large B-cell lymphoma
Inqovi	decitabine and cedazuridine	07-Jun-20	Yes	To treat adult patients with myelodysplastic syndromes
Rukobia	fostemsavir	02-Jun-20	No	To treat HIV
Byfavo	remimazolam	02-Jun-20	No	For sedation
Dojolvi	triheptanoin	30-Jun-20	Yes	To treat molecularly long-chain fatty acid oxidation disorders
Zepzelca	lurbinectedin	15-Jun-20	No	To treat metastatic small cell lung cancer
Uplizna	inebilizumabcdon	11-Jun-20	No	To treat neuromyelitis optica spectrum disorder
Artesunate	artesunate	26-May-20	No	To treat severe malaria
Qinlock	ripretinib	15-May-20	Yes	To treat advanced gastrointestinal-stromal tumors
Retevmo	selpercatinib	08-May-20	No	To treat lung and thyroid cancers
Tabrecta	capmatinib	06-May-20	No	To treat patients with non small cell lung cancer
Ongentys	opicapone	24-Apr-20	No	To treat patients with Parkinson's disease experiencing "off" episodes
Trodelvy	sacituzumab govitecan-hziy	22-Apr-20	No	To treat adult patients with metastatic triple-negative breast cancer who received at least two prior therapies for metastatic disease
Pemazyre	pemigatinib	17-Apr-20	No	To treat certain patients with cholangiocarcinoma, a rare form of cancer that forms in bile ducts
Tukysa	tucatinib	17-Apr-20	Yes	Advanced unresectable or metastatic HER2-positive breast cancer
Koselugo	selumetinib	10-Apr-20	No	Neurofibromatosis type 1, a genetic disorder of the nervous system causing tumors to grow on nerves
Zeposia	ozanimod	25-Mar-20	Yes	Relapsing forms of multiple sclerosis
Isturisa	osilodrostat	06-Mar-20	No	Cushing's disease
Sarclisa	isatuximab-irfc	03-Mar-20	Yes	Multiple Myeloma
Nurtec ODT	rimegepant	27-Feb-20	No	Migraine
Barhemsys	amisulpride	26-Feb-20	No	Nausea and vomiting
Vyepti	eptinezumab-jjmr	21-Feb-20	Yes	Migraine
Nexletol	bempedoic acid	21-Feb-20	No	Heterozygous familial hypercholesterolemia or established atherosclerotic CV disease
Pizensy	lactitol	12-Feb-20	No	Chronic idiopathic constipation (CIC) in adults
Tazverik	tazemetostat	23-Jan-20	No	To treat epithelioid sarcoma
Tepezza	teprotumumab-trbw	21-Jan-20	No	To treat Thyroid eye disease
Ayvakit	avapritinib	09-Jan-20	No	To treat adults with unresectable or metastatic gastrointestinal stromal tumor (GIST)
Ubrelvy	ubrogepant	23-Dec-19	No	To treat acute treatment of migraine with or without aura in adults
Enhertu	fam-trastuzumab deruxtecan-nxki	20-Dec-19	Yes	To treat metastatic breast cancer
Dayvigo	lemborexant	20-Dec-19	Yes	To treat insomnia
Caplyta	lumateperone tosylate	20-Dec-19	No	To treat schizophrenia
Padcev	enfortumab vedotin-ejfv	18-Dec-19	No	To treat refractory bladder cancer

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Veklury	remdesivir	22-Oct-20	Yes	FDA: To treat COVID-19; HC: Antivirals for systemic use
Inmazeb	atoltivimab, maftivimab, and odesivimab-ebgn	14-Oct-20	No	To treat ebola virus
Gavreto	pralsetinib	04-Sep-20	No	To treat non-small lung cancer
Enspryng	satralizumab-mwge	14-Aug-20	No	To treat neuromyelitis optica spectrum disorder
Viltepso	viltolarsen	12-Aug-20	No	To treat Duchenne muscular dystrophy
Olinvyk	oliceridine	07-Aug-20	No	To manage acute pain in certain adults
Evrysdi	risdiplam	07-Aug-20	No	To treat spinal muscular atrophy
Lampit	nifurtimox	06-Aug-20	No	To treat Chagas disease in certain pediatric patients younger than age 18
Blenrep	belantamab mafodotin-blmf)	05-Aug-20	No	To treat multiple myeloma
Monjuvi	tafasitamab-cxix	31-Jul-20	No	To treat relapsed or refractory diffuse large B-cell lymphoma
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