

SUBMITTED VIA EMAIL (pmprb.consultations.cepmb@pmprb-cepmb.gc.ca)

August 31, 2021

Patented Medicine Prices Review Board (PMPRB)
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Subject: CORD Submission on consultations to 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 Members of the PMPRB,

The Canadian Organization for Rare Disorders (CORD) is a registered charity, as are most of our 100+ patient group members. Our mission is to improve the lives of Canadians affected by rare diseases by providing services and support and also by influencing policy and programs to ensure they are addressing the needs of rare disease patients and families. This past year, CORD convened two educational conferences, broadcast 30+ public webinars, developed a 10-session patient advocacy training program, executed or supported a dozen HTA submissions, collaborated in four research projects, and contributed to over 50 partner programs in Canada and internationally. Importantly, CORD achieves all of this with a budget (well) under \$1 million per annum, 2.5 paid staff, and many volunteers.

I provide this as context for our irritation at having to direct so much (unnecessary) time to intervening on PMPRB actions. This past June, we breathed a collectively sigh of relief when implementation of the new PMPRB regulations were delayed for another six months to January 2022. So, one can only imagine our extreme irritation when in mid-July the PMPRB released another set of guideline changes for implementation on July 1, 2022, six months before the regulations would have started to be effectively in force under the October 2021 Guidelines (January 2023). There was no explanation as to why it was necessary to introduce changes to “grandfathered” drug prices at this time.

Upon request, the PMPRB released a short “Frequently Asked Questions” (FAQ) document with an estimated reduction of drug prices by 10% on common drugs and 3.5% on rare disease drugs. There were no data, analyses, or case examples to substantiate or justify these estimates. This means we have no means of validating or challenging these estimates. Obviously as a patient group, we would not have access to the information or the expertise to conduct our own research (nor should we be expected to).

I will not repeat all of the feedback that CORD has provided across many responses to previous consultations on the full set of revised guidelines. Frankly, there is very little evidence that the many well documented and reasoned recommendations we provided have had an impact on the PMPRB subsequent minor guideline adjustments. At this point, to once again provide rational and reasonable feedback on irrational, unreasonable and unanalyzed guidelines is simply an exercise in frustration.

Nevertheless, I am compelled to point out that whatever the average price impact, there will undoubtedly be some grandfathered drugs that could require significant price reductions, and this will jeopardize on-going supply and access.

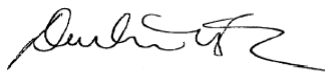
Finally, I want to stress that our skepticism about the intentions of the PMPRB as well as its attitudes toward the patient community are not unwarranted, based on the very negative and prejudicial comments about patient organizations expressed in public and private communications by those at the very highest levels of PMPRB's staff.

CORD recently called for the federal government to consider redirecting the PMPRB back to its originally constituted mandate to ensure drug prices are not "excessive" and to report on pharmaceutical investments in research and development. Perhaps this mandate is still relevant; clearly the revised regulations and guidelines are not justifiable and will have considerable unintended negative consequences harmful to patients and all Canadians.

CORD requests the new federal government that takes office following the September 20, 2021 general election launch a parliamentary review of the PMPRB and its mandate, actions and leadership.

If you require any further information regarding CORD's position on this matter, please do reach out to me.

Sincerely,



Durhane Wong-Rieger
President & CEO
Canadian Organization for Rare Disorders

About CORD

The Canadian Organization for Rare Disorders (CORD) is Canada's national network for organizations representing all those with rare disorders. CORD provides a strong common voice to advocate for health policy and a healthcare system that works for those with rare disorders. CORD works with governments, researchers, clinicians and industry to promote research, diagnosis, treatment and services for all rare disorders in Canada. In 2015, CORD launched Canada's Rare Disease Strategy (<https://www.raredisorders.ca/canadas-rare-disease-strategy/>) to provide recommendations to improve the care and treatment for rare disease patients in Canada.