Dr. Mitchell Levine, Chair, PMPRB

PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

CC: hello@cysticfibrosis.ca

Dear Dr. Levine:

My name is <FIRST NAME> <LAST NAME> and <I, MY SPOUSE, MY CHILD, MY FAMILY MEMBER, MY FRIEND> live with cystic fibrosis (CF) and <I, MY SPOUSE, MY CHILD, MY FAMILY MEMBER, MY FRIEND> need access to highly effective new life-changing medicines.

Cystic Fibrosis Canada provided a written submission to the PMPRB as part of the consultation process.

**I support Cystic Fibrosis Canada’s recommendations outlined in its written submission and urge you to implement them.** Specifically, I call on the PMPRB to:

* Take a phased approach to implementation. Begin with implementation of the changes to the comparator countries. All other changes to further reduce prices should be put on hold until the impact of implementing phase one and until the impact of the new economic criteria is evaluated by an independent third party.
* Remove barriers in the guidelines to accessing Trikafta by amending the Health Canada *approval* deadline for Gap Medicines to an *application* deadline. Under this amendment manufacturers would have until January 2, 2021 to *apply* for a Drug Identification Number (DIN), rather than *secure* a DIN by that time.
* Appoint an independent third party to evaluate the impact of application of the comparator countries and of the revised economic criteria on the availability of medicines in Canada, specifically to inform whether, when and how to implement the use of the new economic criteria for innovative, precision and other high cost medicines.
* Immediately establish a formal mechanism for meaningfully and continuously engaging patient representatives in its drug decision-making processes to ensure patient voice, choice and representation.

Approximately one in every 3,600 children born in Canada has cystic fibrosis. More than 4,300 children, adolescents, and adults live with cystic fibrosis. Now, because of our ability to manage care through specialized multidisciplinary clinics and the availability of therapies to treat the symptoms of cystic fibrosis, the median age of survival of a child born in 2018 is 52.1 years. Still, too many Canadians with CF die young: half of the people with cystic fibrosis who died in 2018 were under the age of 33.

Timely access to medications is crucial to maintaining and in some instances improving, the health and well-being of Canadians with cystic fibrosis. Trikafta is a new life-changing drug for most people with cystic fibrosis and is approved for sale in the United States and in Europe. Access to this drug has been delayed and is at risk of not coming to Canada at all. When asked why the drug has not been introduced in Canada, the manufacturer, Vertex Pharmaceuticals, raised concerns about changes to the Patented Medicines Prices Review Board (PMPRB) regulations, which were recently amended.

On behalf of Canadians with cystic fibrosis who need access to life-changing medicines, we need you to implement these changes now.

Sincerely,

<SIGNATURE>