Cystic Fibrosis
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Canada

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Dr. Paul Eckford

Submission to the PMPRB
Draft Guidelines for PMPRB Staff Administrative Process for Excessive Price Hearing Recommendation

Feedback: Draft Guidelines for PMPRB Staff

Cystic Fibrosis Canada is pleased to provide feedback on the draft guidelines for PMPRB staff regarding the administrative process for excessive price hearing recommendation.

Summary of Recommendations

Recommendation 1: In collaboration with Health Charities Coalition Canada and Best Medicines Coalition, we urgently call upon all levels of governments to ensure that medications, medical devices and supplies are fully exempt from tariffs or trade restrictions. We encourage our provincial health ministries and private insurers to work collaboratively to ensure cost stability and continued access to medicines for patients in Canada.

We ask that our Premiers and Prime Minister continue to outline a path forward that removes any intra-provincial barriers to improve access to medications, medical devices and supplies across our country and that consideration be given to temporary financial relief measures to protect individuals who may face sudden price increases.

Recommendation 2: The PMPRB must work with governments, Rights Holders, industry and, importantly, patients and patient groups to develop and implement strategies to fairly assess excessive drug pricing should tariffs be applied to medicines. These strategies must ensure that there are no disruptions of access to new and existing medicines due to excessive pricing as the result of tariffs.

Recommendation 3: The PMPRB must work with patients and patient groups to determine how and when we should be involved in the complaints process, and to implement shared recommendations toward those ends. This work should start immediately.

Preamble

As noted in the preamble to the draft guidelines:

> *These Guidelines are designed to ensure procedural fairness and consistency in that all similarly placed Rights Holders are subject to the same process and process timelines. The process described in these Guidelines consists of two "screening" steps designed to prioritize the cases that are advanced for recommendation for a hearing. The goal of the process is to allow the PMPRB to focus its limited hearings-related resources most efficiently.*

As a health charity that works on behalf of the Canadian cystic fibrosis community, we are limited in the feedback we can provide on matters that pertain to the PMPRB and Rights Holders, as we are not technical experts. We have, however, provided feedback where we can and appreciate the opportunity to weigh in.

Patient Impact Consideration

The PMPRB's principal mandate is to ensure that the prices of patented medicines sold in Canada are not excessive. In this regard, the PMPRB monitors and reviews the prices of patented medicines and conducts price hearings which may result in orders to reduce prices to a non-excessive level.

Cystic Fibrosis Canada believes that the draft guidelines, as presented, are within the scope of the PMPRB mandate. They are clear in both intentions and operations.

However, Canada and US relations have changed significantly since the PMPRB issued these draft guidelines. With unpredictable threats of tariffs looming, the PMPRB must be ready to ensure no disruption of new, innovative medicines coming to Canada, and no disruption of access to existing medicines due to excessive drug pricing as the result of tariffs. Responding to this unprecedented existential threat to Canadians must be the highest priority for the PMPRB, as it must be for all of government.

Cystic Fibrosis Canda is a member of several coalitions, which are all concerned about the potential impact tariffs may have on the price of drugs, and ultimately the price of access. Two of these coalitions, Health Charities Coalition of Canada (HCCC) and Best Medicines Coalition (BMC), have banded together in the following recommendation, which we support:

Recommendation 1: We urgently call upon all levels of governments to ensure that medications, medical devices and supplies are fully exempt from tariffs or trade restrictions. We encourage our provincial health ministries and private insurers to work collaboratively to ensure cost stability and continued access to medicines for patients in Canada.

We ask that our Premiers and Prime Minister continue to outline a path forward that removes any intra-provincial barriers to improve access to medications, medical devices and supplies across our country and that consideration be given to temporary financial relief measures to protect individuals who may face sudden price increases.

Recommendation 2: The PMPRB must work with governments, Rights Holders, industry and, importantly, patients and patient groups to develop and implement strategies to fairly assess excessive drug pricing should tariffs be applied to medicines. These strategies must ensure that there are no disruptions of access to new and existing medicines due to excessive pricing as the result of tariffs.

Special Provisions on Complaints

We read this section with great interest and some surprise. While we appreciate the sensitivities associated with the matters the PMPRB governs, we were discouraged to see that there was very little thought - and perhaps effort - to find meaningful ways to include and engage patients and patient groups.

Instead, lines 65-70 reflect a paternal approach to patient and patient group inclusion and engagement in certain processes where our perspectives matter. Specifically, lines 67 and 68 tell us not only that we don't have a role in this process, they also tells us that the only way for us to file a complaint is through government, drug programs, or insurance companies.

These approved individuals and organizations, and especially insurance companies, cannot be expected to have patient welfare and patient perspectives as their highest priority. While it is unlikely many patients will have complaints on pricing, there are some that pay out of pocket for drugs that may be subject to excessive pricing at the point of purchase, depending on where they get their medicines.

Moreover, patients and patient groups can provide testimony in hearings on the impact that excessive drug prices have on access. They can also provide testimony on the importance of keeping excessively priced drugs in market at should the Rights Holder wish to withdraw a drug determined to be excessively priced in the wake of penalties.

Recommendation 3: The PMPRB must work with patients and patient groups to determine how and when we should be involved in the complaints process and must implement shared recommendations toward those ends. This work should start immediately.

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About Cystic Fibrosis

Cystic fibrosis is the most common fatal genetic disease affecting 4,445 Canadian children and young adults. There is no cure. Of the Canadians with cystic fibrosis who died in the past five years, half were under the age of 38.4 years of age.

Cystic fibrosis is a progressive, degenerative multi-system disease that affects mainly the lungs and digestive system. In addition to the physical effects of the disease, anxiety and depression are rampant in this population. Double lung transplants are the final option for patients with end-stage disease; most fatalities of people with CF are due to lung disease.

Cystic fibrosis steals many things from people and families. Restful sleep is broken up by coughing fits. Time with friends and loved ones is second to daily physiotherapy and treatment routines. School and work are interrupted by frequent infections and subsequent hospital stays. Family dynamics may be strained by the stress and anxiety, as well as the costs, of managing a chronic illness. Dreams about the future are clouded by heavy realities of a fatal, rare disease.

But there is hope. There are highly effective medicines that treat the basic defect of cystic fibrosis (CF) rather than just the symptoms that can improve the health outcomes and quality of life for many people with cystic fibrosis. These therapies offer a changed reality for many people living with the disease. However, for others in the CF community, these therapies come too late for a full recovery. A lifetime of damage to the body, especially the lungs, means that for many even on this therapy, significant disease and structural lung damage remain and the episodic nature of PEx continues to impact daily life.

About Cystic Fibrosis Canada

Cystic Fibrosis Canada has dramatically changed the cystic fibrosis story. We have advanced research and care that has more than tripled life expectancy. Since being founded by parents in 1960, Cystic Fibrosis Canada has grown into a leading organization with a central role engaging people living with cystic fibrosis, parents and caregivers, volunteers, researchers and healthcare professionals, government and donors. We work together to change lives for the Canadians living with cystic fibrosis through treatments, research, information and support.

Despite our remarkable progress together, we are not yet done. We will keep pushing, keep going further until all people with cystic fibrosis can and do experience everything life has to offer – and enjoy everything life has to offer. Learn more at www.cysticfibrosis.ca.