Cystic Fibrosis Canada
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Submission to the Patented Medicines Prices Review Board
Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines

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Introduction

Cystic Fibrosis Canada is pleased to provide feedback to the Patented Medicines Prices Review Board (PMPRB) on its phase 2 consultations on new guidelines.

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.

Cystic Fibrosis Canada has dramatically changed the cystic fibrosis story. We have advanced research and care that has more than doubled 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.

Cystic Fibrosis Canada supports efforts to lower the costs of prescription drugs for Canadians. We believe that this can and must be done in a way that protects timely access by Canadians to new medicines, especially precision medicines.

We believe the PMPRB can achieve reasonable pharmaceutical price reductions in ways that do not impede timely access, and that the PMPRB must work with drug manufacturers – or rights holders - to strike the right balance. To that end, we provide the follow comments, focused on the PMPRB's work with patient groups.

Feedback: Proposed New Guidelines

The proposed new guidelines outline processes related to monitoring and reporting on patented medicine prices in Canada.

Patient Impact Consideration:

The PMPRB's primary focus is on monitoring the prices of patented medicines to ensure they are not excessive. This monitoring is crucial as it directly impacts patients who rely on these medicines for their health and well-being.

The Board considers factors such as the prices at which medicines are sold in the market, both domestically and internationally, along with changes in the Consumer Price Index. These considerations are essential as they can affect the affordability and accessibility of medicines for patients.

Cystic Fibrosis Canada agrees that it is important for the PMPRB to monitor Canadian drug prices in relation to international prices. This type of indexing will ensure that our pricing is competitive, making Canada more attractive for product launches.

We also agree that it is important to monitor pricing throughout the lifecycle of a drug, particularly given that many of our comparator countries do this.

We caution against any measures aimed at drastically reducing prices, such as the measures introduced in the previous iterations of the proposed guidelines. Applying significant price reductions at the point of entry into Canada or during the product lifecycle impacts manufacturers' – or rights holders' - willingness to bring products to market and to keep products in market, which negatively impacts access to life-changing and life-saving medicines for the patients who need them.

Complaint Mechanism:

Patients indirectly play a role in the process through the complaint mechanism. Complaints can trigger an in-depth review of a medicine's price, which may lead to further actions by the PMPRB. This mechanism ensures that patient concerns about medicine pricing can be addressed through a formal review process.

A number of complaints models are offered, some limited to federal, provincial and territorial ministers of Health, to models that include the ministers as well as public and private drug programs, to anyone who wishes to file a complaint. While the latter option may result in more complaints for the PMPRB to manage, it also provides equity for patients who may have excessive price-related access issues to drugs that have not yet made it to market as well as those that are in market. It is also important for patient organizations to be able to submit complaints on behalf of the patients they represent. Patient groups have direct links to patient communities, and, as such, have a unique understanding of the pricing challenges the patients they represent face. If option 3 is not selected, the option selected should also allow for patient organizations to submit a complaint.

Based on this, Cystic Fibrosis Canada recommends that the complaints process be open to everyone except for rights holders, who have direct commercial interests in drug product pricing and are therefore would be in a conflict of interest.

Transparency and Communication:
The paper mentions ongoing communication with rights holders, which could indirectly impact patients. Transparent communication about pricing decisions and processes can help patients understand the factors influencing medicine prices. Accountability and transparency can also inform patient groups advocacy work in these areas.

Cystic Fibrosis Canada supports transparency and accountability in drug pricing initiatives, including management of excessive pricing. We believe that patients and patient groups should have access to as much information as possible regarding drug pricing and excessive drug pricing activities.

Summary:
In summary, while the paper does not explicitly focus on patients as direct participants in PMPRB processes, the considerations around pricing, complaints, and transparency ultimately aim to protect patient interests by ensuring fair and reasonable pricing of patented medicines in Canada.