# Submission to the Patented Medicine Prices Review Board: Amendment to the Interim Guidance on New Medicines


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## Cystic Fibrosis Canada's Response

Cystic Fibrosis Canada supports efforts to lower the costs of prescription drugs for Canadians. We believe that this must not inhibit access to new drugs but can and must be done in a way that ensures timely access by Canadians to new medicines, especially innovative and precision medicines.

We also expect the government to ensure that the regulatory environment in Canada does not unnecessarily limit our ability to access new life-saving therapies or therapies that can significantly improve outcomes and a patient's quality of life.

Any efforts intended to lower prices must be made in a balanced way that continues to encourage innovation and does not result in the delay of launches and introduction of new medicines and clinical trials to Canada.

We appreciate that the amendments to the *Patented Medicines Regulations* and that the Interim Guidance has been in place since August 18, 2022, for just over a year. Under these guidelines, the PMPRB noted that it:

> *"…will not conduct a price review of any new patented medicines or open any investigations in respect of them until the new guidelines come into effect."*

The Interim Guidance further states:

> *"Medicines without a MAPP (Maximum Average Potential Price) or NEAP as of July 1, 2022, will not be subject to price reviews by PMPRB Staff during the Interim Period. Furthermore, once new Guidelines are in place, no potentially excess revenues will be calculated by Staff retrospectively for any such medicines for sales made during the Interim Period."*

This current consultation has been undertaken due to an increasing number of New Medicines that have not yet been reviewed by the PMPRB:

> *"The proposal aims to provide an expedited assessment for these New Medicines' prices while at the same time affording more time to advance a fulsome consultation process on the new guidelines.*
>
> *An analysis of recent filings found that approximately 55% of New Medicines have list prices that are below the median of the new basket of comparator countries (PMPRB11). This presents an opportunity to provide rights holders of these medicines with greater predictability on their pricing as quickly as possible.*
>
> *The Board proposes to implement the new basket of PMPRB11 countries without further delays by prioritizing New Medicines."*

This latest consultation ties implementation of the schedule of comparator countries with changes to how New Drugs with and without a MAPP or a NEAP will be assessed. While what is being proposed from a pricing perspective is really in the domain of manufacturers and the PMPRB, that the pricing of some New Medicines continues to be put on hold is concerning from an access perspective. The current consultation document further states:

> *"**In order for the PMPRB to move forward with implementing the basket of comparator countries**, the Board proposes to amend the Interim Guidance to give early guidance and greater predictability to certain New Medicines (i.e. medicines without a MAPP or NEAP as of July 1, 2022) regarding their review status.*
>
> *This proposal is responsive to the feedback received during the PMPRB's recent consultations and aligns with the intent of the regulatory amendments.*
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> *The Board proposes that the provisions of the Interim Guidance related to the patented medicines without a Maximum Average Potential Price (MAPP) or projected Non-Excessive Average Price (NEAP) be amended to indicate that they will be considered as reviewed if their list price is below the median international price for the PMPRB11 countries. New Medicines that do not meet this criterion will continue to be under review until new guidelines are in place.*

Quite frankly, we are dismayed that the PMPRB11 schedule of comparator countries has not yet been put in place and that the inability to do so looks to be poor policy design. While we understand that certain calculations must be agreed upon and made in order to make pricing data comparable to the schedule of comparator countries, why it has taken this long to figure out how to do this for New Medicines is concerning.

We believe that the PMPRB's failure to implement the schedule of comparator countries, as many stakeholders agreed to , has sadly resulted in a lost opportunity that could have saved millions of dollars, money that could have been spent on getting new, innovative and life-saving medicines into the hands of Canadians,  rather than delaying access by creating a prolonged environment of uncertainty for drug manufacturers by drawing out the implementation process.

In 2019 the PMPRB proposed drastic changes to the way it determines excessive prices of medicines. Many stakeholders objected and expressed serious concerns about some of the changes proposed. After multiple court rulings, the scope of the proposed changes was significantly reduced.

In June 2022, the Parliamentary Budget Officer (PBO) published a report that underscored what patient communities have been saying for years:

> *"Both lower prices for new innovative drugs may reduce timely access to those drugs for Canadians, and that Canada must inevitably balance the interest of consumers who*

*ultimately pay for pharmaceuticals with obligations to help fund R&D and incentivize the development of future products."*

The PMPRB adopted the change in comparator countries and has implemented interim guidance that includes not conducting a price review of any new patented medicines until new guidelines are implemented. This creates uncertainty in a sector that needs certainty and we know from experience that new guidelines could take several years. Since manufacturers are less likely to launch innovative products in markets of uncertainty the PMRPB should conduct price reviews under the current regulatory and guideline framework until new guidelines are adopted. Years of uncertainty cost Canadians their health, and in some cases, their lives.

The PMPRB must implement the schedule of comparator countries now. It is unconscionable that leadership of both the PMPRB and Health Canada has allowed this to carry on for so long, especially considering the key objective of the regulatory and guideline changes was to save money. The money has been on the table for almost half a decade, but instead of reaching for it, leadership has walked away.

**About Cystic Fibrosis and Cystic Fibrosis Canada**

Cystic fibrosis is the most common fatal genetic disease affecting 4,338 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 38.7 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 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 4,338 Canadian children and adults 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.