

**Joint Submission to the Standing Committee on Health:  
Patented Medicines Prices Review Board's Guidelines**

## Introduction

Since the changes to the Patented Medicines Pricing Review Board (PMPRB) were first proposed in 2017, the patient community has consistently raised concerns that these changes will negatively impact access to new medicines and clinical trials for Canadians.

The federal government and the PMPRB have said that there is a desire to “get this right” and that the intent was to find a way to lower drug costs while also ensuring access to innovative, life-changing medications and clinical trials. This is encouraging. However, our collective organizations were once again dismayed to learn that recommendations that were previously put forward have been insignificantly addressed by the PMPRB. The government still has not got it right.

We know that “getting this right” will take some time, but there are thousands of Canadians that are running out of time. On their behalf, we are asking the federal government to stop the implementation of the proposed changes to the PMPRB, reconsider the changes, and engage with Canadians to find a more balanced approach to lowering prices and protecting access to new, life-changing medicines and clinical trials for Canadians.

On behalf of our collective organizations, we respectfully submit the following recommendations, which reiterate those put forward by the individual participating organizations and that remain of vital importance to Canadian patients.

## Protecting Access to New Medicines

Our collective organizations, and the patients we represent, support efforts to lower the cost of prescription drugs for Canadians. We expect pharmaceutical manufacturers to bring their products to market at a responsible price, but we also expect the government to ensure that the regulatory environment in Canada does not unnecessarily limit our ability to access new therapies that hold promise to improve health for Canadians.

Efforts to lower drug prices must be balanced in a way that encourages ongoing innovation and the launch and uptake of new medicines into the Canadian market. However, we are concerned that the pricing pendulum has swung too far, too fast. This will make Canada an unfavourable market for launching medicines, thereby delaying, or denying access to innovative and potentially life-saving medicines for Canadians.

New regulations have already created a chilling regulatory, review and reimbursement environment and, unfortunately, we are already seeing that new drugs are not only being delayed but may be denied. Moreover, manufacturers have already pointed to concerns about the regulatory changes Canada is poised to adopt as the reason for delays in new drug launches. While the cystic fibrosis community may be the first to experience the negative impact of the proposed changes to the regulatory environment through the delay of access to Trikafta, with such uncertainty around the real-world application of the proposed PMPRB reforms patients are rightfully concerned that they will not be the last.

**RECOMMENDATION:** *Establish a multi-stakeholder advisory group to evaluate the impact on changes on availability of medicines and specifically to inform any decision on whether and how to implement the use of new economic criteria.*

**RECOMMENDATION:** *Implement an independent third party to evaluate the impact of the revised economic criteria on the availability of medicines in Canada specifically to inform any decision on whether, when and how to implement the use of the new economic criteria for innovative, precision and other high-cost medicines. Until this is completed, and the value of these measures is demonstrated, no such measures should be adopted.*

### **Importance of Involving Patients**

One of the biggest challenges the patient community has faced has been the flawed process that led to the PMPRB regulations and guidelines that are to be implemented in January 2021. The lack of meaningful engagement of groups representing patients has resulted in flawed policy. The government has failed to strike the right balance between lowering drug costs and ensuring new life-changing medicines are still made available to Canadians, but just as importantly, has failed to respect and really listen to patient groups.

Patient groups were not identified as a priority group for consultation during the two plus year process, and instead were lumped into a general public category, completely disregarding that ultimately, the group whose lives are most affected by these changes are patients. Moreover, the consultation for both the regulations and guidelines have not been inclusive, with little effort being paid to present the highly complex and technical information in a manner that patients could understand.

Patient groups and health charities have repeatedly offered input and suggestions to improve the process, and the proposed changes, but none of that input has been incorporated to date.

Going forward, we are calling for the establishment of a formal mechanism for ongoing and continuous engagement of patient representatives. Patient Advisory Councils aimed at improving access for themselves and others are utilized in many of Canada's comparator countries. Now that the PMPRB will be weighing in on the economic value of patient lives, patients need to be at the table and weigh in on the value of their lives too.

**RECOMMENDATION:** *Require that the PMPRB immediately establish a formal mechanism for meaningful and continuous engagement of patient representatives in its drug decision-making process to ensure patient voice, choice, and representation.*

### **About Protect Our Access**

Protect Our Access is a group of leading health charities and patient groups that represent the needs of patients across Canada, working together to raise concerns about draft guidelines proposed by the PMPRB. We came together out of frustration that the perspective of patients was not being fully valued by government in this process.

Our objective is to communicate to government and the public the importance of protecting timely and equal access to innovative medicines for patients; striking the right balance between reducing costs and ensuring Canadians continue to have access to new medicines.

The participating organizations of Protect Our Access are:

ALS Society of Canada  
Canadian Cancer Survivor Network  
Canadian Hospice Palliative Care Association  
Coalition Priorité Cancer au Québec  
Colorectal Cancer Canada  
Cystic Fibrosis Canada  
Fighting Blindness Canada  
Lung Health Foundation  
MitoCanada  
Ovarian Cancer Canada  
PROCURE – The Force Against Prostate Cancer  
Québec Breast Cancer Foundation  
The Leukemia & Lymphoma Society of Canada