PROTECT OUR ACCESS

Joint Submission on the PMPRB Guideline Measurement and Evaluation Plan

Since the changes to the Patented Medicines Pricing Review Board (PMPRB) regulations 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 stated a desire to "get this right." These changes are intended to find a way to lower drug costs while also ensuring access to innovative, life-changing medications and clinical trials. Despite such claims, the recommendations put forward by our collective organizations have been largely dismissed by the PMPRB to date. As a result, the patient community continues to have concerns about the impact of these changes on Canadian patients.

Given these concerns, it is critical that, should the changes to the PMPRB regulations be implemented as planned, a robust measurement and evaluation plan also be implemented – one that effectively measures the metrics and indicators that are of most importance to patients. On behalf of our collective organizations, we respectfully submit the following recommendations of vital importance to Canadian patients.

Access to New Medicines

A primary concern of our collective organizations and the patients we represent is the impact that the changes to PMPRB regulations will have on patients' access to new, potentially life-changing medicines and clinical trials.

We support efforts to lower the cost of prescription drugs for Canadians, but only to the extent that this does not unnecessarily limit the ability to access new therapies that hold promise to improve the health and quality of life for patients. We are concerned, however, that the pendulum has swung too far, too fast. This will make Canada an unfavourable market for launching new medicines, thereby delaying, or denying access to innovative and potentially life-saving medicines for Canadians.

The government and the PMPRB have dismissed Canadian patients' concerns by insisting that these regulatory changes and cost-containment policies will not create barriers to new medicines and clinical trials. Unfortunately, the facts don't support this claim. New regulations have already created a chilling regulatory, review and reimbursement environment in the Canadian market. For instance, Canadians living with cystic fibrosis have died waiting for access to a new therapy that could have saved their lives, but which is still not available in Canada because the manufacturer delayed bringing the drug to Canada due to the proposed regulatory changes. And other patients are living with other diseases across Canada that are similarly struggling to access therapies currently available in other countries.

Pricing reforms continue to send the message to global decision-makers that innovation and the advancement of patient care is not a priority in Canada, thereby putting at risk our ability to compete for clinical research investments on the global stage and potentially limiting Canadian patients' early access to improvements in care.

It is unreasonable for the PMPRB to claim that this will not directly and negatively impact clinical trials in Canada. It would be unethical to put patients on clinical trials knowing they may not have access to the drug in the future. Therefore, if manufacturers see no prospects for launch in

Canada or reasonable reimbursement, we can all but be assured that they may opt to bypass the Canadian market altogether.

Access to new medicines and clinical trials is of critical importance to patients and their families. The PMPRB must include rigorous measures to assess the impact that pricing has on introducing new medicines – whether through Health Canada approval or the launch of clinical trials – in the Canadian market. These measures should be established before the coming into force of any changes and reviewed early and regularly by an independent third party. If impediments to access are identified, we must also ensure plans are in place to course-correct as soon as possible to limit the negative impact on Canadian patients.

RECOMMENDATION: *Implement an impartial, independent third party, such as CIHI, to evaluate the impact of the revised economic criteria on the availability of medicines in Canada.*

Health Technology Assessment (HTA)

We understand that healthcare systems across Canada are increasingly under pressure and that governments want more certainty, both on costs and outcomes when considering reimbursement for medications**.** But we must find ways to fund access to innovative medicines despite healthcare budget challenges, which means looking at more than the cost of any one drug and considering its total value.

Many of the conditions that would benefit most from new, life-changing medicines are those associated with lifelong, debilitating, and often worsening symptoms – the burden of which is felt by the patients and the family and friends who care for them. Healthcare must therefore be treated as an investment and not merely as another cost to bear. The impact of innovation, particularly innovative medicines, goes beyond the clinical value to the individual as its value spans beyond the individual being treated to benefit caregivers, healthcare systems, and societies.

The value of new medicines must be an important consideration for payers and policymakers when developing, prioritizing, reimbursing, and implementing health policy to reduce the burden of disease. It is, therefore, increasingly important to understand the value of innovation accurately and holistically.

While health technology assessments (HTA) can be a valuable tool in helping to determine the relative costs and benefits of different technologies, the model is imperfect. There are limitations to traditional health economic modelling methods, especially for precision medicines and for rare diseases. These limitations can potentially negatively impact Canadian patients – especially those living with a rare disease or who would benefit from innovative precision medicines. In addition, ensuring fair and equitable access to new medicines requires a new way of thinking and a new way of evaluating innovative medicines.

It is vital that economic modelling and HTA's understand the true impact of conditions and evaluate the funding necessary to address the medical and social impact of an individual's condition. In developing new ways of thinking and evaluating the benefits of health technologies, including medicines, the government must consider the holistic impacts of new medicines on careers, families, health systems, society, and all those around an individual living with a life-limiting disease.

For someone living with or caring for a life-limiting condition, the value of any one medication goes far beyond the limited assessment currently conducted. Patient organizations, and patients and caregivers themselves, must be involved in the development of metrics that will ultimately determine what medications meet the criteria for cost-effectiveness and, therefore, reimbursement.

RECOMMENDATION: *Require that the PMPRB immediately establish a formal mechanism for meaningful and continuous engagement of patient representatives in its drug evaluation and decision-making process to ensure patient voice, choice, and representation and so that all medications are assessed not only on their cost-per-QALY, but on their true and holistic value to patients, families, and society.*

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 patients' perspective was not fully valued by government in this process.

Our objective is to communicate to the 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 access new medicines.

The participating organizations of Protect Our Access are:

ALS Society of Canada
Canadian Cancer Survivor Network
Canadian Hospice Palliative Care Association
Canadian Association of PNH Patients
Coalition Priorité Cancer au Québec
Colorectal Cancer Canada
Cure SMA
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