

Patented Medicine Prices Review Board

333 Laurier Avenue West, Suite 1400

Ottawa, Ontario K1P 1C1

Subject: 2022 Proposed Updates to the Patented Medicine Prices Review Board (PMPRB) Guidelines

We are a group of physicians who are concerned that Canadians will have increasing difficulty accessing effective new drugs if the Government of Canada proceeds with its plan to bring into force new federal drug pricing regulations on January 1, 2023, and we write to provide input to the Consultation on the Proposed PMPRB Guidelines.

We urge the federal government to halt implementation of new federal drug pricing regulations until a thorough consultation that includes physicians is undertaken. We all agree that the concept of reducing the price of medicines or making medicines more affordable is appealing, however, further evidence-based discussions among all stakeholders is needed to highlight the potential consequences and to ensure we do not limit our abilities to treat patients most effectively.

In the cancer field we are now arriving at a new paradigm in which tumors are less defined by their tissue of origin, and more so by the molecular profile, the presence of specific targets, etc. This NECESSARILY means an ever expanding and changing list of indications for already approved drugs, and even for new drugs which necessarily enter the system with one indication.

The plan to re-review each new indication unquestionably spells death, at least shortened survival, for many cancer patients.

Our fundamental point last year to PMPRB, was to consult to medical and biomedical scientific community BEFORE introducing anything destabilizing. You have failed to do that.

Our key concerns are outlined as follows:

Pending changes will reduce patients' access to new novel drugs

Access to effective medications is a cornerstone of healthcare for Canadian patients. The proposed regulations will make Canada an unattractive market for companies launching effective new drugs. This will markedly delay the introduction of new drugs or cause companies to avoid Canada altogether. This will result in thousands of Canadian life-years lost. Patients will be denied access to medications that could alleviate their suffering.

Pending changes will lower the number of clinical trials for new medications

The proposed regulations are affecting clinical trials. The number of clinical trials in Canada has dropped substantially compared to the years prior to the initial announcement of the new regulations. Clinical trials are important because—in addition to testing the benefits and risks of new therapies—they increase the availability of new agents and provide patient access to new and better medications.

Pending changes will reduce patients' access to new medications

Clinical trials are important because they test the efficacy of treatments, help determine appropriate dosages, and uncover any side effects. No less vital, participation in clinical trials is a way by which patients can access promising new agents that would otherwise be unavailable to them. A reduction in clinical trials means impaired access to new drugs, and who among us wouldn't want the most up to date and effective medications to support our oncology patients?

Over the past many months, we have published numerous articles and Opinion Pieces stating our concerns and desire for further engagement. We attach with this letter some of these publications with the added commentary that points made previously still

pertain and are even more emphatic, given the significant overload of cancer patients with more advanced disease than pre pandemic. The pandemic has made our arguments even more important than previously.

Accordingly, we the undersigned urge the Government of Canada to halt implementation of the pending regulations and work with all groups—including physicians—that have a stake in drug pricing to find a better approach. Let us work together to ensure Canadians have access to the best new medicines.

Dr. Alan Kaplan, Family Physician, Aurora, ON

Dr. David Stewart, Medical Oncologist, The Ottawa Hospital, Ottawa, ON

Dr. Gerald Batist, Medical Oncologist, Jewish General Hospital, Montreal, Quebec

Dr. Shaun Goodman, Associate Head, Division of Cardiology, Unity Health, Toronto, ON

Dr. Silvana Spadafora, Medical Director Algoma District Cancer Program, Sault Ste. Marie, ON

Dr. George Zhanel, Professor, Medical Microbiology and Infectious Diseases, University of Manitoba

Dr. Paul Wheatley-Price, Medical Oncologist, The Ottawa Hospital, Ottawa, ON

Dr. Sandeep Sehdev, Medical Oncologist, The Ottawa Hospital, Ottawa, ON