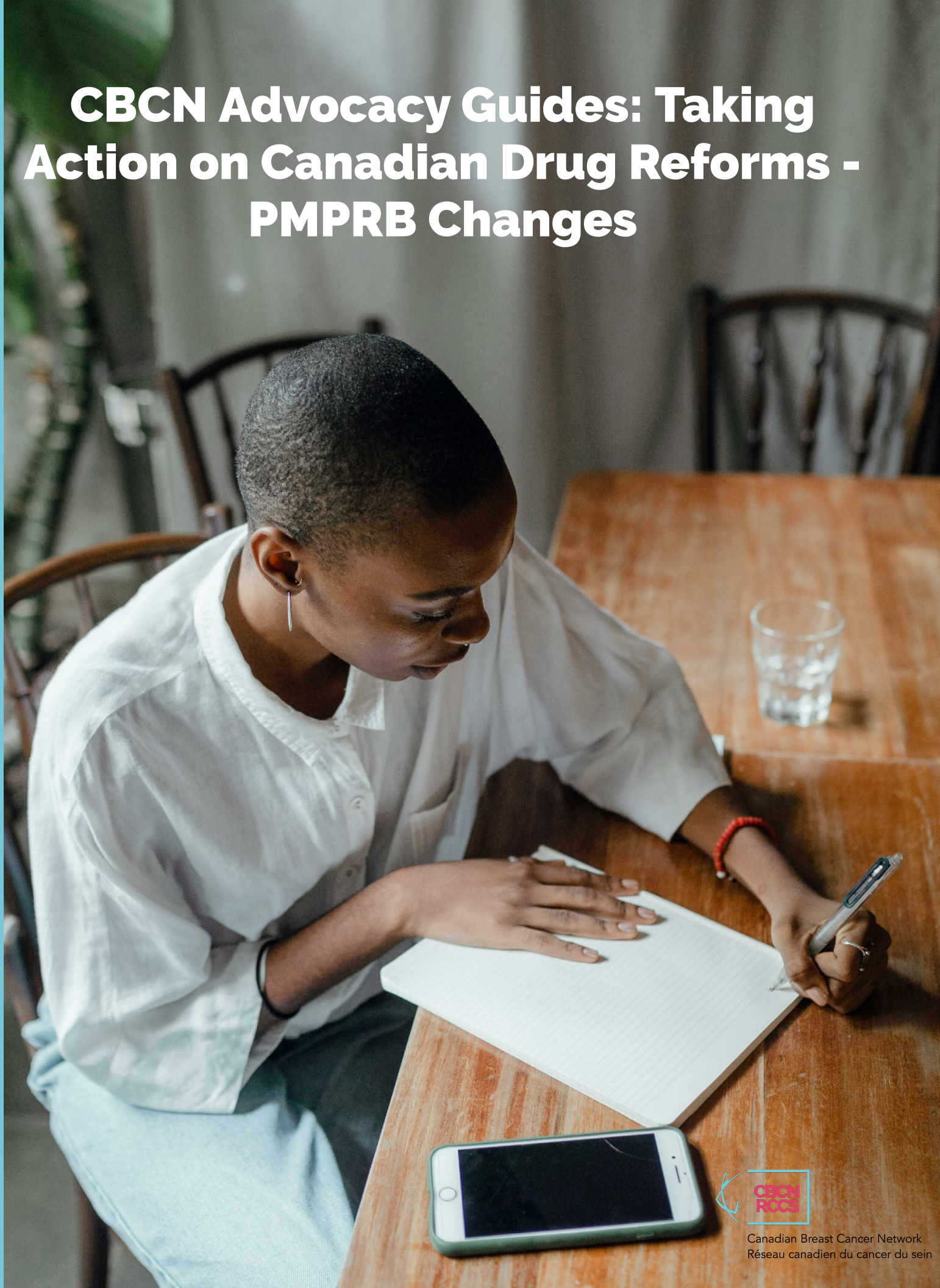
CBCN Advocacy Guides: Taking Action on Canadian Drug Reforms - PMPRB Changes



Canadian Breast Cancer Network
Réseau canadien du cancer du sein

What Is The PMPRB?

The journey of a new drug in Canada involves a lengthy and complicated system of approvals. One of the key steps in the drug approval process is an assessment by the Patented Medicine Prices Review Board (PMPRB). The PMPRB is an independent, quasi-judicial body, in the Health Portfolio, which sets the maximum price that companies can charge for their medications in Canada. The PMPRB's mandate is to protect consumers by ensuring that the manufacturers' prices of patented medicines are not excessive.

New Changes To PMPRB Regulations

In May 2017, Health Canada announced new changes to the Patented Medicines Prices Review Board (PMPRB) regulations. These regulations were further amended in June 2020 with updated guidelines. The proposed changes include new factors for determining whether a drug is being, or has been, sold at an "excessive" price.

The proposed changes are intended to require drug manufacturers to reduce the price of their medications significantly. It is still uncertain what the magnitude of these price reductions will be once the regulations are applied to therapies in the real-world. This uncertainty has led to a lot of concern from both drug manufacturers and the patient community.

What Is The Impact On Patients?

Patient advocates have raised concerns about many of the proposed changes to the regulations. There are concerns that following implementation, Canada could become a less attractive market to launch new therapies-particularly for precision medications often used in oncology. This could lead to a reduction in the number of new cancer therapies that are available in Canada and limited access to clinical trials. It could also create disincentives for continued investment in cancer-related research and development in Canada.

What are Advocates Recommending?

A number of recommendations have been proposed to address these concerns. CBCN has supported calls for a slower, phased approach to implementation, re-evaluating price reduction goals through a patient lens, rigorous monitoring and evaluation and collaborative engagement to make patient voices a permanent part of the decision-making process.

Current PMPRB Process

Scientific review to assess level of improvement of a new patented drug product.

PMPRB reviews pricing information of all drug products sold in Canada.

PMPRB publishes information of price review in "New Patented Medicines Reported to PMPRB"

If a price exceeds the guidelines, an investigation is opened. Results of an investigation could be:

Investigation closed if price is determined to be within guidelines.

Public hearing held to determine if price is too high.

VCU (Voluntary Compliance Undertaking) submitted by patentee to comply with guidelines and reduce drug price.

Taking Action:

The Regulations were initially set to come into force on July 1, 2020 but the implementation date has now been delayed to January 1, 2021. While the formal consultation period has concluded, there are still opportunities for cancer patients to make their voices heard. With the ongoing COVID-19 pandemic, access to new treatments and vaccines has never been more important. It is essential that our health regulatory systems are able to support access to innovative and life-saving treatments for all Canadians.

If you are concerned about the impact that these reforms could have on access to cancer medications for patients, here are some actions you can take:

1. Contact your Member of Parliament and ask them to support the recommendations of patient advocates on PMPRB reform. You can search for your MP and their email address on the Current Members of Parliament directory on the Parliament of Canada's website.
   Mail can be sent postage-free to any Member of Parliament at the following address:
   Name of Member of Parliament
   House of Commons
   Ottawa, Ontario
   K1A 0A6

2. Contact the Minister of Health- Share your thoughts and opinions on the proposed changes and the impacts they could have on cancer patients with the Minister of Health.
   Minister of Health
   House of Commons
   Ottawa, Ontario K1A 0A6
   hcminister.ministresc@canada.ca

You can view and use this sample letter when contacting PMPRB and/or the Minister of Health.