LSTN
Life-Saving Therapies Network
Better Therapies, Faster Access

Submission to the Patented Medicines Prices Review Board on Scoping Paper and Proposed Guidelines

December 18, 2023

Background

The Patented Medicines Prices Review Board (PMPRB) was born in 1987 out of the Patent Act. The Courts have ruled that the PMPRB has the mandate to oversee the review and reporting of excessive pharmaceutical prices in Canada. It is unclear how "excessive" is defined. The PMPRB does not have a consumer protection mandate and cannot require disclosures of confidential rebate information.

The PMPRB's proposed new guidelines will generally limit the maximum price charged for a patented drug in Canada. The price will equal median of the price charged in 11 comparator countries ("the PMPRB11"). None of these comparators have a bureaucratic analogue to the PMPRB.

COVID-19 vaccines and other drugs were excluded from PMPRB oversight because there was a need for expedited access. There is a similar need for accelerated access to potentially life-saving drugs to treat people with lethal diseases. (Bright et al. Frontiers in Health Services 2023;3:1015621). This would mean excluding them from PMPRB scrutiny and its new guidelines. The treatment of COVID-19 vaccines has set a precedent for doing just this.

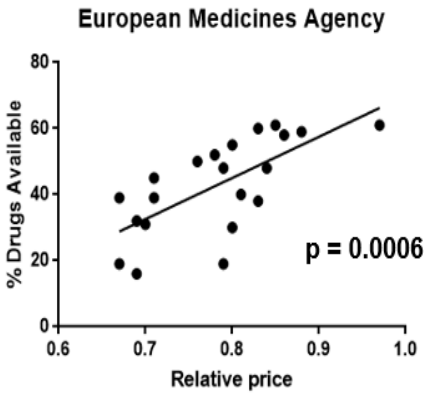
Analysis

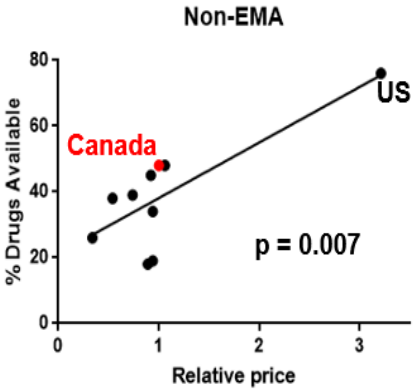
We have analyzed data presented by the PMPRB (https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/2020/PMPRB-Public-Webinar-July8-2020.pdf). Our analysis indicates that these new guidelines would reduce the maximum price that could be charged for a patented medication in Canada by about 20% relative to other countries.

While the approach followed by companies has varied somewhat across drugs, companies have traditionally been most likely to apply first to the US FDA. The US has a population of about 340M people and the US has typically been willing to pay the highest drug prices in the world. Companies then typically apply to the European Medicines Agency (EMA), which reviews drugs for countries with a combined population of about 550M people. While some European countries are generally willing to pay only low prices, others (like Germany) have been willing to pay high prices. In a single step, the EMA gives companies access to a wide range of European countries.

Companies have traditionally only applied to Canada an average of 8 months after applying to the EMA. Health Canada charges a company $565,465 to assess a new drug (Fees for Examination of a Submission: Drugs for Human Use - Canada.ca). This compares to a fee of 345,800 Euros to apply to the EMA (https://www.ema.europa.eu/en/documents/other/explanatory-note-general-fees-payable-european-medicines-agency-1-april-2023_en.pdf).

Despite this high Health Canada cost and Canada's small market size (2% of the global market), Canada has historically been an appealing market since it has been willing to pay more for drugs than many other countries.





Our analysis of PMPRB's data indicates that there is a highly significant association between the price a country is willing to pay for a new medication and the probability of accessing the new medication. This is true for both European countries and non-European countries. (See figures.)

It is reasonable to assume that if Canada begins to pay less for drugs, we will also have worse access. We are unaware of any economic or political reason that this would not happen. Our analysis of PMPRB data indicates that this reduction in Canadian prices would translate into Canada accessing *only about 35% of all new drugs instead of the 48% we currently access*.

It would be a double whammy. We would have access to fewer of the most promising and effective new drugs available in other parts of the world; and, it would take us longer to access those that did eventually come here.

The obvious reason is that most companies would pursue approval in other more lucrative markets before coming to Canada.

It might be reasonable to have decreased access to some types of drugs if it meant getting them cheaper. Delayed access to new sleeping medications, anxiolytics, laxatives, acne medications, hemorrhoid creams, analgesics, erectile dysfunction medications, antihypertensives and diabetes medications might adversely impact the quality of life of some Canadians.

But it would not kill them. Patients with lethal diseases like metastatic cancers and cystic fibrosis suffer unnecessarily and die if access to effective new medications is delayed.

The delay in public funding in Canada for effective new cancer medications is far too long. This translates into thousands of Canadian life-years lost (Gotfrit et al. The Oncologist 2020; 25:e130). Because cancer symptoms are inadequately controlled, it also means more patients cram our emergency departments; there are increased hospitalizations and increased use of expensive but less effective alternatives. There is every reason to believe that *the new PMPRB guidelines will worsen this.*

The healthcare system is far from lean. In a real sense, the PMPRB guidelines are cost cutting measures. Suffice it to say that costs can be cut in other places and in other ways.
The proposed PMPRB guidelines are cruel. They are unacceptable. They are a false economy that will deny Canadians with lethal diseases a longer life, relief from suffering and hope.

Recommendations

1. Application of the PMPRB guidelines should exclude therapies for lethal disorders.
2. Application of the PMPRB guidelines should exclude therapies where a major delay in access could cause irreparable harm.

About Us

Dr. Stewart is a Professor at the University of Ottawa Medical School and former Head of Medical Oncology at the Ottawa Hospital. He is still in active practice and has recently published the book Why Cancer Still Sucks.

Dr. Bradford is a former cancer patient and caregiver to his wife. An accomplished businessperson, published scientist, government advisor and psychotherapist, he co-authored the book Journeys in Cancerland with Lisa Newman.