

BEST MEDICINES COALITION

Submission to the Standing Committee on Health: Patented Medicines Prices Review Board Guidelines

Best Medicines Coalition



November 6, 2020

Standing Committee on Health: Patented Medicines Prices Review Board Guidelines Study

Introduction and core position:

The Best Medicines Coalition (BMC), a national alliance of patient organizations together representing millions of patients, welcomes this opportunity to provide input to the Standing Committee on Health as it considers the Patented Medicine Prices Review Board's (PMPRB) Guidelines to implement the new Patented Medicines Regulations. This submission was informed by position documents developed in consultation with BMC's member organizations. Statements and recommendations expressed here reflect areas of consensus among the organizations listed at the end of this document.

Our focus is ensuring that all Canadians have access to the medicines they need when they are needed – medical necessity is paramount for all patients especially those with unmet needs. We fully support pharmaceutical pricing reform and the need for regulations which make medicines more affordable for all patients, including lowering prices to be in line with similar countries. Equally important, regulations must encourage, not deter, introduction of new medicines and vaccines plus clinical trials sponsored by drug developers, giving patients who volunteer early access to promising new therapies.

Following careful review, our position we wish to express to this committee – as we have with government and parliamentarians - is that by proceeding with the Guidelines as presented the government is taking on significant risk with critical consequences for patients. Specifically, anticipated price reductions go beyond original intent and initial evidence shows significant negative impact on drug introductions and anticipated reductions of clinical trials. We are not alone in this position with a broad range of stakeholders and health system experts expressing substantial concerns. Indeed, the federal government's recent determination to exempt COVID-19 vaccines and medicines from PMPRB consideration, which we fully support, is a tacit admission that the new rules could have a serious negative impact on early access to these new drugs and vaccines.

Recommendations:

1. Phased implementation to immediately lower prices:

- We urge the Standing Committee to recommend that the federal government, through Cabinet, direct a stay of implementation on parts of the regulations, deferring the application of economic factors in the determination of price to a second stage, pending further study and consultation.
- We urge the Standing Committee to request that the application of the new basket of comparator countries should proceed as planned to bring down prices immediately for all patients, especially those paying out of pocket.

2. Full disclosure and analysis of input:

- We urge the Standing Committee to recommend that the federal government fully disclose input provided throughout the reform process, as part of formal consultations and otherwise, including analysis of the breadth of concerns and how they have been addressed or will be mitigated. This would include additional submissions and information in addition to the submissions received and posted online through PMPRB and the governments formal consultation processes for both the guidelines and regulations.
- We urge the Standing Committee to request that the federal government and PMPRB release correspondence and other input from provinces/territories, including from provincial Cabinet Ministers as well as public drug program managers.

3. Evidence-based analysis and decision-making:

- We urge the Standing Committee to recommend that the federal government develop and provide comprehensive evidence to inform the path forward, including on initial impacts on critical markers, that is introductions of new medicines and initiation of clinical trials sponsored by drug developers (Phase 2, 3 & 4 trials).
- In order to bring about transparency with regard to the government and PMPRB's assumptions that the revised Guidelines rely on, we urge the Standing Committee to request that case studies on specific drugs, initially prepared to show the impact of the then proposed Regulations and Guidelines, be made public and updated to reflect provisions in the final Regulations and Guidelines, while protecting any commercially sensitive information.

PMPRB Regulations and Guidelines: Key Considerations and Discussion

Throughout the regulatory reform process begun in 2016, the BMC and its member organizations have reviewed proposed and final Regulations and Guidelines through the lens of the patient communities we represent, asking fundamental questions: How will patient care be impacted? Will policy goals of affordability, access to medicines, accountability, transparency and inclusivity be achieved?

1. Initial signs of negative impact

A key marker for the patient community is whether medicines – particularly those which address unmet needs – will be available to Canadians affordably and in a timely manner. There are early indications that introductions have declined in comparison to other countries, although we acknowledge that some evidence is mixed or unclear.

It was encouraging to learn from PMPRB at its July 8, 2020 webinar that countries with lower prices may have greater availability of new medicines, citing its own 2017 Annual Report. Furthermore, PMBRB also cited Health Canada data indicating that medicines approved in Canada in the first quarter of 2020 have not diminished from previous levels. In addition, the number of medicines approved in Canada within a year after being approved in the United States increased in 2019 over 2018, citing Health Canada and United States (FDA) data.

However, looking at medicine launches, a Life Sciences Ontario report (*New Medicine Launches: Canada in a Global Context*, June 2020) comparing Canada to 24 countries indicates a 40 per cent drop in 2019 here while launches elsewhere increased. Further, of the total number of medicines launched globally less than half are being introduced in Canada with shortfalls in oncology and rare diseases. As patient organizations, we are not in a position to provide analysis, but we note the pharmaceutical industry cites apprehension about the amended regulations and guidelines, including inherent uncertainty, as precipitating this apparent cooling in the Canadian market. The industry refers to the impact on global markets and regulatory complexity as deterrents. Regarding complexity, it is apparent the Regulations and Guidelines introduce various additional layers, rather than streamlining the patented medicines review process. Confusion remains regarding overlapping roles of PMPRB, Canadian Agency for Drugs and Technologies in Health, the pan-Canadian Pharmaceutical Alliance, and individual Ministries of Health.

Moreover, there are concerns about possible negative impacts on decisions on whether to conduct industry-sponsored clinical trials in Canada, in particular those in Phases 2, 3 and 4. Clinical trials are an important conduit to promising new therapies for many patients. While we understand that many factors are considered as decisions are made, among the reasons cited by industry for not conducting these trials in specific countries are prospects for reimbursement and uncertainty regarding price.

These are complicated issues, of course, and the evidence needs to be fully explored. However, findings about timely access are deeply concerning and reflect what some patient organizations see as they are made aware of specific medicines being used in treatment in other countries while Canadian patients wait. Clearer projections of initial impacts are needed to chart the path forward. Decisions on how to proceed must be informed by current, credible and comprehensive evidence, ideally developed in cooperation with all stakeholders.

2. Price reductions beyond and below original intent

We fully support a modernized regulatory framework that reduces prices to reasonable levels, such as the median prices in OECD countries, which was the government's original intent. However, there are indications that the proposed regulations, implemented according to the Guidelines, will deliver prices well below this original intent with potentially negative implications including hurting patient access to new medicines.

While there has been ambiguity about price reduction goals, in 2017 the OECD median was cited by the federal government as a target, achieving approximately a 20 per cent reduction. As stated by PMPRB at its July 8, 2020 briefing, changing only the basket of comparison countries would likely deliver a 20 per cent reduction. Analysts indicate that the additional application of the economic factors would deliver more dramatic and unpredictable reductions and thus impact the pharmaceutical market and availability of new drugs.

We urge careful consideration of price reduction goals balanced by the goal of patient access to medically necessary medicines, to ensure measures are appropriate and necessary and to assess the impacts of the current regulatory package.

3. Inequity regarding affordability gains

We support the general intent and focus of the Regulations and Guidelines on reducing prices for all patients in Canada and especially the changes to the basket of reference countries. However, the regime as proposed by the Guidelines entrenches the negotiated price and rebate system and perpetuates patient inequities.

The framework is centered on reducing the maximum rebated price and is designed to reduce patented medicine prices for patients who access medicines through a public or private health benefits plan. This excludes patients who pay out-of-pocket for their medicines and who therefore will not benefit from reductions in the maximum rebated price. Recent statistics from the Canadian Institute for Health Information estimates that patient out-of-pocket payments account for 20 per cent of prescription medicine spending (with 43 per cent public plans and 37 per cent private insurance). This 20 per cent is too high and is a barrier to medicine access. Further, patients who provide co-payments through their plans will or could also be paying rates based on the maximum list price, resulting in inflated payments to plans (including governments) that receive rebates from patented medicine manufacturers.

We encourage consideration of the impact on all patients, including those who rely on public and private plans and those who pay directly, to ensure that affordability gains are achieved equitably.

4. Lacking transparency, accountability, and meaningful patient engagement

Throughout the reform consultation process, diverse stakeholders have called for measures to improve PMPRB's transparency and embed greater accountability through rigorous monitoring and evaluation. In addition, patient organizations have repeatedly called for improved involvement, both through the consultation process and implementation. We note that the consultation process so far has excluded genuine engagement with stakeholders and has been viewed as a one-way dialogue.

A fundamental flaw in the consultation process to date is that stakeholders have had concerns about fundamental policy choices in the proposed Regulations and then the final Regulations but the scope of consultation was limited to how to implement those policy choices. As a result, we welcome the interest of this Committee to take a deeper dive into the policy choices.

It is unfortunate that concerns about lack of patient participation in this process (including the monitoring, reporting and addressing of adverse impacts on patients) have not been reflected in the Guidelines, despite consistent requests by patient representatives to be present at the table, as is standard practice at other public bodies involved in the review and assessment of pharmaceuticals.

We also note that there is a great deal of uncertainty and lack of transparency regarding PMPRB staff discretion in applying the Regulations and Guidelines. This broad ability to carry out modifications and variations at the staff level without further guidance or explanation for the use of this discretion goes against the spirit of providing clear transparency and accountability on these discretionary actions.

Minimal details have been provided regarding accountability, including ongoing monitoring and evaluation. It is unfortunate that the *Guidelines Modernization and Evaluation Process*, or a plan for its development, was not made available in early 2020 as originally planned, and we believe it is inappropriate for the government to push forward with the Regulations and Guidelines without a clear plan for evaluating impacts.



About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of patient organizations, together representing millions of patients, with a shared goal of equitable, timely and consistent access for all Canadians to safe and effective medicines that improve patient outcomes. The BMC's areas of interest include drug approval, assessment, and reimbursement, as well as patient safety and supply issues. As an important aspect of its work, the BMC strives to ensure that Canadian patients have a voice and are meaningful participants in health policy development, specifically regarding pharmaceutical care. The BMC's core activities involve issue education, consensus building and position development and advocacy, making certain that patient-driven positions are communicated to decision makers and other stakeholders. The BMC was formed in 2002 as a grassroots alliance of patient advocates. In 2012, the BMC was registered under the federal Not-for-profit Corporations Act.



Alliance for Access to Psychiatric Medications	CanCertainty
Asthma Canada	Crohn's and Colitis Canada
Brain Tumour Foundation of Canada	Cystic Fibrosis Canada
Canadian Arthritis Patient Alliance	Canadian Cystic Fibrosis Treatment Society
Canadian Association of Psoriasis Patients	Fighting Blindness Canada
Canadian Breast Cancer Network	Health Coalition of Alberta
Canadian Cancer Survivor Network	Huntington Society of Canada
Canadian Council of the Blind	Kidney Cancer Canada
Canadian Epilepsy Alliance	Lymphoma Canada
Canadian Hemophilia Society	Medical Cannabis Canada
Canadian Mental Health Association	Medicines Access Coalition – BC
Canadian PKU & Allied Disorders	Millions Missing Canada
Canadian Psoriasis Network	Ovarian Cancer Canada
Canadian Skin Patient Alliance	Parkinson Canada
Canadian Spondylitis Association	