



February 12, 2020

Dr. Mitchell Levine  
Chairperson  
Patented Medicines Prices Review Board  
333 Laurier Avenue West, Suite 1400  
Ottawa, Ontario K1P 1C1  
email: [PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca](mailto:PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca)

**re: Response to PMPRB Draft Guideline Consultation**

Dear Dr. Levine:

The Health Charities Coalition of Canada is pleased to respond to the Draft Guidelines Consultation.

The Health Charities Coalition of Canada (HCCC) is a member-based organization comprised of 25 national health charities which represent the voice of patients at all levels of the health continuum. Together we strengthen the voice of Canadians, patients and caregivers, and work with others to enhance health policy and increase investment in health research.

This submission follows on previous input provided to the PMPRB consultation by our Coalition and its members to the Guidelines Modernization Discussion Paper (October 31, 2016) and to the Regulations Amending the Patented Medicines Regulations - Canada Gazette Part 1, Vol 1, 151. No 48. (February 13, 2018). In addition to receiving a submission from our Coalition, many of our members intend to submit further information that supports the recommendations below and provides further detail on how the proposed changes to the guidelines may impact living with a specific disease or condition.

Our submission highlights four key recommendations:

**Recommendation #1:**

*That the PMPRB undertake a stepwise approach to its proposed changes by initially enacting only the changes to the comparator countries. Once the impact of this change is fully understood and if the objective of lowering Canadian prices sufficiently has not been met, then other new elements could be considered.*

**Recommendation #2:**

*That a multi-stakeholder dialogue be established to evaluate the impact of the changes on availability of medicines and specifically to inform any decision on whether and how to implement the use of the new economic criteria.*

**Recommendation #3**

*That the Federal Government require PMPRB to hire a third party to conduct a formal assessment of the potential and real-time impacts of the reforms on research investment and activity in Canada (including clinical trials).*

**Recommendation #4:**

*That the Federal Government require that PMPRB, along with other appropriate agencies, immediately establish a formal mechanism for meaningfully and continuously engaging patient representatives in its decision-making and processes to ensure patient voice, choice and representation.*

Thank you for the opportunity to provide comment. We remain committed to working with the Federal Government and the broader stakeholder community in defining an implementation and evaluation process that will address both cost savings and access to innovation that will optimally serve the needs of patients in Canada.

Sincerely,



Connie Côté  
Chief Executive Officer  
Health Charities Coalition of Canada  
[ccote@healthcharities.ca](mailto:ccote@healthcharities.ca)



# **Submission to PMPRB Draft Guidelines Consultation**

**February 12, 2020**

## **EXECUTIVE SUMMARY & RECOMMENDATIONS**

The Health Charities Coalition of Canada (HCCC) represents 24 of the leading health charities in Canada which are looked to every day for hope and support by millions of Canadians facing serious health challenges.

HCCC supports efforts to lower the costs of prescription drugs for Canadians and believes that this must be done in a way that ensures timely access by Canadians to new medicines or to clinical studies of new medicines.

HCCC is deeply disappointed that patient voices were marginalized during the long consultation process, and that concerns raised in the initial consultations in 2017 remain unaddressed. The PMPRB's patient consultation efforts appear to have been symbolic, without substantive changes subsequently included, despite the constructive and feasible recommendations received from the patient community, including HCCC. Accordingly, HCCC reiterates an earlier recommendation that the PMPRB make an immediate and profound commitment to ensure meaningful and continuous patient engagement in the guideline consultations and its new pricing review framework.

HCCC agrees with securing lower drug prices in Canada by implementing the new basket of comparator countries and strongly recommends delaying use of the proposed new economic factors to determine a maximum drug price in Canada until the effect of using the new comparator countries has been evaluated.

The further new pricing tests proposed by the PMPRB will result in drastically lower prices for new treatments, resulting in an unattractive market for manufacturers, thus many medications may not be available in Canada for years after other developed countries, or perhaps at all. This will have a serious negative effect on Canadian patients who need new medicines to improve their quality of life, and for many to extend or save their lives.

Additionally, we are concerned that these changes may severely reduce new investments in pharmaceutical research in Canada, which will erode Canada's world-leading research infrastructure. This is a precious national and global resource which, once lost, will be very challenging to regain. It is crucial to understand the impact of these changes on the health research environment in Canada and on patients before they are implemented fully.

***Accordingly, HCCC makes the following four recommendations, vital to Canadian patients:***

**Recommendation #1:**

*That the PMPRB undertake a stepwise approach to its proposed changes by initially enacting only the changes to the comparator countries. Once the impact of this change is fully understood and if the objective of lowering Canadian prices sufficiently has not been met, then other new elements could be considered.*

**Recommendation #2:**

*That a multi-stakeholder dialogue be established to evaluate the impact of the changes on availability of medicines and specifically to inform any decision on whether and how to implement the use of the new economic criteria.*

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*That the Federal Government require PMPRB to hire a third party to conduct a formal assessment of the potential and real-time impacts of the reforms on research investment and activity in Canada (including clinical trials).*

**Recommendation #4:**

*That the Federal Government require that PMPRB, along with other appropriate agencies, immediately establish a formal mechanism for meaningfully and continuously engaging patient representatives in its decision-making and processes to ensure patient voice, choice and representation.*

## **DETAILED BRIEF**

The Health Charities Coalition of Canada (HCCC) is a member-based organization dedicated to strengthening the voice of Canadians, patients and caregivers by advocating for enhanced health policy and increased investment in health research.

Access to medicines is important to health charities and the Canadians that they serve as our organizations were founded by individuals and their families who had lived experience with a disease and hoped for a different reality for future generations – a future free from the disease that they lived with. For many of our members their vision is eradication of a specific disease. Until that vision is realized, Canadians look to ways that they can better manage their disease. As such, the use of medicines is often a choice that Canadians make, as medicines can help to slow progression of disease, alleviate side effects and ultimately cure disease.

The issue of pricing of drugs in Canada – particularly patented medicines which offer the most innovation and hope to those facing serious medical challenges – is of vital importance to the millions of Canadian patients represented by HCCC members. These drugs must be affordable for both the health system and for individual patients. However, affordability is only one element that requires consideration. Timeliness to access and availability of medications through Canada’s public and private drug plans are also important considerations.

HCCC strives for excellence in health policy and seeks to ensure that the federal government and policy makers look to HCCC and its members for timely advice and leadership on major health issues of concern to Canadians and that they recognize the competence, commitment and contributions of health charities in improving the health and well-being of Canadians. It is in this spirit that this brief is presented to the Patented Medicine Prices Review Board (PMPRB) in the context of its public consultations on its draft guidelines to implement the new *Patented Medicines Regulations*.

This brief addresses the proposed draft guidelines of the PMPRB in terms of their impact on affordability, availability and research. Additionally, it proposes the Federal Government and PMPRB take further formal steps to ensure the patient perspective is regularly and meaningfully heard and considered in its activities.

## **IMPACT ON AFFORDABILITY**

Canadian patients share governments’ concerns about the affordability of medications, and they support policy efforts intended to lower prices. However, such efforts must be balanced in such a way as to encourage continual innovation and the launch and uptake of new medicines into the Canadian market, as discussed further in the sections on availability and research below. HCCC expressed these concerns in its brief to the consultations on the initial draft of the new regulations in 2017 and is distressed that these concerns have neither been addressed in the final regulations nor potentially ameliorated by the draft guidelines currently under discussion.

Changing the basket of comparator countries used by the PMPRB will have, as the PMPRB has explained, the goal of dropping Canada's prices to or below the median of countries in the Organization for Economic Cooperation and Development (OECD). This will represent a price drop of at least 20%, which is substantial, both for the benefits that will accrue to patients and the health system. Given this, HCCC does not understand the rationale for implementing additional new and untried measures to reduce prices further through reliance on factors such as pharmacoeconomics and market size until such time that the impact of the initial change is fully understood.

**Recommendation #1:**

*That the PMPRB undertake a step-wise approach to its proposed changes by initially enacting only the changes to the comparator countries. Once the impact of this change is fully understood and if the objective of lowering Canadian prices sufficiently has not been met, then other new elements could be considered.*

**IMPACT ON AVAILABILITY**

Access to new medicines and choice of treatment options are key considerations for patients. As previously submitted, HCCC remains concerned that the application of new economic factors as proposed in the draft guidelines will restrain both considerably.

HCCC acknowledges and agrees conceptually with the PMPRB's initiative to streamline the price regulatory process. However, based on a review of the proposed Category 1 criteria, it appears that the majority of new treatments will be subject to the comprehensive review process, which will add additional new factors and thus additional steps to the evaluation process for setting ceiling prices for patent medicines. This appears to defeat the intent of streamlining the process and may cause additional delays in the length of time that it takes for Canadians to be able to access new medicines in Canada.

Under the new schematic, an interim maximum list price is initially set based on the maximum list price of the available PMPRB11 prices. Medicines are then classified into Category 1 or 2 based on whether they have an annual cost and/or estimated market size above the designated threshold. Drugs that fall into Category 1 are then subjected to the new Section 85 factors (pharmacoeconomic, market size and GDP). HCCC is concerned about the impact of the addition of the economic factors on the assessment process for specific patient populations, such as those living with rare diseases or accessing precision medicines therapies, as these medicines are typically found to be "cost-ineffective" according to the methodology used and will be subject to greater price reductions. These apparent inequities will create further barriers to availability for these patients.

Under the previous maximum price assessment regime, medicines were categorized as being breakthrough, showing substantial improvement, moderate improvement or slight/no improvement over current therapy and were allowed maximum prices accordingly. In the new schema, medicines are evaluated under one of two categories and no allowances are made for innovation. This is concerning to patients on several levels, as described below.

Some patients are concerned that such significant decreases in price will result in delays in manufacturers launching their product in Canada and this will have a negative impact on the overall length of time that it takes for Canadians to have access to new medicines in Canada, if at all. Our assessment of the draft price review process shows it is likely that prices of any new therapy designed for a small patient pool would be reduced so low as to make it impractical for them to be offered for sale in Canada. This is because they will almost certainly be deemed to be Category 1 medicines by virtue of an annual cost that is likely to be higher than 50% of the GDP per capita. In order to achieve the required maximum cost of \$60,000 per quality-adjusted life-year (QALY), the price would have to be reduced well below a commercially viable rate even with the opportunity for a 50% increase over the otherwise allowable maximum price.

These fears are borne out by the results of a survey announced on February 3, 2020, by Life Sciences Ontario. In a survey of senior executives from 36 Canadian biopharmaceutical companies, 97% said the changes would have a negative impact on their company's ability to launch or supply medicines in Canada, with 74% saying the negative effect would be "significant." The survey also revealed these negative decisions are already being taken.<sup>1</sup>

Currently, many Canadians access specialty medicines through special access programs that operate across several jurisdictions in Canada. It is unknown what the impact of the proposed changes will be to the special access programs and to the Canadians who rely on these programs to improve their health. However, the same Life Sciences Ontario survey noted above revealed that 70% of executives believe the changes will have a negative effect on their ability to provide compassionate access programs (55% significantly negative) and 73% believe they will have a negative effect on patient support programs (35% significantly negative).<sup>2</sup>

In order to best understand the full impact of the how the implementation of the new guidelines will impact the availability of drugs to Canadians, it is recommended that the Government of Canada instruct PMPRB to convene an on-going multi-stakeholder dialogue to evaluate the impact of the changes on availability of medicines and specifically to inform on any decision on how to implement the use of the new economic criteria.

**Recommendation #2:**

*That a multi-stakeholder dialogue be established to evaluate the impact of the changes on availability of medicines and specifically to inform any decision on whether and how to implement the use of the new economic criteria.*

**IMPACT ON RESEARCH**

Members of HCCC are co-funders, with governments and other investors, of some of the most important leading health research in Canada. Together with their many partners, HCCC members

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<sup>1</sup> Life Sciences Ontario, New federal drug pricing rules are already delaying medicine launches and costing jobs in Canada, survey reveals, press release, Feb. 3, 2020, at: <https://lifesciencesontario.ca/news/new-federal-drug-pricing-rules-are-already-delaying-medicine-launches-and-costing-jobs-in-canada-survey-reveals/>

<sup>2</sup> Ibid.



translate knowledge gathered through research to advocate for better public policy and better health outcomes for Canadians. Members of HCCC invest more than \$155 million annually in health research, including funding ground-breaking new scientific approaches that contribute to the discovery of new and better medicines.

In addition to compromising patient access to new therapies, HCCC is deeply concerned about the impact the pricing changes will have on the health research infrastructure of Canada that has been built to world-class standards over the past 30 years. HCCC members count on the availability of this infrastructure to allow its own investments in research to be as efficient and cost-effective as possible.

HCCC has concerns that the new pricing regulations and guidelines will result in pharmaceutical companies drastically curtailing research investment in Canada. This will not only deprive Canadian patients of an important means of access to new innovative medicines through clinical studies, it will lead to the dissolution of much of the research infrastructure that has been established with so much effort and care. This will not only cost Canada in terms of jobs and expertise, but it will make other health research, such as that financed by HCCC members, less efficient and more expensive – and in some cases impossible if the required infrastructure for it ceases to exist.

These fears about the impact on clinical research are also borne out by the Life Sciences Ontario survey cited above. In that survey, 91% of pharmaceutical executives said the changes would have a negative effect on clinical research in Canada, with 44% saying the negative effect would be “significant.”<sup>3</sup>

**Recommendation #3:**

*That the Federal Government require PMPRB to hire a third party to conduct a formal assessment of the potential and real-time impacts of the reforms on research investment and activity in Canada (including clinical trials).*

**IMPACT ON MEANINGFUL INPUT FROM PATIENTS**

HCCC was profoundly disappointed that the detailed and thorough input and recommendations it and other patient groups provided on the draft regulations were not reflected in the final approved version. As a result, many of those same concerns remain, as do very serious doubts about the commitment of the PMPRB to meaningful dialogue with patients.

It is our understanding that the PMPRB is building a Guidelines Modernization and Evaluation Process (GMEP) that will, in part, track the impact of the guideline changes on patients, healthcare providers and other stakeholders. A specific area of focus will measure Impact on Medicine Access. As organizations that work directly with patients, we are well positioned to provide valuable input to PMPRB on both the qualitative indicators that are relevant to patients as well as contribute by providing valuable quantitative data (such as information gathered through our registries). Unfortunately, opportunities to participate in this level of engagement and multi-

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<sup>3</sup> Ibid.

stakeholder dialogue to determine how best to collectively monitor and evaluate progress going forward have not been extended to the patient community.

The time to act on this is now, yet patients are not being included in this impact process at the front end. Patients must be at the table contributing to the design and ongoing operation of such an evaluation process to ensure that it is capable of tracking such things as the timeliness of medication access, the viability of Canada's research and development industry, and the market for innovative medicines in this country. We are extremely disappointed that a path forward is being built and that the patient voice is not being considered nor integrated into the GMEP process.

It is vital that patients play an active and meaningful role in the review recommended above that must take place before all the elements of proposed pricing regulations are implemented. Following that vital step, patients must play an ongoing formal and meaningful role to ensure their voice is heard and respected into the future.

**Recommendation #4:**

*That the Federal Government require that PMPRB, along with other appropriate agencies, immediately establish a formal mechanism for meaningfully and continuously engaging patient representatives in its decision-making and processes to ensure patient voice, choice and representation.*

**CONCLUSION**

Throughout the consultation process HCCC and its members have brought forward the perspectives and lived experiences of the patient communities that we represent. We are concerned that the views of Canadians living with disease who will be most impacted by these regulatory changes are not being acknowledged, considered and addressed in a collaborative and respectful way.

HCCC urges the PMPRB to take a stepwise approach to implementing its planned reforms in order to achieve cost savings but also to ensure that viable pathways remain open for innovative and life changing medicines to improve patient outcomes. In keeping with the PMPRB motto "Protect, Empower, Adapt" we hope that the implementation of the guidelines will move beyond a one size fits all approach and that the broader stakeholder community will be fully engaged in defining an implementation and evaluation process that will both address cost savings and access to new innovation to optimally serve patients in Canada.