

August 4, 2020

Delivered Via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Douglas Clark

Executive Director
Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Re: Revised PMPRB Guidelines

Thank you for the opportunity to provide stakeholder input on the Revised PMPRB Guidelines.

Asthma Canada is a national charity that provides evidence-based asthma information, education, management tools, and support programs for more than 3.8 million Canadians living with asthma. Asthma Canada also advocates to improve the quality of life for people living with asthma and supports strategic research to unlock better treatments and ultimately, a cure.

Access to medicines is a critical issue to our organization and to the Canadians we serve. Prescription drugs can manage conditions, cure disease(s), improve quality of life, shorten or prevent time spent in hospitals and reduce the demand for health care services, potentially leading to positive health outcomes and decreased costs to the healthcare system. An effective and sustainable drug approval process is key to providing timely access to medicines for all Canadians.

From Asthma Canada's perspective, lowering drug prices is a laudable goal, but we have serious concerns with the approach that is currently being proposed. The new economic considerations that are being introduced to determine maximum drug prices do not take into consideration patient values such as tolerability, ease of use and the improvement to quality of life, and will drastically reduce the range of treatment options available to Canadians, which will result in serious long-term implications for patient health and our healthcare system. We also believe the proposed changes could have a detrimental effect on Canadian research that our country may not be able to reverse.

For those living with Severe Asthma who rely on new and innovative medicines to breathe, this may mean severely limited treatment options, and a life dependent on oral corticosteroids, which are associated with substantial adverse effects such as weight gain, diabetes, osteoporosis, glaucoma, anxiety, cardiovascular disease and impaired immunity. Limited treatment options for the asthma community is unacceptable and negates the Canada Health Act's principles of accessibility and comprehensiveness.

As an active and very engaged member of Health Charities Coalition of Canada, Asthma Canada fully endorses the HCCC submission and asks that you implement the four recommendations attached, so that in partnership, stakeholders and government can transform Canada's healthcare together for lower drug costs, without reducing access to life-changing medicines. We are a world class country and should have

a healthcare system that reflects excellence instead of pursuing a healthcare system based on mediocrity. We also ask that when implementing any changes, you consider a phased-in, gradual approach that allows for continuous learning and adjustments so that unintended consequences arising from the proposed amendments to PMPRB can be appropriately measured and addressed.

If you wish to discuss this matter further, please contact me directly.

Sincerely,



Vanessa Foran
President and CEO
Asthma Canada



**Submission to
PMPRB Guidelines Consultation**

August 4, 2020

EXECUTIVE SUMMARY & RECOMMENDATIONS

The Health Charities Coalition of Canada is pleased to continue to provide feedback as part of the public consultation process on the revised PMPRB Guidelines.

The Health Charities Coalition of Canada (HCCC) represents 25 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. Our members are committed to working together to improve health policy and advance health research to achieve better health outcomes for Canadians.

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 and to participation in clinical trials. Efforts to lower drug prices must be balanced in a way that encourages ongoing innovation and the launch and uptake of new medicines into the Canadian market.

After reviewing the revised guidelines, released in June 2020, we were once again dismayed to learn that the recommendations that were previously put forward by the Health Charities Coalition of Canada in February 2020 had not been addressed. We provided a recommendation to engage an independent third-party entity to conduct a formal assessment of the real-time and potential impacts of the reforms on access to therapies and research investment in Canada. Without this valuable independent review on the impacts of these policy changes it is incomprehensible to patients that the new measures would be adopted and implemented within the previously stated timeframes, acknowledging that the coming into force date for the amended Patented Medicines Regulations has been extended to January 1, 2021.

The proposed guidelines will have varying degrees of impact to our patient populations dependent on several issues including market size, therapeutic criteria level, availability of accessible data and whether existing therapies are currently available. As such, individual members of HCCC will also provide written submissions to the Guidelines Consultation highlighting specific impacts for Canadians living with specific diseases and or conditions represented by their health charity.

As none of the recommendations previously submitted by HCCC were acted on, we respectfully resubmit the following, which remain of vital importance 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.

Recommendation #3

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

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. Our recent experience with the global pandemic has demonstrated the

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). The transition to the PMPRB11 is expected to 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.

The Health Charities Coalition of Canada is supportive of policy efforts aimed at reducing drug prices and managing Pharmacare costs providing that these efforts also take into consideration the broader context of availability and access to medicines. Implementing a step-wise approach by first introducing the changes to the comparator countries and evaluating the impact of this change while allowing for independent third-party analysis and monitoring of the impacts of the other new elements will advance the objective of lowering prescription costs. All other changes aimed at further reducing prices should be put on hold until the impact of the new economic criteria can be thoroughly evaluated by an independent review party.

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.

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 remains 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. The reintroduction of the Therapeutic Criteria Level scale provides some allowances for therapeutic innovation and is a step in the right direction. However, there remain concerns that the currently proposed model falls short in taking into consideration the impacts that will be experienced by specific populations, especially for those requiring precision drugs, drugs for rare disorders or other high-cost specialized therapies.

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. 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.¹

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).²

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.

¹ 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/>

² Ibid.

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 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.”³

Recommendation #3:

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

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. In fact, in the latest guideline consultations patient input was marginalized into a category now known as civil society input.

³ Ibid.

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-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, real world application of the new framework, 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.

While our members originally called for the above action in our submission on February 14, 2020, opportunities for patients to engage in this level of discourse as a true and valued partner is still outstanding.

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

We are committed to working with others to bring about policy changes that will help to improve the health of Canadians. We believe that that PMPRB can achieve reasonable pharmaceutical price reductions in ways that will ensure timely access and availability of pharmaceuticals for Canadians and expect that Canadians living with disease will be acknowledged, considered and included in collaborative and respectful way as changes are being considered and implemented and evaluated.