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Patented Medicine Prices Review Board
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Input Regarding the PMPRB Guidelines Modernization Discussion Paper

As part of our work on behalf of Canadian patients regarding pharmaceutical care, the Best Medicines Coalition (BMC) is keenly interested in the work of the Patented Medicines Prices Review Board (PMPRB) and welcomes the opportunity to comment on some of the issues raised in the PMPRB Guidelines Modernization Discussion Paper. The BMC is a national alliance of 27 patient groups with a shared interest in pharmaceutical approval, review, and reimbursement issues and we actively encourage engagement of patient representatives in pharmaceutical policy development.

We commend the PMPRB for implementing a comprehensive consultative process and for reaching out to ensure that the Canadian patient community is informed and engaged, including the educational webinar presented by PMPRB for BMC member organizations. We trust that the PMPRB will consider all patient input carefully, including individual submissions from our member organizations and from other patient representatives. We trust that the next phase of the consultation will also include full representation from the patient community, and we respectfully request that the BMC be part of this process.

The BMC works to ensure that all Canadians have timely access to necessary medications which improve outcomes for patients. Some of our fundamental positions are outlined in *Equitable Pharmaceutical Care: Principles and Considerations Regarding Pharmacare for All Canadians* (attached), a document prepared within the context of current pharmaceutical reform discussions.

BMC's input to PMPRB on modernization and reform of Canada's pricing regulation framework is informed by the key principles outlined in this document. These principles include universality and equity, timely access to a comprehensive range of therapeutic options and a collaborative approach to policy and program reform which includes patients.

…/2

BMC's comments on the PMPRB's guideline modernization are brief and principle-based, limited to those questions that are relevant to patient needs, perspectives and positions. As such, please consider the following:

- BMC supports a strong regulatory framework for pharmaceutical pricing aimed at both protecting consumers, primarily patients, and contributing to the value and sustainability of the health care system itself.
- A primary goal of the PMPRB, like other agencies operating in the realm of pharmaceutical care in Canada, should be to contribute to an environment that offers Canadian patients access to a comprehensive range of medicines, including newly developed advancements.
- It is appropriate that a pharmaceutical pricing framework be implemented by a national body and that it operate in concert with and reflect the realities of other national and regional bodies which play a role in pricing to avoid duplication.
- All stakeholders, including patients, have a legitimate role in determining the next iteration of a pharmaceutical pricing regulation framework and should be engaged on an ongoing basis.

Regarding specific issues, the BMC offers the following perspectives:

Excessive pricing:
Patients do not evaluate drugs in economic terms but rather in terms of the drug's effectiveness and potential to halt disease or alleviate symptoms, or other significant end points. Therefore, it is challenging for patients to assess use of the word excessive cost in relation to a drug. Certainly if a drug has little value and carries a high price tag this could be considered excessive. However, there are many nuances to this including whether a drug is used by a patient population with very limited treatment options, especially if that population is particularly small and if drug developers invested in research and manufacturing to bring that drug to market.

Comparators/discounts:
Pricing parameters should reflect current realities that determine price, such as negotiated discounts. It would seem that given the current discounting practices less emphasis would be placed on international public list prices in determining price ceilings. If a group of comparator country wholesale prices are referenced, it would be a reasonable approach for Canadian prices to be within a low to medium range. As a principle, Canadian payers should not be subsidizing pharmaceutical care in other countries, nor should those in other countries be subsidizing Canadian drug costs.

Research and development:
In the current environment, many factors contribute to levels of research and development investments in Canada, and pharmaceutical industry leaders are best to offer advice on realities in this area. BMC supports the notion that research investment of all types should be fostered and incentivized and that national policy makers should explore a range of policy levers, not necessarily those just related to price.

…/3

Categorization and other issues

A modernized system for categorizing drugs should be given consideration, taking into account therapeutic benefit as well as other factors such as rare or orphan status. Likewise, it is reasonable that risk of potential for excessive pricing be assessed drug by drug, with different levels of regulatory oversight applied. In addition, in some categories a revision to ceiling prices may be appropriate although this should be considered in context of impact of other pricing mechanisms.

Public and private price discrimination

The question of different pricing levels for public payers, private/corporate payers, and individual patients is important and warrants further examination in light of current system realities. Currently, both private and public payers have tools available to negotiate prices but individual payers do not. This is a hardship for individuals who don't have bulk buying power and could be viewed as discriminatory. Therefore policy makers should address this in the context of broad pharmaceutical reform within modernization of the PMPRB framework.

Moving Forward

Again, we thank the PMPRB for its efforts to educate the patient community and seek its input on these important issues. We look forward to further discussions and to working in partnership with the PMPRB as it endeavors to refine and improve its process to bring value to Canadian health care. At this important time, we suggest that PMPRB consider establishing a patient advisory body to enable greater collaboration moving forward, and that the PMPRB include patient representation in any multi-stakeholder collaboration or review.