Health Charities Coalition of Canada Coalition canadienne des organismes de bienfaisance en santé

October 31, 2016

Patented Medicine Prices Review Board
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Dear Members of the Patented Medicine Prices Review Board,

The Health Charities Coalition of Canada is pleased to provide stakeholder input into the Patented Medicine Prices Review Board (PMPRB) Guidelines Modernization Discussion Paper.

The Health Charities Coalition of Canada (HCCC) is a member-based organization comprised of 30 national health charities who represent the voice of patients at all levels of the health continuum. Our mission is to facilitate the collaboration of Canada's health charities to achieve excellence in health policy, practice and research. Our members are co-funders with the governments on some of the most important leading health research in Canada and together we translate knowledge gathered through research to advocate for better public policy and better health outcomes for Canadians.

Access to medicines is an important issue for our members and to the Canadians that they 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 in being able to provide timely access to medicines for Canadians.

While there are several organizations that play pivotal roles in the drug approval process in Canada, the Patented Medicine Prices Review Board (PMPRB) is uniquely positioned to regulate the ceiling price of patented medicines and act as protector for Canadians in ensuring that excessive drug prices are not being charged to Canadians. In this context, *excessive drug pricing* refers to Canadian prices for patented medicines in comparison to the pricing for the same drug in the identified comparator countries (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States of America).

Under the Patent Act, the PMPRB was established to 1) regulate the price of patented medicines sold in Canada to ensure that they are not excessive based on the criteria outlined in Section 85 of the Patent Act and 2) to report to Parliament through the Minister of Health.

Within the drug approval process, the PMPRB fulfills a role that is distinct from other agencies. Under the current process, Health Canada is responsible for determining market approval and has oversight for product safety, effectiveness and quality. Health technology assessments are conducted by the Canadian Agency for Drugs and Technologies in Health (CADTH) and the Institut national d'excellence en santé et en services sociaux (INESSS) (in the province of Québec) to determine the clinical and cost effectiveness of a drug and make recommendations for its future usage. Once drugs are recommended for use, the pan-Canadian Pharmaceutical Alliance (pCPA) is responsible for negotiating the cost of the drug and finally individual drug plans make the determination on whether or not to list the drug on their formulary. Each agency represented in the

drug approval process fulfils a key function and **we support the unique role that the PMPRB plays in setting the ceiling price for the sale of patented medicines in Canada.**

While the focus of this consultation is on the modernization of the guidelines, it is important to also examine the key function that PMPRB plays in protecting consumers from excessive patent drug costs as well as in establishing access to necessary and innovative medicines for Canadians.

Stakeholders were asked to provide feedback on what the word "excessive" means when thinking about drug pricing in Canada today. The Health Charities Coalition of Canada position statement on access to medicines states that ***"all people living in Canada should have equitable and timely access to necessary prescription medications based on the best possible health outcomes rather than the ability to pay."***

From the perspective of the patients that we serve, excessive pricing is not defined within the limitations of the current guidelines but speaks to the ability of Canadians to be able to afford the medications that they need to manage/cure their respective disease. With this in mind, we ask that the PMPRB consider how it will continue to protect consumers from the rising cost of new drugs and biologics based on the criteria set out in Section 85 and against a backdrop of a lack of transparency in the confidential price listing agreements between private payers and pharmaceutical companies.

This consultation also aims to stimulate a discussion on the changes that have taken place in the PMPRB's operating environment since its inception. A major change in the healthcare environment has been the move to integrate patient partnerships as a key component of healthcare reforms. Patients bring a "lived experience" to the table and are able to provide input and solutions from the perspective of the end-user. Increasingly, patient partnerships are being developed and applied at the individual, organizational and system levels. For example, in the current drug approval process, patients bring valued perspectives to the Health Technology Assessment conducted by CADTH. **We recommend that the PMPRB seek opportunities to meaningfully and continuously engage patient representatives in their decision making and regulatory processes.**

The PMPRB states its vision as "a sustainable pharmaceutical system where payers have the information they need to make smart reimbursement choices and Canadians have access to patented medicines at affordable prices." We look forward to bearing witness to the evolution of the PMPRB in fulfilling its vision of ensuring that Canadians have access to patented medicines at affordable prices.

We thank you for the opportunity to provide comment and look forward to participating in the next phases of the consultation.

Sincerely,

Connie Côté

Connie Côté
Chief Executive Officer
Health Charities Coalition of Canada