

February 14, 2020

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

**RE: Input Regarding Patented Medicine Prices Review Board Draft Guidelines**

Introduction

Arthritis Consumer Experts (ACE) is a national patient-led organization that provides free, science-based information and education programs in both official languages to people with arthritis. ACE serves people living with all forms of arthritis by helping them take control of their disease and improve their quality of life through education and empowerment. Founded and led by people with arthritis, ACE adheres to a strict set of guiding principles established by an advisory board comprised of leading scientists, medical professionals and informed arthritis consumers.

As part of our advocacy efforts on behalf of Canadians living with arthritis, we are responding to the Patented Medicines Pricing Review Board's (PMPRB) request for submissions regarding Draft Guidelines to implement the Patented Medicines Regulations. This follows a meeting in Vancouver that ACE, along with Arthritis Research Canada representatives, held with the PMPRB leadership team as part of the PMPRB's briefing and consultative session with stakeholders across Canada that began in December 2019.

Background: Pricing regulation

As medication policy discussion continues to evolve in Canada, debate over rising drug prices and fair pricing will continue to be the focus of cash-strapped public pharmacare programs in Canada, facing multiple pressures:

- Aging population
- Growing budget pressure from biologic medications
- Reimbursement coverage for new medications
- Expanding access to existing medications
- Funding new blockbuster medications for rare diseases

The PMPRB Guidelines – the first major reforms of the PMPRB in more than 30 years - come after more than three years of extensive consultations, study and review by Health Canada and the PMPRB. Generally speaking, the Draft Guidelines reflect a patient perspective on the “return on investment” and on the “cost effectiveness” of advanced therapies such as biologics (originator and biosimilar) and targeted small molecule medications and the scientific evidence that shows how they deliver value, medically and socially.

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These advanced therapies have revolutionized the treatment and prevention of many disabling and life-threatening diseases, such as inflammatory arthritis, diabetes, inflammatory bowel disease and cancer, over the past 20 years. These medicines allow millions of Canadians to prevent and fight disease, manage chronic illness, ease pain and breathe better.

Treatment with such life-enhancing medicines, however, has contributed to the rising costs of healthcare. Canadians spent \$34 billion on prescription medicines in 2018. Prescription medicines are the second biggest expenditure in health care, after hospitals. We spend even more on medicines than on doctors. On a per capita basis, only the United States and Switzerland pay more for prescription drugs. Yet for all that spending, there are huge gaps in coverage. One in five Canadians struggle to pay for their prescription medicines. Three million don't fill their prescriptions because they can't afford to. One million Canadians cut spending on food and heat to be able to afford their medicine.

Because of growing budget pressures, public and private drug plans are looking for ways to provide continued coverage to patients who need a safe and effective medicine, including expensive biologics to manage their complex, life threatening chronic diseases, cover new and innovative medicines and expand access to existing medications.

During its meeting with the PMPRB, ACE stated the reform and modernization of PMPRB 's regulatory framework must carefully consider these questions:

- Do the Draft Guidelines contribute to improved patient care and outcomes?
- Do they increase accessibility and affordability of medicines to all Canadians?
- Do they improve efficiency, and contribute to value and sustainability of the health care system?

Ultimately, the reform of pricing regulation should reflect not just the "business interests" around drug pricing but also reflect the interest and needs of patient care and outcomes. ACE supports a strong, balanced and fair regulatory framework for pharmaceutical pricing - reflecting a balance between business and patient-healthcare provider interests - aimed at sustaining the life, health and wellbeing of patients. Such a framework should enable public payers to provide coverage for existing medications and list new medications to address unmet needs, while also contributing to the long-term sustainability of the health care system.

#### PMPRB Draft Guidelines:

During ACE's history, it has not, on principle, become intricately involved in the pricing debate or negotiation for biologic medications. One reason quite simply was the lack of full understanding about the process and what a "list price" represented. Patients do not have access to all the information to know what the net price for their medication is. Nor to make a judgement on what is a fair price. What is excessive?

With Health Canada projecting \$13.2B in savings over the next 10 years, patients understand the Draft Regulations will have a major impact on both the affordability of medicines in Canada and the profitability of the broader biopharmaceutical sector. Additionally, the Draft Guidelines will increase net pricing transparency by compelling pharmaceutical manufacturers to disclose the value of previously confidential discounts and price rebates.

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Patients also understand drug manufacturers have serious concerns that the Guidelines may inhibit the introduction of new advanced therapies. That concerns us, too. These manufacturers have the power to decide on whether and when drugs will be introduced in Canada, and the location of clinical trials.

ACE recommends the PMPRB proposed reform and regulation of drug pricing must somehow achieve the delicate balance of protection from excessive pricing and continued access to medicines patients need.

Once implemented, we urge the PMPRB to conduct comprehensive post-implementation surveillance of the new Guidelines, including ongoing monitoring and evaluation. We understand that a strategy will be outlined in a revised *Guidelines Modernization and Evaluation Process and* look forward to learning more.

Patients have an important role in health policy development. We thank Health Canada and the PMPRB to have made the conscious effort to include the patient voice in the consultation process for drug pricing reform and the development of a new pricing regulatory framework that serves the needs of all patients across Canada. We urge the PMPRB to also continue in its commitment to sharing information and education with patients such as the December 2019 consultations.

Moving forward, we recommend renewing this commitment to patient engagement. Regarding governance, we support representation on the Board and establishment of a formal advisory body to the Board. We believe that patients have a role, along with other stakeholders, in strategic planning, policy development and prioritization. Processes for patients and/or patient organization input into specific drug reviews should be explored. Importantly, patients should be involved in establishing monitoring processes and participating in evaluation. As working groups are established, appropriate patient involvement must be facilitated with appropriate support provided.

Sincerely,

A handwritten signature in black ink, appearing to read "Cheryl Koehn". The signature is fluid and cursive, with the first name "Cheryl" and last name "Koehn" clearly distinguishable.

Cheryl Koehn  
Founder and President,  
Arthritis Consumer Experts

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