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February 14, 2020

Patented Medicine Prices Review Board (PMPRB)  
333 Laurier Avenue West, Suite 1400  
Ottawa, Ontario K1P 1C1

**Re: PMPRB Guidelines Consultation**

Dear Mesdames/Sirs:

This submission outlines the Arthritis Society's views on the recent amendments to the *Patented Medicines Regulations* and the PMPRB's draft guidelines and is complementary to the submission made by the Health Charities Coalition of Canada (HCCC), of which we are a member.

As a national health charity with a mission to improve the lives of the 6 million Canadians living with arthritis, we have been very active in the policy discussions regarding access to treatment and care. As there is no cure, medications play a significant role in the management of the condition, and for many people living with arthritis, medications have transformed their lives. We support policymakers' efforts to improve the affordability of medications for patients and the health care system. However, as with any new policy initiative, the full implications on patients must be considered. It is important to consider how the proposed approach to regulating patented medicine prices in Canada will affect patients. There are several questions unanswered, including concerns around delays to access and medicines and clinical trials not coming to Canada, which could negatively impact health outcomes and quality of life.

Improving access to medicines while ensuring medicines are affordable to the system are important objectives. However, those objectives must balance prices that will encourage pharmaceutical manufacturers to continue making Canada a first-tier launch country for new medications and to invest in Canada, while also ensuring prices are affordable and sustainable for patients and private and public payers. We hear many concerns that the balance with the proposed approach is not right. Before moving forward, we encourage the PMPRB to continue discussions to address and mitigate these concerns through meaningful, transparent consultations with all stakeholders.

Access to a range of therapies is important to all patients, but especially those with arthritis. In the case of inflammatory arthritis, for example, finding an appropriate treatment is still very much trial and error – what works for one patient may not for another. A range of choice is therefore critical and will become even more necessary with the entry of new personalized medicines. Ensuring wide choice will not only lead to improved health outcomes but may also lead to health system savings as medicines become more precise and better able to target patients who are most likely to benefit from the treatments.

With respect to the new pricing rules, we are concerned that the PMPRB's mandate to regulate prices based on economic factors could create uncertainty and potentially unsustainable price reductions for new therapies.

The Canadian Agency for Drugs and Technologies in Health (CADTH) is ultimately responsible for carrying out health technology assessment (HTA) and then providing expert advice to guide drug reimbursement decisions by the public plans. Private payers also have access to HTA that incorporates economic factors to help guide recommendations, but not determine outcomes in terms of funding decisions. The PMPRB's mandate is to ensure that prices of patented medicines sold to Canadians are not excessive. It is important to retain this differentiation and ensure that the PMPRB's new framework does not replace the role of individual drug plans (both private and public) in making decisions about which drugs they will cover or negotiates on behalf of those plans.

In addition, the decision to apply population and public health system perspectives might prevent the introduction of medicines that are beneficial for some patients, but which do not meet new thresholds for therapeutic improvement. Patients with arthritis and their treating clinicians need access to a range of therapies, and not just the first-in-class medicine that comes to market for a given condition. There should be a mechanism to ensure a contextualized value perspective that considers clinical, fiscal, and system needs of specific payers and/or consumers.

While some of the new treatments introduced in Canada may not be worth what is being asked or warrant reimbursement, we believe value should be determined by patients and those responsible for managing drug budgets. Regulations should not become an obstacle to access, especially if there are other ways to achieve cost savings.

Moving forward, the Arthritis Society strongly supports the position of the HCCC that patients must be at the table contributing to the design and ongoing operation of the new price 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 new medicines in this country. In this context, we encourage the PMPRB, as one of its key patient engagement immediate steps, to establish a formal mechanism for meaningfully and continuously engaging patient representatives in its decision-making and regulatory processes to ensure patient voice, choice and representation.

All perspectives must be taken into account when determining the best tools for regulating drug prices, particularly from patients – the people the reforms are ultimately intended to benefit.

Thank you for considering our input and we look forward to continuing to engage with the PMPRB and other stakeholders on this important issue.

**Respectfully submitted by:**

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## **About the Arthritis Society**

The Arthritis Society is a national health charity that gives voice to the one in five Canadians – and one in two Canadian seniors – who have arthritis, a collection of conditions affecting joints and other tissues. Arthritis causes pain, restricts mobility and diminishes quality of life. There is no cure, so pharmaceutical treatments play a very large role in management of the condition which persists, for most people, over many years.

The Arthritis Society is Canada's largest charitable source of investment in cutting-edge arthritis research, and a leader in proactive advocacy, education and support towards delivering better health outcomes for people affected by arthritis. Safety and improved care are our top priorities, with our advocacy focused on improving access to care, timeliness of care, and innovative research. The Arthritis Society is accredited under Imagine Canada's Standards Program.