CAPA
Canadian Arthritis Patient Alliance

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December 18, 2023

Re: Response to consultation on PMPRB Guidelines

To whom it may concern,

On behalf of the Canadian Arthritis Patient Alliance, we are writing to you to provide our feedback on the consultation related to the PMPRB guidelines. We have reviewed the proposed guidelines from the perspective of people who live with arthritis, a chronic health condition that affects close to six million people in Canada. Pharmacological treatments are critical to many people with arthritis so they can participate in activities of daily living, make contributions at work and retain quality of life. People with arthritis often need to take medications for their entire lives, not just for specific periods of time.

The Canadian Arthritis Patient Alliance is a grass-roots, patient driven, independent, national organization with members across Canada and supporters in Canada and beyond. We believe the first expert on arthritis is the individual who lives with the condition. We provide a strong voice and concerted effort to promote the well-being of people living with arthritis and we assist our members to become advocates not only for themselves but for all people with arthritis. The organization is a small virtual organization and powered by volunteers who all live with various forms of arthritis.

Access to medications at reasonable prices is an important part of the lives of people living with arthritis. In addition, the health care services offered within our publicly health care system continue to deteriorate and we're in a position where people are experiencing delays in being diagnosed with arthritis and accessing necessary health care services. This situation will increase health care costs in the future and reduce the ability of people with arthritis to participate in personal, social, and economic aspects of life and society. The current state of medicine costs is not sustainable from a patient and healthcare system perspective and high medicine costs result in additional patient stress and anxiety. Patients make significant life decisions based on their ability to pay for prescription medications.

It is an opportune time for PMPRB to consider who it is accountable to and actively include patients and the public in this accountability framework. Through our tax system, patients and their families and Canadians fund government departments like the PMPRB to support Canadians in all aspects of life. Broadly speaking, we need to see PMPRB considering patients and the public in their operations, guiding values and outcome-based decision making, and to

consider a whole of society perspective in their decisions. Many federally funded organizations consider only payer perspectives as their clients, i.e. provinces and territories. We will outline our perspective regarding the themes outlined in the consultation on the PMPRB guidelines in the remainder of this letter.

Theme 1: Efficient Monitoring of Prices without Price Setting

Much has been discussed about value-based and outcomes-based consideration with little of these ideas put into place in the regulation and lifecycle of drugs in Canada. Values and outcome-based measurement and monitoring can be determined using a consultative process involving all who have an interest, including people with lived experience of a condition using the medication. In previous submissions we noted the importance of obtaining input from people with lived experience with the health condition or the medicine when determining pharmacoeconomic value. There are currently processes in place with CADTH and INESSS for obtaining patient input to ensure patient perspectives, needs and values are fully considered. These processes can be expanded upon to provide patient perspectives in the development of the health technology assessment, pharmacoeconomic analyses and medicines development. Established and rigorous methodologies are in place to incorporate patient perspectives including the Patient-Focused Medicines Development Quality Guidance published in BMJ Innovations. These policy changes represent an opportunity to improve and engage patients in a more meaningful, transparent, and active way. The quality guidance also contributes to developing innovative solutions where patient perspectives have not previously been incorporated in decision-making.

To ensure meaningful participation of patients or people with lived experience, it is important to educate and support them to understand the role of PMPRB and for your organization to explicitly consider patients as a key audience in your work. Do patients understand the role of PMPRB? Do they understand what role they play in your work or in seeking a review based on excessive pricing? What supports are available to remove the barriers to participate in engaging with PMPRB? People with arthritis are often faced with ongoing challenges in day-to-day life yet they wish to be heard by governments when it comes to drug policy in Canada. People live with their conditions full-time where symptoms, such as pain and fatigue, can change from day to day and where financial security is continuously at risk because they have reduced work capacity and do not have access to the sufficient insurance to pay for prescription medications. We ask that PMPRB take the time and energy to authentically inquire and understand these lived experiences and find ways to meaningfully engage patients.

Theme 2: Transition to PMPRB11 – New versus Existing Medicines

In determining how to treat new versus existing medicines, it would be helpful to determine the medicines where there is the greater impact or value for patients and their families. Patients and their families could be well placed to determine the value and whether the medicines are meeting their needs. These factors - instead of a date - could be used to guide how medicines might be distinguished and that are above the highest international price (HIP) of the PMPRB11. Patients and caregivers bring considerable expertise based on their lived experiences of illness, current and past treatments, and access to medications.

We know that typically savings in health care budgets are not reinvested directly into healthcare programs that support or benefit patients. We do feel there is a benefit to doing this so patients and their families particularly as out health care system continues to be strained and unable to provide the necessary services and care needed by Canadians. It is important that patients benefit directly from these savings to support the sustainability of health care across Canada and improved patient outcomes. These savings could also be re-directed to reducing the burden of payments, co-payments and deductibles paid by patients and their families. Patients have significant payments, co-payments, and deductibles whether they have no insurance or have private or public plans which are based on the maximum list prices and do not necessarily directly benefit from a reduction in drug prices. Often the same patients who need medicines also self-identify as living with disability and medicine costs further erodes their personal, economic, and social participation in life. Regardless of how the savings are used, we hope to see patients directly benefiting from lower medicine costs and a re-investment of savings in the healthcare system.

Theme 3: Price Reviews during Product Life Cycle

Values and outcome-based measurement and monitoring can be employed using a consultative process involving all interested groups, including people with lived experience of a condition using the medication. In previous submissions we noted the importance of obtaining input from people with lived experience with the health condition or the medicine when determining pharmacoeconomic value. Consulting patients on value and how value changes over time can provide useful information to add context to price reviews. These reviews can be triggered by patient input which can centre on whether something unique or different is continuing to be offered and/or whether new value is provided, e.g. the medication has been studied in a population that is typically underrepresented in clinical trials such as pediatric populations and pregnant and lactating people.

Theme 4: Investigations and Referral to Hearing

To ensure meaningful participation of patients or people with lived experience, it is important to educate and support them to understand the role of PMPRB and for your organization to explicitly consider patients as a key stakeholder in your work. Do patients understand the role of an investigation and referral to a hearing? Do they understand what role they play in your work or in seeking a review based on excessive pricing? This can be an opportunity to make this a reciprocal relationship with patients where PMPRB leaders and staff take the time and energy to authentically inquire and understand these lived experiences and find ways to meaningfully engage patients.

Theme 5: Relation to pan-Canadian Health Partners, Insurers (Private and Public); and Alignment with Broader Government Initiatives

In order to determine the relation to pan-Canadian health partners, insurers, and broader government initiatives, it is important to look more broadly at access to medicines from a pricing and reimbursement perspective. In Canada, the path to medicine reimbursement is lengthy, onerous, and reduces patient access to important medicines. Data show that compared to the United States and major European Union markets, there is a notable regulatory approval lag, and after approval, a longer wait for public reimbursement for new medicines in Canada. This study by Salek et al found that the average overall timelines for public reimbursement after the Notice of Compliance (NOC) were long and most of this time is taken up by Health Technology Assessment (HTA) and pan-Canadian Pharmaceutical Alliance processes, at 236 and 273 days, respectively. These delays have significant impacts on people with inflammatory arthritis where the current recommendations are receiving a diagnosis and starting of treatment for rheumatoid arthritis within 12 weeks of symptoms appearing. People go through a process of trial and error of finding the right treatments that work for their condition and means that lifelong disability can occur without prompt access to treatment, including new therapies that can provide hope of returning to life's usual activities. During the COVID-19 pandemic, we saw situations where government process was reduced for COVID-19 vaccines – why can't we see this sort of commitment for all patients who currently experience significant morbidity and mortality?

Committing to a streamlined national reimbursement process and standard would counteract these anticipated delays by simplifying other aspects of drug policy, such as the complex reimbursement processes of the pan-Canadian Pharmaceutical Alliance (pCPA). A new drug agency was proposed in the 2019 federal budget, and it is critical from a patient perspective

that we see a clear re-alignment of processes to provide patients with access to medicines and value in a timely manner. This requires the Federal Government work with provinces to match international median times for access (from regulatory approval to approved reimbursement) and for accountability with respect to these times to access. This also represents an opportunity to streamline government operations and remove redundancies.

Theme 6: Engaging with Patients, Health Practitioners, Pharmacy, and other Stakeholders

The proposed drug pricing changes represent an opportunity to meaningfully engage patients and patient groups in the governance and operations of PMPRB. This would provide the opportunity to hear directly from people with lived experience with a health condition in implementing the new drug pricing framework. Engaging patients is an important part of good government governance practices where public transparency and accountability are critical to ensuring public trust in institutions which is declining. We would go further to recommend the creation of an independent, armlength patient advisory panel which would provide broad advice on PMPRB operations beyond the clinical context provided by existing governance structures. If implemented, best practices for meaningful inclusion in policy development are needed to ensure the appropriate participation and integration of patient values and perspectives and there exists a significant evidence base and best practices to guide this work.

In closing, we ask that you work with us, people with lived experience, and other patient groups to understand how you can actively and meaningfully consider the role of patients into the work of PMPRB and how this fits within the broader health care ecosystem. Patients experience significant delays in accessing medicines due to complexities within the health care system. We can do better for patients by re-investing savings into the health care system and simplifying processes that have a direct impact on patient care and quality of life. We thank you for the opportunity to provide our perspective on behalf of people living with arthritis.

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Sincerely,

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