

August 4, 2020

Re: Updated 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 updated draft pricing 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. Many people with arthritis need medicines to participate in activities of daily living, make contributions at work and retain quality of life.

To begin, we feel it is important to take steps to reduce the price of medicines in Canada. The current state of medicine costs is not sustainable from a patient and healthcare system perspective. Few people living with inflammatory arthritis can afford to pay for biologic medicines independently without public and private insurance programs. High medicine costs result in additional patient stress and anxiety due to the need to navigate complex government and insurer reimbursement processes and bear a significant financial burden of paying co-insurance and deductibles. Despite these challenges, we have concerns regarding the draft pricing guidelines which we will outline in the remainder of this letter.

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.

Direct patient benefit of lower medicine costs

By reducing the cost of medicines, the new regulatory framework results in savings for public and private drug plans. The federal government can ensure that any savings benefit patients directly by developing and enforcing funding agreements with the provinces and territories. We ask that these savings be reinvested for the provision of health care and not re-distributed to other government programs. It is important that patients benefit directly from these savings to

support the sustainability of health care across Canada and improved patient outcomes.

Consideration could also be given to re-directing these savings towards reducing the burden of co-payments and deductibles paid by patients and their families. Patients have significant co-payments and deductibles through private or public plans which are based on maximum list prices and do not necessarily benefit from a reduction in drug prices. In addition, 20% of Canadians pay directly for medicines and pay the manufacturer's list price for medicines and savings could be re-invested by extending insurance coverage to this vulnerable, and large group of the Canadian population. A [study](#) by Tadrous et al showed that between 2000 and 2015, the use of the Trillium Drug Program increased threefold from 3.6 beneficiaries per 1000 to 10.9 beneficiaries per 1000. 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.

Patient input in determining value

In our previous submission, we noted the importance of obtaining input from people with lived experience with the health condition or the medicine when determining pharmacoeconomic value. Unfortunately, these changes have not been incorporated into the updated guidelines. 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, medicines development and in the creation of real-world evidence. 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.

Addressing potential drug access issues

We remain concerned that the proposed drug pricing changes will result in continued delays in marketing medicines in Canada. To mitigate these negative outcomes, 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 NOC were long and most of this time is taken up by HTA and pCPA processes, at 236 and 273 days, respectively. 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 in a timely manner. This may require 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. The health and quality of life of patients hangs in the balance.

Embedding meaningful patient engagement in PMPRB

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 a patient advisory panel which would provide broad advice on PMPRB operations beyond the clinical context provided by the Human Drug Advisory Panel. If implemented, best practices for meaningful inclusion in policy development are needed to ensure the appropriate participation and integration of patient values and perspectives. This represents an opportunity for Canada to become a global leader in this area and set a path for the meaningful inclusion of patient perspectives.

In closing, we ask that you work with us and other patient groups to fundamentally re-think how the proposed changes fit 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 hope that the broader patient community will be engaged in policy decisions and implementation of the proposed regulatory and administrative changes.

We thank you for the opportunity to provide our perspective on behalf of people living with arthritis.

Sincerely,



Laurie Proulx
2nd Vice-President
Canadian Arthritis Patient Alliance