CAPA
Canadian Arthritis Patient Alliance

www.arthritispatient.ca
contact@arthritispatient.ca

August 17, 2023

Dear Dominic Tan,

On behalf of the Canadian Arthritis Patient Alliance (CAPA), we are writing about the pCPA Temporary Access Process (pTAP) consultations. We appreciated the opportunity to meet with representatives of pCPA on August 3, 2023, and in continuing to engage with your organization as you refine the pTAP and other processes.

CAPA is Canada's only volunteer-based arthritis patient organization run by patients for patients. CAPA is entirely patient-run and -driven, independent, and supports a community of people living with arthritis across the nation. Our belief is that the first expert on arthritis is the person who lives with arthritis and this person provides a critical voice and perspective that needs to be heard in decision-making. CAPA works with diverse groups within the arthritis community to provide information and ensure a voice for those living with arthritis.

As a separate organization, pCPA has the opportunity to operate differently and adapt to the changing drug approval and reimbursement processes in Canada. Convening a meeting of patient organizations was an important step forward, however we feel that the approach could be improved upon. The International Association of Public Participation has developed a framework to guide public engagement and we feel that the approach used at the August 3rd meeting reflects the "Inform" level of the spectrum. There were limited opportunities for dialogue, such as disabling the chat feature and limiting questions from stakeholders. We hope that the approach used at the meeting is not indicative of how future engagement and communications will be undertaken by pCPA.

We can appreciate that the pTAP has a limited scope as a pilot project however there is the opportunity to build processes, approaches, and strategies to influence how pCPA will operate in the future. We feel there is the opportunity to make processes more transparent and clarify what communication and engagement will occur with patients and patient organizations. There are number of outstanding questions, such as:

- How will patient organizations be informed about pTAP processes? How will we be kept informed of pCPA directions and procedures?
- Will there be an opportunity for feedback on drug specific processes? If so, what might this feedback mechanism look like and where will patient feedback be incorporated?

- Will patient reported outcomes (PRO's) be incorporated into pCPA processes (e.g., outcomes-based agreements)? How might be patients and patient organizations be involved in establishing these outcome measures?
- How can patients and patient organizations be involved with pCPA to help co-develop its processes of engagement, so that all parties benefit?

We also question how real-world evidence (RWE) might be incorporated into pTAP processes and any future pCPA processes. As a case study, we have had challenges with communicating the unmet patient needs for people living with Systemic Lupus Erythematosus (SLE) to policy makers. Upon further discussion with CADTH, we were advised the clinical end points of specific clinical trials were not met and the medications received a negative recommendation (e.g., belimumab, anifrolumab). Many treatment options are needed to manage SLE and what works in one person will not work in all. This means that access to many medication options is needed to meet the needs of patients. In our survey of patients taking belimumab, many noted how they had tried many different medications, and none worked completely, thus diminishing their quality of life. We have provided some of the feedback directly from patients in the box above. How might situations like this be addressed with pTAP processes? How can we address unmet patient needs and support effective resource use? The use of RWE could play an important role and allow access to medications to specific groups of patients.

- *"Up to benlysta, the only drug that would work that I could tolerate was prednisone…Long term effects were a concern…Although the prednisone helped to control the disease, the long-term effects of high doses over the 46 years I have had SLE was/is a concern."*
- *"Benlysta has been a lifesaver… the side effects are minimal…With benlysta I am rarely tired at the end of a work week. My joint pain is almost nonexistent…I expect that continued use of benlysta will only improve my health further."*
- *"… Prednisone use has been greatly reduced. Blood counts totally into the normal range. Benlysta is the best thing that has happened for me with my SLE…"*

Lastly, we desire greater clarity about how medications are referred to pCPA and the timelines for the process. Although the new pTAP process provides an opportunity for providing timely access to therapies, it is not clear how the timelines will be reduced. 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 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 those used at pCPA. The role of the provinces is also not clear in the proposed pTAP process.

CAPA
Canadian Arthritis Patient Alliance

www.arthritispatient.ca
contact@arthritispatient.ca

We are open to discussing this letter with you, learning how we may be of help, and continuing to share our perspectives as people who live with arthritis.

Sincerely,

Laurie Proulx
Managing Director and person living with rheumatoid arthritis
Canadian Arthritis Patient Alliance