pan-Canadian Temporary Access Process: Best Medicines Coalition Position Points

(Submitted to pCPA: August 16, 2023)

The following position points were provided to the pan-Canadian Pharmaceutical Alliance (pCPA) as part of its consultation on the panCanadian Temporary Access Process:

- The development and implementation of a pan-Canadian Temporary Access Process (pTAP), including novel procedures and funding arrangements, is an important initiative with positive implications for patient care, specifically potentially providing patients with access to new therapies faster than current timelines and improving outcomes. Resources should be allocated to this initiative with the caveat that these should be new resources and not a net subtraction from pCPA resources devoted to the usual process.

- The Best Medicines Coalition (BMC) congratulates pCPA for opening up this process to engagement of patients, along with other stakeholders. There has been a great deal of interest in this important proposal from patient groups, including those within the BMC network. The position points provided to the pCPA here represent a compilation of initial positions and themes expressed by member patient organizations, and the BMC looks forward to further consideration and consultation.

- BMC supports the fundamental goal of improving processes such that all patients, especially those with critical unmet needs, can access necessary medications in a timely manner. Improved and faster patient access must be enshrined as a fundamental goal of pTAP and all pCPA activities as we move forward. The status quo is taking too long to get new therapies to patients.

- As the pTAP process is developed, the pCPA must make every effort to ensure that the framework is constructed in a way that ensures that drug developers are encouraged and willing to participate so that opportunities for gains in timely access to necessary medication for patients are realized. While program sustainability is important so is patient access to life-sustaining medicines. To be successful, the process must strike an appropriate balance during and after the period of temporary earlier access. In addition, there must be greater clarity and full transparency on timing for milestones and criteria for the continuation or withdrawal of public funding.

- Under no circumstances would it be acceptable for patients who are receiving and deriving benefit from temporary coverage to have that medication withdrawn while they are deriving benefit. Discontinuation would only be acceptable if there is definitive evidence of clear progression of disease in an individual.

- There needs to be greater clarity and transparency regarding decision-making criteria and processes. Specifically, there must be transparency around how pCPA will decide whether to apply the pTAP process for a specific drug from those that are within the CADTH TLR category. It is not clear who would be involved in decision-making, what criteria will be applied, what the timelines for inputs and decisions will be and how decisions will be communicated, and in what detail. It is critical that there be full transparency, including if a manufacturer declined to participate in pTAP for a drug that was eligible. Considerations of whether to apply pTAP must not be made by a limited number of officials deliberating in isolation but rather must be vetted broadly, giving opportunities to all stakeholders, including patients, to offer perspectives.

- The process by which specialists, including oncologists and others treating patients with critical needs, will access medication for their patients under the pTAP program must be time-efficient, transparent, and consistent across manufacturers, contributing to ease of access.

- At its core, the pTAP must be flexible recognizing the unique nature of specific disease conditions and emerging treatments. Unnecessary rigidity and inability to accommodate exceptional situations will risk and not contribute to the success of the initiative.

- There must be flexibility and eased rigidity regarding evidence standards. Limiting the process to only those medicines that have or will have phase III clinical trial data would have unfortunate consequences. Phase III trials will never be conducted for some disease conditions, including some rare diseases and rare cancers. Appropriate evidence must include real world data, including laboratory data that predicts the response that precision medicines have on individuals. Without recognizing a broader scope of types of evidence, pTAP will fail to improve access to many medicines which could greatly benefit those with conditions that do not have populations large enough to conduct clinical trials.

- As pTAP is pursued, the pCPA, in cooperation with stakeholders, must implement a rigorous monitoring and evaluation process. Parameters for evaluation must be developed in concert with all stakeholders but must specifically evaluate gains related to timely access to medicines which address critical unmet needs. Quite simply, a determination of success or failure will depend on whether faster access was achieved. Further clarity is needed on proposed criteria and process for measuring results or plans to develop this. BMC requests to be consulted on the evaluation metrics and process.

About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of 30 patient organizations. The BMC seeks timely access to a comprehensive range of medically necessary, safe, and effective drugs and related treatments, informed by patient-driven evidence and values, and delivered equitably and affordably to all patients in Canada. The BMC's areas of interest include drug approval, assessment, and reimbursement, as well as patient safety and supply issues. As an important aspect of its work, the BMC strives to ensure that Canadian patients have a voice and are meaningful participants in health policy development, specifically regarding pharmaceutical care. The BMC's core activities involve issue education, consensus-based position development, and advocacy, making certain that patient-driven positions are communicated to decision makers and other stakeholders. The BMC was formed in 2002 as a grassroots alliance of patient advocates. In 2012, the BMC was registered under the federal Not-for-profit Corporations Act and operates under the direction of a Board of Directors comprised of representatives of member organizations and elected annually.

Alliance for Access to Psychiatric Medications
Asthma Canada
Brain Tumour Foundation of Canada
Canadian Arthritis Patient Alliance
Canadian Association of Psoriasis Patients
Canadian Breast Cancer Network
Canadian Cancer Survivor Network
Canadian Council of the Blind
Canadian Cystic Fibrosis Treatment Society
Canadian Epilepsy Alliance
Canadian Hemophilia Society
Canadian PKU & Allied Disorders
Canadian Psoriasis Network
Canadian Skin Patient Alliance
Canadian Spondyloarthritis Association
CanCertainty
Crohn's and Colitis Canada
Cystic Fibrosis Canada
Eczema Society of Canada
Fighting Blindness Canada
Health Coalition of Alberta
Huntington Society of Canada
Kidney Cancer Canada
Lymphoma Canada
Medical Cannabis Canada
Medicines Access Coalition – BC
Migraine Canada
Millions Missing Canada
Ovarian Cancer Canada
Parkinson Canada