February 25, 2022

CADTH Consultation: Building Toward a Potential Pan-Canadian Formulary

Introduction:

- The Best Medicines Coalition (BMC) commends each of the Canadian Agency for Drugs and Technologies in Health (CADTH) Advisory Panel members for lending time and expertise to this important endeavour, including reviewing and discussing these complex issues and considering options.
- BMC acknowledges the value of this effort and welcomes the opportunity to provide comments relating to the ongoing consultation process on the proposed framework for a potential Pan-Canadian Formulary.
- BMC looks forward to opportunities to further engage as we better understand the specific context and goals that a potential Pan-Canadian Formulary could advance and how best our organization can contribute to that evolving discussion.
- BMC's positions on National Pharmacare and related topics, including drug formularies, are presented in submissions to the Advisory Council on the Implementation of National Pharmacare, including *Patient Perspectives on National Pharmacare: Current Challenges, Goals and Implementation Issues* (August 2018) and *National Pharmacare Implementation: Patient Perspectives and Considerations* (September 2018).
- This submission to the CADTH Advisory Panel is informed by the positions outlined in the above documents along with input provided by BMC member organizations following recent review of the discussion paper. Positions expressed represent areas of consensus among BMC member organizations.

Positions and Recommendations:

The BMC presents three primary recommendations regarding the goal and principles which guide the potential Pan-Canadian Formulary, criteria, and evaluation. These recommendations are summarized below, followed by discussion and considerations for each.

1. ***Refine and Clarify Goal and Principles:***
   Enshrine improved care and best possible patient outcomes as core objectives

2. ***Develop Inclusive Criteria:***
   Ensure a high standard of equitable and comprehensive care

3. ***Rigorous Impact Analysis:***
   Undertake comprehensive evaluation of value and risks to patient care

Positions and Recommendations: Discussion and Considerations

1. ***Refine and Clarify Goal and Principles:***
   Enshrine improved care and best possible patient outcomes as core objectives

   - The stated goal of a potential Pan-Canadian Formulary, as developed by the Advisory Panel, includes important elements such as providing a broad-range of safe and effective drugs and meeting the health care needs of Canada's diverse population. However, we perceive a missed opportunity to ambitiously propose meaningful and progressive change to address specific needs and improve patient care and outcomes. We propose that the goal be enhanced to directly communicate addressing disparities, inequities, and unmet needs to improve care and patient outcomes, ultimately supporting health system sustainability.
   - The discussion of stated principles, supported by definitions and supporting values, reflects many themes which patient organizations, including the BMC, have presented in previous deliberations. While the outlined principles have merit, addressing patient access disparities and shortfalls and meaningfully improving patient care and outcomes must be enshrined and highlighted to guide all future considerations regarding a potential Pan-Canadian Formulary.

   Considerations regarding additional, or enhanced, patient-driven principles:

   Inclusive and comprehensive access: All patients, without exception, must be able to obtain the medicines they need. All reforms to the pharmaceutical policy framework in Canada, including the potential creation of a Pan-Canadian Formulary, must address existing inequities and strive to deliver timely, comprehensive care, which is appropriate for each individual, regardless of disability, condition, or where they live and work. Importantly, advancements need to address critical deficiencies in pharmaceutical care in Canada. These deficiencies include the following significant challenges and barriers as experienced by patients:

   Extended delays. Prolonged wait times from when Health Canada begins its review/approval process of a drug or related treatment until public drug plans decide whether it will be covered.

   Jurisdictional inequity. Variability across Canada among drug programs regarding what drugs are covered or how, with a lack of portability between jurisdictions.

   Reimbursement uncertainty. Lack of predictability and certainty in whether a drug will be reimbursed, through private or public programs, and related processes.

   Limiting criteria. Narrow reimbursement criteria which may not be in line with medical practices and impedes access for some patients who may have benefitted.

   Uninsured and underinsured. Some patients do not qualify or face enrollment barriers for public or private programs or have insufficient coverage, including exclusion of a drug deemed necessary by a prescribing healthcare provider or a plan not adequately covering out-of-pocket costs.

   Any changes contemplated for the implementation of a potential Pan-Canadian Formulary must not have the effect of rendering any patient community or individual patient any worse off than before the formulary was implemented. This basic protection ought to apply to what drugs are covered as well as to related access challenges, as outlined above, including timeliness and eligibility.

Consistency and cohesion: The introduction of a potential Pan-Canadian Formulary needs to be considered in conjunction with other suggested changes to the pharmaceutical care framework in Canada, including the creation of a Canadian Drug Agency, a National Strategy for Drugs for Rare Diseases, health technology assessment and management and proposed changes to pricing regulations. Health Canada, CADTH and the pan-Canadian Pharmaceutical Alliance, and indeed all relevant agencies, must ensure all aspects of the broader drug reform agenda work together cohesively to address patient unmet needs.

Patient informed policy development: Patients and the organizations that represent them must continue to play an integral role and that role must be enhanced during the development and integration of pharmaceutical care policies, including the development of a potential Pan-Canadian Formulary.

2. ***Develop Inclusive Criteria:***
   Ensure a high standard of equitable and comprehensive care

- While health system sustainability is critical, improvement of patient care and health outcomes, essentially the sustainability of patient lives, must always be the paramount tenet of pharmaceutical policy reform, including regarding a Pan-Canadian Formulary. While acknowledging considerable challenges, we are concerned that the framework for the potential Pan-Canadian Formulary, as presented, is informed and motivated by a perceived need for drug plan cost containment, rather than aiming to deliver the best possible care and improve patient outcomes.
- Quite simply, criteria for a potential Pan-Canadian Formulary must ensure that no patient community or individual patient is left unable to access a medically necessary drug, be that a long-standing, recently approved or yet to be discovered drug. Obvious redundancies aside, by their nature, formularies which are limiting and not inclusive of drugs that current or future patients benefit from do not deliver on the principles identified and would not add sufficient value to patient outcomes.
- Regarding criteria and prioritization based on national health priorities, clearly such an approach does not serve the critical principles of equity, fairness, and comprehensive care. There must be room in the potential Pan-Canadian Formulary to address all disease types, regardless of current profile, incidence, severity, or other factors, and to do otherwise would be unethical.

Considerations on criteria to achieve comprehensive coverage:

Formulary breadth and depth: To be comprehensive, a formulary would be broad in scope and encompass a range of drugs. It is not appropriate, or ethical, to limit coverage by choosing between depth of options and breadth of drugs for a wider range of conditions. Forcing choice between depth and breadth does not support the advancement of patient outcomes that is in the best interests of all patients, which is, or ought to be, the purpose of the health system. The range of medications covered must meet the individual needs of all, regardless of type of condition, whether acute and chronic, or incidence/rareness of disease, including the realm of precision medicine. Likewise, it must include drugs not yet supported by a full body of clinical evidence, drawing instead on real world and patient-reported evidence. Criteria must encompass both widely prescribed drugs used in primary care, and specialty drugs.

Criteria to encompass future drugs to address unmet needs: Importantly, there must be capacity and flexibility to incorporate yet to be discovered and introduced medications, as well as related tests and diagnostics, including those that address unmet patient needs. For a formulary to be comprehensive, it must include drugs which are considered curative or breakthrough, offering significant improvements to life threatening or debilitating conditions. There must also be the capacity to provide for future, next generation treatments such as rapidly emerging gene and cell therapies.

Defining formulary scope: Drug formularies must have capacity to address individual patient needs. Through the lens of fairness and equity, the range of drugs currently provided through formularies of many private, employer-based plans have capacity to meet individual needs. Plans for employees, dependents and retirees of the Government of Canada are examples. In addition, the current Quebec formulary is the largest and arguably the most comprehensive public drug plan formulary in Canada. Levelling up all existing public formularies, perhaps through a Pan-Canadian Formulary, to that standard of coverage would be a reasonable and supportable early step. Recognizing unique patient needs will arise, a potential Pan-Canadian Formulary must also provide for a type of "safety valve" for consideration of those exceptional cases where a treatment is medically necessary but not provided for otherwise. The "exceptional patient" provision of the Quebec plan is a solid example that should be addressed in the framework for a potential Pan-Canadian Formulary.

Timeliness and efficiency: Drugs should be accessible to all within reasonable time frames. Likewise, for drugs with a high potential for improved outcomes where there are unmet needs, there should be an accelerated review process. Related to this, reform should address the current, overly complicated system of reviews and decision-making. Bureaucratic and administrative burdens should be addressed by streamlining and standardizing approvals and formularies.

3. ***Rigorous Impact Analysis:***
Comprehensive evaluation of value and risks to patient care

- As the Advisory Panel continues its work in developing recommendations on how to move towards a potential Pan-Canadian Formulary, the BMC will continue to assess how its output, including proposed processes and other recommendations, would support patient-driven goals and whether such a potential list will ultimately improve or diminish patient care and outcomes.
- We expect that the Advisory Panel will also evaluate its recommendations as it enters the next phase. We recommend that a detailed impact analysis of the proposed framework and sample lists be undertaken and released for public comment. This impact analysis would examine scenarios where the potential Pan-Canadian Formulary would be applied and evaluate the impact on patient access and outcomes. Before proceeding, it is critical to fully understand if and to what extent patients will have improved access to the medications they need and whether there will there be patients left behind, and if there be a process for addressing this. Each of the sample lists must be subject to this critical analysis.

Considerations on impact evaluation and analysis:

Clarifying potential gains and losses: We call for greater clarity on how the creation of a Pan-Canadian Formulary will improve access to medications for patients and whether there will be diminished access for some or any. It is imperative that implementation of a potential formulary support the goal of improving access and patient outcomes and that it do so in a meaningful and measurable way.

Avoid cost containment tools. There is particular concern that a Pan-Canadian Formulary could be used by public drug plans to rationalize the delisting of medications as a cost containment tool thereby reducing the quality of pharmaceutical care provided to patients in Canada. A formulary which ultimately leads to some patients losing access to medications they currently have access is not something that we can support. This is a potential outcome, if realized, that is of significant concern to the BMC and its member organizations.

Impact on broad policy priorities. A comprehensive impact assessment should also examine and balance whole of government priorities and assess how the potential Pan-Canadian Formulary would contribute to or detract from both the national pharmaceutical policy agenda as well as broader health priorities, including health and social issues beyond the realm of pharmaceuticals and drug plan budgets.

BEST MEDICINES COALITION
COALITION POUR DE MEILLEURS MÉDICAMENTS

About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of patient organizations, together representing millions of patients, with a shared goal of equitable, timely and consistent access for all Canadians to safe and effective medicines that improve patient outcomes. 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 building, planning 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.

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 Spondylitis Association
CanCertainty
Crohn's and Colitis Canada
Cystic Fibrosis 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