



**BEST
MEDICINES COALITION**
COALITION POUR DE
MEILLEURS MÉDICAMENTS

**Health Canada Consultation:
Proposed agile regulations and guidance for licensing drugs and medical devices**

Best Medicines Coalition



April 26, 2023

Introduction:

- The Best Medicines Coalition (BMC), a national alliance of 29 patient organizations together representing millions of patients, welcomes the opportunity to provide input to Health Canada regarding proposed agile regulations and guidance for licensing drugs and medical devices. The BMC and its members appreciated the briefing session on the consultation content provided by Health Canada officials on April 13, 2023.
- As its mission, the BMC seeks timely access to a comprehensive range of medically necessary, safe, and effective drugs and other treatments, informed by patient-driven evidence and values, and delivered equitably and affordably to all patients in Canada. The following standing goals drive the BMC's advocacy and inform its positions:
 - Effective models for meaningful, proactive, and impactful patient engagement in health and pharmaceutical policy development, recommendations and decision making, where patients and patient organizations are recognized as legitimate and integral contributors and patient-informed evidence is valued and incorporated.
 - Drug programs deliver higher standards of equitable and consistent access to a comprehensive range of safe, effective, and affordable medicines for all patients in a timely manner.
 - Streamlined, transparent and accountable health policy and regulatory frameworks uphold patient-driven principles, invest in both incremental and breakthrough advancements, provide improved pathways to timely access to all medically necessary medications, protect patient safety and ensure ongoing secure drug supply.
- The content of this submission is reflective of BMC's goals and ongoing positions and was developed with the participation and contribution of BMC member organizations, specifically those member organizations which were represented at the April 13, 2023 Health Canada briefing.

Positions and Issues for Consideration:

The BMC supports the direction and goals of Health Canada's regulatory modernization effort, including the proposed agile regulations and guidance for licensing drugs as outlined in the consultation materials, and acknowledges the dedication and commitment of all officials involved in this initiative.

The following points are offered regarding the current proposed regulations and for future consideration through implementation and review phases:

Ongoing patient engagement processes:

- We encourage Health Canada to explore improved patient engagement in concert with the patient community to develop processes which are meaningful and will enable patients to be heard and to contribute to increasingly effective policy. Concepts for consideration include:
 - Creation of a patient/lived experience advisory council, with regular touchpoints, as a mechanism to share information and receive input.

- Regular update briefings to broad patient audiences to build understanding of initiatives and progress and to provide opportunities for dialogue and feedback.
 - The BMC is available to explore these and other patient engagement initiatives.
- Moving forward, the BMC supports adoption of a holistic approach to patient engagement, including opportunities for input and involvement throughout implementation, evaluation, and future policy development phases.

Rigorous monitoring and evaluation processes:

- As the reform process progresses and is implemented, there must be rigorous impact analysis to ensure that initiatives are resulting in a positive impact, specifically regarding contribution to the best possible care and outcomes for patients.
- Evaluation processes must be clear and transparent and focus on impact to patients, not just program budgets. A key marker is whether medicines, particularly those which address unmet needs, will be available to Canadians efficiently and in a timely manner.
- Importantly, patient voices have a legitimate role in determining criteria for evaluation, and in reviewing analysis and possible course corrections, if needed. The patient engagement concepts described above could be effective mechanisms to ensure patient values inform monitoring, analysis, and evaluation.

Clarity and transparency regarding integration:

- Moving forward, BMC supports increased clarity and transparency on how elements of the initiative will integrate with work conducted by other agencies. Specifically, as a goal, there should be greater clarity on how the terms and conditions and risk management plans will integrate with CADTH and INESSS recommendations that identify uncertainty, for example.
- Importantly, this should be managed in a transparent and thoughtful manner that meaningfully includes patients' objectives, perspectives, and experiences.

Address needs of under-represented populations:

- The BMC supports the requirement for manufacturers to submit human clinical trial data broken down by population subgroups (disaggregated data) for new and supplemental human drug submissions. Related to this, there is value in ensuring that ethnocultural background is included as a requirement for when clinical trial data is reported back to ensure inclusivity regarding under-represented populations.

Enabling on-label authorizations to improve patient access:

- Health Canada's work in reviewing new treatments for their safety, efficacy and manufacturing quality is greatly valued but this process can be protracted and may have the unintended consequence of preventing some companies from seeking authorization to move indications from off-label to on-label. The efforts by Health Canada to address this are important and we support prioritization of further work in this area.
- When treatment is off-label, reimbursement for individual patients is not assured, highly inconsistent, and contributes to inequity, poor health outcomes and worsening quality of life. While some patients benefit from exceptional/special access programs, many do not. Foreign reviews offer a potential pathway to reduce barriers to authorization in Canada. We encourage Health Canada to introduce further flexibilities that will improve the likelihood that patients in Canada can have access to necessary treatments.



About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of patient organizations, together representing millions of patients. 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 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