Building Toward a Potential Pan-Canadian Formulary Focus Group Discussion Summary

Introduction

In July 2021, Health Canada engaged CADTH to support the development of a framework for a potential pan-Canadian formulary. A time-limited, multidisciplinary advisory panel was established by CADTH to carry out the following:

- develop principles and a framework that could guide the development of a potential pan-Canadian formulary
- create a proposed sample list of commonly prescribed drugs and select related products as a test case based on a subset of the therapeutic areas that could be included on a potential pan-Canadian formulary
- establish criteria and a transparent process that could expand the proposed sample list to other therapeutic areas, and guide how new products could be added to the list and how a proposed list could be maintained over time
- consult with key stakeholders, including federal, provincial, and territorial governments; patients; clinicians; industry; and other interested parties

A *Discussion Paper for Engaging With Stakeholders In Building Toward a Potential Pan-Canadian Formulary* was published by CADTH in January 2022. It sought input through an online questionnaire that closed on February 25, 2022. To provide an opportunity for more in-depth dialogue, CADTH also conducted a focus group discussion with organizations representing populations made vulnerable by social and/or economic policies.

A summary of the key themes and comments emerging from the discussion with the participants are summarized in the following. Refer to Appendix 1 for a list of participating organizations.

What We Heard

Organizations Representing Populations Made Vulnerable by Social and/or Economic Policies

CADTH has an established process for general consultation with stakeholders. To ensure the perspectives of populations made vulnerable by social and/or economic policies are included in developing a potential pan-Canadian formulary, CADTH purposefully reached out to organizations that serve groups that are traditionally underrepresented for their input. This allows for a shared experience and to elicit deep and meaningful input from groups that CADTH typically would not have the opportunity to engage with or who may have specific insights that would not typically be captured by CADTH's existing stakeholder network. CADTH issued 15 invitations to organizations who serve communities that are traditionally underrepresented at a national or pan-Canadian level and have a mandate or program that supports access to medication and related issues. The invitations included those who work with the Black community, immigrants and refugees, people who are LGBTQ+, people who are unhoused, older adults, people who are uninsured, people living with mental

health issues and addictions, and people living with disabilities. Only 6 participating organizations accepted the invitation (please refer to Appendix 1).

Discussions with the participants centred on soliciting feedback on 4 major areas: guiding principles, approach for selecting drugs for such a formulary, considerations for related products to be included in the same list as drug products, and additional or novel perspectives to undertake this work differently. The key comments for each area are summarized in the following.

Guiding Principles

The panel recommended 6 guiding principles and accompanying definitions that would shape the overall system for a potential pan-Canadian formulary. These are meant to be important commitments that the health system would live up to if a pan-Canadian drug list were to go forward. They are also principles the panel is using for its own decisions and recommendations to develop the proposed sample list of products. The principles are not ranked in order of importance. They also are not stand-alone principles; they influence, balance, support, and, in some cases, build on each other.

For each, the panel has identified related content values (to guide decisions such as which drugs to include in a formulary) and process values (to guide how systems should function and decisions should be made). The participants commented on the following questions with respect to the principles and values.

- How would you define each principle?
- What values should underpin each one?
- Is the language appropriate?

Overall, the participants agreed with the proposed principles as presented but suggested that select definitions be clarified and/or that uncertain terms be removed to better support the intent of the proposed principles.

- Universal and integrated: All people in Canada should have access to the prescription drugs they need regardless of their diversity characteristics (which include, but are not limited to, socioeconomic status, age, sex, gender, genetic characteristics, disability, geography, and membership in a cultural group).
  - "All people in Canada" — clarify that migration status or citizenship status does not impact access.
  - "Access to drugs" — distinguish the provision of drugs to treat health conditions versus a supply of products or those for substance use circumstances to eliminate ambiguity for access, which could open the floodgates.

    > "People who will believe that they should have access to those substances [for abuse] and if you're just saying that it should be for their needs, regardless of other characteristics, you may be opening certain floodgates there that I don't know if you want to necessarily…"

  - *Disability* versus *chronic health conditions* — patients may not identify having an illness as being the same as having a disability (e.g., individuals with cardiovascular conditions, diabetes, or mental illness may not perceive themselves as people with a disability but as someone living with a chronic condition).
  - Rural and remote should be expressly called out.
  - Safe access to treatment is an integral component of this principle.

- Suggest aligning the diversity characteristics with the grounds outlined under the *Canadian Human Rights Act* to protect against harassment or discrimination. The prohibited grounds of discrimination are race, national or ethnic origin, colour, religion, age, sex, sexual orientation, gender identity or expression, marital status, family status, genetic characteristics, disability and conviction for an offence for which a pardon has been granted or in respect of which a record suspension has been ordered (refer to the Justice Laws Website for more information).

- **Effective and high quality:** A potential pan-Canadian formulary should strive to provide access to Canadians to meet the highest standard of health and patient experience. Choices should be based on an evaluation of the options and viewed in the context of benefit to patients and to the Canadian population as a whole. A potential pan-Canadian formulary should be monitored so that it can be continuously improved.
  - Decisions must be evidence-based.
  - Differentiating medications versus **therapeutic** medications is also important (e.g., harm reduction and safe supply).
  - Process should be responsive to emerging scientific evidence to ensure a progressive formulary is developed and maintained.
  - Process must be independent and transparent, without political interference.

    "… an opportunity to really drive progress…absence from changing political winds that may cause real harm in people's lives should drugs come on and off the formulary."

- **Sustainable:** The people of Canada should benefit from a formulary management system that maintains its own viability and supports long-term development and vision.
  - Participants felt that the process and results should be agnostic from politics.

- **Efficient and timely:** The process should minimize duplication of steps and ensure that access to prescription drugs on the potential pan-Canadian formulary is provided in a seamless manner to ensure the right drug gets to the right patient at the right time.
  - Clarity on "right drug" and who gets to decide (e.g., patient in consultation with the prescriber)
  - Timeliness is paramount, especially for certain conditions where risk of significant morbidity or mortality associated with delayed access is a particular concern (e.g., oncology, addiction)
  - Prioritization of critical drugs for evaluation may improve timeliness of access. (e.g., opioid agonist therapy for treatment of opioid addictions)

- **Inclusive, transparent, and fair process:** A potential pan-Canadian formulary should be developed and managed in collaboration with stakeholders, such as patients; people with lived and living experience, including caregivers; health care providers; health organizations; governments; industry; and patient and other advocacy organizations.
  - Clear, transparent, and accountable process is critical.
  - Availability of or access to resources (e.g., human, technology) varies significantly across different patient and stakeholder groups and impacts ability and capacity to participate in collaborative or consultation processes fully or equitably. Meaningful engagement could mean investing in resources that allow select groups the ability to participate to ensure inclusive, transparent, and fair process.
  - Decision-makers should be proactive in reaching out to all stakeholders and implement mechanisms that facilitate true engagement, particularly groups or populations that may be made vulnerable due to socioeconomic status or policies, or stigma that surrounds certain health conditions (e.g., mental illness).

- Equitable: Equity recognizes that individuals have different circumstances that require variable allocation of resources to provide opportunities to achieve equal outcomes. Policies and processes for a potential pan-Canadian formulary should close gaps in access to prescription drugs, especially when the gaps arise from unintended consequences of policies that may create variation in access.
    - Recognition of barriers to equity — to achieve equal outcomes, this should be done from multiple lenses.
    - Equity in outcomes requires ongoing evaluation and monitoring to ensure the benefits seen in clinical trials are achieved in a real-world setting. There is a need for a robust and transparent mechanism to ensure equal outcomes are achieved.
    - Individuals with certain impairments (e.g., vision, hearing) or those living in rural and remote communities encounter additional barriers to access. Equitable needs to mean equal across the country no matter where a person lives (rural, remote, urban) or if one is moving from one jurisdiction to another.

Selecting Drugs for a Potential Pan-Canadian Formulary

The panel proposes a 3-stage process to develop a potential pan-Canadian formulary.

Stage 1 involves creating a sample list of drugs and related products. This stage is meant to be a starting point to test the process as proof of concept.

Stage 2 involves scaling the process so that the sample list could be expanded to include products in other therapeutic areas.

Stage 3 involves the process of adding new drugs and related products that enter the Canadian market; that is, how they could be evaluated and considered for listing.

The panel recognizes there are multiple approaches that could be taken to create a list of commonly prescribed drugs and has identified numerous criteria to support this step. The participants discussed the criteria or considerations that should be taken into account when initially adding a drug to this list or on a go-forward basis.

There was general agreement that the proposed criteria outlined in the discussion paper are appropriate. Comments provided identified themes of ensuring true inclusivity and equity and encouraging pragmatic considerations to support adoption while safeguarding accountability and integrity of the overall process. The participants provided some in-depth thoughts on the following specific criteria:

Societal Preferences

- Due to diverse perspectives, *societal preferences* require a clear definition, as well as clarity around decision-making responsibilities. Stigma is associated with various illnesses, and there is concern that perception due to stigma may negatively influence societal preferences, potentially further jeopardizing those who are already made vulnerable by social and/or economic policies.
- National priorities and political landscape often impact societal preferences and decisions.
    - "To what extent are we aligning future work around this with national priorities that can change again with political wins and put certain population groups at greater risk."

Clinical Benefit

- Clinical trial data used in formulary evaluation often do not reflect real-world population and use (e.g., comorbidities, age).
  - Post-market outcomes monitoring needs to be considered.

Feasibility of Adoption

- Practical considerations are important (e.g., once daily administration versus multiple daily dosing could impact real outcomes, particularly for some populations, such as those who are unhoused)
- Treatment and adherence may require wrap-around support and services to optimize clinical benefits. Feasibility should also take individual needs into consideration; as an example, a person living with visual impairment cannot draw their own medication to self-administer.
  - "…without the supports or services, patients will forgo drug treatment."

Additional Considerations

- Clear accountability for processes and decisions is needed. Mechanisms to safeguard against government over-reach and other conflicts of interest measures should be put in place to ensure accountability and support adherence to the proposed principles.
- A broader perspective that takes into consideration costs and affordability, as well as coordination beyond the immediate (traditional) health care system (e.g., criminal justice system), is needed to achieve universal and equitable access.
- Reconciliation of the patchwork of separate federal, provincial, and territorial formularies and their respective priorities is necessary to address silos.

Related Products for a Potential Pan-Canadian Formulary

Similar to the exercise for selecting drugs for a potential pan-Canadian formulary, the participants were asked to advise on an appropriate approach to selecting related products for inclusion. This includes factors such as criteria to determine how related products are put on a formulary (e.g., devices that assist with the administration of and/or are necessary for optimal drug use), and opportunity to streamline the process, including the potential for a single point of entry to facilitate patient access to drugs and related products. It is acknowledged that new or emerging technologies could be numerous and costly, which could impact the sustainability of a potential pan-Canadian formulary.

The participants felt that the proposed criteria for selecting drugs are generally applicable to related products selection. Devices or related products and services that help to optimize clinical outcomes or safe use should be included in a potential pan-Canadian formulary for universal access. Patients should not be disadvantaged due to affordability.

- Related products for inclusion should be rooted in equity and affordability.
- Related products are those that also offer safe use or make it easier for individuals to take the drug.
- Lack of access to wrap-around products and services (e.g., additional health care offerings, such as wearable devices to monitor a patient's progress) may compromise outcomes.
- The process for access must be streamlined.

Thinking About Things Differently

The panel has discussed other ways to work through its mandate, how to think about a potential formulary (and related products), and how it might work. As it is recognized that this is a very traditional approach to developing policy, the participants were asked to provide suggestions on possible alternatives or additional considerations to doing things differently — both now and on an ongoing basis if a pan-Canadian formulary could be implemented in the future.

The participants suggested improving the current process for drug approval and formulary access to increase accountability, impartiality, and adaptability. They noted that a holistic perspective to health should be taken, including enhancing or leveraging preventive and allied health measures.

- Create a process that is iterative, flexible, and adaptable to an evolving environment to ensure both the process and resultant formulary continue to meet the needs of patients.
- Place more emphasis on preventive health measures and allied health and adjunct therapies, as many do not conform to standard drug definitions.
- Update the drug approval process to be less dependent on pharmaceutical industry submissions.
- Establish transparent and accountable relationships between consumer, patient groups, clinicians, and the pharmaceutical industry to remove potential bias. Because the pharmaceutical industry is largely responsible for driving the drug approval process in Canada, there is a need to establish mechanisms to mitigate such conflicts. This may include full disclosure of individuals or groups who receive funding or other benefits from pharmaceutical companies.
- Involve and find ways to facilitate participation of individuals with lived or living experiences, especially populations made vulnerable by social and/or economic policies, in these important discussions.

Acknowledgement

CADTH would like to thank all participants in this focus group for their time and contributions.

Appendix 1: Participants

Organizations representing populations made vulnerable by social and/or economic policies:

- Canadian Centre on Substance Use and Addiction
- Canadian Mental Health Association
- Canadian Network for the Health and Housing of People Experiencing Homelessness
- CanAge
- Council of Canadians with Disabilities
- Federation of Black Canadians.