Canada's Drug and
Health Technology Agency

Building Toward a Potential Pan-Canadian Formulary

Summary of the Panel 's Work and Recommendations: Highlights from the Report

June 30, 2022

Table of Content

Topic
Work of the advisory panel • Summary of the project and framework
Stakeholder insights • Who we heard from • What we heard
Panel deliberation • What was the process for discussing the feedback • What were the key topics discussed
Highlights of panel recommendations
Future scope topics
Concluding message
Important information: For complete information about this work, please read the report available on the CADTH website: https://www.cadth.ca/pan-canadian-advisory-panel-framework-prescription-drug-list.

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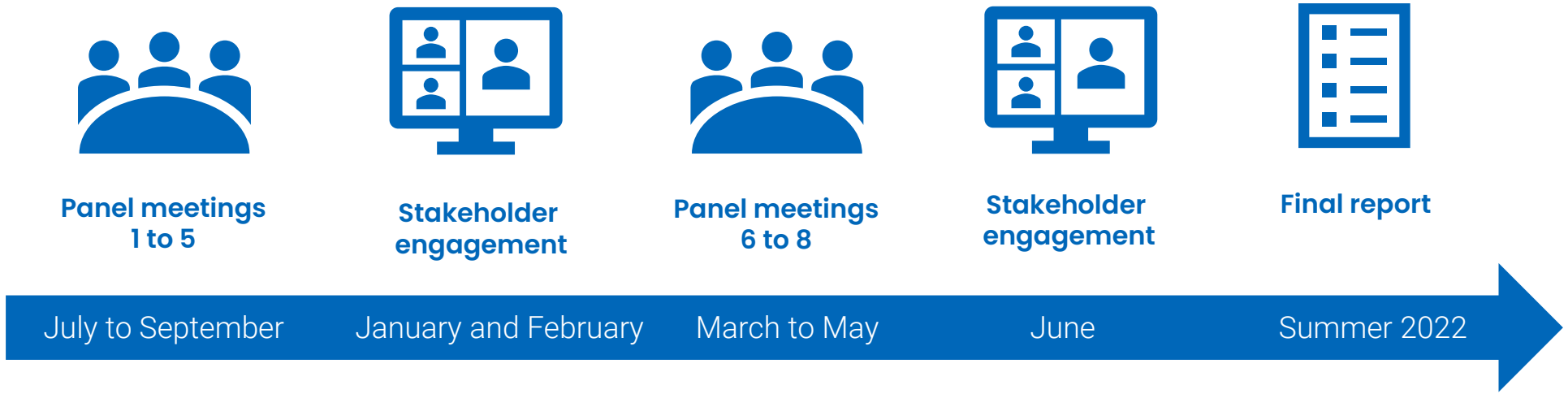
Work of the Advisory Panel

Summary of the Project and Framework

Project Overview



About the Panel (2 Co-Chairs and 12 Members)

Members were **recruited from across Canada and represent diversity** across gender, culture, race, and geographic region

Brings together members **with a range of expertise and experience**:

health care providers (nursing, pharmacy, and medicine); persons with lived and living experience; persons working with Indigenous and other communities often made vulnerable through a combination of social and economic policy, as well as those with designated representatives; and individuals with backgrounds in ethics, health policy, and drug plan leadership

The Panel's Mandate

In Scope

- **Develop principles and a framework** that could guide 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 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 and how a list could be maintained over time
- **Develop and conduct a stakeholder engagement process** to solicit input from interested parties

Out of Scope

- Assessment of current drug plan processes or expectations about whether or how coverage on existing drug plans might be impacted by a potential pan-Canadian formulary
- Identifying governance structures to implement a pan-Canadian formulary
- Financing issues (e.g., funding allocation; financial contributions; funding models; budget scope, size, and amount; or individual drug plan budgets or projected estimates for those budgets)
- Defining terms of coverage (e.g., patient contributions such as copayments or deductibles) and patient eligibility, including status (e.g., international workers or refugee status [undocumented])
- Interplay between public and private insurance plans (e.g., coverage as first and second payor)
- Other ongoing pharmaceutical initiatives

Proposed Framework

Goal

To create a pan-Canadian formulary that includes a broad range of safe, effective, evidence-based drugs and related products that would be reflective of the health care needs of Canada's diverse population

Guiding principles

- Universal and integrated
- Equitable
- Effective, safe, and high quality
- Sustainable
- Efficient and timely
- Inclusive, transparent, with fair process

Staged approach

Stage 1 Creating the proposed sample list of commonly prescribed drugs and related products	Stage 2 Expanding to other therapeutic areas	Stage 3 Adding new products and maintaining a potential pan-Canadian formulary
• Create proof of concept to test the process approach for developing a proposed sample list • Three therapeutic areas (cardiovascular disease, diabetes, and psychiatric illnesses) were selected based on high drug use, disease prevalence, and high number of physician visits and/or hospitalizations. • Refine proposed list with further assessment of therapeutic use, safety, or relative clinical and/or cost-effectiveness.	• Replicate the approach used in Stage 1 to other therapeutic areas. Process and type of information used for assessment should evolve with changing pharmacotherapeutic landscape for the different therapeutic area. • May require different expertise depending on therapeutic area. • Application of proposed principles is recommended.	• Apply proposed evaluation criteria for new products (e.g., alignment with patient and societal values, clinical benefit, equitable access, feasibility of adoption into health systems, economic implications, additional considerations or long-term thinking). • Apply formulary modernization strategies (e.g., reassessment, therapeutic reviews).

Other key elements

Deliberative process to select and evaluate products, listing recommendations, and an appeal process (i.e., a procedural fairness process in which stakeholders can engage to understand the rationale behind the decisions)

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Stakeholder Insights

Who We Heard From
What We Heard

Stakeholder Consultation

Consultation Overview

- Online questionnaire (on specific aspects of the panel's work) was available January 11 to February 25, 2022
  - Information webinar held on January 18
- 1 focus group held in February
  - With organizations that represent populations made vulnerable by social and/or economic policies
- Original submissions to questionnaire and focus group summary are posted on the CADTH website
- The entirety of the broad consultation informed the final report

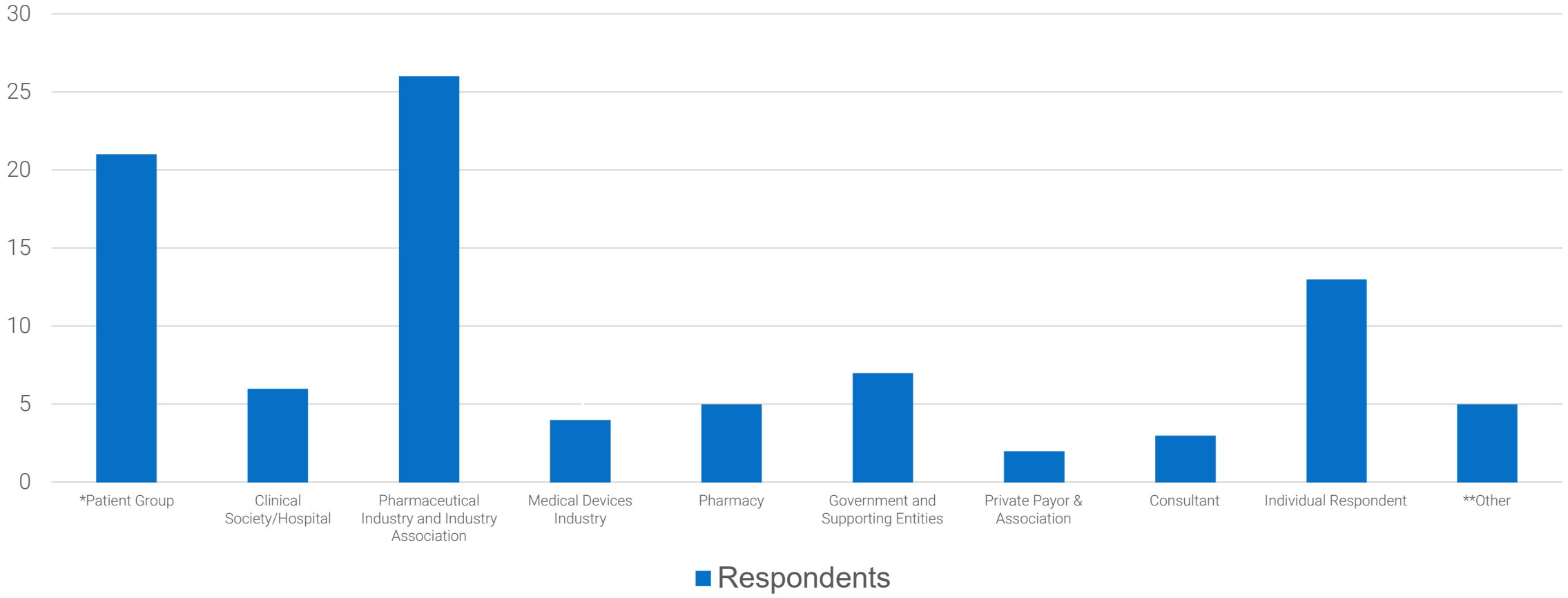
Stakeholder Consultation: Online Questionnaire

Questionnaire Overview

- 8 specific questions + 1 open-ended question for additional comments
- Focused on the process for developing the proposed framework
- Questions included topics related to:
  - principles to guide the development and maintenance of a potential pan-Canadian formulary
  - assessment criteria used to create a sample list of commonly prescribed drugs
  - standard definition and criteria for related products
  - criteria to expand to other therapeutic areas
  - submission process for reviewing new products and indications
  - evaluation criteria for new products
  - deliberative process
  - operational sustainability
  - other comments

Online Questionnaire — Who We Heard From

92 Submissions



*There were 2 patient groups respondents that represented 22 patient organizations.
** Other includes academia and research, community health centres, labour groups.

Stakeholder Consultation: Focus Group

Outreach Efforts

- The panel felt it is critical to understand and account for the possible impacts of a potential pan-Canadian formulary on populations made vulnerable by social and/or economic policies
  - Organizations that serve underrepresented groups were contacted to:
    - ensure diverse perspectives are heard
    - elicit deep and meaningful input from such groups
  - Issued 15 invitations to organizations that:
    - serve communities at a national level
    - have a mandate or program that supports health-related initiatives, such as access to medication
- Careful thought and effort was made to engage with representatives from the Assembly of First Nations, Inuit Tapiriit Kanatami, and Métis National Council
  - This invitation remains open, and CADTH is committed to engaging respectfully and humbly with First Nations, Inuit, and Métis peoples, communities, organizations, and governments

Focus Group — Who We Heard From

Attendees

- Canadian Centre on Substance Use and Addiction (CCSA)
- Canadian Mental Health Association (CMHA)
- Canadian Network for the Health and Housing of People Experiencing Homelessness (CNH3)
- CanAge
- Council of Canadians with Disabilities (CCD)
- Federation of Black Canadians (FBC)

Focus Group Overview

- Covered the following topics:
  - guiding principles
  - selecting drugs and related products for a potential pan-Canadian formulary
  - approaches to, or considerations for, creating a potential pan-Canadian formulary

Overall Summary – What We Heard

The panel would like to thank all respondents who took the time to submit feedback through the online questionnaire or who participated in the focus group

Principles

- About the principles

Stage 1

- Assessment criteria
- Related products — definition and eligibility
- Related products— inclusion and evaluation criteria

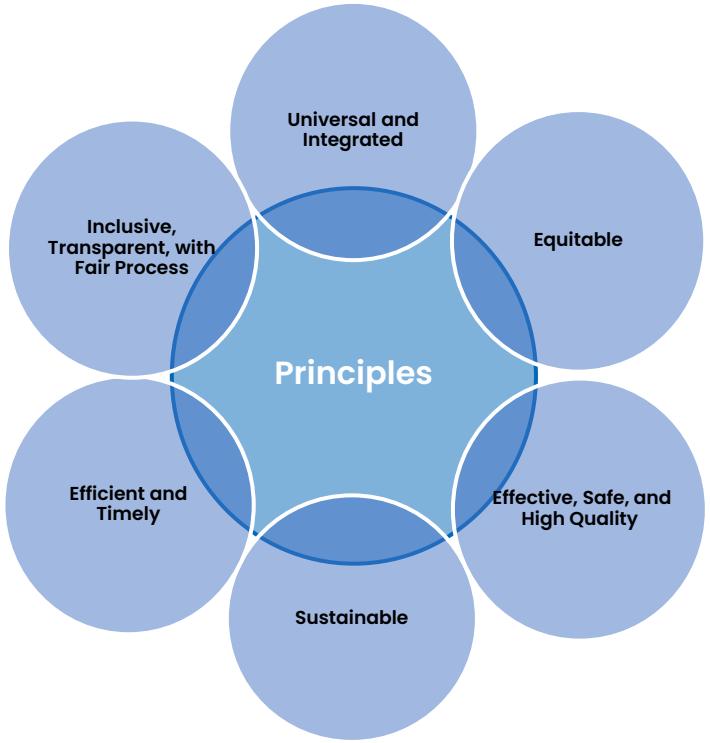
Stage 2

- Expansion

Stage 3

- New products — review initiation and evaluation
- New products — deliberation
- Formulary modernization

Questionnaire Response and Focus Group Discussion — Highlights



Proposed Principles and Definitions

- General agreement
- Suggestions
  - Inclusive and transparent public engagement
  - Align diversity characteristics with Canadian Human Rights Act
  - Enhance clarity of what culturally appropriate access means and how it would be addressed
  - View medications as an investment
- General comments
  - Information about how principles would be implemented

Questionnaire Response and Focus Group Discussion — Highlights

Stage 1: Creating a Proposed Sample List

Proposed Assessment Criteria

- General agreement
- Suggestions
  - Revisit how principles are reflected and whether biases or gaps were created by applying them to the sample list
  - Cross reference or build in additional sources of information beyond listing status
  - Additional clarity about:
    - consultations on OTC drugs
    - consideration of combination products
    - flagged products
    - issues related to drug shortages
- General comments
  - Be flexible enough to meet the needs of special populations, while ensuring populations made vulnerable by social and/or economic policies are not further disadvantaged
  - Ensure no additional gaps in access to drugs are created
  - Support for use of biosimilars and generics; though some did not agree with substitution policies

Questionnaire Response and Focus Group Discussion — Highlights

Stage 1: Creating a Proposed Sample List

Related Products — Definition

- No clear agreement about whether to restrict or broaden the definition
- Suggestions to improve clarity to recognize the value extends beyond simply improving adherence

Related Products — Determining Eligibility for Assessment

- Respondents generally agreed with the need to establish clear eligibility criteria to identify which related product could be assessed further for inclusion
- Call for clear criteria to identify inclusion and exclusion criteria, calling on, for example, existing provincial and territorial drug plan programs and policies to inform the decision

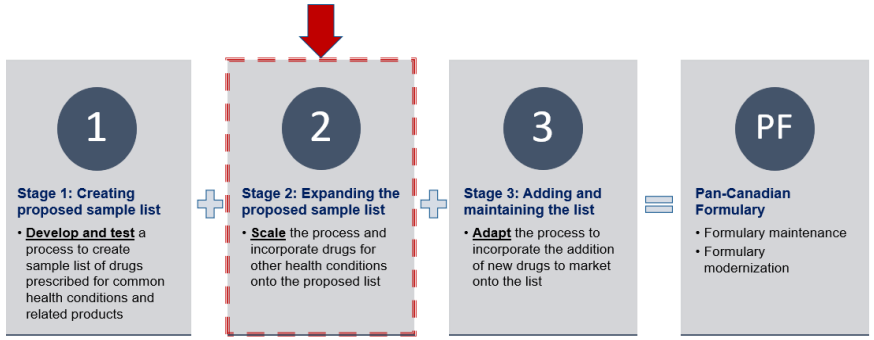
Questionnaire Response and Focus Group Discussion — Highlights

Stage 1: Creating a Proposed Sample List

Related Products — Inclusion on Drug List and Evaluation Criteria

- General agreement that related products should be included in the same list as drugs
- Recognition by some that related products may not have the same level of evidence as pharmaceuticals, leading to call for modification of criteria for related products
- Reasons were shared for and against using the same evaluation criteria for both drugs and related products
    - Agreement
        - Similar evaluation standard could ensure timeliness and alignment of therapeutic use for both drugs and related products
    - Some disagreement
        - Modification of proposed evaluation criteria may be needed
    - Disagreement
        - A different set of criteria for related products may be needed

Questionnaire Response and Focus Group Discussion — Highlights



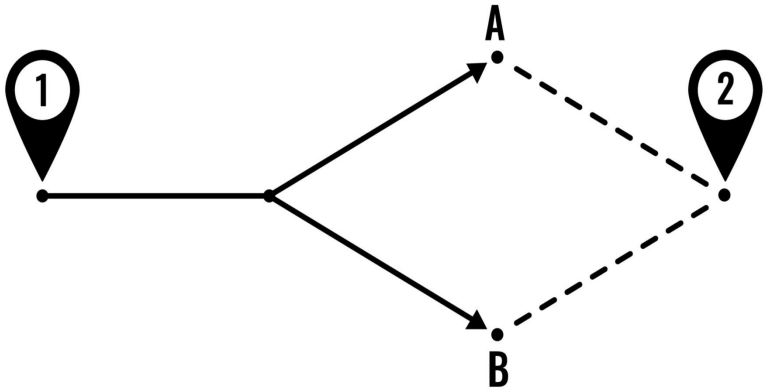
Stage 2: Expanding to Other Therapeutic Areas

- Majority of opinion expressed that out-of-scope issues should be addressed in parallel or before proceeding
- Suggestions
  - Involve broad consultation
  - Consider gap analysis before expansion
- General comments
  - Consider whether different criteria may be needed (e.g., for oncology)
  - Some respondents who supported prioritizing remaining therapeutic areas based on national health priorities noted that it cannot be overly political and should be nimble
  - Suggest against prioritizing 1 therapeutic area over others — develop a full formulary before implementation

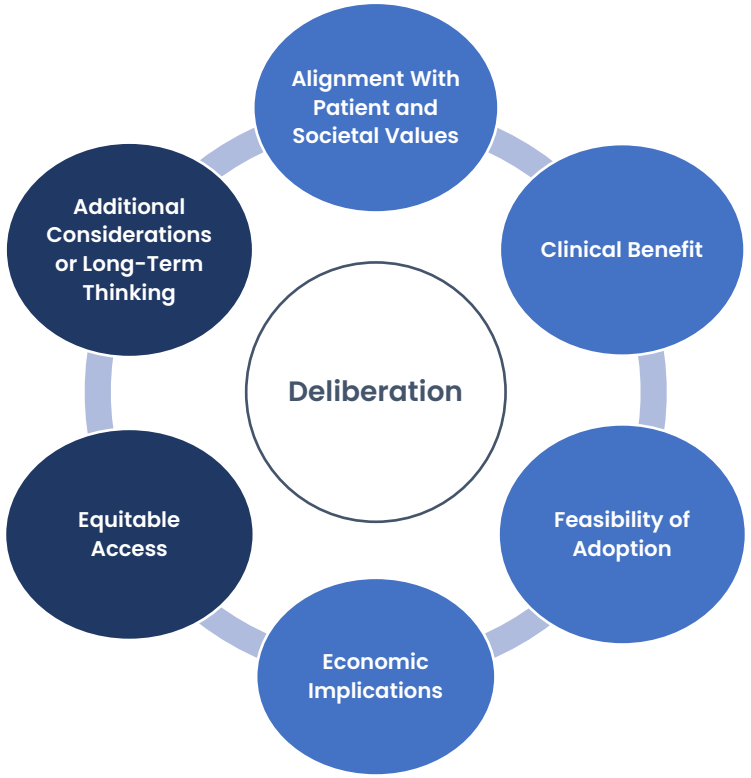
Stage 3: Adding to and Maintaining a Potential Pan-Canadian Formulary

Process for Initiating Review of New Products

- Three potential options were presented on how reviews of new drugs and indications could be initiated
- No agreement on any 1 option; mixed views received on:
  - maintaining first-in, first-out approach
  - alternative to a first-in, first-out submission review
- Suggestions
  - Approach to submission review initiation process:
    - combination approach, entirely different approach, follow other countries
- General comments
  - Opportunities to share best practices should be optimized



Questionnaire Response and Focus Group Discussion — Highlights



Stage 3: Adding to and Maintaining a Potential Pan-Canadian Formulary

Adding New Products to a Potential Pan-Canadian Formulary

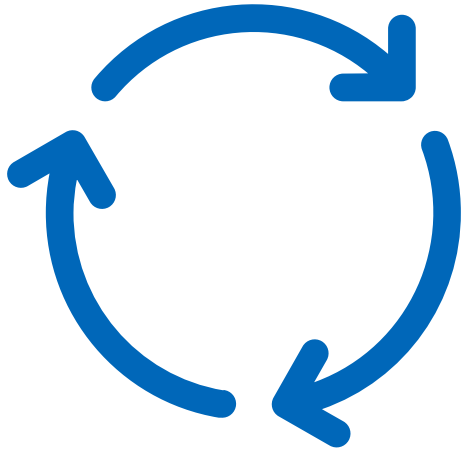
- General agreement with proposed evaluation criteria and considerations
- Suggestions
  - Refine proposed evaluation criteria
  - Accommodate for future advancements in evidence generation methods and reimbursement mechanisms
- General comments
  - Effectively apply the principles to remain patient-centred
  - Mixed views on which criteria should be prioritized — potential for tension between the application of these criteria
  - Ensure clear accountability for processes and decisions

Stage 3: Adding to and Maintaining a Potential Pan-Canadian Formulary

Deliberative Process

- General agreement that the deliberative process should include weighting of the evidence
  - Example: Multi-criteria decision analysis (MCDA) model
  - Small number of respondents did not explicitly agree with incorporating an MCDA in decision-making process
- General comments
  - Mixed views on which criteria should be prioritized or given greater weight than others
  - Recommend flexibility in the process to account for the specific needs of different therapeutic areas
  - Adapt, streamline, and integrate into existing drug review processes
    - Reduce duplication of effort, while giving due consideration to current gaps in the processes

Questionnaire Response and Focus Group Discussion — Highlights



Formulary Modernization

- Generally in favour of timely, ongoing modernization, recognizing the resource intensity required
- Some felt that immediate priority should be on the creation of a pan-Canadian formulary — process for modernization should be addressed afterward
- Suggestions on strengthening processes
  - Transparent and collaborative prioritization process
  - Flexibility of processes for different categories of therapies, with a potential for expediting certain drugs
  - Leverage current formulary modernization initiatives within Canada and internationally
- General comments
  - Mixed views received on frequency of reassessments
    - Regular pre-set cycles for review, including having it as a condition for funding in certain circumstances
    - Develop criteria to trigger reassessments, and a scoring system to prioritize a drug for reassessment

Questionnaire Response and Focus Group Discussion — Highlights

Additional Comments

- Require more information on the plan and program design
- Considerations for designing a potential pan-Canadian formulary:
  - more effective and integrated data systems in Canada
  - inclusion of hospital formularies
  - build the system around the most vulnerable
  - meaningful and early engagement with all parties throughout
  - more emphasis on preventative health measures
- Inclusion and overlapping issues across rare diseases, oncology, and other areas raised but no clear consensus on whether or how to address
- Consider alternatives to the current system in creating a pan-Canadian formulary
- Overall, the feedback agreed on the fundamental need to improve medication access for patients
  - Recognized limitations and challenges with the current infrastructures, complex funding arrangements, and multitude of drug programs
  - Pan-Canadian formulary could provide an opportunity to strengthen collaboration among all key entities and partners to improve the reimbursement ecosystem in Canada

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Panel Deliberation

What Was the Process for Discussing the Feedback
What Were the Key Topics Discussed

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Feedback Review Process

- Discussed the feedback over 3 meetings
- Panel members carefully reviewed all feedback received, and discussed key themes to collectively identify how the comments and suggestions could further shape their work
- When feedback involved out-of-scope topics, comments were flagged for future work
- All comments have been carefully considered, and every effort has been taken to incorporate what was heard through this consultation process.

Panel Discussion — Highlights

Thinking broadly about the potential pan-Canadian formulary

The formulary is a long-term investment to advance and maintain the health and wellbeing of all people of Canada.

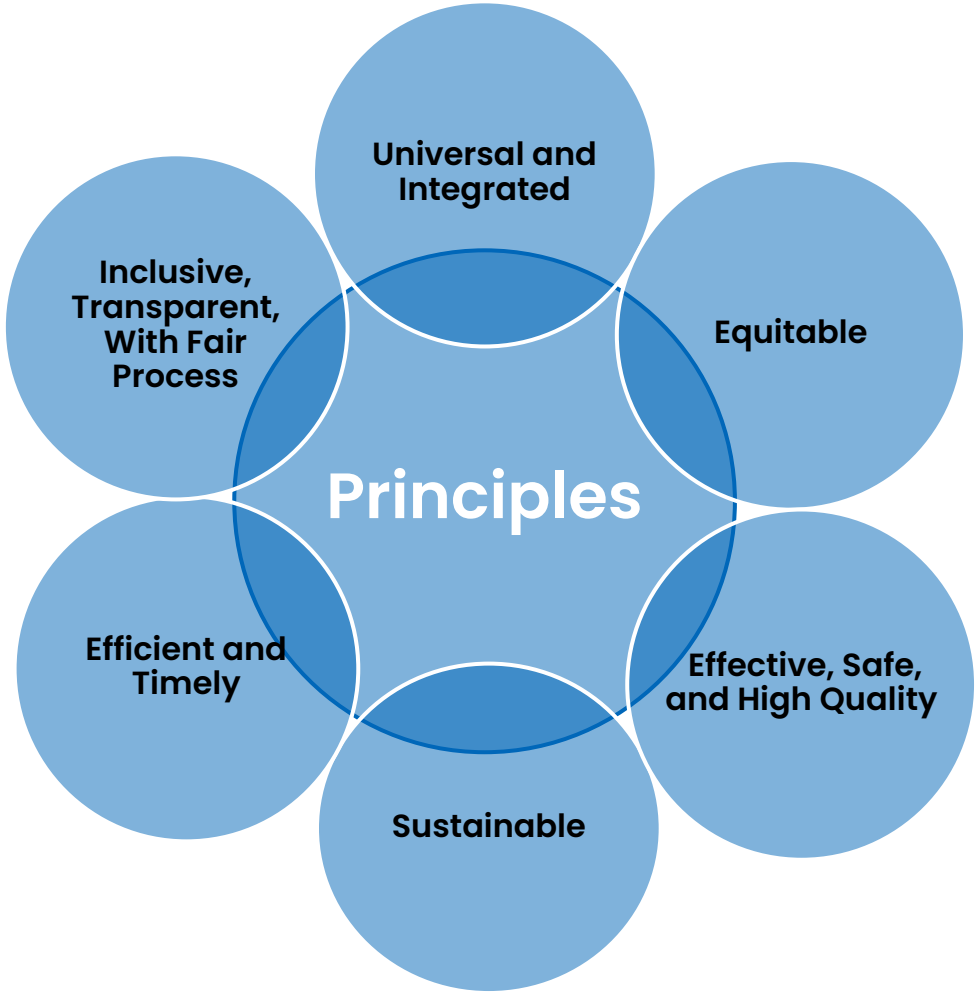
Emphasizing the commitment of the pan-Canadian Formulary

A holistic approach to patient-oriented care involves being mindful of what determines the health of a population, as well as the need to reduce inequities within a population.

Panel Discussion — Highlights

Clarifying the purpose of and interplay between the 6 principles

The principles are guideposts; they are not listed in any specific order, and the application of each will be context-dependent.



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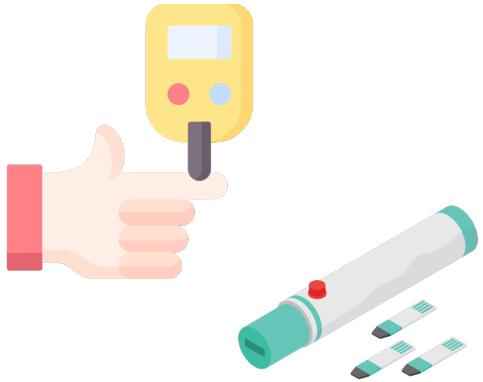
Panel Discussion — Highlights

Revisiting the approach taken to create a sample list of drugs and related products

The approach was pragmatic and considered the proposed principles to create a comprehensive list while being mindful about patient diversity.

Panel Discussion — Highlights



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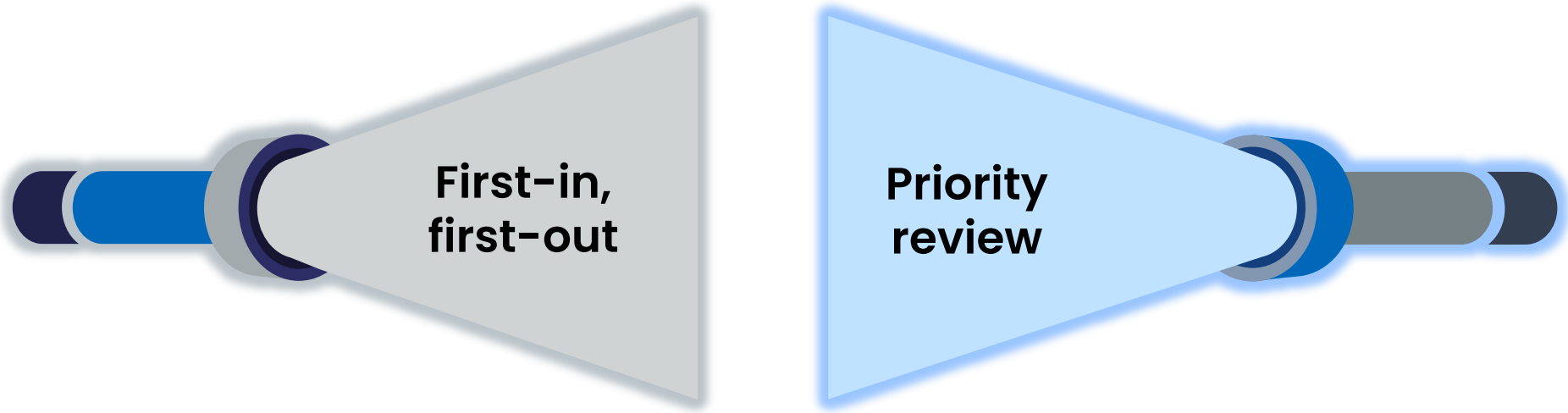
Reviewing the importance of *related products*

Related products (devices that directly support the delivery, administration, and optimal use of drugs) should have a clear set of eligibility criteria.

Reflecting on the expansion to other therapeutic areas

The expansion to other therapeutic areas should be guided by meaningful engagement with diverse individuals and experts, and consider the lived and living experiences of patients.

Panel Discussion — Highlights



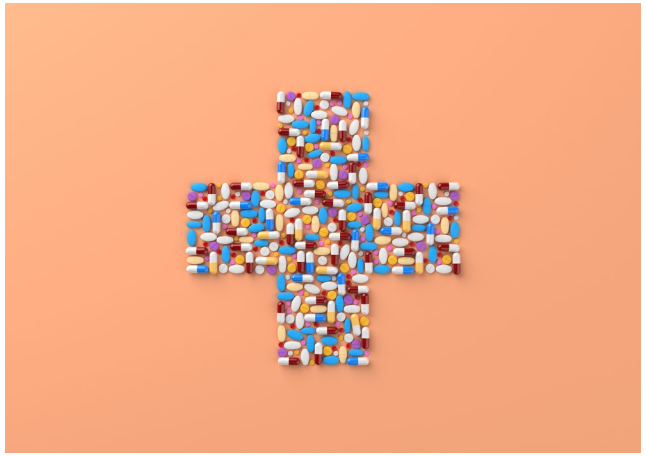
Recommending an alternative to a first-in, first-out submission review process

Explore a hybrid model that allows for a standardized process (first-in, first-out) to review drugs, as well as a fast-track model for select drugs.

Panel Discussion — Highlights

Elaborating on the criteria for evaluating new drugs and indications

Enhance innovative ways to strengthen evidence and meaningfully incorporate patient perspectives and experiences.



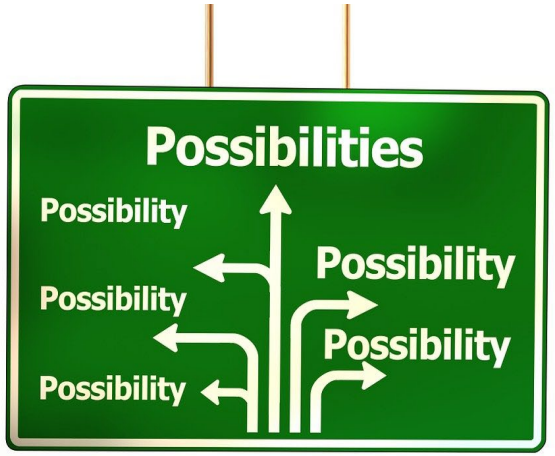
Affirming a holistic deliberative framework

For a transparent and fair process, consideration at both conceptual (principles) and operational (how the process is organized and structured) levels are important and will need to be supported by objective decision-making frameworks.

Panel Discussion — Highlights

Exploring formulary modernization

Ensure appropriate resource allocation for this resource-intensive process, while applying a transparent and collaborative approach to meaningfully engage all partners in the health system.



Highlighting out-of-scope key messages

Out-of-scope elements on the design and implementation of a potential pan-Canadian formulary should be addressed, ideally before further work is undertaken, or in parallel.

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Highlights of Panel Recommendations

Highlights of Recommendations

1. **Adopt 6 principles:** *Universal and integrated*; *equitable*; *effective, safe, and high quality*; *sustainable*; *efficient and timely*; and *inclusive, transparent, with fair process* — these are meant to act as guideposts; and are not in any specific order.
2. **A potential pan-Canadian formulary should:**
    a. be a dynamic and living system that involves multiple perspectives
    b. be aligned with, if not integrated into, other elements of the health system
    c. be equitable and support a distinction-based approach that promotes self-determination
    d. incorporate evidence that considers diverse populations, perspectives, and experiences
    e. be aligned with current evidence

Highlights of Recommendations (cont'd)

2. **A potential pan-Canadian formulary should (cont'd):**
    f. be sustainable
    g. adopt systems and process efficiencies
        i. provide simplified points of access for related products
        ii. explore a hybrid submission review model
3. **Take a staged approach to develop a potential pan-Canadian formulary**
4. **Build public trust through transparent decision-making**
5. **Ensure accountability and reason-driven decision-making**

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Future Scope Topics

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Future Scope

Further clarity of these elements could result in the recommendations being refined and enhanced. The panel felt that the key areas to consider include:

- addressing elements that were beyond the panel's mandate (e.g., expectations about whether or how coverage on existing drug plans might be impacted by a potential pan-Canadian formulary; consideration of financing issues)
- follow-on work (e.g., process to scale and expand the work)
- transparency regarding governance
- leveraging and enhancing existing processes to reduce duplication of processes
- ensuring continuity of care
- centralizing data systems
- supporting appropriate use
- change management for implementation and performance measurement frameworks

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Concluding Message

Concluding Message

Developing a framework for the design and implementation of a potential pan-Canadian formulary is complex.

The panel strongly feels that, while policies need to respond to the issues of today, a lasting framework must be resilient, agile, sustainable, and adaptable to the unforeseen but inescapable changes of tomorrow. It is our belief that the recommendations will provide decision-makers with the framework and tools necessary to initiate the steps to creating and implementing a pan-Canadian formulary.

We encourage decision-makers to consider our recommendations, and to meaningfully engage all interested parties to explore the changes needed to ensure that all people living in Canada have access to a broad range of safe, effective, evidence-based drugs and related products.

Thank You

As an independent panel making non-binding recommendations in support of a broader discussion about a potential pan-Canadian formulary, we are grateful to CADTH and the government for this opportunity to be part of the process and this discussion.

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