

Reflections on a Potential Pan-Canadian Drug Formulary: Medicines Industry Response to CADTH Consultation

February 25, 2022

Background and pharmaceutical policy context

The pan-Canadian drug formulary discussion can be considered as one possible element within a broader context of evolving pharmaceutical policies in Canada. In December 2021, after five years of policy challenges and stakeholder concerns posed by changes to the Patented Medicine Prices Review Board (PMPRB), the Federal Government constructively signaled its intent to consider pharmaceutical policy in Canada from a more holistic perspective.¹ The government's renewed focus includes the new context brought on by the COVID-19 pandemic, the launch of [Canada's Biomanufacturing and Life Sciences Strategy](#) in July 2021 and the progression of other initiatives such as the [National Strategy for Drugs for Rare Diseases](#) and the development of a [Canadian Drug Agency](#) (CDA). The federal government has also asked the Canadian Agency for Drugs and Technologies in Health (CADTH) to examine a potential pan-Canadian drug formulary.

In this context of evolving life sciences and pharmaceutical policies, Innovative Medicines Canada (IMC) and BIOTECanada welcome the opportunity to provide the industry's perspective to the consultation on a proposed framework for developing a potential pan-Canadian Formulary. The industry believes that Canadian governments, industry, and other stakeholders can collaborate on a productive path forward for pharmaceutical policy to enhance system resilience in Canada. We also view this potential pan-Canadian formulary consultation as an initial opportunity to advance one element of the discussion in relation to the agencies that provide decision-making support to the provinces.²

There is no current definition or articulated role for a pan-Canadian formulary within the Canadian federation. Formularies are, by nature, directly tied to medicine funding decisions, however, the federal government does not make funding decisions for provincially insured populations. Perhaps as a result, the scope of CADTH's consultation has been limited to exclude how such a centrally developed drug list would be used within Canadian systems of funding, relationship to existing provincial formularies, and how patient access (coverage) under existing plans might be impacted.³ We acknowledge that this is framed as being out of scope for the current consultation. However, we believe that this is highly material information that requires further elaboration and discussion. Without such context, it is unclear what problem the formulary is positioned to solve. Additionally, without visibility or context to the real-world use of a potential formulary, it is difficult for stakeholders to comment in an informed manner on many of the detailed questions in CADTH's consultation

¹ <https://www.gazette.gc.ca/rp-pr/p2/2022/2022-01-05/html/sor-dors273-eng.html>

² CADTH currently makes pharmaceutical reimbursement recommendations to federal, provincial, and territorial drug plans other than Quebec regarding decisions made at a jurisdictional level, while the Institut national d'excellence en santé et en services sociaux (INESSS) plays a similar role for Quebec. Provincial drug plans maintain their own formulary lists and associated listing criteria that account for local health and patient needs and available resources.

³ *Building Toward a Potential Pan-Canadian Formulary*, [CADTH Consultation Document](#) January 2022, page 8.

document. Indeed, for numerous stakeholders, the issues that have been deemed to be out of scope are the most fundamental matters of importance with respect to a potential pan-Canadian formulary. These key factors include but are not limited to financing, and impact on existing provincial formularies.

Given these limitations, we feel it will provide most value to focus on higher-level considerations rather than each granular issue that cannot be fully explored without context. Our comments are organized as follows: 1) proposed core principles to support patient access; 2) the appropriate federal role in relation to provincial responsibilities for health; 3) considerations for decision making; and 4) possible paths forward to enhance future dialogue to bring about a more resilient Canadian healthcare system.

Core principles to support patient access

CADTH offers some initial principles that can be a useful starting point for discussion (p. 11). All stakeholders can agree with broad principles of enhancing patient access and decision making that is based on best available evidence and meaningful stakeholder engagement processes. Patient access is closely dependent on federal and provincial formularies that are robust in the sense that they include the full range of available therapeutic options. The consultation document's focus on improving patient access is a critical objective, even if the path to achieve this requires further discussion and ultimately depends on considerations beyond a federally directed formulary itself. In response to question 1, we propose that CADTH and the federal government consider the following core principles as a basis to support robust patient access, regardless of policy mechanism:

- 1. Patient Centered** - IMC and BIOTECanada support a system for the regulatory approval, HTA assessment and pricing and reimbursement of medicines that starts and ends with the patient. More specifically, the ultimate purpose of Canada's system of reviewing and enabling access to medicines must meet current and future health needs of Canadians at a world-class standard, and fully involve patients in decision making, such that significant improvements in patient relevant outcomes are achieved. These outcomes can include, for example, ease of administration, quality of life measures, alleviating caregiver burden, and reducing hospital visits.
- 2. Access Enhancing**- Any framework should aim to enhance and not undermine access to the full range of available and leading-edge medical innovations. Formulary decisions should not be unduly focused on cost containment but rather should also include other important considerations such as the value they bring to patients and health systems. It should recognize that in many therapeutic areas (e.g., mental health) there are no one-size-fits-all solutions and diversity of therapeutic and delivery options is required. If governments proceed with a pan-Canadian formulary, it should always support full patient choice and clinical judgement. According to our provisional analysis, the 29 products specifically excluded from the sample list comprise approximately 486,000 patient claims in Canada in 2020 alone. Additionally, a total of 18 million patient claims were filed for the list of products identified for "further discussion" with experts and comprise over \$500 million in value that supports patient access to medicines. While some formulary maintenance and updating in Canada is likely possible, we would like to better understand how patients on those therapies could be impacted.

3. ***Predictable, Efficient, and Transparent Processes and Appeals*** – It is important that any pan-Canadian Formulary not add additional administrative processes to an already complex, lengthy, and onerous drug review and reimbursement system. In addition to being efficient and timely (p.11), any CADTH process must have predictable, transparent policies, procedures, deliberative frameworks, and mechanisms to review or appeal any decisions. It is particularly important for stakeholders to understand how decision-making standards are applied. In this context we appreciate CADTH’s recognition of the need for appeal mechanisms.

4. ***Expertise and Stakeholder Perspective in Decision-Making*** – Any decision-making process should be informed by the best available clinical expertise in a given therapeutic area and should allow for direct engagement between decisions makers, manufacturers, and those stakeholders impacted to proactively address real-world issues and questions. These elements are a precondition to an “effective and high quality” process (p. 11).

5. ***Excellence in HTA*** – If HTA analysis is to form the basis of formulary recommendations, efforts can be directed to make Canada a leader in HTA processes and recommendations that recognize value to the overall healthcare system and patients. There is opportunity for greater alignment between manufacturers assessment of cost-effectiveness and CADTH’s reanalysis. For example, provisional third party analysis suggests that the gap exceeds 58% (the gap between manufacturer-submitted incremental cost effectiveness ratio and CADTH’s reanalysis of that ICER). A first step to developing a pan-Canadian formulary should be to collectively address issues in the underlying HTA reviews to make these analyses work better for Canadians (see discussion below regarding future directions).⁴

CADTH has proposed other principles, including: “universal and integrated,” “equitable,” and “sustainable.” (p.12). While these are agreeable in general terms, for the reasons identified above, it is unclear how specifically they could be addressed through a pan-Canadian formulary, or by CADTH, in isolation. We would welcome additional context and further discussion on how specifically these elements could be addressed and believe that they are likely best considered through direct discussions with provinces.⁵

If payers are interested in implementing elements of a pan-Canadian formulary, they should be mindful to minimize disruption to existing listings and work to enhance access (i.e., to fill existing coverage gaps). Varying criteria and covered indications across the country will need to be understood and addressed. As such, any pan-Canadian formulary should reflect the best and most comprehensive standards of coverage across the country. Because population needs differ significantly between publicly and privately ensured populations, any pan-Canadian formulary would not be appropriate as a reference for private payers who have their own distinct processes and procedures resulting from the different patient populations served by private plans.

⁴ Cost-effectiveness should include a full assessment of the value a medicine brings to patients and the overall healthcare system.

⁵ The specifics of listing are a matter of provincial oversight and remain to be clarified (e.g., are products listed for the full Health Canada label, or for certain subpopulations, and if so with what criteria? These details make a significant difference to the level of access for patients.)

The appropriate federal role in relation to provincial responsibilities for health

While the population of uninsured patients in Canada is small, there are nevertheless some gaps that can be addressed on a province-specific basis.⁶ Governments are working to address these coverage gaps, for example, through federal government investments, such as the [agreement with PEI](#) in 2021, and through efforts to fill targeted gaps in coverage such as Ontario's recent 2022 workstream to make benefits more [portable](#) and independent of employer. Given the provinces' primary responsibility for healthcare, it is essential that health and pharmaceutical transfers remain flexible and unrestricted to allow the provinces to better address their local needs and system-specific requirements.

Given this perspective, the most practical manifestation of a pan-Canadian formulary may be a voluntary or non-binding list that reflects the federal government's best advice to the provinces regarding the highest standards of coverage. If advanced, such a list should not be tied to funding "strings", much in the same way that the Canada Health Transfer does not have onerous requirements on how that funding is deployed within provincial health systems. In this regard, it may be helpful to think of a pan-Canadian formulary more in terms of a set of recommendations to help inform decisions, influence evidence-based prescribing, and promote medicine adherence through associated knowledge translation. Beyond CADTH's formulary analysis, there are many high-quality clinical practice guidelines in Canada that should be consulted for learnings, for example, those produced by experts via the Canadian Diabetes Association.

This evidence base can be paired with province-specific, patient-centered programming designed to improve non-adherence to prescribed therapies, which is primarily a function of factors other than cost.⁷ If health outcomes associated with non-adherence are a primary concern, this would tend to support policy approaches based more on adherence and insurance design gaps as opposed to one that emphasizes altering the mix of available treatment options via a binding formulary. To the extent that it may be an issue, cost-based non-adherence will differ significantly across the country based upon provincial insurance policies. This suggests that any federal funding transfers must be unrestricted to allow provinces to address funding gaps and co-payment or deductible considerations in a province-specific manner. Industry invites further research on the root causes of restricted access to medicines, which may include factors such as voluntary opt out, lack of awareness of available provincial or territorial programs, high co-payments, and non-adherence due to medical or social issues.

Considerations for decision making

IMC and BIOTECanada would be interested in further dialogue and specifics on multi-criteria decision analysis approaches (MCDA) and generally support efforts to broaden decision making beyond primarily cost considerations to also incorporate on societal considerations. HTA recommendations from CADTH and INESSS typically highlight the key elements that the expert committee took into consideration, however the

⁶ We recommend consulting analysis based on analysis insurance gaps which illustrate those that can be filled through incremental provincial insurance reforms. https://www.conferenceboard.ca/temp/237f367c-b6d8-4105-9e07-8aad34329718/9326_Understanding-the-Gap_RPT.pdf

⁷ <https://www.longwoods.com/content/25909/healthcare-quarterly/non-adherence-to-prescribed-therapies-pharmacare-s-existential-challenge>

relative importance of each factor is often lacking. This is frustrating for stakeholders who may disagree with the final recommendation rendered, particularly when that recommendation is highly restrictive or negative.

We are particularly interested in discussing forms of MCDA that are not overly arithmetic and appropriately weigh patient input preferences.⁸ CADTH rightly highlights a broadening of value considerations, for example, by referencing patient convenience, which is a factor that stakeholders have long argued should be a criteria to favorably influence a decision to list a therapy. Another factor that is not always taken into consideration in current HTA-based decision making is the need to appropriately incentivize the use of products that reduce reliance on institutional/primary care, which is an important lesson emerging from the COVID-19 pandemic. If MCDA is used, it is probably most relevant at the CADTH drug programs recommendation level and must include discussion and stakeholder acceptance of weightings specific to different therapeutic areas.

Decision making must also remain flexible to address unique treatments in certain therapeutic areas and evolve to accommodate innovative outcomes-based payer models and real-world evidence development. How these access-enhancing directions would be impacted by a possible pan-Canadian formulary requires further elaboration and discussion. We are particularly interested in learning how this initiative may relate to CADTH's new role and program for Post-Market Drug Evaluation,⁹ in addition to CADTH's intention to improve and consult on its deliberative framework. Prior to determining a theoretical process to update a list whose role remains to be defined, CADTH could consult on the deliberative processes that drive current expert committee deliberations, which form the ultimate basis for CADTH's decision support. This will support transparency and understanding of CADTH processes and output of the deliberations. Industry would value the opportunity to explore with CADTH the deliberative process and make suggestions in this context, such as opportunities for direct stakeholder engagement with expert committees on individual reviews (e.g., patients/patient groups, clinicians, manufacturers, etc.).¹⁰

Possible paths forward to enhance future dialogue

Patients around the globe are benefiting from a revolution in pharmaceutical and diagnostics innovation. The traditional medicines paradigm of "one-pill-for-all" is rapidly shifting towards a more tailored approach based upon "precision medicines", where therapies are targeted to those patients who will specifically benefit from them. It is unclear how such a formulary, if expanded, could be useful in the context of this type of innovation. Similarly, the prospect of a single formulary for oncology medicines raises many questions that are not easily answered with the currently available information. We note the significant challenges associated with implementing oncology algorithms as an example of the complexity, and the questionable value of more

⁸ For example, if an evidence weighting system is used, the relative weights cannot be static across all therapeutic areas or treatments and must instead be context-specific, particularly when considering rare diseases, oncology, or other more complex therapeutic areas.

⁹ Previous Drug Safety and Effectiveness Network budget prior to its transfer to CADTH was \$10 million per year.

¹⁰ Ideally, all CADTH committee meetings would open to the public to view and listen to the discussion (similar to how FDA Advisory Committee meetings are held). If this is not feasible, a portion of the discussions could be open with the deliberation portion itself closed. An alternative could be to record portions of the meeting and/or provide transcripts of the discussion that are publicly accessible.

directive approaches in the therapeutic space. Appropriately assessing the value of combination therapies and their constituent medicines is also a complicating factor.

The challenges associated with recent changes in the informal thresholds used for oncology medicines should also be noted. The growth in recent CADTH recommendations, particularly in oncology and drugs for rare diseases (DRDs), calling for 90%+ price reductions, has caused considerable concern among patients and industry. We understand that one of the drivers of this shift has been the move from an implicit \$100,000 cost-per-QALY threshold to a \$50,000 threshold, which is a topic that requires further dialogue and consultation. This shift may produce more protracted negotiations downstream and is a cautionary consideration if the pan-Canadian formulary were to be extended to oncology and rare disease areas. The addition of therapeutic areas should not be considered until there is greater clarity on how the initiative might be implemented and how the stated goals may be achieved.

Due in part to the imperatives of the COVID-19 pandemic, the federal government is clearly making progress with respect to several pharmaceutical policies, with the Canadian Life Sciences Strategy unfolding in real time, a DRD Strategy close to finalization, a CDA transition office in place, and a potential reconsideration of the 2019 PMPRB reforms that focus exclusively on price without consideration of their negative impact to access to new treatments or the life sciences environment. A key recommendation regarding next steps would be to incorporate the potential formulary with other major policy initiatives into a more comprehensive, multi-stakeholder policy dialogue or forum to address pharmaceutical access and innovation in Canada. This forum could connect the many interrelated, but disparate policy streams currently being discussed in isolation within a whole-of-federal government approach.

In conclusion, IMC and BIOTECanada support efforts to ensuring timely and affordable access to medicines for all Canadians. We agree with the statement in the discussion paper that "all people should have access to the prescription drugs they need regardless of their diversity characteristics". An important value that should be added is "continuity" – regardless of the model the government ultimately adopts it must ensure Canadians maintain access to at least the same range of cutting-edge medicines they rely on today to maintain and improve their quality of life. Federal pharmaceutical policies must also look towards the future to evolve in anticipation of the new treatment modalities emerging internationally. Canada's participation in biopharmaceutical innovation can benefit both patients and the economy and will be enabled by policies that create an environment attracting investment and enabling access to innovative therapies.

We appreciate the CADTH committee's work and look forward to further dialogue as one possible element within a broader strategy to address access barriers, rebuild the life sciences sector, and collectively emerge from the COVID-19 pandemic with a more resilient Canadian healthcare systems for the future.

With Kind Regards,

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A handwritten signature in blue ink, appearing to read "A. Casey".

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