July 22, 2025

Reflections on a Potential Federal Drug Formulary: Medicines Industry Response to CDA Consultation

Innovative Medicines Canada (IMC) and BIOTECanada are the primary associations representing Canada's research-based pharmaceutical, biotechnology, and vaccines industry. We welcome the opportunity to provide our perspective to the current consultation with Canada's Drug Agency's (CDA) on a proposed framework for a potential federally-directed formulary. We request that the present consultation response document be attached to the CDA's report as appendix to ensure the industry's perspectives are reflected.

The task at hand is challenging because there is no clear definition or role for a federal formulary in Canada. Public drug formularies are the responsibility of public drug programs funded by provinces and territories, federal drug programs, with private drug insurers maintaining their own coverage policies. How this list would be implemented or used in practice is explicitly out of scope. Therefore, we take no position on the list itself in absence of critical real-world context.

We understand that CDA is obligated to publish this report and others under the *Pharmacare Act*, which received royal assent on October 10, 2024. Our criticism below stems from a flawed public policy purpose under the *Pharmacare Act* and is not directed at the CDA itself. We recognize a best effort to work within an unclear mandate from a previous government. This mandate is in fact duplicative of work already completed by CDA in 2022; is based on the World Health Organization approaches for 'essential medicines' (which are not comprehensive!); excludes core pharmacare-related therapeutic areas (e.g. diabetes); excludes rare diseases; and raises new questions about the management of cancer medicines in Canada.

Federal formulary is unnecessary - A formulary is the list of medicines that are covered for reimbursement on drug insurance plans for eligible patients. The development and management of provincial and territorial formularies is the mandate of individual jurisdictions. As iterated in our 2022 consultation document on the same topic,[i] it remains unclear what problem the federal formulary is positioned to solve. Given the lack of clarity on what the federal formulary will be used for, we are not in a position to provide full commentary. Canada's drug system functions as a mixed public and private system and this must remain the case for continuity for patients and viability of the sector. See Appendix where we reiterate some key principles that can be foundational to *any* future policy approach.

The proposed federal formulary is not comprehensive - Coverage decisions should not be linked to this federal "formulary" because it is not comprehensive (see Provincial Concerns below). There is no national drug insurance system, nor a fiscally responsible path to create a single-payer in Canada (see *Costs* below).[ii] Similarly, "Bulk-Purchasing" does not have a definition nor align with the role of the pan-Canadian Pharmaceutical Alliance (pCPA) which negotiates pricing on behalf of the provinces and territories for medicines reimbursed by public insurance plans (see industry comments on CDA's separate consultation, due August 1, 2025). Provincial and territorial public formularies are comprehensive of medicines that are funded. The CDA panel acknowledges that the list is a starting point "and is not intended to be a comprehensive list" (p. 5). A specific example is that scope is limited to first-line treatments, when many important therapeutic options, and real-world utilization are comprised by subsequent lines of treatment. We understand it is not the CDAs intent to limit future access, therefore the CDA should also explicitly acknowledge to government that future access to treatments should not be restricted by line of therapy.

Cannot be implemented as payer policy nor used as a basis for pharmacare expansion – The CDA panel has included an important qualifier: *"This work is not intended to replace existing drug and related product coverages under the different plans in both the public and private sectors. In other words, if a product that is currently funded by public or private drug plans was not included on this proposed list, it is assumed that there would be no loss of existing access to treatments for patients should governments consider adopting the products in this proposed list in the future"* (p. 5). We agree with the point that the formulary is not comprehensive and cannot replace public and private approaches. We do not agree that no loss of existing access can be assumed if a national formulary approach were to be implemented, which is contrary to the real-world situation happening in provinces that have implemented Federal Pharmacare to date.

Provincial concerns – Notwithstanding the qualifier above regarding the formulary not replacing existing coverage, the establishment of a federal formulary could be misinterpreted to suggest that provincial and territorial governments conform to federal direction despite having their own systems and local realities. For example, it would be unrealistic (both politically and legally) for the Government of Quebec to replace local Quebec decisions and INESSS formulary assessments with a federal formulary approach. This would clearly not be tenable for Quebecers, and perhaps accordingly, Quebec has not signed on to federal pharmacare.

Ontario is currently demonstrating national leadership to Accelerate the Speed of Access for Patients via a pathway for new medicines that address high unmet clinical need. It is unclear how the proposed federal cancer formulary connects with this important Ontario work. The Ontario formulary lists thousands of products that have been the result of years of clinical

practice, cost-effectiveness analysis and negotiations, whereas the proposed federal list only includes 513. The federal list of medicines is not exhaustive, and our members have specifically noted it may not provide important cancer medicines that are a part of future combination treatment regimes. Ontario has not signed on to federal pharmacare.[iii]

Similarly, Nova Scotia is actively improving its access timelines for new medicines. The provinces should continue with this important progress. Now would not be the time to incur significant new costs on a single payer model under a federal formulary. Nova Scotia has not signed on to federal pharmacare.

New challenges – On the other end of the spectrum, provinces that have implemented elements of the National Pharmacare policy (i.e. Manitoba and PEI) are facing new challenges. The federal policy linking funding to single payer frameworks has created unnecessary and unrealistic expectations that current pCPA-negotiated prices would apply in a system in which private payers have delisted previously covered products. pCPA-negotiated prices are predicated on the existence of a dual-payer system and applying these prices to a single-payer system is neither sustainable for manufacturers nor for the public system.[iv] This would undoubtably also happen in additional jurisdictions.

Potential costs – The Federal Parliamentary Budget Office (PBO) reports that pharmacare would cost $5.7 billion over five years for select diabetes and contraception medications alone. There appears to be no plan for provincial governments to recover the billions in private payer value needed to reconcile the PBO assessment under a single-payer model. These estimated costs would clearly balloon if the proposed federal formulary was implemented under a single-payer model. There has been no assessment of the magnitude of these costs. Provinces should remain cautious given that there is no federal commitment for sustained funding.

Focus on accelerated access and filling insurance gaps – The Federal Government should focus on providing funds to provinces to fill gaps in coverage[v], and improve access for publicly insured populations – an area where Canada ranks last among G7 nations. Two years is too long for publicly insured patients to wait for the new medicines they need. The industry also believes that Canadian governments, industry, and other stakeholders can collaborate on a productive path forward for pharmaceutical policy to enhance system resilience and address the trade, tariffs, and international policy issues that are currently impacting Canada.

In conclusion, IMC and BIOTECanada support efforts to ensure timely and affordable access to medicines for all Canadians. Regardless of the models that governments ultimately adopt, they *must* ensure that Canadians – at minimum - maintain access to at least the same range of cutting-edge medicines they rely on today to maintain and improve their quality of life.

APPENDIX: Key principles to support patient access

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. We propose that CDA 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 timely 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 –*** Canadian frameworks 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. Additionally, access to treatments should be irrespective of line of therapy. With the advancement of incremental innovation and dynamic treatment pathways, patients should have equal access to all available treatments for their specific disease and not based on which treatment was available to them in the first-line setting.
3. ***Predictable, Efficient, and Transparent Processes and Appeals –*** It is important that any federal 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, any CDA 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 any future process must have an appeals mechanism.

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.

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 CDA's reanalysis. 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. Furthermore, HTA should not be used as a factor in establishing an Essential Medicines List which is different than formulary listing decisions.

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[i] *Building Toward a Potential Pan-Canadian Formulary*, CADTH Consultation Document January 2022

[ii] 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.

[iii] Ontario also has the real-life example of the implementation of OHIP+; single-payer coverage for young people in 2018. This system resulted in well-documented interruptions in care, reduced level of access for young Ontarians and elevated costs to the point where the government of Ontario reverted to a second-payer approach, thereby providing full coverage for all young Ontarians without disrupting care for those with private plans and at much lower costs

[iv] The situation is compounded by existing administrative issues where Manitoba is last in Canada to recover the funds from manufacturers stemming from previous listings, involving years of delays. IMC has received multiple reports of Manitoba not invoicing manufacturers for funds the government is owed, sometimes with delays of several years, producing sizable accruals. This reflects millions of dollars that could be used now for Manitoba patients.

[v] The Conference Board of Canada finds that less than 2% of Canadians lack access to any coverage, which can be address through targeted measure to fill provincial gaps.