Neighbourhood Pharmacy Association of Canada
Association canadienne des pharmacies de quartier

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RE: Submission to the Canadian Agency for Drugs and Technologies in Health (CADTH) Stakeholder Consultations on a Pan-Canadian Drug Formulary

Submission Q&A :

1. **As part of developing a framework, the panel recommended 6 guiding principles and accompanying definitions that would shape the overall system for a potential pan-Canadian formulary. Please refer to Table 1 in the discussion paper.**

   Do you agree with the proposed principles and definitions? Please provide the reason(s) and suggested changes, if any.

   The top priority for Neighbourhood Pharmacies has been, and always will be, improving access to prescription medications for all Canadians. Pharmacies want to be a part of the solution that ensures no Canadian will go without the prescription medication they need.

   As healthcare providers working on the frontline, pharmacists and pharmacy teams know the importance of ensuring that Canadians have access to the medication they need in a timely manner and without financial barriers.

   Whether through public or private prescription drug plans, all Canadians should have access to drug coverage. All providers — government, pharmacy, insurers and employers — have a role to play in ensuring medication access for everyone.

   To best support Canadians and to ensure access to the medications they need, any pan-Canadian formulary must maintain and build on the current drug coverage millions of Canadians currently receive through private drug plans. With more comprehensive formularies, private drug plans are seen to provide more options for their participants, as well as more timely access to medicines. This ensures that patient choice is fundamental.

2. **The panel recommended a 3-stage approach to creating a potential pan-Canadian formulary. Stage 1 is developing a process to create a proposed sample list of commonly prescribed drugs and related products. The proposed sample list is a**

starting point and is meant to be a proof of concept for the process. Part of the process involved comparing the listing status of each drug on existing public drug plan formularies and identifying gaps in access. The proposed principles were also applied when discussing each drug. A predefined assessment criteria was used by the panel to determine if a drug or related product should be included, flagged for additional expert consultation, or excluded from the proposed sample list. Please refer to Table 2 in the discussion paper for more information on the proposed assessment criteria.

Do you agree with the proposed assessment criteria? Please provide the reason(s) and suggested changes, if any.

To ensure an equitable approach, the federal government should identify a common baseline for coverage for all Canadians while maintaining the coverage levels of existing provincial and private plans. The fundamental reason for this is to ensure both a robust formulary and stockpile, but also to put patient choice at the center of any national or pan-Canadian programs.

This will allow the government to set a higher bar for drug coverage in Canada that maintains the medications available through public or private plans that already support millions of Canadians. It is important that this framework include flexibility to allow provinces and territories to maintain their respective formularies or allow them to top up plans to meet unique regional needs

Looking ahead, any pan-Canadian formulary should aspire to reach the highest denominator — the Québec formulary which is the most comprehensive in Canada.

3. **Related products (devices that assist with the delivery or administration of drugs and/or are necessary for the optimal use of drugs), primarily those for patients with diabetes, were assessed by the panel for inclusion on the proposed sample list. The panel felt strongly that the inclusion of related products on a potential pan-Canadian formulary should be explored because this could help improve patient access and could potentially improve adherence with drug treatment. In many cases, these related products are covered through different programs within the health system, which makes accessing coverage difficult for patients. As such, a potential pan-Canadian formulary could be an opportunity to streamline the process, provide simplified access, and ultimately help patients access these types of products. The panel noted the importance of having standard criteria to help determine which related products should be eligible for inclusion on the potential pan-Canadian formulary. This standardization will be particularly important when assessing new or emerging technologies that could be numerous and costly and might impact sustainability.**

a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a potential pan-Canadian formulary? Please provide details.

b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them (see Table 3 in the discussion paper)?

Please provide the reason(s). Note that this question pertains only to evaluation of related products; there will be an opportunity to comment on the proposed criteria for evaluation of new drugs in question 6.

We believe it is possible to achieve both an incredibly high level of patient care with an approach that focuses on value for money. In order to do this, a pan-Canadian formulary should look to include related products as well as related services.

Patient support services delivered by pharmacies are designed to provide personalized patient care and support, often anticipating the needs of patients with complex medication therapy, to ensure patients receive the greatest value out of the medicines they are prescribed.

Pharmacy services are executed with compassionate care and support and ease the burden of care for patients and healthcare professionals. In many cases, care teams, comprised of nurses, pharmacists and other healthcare providers with experience in multiple disease states and therapeutic areas, oversee all elements of programs that include patient enrollment, reimbursement assistance, drug distribution and delivery through either a retail pharmacy or specialty pharmacy network, patient and healthcare professional education and training, and adherence support with robust data reporting.

As we continue to explore what a pan-Canadian formulary could look like, we need to ensure that the conversation takes into account related and equally important services that patients rely upon.

4. **Stage 2 involves scaling the process to add drugs and select related products for other health conditions to the proposed sample list. The proposed approach would follow the review steps described for stage 1 — considering the listing status from existing federal, provincial, and territorial formularies; utilization data; availability of generic or biosimilar for the drug molecule; information about safe use in pregnant and lactating women; and references summarizing available drugs and use in Canada. These considerations would be supplemented with literature reviews of pharmacotherapeutic areas that have been shown to improve health outcomes in people made vulnerable by systemic inequities (if available). Assessment would include reviewing the totality of the information.**

The panel recommends that the proposed principles (e.g., universal and integrated) be applied. As part of the refinement, the panel suggests that products listed under specialized programs (e.g., cancer and special drug programs) be included. This is because product listing and eligibility, among other aspects, may differ across the country and a gap could inadvertently be created. The panel also suggests that therapeutic areas could be prioritized based on national health priorities. Further details can be found in the Stage 2: Expanding to Other Therapeutic Areas section of the discussion paper.

a. Do you support the proposed approach to expand to other therapeutic areas? Please provide the reason(s).

b. Should the remaining therapeutic areas be prioritized based on national health priorities?. Please provide the reason(s).

A pan-Canadian formulary that results in fewer drug choices for Canadians is a major concern. We cannot back track with a reduced public formulary for Canadians who are already used to and reliant on comprehensive private drug coverage.

As work continues to develop and refine the evaluation model and criteria for the pan-Canadian formulary, we would like to reiterate our position that a successful pan-Canadian formulary is one that is robust and offers patient choice.

This can be done through identifying a common baseline for coverage for all Canadians while maintaining the integrity of existing provincial and private plans and include flexibility to allow provinces and territories to either maintain their respective formularies at this base level or allow them to top up plans to meet unique regional needs. In the event that a provincial formulary is expanded, the national baseline should be re-evaluated to ensure there is no gap in coverage for Canadians.

It is again worth reiterating that a pan-Canadian formulary should strive to be best-in-Canada and we can look toward the Québec formulary which is the most comprehensive in Canada.

5. **The panel explored alternative approaches to the first-in, first-out process for reviewing new products and indications for inclusion on a potential pan-Canadian formulary (see the Selecting New Products to be Considered on a Potential Pan-Canadian Formulary section of the discussion paper). The following options were explored:**

- **Option #1: A prioritization model could be developed to align with Health Canada's priority reviews. This would allow for a predictable process for identifying products that represent a significant therapeutic advancement. Although this approach could support a seamless integration between regulatory and health technology assessment (HTA) processes, it does not address the inability to control when a submission is initiated.**
- **Option #2: A clear and transparent scoring system that would prioritize new drug submissions could be created and applied (e.g., new innovative products that address unmet needs of a population could score higher and be prioritized on a review agenda).**
- **Option #3: Opportunities to work together at an international level to review and prioritize products collectively could be explored. There have been international collaborations in several areas of regulatory and HTA processes. This could potentially save on resources and accelerate access for Canadians and international partners.**

The panel encourages strong engagement and collaboration with all key stakeholders (e.g., patients, clinicians, industry, government, and HTA bodies) through all steps in the process and recommends the use of a transparent process.

a. Which option could be adopted as an alternative to a first-in, first-out submission review process? Please provide the reason(s) for your choice.

b.What criteria could be used to identify priority products?

As this work continues, it is imperative that thorough consultations with industry stakeholders continues. This needs to be done to ensure that no one in Canada loses coverage or access to the medicines they rely upon, and that appropriate and relevant information is being taken into consideration during the evaluation process.

Pharmacists are the first and most frequent touchpoint most Canadians have with the health system and are a key community health resource. Their role in education, adherence, financial support, handling and monitoring, as well as medication waste reduction, is vital when evaluating reimbursement and coverage for prescription drugs as well as high-cost drugs for rare diseases and the services and infrastructure that support them.

6. **To guide the evaluation of new drugs and new indications for a potential pan-Canadian formulary, the panel considered the following proposed criteria:**

- **alignment with patient and societal values**
- **clinical benefit**
- **feasibility of adoption into health systems**
- **value for money**

The panel proposed 2 additional criteria — equitable access and additional considerations or long-term thinking — to enhance the deliberative process. The proposed criteria are linked with the guiding principles and provide the basis for decision-making with respect to the selection and evaluation of drugs for a potential pan-Canadian formulary. Please refer to Table 3 in the discussion paper for details on the proposed evaluation criteria for new products.
Do you agree with the proposed evaluation criteria and the considerations for new products?. Please provide the reason(s) and suggested changes, if any.

Overall this approach makes sense for the evaluation of new drugs. As the panel continues their work on this front, we encourage the panel to adopt more holistic approach at evaluating value for money.

As previously submitted, it is expected the federal governments proposed amendments to the PMPRB will result in patients, pharmacies and distributors experiencing a disproportionate burden of changes to Canada's drug pricing policy in a way that will wholly affect businesses, services and quality of care. The reimbursement models in Canada are such that funding formulas for pharmaceutical distributors – who ensure that Canadians have timely access to vital medications in a safe, secure and efficient manner – and pharmacy services – that provide personalized patient care and support the needs of complex medication therapy – are directly related to drug prices

These services are designed to provide personalized patient care and support to ensure patients receive the greatest value out of the medicines they are prescribed. There is

almost no government funded support for the medication management of these patients, beyond a basic dispensing fee

7. **The panel also provided recommendations on a deliberative process for using the proposed criteria and applying them in practice. Of particular interest, they explored ways to structure the deliberative process so that evidence from multiple disciplines and perspectives could be weighted. The panel proposed that evaluating and selecting products for a potential pan-Canadian formulary should involve an expert committee. Please see the Deliberative Process section in the discussion paper for details.**

   Should the deliberative process include weighting of the evidence or a score for each criterion? If yes, how should weight be distributed among the proposed criteria?

   As the panel looks to identify the best method for a deliberative process for applying the decided criteria for selecting new products, robust engagement with stakeholders and experts is key. This must include pharmacy.

   If the decision is made to lean on the advice of an expert panel, we want to ensure that the pharmacy sector is at the table. Pharmacists are the first and most frequent touchpoint most Canadians have with the health system and are a key community health resource. Their role in education, adherence, financial support, handling and monitoring, as well as medication waste reduction, is vital when evaluating reimbursement and coverage for prescription drugs as well as high-cost drugs for rare diseases and the services and infrastructure that support them.

8. **Current Canadian drug review processes generally focus on assessment of new products. There is a desire to ramp up formulary modernization strategies (e.g., reassessments, therapeutic reviews) and to re-evaluate existing listed products with emerging new evidence on a regular cycle (e.g., every 3 years to 5 years). This would likely increase the workload of stakeholders throughout the health system (e.g., clinicians, patients and patient groups, researchers, industry, regulators, and plan administrators).**

   What measures could be put in place to ensure operational sustainability, with limited resources and time, including the ability of stakeholders to participate meaningfully in multiple processes (e.g., should there be a prioritization system for listed products to be re-evaluated or other criteria to determine eligibility for reassessment or therapeutic review)?

   Recognizing the incredible challenges with meeting the healthcare needs of Canadians, the federal government can minimize costs of drug coverage by utilizing a pan-Canadian formulary as a baseline for coverage for all Canadians while maintaining the integrity of existing provincial and private plans and include flexibility to allow provinces and territories to either maintain their respective formularies at this base level or allow them to top up plans to meet unique regional needs. Under a mixed payor model, we estimate the total net new cost to provide coverage for all Canadians who are currently uninsured

or under insured could cost up to $5.1 billion which would be significantly less than the more than $19 billion net new cost to create a single-payor model outlined in the Parliamentary Budget Officer's report.

This would provide prescription drug access to every Canadian and peace-of-mind to nearly the 5.2 million Canadians who are currently without coverage for prescription medications, resulting in a sustainable Pharmacare approach that will allow government to look at a more robust drug review process and to direct healthcare funds to new products including drugs for rare diseases, and to other significant healthcare priorities, including mental health, seniors care, long-term care, First Nations health, reduced surgical and diagnostic wait times and home care.

9. Are there any other comments that you would like to share with us?

As pharmacists and healthcare providers working on the frontlines, we know there are still gaps that exist.

The Neighbourhood Pharmacy Association of Canada (Neighbourhood Pharmacies) represents Canada's leading pharmacy organizations who deliver high value, quality care to Canadians in all models including chain, banner, long-term care, specialty and independent pharmacies as well as grocery chains and mass merchandisers with pharmacies. Our members are home to the most trusted providers of drug therapies, pharmacy-based patient services and innovative healthcare solutions. We advocate for community-based care through our members' high accessibility and proven track record of providing optimal patient care closer to where patients live, work and play. By leveraging over 11,000 points of care with pharmacies conveniently located in every community across Canada, Neighbourhood Pharmacies aims to advance sustainable healthcare for all stakeholders.

From the introduction of Ontario's OHIP+ program in 2018, we know there can be unintended consequences when patients are switched from a private plan to a public first-payor system, like medication disruption and unnecessary administration and access hurdles.

By protecting the comprehensive care many Canadians already have, we can learn from the Ontario experience and create a smoother pathway to universal drug access, building on the private and public drug coverage that most Canadians already rely upon.

It is vital that a pan-Canadian formulary not only preserve individual levels of care and service, but extend access to the highest level of choice and coverage equitably across Canada. Formularies must continue to provide a balanced offering of a broad scope of medications with strong supporting evidence — allowing for individualized care and patient choice.