Stakeholder Feedback

Consultation on Proposed Framework For a Potential Pan-Canadian Formulary

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Abbott Diabetes Care

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

We agree with the proposed assessment criteria, apart from the statement "product is not listed on any of the identified public drug plans". The fact that the product has not been listed on any of the identified public drug plans is not necessarily an indication that there is not a need for the product. If the product has received a positive HTA recommendation, it should not be excluded on the basis that it has not been listed on any of the identified public drug plans yet.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

Related products should be listed in the same list for drugs so as to improve patient access and potentially improve adherence to drug therapy. Generally, many of the same criteria may apply to a non-drug therapy but there should be flexibility. For example, devices often will not have the same level of RCTs given the nature of these products and how quickly these technologies evolve. Real-world studies in non-drug therapies, such as devices/technologies, often may make more sense to consider.

Additionally, products with existing HTA reviews should be considered to have a higher level of evidence. The number of HTA assessments should also be taken into consideration, rather than grouping similar products together when issuing a recommendation. This speaks to the fairness of the process.

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

Criteria listed in Table 3 make sense. Regarding "Value for money", it is suggested that societal benefit be included, i.e., not only include costs outside the public health system that are unique to relevant subpopulations, rather costs and benefits outside the public health system should always be considered. The question remains as to how these proposed principles differ from the provincial principles.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The proposed evaluation criteria seem reasonable. The process should ensure that patient input is included, to ensure alignment with patient and societal values. For the criterion "Value for money", innovation and impact to society and to systems outside of the health system should also be considered.

While "novelty of therapy", an item included in the criterion "long-term thinking" is an important consideration, there are the questions of (1) How "novelty of therapy" is defined and (2) How or would devices/technologies be considered differently from drugs.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

Weighting of the evidence can be of merit, though it depends on the method. For example, RWE/RWD makes more sense for devices/technologies rather than RCTs but are typically viewed as less rigorous than RCTs because this is the standard that has been set when reviewing drugs. The number of studies and number of individuals that the product has been studied in should also be considered. A score for each criterion would help to make the decision-making more transparent and consistent, but there could be issues in how the criteria are selected and their associated scores. These could be subject to bias.

Additionally, products with existing HTA reviews should be considered to have a higher level of evidence. The number of HTA assessments should also be taken into consideration, rather than grouping similar products together when issuing a recommendation. This speaks to the fairness of the process.

8. 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 reviews)?

No response provided

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

It was noted that in Table 4, the list of diabetes products did not include ketone strips. For completeness, this item should be added.

While the process is evolving, there should be nothing stopping the FPT plans from moving ahead themselves on adding new products to their formularies, since these seem to be based on the same proposed guiding principles.

Additionally, products with existing HTA reviews should be considered to have a higher level of evidence. The number of HTA assessments should also be taken into consideration, rather than grouping similar products together when issuing a recommendation. This speaks to the fairness of the process.

AbbVie

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

Thank you for the opportunity to provide feedback on the Discussion Paper on the Pan-Canadian Formulary.

AbbVie is a global pharmaceutical company whose mission is to discover and deliver innovative medicines across several therapeutic areas, including immunology, oncology, neuroscience, eye care, virology, women's health and gastroenterology.

AbbVie supports efforts to improve access to medicines by Canadian patients who need them and applauds the Discussion Paper's focus on this principle. However, in line with the IMC/BIOTECanada industry consultation submission, we are unable to answer the detailed questions in the Discussion Paper without understanding how a Pan-Canadian formulary might be used in practice. It is not clear how this formulary would fit within the current public-private system of drug reimbursement. A National Formulary would be a step removed from the provincial jurisdictions that deliver health care and the patients and health care providers to whom they are accountable. Moreover, it is not clear how this list would resolve the challenges that patients currently face in accessing drugs, which are largely connected to provincial drug formulary design. Regardless of next steps, we wish to underscore the importance of ensuring that no Canadian patients are left worse off than today with respect to access to medicines.

ALS Society of Canada

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

As a member of the HCCC, ALS Canada recognizes and supports the existing alignment between CADTH principles and those of HCCC.

We recognize that a sustainable and modern formulary, that places principles of patient need ahead of cost containment, is an aspirational goal to be achieved through the integration of formulary decision making within the greater healthcare system.

We recommend that point in time decisions influenced by competing principles of cost-effectiveness and patient need be viewed as opportunities for transparent patient engagement and issue identification for immediate or ongoing system change.

Additionally, we recommend that consideration be given to updating Principle 3: Effective and High Quality: An effective and high-quality national formulary is one that achieves better patient outcomes, comprehensive access to modern medicine and cost savings over what could be achieved by any one provincial or territorial formulary on its own. As access to innovative medicines are essential to Canadians affected by ALS, we note the importance of balancing efforts to lower drug prices with the value of making innovative medicines accessible in a timely and equitable manner.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

As a member of the HCCC, we are commenting on this question, however we must acknowledge the barrier in doing so without understanding the entirety of the approach to connect the creation of the pilot list to a functional national formulary. For progressive diseases, like ALS, time is of the essence. Therefore, a full plan must be established in a timely manner to ensure the right treatments gets to the right patients at the right time.

In alignment with HCCC, ALS Canada recognizes the benefits to a staged approach and efforts that have led to the pilot list of products. We note that the success of the pilot will be determined by the impacts of any unmanageable changes to patient therapies and improved or loss of therapies.

We would also like to highlight that the creation of a national formulary is an opportunity to take into account information not previously considered as well as improve interfaces between formulary decisions and other aspects of healthcare. We recommend that in parallel to exercises that nominate products from existing formularies, a new process also be considered that re-sets past decisions based on current healthcare considerations and principles that support holistic patient care.

We recommend that a change management strategy should accompany any transition to a national formulary and a principle of avoiding any changes to therapy could/should/must be considered. We

would like to emphasize that with such limited ALS therapies available, we do not want the national formulary to result in a removal of access to any drugs that are currently on existing formularies.

As a member of the HCCC, we recommend that principles should reflect opportunities to manage costs through modern procurement avenues/negotiations and include dynamic features to respond to marketplace cost changes.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

In alignment with HCCC, we support the creation of new or additional criteria that can address both immediate needs for complementary therapies but also support a scalable to whole of person therapeutic approach, especially given the heterogeneous nature of ALS.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

We support the inclusion of related products by making use of the most effective operational model (existing lists or new/dynamic methods) necessary to achieve the patient outcomes identified in the principles. In addition to the products, the methods of drug administration must also be considered within the criteria as many innovative ALS drugs are complex in their method of administration (i.e., intravenous infusion, lumbar puncture).

As a member of the HCCC, we support the changes to CADTH approaches that capitalize on this opportunity to establish a world leading HTA process inspired by the best practices of other jurisdictions while contemplating integration with national centres of clinical excellence and continuous/dynamic methods of incorporating modern medicine.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

We recommend that the goal of achieving a truly universal and equitable national formulary is satisfied by achieving access to products that support all disease states and conditions.

We recommend that therapeutic areas not be compartmentalized for prioritization as many patients, particularly those living with comorbidities of ALS, will face challenges across multiple therapeutic areas.

We acknowledge the aim of developing a rare disease strategy with its own unique approach. However, we hope that one day ALS therapies are not considered under a rare diseases framework and that emerging therapies are taken into consideration under this proposed expansion.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

As a member of the HCC, we support on-going efforts and engagement to overcome any constraints that may be impeding a national formulary and that are contributing to the need to prioritize.

To ensure a transparent way of determining such priorities, we support and encourage further engagement opportunities to clarify and determine the planning and operational consequences of setting priorities.

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5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

As this consultation does not include a strategy for rare diseases drugs, ALS therapies would not be subject to any of these options. However, we support HCCC's recommendation for CADTH to explore and analyze the options further to determine feasibility.

5b. What criteria could be used to identify priority products?

We support clarity in the resource constraints that are contributing to the necessity of an option analysis and priority setting exercise.

We recommend consideration be given to changing operational approaches to allow for a dynamic method of resource management and consultation on those constrains and metrics that are driving the need to engage in a priority setting dialogue.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

ALS is a progressive and fatal neurodegenerative disease. Therefore, equitable access to approved therapies is a critical element for people living with ALS. We consider the need for timely access in alignment with patient and societal values, as equitable access to therapies will play a significant role improving the lives of people with ALS and their families' quality of life.

As a member of the HCCC, we recommend that the feasibility of adopting a therapeutic should be viewed as an opportunity to include emerging therapeutics supportive of on-going improvements to patient care.

We are concerned that limiting inclusion of therapies on a National Formulary that are overcoming challenges with adoption (feasibility) will only further hinder their uptake and could undermine the adoption of new effective products and therapies, which are essential to those living with ALS and other rare diseases.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

As a member of the HCCC, we recognize the importance of a governance model to a successful national formulary and support a governance model that is objective and takes into account authentic and regular patient input.

We recommend that patients and patient caregivers should be among the experts consulted to arrive at the score.

We support the use of a governance model that is inspired by and improves upon existing models of patient inclusion and HTA around the world.

8. 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 reviews)?

We recognize that changes to existing processes will require the input of many different stakeholders.

In accordance with HCCC, we support an iterative process to manage a workload while engaging all groups necessary to achieve a successful National Formulary that is integrated within health systems and remains both sustainable and modern.

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

We express our sincere appreciation for the opportunity to participate in this consultative process. We believe a National Formulary is an important component of a modern and patient focused healthcare system – and we applaud the progress made to date and look forward to continued engagement.

However, given the nature of ALS and the limited therapies available to this community, any new therapies for ALS would likely be managed under a rare disease strategy. As such, we have commented on this submission as a member of HCCC with the hope that ultimately ALS therapies will be considered under a proposed national formulary.

The current approach for rare disease therapies is fragmented across the country. We believe a rare disease strategy in which provincial, territorial and federal governments work collaboratively, is vital to ensuring timely, affordable and equitable access to ALS therapies to Canadians.

In agreement with HCCC, we propose the following considerations in support of a successful National Formulary within the greater context of achieving an integrated patient outcome-based health care system:

• Changing the Conversation – Recognizing that Patient Centric Policy is Cost Effective

• Treating Patients as a Whole

• Rising above Jurisdictional Issues and Creating Systemic Solutions

• Embracing Change as Part of Preserving Canada's Healthcare Legacy

We emphasize that patients must be engaged as equal partners in all consultations and decision-making processes that affect their care. While this consultation represents positive progress, it remains difficult to assess elements of a pan-Canadian formulary in isolation of the other three components that are core to its implementation – that is: terms of coverage, financing and clear decision-making authority.

As we recover from the impacts of the pandemic, we must take this opportunity to apply the lessons we have learned to improve the lives of people living with ALS and other rare diseases. With promising new ALS therapies on the horizon, now is the time act to ensure Canadians living with ALS can access innovative therapies in a timely and equitable fashion.

We look forward to providing continued comment on the outstanding elements that are relevant to the development of a national formulary. We thank CADTH for this opportunity and the important contribution they make to our healthcare system.

Amgen Canada Inc.

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

To the Canadian Agency for Drugs and Technologies in Health ("CADTH"):

We wish to thank you for the opportunity to provide feedback on consultations for a potential pan-Canadian Formulary ("PCF"). Please find below Amgen's feedback and position statements relating to CADTH's consultation and discussion paper released January 11th, 2022.

Canadians need a policy environment that is more patient-centric and sets out to achieve this by promoting research and development, providing predictability for manufacturers, incentivizing technological advances and securing access to novel drugs so that we can keep people out of hospitals, have a healthier and productive workforce, and create resiliency by preventing and better managing chronic diseases.

The federal government has recognized the need for greater investment in health in order to bring about stronger and more resilient Canadian health care systems built around patient outcomes and enhanced adoption of health innovations. Resilient healthcare systems are those best positioned to "predict and prevent" disease by proactively intervening early and delivering solutions that provide the highest value to patients and to society. The current "break and fix" focus of our health system places the majority of our resources on treating health events, as opposed to preventing these events from happening in the first place.

COVID disproportionally impacted patients with non-communicable diseases, highlighting the importance of prevention, diagnostic testing and treatment in order to mitigate morbidity/mortality from future pandemics and system shocks. Amgen is committed to engaging with other healthcare system stakeholders, such as the Resilient Healthcare Coalition. Working together, leaders should be focused on:

• Building health systems that are faster, more agile, and more proactive

• Accelerating and expanding access to innovative diagnostics and therapeutics

• Better leveraging healthcare data to advance value-based procurements in decision-making for access

• Working with the private sector to identify the most pressing care gaps and develop solutions for patients

Amgen supports efforts to make prescription drugs more affordable and more accessible to all Canadians, and 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". We acknowledge that there are gaps in coverage that adversely impact a small percentage of Canadians. Amgen supports reforms to the current system provided they improve patient access to medicines, including by accelerating time to listing and providing greater value recognition for innovations. Such reforms should always be limited to closing identified gaps. A proper review of the pharmaceutical drug access system must be open and inclusive of a broad range of stakeholders, including industry and patient advocates.

Furthermore, policy reform must respect provincial jurisdiction in healthcare and pharmaceutical access, and should not add additional regulatory or administrative burden on manufacturers. Amgen supports Canada's mixed model of private and public coverage, as it provides options for Canadian patients. A public PCF would not be an appropriate reference for privately funded drug coverage.

We applaud the Government of Canada for its recently announced national Biomanufacturing and Life Sciences Strategy, which has also been widely welcomed by industry, patients, and consumers alike. Similarly, we see progress on a Drugs for Rare Diseases Strategy, the Canadian Drug Agency Transition Office, and reconsideration of the outdated and damaging 2019 PMPRB reforms that focused exclusively on price without consideration of their negative impact to access to new treatments or the life sciences environment. We recommend incorporating the potential PCF with these and other major policy initiatives into a more comprehensive, multi-stakeholder policy dialogue 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.

We endorse the response to the PCF Consultation submitted by Innovative Medicines Canada and BIOTECanada, and we would like to emphasize some key aspects:

1) Context and Scoping of PCF Framework

The scope of the current consultation exercise is limited to the development of the PCF list, but specifically excludes discussion of its implementation. The consideration of the PCF list cannot be taken in absence of all other important considerations. It is extremely challenging to provide feedback on a hypothetical product without understanding how it is to be used, including such critical context as to how a federally-conceived list would be funded, how it would be integrated with existing provincial formularies, and to what degree (if at all, even if inadvertently) it would impact private drug coverage. In fact, these are the guiding issues that should be resolved prior to developing the PCF. Given provincial jurisdiction over health care and general cross-province formulary concordance*1 (in part, achieved via the Pan Canadian Pharmaceutical Alliance over the past decade), it is unclear what problem the proposed formulary is trying to solve, and consequently very challenging to answer the questions provided about the list's composition.

Consequently, the remainder of Amgen's response focusses on higher level positions regarding the proposed PCF in the context of a resilient health care system aligned with our position statements above.

2) Gaps in Patient Access

No Canadian should be denied access to necessary medication. There are currently gaps in patient access that we can resolve together, by (1) accelerating time to access, and (2) filling gaps in coverage.

Regarding the first aspect (time to access), Canadian public drug launches and coverage already lag peer countries *2. Additionally, Canadian patients suffer from the lengthening time lag between regulatory approval and reimbursement that several peer countries share. The addition of a PCF would add yet another process to the already extremely crowded and complicated access pathway that Canadian patients must navigate, contrary to the goal of faster access to healthcare. Instead, the government should be focused on creatively considering new pathways for reimbursement promptly upon Health Canada providing regulatory approval for each novel indication (NOC/NOC-c), and only if a PCF could play a part in achieving that objective would it provide great value to Canadians.

Regarding the second aspect (gaps in coverage), although Canada's dual payer system of public and private drug coverage generally works to meet the needs of Canadians and should be fundamentally preserved, there are nevertheless some gaps in coverage that governments are working to address, for example, through provincial efforts to fill targeted gaps in coverage such as Ontario's recent 2022 workstream to make benefits more portable and independent of employer. Amgen supports closing coverage gaps and remains prepared to engage in dialogue to ensure every Canadian has access to medicines.

Should a PCF emerge, it would certainly need to be access-enhancing, in support of full patient/clinician choice, and work to bring public drug plans up to the highest standards, as opposed to a minimalist, lowest common denominator, approach. However, the approach outlined in the discussion paper

specifically excludes 29 medicines (and flags 54 more); some of these medicines may very well have an appropriate place in therapy for certain patients in certain circumstances. The specifics around indication and reimbursement criteria/mechanism make a huge difference to the level of access for patients, yet such specifics remain unaddressed. This list should act only as a guidance to provincial formularies and should be applicable for all Health Canada-approved populations.

3) Focus on Value

A formulary that is patient-centred and designed to be in the public interest must reflect the full value that the innovation brings to Canada and Canadians. Such decisions should not be driven primarily by cost (particularly if assessed based solely on list price), as that will certainly drive down the ability for Canadians to access the most innovative cutting-edge therapies. With Health Technology Assessment (HTA) analysis forming the basis of formulary recommendations, efforts should first be made to improve the appropriateness and utility of HTA to Canadians and within the context of our healthcare system. There are significant disagreements between manufacturers assessment of cost-effectiveness and CADTH's reanalysis, and comparative analysis suggests that CADTH may be structurally more restrictive in its recommendations than some peer HTA jurisdictions, such as NICE in the United Kingdom. HTA value assessments must also remain flexible to address unique treatments in certain therapeutic areas (see below) and evolve to facilitate the use of tools to define and revisit value based on available information so that patients can gain the earliest possible access to new treatments; such tools may include innovative outcomes-based payer models and real-world evidence supplementing more mature clinical data from larger and/or comparative trials. How these value- and access-enhancing directions would be impacted by a possible PCF requires further discussion and elaboration.

It should go without saying that any PCF would clearly not be appropriate as a reference for private payers who have their own distinct processes and value assessments reflecting the different patient populations and needs served by private plans.

Given the valuation challenges posed by precision and oncology medicines, Amgen does not believe that a PCF could be appropriately expanded to those areas. There are significant challenges associated with implementing oncology algorithms or of appropriately assessing the value of combination therapies. Additionally, we would like to note the controversy associated with recent changes in the informal willingness to pay (WTP) thresholds being cited in CADTH recommendations for oncology medicines, shifting from an already deflated implicit $100,000/QALY WTP threshold in the oncology space to a $50,000/QALY WTP threshold. This has contributed to the increase in recent CADTH recommendations calling for 90%+ price reductions, thereby leading to more protracted negotiations and reduced access downstream. It has caused considerable concern among industry and patients, and is a topic that requires urgent dialogue and consultation. These complexities are a cautionary consideration against the PCF being extended to oncology and precision medicine areas.

Amgen appreciates the opportunity to provide feedback and remains open for dialogue and collaboration with CADTH with the goal of developing a more resilient healthcare system.

John Snowden

Executive Director – Value, Access & Policy

Amgen Canada Inc.

*1 Alignment Among Public Formularies in Canada, Part 1: General Overview, National Prescription Drug Utilization Information System – Patented Medicine Prices Review Board, 2017

*2 Access to Medicines in Public Drug Plans: Canada and Comparable Countries, Innovative Medicines Canada, 2016

Apotex Inc.

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

• Overall, Apotex agrees with the proposed principles. The procedures for how these principles will be implemented, however, lack detail and remain a concern.

• Specifically, Apotex has identified Sustainability as a key principle for a national formulary. Cost-effectiveness is an important strategy to achieve a sustainable formulary. Cost-saving off-patent prescription medicines, including biosimilars and generics, will support feasibility and long-term thinking for a proposed pan-Canadian formulary. Apotex is pleased to see the commitment to emphasize the use of generic and biosimilar products, as they provide safe and effective treatments that are cost effective.

• Making prescription drugs more affordable and accessible is a key value proposition of the pharmaceutical industry. Apotex supports the recommendations in the Final Report of the Advisory Council on the Implementation of National Pharmacare for mandatory generic substitution policies to encourage patients and prescribers to choose the most cost-effective therapies, and increase patient and prescriber awareness about the equivalency of generic and brand-name prescription medicines.

• Part of cost-effectiveness includes transparent pricing to ensure that the formulary can achieve maximum benefit for expenditure. Thanks to initiatives between CGPA and the pan-Canadian Pharmaceutical Alliance (pCPA), the National Generic Tiered Pricing Framework and generic drug prices are publicly available and transparent. That being said, there are some issues that any formulary will need to address in pricing transparency to maximize cost-effectiveness. First, actual prices of multi-source products should be transparently listed on formularies.

• Confidential product listing agreements (PLAs) for originator medications can and often do limit the ability to introduce lower-cost generic and / or biosimilar medicines, hindering a formulary's ability to achieve maximum cost-effectiveness. When establishing a national formulary based on the principles of sustainability, confidential PLAs must not be allowed. If they are allowed, any confidential PLA put in place prior to the market entry of generic versions should be removed upon generic market entry.

• Reference based pricing, where reimbursement in a therapeutic category is limited to the lowest cost molecule, undermines the stability and predictability of generic pricing, an environment achieved through the pCPA/CGPA Generic Pricing Framework. Under the principles of transparency and fairness, a future Pan Canadian formulary should avoid reference based pricing. Similarly, step-based therapy, or "tiering", should only be implemented on a basis of clinical need

• Sustainability as a principle should support domestic manufacturing capability to foster a strong and resilient domestic drug supply. Domestic drug manufacturers, such as Apotex, are committed to the health and wellbeing of Canadians as their first priority

• In addition, Principle 1 (Universal and integrated) is also important to ensure Canadians have access to the prescription medicines they need through a national formulary. It is recommended that hospital products are included on the proposed formulary to ensure improved continuity of care between hospital and community pharmacy settings.

• "Efficient and Timely": Duplication caused by the varied formulary listing and interchangeability designation processes employed by each province and territory increases administrative costs for both public drug plans and pharmaceutical manufacturers, and leads to uneven patient access and care across Canada. This can result in delays to access to cost-saving medicines to payers and patients. Generic and biosimilar medicines must be added to the formulary without delay following market authorization by Health Canada in order to clear budget headroom to fund new treatments and increase patient access.

• With respect to the priority of "Effective and High Quality", all drugs, both brand-name and generics, are reviewed and authorized for sale by Health Canada before they are available for prescription. When a generic drug is approved, Health Canada continues to monitor its safety, effectiveness, and quality. Generic medicines are required to work the same way in the body as the original brand-name drug.

• Generic medicines have the same active ingredient as the brand-name and must have the same amount of active ingredient in the prescription. Non-medicinal ingredients, like fillers and preservatives, may be different from the brand-name product, but they are also regulated and reviewed by Health Canada. To receive a license to manufacture and sell drugs in Canada, both brand-name and generic drug companies must follow the same Good Manufacturing Practices (GMP) guidelines, which ensure consistent production and quality standards.

• A Health Canada approval for a biosimilar product confirms there are no expected clinically meaningful differences in efficacy and safety between a biosimilar and the biologic drug that was already authorized for sale. Further, Health Canada's Biosimilar Biologic Drug fact sheet states: "Patients and health care providers can have confidence that biosimilars are effective and safe for each of their authorized indications. No differences are expected in efficacy and safety following a change in routine use between a biosimilar and its reference biologic drug in an authorized indication."

2. Do you agree with the proposed assessment criteria?

Yes

Please provide the reason(s) and suggested changes, if any.

• Apotex supports maximizing the use of cost-saving off-patent products through policies requiring well-controlled physician-supervised biosimilar switching and generic substitution when these products are available, as recommended by both this Panel and the Advisory Council on the Implementation of National Pharmacare. Biosimilar and generic versions of the most commonly prescribed products are available soon after patent issues are resolved.

• Generic and biosimilar medicines must be added to the formulary without delay following market authorization by Health Canada in order to clear budget headroom to fund new treatments and increase patient access.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

• The process must be transparent and include related products to ensure that patients access to the medicine is provided without further barriers, which is a key principle for the establishment of a national formulary. This would include, for example, ongoing testing needed for appropriate monitoring and patient adherence. Generic and biosimilar medicines must be added to the formulary without delay following market authorization by Health Canada in order to clear budget headroom to fund new treatments and increase patient access.

• There should be no clinical re-evaluation for biosimilar and generic medicines, whose approval by Health Canada are based on comparison to the originator reference product.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

• If the drug meets the evaluation criteria, then any devices / testing needed for the patient to effectively use the drug must be listed on the formulary

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

• Apotex supports maximizing the use of cost-saving off-patent products through policies requiring well-controlled physician-supervised biosimilar switching and generic substitution when these products are available, as recommended by both this Panel and the Advisory Council on the Implementation of National Pharmacare. Biosimilar and generic versions of the most commonly prescribed products are available soon after patent issues are resolved.

• Generic and biosimilar medicines must be added to the formulary without delay following market authorization by Health Canada in order to clear budget headroom to fund new treatments and increase patient access.

• There are certain products – such as oncology and HIV drugs – that are not funded as a regular benefit on all drug plans. Additional analysis may be needed to determine whether these products are covered in other ways. The Panel suggests that these products be included in a national formulary, and Apotex supports their inclusion.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

• Any expansion should be based on medical needs and sustainability, patient access and cost-saving, such as the availability of generic and biosimilar medicines.

• An expansion focused on chronic therapies where biologic drugs have high utilization would provide significant value to those patient populations. Therapeutic areas where cost-saving biosimilars are available should be prioritized to support sustainable access. These therapeutic areas include diabetes (already included on sample list), rheumatoid arthritis, inflammatory bowel disease, dermatology, and ophthalmology.

• Covering the biosimilar and generic in approved indications where the originator was not reimbursed warrants consideration as cost-effectiveness is improved.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #1

Please provide the reason(s) for your choice.

• Apotex recommends a combination of Option #1 and Option #2 be adopted. Option #1 is aligned with the current HTA process, and the inclusion of Option #2 would help to address unmet medical needs. Apotex does not support Option #3 as this approach is inefficient and would lead to delayed access to new products

5b. What criteria could be used to identify priority products?

• Generic and biosimilar medicines must be added to the formulary without delay following market authorization by Health Canada in order to clear budget headroom to fund new treatments and increase patient access.

• Cost-saving biosimilar and generic medicines should be automatically identified as priority products. Apotex supports a streamlined approach for the additional of biosimilars and generics whereby standardized and accelerated listing criteria is employed. In addition, prior authorization requirements for biosimilar and generic medicines should be removed.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

• Apotex agrees with the proposed evaluation criteria and recommends that priority emphasis be given to "Value" as a criterion, where "Value" means meeting patient needs in a sustainable way with multiple therapy options available, and not limiting treatment to only the lowest cost product.

• Generic and biosimilar medicines must be added to the formulary without delay following market authorization by Health Canada in order to clear budget headroom to fund new treatments and increase patient access.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

• Value as a criterion should be given priority. "Value" should relate to meeting patient needs in a sustainable way where multiple therapy options are available, and not limiting treatment to only the lowest cost product. Apotex supports a streamlined process for biosimilar and generic medicines, including for any biosimilar or generic indications that are not covered for the originator product.

• The Panel's intended meaning for "integration into other systems" is not clear. Apotex would appreciate clarification.

8. 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 reviews)?

• Clear timelines with expedited / automatic listings should be available for generic and biosimilar medicines.

• In addition to a lowest-cost alternative rule, only generics and biosimilars should be listed on any national formulary if they are approved by Health Canada and available in the Canadian market. An example of this approach is the Government of Prince Edward Island's Generic Drugs Program

• Reference based pricing, where reimbursement in a therapeutic category is limited to the lowest cost molecule, undermines the stability and predictability of generic pricing, an environment achieved through the pCPA/CGPA Generic Pricing Framework. Under the principles of transparency and fairness, a future Pan Canadian formulary should avoid reference based pricing. Similarly, step-based therapy, or "tiering", should only be implemented on a basis of clinical need.

• The implementation of a national formulary should also include a national interchangeability designation for all authorized drugs, based on Health Canada's Declaration of Equivalence (DoE). Furthermore, a single governance structure for interchangeability designation that all public plans defer to would provide consistency, streamline drug evaluations, and reduce gaps in access.

• To guarantee long-term sustainability for biosimilar manufacturers and maintain Canada as an attractive market while providing clinicians & patients with more choice, all biosimilars approved by Health Canada should be listed on the formulary. Biosimilar switching policies should be implemented and new products should be quickly added to the policies when available to maximize potential savings.

• The pan-Canadian Pharmaceutical Alliance (pCPA) has identified several measures that support sustainability on page 8 of its Biologic Policy Directions & pCPA Negotiations document and its September 2019 Biosimilars Review Process and pCPA Negotiations Update. Both documents can be accessed at https://www.pcpacanada.ca/biologics-biosimilars

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

• The pCPA / CGPA Generics Initiatives have achieved significant savings for all Canadian payers and no new initiatives should interfere with this pan-Canadian success.

• Some of the most prescribed generic medicines are priced at a 90 percent discount off the price of the brand-name versions. That means up to 10 patients can be treated for the cost of treating one patient with the brand-name version.

• The COVID-19 pandemic has highlighted the need to strengthen Canada generic pharmaceutical manufacturing capacity and the international pharmaceutical supply chain. A recent study by consulting firm EY Canada commissioned by CGPA reports that global supply chains have become increasingly complex, introducing risks, disruptions and shortages of prescription medicines. These risks, such as export restrictions, interruptions to international transportation, and reliance on foreign partners, highlight the importance of measures to support the manufacture of prescription drugs in Canada and secure channels of import for medicines and inputs needed to produce them.

• The generics market in Canada faces downward pressure on pricing with increasing costs of labour, land, transportation and a complex regulatory regime. Combined, these elements are increasing the fragility of the domestic industry.

• While Apotex is supportive of efforts to improve drug coverage for Canadians, we caution against the pursuit of risky tendering schemes with unknown savings results that could threaten the current and future supply of cost-saving generic and biosimilar pharmaceutical products in Canada.

• By limiting the number of suppliers for a given medicine, tendering increases the risk of drug shortages and could lead to higher prices in the long-term as manufacturers are forced out of the market. If the chosen supplier or suppliers have production or other issues, alternatives to meet patient needs may not be available. International experience has demonstrated that tendering for biosimilar medicines is unsustainable and, as such, must be avoided in Canada.

• Unlike pricing mechanisms such as tendering schemes, the Tiered Pricing Framework of the pCPA Generics Initiative helps maintain the incentive for generic pharmaceutical manufacturers to challenge invalid and / or non-infringed patents under Canada's patent rules for pharmaceuticals. It is in the interest of all Canadian payers and patients to ensure that these incentives remain in place.

• In line with best practices employed for biosimilar switching policies implemented by Canadian jurisdictions, biosimilars should automatically be listed where the reference biologic drug is listed and trigger the start of a six-month biosimilar switch/transition period. A shorter transition period may be justified for some products. The reference biologic drug should then be delisted after the specified period and only be available in rare circumstances when there is an acceptable medical justification for the patient to remain on the reference biologic drug.

• Care must be taken to ensure that the potential benefits of a national formulary are not undercut by pricing schemes that reduce the current and future availability of cost-saving generic and biosimilar prescription medicines.

• Implementation of a national formulary should include processes that defend against marketing efforts to switch patients to a more expensive new patented medicine that does not provide therapeutic improvement when biosimilar or generic competition is set to enter the market.

• Multiple drug options should be included in the same therapeutic category to meet individual patient needs and to mitigate any impact of a drug shortage.

• Reference based pricing, where reimbursement in a therapeutic category is limited to the lowest cost molecule, undermines the stability and predictability of generic pricing, an environment achieved through the pCPA/CGPA Generic Pricing Framework. Under the principles of transparency and fairness, a future Pan Canadian formulary should avoid reference based pricing.

• Similarly, a national formulary should avoid "tiering" where certain drugs are "preferred" over / prior to reimbursement of other medicines, except in clinical necessary cases.

• The ongoing sustainability of our health-care system and drug benefit plans is highly dependent on the increased use of generic and biosimilar prescription medicines. More must be done to increase generic and biosimilar utilization and the resulting savings to Canada's health-care system.

Arthritis Society

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

The Arthritis Society agrees with proposed principles and there is alignment with the principles developed by Health Charities Coalition of Canada (HCCC). We support comments submitted by HCCC for this question.

We support HCCC's recommendation that consideration be given to updating Principle 3: Effective and High Quality: An effective and high-quality national formulary is one that achieves better patient outcomes, comprehensive access to medicine and cost savings over what could be achieved by any one provincial or territorial formulary on its own. We recommend expanding the content/process values under Principle 3 to include consideration of patient preference and benefits as mentioned in the document (ease of administration, time required for treatment, access to treatment etc).

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The Arthritis Society supports the comments provided by HCCC for this question. We agree with HCCC's comment that this is an opportunity to look at information not previously considered or that is new using the lens of the proposed principles. The Arthritis Society supports the availability of biosimilar products as being part of the assessment criteria. We note that for people living with arthritis, it is essential that there be a broad range of treatment options, including biologics, as finding the right treatment is still very much trial and error. Ensuring that the right drug gets to the right patient at the right time must always be the core objective.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

The Arthritis Society supports the comments submitted by HCCC. We also agree with comments made by the Advisory Panel on the potential to improve patient access and adherence. We strongly recommend that patients, caregivers and family members be involved right from the start in developing criteria and eligibility for related products to be listed on the pan-Canadian formulary.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

We support the comments submitted by HCCC for this question.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

We agree with HCCC that the goal of achieving a truly universal and equitable national formulary is satisfied by achieving access to products that support all disease states and conditions.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

The Arthritis Society agrees with HCCC that there should be on-going efforts and engagement to overcome any constraints that may be impeding a national formulary and that are contributing to the need to prioritize.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

We agree with HCCC and recommend that CADTH further explore and analyse the options through engagement and collaboration with all stakeholders to determine a recommended option.

5b. What criteria could be used to identify priority products?

We support the comments made by HCCC in response to this question

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The Arthritis Society supports the comments provided by HCCC.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

The Arthritis Society supports the comments provided by HCCC to the question.

8. 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 reviews)?

The Arthritis Society support HCCC's response to this question. We support an iterative process to mange workload while engaging all groups necessary to achieve a National Formulary that is integrated within health systems, supports better health outcomes, and remains sustainable and modern.

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

We echo HCCC's comments that patients must be engaged as partners in all consultations and decision-making processes that affect their care. While this consultation represents positive progress, it remains difficult to assess elements of a pan-Canadian formulary in isolation of the other three components that are core to its implementation: terms of coverage, financing and clear decision-making authority. We must capitalize on emerging opportunities to address the well-known gaps in our healthcare system. Now is the time to act as we recover from the impacts of the pandemic. Along with HCCC, the Arthritis Society looks forward to providing continued comment on the outstanding elements that are germane to the development of a national formulary. Thank you for the opportunity to provide feedback.

Association des médecins endocrinologues du Québec

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

While you identify sustainability (of the drugs coverage plan) as one of the principles, we believe that it should be the key principle. With the steep increase in the use and cost of new medications and related products over the past decade and with an aging population with many chronic illnesses, decisions concerning the addition of a drug to the formulary must take into account the survival of the coverage plan if a drug (and similar drugs) is to be added.

In the principle «effective and high quality», the criterion «evidence-based» is mentioned as the cornerstone to evaluate drugs for listing. We cannot agree more. However, for many orphan and low incidence diseases, evidence is often scarce and of a low level of evidence. It should be determined how this low level of evidence will be dealt with.

We agree with all other principles.

2. Do you agree with the proposed assessment criteria?

No

Please provide the reason(s) and suggested changes, if any.

We are puzzled by the procedures put into place to assess the addition of a drug to the list. While the list of principles (mentioned in question 1) is clear and adequate, procedures to create the first list use shortcuts that are not rigorous on scientific grounds and do not take into account sustainability. For example, the fact that a drug will be listed only because it is part of most provincial lists without taking into account if there are restrictions to its prescription or consideration to its place in the treatment algorithm is worrying. The decision should, at least, be based on a literature review and be informed by evaluation made by other bodies such as INESSS, NICE (in the UK) and the like.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

It is important to have related products on the list. These products often changed the quality of life of patients (for example, the use of CGMS in diabetes) or they relieved symptoms of a disease (e.g. CPAP for sleep apnea). The proposed criteria should be applied in evaluating related products.

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No

If yes, how should weight be distributed among the proposed criteria?

A complex issue such as drug coverage should not be reduced to a sum of weighted appraisal. The richness of the discussion and appraisal of the different aspects, in all transparency, is more likely to develop into a balanced decision than a mere addition of subjective weighted criteria.

8. 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 reviews)?

No response provided

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

No response provided

Association québécoise des pharmaciens propriétaires (AQPP)

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

Les principes proposés semblent tous appropriés. Nous pensons que le concept de solidarité sociale pourrait être ajouté à l'un des principes afin de reconnaître les besoins médicaux uniques de certaines populations.

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

Les critères d'évaluation proposés ne semblent pas articuler clairement comment la décision serait prise d'ajouter un produit qui répond aux besoins d'un petit groupe de patients dans une région. Nous suggérons que les différences régionales soient prises en compte d'une manière ou d'une autre. Le Canada présente certaines particularités géographiques qui sont plus évidentes lorsqu'il s'agit de maladies rares, c'est d'ailleurs le cas au Québec. Nous n'avons pas trouvé que la reconnaissance et le soutien des citoyens ayant des besoins cliniques uniques est reflété. Dans une optique d'universalité, il faut également un mécanisme pour garantir l'accès aux thérapies pour les patients ayant des besoins particuliers.

En outre, les régimes d'assurance-médicaments provinciaux évaluent depuis de nombreuses années les médicaments à inclure dans les formulaires provinciaux. Il semblerait logique de veiller à ce que ceux-ci soient consultés afin d'intégrer leur expertise dans le processus.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

Si un produit est inscrit sur une liste de médicaments, il est tout à fait naturel que les produits connexes qui sont utilisés pour faciliter son administration soient également couverts. À ce titre, les critères d'admissibilité pourraient être simplifiés et principalement reconnaître l'inscription du médicament.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

L'approche proposée semble pouvoir être étendue à d'autres domaines thérapeutiques. Toutefois, avant de s'engager dans des investissements supplémentaires en temps et en efforts, il semblerait sage de s'assurer d'abord qu'il existe une vision de la manière dont tout cela serait intégré dans d'autres stratégies. Nous comprenons que le travail du panel était complexe et limité puisqu'il n'incluait pas les points suivants. Nous pensons que ces points doivent être clarifiés avant de poursuivre les travaux.

- une évaluation des processus ou des attentes des régimes d'assurance-médicaments actuels quant à l'incidence d'un éventuel formulaire pancanadien sur la couverture des régimes d'assurance-médicaments existants ou sur la façon dont celle-ci pourrait être modifiée

- la détermination des structures de gouvernance pour la mise en œuvre d'un éventuel formulaire pancanadien (c.-à-d. quelle organisation ou entité devrait superviser la mise en œuvre d'un éventuel formulaire pancanadien ou prendre les décisions de financement)

- l'examen des questions de financement (p. ex., l'affectation des fonds ; les contributions financières ; les modèles de financement ; la portée, la taille et le montant du budget ; les budgets des régimes d'assurance-médicaments individuels ou les estimations prévues pour ces budgets)

- les conditions de couverture (par exemple, les contributions des patients telles que les copaiements ou les franchises) et l'admissibilité des patients, y compris leur statut

- la prise en compte de l'interaction entre les régimes d'assurance publics et privés (c'est-à-dire la couverture en tant que premier et deuxième payeur)

- d'autres initiatives pharmaceutiques en cours (p. ex. la stratégie de Santé Canada sur les médicaments pour les maladies rares) ; bien qu'elles ne fassent pas partie du mandat du groupe, on prévoit que les recommandations de ce rapport préliminaire pourraient être utilisées pour éclairer la discussion sur un cadre décisionnel pour les médicaments pour les maladies rares.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

D'après ce que nous comprenons, les évaluations d'inscription au formulaire se feraient après qu'un produit ait reçu un avis de conformité de Santé Canada et que l'ACMTS/INESSS ait terminé son examen. Ainsi, un processus d'examen de type " premier entré, premier sorti " semblerait déjà tenir compte des critères d'examen prioritaire des autres organisations.

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

Les critères proposés semblent englober les différentes facettes à inclure. Nous nous demandons comment ce processus pourrait faire double emploi avec le travail d'organisations existantes telles que l'INESSS.

L'AQPP désire aussi souligner qu'il est important d'évaluer les programmes de soutien aux patients qui accompagnent plusieurs médicaments. Ces programmes se multiplient avec l'arrivée de nouveaux médicaments pour des maladies plus rares. Ce sont habituellement des médicaments dispendieux. Ces programmes ont une incidence importante dans l'utilisation et la distribution des médicaments. Malgré les prétentions des programmes, ceux-ci ne servent pas toujours l'intérêt des patients. L'AQPP a constaté que de nombreux programmes créent des réseaux de distribution parallèles en ayant recours à des pharmacies dites de spécialité. Cette pratique est à l'encontre des lois et règlements en vigueur au Québec alors qu'un patient doit voir son droit de choisir son pharmacien être respecté en tout temps. Les programmes viennent s'immiscer dans des relations thérapeutiques et ajoutent de la complexité. De plus, les services offerts dans le cadre de ces programmes ne sont souvent pas économiquement rentables pour la société alors que les mêmes services peuvent être offerts ailleurs par les réseaux existants à moindre coût. Les coûts de ces programmes de soutien mis en place par l'industrie sont inclus dans le prix des médicaments. Ainsi, ce sont les payeurs privés et publics, individuels ou collectifs, qui absorbent les coûts des programmes de soutien alors que les mêmes services peuvent être obtenus ailleurs ou sont même dupliqués. Ainsi, l'AQPP demande à ce que l'évaluation d'un médicament inclue aussi systématiquement l'évaluation d'un programme de soutien aux patients ou un plan de gestion de risques. Il est important que ces programmes :

• Respectent les lois et les règlements partout à travers le Canada_;

• Ne limitent pas la distribution du médicament à certaines pharmacies choisies par un programme ou un manufacturier_;

• Ne restreignent pas la capacité d'une personne de choisir librement son pharmacien_;

• Démontrent que les services offerts ne sont pas disponibles autrement dans le réseau public de la santé ou dans les pharmacies communautaires_;

• Démontrent une juste valeur marchande pour les services offerts dans le cadre du programme afin de payer un juste prix pour les médicaments.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

Nous suggérons que les processus suivis par l'INESSS et l'ACMTS soient mis à profit. Le Québec possède une grande expertise dans l'évaluation des médicaments en vue de leur inscription au régime d'assurance-médicaments provincial.

8. 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 reviews)?

Étant donné que l'ACMTS et l'INESSS étendent déjà certains de leurs travaux en matière de réévaluation des recommandations d'inscription ou d'examens thérapeutiques, il semble approprié d'explorer comment les travaux en cours dans ce domaine pourraient être optimisés, surtout lorsqu'il s'agit de fournir des conseils fondés sur des données probantes aux professionnels de la santé.

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

L'AQPP croit à l'importance de permettre à tous les canadiens de bénéficier d'une couverture d'assurance médicament. Cependant, cela ne doit pas se faire sans prendre en compte les risque de diminution de l'accessibilité à un inventaire adéquat des médicaments. Bien qu'imparfait, le RGAMQ fait bonne figure et permet aux québécois de bénéficier d'une couverture adéquate. L'AQPP souhaite le maintien d'un système mixte, à l'image du système actuellement en place au Québec. Pour ce faire, l'AQPP s'appuie sur quelques principes directeurs qui viennent renforcer la pertinence de cette position :

a. Accessibilité et équité

b. Coûts

c. Respecter les compétences des provinces

d. Indépendance et efficacité

Ainsi, quoique l'AQPP reconnaisse l'excellent travail qui a été accompli par le comité d'expert, il est de notre avis que tous travaux futurs en lien avec cette initiative soient suspendus jusqu'à ce que les discussions entre les provinces et le gouvernement fédéral permettent de comprendre comment se

déroulerait la mise en œuvre d'un tel formulaire. Pour l'instant, rien ne porte à croire que le Québec se joindrait à une telle approche, préférant maintenir l'expertise provinciale en place qui répond très bien aux besoins des québécois.

Astellas Pharma Canada, Inc.

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

Astellas Pharma Canada, Inc. Response to the CADTH Consultation on a Potential Pan-Canadian Drug Formulary Framework

On behalf of Astellas Pharma Canada, Inc. (Astellas), thank you for the opportunity to provide feedback on the CADTH Consultation on a Potential Pan-Canadian Drug Formulary Framework. Astellas has

contributed to and supports the joint Innovative Medicines Canada-BIOTECanada response to the CADTH consultation. Herein, our aligned position is further articulated with feedback on opportunities for the potential framework.

Astellas' vision is to be at the forefront of healthcare change to turn innovative science into value for patients. We are relentless in our pursuit of scientific progress and in identifying unmet medical needs from multiple perspectives. Our current and future research includes a focused area approach within blindness and regeneration, mitochondria biology, genetic regulation and immuno-oncology. We seek to enhance value in a sustainable manner, to gain and maintain the trust of our stakeholders, and thereby to be a preferred partner in the delivery of healthcare for Canadians.

The Need to Focus on Innovation

The management of drug expenditures is the responsibility of the jurisdictional federal, provincial, and territorial governments. Hence each jurisdiction already has its own drug formularies which undergo periodic updates and revisions. The proposed test case illustrates this point. Across the therapeutic areas included (i.e., cardiovascular disease, diabetes and psychiatric illness), the drug formularies are similar across the country. Re-examining drugs already on the formularies is not necessary. From our company's perspective, public drug formularies should anticipate treatments for rare diseases, continuity of funding for oral oncolytics, cell and gene curative therapies, and personalized medicine, which may include companion diagnostics.

Proposed Guiding Principles

CADTH has proposed six guiding principles, which are reasonable as stand-alone virtues. The guiding principles should be applied to make innovative new medicines available to Canadians. The narrow scope of the test case is insufficient to capture how any guiding principles will be applied to enhance access to innovative medicines.

Limited Scope of Consultation

The scope of the consultation limits the ability to provide specific responses to the granular questions posed. For example, the consultation purposely excludes consideration of "current drug plan processes or expectations about whether or how coverage on existing drug plans might be impacted" and "the interplay between public and private insurance plans".1 Existing formularies need to serve as performance benchmarks for enhanced access (e.g., listed drugs, terms of access, copay structures, and other policies accounting for prudent utilization and affordability) . Excluding these considerations removes necessary context for the evaluation of the proposed framework.

Thank you for the opportunity to submit our feedback. Astellas welcomes opportunities to work with CADTH, federal, provincial, territorial, and third-party drug plans, patients and related stakeholders on initiatives to optimize the delivery of innovative medicines to Canadians.

1. Building Toward a Potential Pan-Canadian Formulary, CADTH Consultation Document. CADTH, January 2022.

2. Understanding the Gap. A Pan-Canadian Analysis of Prescription Drug Insurance Coverage. The Conference Board of Canada, December 2017.

Asthma Canada

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Asthma Canada is the only national health charity solely dedicated to providing evidence-based, education, management tools and support programs for Canadians living with asthma. We also advocate to improve the quality of life for people living with asthma and invest and support strategic research to ultimately find a cure.

Asthma is a chronic lung disease which restricts the airflow into the lungs, making it difficult for more than 3.8 million Canadians to breathe. Asthma symptoms are triggered by many environmental factors that cause symptoms such as shortness of breath, chest tightness, wheezing and coughing which constrict the airways (bronchial tubes). In 2018, it was estimated that nearly 300 Canadians are diagnosed with asthma every day, and roughly 4 Canadians die from an asthma attack each week.

While asthma cannot be cured, it can be managed by using appropriate medications. Using prescribed medications reduces exacerbations, prevents hospital admissions and deaths. The ability for those living with asthma to access new and innovative drugs in Canada is essential to our community's wellbeing. It can be the difference between living an active, productive life and not being able to function or even breathe. For our community, access to prescription drugs also has the potential to save lives.

Our 2019 annual survey revealed the following from our community:

How is the cost of your asthma medication covered?

- Provincial Drug Plan: 38%

- Full Private Coverage by Employer: 24%

- Partial Private Coverage by Employer: 34%

- Private Insurance: 13%

- Self-Finance: 21%

Close to one-third (30%) of respondents indicated that their current drug coverage is not sufficient to help them keep their asthma symptoms under control.

Not surprisingly, respondents in the lower income groups are most dependent on the provincial government's support to cover the cost of their asthma medications with almost 56% respondents in the ≤$19,000 income group reporting that they rely on the provincial drug plan to cover the cost of their asthma medications as against 40% average of all income groups.

Additionally, 30% respondents in this group reported that they self-finance the cost of their asthma medications - the highest proportion among all the income groups.

In addition, only 11% of those in the ≤$19,000 income group, and 33% of those in the $20K-$49,000 income group reported that their employer covers their asthma-related expense either partially

or completely through private insurance.

Asthma Canada's position on access to medicine is that inability to access and afford medications has adverse effects on already vulnerable populations and leads to poor health outcomes. It is essential that all levels of government work to eliminate this barrier and establish consistent support across the country that enables access to prescription medications and offers choice in treatments based on health outcomes, not cost.

As an active member of Health Charities Coalition of Canada, we fully support HCCC's responses to this consultation that was developed by and for its members including Asthma Canada. Asthma Canada recognizes and supports the existing alignment between CADTH principles and those of HCCC.

Asthma Canada recognizes that a sustainable and modern formulary, that places principles of patient need ahead of cost containment, is an aspirational goal to be achieved through the integration of formulary decision making within the greater healthcare system.

Asthma Canada recommends that point in time decisions influenced by competing principles of cost-effectiveness and patient need be viewed as opportunities for transparent patient engagement and issue identification for immediate or ongoing system change.

Asthma Canada recommends that consideration be given to updating Principle 3: Effective and High Quality: An effective and high-quality national formulary is one that achieves better patient outcomes, comprehensive access to modern medicine and cost savings over what could be achieved by any one provincial or territorial formulary on its own.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Asthma Canada recognizes the benefits to a staged approach and efforts that have led to the pilot list of products. We note the success of the pilot will be determined by the impacts of any unmanageable changes to patient therapies and improved or loss of therapies.

We would like to highlight that the creation of a national formulary is an opportunity to consider information not previously considered as well as improve interfaces between formulary decisions and other aspects of healthcare. We recommend that in parallel to exercises that nominate products from existing formularies, a new process also be considered that re-sets past decisions based on current healthcare considerations and principles that support holistic patient care.

Asthma Canada recognizes that biosimilars are by definition not the same as biologics. This is reflected in the nature of the evidence required, and process for authorization by Health Canada which is distinctly different than that of generic drugs. Clinically, biosimilars and biologics are recognized as not being the same and substitution principles should be tailored accordingly to ensure that a switch will not jeopardize a patient's treatment stability due to immunogenicity. Ensuring that the right drug gets to the right patient at the right time must always be the core objective. While there are no biosimilars for asthma at the present time, it is imperative that these principles be considered when biosimilars

are added to the formulary for those living with asthma who depend on a biologic to save their lives. Medication and device choices/switches should only be conducted by prescribers, with patient knowledge, consent, and training, to support adherence and optimize outcomes.

Asthma Canada notes that the full plan (timelines, necessary steps, transitions, decisions, considerations) is not clear and that it is difficult to comment on discrete aspects of a plan to reach a national formulary without understanding the entirety of the approach.

We recommend that a change management strategy should accompany any transition to a national formulary and a principle of avoiding any changes to therapy could/should/must be considered. (A 'grandfather' clause etc).

We also recommend that principles should reflect opportunities to manage costs through modern procurement avenues/negotiations and include dynamic features to respond to marketplace cost changes in addition to cost savings from classic substitution of generics/biosimilars.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

Asthma Canada supports the creation of new or additional criteria that can address both immediate needs for complementary therapies but also support a scalable to whole of person therapeutic approach.

For the Asthma Community, this would include the use of several different types of devices to deliver life-saving medications which included inhaled corticosteroids, short acting beta agonists, long acting-beta agonists, long-acting muscarinic agonists, as well as devices for dual and triple therapy. Also, it's important to the asthma community to have access to devices that make it easier for individuals to take their medicine properly such as valved-holding chambers/spacers. These devices are useful for children and for those who may have dexterity or cognitive issues, for whom coordinating the proper use of an inhaled medication is very difficult. Unfortunately, the improper use of inhaled medication is a serious concern for the Asthma community, leading to poor management and adherence. This is particularly of concern to children, teens/young adults, and seniors.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

Asthma Canada supports the inclusion of related products by making use of the most effective operational model (exiting lists or new/dynamic methods) necessary to achieve the patient outcomes identified in the principles. We also support changes to CADTH approaches that capitalize on this opportunity to establish a world leading HTA process inspired by the best practices of other jurisdictions while contemplating integration with national centres of clinical excellence and continuous/dynamic methods of incorporating modern medicine.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

Asthma Canada recommends that the goal of achieving a truly universal and equitable national formulary is satisfied by achieving access to products that support all disease states and conditions. We recommend that therapeutic areas not be compartmentalized for prioritization, as many patients will face challenges across multiple therapeutic areas.

Through Asthma Canada's annual surveys, we have been able to identify critical gaps in asthma care in Canada. There are three groups most vulnerable and adversely impacted by asthma – individuals in lower income brackets, young adults, and those with Severe Asthma. Asthma disproportionately impacts their mental health and the overall quality of life. Lower annual income not only makes it difficult to afford prescription medicines, but it also leads to circumstances that can exacerbate asthma such as, poor quality housing/maintenance, and/or longer working hours. It is also clear that those with Severe Asthma require additional supports to help them improve their overall quality of life, as well as support with the cost of medications.

Revealed from our 2019 annual survey:

Have you skipped filling a prescribed asthma medication due to inability to afford it? (Yes – Variation by income level)

- <$19K: 54%

- $20-49K: 26%

- $50-99K: 24%

- $100-149K: 14%

- $150K +: 8%

Have you skipped filling a prescribed asthma medication due to inability to afford it? (Yes – Variation by Age Group)

- 17 and under: 3%

- 18-34: 33%

- 35-64: 25%

- 65 and above: 12%

Respondents that believe their drug coverage support is insufficient: (variation by asthma severity)

- Mild Asthma: 12%

- Moderate Asthma: 29%

- Severe Asthma: 49%

Hear the patient voice:

"The cost of controller inhalers is insane. Thankfully, my family doctor gives me free samples so that I have the meds I need, otherwise would just rely on environmental control and my rescue inhaler, like many do. I had to leave my last job because it bothered my asthma too much and at that point, was on controller inhalers costing $200 plus each. It 's something that very much needs to change for asthma patients, the cost of these medicines."

"Asthma meds are too expensive for a person on minimum wage and no benefits. Eat or breathe, what a choice."

"When I have been unable to afford coverage, I have reduced my dosage to make it between paydays."

"I had to take more of my medication and wasn't able to refill it early, so I waited and used my kid's asthma medication."

"Some drugs cost a lot — and not all are covered due to special authorization requirements. These take a long time to get filled out, as a specialist has to fill them. It is hard to get into see a specialist, there are long wait times, and they can be difficult to contact via phone. When they get processed, they are often declined, even if they are the best thing that works for me. The requirements for coverage are too restrictive."

"My name is Sheila DeVries. 6 years ago I gave birth to an amazing little girl named Payton. As a little toddler she began having very bad eczema. We started to take her off diff foods to see if that would help. We switched to all natural soaps and cleaning products and natural food. She soon started to suffer from allergies and asthma attacks. We began having lots of doctor's appointments, pediatrician appointments and allergist appointments. Thru all this became numerous wheezing and coughing episodes to numerous emergency trips which led to numerous hospital stays. This led to trying numerous medications to try finding what works best. We ended up having to buy a nebulizer and oxygen reader for our home to save on having to rush her to emergency each time and to be able to track her oxygen at home. Fast forward to 2021 her allergist did blood work on her and found out how bad her asthma really was by her number count from her blood work. He decided to put her on a shot called Nucala. Her allergist was able to get it covered thru a company, so she began receiving this shot once a month. It made such a difference in her life. We had no more emergency visits, no more hospital stays last year, she was able to have a great year being able to run and play without constantly being wheezy and trying to catch her breath like the years previous. While receiving the Nucala Shot she was also on a pill form medication, nasal spray, 3 inhalers and 3 different nebulizer meds and allergy med everyday and creams for her skin. The beginning of December, Payton was to go to her allergist appointment but the day before they called and told us there was a delay in them receiving her medication. 2 weeks had passed, and they still never received and found out that the company that was covering it now will not cover the cost of her shot or medication. We also do not have coverage through my husband's work and most companies won't accept her to be covered since she already has a medical condition. I am a stay-at-home mom of 6 children, and we also host exchange students into our home each year, so I do not have benefits either to cover all the expenses. Since the beginning of January, she has been put back on prednisone and has had to have numerous nebulizer treatments throughout the week for her to be able to play and not having to struggle to get her breath. With covid the last couple years she has also not attended school due to the high risks of getting Covid which would not be good for someone with her illness and her 5 siblings as well have not been attending and

have been doing all remote learning since the beginning of the pandemic. We are looking for a miracle to be able to get her back on Nucala. Her condition has definitely affected each one of us to help protect and keep her healthy and not to suffer more than she already does. We have had to take many days off work and have had to change our lifestyle to give her the best life we can while living with Asthma."

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

No, remaining therapeutic areas should not be prioritized based on national health priorities.

Asthma Canada supports on-going efforts and engagement to overcome any constraints that may be impeding a national formulary and that are contributing to the need to prioritize. Asthma Canada supports further engagement opportunities to clarify and determine the planning and operational consequences of setting priorities.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

Asthma Canada recommends that CADTH explore and analyze the options further to determine feasibility.

5b. What criteria could be used to identify priority products?

Asthma Canada supports clarity in the resource constraints that are contributing to the necessity of an option analysis and priority setting exercise.

Asthma Canada recommends consideration be given to changing operational approaches to allow for a dynamic method of resource management and consultation on those constrains and metrics that are driving the need to engage in a priority setting dialogue.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Asthma Canada notes that values are a more appropriate term than preferences and recommends that the feasibility of adopting a therapeutic model should be viewed as an opportunity to include emerging therapeutics supportive of on-going improvements to patient care.

Asthma Canada is concerned that limiting inclusion of therapies on a National Formulary that are overcoming challenges with adoption (feasibility) will only further hinder their uptake and could

undermine the adoption of new effective products.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

Asthma Canada recognizes the importance of a governance model to a successful national formulary and supports a model that is objective and considers authentic and regular patient input, and a model that achieves the patient outputs described in the principles of the formulary.

Asthma Canada also supports the use of a governance model that is inspired by and improves upon existing models of patient inclusion and HTA around the world

8. 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 reviews)?

Asthma Canada recognizes that changes to existing processes will require the input of many different stakeholders and supports an iterative process to mange workload while engaging all groups necessary to achieve a successful National Formulary that is integrated within health systems and remains both sustainable and modern.

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

Asthma Canada expresses its sincere appreciation for the opportunity to participate in this consultative process. We believe a National Formulary is an important component of a modern and patient focused healthcare system. We applaud the progress made to date and look forward to continued engagement.

Asthma Canada proposes the following considerations in support of a successful National Formulary within the greater context of achieving an integrated patient outcome-based health care system:

• Changing the Conversation – Recognizing that Patient Centric Policy is Cost Effective

• Treating Patients as a Whole

• Rising above Jurisdictional Issues and Creating Systemic Solutions

• Embracing Change as Part of Preserving Canada's Healthcare Legacy

We can not stress enough that patients must be engaged as equal partners in all consultations and decision-making processes that affect their care. While this consultation represents positive progress, it remains difficult to assess elements of a pan-Canadian formulary in isolation of the other three components that are core to its implementation - that is: terms of coverage, financing and clear decision-making authority. We must capitalize on emerging opportunities to address the well-known gaps in our healthcare system.

Patients with chronic diseases, like asthma, depend upon medication for day-to-day functioning and risk being most affected by treatment disruption. Unexpected changes in medications can lead to an increase of symptoms and exacerbations, additional healthcare costs, and an emotional burden that can affect work and school life productivity and commitments to family and home life. It is crucial that a national formulary should provide Canadians with choice, and that patients and their healthcare provider participate in the decision-making regarding control of treatment options, rather than exclusively insurers, governments, or other stakeholders.

Now is the time to act as we recover from the impacts of the pandemic. Asthma Canada looks forward to providing continued comment on the outstanding elements that are germane to the development of a national formulary. We thank CADTH for this opportunity and the important contribution they make to our healthcare system.

Bayer Inc.

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Bayer Inc. (Bayer) both contributed to and supports the input on this consultation provided by Innovative Medicines Canada (IMC) and BIOTECanada. As such, in Bayer's response to all questions we are selectively highlighting a few key aspects.

In general, Bayer agrees with many of the principles proposed in the consultation and we echo the principles proposed by our industry associations for consideration. It is difficult to provide more specific feedback given the lack of context as to how the proposed pan-Canadian formulary will be used. The consultation document principles such as "Equitable" and "Universal and integrated" are laudable in almost all contexts and something to strive for. However, without further context on how this formulary could be applied (by whom and for whom) it is challenging to interpret and comment further on how these principles should manifest in the context of the pan-Canadian formulary. Bayer acknowledges that this was stated as being out of scope of CADTH's work on a pan-Canadian formulary, however this unfortunately does not address the centrality of such context in providing detailed feedback.

Lastly, we highlight that formulary decisions should not be overly dictated by pre-defined budgets, but rather should identify and reflect the value that innovative medicines bring to Canadians and hence emphasize the need to find timely funding solutions to meet the needs of patients.

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

It is difficult to answer this question without knowing for whom the pan-Canadian formulary is intended and what the objective is relative to existing public formularies across jurisdictions. For example, the assessment criteria should differ if the formulary is intended to apply to those patients who currently are underserved by existing public drug plans and face gaps in access versus creating a "minimum" list of treatments that should be covered by a public formulary versus creating a formulary that would replace existing public formularies. The proposed assessment criteria also appear to be heavily reliant on what is already broadly covered by public plans which may or may not be the optimal approach depending on what the intended use of the formulary is. It is also noted that the availability of biosimilars or generics as an assessment criterion emphasizes a more historical perspective and may not reflect current standard of care and best practice in a given therapeutic area. Bayer looks forward to having more context and being able to provide a more definitive response to this important question in the future.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

Access to related products is an important consideration and should also encompass access to diagnostic tests that are required to identify appropriate patients for treatments that are included on the formulary. Precision medicine treatments, increasingly more common in both the oncology and non-oncology settings, typically require that a particular biomarker be identified for a treatment to be appropriate for a patient. Therefore, "related products" could be defined as: products, diagnostic tests or other services that are essential for a patient to either initiate on or continue to receive a treatment and/or are required to ensure optimal treatment benefit. It is noted that such a definition has a broad scope and requires healthcare integration beyond just a formulary.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

Related products, diagnostic tests or other services should be included with the list of drugs, however the evaluation to include them should simply be based on the inclusion of the treatment itself, i.e. if a treatment has been selected for inclusion having met the criteria then the essential related product/diagnostic test/service also needs to be included. This is akin to the approach taken in Quebec when INESSS evaluates treatments that also have a companion diagnostic test.

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

It is difficult to comment on expanding this work without first having further context around the pan-Canadian formulary. As highlighted previously, the criteria used to evaluate the current list of treatments in the areas of cardiovascular disease, diabetes and psychiatric illnesses may or may not be the optimal approach for building a formulary depending on how such a formulary would be used and by whom. A better approach seems to be to establish this critical context for the pan-Canadian formulary first, re-evaluate if the proposed principles/criteria/processes are appropriate for the needed role of the formulary (including consultation with relevant stakeholders) and then proceed to expand to other therapeutic areas having more confidence in the appropriateness of the approach. It would be a particular challenge to evaluate more complex therapeutic areas such as oncology in the continued absence of context.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

Like the response in section a) above, Bayer instead recommends first establishing the context around the pan-Canadian formulary and then revisiting this question. How the formulary will be used would have a significant impact when considering how to integrate national health priorities.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

Again, it is difficult to recommend an option in the absence of more context around the formulary. In principle, Bayer supports applying Health Canada's priority review designations throughout the regulatory and reimbursement processes to create policy consistency, however this may not be the optimal approach depending on how the pan-Canadian formulary will be used.

5b. What criteria could be used to identify priority products?

The criteria should align with the goals and intent of the pan-Canadian formulary and be designed to efficiently and objectively identify products that meet the health priorities of the intended populations covered by the formulary. Without knowing this information, one cannot reliably recommend specific priority criteria.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

The proposed evaluation criteria in Table 3 of the discussion paper reflect a very comprehensive list of considerations around selecting treatments for reimbursement. Changes to this list, including consolidation, may be required depending on how the pan-Canadian formulary would be used. Bayer would like to highlight two important considerations on this topic:

1. The criteria of "additional considerations (long-term thinking)" is important given the increasing breadth of truly innovative therapies currently approved and in development. These innovations will require a more forward-looking, advance planning perspective to ensure that Canadian patients are realizing the full benefits of these treatments. For example, cell and gene therapies can provide incredible value to patients, the broader healthcare system and even society at large however we need to plan more effectively in advance to adopt these treatments in Canada.

2. There is a high degree of overlap with the proposed criteria for a pan-Canadian formulary and those currently used by CADTH, INESSS and even private payers when assessing reimbursement of new therapies. What defines appropriate criteria for a pan-Canadian formulary therefore also heavily depends on if such an evaluation process would augment or replace the existing review processes.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

Bayer agrees with the position put forward by IMC and BIOTECanada in this regard: we are supportive of a process that clearly weights evidence and provides a transparent rationale for inclusion/exclusion of a given treatment. This particular element is often lacking in current Canadian HTA recommendations where key elements that were considered are highlighted however the relative importance placed on each by the expert committee is not always apparent. It is also critical that weighting of the evidence be tailored to the treatment or therapeutic area being evaluated because a single, static weighting would not be appropriate, particularly when considering rare diseases, oncology, or other more complex treatment areas. Bayer is also highly supportive of incorporating outcomes-based or other innovative funding agreements, in addition to conditional access contingent on real-world evidence development, within the deliberative process itself. Leaving such approaches to later, subsequent steps (such a negotiation through the pCPA) will continue to limit the opportunities for all stakeholders to collectively find ways to deliver earlier and more broad access to meet the needs of Canadian patients.

8. 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 reviews)?

Broad stakeholder involvement at all stages of product assessment is critical and this includes both initial assessments and any reassessments that may occur. As highlighted in this question, it is also not feasible to re-evaluate all treatments on a regular basis and still include robust stakeholder involvement and hence this necessitates deciding which treatments/therapeutic areas to prioritize for reassessment. We interpret this question to apply in the context of a pan-Canadian formulary, rather than the existing, multiple drug review processes that currently exist in Canada. As such, knowing how a pan-Canadian formulary will be used in Canada and how it fits with the current processes is a pre-requisite to providing meaningful feedback.

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

Bayer acknowledges the significant efforts of the panel members to-date and we applaud their efforts to enhance Canadian's access to treatment in an equitable way. Bayer also appreciates this opportunity to provide our perspective on the development of a pan-Canadian formulary. We have attempted here to provide meaningful input, however, as highlighted throughout it is difficult to provide more specific responses without knowing how such a formulary may be applied. We also highlight the importance and opportunity to integrate pan-Canadian formulary planning with the ongoing National Strategy for Drugs for Rare Diseases and Canada's Biomanufacturing and Life Sciences Strategy. It is our sincere hope that we can provide further feedback on the development of a pan-Canadian formulary in conjunction with these parallel initiatives in subsequent rounds of engagement (ideally as both an individual company and as members of our industry associations) once further context on the pan-Canadian formulary is available.

BC Cancer Agency

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

"Devices that assist with the delivery or administration of and/or are necessary for the optimal use of drugs" seems a very broad definition and I am concerned that significant resources and additional separate processes need to be established. Also, would these devices be limited to those used on individual basis and only in ambulatory settings? Many oncology drugs are administered at hospital ambulatory clinics - would devices used there be considered "related products"? Many specific genetic mutation tests are necessary for the optimal use of drugs, and the accessibility of these tests are not always consistent across the country. Would these be included?

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

They can be listed in the same list for drugs but they may require different evaluation criteria, because many related products are not directly linked to the "Efficacy and effectiveness of clinically meaningful outcomes for the drug", unless we assume the benefits of the drugs can only occur with the presence of those related products. For example, there are no direct evidence that specific genetic mutations tests can lead to improved cancer survival, but using those tests to direct a drug treatment can lead to improved cancer survival.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #1

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No

If yes, how should weight be distributed among the proposed criteria?

Different drugs being different emphasis of potential weightings, and setting a score gives a false impression that we can be that precise in our evaluation of clinical significance.

8. 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 reviews)?

If a new standard drug is introduced, the outdated standard should become restricted or deleted from formulary, rather than leaving it linger on the formulary. So if Drug A is supplanted by Drug B, we should revise formulary status of Drug A, because manufacturer of Drug A would never submit a request to revise its downgraded status.

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

No response provided

BD Canada

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

To whom it may concern,

BD appreciates this opportunity to comment on the CADTH pan-Canadian formulary project in relation to the Diabetes Care related products - Pen Needles and Syringes.

BD (Becton, Dickinson and Company) is a global medical technology company that is advancing the world of health.TM BD has been in business for 125 years, and our products are found in almost every country around the world. We have a deep history and strong track record in making quality products at scale — more than 45 billion products manufactured each year1.

BD has deep expertise and advanced technologies related to diabetes care. We continue to leverage our longstanding expertise to continuously innovate pen needles, insulin syringes and other diabetes care products. Our products are diligently designed with patient outcomes in mind, and to enable people who are living with diabetes to benefit from safe and effective diabetes care.

BD would like to bring attention to the following topics for discussion in relation to the discussion paper :

Real world implications:

• We understand that the implementation (governance, funding, terms for coverage, interplay between public and private plans) is out of scope for the Advisory Panel. Given the existing gap between this panel and funding accountability at the provincial/territorial level, more details on the real-world implications of a pan-Canadian Formulary are critical to enable a fulsome response to the questions for feedback.

• Provinces have disparities in healthcare funding policies regarding diabetes related products. The proposed framework excludes how a pan-Canadian formulary affects existing provincial formularies, and how patient access (coverage) under existing plans will be impacted.2.

In the absence of details on real-world implications, we would like to raise a number of areas for consideration:

Medical technology has unique attributes from therapeutics3. Medical devices, unlike pharmaceuticals, depend on clinician/patient training and experience, the care delivery setting among other factors. For example, unlike prescribed-drugs, Pen needles and Syringes are end-consumer products where patients are fully involved in decision making due to patient Preference-related parameters4 that are influenced by a dynamic and a constantly evolving innovative market. BD supports patients and clinicians with trainings on injection technique in an effort to help enable best outcome. It is unclear how this would be considered in the context of the Formulary. The value of the support provided to patients and healthcare society goes beyond primarily cost considerations.

• Like businesses in Canada and around the world, BD is experiencing unprecedented demand and supply chain challenges, resulting in limited availability of and access to raw materials, shipping and transportation delays, and labor shortages.

• Global supply of critical medical devices has undergone tremendous strain over the past couple of years, and constraints will continue as countries around the world emerge from the COVID-19 pandemic and experience pressures to alleviate the backlog in medical care. BD's globally integrated supply system, together with predictable domestic market conditions, helps ensure products are transported to customers as quickly and efficiently as possible. Adding a formulary for diabetes products will create greater unpredictability to domestic market conditions, which may have an adverse impact on our ability to support continuity of care across hospitals, clinics, retail pharmacies, Long Term Care Homes, HCP clinics, and patient homes in Canada.

BD is supportive of efforts to make prescription drugs and related products more affordable and more accessible to all Canadians. BD encourages the multi-criteria decision analysis approach that is both,

patient-centric in nature and focused on leveraging innovation in treatment modalities. In conclusion, BD would appreciate the opportunity to meet with the CADTH committee to discuss the specified key elements further.

References:

1. BD (2022). Advancing the World of Health.| BD. https://www.bd.com/en-ca.

2. Building Toward a Potential Pan-Canadian Formulary, CADTH Consultation Document January 2022, page 8.

3. Medical Devices and pharmaceuticals: Two different worlds in one health setting. MedTech Europe. (2018, October 9). Retrieved February 24, 2022, from https://www.medtecheurope.org/news-and-events/default/medical-devices-and-pharmaceuticals-two-different-worlds-in-one-health-setting/

4. Whooley S, et al. Evaluating the User Performance and Experience with a Re-Engineered 4 mm x 32G Pen Needle: A Randomized Trial with Similar Length/Gauge Needles. Diabetes Ther. 2019;10(2):697-712.

Best Medicines Coalition

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The Best Medicines Coalition (BMC) is providing its input to the Advisory Panel in full submission format, addressing many of the topics in the consultation questionnaire at a high level, representing consensus positions informed by the coalition's member organization. The submission, posted here https://bestmedicinescoalition.org/wp-content/uploads/2022/02/BMC-CADTH-PanCanadian-Formulary-Submission-February-25-2022-FINAL.pdf, does not provide specific answers to to each of the questions but many of the issues under consideration are addressed.

Please consider the document in its entirety at the link above to be BMC's formal submission. In addition, we have inserted sections of the submission into this questionnaire, where appropriate, specifically regarding principles (below), criteria and evaluation, placed within other comments. If there are issues with this format of providing input to the Advisory Panel, we trust that you will contact the BMC to discuss and address.

Best Medicines Submission:

Section One: Introduction, Goal and Principles

CADTH Consultation: Building Toward a Potential Pan-Canadian Formulary

Introduction:

• The Best Medicines Coalition (BMC) commends each of the Canadian Agency for Drugs and Technologies in Health (CADTH) Advisory Panel members for lending time and expertise to this important endeavour, including reviewing and discussing these complex issues and considering options.

• BMC acknowledges the value of this effort and welcomes the opportunity to provide comments relating to the ongoing consultation process on the proposed framework for a potential Pan-Canadian Formulary.

• BMC looks forward to opportunities to further engage as we better understand the specific context and goals that a potential Pan-Canadian Formulary could advance and how best our organization can contribute to that evolving discussion.

• BMC's positions on National Pharmacare and related topics, including drug formularies, are presented in submissions to the Advisory Council on the Implementation of National Pharmacare, including Patient Perspectives on National Pharmacare: Current Challenges, Goals and Implementation Issues (August 2018) and National Pharmacare Implementation: Patient Perspectives and Considerations (September 2018).

• This submission to the CADTH Advisory Panel is informed by the positions outlined in the above documents along with input provided by BMC member organizations following recent review of the discussion paper. Positions expressed represent areas of consensus among BMC member organizations.

Positions and Recommendations:

The BMC presents three primary recommendations regarding the goal and principles which guide the potential Pan-Canadian Formulary, criteria, and evaluation. These recommendations are summarized below, followed by discussion and considerations for each.

1. Refine and Clarify Goal and Principles:

Enshrine improved care and best possible patient outcomes as core objectives

2. Develop Inclusive Criteria:

Ensure a high standard of equitable and comprehensive care

3. Rigorous Impact Analysis:

Undertake comprehensive evaluation of value and risks to patient care

–

Positions and Recommendations: Discussion and Considerations

1. Refine and Clarify Goal and Principles:

Enshrine improved care and best possible patient outcomes as core objectives

• The stated goal of a potential Pan-Canadian Formulary, as developed by the Advisory Panel, includes important elements such as providing a broad-range of safe and effective drugs and meeting the health care needs of Canada's diverse population. However, we perceive a missed opportunity to ambitiously propose meaningful and progressive change to address specific needs and improve patient care and outcomes. We propose that the goal be enhanced to directly communicate addressing disparities, inequities, and unmet needs to improve care and patient outcomes, ultimately supporting health system sustainability.

• The discussion of stated principles, supported by definitions and supporting values, reflects many themes which patient organizations, including the BMC, have presented in previous deliberations. While the outlined principles have merit, addressing patient access disparities and shortfalls and meaningfully improving patient care and outcomes must be enshrined and highlighted to guide all future considerations regarding a potential Pan-Canadian Formulary.

Considerations regarding additional, or enhanced, patient-driven principles:

Inclusive and comprehensive access: All patients, without exception, must be able to obtain the medicines they need. All reforms to the pharmaceutical policy framework in Canada, including the potential creation of a Pan-Canadian Formulary, must address existing inequities and strive to deliver timely, comprehensive care, which is appropriate for each individual, regardless of disability, condition, or where they live and work. Importantly, advancements need to address critical deficiencies in pharmaceutical care in Canada. These deficiencies include the following significant challenges and barriers as experienced by patients:

Extended delays. Prolonged wait times from when Health Canada begins its review/approval process of a drug or related treatment until public drug plans decide whether it will be covered.

Jurisdictional inequity. Variability across Canada among drug programs regarding what drugs are covered or how, with a lack of portability between jurisdictions.

Reimbursement uncertainty. Lack of predictability and certainty in whether a drug will be reimbursed, through private or public programs, and related processes.

Limiting criteria. Narrow reimbursement criteria which may not be in line with medical practices and impedes access for some patients who may have benefitted.

Uninsured and underinsured. Some patients do not qualify or face enrollment barriers for public or private programs or have insufficient coverage, including exclusion of a drug deemed necessary by a prescribing healthcare provider or a plan not adequately covering out-of-pocket costs.

Any changes contemplated for the implementation of a potential Pan-Canadian Formulary must not have the effect of rendering any patient community or individual patient any worse off than before the formulary was implemented. This basic protection ought to apply to what drugs are covered as well as to related access challenges, as outlined above, including timeliness and eligibility.

Consistency and cohesion: The introduction of a potential Pan-Canadian Formulary needs to be considered in conjunction with other suggested changes to the pharmaceutical care framework in Canada, including the creation of a Canadian Drug Agency, a National Strategy for Drugs for Rare Diseases, health technology assessment and management and proposed changes to pricing regulations. Health Canada, CADTH and the pan-Canadian Pharmaceutical Alliance, and indeed all relevant agencies, must ensure all aspects of the broader drug reform agenda work together cohesively to address patient unmet needs.

Patient informed policy development: Patients and the organizations that represent them must continue to play an integral role and that role must be enhanced during the development and integration of pharmaceutical care policies, including the development of a potential Pan-Canadian Formulary.

2. Do you agree with the proposed assessment criteria?

No

Please provide the reason(s) and suggested changes, if any.

Best Medicines Submission:

Section Two: Criteria

2. Develop Inclusive Criteria:

Ensure a high standard of equitable and comprehensive care

• While health system sustainability is critical, improvement of patient care and health outcomes, essentially the sustainability of patient lives, must always be the paramount tenet of pharmaceutical policy reform, including regarding a Pan-Canadian Formulary. While acknowledging considerable challenges, we are concerned that the framework for the potential Pan-Canadian Formulary, as presented, is informed and motivated by a perceived need for drug plan cost containment, rather than aiming to deliver the best possible care and improve patient outcomes.

• Quite simply, criteria for a potential Pan-Canadian Formulary must ensure that no patient community or individual patient is left unable to access a medically necessary drug, be that a long-standing, recently approved or yet to be discovered drug. Obvious redundancies aside, by their nature, formularies which are limiting and not inclusive of drugs that current or future patients benefit from do not deliver on the principles identified and would not add sufficient value to patient outcomes.

• Regarding criteria and prioritization based on national health priorities, clearly such an approach does not serve the critical principles of equity, fairness, and comprehensive care. There must be room in the potential Pan-Canadian Formulary to address all disease types, regardless of current profile, incidence, severity, or other factors, and to do otherwise would be unethical.

Considerations on criteria to achieve comprehensive coverage:

Formulary breadth and depth: To be comprehensive, a formulary would be broad in scope and encompass a range of drugs. It is not appropriate, or ethical, to limit coverage by choosing between depth of options and breadth of drugs for a wider range of conditions. Forcing choice between depth and breadth does not support the advancement of patient outcomes that is in the best interests of all patients, which is, or ought to be, the purpose of the health system. The range of medications covered must meet the individual needs of all, regardless of type of condition, whether acute and chronic, or incidence/rareness of disease, including the realm of precision medicine. Likewise, it must include drugs not yet supported by a full body of clinical evidence, drawing instead on real world and patient-reported evidence. Criteria must encompass both widely prescribed drugs used in primary care, and specialty drugs.

Criteria to encompass future drugs to address unmet needs: Importantly, there must be capacity and flexibility to incorporate yet to be discovered and introduced medications, as well as related tests and diagnostics, including those that address unmet patient needs. For a formulary to be comprehensive, it must include drugs which are considered curative or breakthrough, offering significant improvements to life threatening or debilitating conditions. There must also be the capacity to provide for future, next generation treatments such as rapidly emerging gene and cell therapies.

Defining formulary scope: Drug formularies must have capacity to address individual patient needs. Through the lens of fairness and equity, the range of drugs currently provided through formularies of many private, employer-based plans have capacity to meet individual needs. Plans for employees, dependents and retirees of the Government of Canada are examples. In addition, the current Quebec formulary is the largest and arguably the most comprehensive public drug plan formulary in Canada. Levelling up all existing public formularies, perhaps through a Pan-Canadian Formulary, to that standard of coverage would be a reasonable and supportable early step. Recognizing unique patient needs will arise, a potential Pan-Canadian Formulary must also provide for a type of “safety valve” for consideration of those exceptional cases where a treatment is medically necessary but not provided for otherwise. The “exceptional patient” provision of the Quebec plan is a solid example that should be addressed in the framework for a potential Pan-Canadian Formulary.

Timeliness and efficiency: Drugs should be accessible to all within reasonable time frames. Likewise, for drugs with a high potential for improved outcomes where there are unmet needs, there should be an accelerated review process. Related to this, reform should address the current, overly complicated system of reviews and decision-making. Bureaucratic and administrative burdens should be addressed by streamlining and standardizing approvals and formularies.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

Refer to BMC submission at link above.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

Refer to BMC submission at link above.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

Refer to BMC submission at link above.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

Refer to BMC submission at link above.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Refer to BMC submission at link above.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

Refer to BMC submission at link above.

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

Best Medicines Submission:

Section Three: Impact Analysis

3. Rigorous Impact Analysis:

Comprehensive evaluation of value and risks to patient care

• As the Advisory Panel continues its work in developing recommendations on how to move towards a potential Pan-Canadian Formulary, the BMC will continue to assess how its output, including proposed processes and other recommendations, would support patient-driven goals and whether such a potential list will ultimately improve or diminish patient care and outcomes.

• We expect that the Advisory Panel will also evaluate its recommendations as it enters the next phase. We recommend that a detailed impact analysis of the proposed framework and sample lists be undertaken and released for public comment. This impact analysis would examine scenarios where the potential Pan-Canadian Formulary would be applied and evaluate the impact on patient access and outcomes. Before proceeding, it is critical to fully understand if and to what extent patients will have improved access to the medications they need and whether there will there be patients left behind, and if there be a process for addressing this. Each of the sample lists must be subject to this critical analysis.

Considerations on impact evaluation and analysis:

Clarifying potential gains and losses: We call for greater clarity on how the creation of a Pan-Canadian Formulary will improve access to medications for patients and whether there will be diminished access for some or any. It is imperative that implementation of a potential formulary support the goal of improving access and patient outcomes and that it do so in a meaningful and measurable way.

Avoid cost containment tools. There is particular concern that a Pan-Canadian Formulary could be used by public drug plans to rationalize the delisting of medications as a cost containment tool thereby reducing the quality of pharmaceutical care provided to patients in Canada. A formulary which ultimately leads to some patients losing access to medications they currently have access is not something that we can support. This is a potential outcome, if realized, that is of significant concern to the BMC and its member organizations.

Impact on broad policy priorities. A comprehensive impact assessment should also examine and balance whole of government priorities and assess how the potential Pan-Canadian Formulary would contribute to or detract from both the national pharmaceutical policy agenda as well as broader health priorities, including health and social issues beyond the realm of pharmaceuticals and drug plan budgets.

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Biogen

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Biogen Canada is overall aligned with the current proposed principles and definitions. However, additional core principles or additional elements to the current core principles should be added to support patient access and address several gaps:

- Patient centred: the reimbursement of any medicine should include the patients/caregivers perspectives and they must be fully involved in the decision-making process

- Patient choice: although the potential pan-Canadian formulary must be fiscally sustainable, it must ensure that within any therapeutic category, there is patient choice to support their individual needs; prioritizing the least costly product in therapeutic categories and having a one-size-fits-all model would go against ensuring that individual patients needs are met and there is equitable access

- Collaborative decision-making: with current and other therapeutic categories where the framework would be expanded to. The decision-making processes should be informed using a collaborative process with a multistakeholder group of Patients/caregivers, clinicians, manufacturers, and other stakeholders such as patient associations to address real-world issues and questions

- 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 concerns and questions. These elements are a precondition to an "effective and high quality" process that is needed for these decisions.

2. Do you agree with the proposed assessment criteria?

No

Please provide the reason(s) and suggested changes, if any.

Biogen Canada believes that additional insight is needed with the proposed assessment criteria. The scope of CADTH's consultation has been strictly limited to exclude how 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. While this is out of scope of this framework, it is a critical component that requires further elaboration and discussion. Thus, it poses a challenge to comment in detail on some of the detailed questions in CADTH's consultation document.

The proposed assessment criteria states that if biosimilars/generics are available, the least costly product is prioritized for listing. It would be important to understand the impact of prioritizing the least costly products on patient choice and drug supply. The proposed assessment criteria would also affect other therapeutic categories that the framework would be expanded to. Please refer to responses in questions 4a and 4b for more details.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

Biogen Canada encourages related products including diagnostic tests and monitoring technologies be addressed alongside the list for drugs to ensure access is not limited due to a lack of diagnostic tests. Related tests can be directly related to drugs, and without them, patients will not be able to access a wide array of therapies. These related tests are essential to start, continue, or exclude patients for certain therapies. In most jurisdictions, they are not funded or there is no clear pathway to facilitate consideration of them. These issues must be addressed and an evaluation criteria be applied on the eligibility of related products.

4a. Do you support the proposed approach to expand to other therapeutic areas?

No

Please provide the reason(s) for your choice.

The proposed approach on the pan-Canadian formulary used for diabetes, cardiovascular, and psychiatric medicines are mainly for commonly prescribed medications. If the proposed framework approach was to create a list of medicines to offer a minimum range of effective medicines, this has already been done by most public health plans. However, if this exercise is to create a list that every public plan must offer, the same approach cannot be expanded to all other therapeutic categories, and a different approach must be taken for certain therapeutic areas such as rare diseases. In these therapeutic categories, provinces reimburse therapies with slight discrepancies from one another. Rare diseases and other specialty areas need a tailored and personalized approach that require input from clinicians, caregivers, and patients to address patient needs and barriers. Placing therapies for rare diseases and specialty medicines should not and cannot be placed in a general formulary list that can be prescribed by a broad range of possible prescribers. The potential pan-Canadian formulary needs to ensure a level of flexibility to be offered for potential rare disease treatments and other specialty medicines.

The evidence for rare disease drugs are often not black and white, making CADTH's proposed approach to expand to other therapeutic areas difficult. Large randomized-controlled trials are not always available for sub-groups of patient populations and real-world evidence is an important consideration for these small patient populations. Drugs for rare disorders should be accessible as per the Health Canada product label, and publicly funded supported by managed access programs, data collection, and outcomes-based agreements.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

Biogen Canada believes that the first-in, first-out submission review process of reviewing new medications and indications used by regulators and evaluators should also be used by formulary designers and policy makers. There are many uncertainties when it comes to launching a new medicine in Canada. However, the first-in, first-out review process allows manufacturers and innovators to make informed decisions on when and if they should launch new medicines in Canada, with clear expectations of when a review will be undertaken and how long it will take. Biogen recognizes that there are limited resources for reviewing new medicines and indications, but these could be managed in other ways such as, international collaboration on reviews, finding ways to conduct efficiency reviews, etc. One important example to highlight is when CADTH decided to not conduct reviews of biosimilars making room for resources to be used on innovative therapy reviews.

5b. What criteria could be used to identify priority products?

There are already some other organic ways within the Canadian system to prioritize specific products without changing the entire system's expectations and timeframes for submission reviews. Such examples include Health Canada's priority review for certain treatments and finding ways to expedite pCPA timeframes for Letter of Intent as close to a positive CADTH recommendation. Biogen believes that priority reviews like these need to be emphasized for breakthrough treatments such as, those for rare diseases and other specialised treatments for diseases with a high unmet need since these patients already have to wait an average of two years to get access to treatment.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

The scope of CADTH's consultation has been strictly limited to exclude topics such as systems of funding, how public and private formularies would be impacted, potential health transfers, and how patient access under existing plans would be impacted. Biogen Canada recognizes that these topics are out of scope but this information is essential to discuss in future consultations and for stakeholders to then be able to provide more informed feedback.

Such conversations in the future include that the pan-Canadian formulary should be an advising list that is voluntary or non-binding for provinces; health and pharmaceutical transfers must remain flexible and unrestricted to allow provinces to address local needs and their own system-specific requirements.

Thank you for the opportunity to participate in this consultation. Biogen looks forward to continued dialogue with CADTH and other stakeholders.

Biosimilars Canada, a division of the CGPA

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

Overall, Biosimilars Canada agrees with the proposed principles. The procedures for how these principles will be implemented, however, lack detail and remain a concern for Biosimilars Canada.

Biosimilars Canada recommends that priority be given to the following three principles:

1. "Sustainable" – Cost-saving off-patent prescription medicines, including biosimilars and generics, will support feasibility and long-term thinking for a proposed pan-Canadian formulary.

2. "Efficient and Timely" – The current patchwork of requirements is inefficient and creates delays. Existing systems should be leveraged where possible to reduce costs and the potential for delays. It is important to ensure the approach does not duplicate industry and government resources.

3. "Universal and Integrated" – Biosimilars Canada supports a universal and integrated approach to expand prescription drug access to those who currently lack access. We recommend that hospital products are included on the proposed formulary to ensure improved continuity of care between hospital and community pharmacy settings.

With respect to the priority of "Effective and High Quality", a Health Canada approval confirms there are no expected clinically meaningful differences in efficacy and safety between a biosimilar and the biologic drug that was already authorized for sale. Further, Health Canada's Biosimilar Biologic Drug fact sheet states: "Patients and health care providers can have confidence that biosimilars are effective and safe for each of their authorized indications. No differences are expected in efficacy and safety following a change in routine use between a biosimilar and its reference biologic drug in an authorized indication."

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Biosimilars Canada supports maximizing the use of cost-saving off-patent products through policies requiring well-controlled physician-supervised biosimilar switching and generic substitution when these products are available, as recommended by both this Panel and the Advisory Council on the Implementation of National Pharmacare. Biosimilar and generic versions of the most commonly prescribed products are available soon after patent issues are resolved.

Biosimilars Canada believes it is important to ensure access to medicines is equitable and to support the principle of continuity of care.

In order to ensure the system is efficient and does not have undue delays, additional layers of review should not be required.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

Biosimilars Canada supports maximizing the use of cost-saving off-patent products through policies requiring generic substitution and well-controlled physician-supervised biosimilar switching when these products are available, as recommended by both this Panel and the Advisory Council on the Implementation of National Pharmacare. Biosimilar and generic versions of the most commonly prescribed products are available soon after patent issues are resolved.

While we view the general approach as reasonable, Biosimilars Canada believes it is important to ensure access to medicines is equitable and to support the principle of continuity of care.

In order to ensure the system is efficient and does not create undue delays, the process should avoid any duplication of steps, guarantee transparency, and additional layers of review should not be required.

There are certain products – such as oncology and HIV drugs – that are not funded as a regular benefit on all drug plans. Additional analysis may be needed to determine whether these products are covered in other ways. The Panel suggests that these products should be included in a national formulary, and Biosimilars Canada supports their inclusion.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

An expansion focused on chronic therapies where biologic drugs have high utilization where would provide significant value to those patient populations.

Therapeutic areas where cost-saving biosimilars are available should be prioritized to support sustainable access. These therapeutic areas include diabetes (already included on sample list), rheumatoid arthritis, inflammatory bowel disease, dermatology, and ophthalmology.

Covering the biosimilar in approved indications where the originator was not reimbursed warrants consideration as cost-effectiveness is improved. For example, Humira adalimumab was not covered by the Quebec public drug program for the treatment of Hidradenitis Suppurativa but coverage was expanded to include this indication for adalimumab biosimilars.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #1

Please provide the reason(s) for your choice.

Biosimilars Canada recommends a combination of Option #1 and Option #2 be adopted.

Option #1 is aligned with the current HTA process, and the inclusion of Option #2 would help to address unmet medical needs. Biosimilars Canada does not support Option #3 as this approach is inefficient and would lead to delayed access to new products.

5b. What criteria could be used to identify priority products?

Cost-saving biosimilar and generic medicines should be automatically identified as priority products. Biosimilars Canada supports a streamlined approach for the addition of biosimilars and generics whereby standardized and accelerated listing criteria is employed. In addition, prior authorization requirements for biosimilar and generic medicines should be removed.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

Biosimilars Canada agrees with the proposed evaluation criteria and recommends that priority emphasis be given to the evaluation criteria "Value", where "Value" means meeting patient needs in a sustainable way with multiple therapy options available, and not limiting treatment to only the lowest cost product.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

"Value" as a criterion should be given priority. "Value" should relate to meeting patient needs in a sustainable way where multiple therapy options are available, and not limiting treatment to only the

lowest cost product. Biosimilars Canada supports a streamlined process for biosimilar and generic medicines, including for any biosimilar or generic indications that are not covered for the originator product.

The Panel's intended meaning for "integration into other systems" is not clear to Biosimilars Canada. We would appreciate clarification.

8. 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 reviews)?

Clear timelines with expedited/automatic listings should be available for biosimilar and generic medicines. To guarantee long-term sustainability for biosimilar manufacturers and maintain Canada as an attractive market while providing clinicians & patients with more choice, all biosimilars approved by Health Canada should be listed on the formulary. Biosimilar switching policies should be implemented and new products should be quickly added to the policies when available to maximize potential savings.

International experience has demonstrated that tendering especially 'winner takes all' is one of the key factors driving market consolidation and subsequent shortages, therefore this model is unsustainable for biosimilar medicines and, as such, must be avoided in Canada.

The pan-Canadian Pharmaceutical Alliance (pCPA) has identified several measures that support sustainability on page 8 of its Biologic Policy Directions & pCPA Negotiations document and its September 2019 Biosimilars Review Process and pCPA Negotiations Update. Both documents can be accessed at https://www.pcpacanada.ca/biologics-biosimilars.

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

Making prescription drugs more affordable and accessible is the key value proposition of Canada's biosimilar medicines industry. Biosimilars Canada supports the recommendations in the Final Report of the Advisory Council on the Implementation of National Pharmacare for the implementation of biosimilars switching policies to encourage patients and prescribers to choose the most cost-effective therapies, and increase patient and prescriber awareness about the benefits and the science behind biosimilar medicines.

Criteria needs to be flexible enough to assess evidence-based real-world clinical practice through stakeholder consultations (healthcare professionals, patients, etc.). Clinical re-evaluation should not be required for biosimilar and generic medicines, whose approval by Health Canada are based on comparison to the originator reference product.

In line with best practices employed for biosimilar switching policies implemented by Canadian jurisdictions, biosimilars should automatically be listed where the reference biologic drug is listed and trigger the start of a six-month biosimilar switch/transition period. A shorter transition period may be justified for some products. The reference biologic drug should then be delisted after the specified period and only be available in rare circumstances when there is an acceptable medical justification for the patient to remain on the reference biologic drug.

Patients should have access to biosimilar biologic drugs when moving from a hospital to community setting, and vice-versa.

Implementation of a national formulary should include processes that defend against marketing efforts to switch patients to a more expensive new patented medicine that does not provide therapeutic improvement when biosimilar competition is set to enter the market.

Boehringer Ingelheim (Canada) Ltd.

1. Do you agree with the proposed principles and definitions?

No

Please provide the reason(s) and suggested changes, if any.

The discussion paper notes that the principles were sourced from key Canadian documents such as the Canada Health Act as well as a limited literature search. However, it is important to note that the Canada Health Act and its governing principles were developed nearly fifty years ago and may not be fit-for-purpose in terms of principles to inform this type of initiative. Other frameworks and principles at the global and national level could be referenced, starting with the eight principles that informed and govern the development and implementation of the pan-Canadian Oncology Drug Review and the pan-Canadian Pharmaceutical Alliance. These are described in some detail, below, based on how they have been applied in the context of cancer medicines (pCODR):

1. Governance - A review process with governance structures that are fair, objective, transparent and accountable to patients, payers and the public

2. Representation – A review process that is multidisciplinary, cross- jurisdictional and collaborative in nature with appropriate representation from diverse stakeholders and linked to other key national initiatives

3. Efficient and Effective – A review process that is cost-efficient, effective and streamlined (i.e. reduced duplication) to support timely decision-making

4. Evaluation – A review process with capacity for data capture and ongoing evaluation (decision monitoring / performance measurement) to support continuous process improvements. In addition, capacity for health outcomes and economic impact analysis to support decision-making and planning

5. Health System Focus - Medications are evaluated within a review process and decision- making framework that are consistent with those used for medicines for other diseases

6. Evidence-based - A review process with capacity for rigorous and consistent evidence-based clinical and pharmacoeconomic reviews to support evidence-based decision-making

7. Excellence - A review process that reflects an ongoing commitment to excellence through incorporation of best practices in a spirit of continuous quality improvement

8. Ethical Framework - A review process that includes an ethical framework which balances the need for timely and quality cancer therapies with broader societal values

Regardless of the set of principles that are selected and applied, we believe adding another principle on supporting innovation and the life sciences ecosystem would also be appropriate. This point and opportunity was raised at the beginning of the webinar on the Discussion Paper, and we are strongly supportive of including it formally as one of your guiding principles. This would align the effort with federal and provincial governments that are developing, updating and implementing life sciences strategies. In the context of the COVID-19 pandemic, including this principle will support the imperative to emerge from the health crisis with a policy framework and approach that encourages the

development and adoption of a range of new health technologies.

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

We feel that the level of already-existing concordance across the public drug programs in Canada could have been better communicated in the discussion paper. In other words, if there is already a significant concordance across a common list of new medicines that has been curated effectively through the pan-Canadian Pharmaceutical Alliance over the last decade, the development of another pan-Canadian formulary could be redundant and unnecessary. We provide more thoughts on this point in question 9, below.

We believe re-introducing some of the currently "out-of-scope" considerations (e.g., governance, terms of coverage, and financing) would help significantly to inform the approach and would elucidate the utility and current need to develop a pan-Canadian list.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

We recognize the importance of ensuring funded access to related diagnostics and devices, so that patients can access the full range of health technologies needed for better health. At the provincial level, these efforts are already incorporated into the public drug programs in many cases. The key Ontario program, for example, is the Drugs and Devices Directorate. There are also already systems in place in pan-Canadian and provincial health technology assessments that evaluate these devices, such as CADTH's Rapid Review program and the Ontario Health Technology Advisory Committee. It is important to determine if there is an access problem that needs solving, as any changes related to devices could end up being disruptive. In any case, the most important consideration should be to ensure timeliness, so that there is not a lengthy step in the review process to determine if a device or diagnostic is funded.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

We recognize the importance of ensuring funded access to related diagnostics and devices, so that patients can access the full range of health technologies needed for better health. At the provincial level, these efforts are already incorporated into the public drug programs in many cases. The key Ontario program, for example, is the Drugs and Devices Directorate. There are also already systems in place in pan-Canadian and provincial health technology assessments that evaluate these devices, such as CADTH's Rapid Review program and the Ontario Health Technology Advisory Committee. It is important to determine if there is an access problem that needs solving, as any changes related to devices could

end up being disruptive. In any case, the most important consideration should be to ensure timeliness, so that there is not a lengthy step in the review process to determine if a device or diagnostic is funded.

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

We do not believe the development and implementation of a national list or formulary is suited to ensure equitable access to cancer and rare disease medicines. As medical technologies become increasingly personalized, clinicians and patients with cancer and rare diseases need access to a broad range of potential therapeutic interventions and limiting access to a positive list of medicines only will constrain clinical best practices. These drawbacks, we believe, will be further clarified and analyzed given the three therapeutic areas that are already under review for the pan-Canadian National Formulary. Time for discussion, deliberation and consideration of the pilot project should be taken before any consideration of expansion, especially given the fact that the vast majority of Canadians already have (or can have) access to a private or public program that is more comprehensive than the formulary proposed in the Discussion Paper.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

We do not believe prioritization is a necessary consideration at this point, given that the draft pan-Canadian formulary for the first three therapeutic areas has only recently been shared for discussion. Before a discussion on expansion should take place, the Advisory Panel and the funders of this project should review and consider input on the approach taken to date, bringing back into scope some of the key issues that were removed from consideration for your panel.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

A first-in, first-out approach is fair, logical and the least problematic way to deal with new products. Medicines will have already been subject to multi- million dollar investments in plans for regulatory fees, HTA fees, health system adoption and launch plans, medical affairs and other initiatives to bring new medicines to markets. Ensuring there are clear guidelines and target timeframes for review is essential to support these long-term investments and initiatives.

Having “outside guardrail” targets, however, does not preclude any review body from providing streamlined/fast access to life-saving therapeutics in a streamlined way, similar to the approach Health Canada takes with priority reviews.

5b. What criteria could be used to identify priority products?

A first-in, first-out approach is fair, logical and the least problematic way to deal with new products. Medicines will have already been subject to multi- million dollar investments in plans for regulatory fees, HTA fees, health system adoption and launch plans, medical affairs and other initiatives to bring new medicines to markets. Ensuring there are clear guidelines and target timeframes for review is essential to support these long-term investments and initiatives.

Having "outside guardrail" targets, however, does not preclude any review body from providing streamlined/fast access to life-saving therapeutics in a streamlined way, similar to the approach Health Canada takes with priority reviews.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

Additional criteria and considerations that should be added include:

• The need to stimulate innovation and build a viable life sciences sector in Canada (we noted that CADTH's lead on strategic projects, Heather Logan, noted this imperative at the beginning of the webinar, and we would encourage that this be formally incorporated throughout the Advisory Panel's work)

• Societal values such as "rule of rescue" and other ethical considerations around disorders and life-saving therapeutics

• Value to the health system

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

Multi-criteria decision analysis (MCDA) is a good framework to inform prioritization, however, it should be one tool for informing a deliberative discussion and consideration. There are some drawbacks to over-formalizing the MCDA approach that could lead to inequitable outcomes. One important aspect of MCDA is understanding conflict in frameworks. In this deliberative framework is there a way the panel intends to identify and analyze variables of conflict? Additionally, is there a weighting mechanism that can be easily adopted when the scale of the formulary changes? A full review of the best use of MCDA should be considered by the Advisory Panel and communicated to stakeholders.

8. 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 reviews)?

Operational sustainability is already happening naturally as clinical practices change. Moreover, there are already formulary modernization initiatives underway that address these issues, including CanReValue, CADTH's therapeutic review process, Choosing Wisely Canada, and other related campaigns. As noted above, if there is already a de facto national formulary that can be developed by the very high concordance of pCPA successful negotiations and public drug plan formularies, and there are other initiatives that address issues and involve stakeholders, there may not be a real need for a pan-Canadian national formulary developed from the ground-up in the first place.

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

We would like to provide the following additional considerations to help inform and contribute to the panel's work and broader national pharmacare discussions:

• Many questions left unanswered: The discussion paper focuses on the processes for developing and managing a formulary (i.e., what & why), but explicitly leaves out the much tougher questions that need to be addressed in the creation of a national formulary, such as defining the problem, financing, governance, coverage terms, how the list would be used by public and private payers and how it would affect other important pharmaceutical policy initiatives. Stakeholders need more clarity on how these pieces will fit together to provide more informed feedback.

• What is the added value of a national formulary? On the issue of defining the problem, it isn't clear how a new national formulary would improve the current system. Provincial collaboration under the pCPA has already led to significant uniformity in coverage (about 90% of the same drugs are covered) across participating public plans and serves as a de facto national pan-Canadian formulary. Moreover, current HTA systems already advise on what drugs to cover and under what conditions.

• Addressing the real affordability gaps: According to a 2017 Conference Board of Canada study, there are less than 2 percent of uninsured Canadians, all of them residing in Ontario or Newfoundland and Labrador. Meanwhile, high out-of-pocket costs related to co-pays, deductibles, and premiums can be a major barrier to access/affordability and can vary significantly between provinces, types of public plans (e.g., Universal, Seniors, Catastrophic plans for the underinsured, etc.), and income levels. Both challenges can be addressed by keeping the current public/private system in place while targeting efforts on reducing co-pays and improving access for people without coverage. The resolution of these challenges does not rely on the development and adoption of a single national formulary. The expansion of current public programs, such as PEI's generic drug plan and BC's decision to exempt all lower-income citizens from co-pays and deductibles, are far more feasible and would have immediate benefits for those beneficiaries.

• Potential alternatives to a national formulary starting with increased funding for provincial and federal programs: Building on the above point, in terms of potential alternatives, a more pragmatic and cost-effective approach could be to increase health funding to the provinces and territories so they can expand their current programs (as was done recently in PEI), in exchange for federal standards on

national pharmacare and Drugs for Rare Diseases that support timely, equitable and affordable access for patients. Such standards could include establishing criteria to reduce time to listing, reducing or eliminating co- pays, requiring all individuals to have public or private insurance and requiring private plans to cover at least what the public sector programs do, like the Quebec model.

• Addressing wait times for new treatments: In Canada, it takes on average 632 days for a new drug to be listed following Health Canada approval (http://innovativemedicines.ca/resources/pcpa-trends-update/). This is about twice the OECD median and places us 19th out of 20 other OECD countries. As one of the most developed and advanced economies, we should, at the very least, strive to be in the top quartile of the OECD with respect to timelines from authorization to reimbursement. When it comes to rare diseases, we should also consider metrics and best practices for access and wait times from key innovators such as the US, UK, Germany and France. One important problem that the Advisory Panel could be well positioned to highlight in another iteration of the Discussion Paper is the significant disparities that exist between the provinces in terms of time to listing following pCPA negotiations. This – far more than the absence of a single, national list – contributes to access gaps for patients. To address this issue, the federal government could play a role in establishing standards to accelerate time to listing (e.g., within 3 months of an LOI). Finally, efforts need to be made to ensure that any evaluation process regarding additions to the formulary or removal of medicines from the list are done in a timely and transparent fashion. Adding another process that has duplicative elements (e.g., economic and clinical considerations) has the potential to create another step in the process from research to bedside that will negatively affect patient access to medicines they need for better health.

• Avoiding a potential race to the bottom: At the moment, the more than two-thirds of Canadians who have access to private insurance enjoy much faster and more comprehensive coverage than those that rely on public plans – private plans cover about twice as many drugs and make them available about three times faster than public plans (Canadian Health Policy Institute. Coverage of new medicines in private versus public drug plans in Canada 2009-2018. Canadian Health Policy, September 2019: https://www.canadianhealthpolicy.com/products/coverage-of-new-medicines-in-public- versus-private-drug-plans-in-canada-2008-2017.html.) A national pharmacare program must be designed to correct existing inequities, but not through a race to the bottom by making the current deficiencies of our public drug plans applicable to all. There is no need to expend already-limited public resources on efforts that are successfully undertaken by employers, unions and other group benefits plan funders, that work well for beneficiaries. We need additional public resources and a simplification of procedures to ensure Canadians enroll in public plans for which they are eligible and that those plans provide much more equitable coverage compared to private plans than they do today. We also need to be wary of potential unintended consequences of a national formulary, such as bringing all plans down to the lowest common denominator. For instance, some private plans could potentially use the national formulary to lower their coverage levels to meet the minimum requirements of a national list.

• Population health perspective is problematic: The panel's population health approach, exemplified by the reference to and support of reference-based pricing, has been shown to limit treatment options for patients. It is important to note that medications affect people differently. What works for one person may not necessarily work for another. And as we saw during the COVID-19 pandemic, having access to multiple therapeutics is vital. Moreover, choosing just a couple of therapeutic options in an individual class and then closing the list will dissuade innovators from bringing incremental improvements to Canada that could, in time, grow to become the gold and clinical standard for those patients. Once again, COVID vaccines and therapeutics are instructive on this point, but so are other commonly prescribed medicines for chronic conditions and preventive health, such as statins and anti-coagulants.

We recommend reviewing how multiple therapies competing and being introduced at different times, with multiple indications, in major therapeutic classes, could be used as a case study. This would allow stakeholders to consider how access to medicines in those therapeutic areas would have been affected if a national pan-Canadian formulary had been in place when those new innovations were introduced globally.

Bristol Myers Squibb Canada Inc.

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

Bristol-Myers Squibb (BMS) Canada welcomes the opportunity to participate in the Potential Pan-Canadian Formulary consultation.

BMS shares the views of the BIOTECanada and Innovative Medicines Canada Response to this CADTH Consultation.

Drug funding decisions fall under provincial jurisdictions and the Potential Pan-Canadian Formulary drug list proposed in the "Discussion Paper for Engaging with Stakeholders - Building Toward a Potential Pan-Canadian Formulary" can therefore only serve as a non-binding potential recommendation to provinces. In the absence of proper context setting, how responses to the questions above would ultimately be used remains unclear.

Nonetheless, BMS wishes to collaborate with CADTH on this stakeholder engagement. BMS strives to address access gaps and to provide the right product at the right time for the right individual.

As such, BMS appreciates the following points put forth in the Discussion Paper:

Relative to the principles specified in Table 1, comprehensiveness is an important value to ensure that diverse patient needs are met. Beyond clinical efficacy and safety, considerations such as ease of use, impact of care settings, and subgroup particularities are important aspects to consider when assessing the value of novel therapies. A patient centric approach, a diversity of perspectives in the decision-making process, and striving for equity in health outcomes are welcomed principles.

BMS also welcomes the mention that real-world evidence would be part of the evidence-base that could serve to support drug inclusion on drug formularies. Real-world evidence can serve to inform actual usage. It can serve to identify treatment and access gaps among specific patient groups, and it may help uncover treatment benefits in patient groups not initially included in pivotal clinical trials. Recognizing the value real-world evidence can bring supports the comprehensiveness value.

To bring further clarity to the work done by the CADTH Committee, BMS would like to bring forth the following questions or points of discussions:

• How can the process surrounding the definition and assessment of patient needs be improved? The Discussion Paper does not define how patient needs were assessed in the preparation of the Potential Pan-Canadian Formulary list. The current CADTH drug evaluation process favours patient group input and this is an asset to the CADTH deliberative process. Would patient needs be included in the proposed process with the same level of consideration as currently established in the CADTH drug reimbursement assessments? To further improve the patient input process and better identify treatment or coverage gaps, including a section in the patient group input template that aims to identify unmet needs among a diversity of subgroups (patients with mobility issues, cognitive issues, sensory issues, or patients facing cultural or socioeconomic barriers) may provide valuable insights on how to address care gaps. Furthermore, understanding this was deemed out of scope, the Discussion Paper shared for consultation does not describe how the principle of universal and integrated coverage could be operationalized through federal and provincial transfers to expand public coverage to broader sections of the Canadian population.

• How can transparency around the deliberation of this proposed process be improved? As mentioned in the BIOTECanada/IMC response on this consultation process, greater transparency on how the different criteria and discussion points weight in the CADTH recommendation process would be appreciated by all stakeholders. CADTH explains well what the major points of consideration were but there is less transparency on the various positions held within the expert committee. In the current INESSS recommendations, the rationale behind the position of the majority and minority of the decision makers is detailed. This approach helps to illustrate where there may have been diverging opinions, provides additional clarity on the points that may have weighed in the decision and helps in the understanding of the recommendation rendered. It is an approach to consider to further improve clarity around the CADTH decision making process. As outlined by CADTH in their Discussion Paper, the multicriteria

decision analysis (MCDA) approach which requires the application of weights to specific criteria is not an optimal approach. BMS appreciates that the proposed process would be open to appeal but would warrant further clarity from CADTH than actually provided in the current process for reconsideration. While CADTH currently allows the manufacturer to request a reconsideration following a draft recommendation, the manufacturer has to provide the evidence necessary to clarify and explain their points in the absence of a full understanding of the reasons behind the CADTH draft recommendation. Increased transparency around the reasons behind the pERC recommendation and an opportunity for sponsors to provide clarity and answer questions directly to pERC members before the committee votes and issues the draft recommendation, would help to better understand the rationale behind the recommendation. Moreover, this would highly likely reduce the number of requests for reconsideration from sponsors. Moreover, should an appeal still be required, to ensure an inclusive, transparent, and fair process, a two-way dialogue should be opened such that CADTH also clearly shares and verbalizes the reasons behind the recommendations given.

• With regards to the process detailed in Table 2, it would be of value to explicit what are the products for which coverage would be improved with the proposed list? As per the criteria used, most of these products are already listed on the majority of provincial formularies. The coverage gaps addressed through the creation of this potential pan-Canadian formulary are not detailed. BMS is concerned that this potential formulary may lead to new gaps between publicly and privately covered people. Public coverage may be better harmonized but Canadians who access drugs only through their private plans may lose their coverage. How privately covered drugs were taken into account in the Table 2 process was not discussed.

• How does the potential addition of a non-binding pan-Canadian formulary help streamline the decision processes? At the end of the day, the provision of care and access to care and therapies depends on the interaction between the healthcare professional and the patient. Since the potential formulary proposed would not replace existing provincial formularies, this additional formulary list could generate confusion and increase the duplication of steps for healthcare professionals when deciding of the appropriate drug for their patients. An approach where federal bodies would partner with provinces to address their potential coverage gaps would be preferred as opposed to possibly adding a new layer of complexity.

The COVID-19 pandemic has highlighted the role the Federal government could play in supporting the health of Canadians. Reinforcement of public health messages and improving health literacy and knowledge translation can have a significant impact on the three therapeutic areas identified by CADTH in their Discussion Paper. Greater harmonization in the terminology used to refer to the various provincial drug plans can also help address some of the issues raised in the Discussion Paper, whereby patients and healthcare providers sometimes have difficulty navigating through drug coverage. To ensure continuity of care, federal support to provinces for interprovincial coverage would be encouraged. The work presented in the discussion paper and through this consultation could serve to inform and address interprovincial coverage discussions. For example, questions such as should the coverage in the province where treatment was initiated prevail over the coverage existing in the patient's final provincial location may be further addressed as part of this consultation.

Through its innovative research, BMS strives to close inequities in health outcomes by bringing to the forefront drugs with novel mechanism of actions addressing a variety of health care needs in multiple therapeutic areas. Ensuring Canadians can access these therapies is a goal common towards which all stakeholders ca

British Columbia Ministry of Health, Therapeutic Assessment & Access Branch

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Overall, BC PharmaCare agrees with the guiding principles developed by the panel with the assumption that safety falls within the principle of 'effective and high quality', however, the panel may want to consider making safety more overt as the benefits of pharmacotherapy must always be balanced by their potential to harm, especially when usage is not based in evidence. BC believes that plan managers, not just clinicians, must follow the need to do no harm, which includes the recognition that a formulary cannot always provide additional treatment options, especially when there is a paucity of scientific data to support that decision, and in resource constrained settings where trade-offs must be made (i.e., funding one drug means another public service cannot be provided). Furthermore, the current definition of 'effective and high quality' may better fit a principle of 'patient-centered,' and instead should be clear on the appropriate levels of evidence. For example, the need for well-designed clinical trials with peer-reviewed data.

Another principle for the panel to consider is changing 'sustainable' to 'value-for-money,' which matches the panel's criteria used to assess new drugs. To BC, this means not spending money on a drug, even if there is budgetary slack, unless there is evidence that such a decision is cost-effective. One of the fundamental challenges for drug plans is allocating resources and identifying and funding medications which are cost effective, the panel should openly acknowledge the challenge and the need to identify and fund cost-effective drugs. In the current definition, we are unsure what " supporting long-term development and vision" means in relation to sustainability.

Lastly, BC is unclear why 'universal' and 'integrated' are coupled as one principle. For example, hospital and physician care in Canada is universal but not integrated across the country. Health care needs and administrative values differ amongst jurisdictions and consensus decisions rarely satisfy stakeholders as they are compromised decisions rather than strategic, or they skew to the benefit of larger jurisdictions.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

BC PharmaCare understands the pragmatic rationale for using whether a product is listed by public plans as an assessment criteria for the drug list. However, a final drug list should consider the underlying reasons that public plans differ in their formulary offerings such as cost and susceptibility to the lobbying of special interest groups. Differences in formulary that do not result in a difference in health outcomes need to be considered, and that filling in "gaps" should not be the primary goal.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

It should go without saying, but before considering related products (e.g., administration devices), the drug itself must demonstrate safety and efficacy, and the related product should directly link to the effective use of the drug and provide value that could not be achieved without it. One general principal in BC is not to pay solely for convenience.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

BC believes that as other therapeutic areas are reviewed, the price of the therapies must be considered. There is less uncertainty in the evidence-base of the currently selected conditions (diabetes, cardiovascular and psychiatric), and the cost per patient is relatively low.

Where expensive therapies (e.g., biologics) dominate the treatment paradigm of a therapeutic area, and/or the incidence and prevalence of patients is small, it is unclear if the current assessment approach used by the panel will also result in an appropriate drug list. By proceeding in compartments, it becomes difficult to consider the totality of trade-offs that must occur when managing a formulary for an entire population; we believe it becomes more difficult to balance the severe needs of the few ,with the less severe needs of the plurality.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

Prioritization based on national health priorities makes intuitive sense, but success will ultimately depend on the definition and implementation of this. Priorities should be based on clear health disparities that are common across Canada, rather than be dictated by industry or their affiliates.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #2

Please provide the reason(s) for your choice.

A first in and first out approach is not an accurate assessment of the entire drug review process in Canada. The pan-Canadian Pharmaceutical Alliance (pCPA) prioritizes files for negotiations and some public drug plans also prioritize drug listings based on need.

Criteria that BC uses to prioritize drug listings include the budget impact analysis (and the available budget that can be allocated), the number of patients impacted, whether alternative therapies exist, the magnitude clinical benefit (e.g., proven mortality/hospitalization reduction), and the submission order.

BC does not believe a prioritization model should align with Health Canada's priority reviews, as their priorities do not always align with clinical needs as assessed by provincial Ministries of Health. This is evidenced by public drug plans not listing drugs that have been considered a priority by Health Canada. Such a model would only work if Health Canada adjusted their criteria for priority reviews.

As a concept, collaborating with other international HTAs is worth considering but the details of this first need to be described before a decision can be made. BC is aware that there are numerous reports describing the differences in recommendations from HTA agencies across the world and therefore we cannot comment on whether collaborating more closely with another organization is a beneficial option for Canadians unless we understand the terms of this partnership.

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

BC does not have additional criteria to consider and suggests the same evaluation criteria be used for 'related drug products'.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

Weighting should absolutely be used for each criterion as not all criteria are equal. For example, in BC, the severity of a disease for which the drug is used to treat is factored into a funding recommendation, but this criterion does not outweigh the evidence for the clinical effectiveness and safety of the drug itself.

If a drug is not demonstrated to be clinically effective, it cannot be added to a formulary just because the disease is rare, severe, or lacks therapeutic options. Weighting should always be greatest on the proven clinical effectiveness, safety, and value for money of a drug.

In regards to weighting clinical evidence, type and quality should be considered. For example, multi-centered, randomized-controlled trials should be heavily weighted, observational studies weighted lowly and case series/reports weighted the lowest, if at all. Other forms of evidence such as testimonials should be proven to be objective and weighted appropriately within the hierarchy of evidence.

8. 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 reviews)?

Current Canadian drug review processes generally focus on assessment of new products because of resource limitations. Therefore, proper resources should be provided to the management of a formulary, not just to funding the drugs themselves.

Considerations to ensure sustainability include:

• Providing incentives such as reinvestment of funds within a therapeutic area where formulary modernization has found efficiencies, this promotes engagement of clinicians and patients who are impacted.

• Exploring deeper collaborations with academia. Whether it's a small stipend for students, or expedited access to administrative data, there maybe willingness to assist in the evaluation of our formularies.

• Having automatic triggers for re-evaluation such as the level of competition in a therapeutic area (e.g., X or more competitors), or a weak level of evidence at initial listing.

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

BC recognizes the consequences to Canadians when there isn't a universal PharmaCare program like there is for hospital care and physician care in our country. However, we are not yet convinced that a single, national formulary is the best options for British Columbians, or for all Canadians. Instead of combining over a dozen formularies into one, there could be some exploration of consolidation based on geography and population, but more importantly it should be ensured that current resources, experience, and systems be leveraged. Detailed assessments on all drugs evaluated by the panel have already been completed by Ministries of Health, and their net prices known. Importantly, the reasons for discrepancies in coverage between jurisdictions should be discussed.

Canadian Association of Provincial Cancer Agencies

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

The Principles look sound; however, we do have some suggested revisions to consider. While the values to support the principles go into further detail, the Equitable principle may need further division. For example, Equitable can be separated into vertical equity to address inequities in health outcomes, and horizontal equity to address equal access. The Sustainable principle should make budget impact and cost-effectiveness clearer and make specific reference to opportunity cost. This would also require consideration of cost-effectiveness thresholds. We are not clear on where culturally appropriate access is factored into the Principles and where considerations are made for First Nations, Inuit and Métis health. This should this be more explicit in the Principles.

2. Do you agree with the proposed assessment criteria?

Yes

Please provide the reason(s) and suggested changes, if any.

Yes, we agree in principle with the three categories - include, flag, exclude. There are additional considerations we would like to point out from a pan-Canadian cancer systems perspective. The main issue with criteria is the differential access to different oral chemotherapies in different provinces. Some Canadians pay for these out of their own pockets (e.g., NS and NL), whereas other provincial systems cover those drugs (e.g., BC, AB, SK and MB). One of the key questions for a cancer system is how oral cancer drugs will be considered using criteria as proposed. Is “listed by most” public drug plans a simple majority and is there a defined list of “public drug plans” by which this criterion is tested? The inclusion or exclusion in the sample process seems predicated on the medication already being listed by several or all jurisdictions. This appears more consensus driven around current practice than creating a pan-Canadian process. Other criteria that could be considered when deciding whether to place a drug in a particular recommendation category is; has the drug been reviewed by CDR (or pCODR in future for cancer drugs) and received a positive recommendation as well as a subsequent pCPA negotiation and successful letter of intent. For those flagged as requiring further consideration, it may be problematic to add another layer of HTA by a different body such as duplication of effort, inconsistency in process, potential delays, and inconsistency in recommendations. Thinking ahead to cancer, another challenge that may not fit this model is how combinations of drugs for specific indications will be dealt with. The criteria do not speak to cost, cost effectiveness, pharmacoeconomic analyses. This is an important element to consider upfront because the national formulary process could form the basis for contract negotiations. Given that pharmacoeconomics is one of the four quadrants for the CADTH pCODR process, an exclusion of this in the proposed assessment criteria appears to be a gap.

For products with a restricted listing status in provinces being accepted as funded for the purposes of creating the sample list, further clarity is required around if and how restriction criteria will continue to be applied and will these be considered pan-Canadian restrictions or provincial restrictions. If the restrictions continue to be determined by the provinces and they are not aligned across the country, this may continue to widen the gaps in access amongst Canadians.

Prescription data from retail pharmacies underrepresents oncology drugs as retail pharmacies in western provinces do not dispense oral chemotherapy drugs. This discrepancy in data should be closely considered.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

a) For the definition, supplies that are required to safely take prescription drugs on the formulary list should be included.

Suggestions for criteria for inclusion of a related product:

• Is the related product required for monitoring to ensure appropriate use of an approved drug product (e.g., blood glucose monitor and strips to ensure appropriate dosing of insulin, point of care INR testing for warfarin monitoring /dosing in remote areas)?

• Does the product provide information that a patient needs to know to manage their condition (e.g., spirometry for dose adjustment of medications in asthma and COPD patients as compared to information that is nice to know but not actionable)?

Will the related product improve adherence and if so, is there demonstrated evidence of clinical benefit and improved outcomes?

• Under the "Value for Money" criterion, drug budget impact could be listed, and for the other considerations, how will this new therapy affect other drugs that are used in this space. For example, how does it affect treatment algorithms.

• Does this include things like companion tests for drugs? These are becoming increasingly common in the cancer space. This is tricky because there is sometimes a clear association with a specific test result and use of a particular drug but there are also situations where a test has multiple uses e.g., hereditary risk, prognosis, correlative but not predictive and a move to panel testing incorporating multiple heterogenously useful results in a single test. In situations where a test result is necessary to ensure the clinical effectiveness (and cost effectiveness) of a drug, these ancillary tests should be part of the funding package.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

Yes, related products should appear in the same list and have the same evaluation criteria applied. We agree with the panel that having the related products in the same list will streamline the process for patients and provide a simplified point of access which could improve adherence and patient outcomes. Including related products alongside the formulary drug will also make it is very transparent that the supply is covered specifically with that drug.

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

We would be supportive of including cancer and drugs for rare disease in a pan-Canadian formulary. In cancer, we do already have a fairly good process with pan Canadian HTA, pCPA and forums like PAG where we can seek alignment and consistency of listings. We would prefer leveraging these existing mechanisms or if you want to use the same process for the other categories of drugs, including criteria that include whether a drug has been reviewed by CADTH, the outcome of that review and whether there has been a successful negotiation and LOI. These would form the basis of a core drug list for drugs already funded. The lack of consistency in cancer drug funding may not be disagreement on the merits of a drug but budgetary-based decisions by individual provinces. What is covered and not covered will depend on the budget and who is paying. If this is based on provinces who are willing and able to pay less, then this could disadvantage larger provinces and specialty diseases like cancer. What if it is a measured decision for a therapeutic group that other provinces should also implement. The way it is worded implies their work would be unidirectional instead of bidirectional.

For oncology medications there are also very specific eligibility criteria for many treatments. Various mechanisms are in place to ensure equitable access across the country e.g., pCPA, PAG, etc. It will be important to ensure that eligibility criteria remain clear given the rising cost of these treatments. Effectiveness of a treatment is not guaranteed across cancer subtypes (e.g., what is effective for breast cancer may not be effective for colon cancer) and cannot be assumed across the spectrum of cancer. It will be particularly important for oncology and hematology drugs that experts be included in the decision-making process

It is unclear how the subsequent therapeutic areas will be selected or prioritized. If the intention is for all therapeutic areas to be reviewed and included in the pan-Canadian formulary prior to implementation, then the order of review is less important. However, if not all therapeutic areas are reviewed prior to implementation then careful consideration will be required.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

The discussion paper mentions prioritization based on national health priorities; however, we are unable to comment further as these priorities were not described and no reference was provided for further review.

The discussion paper also mentions the WHO anatomic Therapeutic Chemical (ATC) Classification System. For oncology, there is one category that applies 'Antineoplastic and Immunomodulating Agents'. Given the rapid advances in cancer care and treatment, this category would likely need to be subdivided to allow for meaningful review, possibly based on cancer site of origin. Another consideration for which therapeutic areas to review next could include patient burden and cost associated with a particular condition.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #2

Please provide the reason(s) for your choice.

We would favour Option 2 taking Health Canada's prioritization model into consideration to ensure elements of alignment. Whichever option is chosen transparency of process must be at the forefront. We need a way to address priority areas of unmet need outside of the current regulatory submission process if the scoring system is made clear, and can be applied in a timely manner, and is efficient and easy to understand. As an alternative, a scoring system could be a component of Option 1, the prioritization model.

Other considerations:

• Option 1 is a duplication of the prioritization processes. We have three now - Health Canada prioritizes regulatory review, the CADTH HTA has a prioritization process and now during the COVID-19 pandemic, pCPA has a prioritization process. Option 1 would be a fourth prioritization process and would need recommendations on which one to follow.

• How would Option 1 or 2 address treatment priorities across disease sites? Is the same scoring system applicable to all therapeutic areas? For example, there are currently separate pCODR processes for oncology vs. non-oncology drugs.

• Option 3 is not realistic. One could consider sharing steps in the process e.g., shared HTA but cannot ignore the role of independent jurisdictions in drug funding decision-making. Different national governments have different relationships with different manufacturers. It is difficult to come to agreement currently, maintain trust and buy-in within a single jurisdiction let alone at a national or international level. These processes have evolved over many years, as have processes in other countries. The national formulary should not add a drug unless it has been recommended by HTA and an LOI negotiated by pCPA, otherwise it will undermine these important structures and risk undermining the trust and legitimacy of these well- established processes.

5b. What criteria could be used to identify priority products?

We would suggest the primary focus be unmet need, with consideration of how to prioritize within the unmet need group (e.g., unmet need for a small group of patients that is very expensive as compared to an unmet need for a large group of patients that is inexpensive). We would also suggest that there be alignment between pan-Canadian formulary review and HTA processes as the information from an HTA review will be important to help inform formulary decisions

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

Patient and societal preferences will not align in many situations. This needs additional thought. As a patient I may want the quickest access to any drug that may benefit me. As a member of society, I may

want opportunity cost to be the key criteria. These may conflict. So, what are the key concepts you are trying to capture? CDR and pCODR already have an established deliberative framework for considering new drug products. A national formulary process should ideally be a downstream process to the HTA and pCPA processes and should defer to those processes. In which case, the criteria for new products to be added to the pan-Canadian formulary should be criteria that are not addressed in those processes and be either an additional checklist/scoring system or additional deliberative component. For example, the inputs into a pan-Canadian formulary decision could be criteria not included in the current deliberative framework, and the CADTH HTA recommendation and negotiated price compared to cost effectiveness threshold that is able to be achieved by pCPA negotiations. Consideration should also be given to how implementing new therapy may affect downstream therapies (i.e., algorithms).

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

Yes, weighting should be included using established, robust and scientific methods from decisions analysis and utility measurement. Failure to weight criteria often means they are given equal weight (which can be invalid) or they are given implicit weights during qualitative discussion. The latter could mean that we know there are weights, but we just do not want to be explicit about them. If a multicriteria decision analysis (MCDA) tool is recommended, it should be created by an experienced MCDA team to develop weights with the expert committee. The expert committee should be made up of representatives from the treatment areas of interest e.g., cancer drug assessment tool should be created with cancer stakeholders.

We recognize that funding was outside of the mandate of the panel; however, we would suggest that it will impact the ability to continue to add new treatments to the formulary and will need to be included in the decision framework. For example, the overall drug budget is not reflected in the evaluation criteria for individual drugs; however, that would need to be considered as well as consideration of total budget available - if something new is added does something else need to be removed.

8. 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 reviews)?

We agree that a process for re-evaluation is required. Given the multimillion-dollar costs involved, and the potential to improve efficiency and reduce wasteful spending on drugs, even a very small amount of any notional pan-Can formulary budget (even 0.1-0.5% would be a lot of funding) and should be allocated to develop and sustain the expertise needed to evaluate and re-evaluate drugs. Even with increased funding; unless we invest in expanding the human capital and expertise, the same small number of people will be tapped. An process for re-evaluation once there is no longer patent protection and generic/biosimilar entries occur with a substantial price decrease would also be important to consider.

CADTH is considering a life management system for drugs, and this is the right direction. A regular review at three to five years about how the drug is performing or underperforming is critical. Including that cycle assessment will lead to sustainable systems with value for money agents.

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

We feel there is the potential to create efficiencies from the perspective of regulators and plan administrators to reducing duplication of work across the country. This is only true if the suggested processes replace those that are existing. If the suggested processes are in addition to current, then ensuring there are adequate resources to manage the workflow will be critical. As much as possible, the existing well-established drug review processes should be leveraged.

The definition of associated devices, for example glucose monitors, was not clear. Their definition did not include add-on diagnostics such as molecular studies that allow oncology drugs to be given to those that fit a specific criterion such as xtrastuzumab only used in 13% of patients who have HER2 overexpression.

Specifically related to oral oncology treatments, there are currently various processes in place across the country with certain provincial cancer agencies providing oral cancer medications to patients and others requiring patients to fill the prescriptions in community pharmacies. Will the implementation of a pan-Canadian formulary require changes to the current models?

One area for the panel to contemplate is how we define magnitude of benefit. For example, a drug had to demonstrate that it was beneficial, but they did not define the metrics they would use. This is not easy to do as many trials define the benefit of a drug in many different ways; however, this is a disadvantage to oncology drugs. In oncology we use as our gold standard improvement in life expectancy, something that may be difficult to show in, for example, a psychiatric drug. Oncology drugs that have statistically significant improvements in overall survival but not what we would consider clinical beneficial may have more benefit than a drug that was approved as it decreases cholesterol which decreases coronary events which decreases deaths, but when you do the measures of overall survival for some statins benefit is measured as improves survival by days not weeks or months. Thus, the relative value of benefit may disadvantage some areas over others.

Canadian Blood Services

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

As part of the management of the national blood supply system, Canadian Blood Services has been operating a pan-Canadian formulary of plasma protein and related products (PPRP) for over two decades on behalf of all provinces and territories (with the exception of Québec). We agree with the principles put forward by the framework. They are similar to those that inform our decision-making as we strive to balance equity, access, product choice and cost-effectiveness in our product selection and competitive tendering processes.

Our program is an example of a successful pan-Canadian formulary for specialized therapeutic areas. We believe our experience is worth consideration by the Advisory Panel because it provides tangible Canadian examples of some of the key benefits that a pan-Canadian formulary could eventually bring.

We offer the following background as context for the rest of our answers:

Canadian Blood Services operates the blood and plasma supply system, including a national formulary of about 50 brands of plasma protein and related products (PPRP), in all provinces and territories except Québec, which has its own similar system and blood operator. The organization is regulated by Health Canada and funded primarily by provincial and territorial ministers of health, who are also our corporate members. (Note that "related" in the term "plasma protein and related products" refers to synthetic alternatives for products derived from human plasma, not the "related products" discussed in Question 3).

These biologic products are used to treat bleeding disorders, immune disorders, trauma and burn injuries, and other conditions. We store, ship and deliver these Health Canada-approved drugs to hospitals and clinics across the country using a distribution network already approved and funded as part of our national blood supply responsibilities. Increasingly, however, some of these products are being administered at home via sub-cutaneous injection.

Our formulary program leverages the combined buying power of provincial and territorial health budgets to offer equitable access to plasma protein and related products across the jurisdictions we serve, at no direct cost to patients. Like other publicly funded formulary programs, ours includes a rigorous product selection process supported by CADTH-generated evidence, a special authorization process, and utilization management. Unlike other formularies, however, a number of the products we carry are manufactured from human plasma collected through our supply chain, and the formulary, as a whole, requires a unique and essential expertise related to hemovigilance and supply chain management. It is within this national, integrated blood system context that the program ensures traceability, equity, bulk purchasing power, etc.

While we offer a substantial range of products, ours is a managed formulary, not an open formulary. Paths for a product to be added involve product selection and competitive bid processes. Once a potential new product is considered within scope, Canadian Blood Services, in collaboration with its corporate members, determines whether the new product should be subject to the CADTH and Canadian Blood Services Interim Plasma Protein Products Review Process (https://www.blood.ca/sites/

default/files/CADTH-Canadian_Blood_Services_Process_Brief.pdf) or a competitive tendering process. (Note that the use of generic drugs and biosimilars to contain costs is not a tool that is generally applicable to our formulary. To our knowledge, there are no generic or biosimilar options for any products currently on the Canadian Blood Services formulary; the multiple brands that we carry of some products are all considered innovator products).

As part of our practice, we maintain relationships with key stakeholder groups (patients, physicians, and suppliers) to better understand the product pipeline, physician and patient preferences, and to help optimize access, effectiveness and choice. Our procurement processes give patient groups and health professionals a voice in decision-making, although Canadian Blood Services maintains the "final say" in competitive tendering decisions. We strive to offer a reasonable degree of product choice within the formulary. When decisions result in changes to product choices, and therefore the need for patients to switch to a new brand of product, we work with stakeholders to facilitate safe and effective product transition processes.

Our goal is to offer an evidence-based, transparent, and sustainable_national_formulary program that provides equitable_access to safe and effective products for patient care in_Canada.

2. Do you agree with the proposed assessment criteria?

Yes

Please provide the reason(s) and suggested changes, if any.

We understand the need to select products for a proof-of-concept model. Again, in our experience as manager of a pan-Canadian formulary, the question of balancing equity, access, product choice and cost-effectiveness will be a defining tension, should the proposed framework move forward. Clear and effective processes and communications will be essential for success.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

While we don't have suggestions for specific criteria to determine eligibility, in general, we believe related products should be defined as any device required for the administration of a listed drug or for medically required monitoring when taking a listed drug.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

Where appropriate, some of our tenders include stipulations that vendors will provide the necessary administration device for the drug (injection kits, for example) as well as the drug itself. Including related products in this way provides an opportunity to negotiate in one discussion both the cost of the drug

and the cost of the tool needed for its administration. This provides good value to funders as well as to clinicians and patients and helps represent the true cost of the therapy.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

Canadian Blood Services' formulary serves all provinces and territories except Québec. Once a therapy is accepted into our portfolio, it is available to patients and practitioners in all member jurisdictions and subject to individual provincial and territorial access guidelines for some products, like immunoglobulin. Equity of access to plasma protein and related products is a significant outcome of blood system principles and is in line with principles informing the Canada Health Act (e.g., universal access).

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

Our experience has shown, however, that establishing a consensus on formulary matters requires a strong governance model. In our model, agreement among corporate members is required to bring a new product into the formulary.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

In general, the criteria listed are addressed by Canadian Blood Services' product selection and competitive tendering processes. We are in strong agreement that the additional criteria (equitable access and long-term thinking) are essential to the evaluation of new drugs within a pan-Canadian context. We would further suggest that long-term thinking around sustainability and value for money

include consideration of how to decrease or remove health-care silos. Drugs are often evaluated in terms of savings to the budgets that fund them, but a system-wide approach would also consider opportunity costs for hospitals, health human resources, clinic visits, and so on. This type of thinking would put greater onus on suppliers to provide quantitative evidence of exactly how their product benefits the overall health-care system.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No

If yes, how should weight be distributed among the proposed criteria?

We would support a values-based discussion approach rather than quantitative scoring. If scores are used, they should be a starting point for discussion.

For new products under review, each case is unique, and discussion is needed to weigh different risks and benefits. Our process for adding products to the pan-Canadian plasma protein and related products formulary is based on deliberative discussion by an expert committee. The committee reviews the relevant CADTH recommendation and prioritizes evidence on efficacy and safety. This is followed by discussions on stakeholder input, unmet patient needs, implementation and equity issues, budget impact, and other information.

For products already available on the Canadian market, we run a competitive tendering process. This process does include a criterion-based scoring component that is used to rank similar products. However, it is important to note that in this setting, products being scored are similar to each other and the scoring is still followed by a values-based discussion to determine the best product mix for the patients and health systems we serve.

8. 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 reviews)?

Meaningful stakeholder engagement is necessary and challenging, requiring clear processes, such that stakeholders' time and expertise can be best used. Within our formulary, tendering processes provide an example of how we approach engagement (although there are others). Review committees are convened comprising Canadian Blood Services' experts, as well as clinician nominees from relevant treating medical specialty societies and representatives from patient organizations. Throughout the tendering process, stakeholder members of these committees play meaningful roles, including providing input on evaluation criteria for product classes, working collaboratively with staff in assessing each product (using evaluation criteria), and deliberating on a recommended product mix as an outcome of the request-for-proposal. Having this "seat at the table" in product selection is rated highly both by clinicians and patient organizations. From a formulary management perspective, it also incorporates additional expertise and first-hand experience from treaters and patients to help the organization make the best possible decisions.

With regard to re-assessment, we agree that there is a need on a cyclical basis to re-evaluate drugs within a therapeutic area. While we go to tender for various products within the formulary when contract terms end, the tender does not currently include a full therapeutic review. In the future, this is something the organization may consider as part of further modernizing its formulary processes.

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

The answers provided in this consultation update and build upon our submission to the Advisory Committee on the Implementation of National Pharmacare (Sept. 28, 2018).

Since that submission was made, Canadian Blood Services has engaged in a formulary modernization exercise that includes revising our product selection process, enhancing our stakeholder engagement efforts, strengthening our tendering policies and processes, and leveraging data to inform decision making. For more information, see our website and the material provided describing the plasma protein and related products formulary program. (https://www.blood.ca/en/plasma/plasma-protein-and-related-products)

We believe our experience is worth consideration by the Advisory Panel because it provides tangible Canadian examples of some of the key benefits that a pan-Canadian formulary could eventually bring. We would be pleased to meet with the committee to discuss any of this material further.

Canadian Cancer Society

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Please refer to our separate, emailed submission for our complete response to this discussion paper.

The Canadian Cancer Society (CCS) appreciates the opportunity to provide feedback on the proposed framework to develop a pan-Canadian formulary. We commend the Canadian Agency for Drugs and Technologies in Health (CADTH) and the Advisory Panel for the work they have undertaken so far to draft processes and best practices for creating and managing the formulary.

We support the submission made by the Health Charities Coalition of Canada (HCCC) on behalf of CCS and other leading national health organizations dedicated to advocating for sound public policy on health issues and promoting high quality health research.

CCS is also providing a separate submission from the perspective of people living with cancer and their caregivers. CCS is the only national charity that supports Canadians with all cancers in communities across the country. More than 1 million Canadians are living with and beyond cancer.

Cancer is a disease that affects us all in some way: 2 in 5 Canadians are expected to be diagnosed with cancer in their lifetime and approximately 1 in 4 Canadians is expected to die of the disease.

Drugs required for cancer care play an essential role in treatment and can greatly improve health outcomes and quality of life for people living with and beyond cancer. However, the current drug funding model in Canada creates significant discrepancies in coverage due to varying funding models between provinces and territories, private and public plans, and drugs administered in the hospital or in other settings.

The inconsistent availability of take-home cancer drugs is a significant gap in Canada's drug coverage. In provinces where the funding for take-home cancer drugs is not guaranteed by the government (Ontario, New Brunswick and Nova Scotia), people must cover the cost of these drugs through various means including private insurance, special public programs or out-of-pocket expenses. Eligibility for coverage and level of coverage is variable, leaving many people underinsured or uninsured. This often results in people with cancer having to access a patchwork of several funding programs to cover the cost of their treatment.

A recent report commissioned by CCS found that the hidden costs in the three provinces where take-home cancer drugs are not covered in the public health insurance approximately amounts in a range between $19 million to $52 million per year. This process of obtaining authorization and reimbursement of approved cancer medications can be time-consuming, exhausting and overwhelming. Unfortunately, it can also delay or prevent individuals from accessing cancer medications, which can have negative consequences for their health.

The COVID-19 pandemic created new challenges for people living with cancer. The pandemic brought on health system pressures that have disrupted screening programs and cancer treatments, delayed cancer surgeries, and led to a rise in late-stage diagnoses. Pandemic-related underemployment (i.e.,

reduced hours) or unemployment have made it difficult for people who typically had drug coverage through their work insurance.

CCS actively engaged with and listened to Canadians living with cancer and their caregivers throughout the pandemic to get a unique insight into the continued impact that the pandemic has had on the cancer journey. Access to drugs and prescriptions was ranked by both people with cancer and caregivers as one of the most important supports required to manage their care moving forward.

CCS appreciates the Advisory Panel's efforts to identify principles that recognize and intend to address the gaps in drug coverage. We support the framework's draft principles and look forward to providing more in-depth feedback once we understand how the principles will be applied to cancer therapies. We recognize that while the Advisory Panel has not specifically highlighted cancer therapies, the panel intends to review specialized cancer drug programs as part of its plan to expand the draft pan-Canadian formulary.

We recommend that the work on the pan-Canadian formulary and broader pharmaceutical reforms should prioritize closing gaps in drug access. Canadians should have equitable access to drugs required for cancer care without financial hardship, regardless of where they live and where the drugs are taken.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Please refer to our separate, emailed submission for our complete response to this discussion paper.

CCS believes that the Advisory Panel is reasonable in taking a staged approach to develop a pan-Canadian formulary, starting with the most common therapeutic areas. The current set of assessment criteria relies on information that is useful in helping to narrow down the draft list of the formulary. While this is a good start, we seek more information on how the Advisory Panel plans to scale up the sample list from the first stage of the formulary to health conditions with more complex treatments that require nuanced responses.

Cancer isn't just one disease, which makes the range of drugs required for cancer treatment extremely diverse.

Precision medicine is becoming a more popular treatment for cancer that helps doctors choose treatment based on a person's genes and the genetic and molecular profile of the cancer. While CCS recognizes the value of including biosimilar drugs and generic products in the assessment criteria used to scale up the sample list, biological drugs are not interchangeable with a reference drug the way a generic drug is.

Relying on assessment criteria like the availability of biosimilar drugs or generic products and drug utilization data may diminish the value of drugs used in less common and/or more complex cancer treatments. It is, therefore, extremely important to hear from patients. People receiving care are able to offer a range of perspectives that can contribute to evaluating the treatment. They have perspectives on the burden of illness, impact of the disease on their day-to-day life, most challenging aspects of their condition, unmet medical needs and experience with treatments.

We recommend that the Advisory Panel add the person-centered perspective in the assessment criteria and develop person-centered processes to provide a balanced review of drugs that align with patient needs.

We also encourage the Advisory Panel to provide more detail on the steps that occur after the panel categorizes a drug for further consideration or exclusion from the formulary. The Advisory Panel should ensure that the formulary does not inadvertently create new barriers to drug access by excluding biological or reference drugs from the list in favour of biosimilars or generic drugs.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

Please refer to our separate, emailed submission for our complete response to this discussion paper.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

Please refer to our separate, emailed submission for our complete response to this discussion paper.

Cancer continues to be the leading cause of death in Canada. Managing the ongoing impacts that COVID-19 has had on the cancer journey may require a collective effort to identify where cancer control systems have experienced temporary setbacks in order to restructure processes to prepare them for extraordinary disruptions and be ready to respond to the needs of all Canadians.

People living with cancer rely on a number of drugs and related products to support every stage in the cancer journey: prevention, early detection and screening, diagnosis, treatment, pain management and relief from side effects, palliative care, survivorship or end-of-life care.

As the Advisory Panel determines the scope and size of a pan-Canadian formulary, we recommend that the panel considers the individuals' needs throughout the cancer journey. There should be a consistent approach to ensure that the methods used to assess whether to include drugs and/or related products in the formulary align with experiences of people receiving care. CCS believes this would help to minimize disruption in care and the unnecessary burden of navigating the patchwork of drug coverage.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

Please refer to our separate, emailed submission for our complete response to this discussion paper.

We support the Advisory Panel's recommendation to include products listed under specialized programs like cancer-related programs. The panel should also consider reviewing and, if applicable, adopting recommendations on cancer care that have been created by past pan-Canadian or provincial initiatives.

For example, recommendations on medications, supplies and equipment have been made in a number of palliative care reports, including the Pan-Canadian Gold Standard for Palliative Home Care. As noted in the Government of Canada's Framework on Palliative Care in Canada, several provinces and territories already have a palliative care formulary, including Nova Scotia, Ontario, Manitoba, Saskatchewan, Alberta, British Columbia, and Yukon. Similarly, the federal government also offers coverage through the End of Life Care Formulary under the Non-Insured Health Benefits program offered by Indigenous Services Canada, which Northwest Territories and Nunavut also use to determine extended drug benefit coverage.

A pan-Canadian formulary that includes medication, supplies and equipment across the cancer journey is critical to ensure Canadians have equitable access to the treatments and supports in the setting of their choice that can maximize their quality of life in the face of a diagnosis of a life-limiting disease.

The development of the formulary should not override existing and strong drug programs and must be complimentary and consider how the programs will work together without additional administrative burden on the person receiving care or their caregiver(s).

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

Please refer to our separate, emailed submission for our complete response to this discussion paper.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

Please refer to our separate, emailed submission for our complete response to this discussion paper.

CCS believes that a sustainable pan-Canadian formulary should be flexible and responsive to new products, to disruptions that are short-term (i.e., drug shortages) or large-scale (i.e., global pandemics), and to evolving population needs and trends. There should be a seamless integration with existing drug programs.

CCS shares the same reservations with the Advisory Panel on the current process for reviewing drug products. We appreciate the alternative options the panel created to replace the first-in, first-out process and can provide in-depth feedback once these options have more information on how they will

be implement-ed. In particular, we request more information on the role that CADTH's pan-Canadian Oncology Drug Re-view (pCODR) and the Expert Review Committee (pERC) may have in providing expert feedback for adding drugs required for cancer care to the formulary as well as details on timelines to improve new drug reviews.

5b. What criteria could be used to identify priority products?

Please refer to our separate, emailed submission for our complete response to this discussion paper.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Please refer to our separate, emailed submission for our complete response to this discussion paper.

Overall, the process of identifying a potential new drug and making it available to Canadians can take many years. The length of approvals for new cancer drugs in Canada is longer than most countries. This process is long and can be torturous for people with cancer and their families. CCS believes the method and timing in which new cancer drugs are reviewed, approved, and funded should be accelerated and the process should be made more transparent.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

Please refer to our separate, emailed submission for our complete response to this discussion paper.

8. 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 reviews)?

Please refer to our separate, emailed submission for our complete response to this discussion paper.

Discussions about the sustainability of a pan-Canadian formulary are incomplete if they are not part of the broader discussions of pharmaceutical reforms underway. For example, in CCS's previous submissions on Canadian pharmaceutical reforms, we recommended that decision-makers look to unique ways to close the gaps in drug access when there is not enough evidence to inform a funding decision for a new drug. We pointed to the United Kingdom, in which the Cancer Drugs Fund (CDF) is a system that aims to make promising cancer drugs available to individuals before they are fully approved for use in the National Health Service (NHS), where drugs are subsidized by the government. When drugs are reviewed by the Na-tional Institute for Health and Care Excellence (NICE), the UK's HTA

authority, one of 3 decisions will be made: yes - the drug should be routinely available on the NHS; no - the drug should not be routinely availa-ble on the NHS; maybe - the drug can be made available via the CDF to gather further information on its effectiveness.

We recommend that the development of a pan-Canadian formulary should seamlessly fit within the broad-er pharmaceutical reforms occurring and share the same objective: removing barriers and streamlining the administrative process for accessing drugs so that people with cancer do not experience unnecessary delays in accessing their treatment.

As the Advisory Panel looks ahead to consider how a pan-Canadian formulary may integrate with existing programs to help expand access to all Canadians in need, we encourage the panel to also identify data collection and management initiatives that support cancer control strategies. The panel may also consider where there are data or information gaps that need to be resolved to help eliminate inequities in drug access.

Healthcare systems should be integrated so the administrative burden of accessing treatment does not fall on the person with cancer. Pharmaceutical coverage for all Canadians should be straightforward, easy to access and not create any barriers that would prevent or delay a person from accessing their drugs.

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

Please refer to our separate, emailed submission for our complete response to this discussion paper.

In our submission, we highlight the unique challenges that people experience in accessing drugs required for cancer care including cancer drugs, symptom relief and pain management. We also recognize the impacts that COVID-19 has on the cancer control continuum, which will be felt for months and years to come. Our submission offers the following recommendations:

• The formulary must lead to equitable access to drugs required for cancer care

• The formulary should develop person-centered processes for integration with existing programs that people access to receive drugs required for cancer care

• The scope of the formulary should cover the entirety of the cancer journey, including treatment, pain and symptom management (including drugs used for palliative and end-of-life care), and to support cancer survivors with any lingering impacts of their cancer treatment

• The long-term outlook of the formulary should include its ability to anticipate and promptly respond to current and future needs of people living with cancer, which continues to evolve in relation to pandemic pressures and national population trends

We look forward to continuing engagement with the Advisory Panel as it prepares its report by the end of April 2022 and the ongoing work related to the larger conversation on pharmaceutical reforms in Canada.

CCS is grateful for the opportunity to participate in the discussions to help develop a pan-Canadian formulary. Our recommendations are in response to CADTH's discussion paper on the formulary's proposed framework and supporting principles.

The pandemic has presented new challenges in Canada's drug coverage while exposing existing gaps. Although there is uncertainty over the timelines for when the COVID-19 pandemic will end, the impact that it has had on the cancer journey will be felt for months and years to come. Given these circumstances, it is time to re-build our health care systems to be responsive, integrated and resilient.

CCS would appreciate the opportunity to stay engaged with the Advisory Panel to help provide perspective of how a pan-Canadian formulary may impact the cancer journey. We would be pleased to offer supportive solutions on how a pan-Canadian formulary can improve the quality of life for millions of Canadians who are living with and beyond cancer. We look forward to providing in-depth feedback as the work to-wards a pan-Canadian formulary and broader pharmaceutical reforms continues to evolve.

Canadian Cardiovascular Society & Canadian Cardiovascular Pharmacists Network

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

N/A

2. Do you agree with the proposed assessment criteria?

Yes

Please provide the reason(s) and suggested changes, if any.

Agree for a small sample size but for provincial formularies are extremely delayed and restrictive. Once the process of evaluation is complete, there should be the ability to include products from any formulary not a majority or all to address equity. We recommend taking caution when comparing listing status of each drug on existing public plan formularies - significant delays from when evidence/Health Canada indication occurs to when considered/covered by provincial formularies, or for certain indications. There may be significant gaps if going to indication level.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

As related products may not have the same level of regulatory rigor, it would be important to use or adapt existing quality criteria for vetting specific products (e.g. for blood pressure machines, including only devices included among the list of devices recommended by Hypertension Canada). It should include both a combination of top tier expert guideline recommended therapies and cost effectiveness as an ongoing criteria beyond the initial sample. Beyond expert guidelines what other evidence will be used for clinical benefit?

Consider the possibility of creating a specific set of principles with respect to the required level of evidence to confirm improved clinical outcomes for patients. We recommend any product that is necessary for adjustment of pharmacotherapy should be considered for inclusion. Perhaps provincial/territorial public drug benefit programs have established a set of criteria to determine the eligibility of related products.

Any product that is necessary for adjustment of pharmacotherapy should be considered for inclusion. Perhaps provincial/territorial public drug benefit programs have established a set of criteria to determine the eligibility of related products.

We would also like to see warfarin INR point of care devices and test strips - if looking to improve equity and care (for those patient ineligible for a DOAC or unable to afford a DOAC). Often times patients on warfarin have a hard time accessing labs, especially rural Canadians with winter 6 plus months per year. Those patients that remain on warfarin (e.g. mechanical valves) are high risk and having access to POC INR testing (like accuchek) helps them play an active role in self-monitoring and can contribute to efficacy and safety of this high risk therapy.

Also, we would want to ensure all patients have access to syringes & needles (if needed for their medication) and sharps containers (wasn't included) and not just for limited/specific indications (e.g. diabetes) - needs to be equal access.

While unrelated to the criteria, agree with the inclusion of BP monitors on the list. I recommend adding scales to this list for monitoring heart failure patients.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

Agree with including, but the criteria will be challenging for different devices: BG monitors, inhaler spacer devices, BP monitors, etc. It would be difficult to use the same evaluation criteria because the evaluations are not always done in the same manner. Therefore, a process for expert input that is rationale and unbiased will need to be defined. I would think that the related products should also have evidence of efficacy if they going to be added to the formulary.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

Agree. All drugs should be managed with the same framework and principles which fits with the equitable principle. The relevant experts need to be consulted.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

It make sense to follow national health priorities. The definition of national priorities is paramount to understanding how this step will be realized. Vocal patient advocacy groups, vocal medical specialties, pharma, etc. voices will need to be balanced with real patient needs and priorities. We also need to ensure small groups of patients are not disadvantaged. We need to think about high cost drugs (not large populations that use), or rare diseases, or often forgotten groups/less prioritized (women and their medication/healthcare needs across the age span (reproductive years to menopause).

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #2

Please provide the reason(s) for your choice.

For option #2, there need to be time definers for process, medications that have new indications with significant impact to health care costs or first in class treatment options need to be reviewed and approved/denied in a timely manner (e.g. 3-6 months). This approach seems the 'fairest' compared to first in, first out, although there will be some subjectivity on who these products are assessed for innovation. Priority for drugs which fulfill an unmet need in patient care and provide significant improvement in outcomes – also need to have some manner to evaluate the value of the benefits for the costs compared to existing therapies.

Some noted the following with regards to option #3 - it offers an opportunity to improve the efficiency of the system if all of the partners agree to the same principles. It would save resources and guidelines are similar in many jurisdictions. More timely turnaround would be highly desirable with this option, but it would depend on which agency and their perspectives and if they align with Canadians. It should be noted that the unique features of practice patterns should be represented and local experts should have a strong voice.

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Equitable access should be criteria #1 - all heath conditions across the sex and age continuum should have some access to medications that have been shown to have clinical benefit.

Clinical benefit based on practice guidelines and cost benefit (value for the money). The other two criteria are unclear. What is feasibility? Who determines this and based on what objective measure? Social values?

How will equitable access be defined (honestly)? The values of a man who is an elderly patient will be much different than a 30 year old woman. This should be criteria #1 - all heath conditions across the sex and age continuum should have some access to medications that have been shown to have clinical benefit.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

Yes and only include objective clearly measured data of high quality. There is uncertainty around how you would weight the criteria and how that weighting would change for different agents or disease states. It is noteworthy that some provincial formularies employ a weighting process, so a national process could be adapted from these. I would add that, whatever the process, it should be transparent, scores should be publicly reported and used to iterate on the process periodically. We need to ensure all medications are fairly assessed in terms of societal impact and proactive vs reactive care (e.g., cardiovascular medications are important to a large proportion of Canadians, but so is access to birth control etc.)

As an aside, it would be helpful to see reference to COI of committees as well. Ideally since this is done on a national scale, limitation of committee membership to non-conflicted individuals.

8. 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 reviews)?

Prioritization system seems appropriate. There needs to be a transparent/pre-defined process/plan that applies to all medications. Prioritization for listed products to be reviewed should be predetermined/ predefined prior to establishing a national formulary - to better understand capacity required to maintain overtime. If new drugs are being added - consider building criteria that would trigger review of all other agents in class as well (changes in evidence/need for ongoing use). Evidence changes more often than 3-5 years - if want to put patients health first and ensure cost effective use of therapeutics - needs to be a process that triggers review with significant change in evidence and not just of the new drug in isolation - unless there hasn't been major changes in practice/evidence and the 3-5 year wait is deemed appropriate. Delayed use of optimal medication therapy costs society and healthcare systems a lot more money than building a robust review process for old and new medications upfront.

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

Timeliness of review of new medications is key - consider completing a complete class review when a new drug is added/being considered - should ensure all medications being used for similar indications are still valid to be listed or not listed - often formularies due not align with clinical practice guidelines, especially in CV disease. This results in 10 years before best practices are adopted in populations.

Limit the number of agents available/listed - you don't need 10 ACE inhibitors - pick 3-4.

When considering medications, often the complicated "restriction" or "exception drug status" criteria are major barriers for safe transitions in care (from hospital to home or from home to hospital), consider limiting the amount of restrictions to when absolutely necessary - what is the cost of administration vs the cost/impact to healthcare system of patient not having access to the medications?

Ensure it is clearly defined what interchangeability means - is it not interchangeable due to cost or due to lack of clinical equivalence - ensure this information is published.

Biosimilars are going to become important - what is the plan?

Currently there is a big gap of availability of products on the Canadian market. One area that comes to mind is arrhythmia. When a product is not on the market but is available via SAP there needs to be an avenue for coverage in this formulary. With legacy products being discontinued or backordered, this is very important.

Prescribing guidelines must be the basis for any formulary. Practice guidelines are the starting point following the initial list to create a criteria. A fragmented delayed provincial formulary should not be used after the initial list.

Based on the Excel file, there is one drug class missing - SGLT2i - however we suspect that this would be covered under the diabetes section, despite it also being used specifically in patients without diabetes + HF (dapagliflozin and empagliflozin). So you may want to note this. One comment on ASA - the document refers to not including OTC products, but I think it is really important to include ASA as it is essential in CVD and may be a barrier to folks that do not have coverage. One other drug missing is Tafamidis from amyloid. Finally, there is a brief reference to COI and I think this should be noted in other sections (e.g. expert committee, discussion re: transparency, etc.).

Canadian Forum for Rare Disease Innovators (RAREi)

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

While RAREi has no major objections to the principles outlined by the panel, it would propose adding at least one that would require national formulary managers to administer the list in a way that supports continued treatment innovation and the introduction of new technologies on an ongoing basis. This will ensure that Canada will be able to maintain a globally competitive stance in terms of providing patients with timely access to the latest scientifically advanced treatment options to improve outcomes, reduce health system utilization, improve productivity and meet their quality of life expectations and needs. It will also align with the broader national policy objective of supporting a globally competitive innovation economy and a viable and productive biomanufacturing and life sciences strategy in this country.

RAREi also notes that the chosen principles were developed in the context of health funding transfers and inter-jurisdictional relations, as opposed to addressing an evaluation framework. For this reason, the panel should review and consider adapting the principles developed and followed by the pan-Canadian Oncology Drug Review and later, largely adopted by the pan-Canadian Pharmaceutical Alliance.
These principles were developed in the context of a review program for health technologies which, fundamentally, is the core function of the advisory panel as well. Notably, these guiding principles also will be helpful in responding to many of the "out of scope" issues noted in the discussion paper. They include:

1. Governance - A review process with governance structures that are fair, objective, transparent and accountable to patients, payers, the public and innovators

2. Representation – A review process that is multidisciplinary, cross-jurisdictional and collaborative in nature with appropriate representation from diverse stakeholders and linked to other key national initiatives

3. Efficient and Effective – A review process that is cost-efficient, effective and streamlined (i.e. reduced duplication) to support timely decision-making

4. Evaluation – A review process with capacity for data capture and ongoing evaluation (decision monitoring / performance measurement) to support continuous process improvements. In addition, capacity for health outcomes and economic impact analysis to support decision-making and planning

5. Health System Focus - Medications are evaluated within a review process and decision making framework that are consistent with those used for medicines for other diseases

6. Evidence-based - A review process with capacity for rigorous and consistent evidence-based clinical and pharmacoeconomic reviews to support evidence-based decision-making

7. Excellence - A review process that reflects an ongoing commitment to excellence through incorporation of best practices in a spirit of continuous quality improvement

8. Ethical Framework - A review process that includes an ethical framework which balances the need for timely and quality therapies with broader societal values

2. Do you agree with the proposed assessment criteria?

Yes

Please provide the reason(s) and suggested changes, if any.

Once again, there is little to criticize conceptually in the proposed assessment criteria adopted by the panel. However, it appears to be an exercise without much point. According to a 2017 Patented Medicine Prices Review Board report examining alignment among public formularies, there is already a high degree of concordance (at least 80%) among public drug plan formularies in Canada, and that alignment is even higher when one considers the most utilized products. (Ref: PMPRB, Alignment Among Public Formularies in Canada, Part 1: General Overview, October 2017: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1327&lang=en.) Those findings beg the question of what problem the panel is being asked to solve.

If the intention is to ensure that every medication coverage plan offers a minimum range of effective medicines, then it would appear that objective has been met already since public plans across the country offer a similarly broad range of treatments, and private plans almost always cover a more extensive list of medicines than are reimbursed publicly.

If, on the other hand, the hope is to create one common list that all plans must offer, then much more fundamental questions arise about who pays, how such a program would be administered and how existing programs would be affected. The concepts of equality (same) and equity (fairness) need to be considered carefully, especially in the context of rare disorders where it is especially critical for a range of clinical options and tools to be made available in order to treat some of the most complicated and challenging medical conditions. In any case, a broader national discussion that takes into account many of the "out of scope" issues for this exercise is required in order for it to remain a principles-guided exercise.

In addition to policy-design challenges, the proposals raise administrative and resource issues. Already, the Canadian public medication review and approval process is duplicative, lengthy and often backlogged. (Ref: Innovative Medicines Canada, Explaining Public Reimbursement Delays for New Medicines for Canadian Patients, July 30, 2020: http://innovativemedicines.ca/resource/explaining-public-reimbursement-delays-new-medicines-canadian-patients.) It relies on a large number of expert reviewers who are kept quite busy with the workload currently facing them. Diverting that expertise to undertake the additional assessments required by this national formulary development exercise seems counter-productive to the ongoing effort to increase the efficiency of the existing processes.

Anything that would add steps or extend the timelines associated with the current review process would be viewed as highly problematic by RAREi members.

In the context of rare disease treatments specifically, RAREi encourages the panel to consider starting from the first article of the United Nations resolution on rare diseases adopted by the General Assembly on December 16, 2021. It calls upon all member states to strengthen their respective health systems, notably in terms of primary health care, in order "to provide universal access to a wide range of healthcare services that are safe, of quality, accessible, available and affordable, timely, and clinically and financially integrated, which will help to empower persons living with a rare

disease in addressing their physical and mental health needs to realize their human rights, including their right to the highest attainable standard of physical and mental health, to enhance health equity and equality, end discrimination and stigma, eliminate gaps in coverage and create a more inclusive society." (Ref: United Nations Resolution 76/132 - Addressing the challenges of persons living with a rare disease and their families. Adopted by the General Assembly on December 16, 2021: https://www.rarediseasesinternational.org/wp-content/uploads/2022/01/Final-UN-Text-UN-Resolution-on-Persons-Living-with-a-Rare-Disease-and-their-Families.pdf.)

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

RAREi members support the notion that devices that assist with the delivery or administration of medicines and/or are necessary for the optimal use of medications should be included as covered benefits within medication coverage programs.

In particular, members are keenly aware of the lack of clear budgets and defined assessment processes related to companion diagnostics. These important clinical tools, which are relied upon to aid in selecting or excluding specific patients for treatment with a given medication based on the patient's biological characteristics that determine responders and non-responders to the therapy, are increasingly vital to effective treatment in a range of therapeutic circumstances. However, they are often not funded and in most jurisdictions there is no obvious mechanism to facilitate consideration of them.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

If this exercise was being undertaken in the context of informing a health system formulary consultation, we would agree that other related products that are directly associated with a given medication should also be included as benefits at the same time as the relevant product is listed on the formulary.

4a. Do you support the proposed approach to expand to other therapeutic areas?

No

Please provide the reason(s) for your choice.

Question 4a pre-supposes support for the creation of a national formulary in the first place and, as stated above, the objective of the exercise is unclear, which makes it challenging to comment effectively on individual process elements. It is difficult to assess the value of doing so without understanding the ultimate aim of the project and its potential impact on access to medicines in Canada.

On a general note, RAREi has consistently called for equitable coverage for rare disease treatments for Canadians, and for each component of the current medication review and approval process to be customized in ways that meet the needs of rare disease patients. That requirement also applies in the context of formulary design.

It is clear that the traditional population-based approach to identifying a range of potential medications to be prescribed to treat a given condition by placing them on general list of benefits for a broad range of possible prescribers to consider is not a practical model to meet the needs of rare disease patients.

The nature of rare disease treatment demands a more personalized approach that takes into account the specific medical needs of each patient and permits treating clinicians, who often have highly specialized expertise, extensive leeway in finding ways to address their patients' needs most effectively. Any national formulary would need to be adapted to ensure that the appropriate level of flexibility is offered for potential rare disease treatments to be made available to those in need.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

RAREi has no feedback to offer regarding the sequence of additions to three therapeutic classes already evaluated by the panel, or how additional classes should be prioritized.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

RAREi believes that the current first-in, first-out approach to undertaking reviews of new medications / indications by regulators (Health Canada) and evaluators (CADTH, INESSS, etc.) should also be adopted by formulary designers and policymakers. That approach is necessary in order to permit innovators, which are managing within a complex global environment, to make an informed decision about whether to launch of new medicine in Canada based on a set of clear expectations regarding when a public funding review will be taken up and how long it should take to be completed.

We would ask the panel to appreciate that bringing a new medicine to Canada requires investments of multiple millions of dollars to support years of development and testing. It also involves the dedication of myriad human resources, logistical supports , marketing efforts, and a not insignificant outlay to cover submission fees at Health Canada, CADTH and INESSS. The current medication review and approvals patchwork system in Canada already challenges innovators with several layers of uncertainty, (such as the PMPRB changes, both in terms of how comparator countries are applied and the economic factors, a range of national and provincial HTA reviews and the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations maze). Within this already challenging process, some level of regulatory and government decision-making certainty is necessary. With those considerations in mind, RAREi believes that innovator expectations can only be met effectively with a first-in-first out review system.

5b. What criteria could be used to identify priority products?

If the issue driving this desire to implement a prioritization scheme is about limited resources for review, then it must be managed as a resourcing issue, which could be addressed effectively in other ways (i.e., efficiency reviews, more funding, etc.), rather than by subjecting new products to more bureaucracy and additional reviews that could well lead to an arbitrary, resource-intensive, time-consuming and ultimately controversial determinations.

That said, there are already ways to prioritize certain products for faster reviews without changing the overall target timeframes for evaluation and decision-making. One good example is Health Canada's priority review system which operates in a manner that gives enhanced attention to important new therapies without affecting the efficiency of the review process for non-priority products. There are also clear examples at other levels of the current medication review and approval processes where prioritization occurs organically. For example, when a pCPA Letter of Intent is finalized just days or weeks after receiving a positive CADTH clinical recommendation. RAREi believes more efforts of that nature should be applied in the context of rare diseases treatments in order to streamline the existing process and speed up access for people living with rare disorders to fully realize the benefits and improved outcomes for those living with rare disease given they already face a five-year wait on average for a correct diagnosis.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Broadly-speaking, RAREi supports the concept of deliberative frameworks and the criteria they rely on to guide the development of formulary recommendations and decision-making. That said, the current processes used by CADTH and INESSS have significant gaps and inconsistencies that we believe must be remedied before they are adopted by a pan-Canadian formulary design initiative.

As a starting point, RAREi recommends incorporating concepts such as the "rule of rescue," ethical considerations and societal values, such as the need for an innovative life sciences and pharmaceutical sector in Canada. In addition, the deliberative process should be open, transparent and available for external reviews to ensure accountability for reasonableness.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No

If yes, how should weight be distributed among the proposed criteria?

While multi-criteria decision analysis (MCDA) has some utility, it should be used as a tool, not a rule, given that it could in some cases lead to inequitable outcomes. An evidence weighting system needs to account for specific therapeutic contexts, such as ensuring access to rare disease treatments. If the panel proposes an MCDA approach, then further stakeholder dialogue involving methodological expertise would be required.

8. 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 reviews)?

RAREi understands the desire to manage the proposed national formulary in the context of the full life cycles of all the products on the list, and to ensure that the list of benefits remains current with respect to meeting clinical needs. However, care must be taken to avoid directing vital resources away from the already demanding reimbursement review process in Canada.

RAREi members believe that maintaining an efficient and timely HTA review process and ensuring ongoing and regular updates to existing public formularies for new medicines / indications must take precedence over efforts to build or maintain a national formulary and/or to conduct after-market review reassessments and therapeutic class reviews.

Canadian patients already wait longer than those in most comparable nations for access to new treatments. For example, Canada ranks 18th out of 20 Organization for Economic Co-operation and Development countries when considering the time from the first global authorization of a new treatment to public reimbursement for at least 20% of public plan beneficiaries. (Ref: Innovative Medicines Canada, Explaining Public Reimbursement Delays for New Medicines for Canadian Patients, July 30, 2020: http://innovativemedicines.ca/resource/explaining-public-reimbursement-delays-new-medicines-canadian-patients.) Given that reality, RAREi recommends that additions to those existing processes should be deferred until efforts to streamline and improve those existing processes are exhausted.

In reality, there are already mechanisms in place within the existing formulary review system that help ensure that the formularies remain relevant and support plan sustainability. Reimbursement policies such as the identification of lowest cost alternatives, mandatory generic substitution and preferential listings for biosimilars already – and in some cases problematically – move patients to less costly versions of specific medicines. In addition, therapeutic class reviews and various reference pricing schemes are used to incent the use of lower cost options within a particular class. At the same time, the system responds organically as clinical practices change. Given all that, it is unclear that dedicating substantial new resources to creating and maintaining a national formulary will be any more effective at keeping the system current or supporting system sustainability.

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

The biggest challenge in responding to the discussion paper is the lack of clarity about what problem or objective the exercise is directed at solving.

Given that lack of clarity in terms of how the new formulary would be used, which patients would be served, how it would be governed administered and financed, what impact it might have on existing medication coverage programs in Canada and its place in the broader national pharmaceutical policy proposals currently under development, it is hard to assess the proposal. To be clear, given additional understanding of those questions, RAREi's feedback would likely be quite different.

In light of the many relevant matters that remain unanswered, it appears that the panel's efforts are premature and lacking the necessary context that would allow for a more pragmatic assessment of the necessity and value of pursuing the creation of a new national formulary.

At the same time, the nature of medical care is shifting quickly towards more personalized care models that will demand new ways of thinking regarding what products are made available to which patients. The traditional population-based approach to building and maintaining a list of eligible treatment benefits that are available to a wide range of patients is not a practical model for managing reimbursement of pharmaceutical care in the future, especially within a developed and mature health system such as Canada's. This will require a fundamental rethinking about how we will be able to ensure that the right patient is able to access the treatments that meet their individual clinical needs. With that in mind, it seems counter-productive to invest in building a new national formulary.

This is particularly the case given that most Canadians are well-served by their existing medication coverage. In fact, a national poll conducted by Abacus Data in January 2020 for the Canadian Life and Health Insurance Association found that 83% respondents reported having access to some kind of pharmaceutical coverage, 85% were broadly satisfied with the costs they were required to pay and 84% were satisfied with the range of medicines covered. Among those whose plan required patient cost-sharing, 88% say the co-pay amount was affordable or "affordable enough." (Ref: Abacus Data, Canadians' views surrounding pharmacare, February 27, 2020: https://abacusdata.ca/pharmacare-views-canada.)

What these data indicate is that there is no broad public demand for a single national formulary in Canada. Where the need exists is among communities, like rare disease patients, whose needs are not being well met by the current coverage system. RAREi believes that rather than pursuing the creation of a national formulary, pharmaceutical policy reform efforts should be focused on addressing coverage gaps. In that context , RAREi members are hopeful that the still-to-be announced national rare disease treatment strategy under development by Health Canada will be organized in such a way as to improve affordable and funded access to treatments for rare disorders.

Canadian Generic Pharmaceutical Association (CGPA)

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Overall, the Canadian Generic Pharmaceutical Association (CGPA) agrees with the proposed principles. The procedures for how these principles will be implemented, however, lack detail and remain a concern for CGPA.

Specifically, CGPA has identified Sustainability as a key principle for a national formulary. According to data from IQVIA, generic medicines are dispensed to fill 74 percent of all prescriptions in Canada yet account for less than 21 percent of the $35-billion Canadians spend annually on prescription medicines. The average price for a generic prescription in Canada has declined from $23.58 in 2012 to only $20.29 in 2021. Over the same period, the average price of a brand-name prescription has increased from $77.03 to $121.20.

CGPA's calculations based on IQVIA data show that, for every one percent increase in the use of generic prescription medicines, Canadians could save up to $704-million annually.

Cost-effectiveness is an important strategy to achieve a sustainable formulary. CGPA is pleased to see the commitment to emphasize the use of generic and biosimilar products, as they provide safe and effective treatments that are cost effective.

Making prescription drugs more affordable and accessible is the key value proposition of Canada's generic pharmaceutical industry. CGPA supports the recommendations in the Final Report of the Advisory Council on the Implementation of National Pharmacare for mandatory generic substitution policies to encourage patients and prescribers to choose the most cost-effective therapies, and increase patient and prescriber awareness about the equivalency of generic and brand-name prescription medicines.

Part of cost-effectiveness includes transparent pricing to ensure that the formulary can achieve maximum benefit for expenditure. Thanks to CGPA's initiatives with the pan-Canadian Pharmaceutical Alliance (pCPA), the National Generic Tiered Pricing Framework and generic drug prices are publicly available and transparent. That being said, there are some issues that any formulary will need to address in pricing transparency to maximize cost-effectiveness. First, actual prices of multi-source products should be transparently listed on formularies.

Confidential product listing agreements (PLAs) for originator medications can and often do limit the ability to introduce lower-cost generic and / or biosimilar medicines, hindering a formulary's ability to achieve maximum cost-effectiveness. When establishing a national formulary based on the principles of sustainability, confidential PLAs must not be allowed. If they are allowed, any confidential PLA put in place prior to the market entry of generic versions should be removed upon generic market entry.

Reference-based pricing, where reimbursement in a therapeutic category is limited to the lowest cost molecule, undermines the stability and predictability of generic pricing, an environment achieved through the pCPA/CGPA Generic Pricing Framework. Under the principles of transparency and fairness,

a future Pan Canadian formulary should avoid reference-based pricing. Similarly, step-based therapy, or "tiering", should only be implemented on a basis of clinical need.

In addition, Principle 1 (Universal and integrated) is also important to ensure Canadians have access to the prescription medicines they need through a national formulary. CGPA recommends that hospital products are included on the proposed formulary to ensure improved continuity of care between hospital and community pharmacy settings. It is also recommended that oncology products are included as this therapeutic area currently has significant disparities in access between jurisdictions.

"Efficient and Timely": Duplication caused by the varied formulary listing and interchangeability designation processes employed by each province and territory increases administrative costs for both public drug plans and pharmaceutical manufacturers, and leads to uneven patient access and care across Canada. This can result in delays to access to cost-saving generic medicines to payers and patients. Generic and biosimilar medicines must be added to the formulary without delay following market authorization by Health Canada in order to clear budget headroom to fund new treatments and increase patient access.

With respect to the priority of "Effective and High Quality", all drugs, both brand-name and generics, are reviewed and authorized for sale by Health Canada before they are available for prescription. When a generic drug is approved, Health Canada continues to monitor its safety, effectiveness, and quality. Generic medicines are required to work the same way in the body as the original brand-name drug.

Generic medicines have the same active ingredient as the brand-name and must have the same amount of active ingredient in the prescription. Non-medicinal ingredients, like fillers and preservatives, may be different from the brand-name product, but they are also regulated and reviewed by Health Canada. To receive a license to manufacture and sell drugs in Canada, both brand-name and generic drug companies must follow the same Good Manufacturing Practices (GMP) guidelines, which ensure consistent production and quality standards.

2. Do you agree with the proposed assessment criteria?

Yes

Please provide the reason(s) and suggested changes, if any.

CGPA supports the recommendations in the Final Report of the Advisory Council on the Implementation of National Pharmacare for mandatory generic substitution policies to encourage patients and prescribers to choose the most cost-effective therapies, and increase patient and prescriber awareness about the equivalency of generic and brand-name prescription medicines.

Generic and biosimilar medicines must be added to the formulary without delay following market authorization by Health Canada in order to clear budget headroom to fund new treatments and increase patient access.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

The process must be transparent and include related products to ensure that patients access to the medicine is provided without further barriers, which is a key principle for the establishment of a national formulary. This would include, for example, ongoing testing needed for appropriate monitoring and patient adherence.

Generic and biosimilar medicines must be added to the formulary without delay following market authorization by Health Canada in order to clear budget headroom to fund new treatments and increase patient access.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

If the drug meets the evaluation criteria, then any devices / testing needed for the patient to effectively use the drug must be listed on the formulary.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

CGPA supports the recommendations in the Final Report of the Advisory Council on the Implementation of National Pharmacare for mandatory generic substitution policies to encourage patients and prescribers to choose the most cost-effective therapies, and increase patient and prescriber awareness about the equivalency of generic and brand-name prescription medicines.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

Any expansion should be based on medical needs and sustainability, patient access and cost-saving, such as the availability of generic and biosimilar medicines.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #1

Please provide the reason(s) for your choice.

CGPA recommends a combination of Option #1 and Option #2 be adopted. Option #1 is aligned with the current HTA process, and the inclusion of Option #2 would help to address unmet medical needs. CGPA

does not support Option #3 as this approach is inefficient and would lead to delayed access to new products. Cost-saving biosimilar and generic medicines should be automatically identified as priority products.

5b. What criteria could be used to identify priority products?

Generic and biosimilar medicines must be added to the formulary without delay following market authorization by Health Canada in order to clear budget headroom to fund new treatments and increase patient access.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

CGPA agrees with the proposed evaluation criteria and recommends that priority emphasis be given to "Value" as a criterion, where "Value" means meeting patient needs in a sustainable way with multiple therapy options available, and not limiting treatment to only the lowest cost product.

Generic and biosimilar medicines must be added to the formulary without delay following market authorization by Health Canada in order to clear budget headroom to fund new treatments and increase patient access.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

"Value", as a criterion should be given priority. "Value" should relate to meeting patient needs in a sustainable way where multiple therapy options are available, and not limiting treatment to only the lowest cost product. Generic and biosimilar medicines must be added to the formulary without delay following market authorization by Health Canada in order to clear budget headroom to fund new treatments and increase patient access.

The Panel's intended meaning for "integration into other systems" is not clear. CGPA would appreciate clarification.

8. 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 reviews)?

Clear timelines with expedited / automatic listings should be available for generic and biosimilar medicines.

In addition to a lowest-cost alternative rule, only generics should be listed on any national formulary if they are approved by Health Canada and available in the Canadian market. An example of this approach is the Government of Prince Edward Island's Generic Drugs Program. https://www.princeedwardisland.ca/en/service/apply-for-the-generic-drug-program

Reference based pricing, where reimbursement in a therapeutic category is limited to the lowest cost molecule, undermines the stability and predictability of generic pricing, an environment achieved through the pCPA/CGPA Generic Pricing Framework. Under the principles of transparency and fairness, a future Pan Canadian formulary should avoid reference-based pricing. Similarly, step-based therapy, or "tiering", should only be implemented on a basis of clinical need.

The implementation of a national formulary should also include a national interchangeability designation for all authorized drugs, based on Health Canada's Declaration of Equivalence (DoE). Furthermore, a single governance structure for interchangeability designation that all public plans defer to would provide consistency, streamline drug evaluations, and reduce gaps in access.

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

The pCPA / CGPA Generics Initiatives (https://www.pcpacanada.ca/generic-drug-framework) have achieved significant savings for all Canadian payers and no new initiatives should interfere with this pan-Canadian success.

Some of the most prescribed generic medicines are priced at a 90 percent discount off the price of the brand-name versions. That means up to 10 patients can be treated for the cost of treating one patient with the brand-name version.

The COVID-19 pandemic has highlighted the need to strengthen Canada generic pharmaceutical manufacturing capacity and the international pharmaceutical supply chain. A recent study by consulting firm EY Canada commissioned by CGPA (https://canadiangenerics.ca/wp-content/uploads/2022/02/02.22-EY-CGPA-Capacity-Study_FINAL-1.pdf) reports that global supply chains have become increasingly complex, introducing risks, disruptions and shortages of prescription medicines. These risks, such as export restrictions, interruptions to international transportation, and reliance on foreign partners, highlight the importance of measures to support the manufacture of prescription drugs in Canada and secure channels of import for medicines and inputs needed to produce them.

The generics market in Canada faces downward pressure on pricing with increasing costs of labour, land, transportation and a complex regulatory regime. Combined, these elements are increasing the fragility of the domestic industry.

While CGPA and its members are supportive of efforts to improve drug coverage for Canadians, we caution against the pursuit of risky tendering schemes with unknown savings results that could threaten the current and future supply of cost-saving generic pharmaceutical products in Canada.

By limiting the number of suppliers for a given medicine, tendering increases the risk of drug shortages and could lead to higher prices in the long-term as manufacturers are forced out of the market. If the chosen supplier or suppliers have production or other issues, alternatives to meet patient needs may not be available.

Unlike pricing mechanisms such as tendering schemes, the Tiered Pricing Framework of the pCPA Generics Initiative helps maintain the incentive for generic pharmaceutical manufacturers to challenge

invalid and / or non-infringed patents under Canada's patent rules for pharmaceuticals. It is in the interest of all Canadian payers and patients to ensure that these incentives remain in place.

Care must be taken to ensure that the potential benefits of a national formulary are not undercut by pricing schemes that reduce the current and future availability of cost-saving generic prescription medicines.

Implementation of a national formulary should include processes that defend against marketing efforts to switch prescriptions from a generic medicine to a more expensive new patented drug that does not provide therapeutic improvement.

Multiple drug options should be included in the same therapeutic category to meet individual patient needs and to mitigate any impact of a drug shortage.

Reference-based pricing, where reimbursement in a therapeutic category is limited to the lowest cost molecule, undermines the stability and predictability of generic pricing, an environment achieved through the pCPA/CGPA Generic Pricing Framework. Under the principles of transparency and fairness, a future Pan Canadian formulary should avoid reference-based pricing.

Similarly, a national formulary should avoid "tiering" where certain drugs are "preferred" over / prior to reimbursement of other medicines, except in clinically necessary cases

The ongoing sustainability of our health-care system and drug benefit plans is highly dependent on the increased use of generic prescription medicines. Now that Canadian prices have been dramatically cut, more must be done to increase generic utilization and the resulting savings to Canada's health-care system.

Canadian Labour Congress

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The Canadian Labour Congress (CLC) generally agrees with the proposed principles, but would like to see some additions and changes. Please find below our suggested changes and the reasons behind them:

1. Proposed principle: Overall proposed principles.

Suggestion: The CLC recommends a mapping of the proposed principles of the pan-Canadian formulary to the five Canada Health Act (CHA) principles to demonstrate the extent to which the proposed principles of the pan-Canadian formulary support and strengthen the CHA principles of public administration, comprehensiveness, universality, portability and accessibility.

Reasons: The pan-Canadian drug formulary principles must contribute to the continual improvement and strengthening of the CHA principles for a stronger public healthcare in Canada.

2. Proposed principle: Inclusive, transparent, and fair process

Suggestion: The CLC recommends the addition of unions as a stakeholder that will develop and manage in collaboration a potential pan-Canadian formulary.

Reasons: Most public sector workers at the federal, provincial, territorial and municipal levels have prescription drug coverage as a benefit of their employment. About 30 percent of all private plan beneficiaries are public sector employees. In 2021, it was estimated that private drug costs totalled $13.08 billion, and public sector workers' share is estimated to be $3.9 billion or almost 20 percent of all private drug plan spending. Unionized workers currently negotiate the best drug benefit coverage at the bargaining table, and have a perspective that is unique and very relevant to the development and management of a pan-Canadian formulary.

Unions bargain drug benefit coverage because they represent workers including patients and people with lived experience as well as many paid and unpaid caregivers. In addition, unions represent workers from every stakeholder group listed in this consultative document: health care providers, and workers in health organizations, governments, and industry. Unions also represent many essential, low-waged and precariously employed workers who deserve equitable access to prescription drugs.

Labour must be at the table as an active stakeholder for the development of the pan-Canadian formulary. The Canadian Labour Congress is Canada's largest central labour body, representing 3 million unionized workers in every sector across Canada. It brings together over 54 national and international unions. Our affiliates are public and private sector unions, and include 12 provincial and territorial federations of labour, and 104 local labour councils. The CLC and its affiliates are ready to actively contribute to the development of the pan-Canadian formulary.

3. Proposed principle: Efficient and timely

Suggestion: The CLC recommends further elaboration and explanation to "streamlined" and "timeliness"

under the process values section.

Reason: The CLC is seeking further clarity as to what is meant by “streamlined” and “timeliness” under this proposed principle.

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

The CLC appreciates the thoughtfulness the panel members have put towards the proposed assessment criteria.

Although, the context of this consultative process is stated at the beginning, the fact is that the work on developing the pan-Canadian formulary is within a rich environment where a lot of work has already been done by many experts, stakeholder groups and by the Advisory Council on the Implementation of National Pharmacare. This Advisory Council’s work culminated in the Hoskins Report that has an implementation plan for a national universal first-payer pharmacare plan. There is also strong and increasing support for such a national universal pharmacare plan that would strengthen Canada’s public healthcare system as people are losing or have reduced access to their employment-based drug coverage over the last two years of the COVID pandemic. So, the work of developing the pan-Canadian drug formulary is unavoidably contextualized in terms of politics, policy and the increasing needs of people in Canada, especially during the pandemic.

The CLC would like to receive more information on the proposed assessment criteria in this consultative document. In the Hoskins Report, the initial phase of the formulary was the essential medicines list. There is already a robust body of policy work and academic research on the essential medicines list internationally and in Canada, such as at the World Health Organization and by Canadian researchers. Thus, the essential medicines list can be developed in a very short time. In addition, the essential medicines list in the Hoskins Report covers most major conditions and represents about half of all prescriptions.

The CLC would appreciate more information from the Panel as to how the proposed assessment criteria for Stage 1: Creating the Proposed Sample List compares to the Hoskins Report’s essential medicines list, in terms of:

• the share of all prescriptions;

• the impact on timelines on the development and delivery of a pan-Canadian formulary; and

• the reasons considered and how each corresponds to key principles of equity, universality, and integration as well as effectiveness, efficiency, and quality as outlined in this consultative document.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

The CLC supports the inclusion of devices that assist with the delivery or administration of drugs and/or are necessary for the optimal use of drugs; that help improve patient access; and could potentially improve adherence to drug treatment on a pan-Canadian formulary. The standard criteria to help determine which related products should be eligible for inclusion on the potential pan-Canadian formulary must include equitable access.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

The CLC would like equitable access and clinical benefit to be central in the evaluation criteria for related products.

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

Please refer to the CLC's input in question 2. Stage 2 of the proposed approach should result in a full and complete pan-Canadian formulary that is available and used for the implementation of national universal single-payer pharmacare plan.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

Please refer to the CLC's input in question 2 and question 4a. The pan-Canadian formulary consultation document refers to "national health priorities" but does not refer to what these are, how they are set and who is responsible for setting them.

The consultation document on the pan-Canadian formulary reflects a high level of awareness and integration of equity in the consideration of the work. National health priorities must also be equitable and not be determined and/or influenced by:

• lobbyists in the prescription drug supply chain including those in insurance and pharmaceutical industries; and

• stakeholders such as drug manufacturers, researchers, academics, clinicians, patients' groups with financial conflicts of interests.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

As with the Panel, the CLC also has reservations about the current process for reviewing drug products. The current "first-in, first-out" process based on when submissions are filed has not served Canadians well. Between 2010 and 2019, 95 percent of new drug therapies offered no, slight, or moderate improvement to other medicines sold in Canada—leaving a mere 5 percent of new drugs offering breakthrough or substantial improvement according to the PMPRB.

The CLC supports elements of all three options summarized as: Create a clear and transparent scoring system that would prioritize new drug submissions. This scoring system must allow for a predictable process for identifying products that represent a significant therapeutic advancement and benefit. Opportunities to work together at an international level to review and prioritize products collectively could be explored as an additional resource where possible.

5b. What criteria could be used to identify priority products?

The CLC supports the six proposed evaluation criteria for new products to be considered in a potential pan-Canadian formulary, with priority given to equitable access, clinical benefit, and long-term thinking that looks at the broader impact of a drug on the health system and Canadian society.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The CLC supports the six proposed evaluation criteria for new products to be considered in a potential pan-Canadian formulary, with prioritizing equitable access, clinical benefit, and long-term thinking that looks at the broader impact of a drug on the health system and Canadian society.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

The CLC supports structuring the deliberative process so that evidence from multiple disciplines and perspectives can be weighted. However, the main challenges that need to be addressed in weighting are who defines the criteria, based on what and according to whose preferences. Our concern is that people living with health inequities in society and communities will have no voice or little voice in deciding how weighting is carried out. For this reason, the CLC will be looking for a process that is accountable and transparent in determining the weighting of the deliberative process that prioritizes the integration of equity.

8. 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 reviews)?

The CLC supports timely and on-going formulary modernization strategies (e.g., reassessments, therapeutic reviews) and the re-evaluation of existing listed products with emerging new evidence on a regular cycle (e.g., every 3 years to 5 years).

Labour is ready to contribute to develop measures that will be taken to ensure operational sustainability. Unions must be included as key stakeholders in the health system. Reiterating the CLC's rationale for the inclusion as a stakeholder (as in response to question 1):

Most public sector workers at the federal, provincial, territorial and municipal levels have prescription drug coverage as a benefit of their employment. About 30 percent of all private plan beneficiaries are public sector employees. In 2021, it was estimated that private drug costs totalled $13.08 billion, and public sector workers' share is estimated to be $3.9 billion or almost 20 percent of all private drug plan spending. Unionized workers currently negotiate the best drug benefit coverage at the bargaining table, and have a perspective that is unique and very relevant to the development and management of a pan-Canadian formulary.

Unions bargain drug benefit coverage because they represent many workers including patients and people with lived experience, including many paid and unpaid caregivers. In addition, unions represent workers from every stakeholder group listed in this consultative document: health care providers, and workers in health organizations, governments, and industry. Unions also represent many low-waged and precariously employed workers who deserve equitable access to prescription drugs as well.

Labour must be at the table as an active stakeholder for the development of the pan-Canadian formulary. The Canadian Labour Congress is Canada's largest central labour body, representing 3 million unionized workers in every sector across Canada. It brings together over 54 national and international unions. Our affiliates are public and private sector unions, and include 12 provincial and territorial federations of labour, and 104 local labour councils. The CLC and its affiliates are ready to actively contribute to the development of the pan-Canadian formulary.

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

No response provided

Canadian Life and Health Insurance Association

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

On page 7 of Setting the Context, the first paragraph identified that "the general purpose of a formulary is to ensure that the treatments that are used are safe, effective, affordable and cost-effective." We would agree with this definition and yet the work of the panel specifically excluded any review of affordability and cost-effectiveness in the context of the development of the pan-Canadian formulary.

The principle, noted on page 13, is to develop and maintain the formulary on an "inclusive, transparent, and fair process". The process is not inclusive to the perspective of a major funder of prescription drugs in Canada, given that the perspectives of private plans are not considered.

We would request that a review of the suggested formulary be undertaken with a lens of affordability and cost-effectiveness to ensure that both public and private health plans remain sustainable and best able to meet the health needs of all Canadians.

Further, we recognize that the proposed principles and definitions may, from time to time, come into conflict with one another and may need to be prioritized.

We support the criteria that priority be given to biosimilars and generics, where available.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The proposed assessment criteria for the proposed sample list is guided mostly by the requirements of the current Canadian public drug plans, for example, reducing hospitalizations. We would ask that the assessment criteria be expanded to include a broader perspective and more comprehensive definition of health and wellness.

In assessing drug effectiveness, private plan considerations also include the need to provide prescription drug coverage for employees on disability and helping people return to work, when appropriate. Private plans often have more comprehensive coverage of mental health treatments, as one example. Employers fund prescription drugs that keep employees healthy and productive, and that minimize absences from the workplace.

It appears the panel has assumed that the drugs currently covered by public formularies are already cost effective for all payers as it is these plans that the pan-Canadian formulary draws upon for the proposed list of covered drugs. We think that this assumption needs to be examined further, especially given confidential discounts that may differ between provinces, and may not be available to employers who fund prescription drugs. The concept of a pan-Canadian formulary opens the discussion to transparent and common pricing for products on the formulary that should be brought forward into future discussions.

We would like to raise the issue of combination therapies that are frequently developed by manufacturers in order to maintain patent exclusivity. Certain combination therapies can become much more costly to fund as a result. However, consideration should also be given to whether a combination therapy provides additional value that may result in improved outcomes such as better adherence.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

Related products could include products that:

• Are currently funded through drug programs

• Support the treatment or maintenance of conditions primarily treated by prescription medications

• Are not used as a diagnostic tool

We would recommend that when reviewing a therapeutic category, it is done holistically. For example, when reviewing with diabetes, include all supplies (syringes, pen needles) and testing options (strips, lancets, flash glucose monitoring (FGM), continuous glucose monitoring (CGM)) in the review.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

Related products should be listed on the proposed formulary or continue to be offered through another benefit program. Related products should be evaluated on similar criteria to prescription drugs, that is, through an evidence-based review.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

Yes - in Part.

In this section 'national health priorities' are not defined but appear to consider only the public drug plans, excluding private coverage that more than 26 million Canadians access through their workplace. We would ask that privately funded prescription drug programs be included as a step in the proposed approach for consideration of listing status. This would include whether certain drugs are currently funded on private formularies and reviewing utilization data. As noted above, national health priorities will likely consider impacts to the overall Canadian healthcare system (e.g.: hospitalizations) which is essential, but we would also recommend taking a broader view to prevent disability and more.

The proposal to include cancer and special drug programs in the pan-Canadian formulary is interesting as typically these programs are funded partially or entirely by the public plans. Cancer programs vary substantially across the country. There have been changes to the types of products covered with the advent of oral cancer products, as an example. In certain jurisdictions such as Ontario, IV chemotherapy is primarily funded by the provincial program. Other jurisdictions have a program that covers a mix of IV and oral products. The variations in public plan coverage for cancer, using only those programs as the basis for assessment criteria will leave a large void in the number of products reviewed and potentially included in a pan-Canadian National Formulary. It may be helpful to consider the unique nature of cancer drug coverage when developing final recommendations.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

The insurance industry is supportive of any approach that moves drugs onto formularies more quickly while reducing duplication.

This section mentions the steps that must be taken to by a manufacturer in order to be considered on a "for inclusion in a public drug plan". The requirements of Health Canada, the HTA bodies, the pCPA and the FPT payor are listed. We have long requested that the requirements of private drug plans and employers be considered as part of the review. While some manufacturers have taken steps to include some data on productivity, disability impacts and workplace concerns such as mental health etc., many have not. We would suggest that this is a good opportunity to include these broader health concerns as a mandatory part of the submission review.

Another question to be considered is whether the additional review required to be covered on the pan-Canadian formulary through the working group might actually cause a further delay in coverage. The average time from marketing authorization to public listing in Canada was 534 days between 2011-2016. (Innovative Medicines: http://innovativemedicines.ca/wp-content/uploads/2019/04/2019-CADTH-Poster-EN-1.pdf)

5b. What criteria could be used to identify priority products?

The insurance industry is supportive of any approach that moves drugs onto formularies more quickly while reducing duplication.

This section mentions the steps that must be taken to by a manufacturer in order to be considered on a "for inclusion in a public drug plan". The requirements of Health Canada, the HTA bodies, the pCPA and the FPT payor are listed. We have long requested that the requirements of private drug plans and employers be considered as part of the review. While some manufacturers have taken steps to include some data on productivity, disability impacts and workplace concerns such as mental health etc., many have not. We would suggest that this is a good opportunity to include these broader health concerns as a mandatory part of the submission review.

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6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

We'd like to propose that the 'Value for Money' proposed criteria be expanded to include a bullet point that speaks to the needs of employers and private insurers, as well as the 26 million Canadians that enjoy private prescription drug coverage.

• "Impact that adding the drug on the list will have on the health of employed populations, including the ability to remain physically and mentally healthy."

In addition, further consideration to elaborating on how cost-effectiveness is determined may be warranted. Current public facing health technology assessments include the costs to the public health system and not those used by private drug plans, such as disability impacts and productivity. Including the various offsets will provide a holistic view of cost-effectiveness for all Canadians.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

Yes - in Part. Page 20 speaks to the creation of a working group to weigh evidence, conduct reviews and identify drugs to be included on the pan-Canadian formulary on a go-forward basis. There are many nuances that make it difficult to apply a rigid scoring system. Expertise on the working group is required to take into consideration all of the principles and produce a well thought out, balanced decision. Given the importance of private drug plans to the Canadian economy and to employers and their employees, we'd like to suggest that our industry's expertise will be key to the development of a successful formulary.

8. 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 reviews)?

As mentioned throughout this document, private insurers have the resources and expertise to contribute to the development and the maintenance of a pan-Canadian formulary. The needs of Canadian employers and their employees need to be taken into account as this important work develops so that the pan-Canadian formulary is relevant to all Canadians. Over the years, private drug plans have developed innovative solutions benefiting working Canadians, including in the areas of opioids, diabetes and mental health.

Is there possibility that the review for the pan-Canadian formulary replace any other reviews that are undertaken?

Another point to be considered as your report is finalized is whether the implementation of a pan-Canadian formulary could actually result in a loss of coverage. The implementation criteria (ie: mandatory, optional, as a base) need to be clearly agreed-upon very early on in development.

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

No response provided

Canadian Liver Foundation

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The Canadian Liver Foundation supports the establishment of an effective, sustainable, and modern pan-Canadian formulary that is based on principles that result in better health outcomes for all Canadians living with liver disease.

The Canadian Liver Foundation agrees with the six proposed principles and their definitions, with two important stipulations:

Regarding Principle 1, "Universal and Integrated", the Canadian Liver Foundation would like to highlight the diversity of the Canadian liver disease community and the direct impact the social determinants of health have on health outcomes. For example, many people who are at risk of, or are living with Hepatitis C Virus (HCV) face stigma and discrimination, which discourages them from seeking prevention, testing, treatment, and care. De-stigmatizing HCV is crucial for the successful delivery of services, including medicines, that will reach people who need them most. Therefore, when considering "universal" access to medicines, there needs to be dialogue around accessing care and alignment with public health initiatives to ensure all Canadians are receiving equitable access to health care.

Regarding Principle 3, "Effective and High Quality", the Canadian Liver Foundation would like to highlight the importance of patient and caregiver input in the monitoring of a pan-Canadian formulary to ensure it continues to meet the needs of all Canadians and its goal of better patient health outcomes.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The Canadian Liver Foundation recognizes the benefits to a staged approach in implementing a pan-Canadian formulary. Currently, the full plan for implementation, importantly the consultation and consideration stages, is not clear, making it difficult to comment on the proposed assessment criteria.

The Canadian Liver Foundation would like to highlight the importance of individualized therapy to achieving better patient health outcomes, particularly as it relates to substitute medicines. The Canadian Liver Foundation's position is that any medication switching, even those deemed biosimilar, be done in consultation with the patient's healthcare provider(s). This is particularly important to the liver transplant community, whereby uncontrolled switching of critical dose anti-rejection medications could lead to the development of acute rejection, renal or cardiovascular toxicity and even graft loss or patient death, not to mention increases to health care costs. It is critical that patients in collaboration with their healthcare teams, have both choice and knowledge of treatment options to ensure optimal health outcomes.

The Canadian Liver Foundation, in agreement with the Health Charities Coalition of Canada, would like to see other opportunities to manage drug costs through modern procurement avenues and negotiations.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No

Please provide details.

The Canadian Liver Foundation is not in a position to determine the eligibility criteria of related products to include on a pan-Canadian formulary. The Canadian Liver Foundation supports the development of new or additional criteria to determine the eligibility of related products through consultation with medical experts/associations.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

The Canadian Liver Foundation supports whole person health focused on restoring health, promoting resilience, and preventing disease across a lifespan. To this end, the Canadian Liver Foundation supports the inclusion of related products on a pan-Canadian formulary in alignment with the principles and in achieving the best health outcomes for Canadians.

The Canadian Liver Foundation supports changes that will lead to a modern, improved, and world leading HTA and HTR process inspired by best practices and an openness to continuous improvement.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

The Canadian Liver Foundation supports the creation of a pan-Canadian formulary that achieves universal and equitable access to therapies for all disease states and conditions.

The Canadian Liver Foundation recommends that therapeutic areas not be reviewed in isolation of each other due to the relevancy of co-morbidities requiring treatment across multiple therapeutic areas. For example, 59% of Canadians with Type-2 Diabetes also have Non-Alcoholic Fatty Liver Disease. In addition, patients with chronic liver disease (e.g., advanced stage hepatic fibrosis and progressive portal hypertension) consume on average nine medications each day from a variety of therapeutic classes to manage complications and co-morbidities. Optimal use of medications is critical to achieve positive patient health outcomes.

The Canadian Liver Foundation would need to further understand the impact of this approach on the diverse liver disease community.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

Liver disease may affect 1 in 4 Canadians and is on the rise. The Canadian Liver Foundation recommends the liver disease community be more involved in healthcare decisions and priority setting in Canada. For example, the Canadian Liver Foundation was not engaged in the 2017 "A Common Statement of Principles on Shared Health Priorities". The Canadian Liver Foundation supports further engagement opportunities for priority setting.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

The Canadian Liver Foundation supports strong engagement and collaboration with all key stakeholders in the review process. The Canadian Liver Foundation recommends further analysis of these options to determine feasibility and the selection of the approach that best aligns with the principles and goal of better patient health outcomes, particularly as it relates to the liver disease community. Further exploration of Option 3 is of interest as Canada often lags other countries in terms of access to drugs.

5b. What criteria could be used to identify priority products?

The Canadian Liver Foundation, in alignment with the Health Charities Coalition of Canada, is unclear what resource constraints are contributing to the need of an option analysis and priority setting exercise. Further analysis of the options in consultation with experts should be done to understand feasibility.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The Canadian Liver Foundation agrees with the proposed evaluation criteria for new products but notes an issue with criteria #4 "Feasibility of adoption into health systems". The Canadian Liver Foundation is concerned that this criterion could limit the inclusion of a new effective therapy/device due to challenges with its adoption. The Canadian Liver Foundation recommends improvements to patient care (e.g., public awareness campaigns, better screening) be considered when reviewing the feasibility criteria of a new therapeutic. A treatment can only work if you can access it.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

The Canadian Liver Foundation, in alignment with the Health Charities Coalition of Canada, recognizes the importance of an effective governance model to a successful pan-Canadian formulary. The Canadian Liver Foundation supports a model that is objective, aligns with the principles, includes patient input, and results in better patient health outcomes. The Canadian Liver Foundation supports a model that improves upon existing models of patient inclusion and HTA around the world, but also considers the diversity of the Canadian liver disease community.

8. 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 reviews)?

The Canadian Liver Foundation supports an interactive process that is thorough, inclusive, agile, and expeditious to achieve a successful pan-Canadian formulary.

As a research funder, the Canadian Liver Foundation recognizes the importance of new research in an evidence-driven, patient-centered approach to the HTA and HTR processes. The goal of these processes should always be optimal patient care and improved patient health outcomes.

Regarding clinical practice guidelines, the charitable sector works hard to form close partnerships and relationships with their respective clinical community. The Canadian Liver Foundation has many clinical partnerships including with the Canadian Association for the Study of the Liver (CASL). Together with CASL, clinical practice guidelines (CPGs) have been developed (e.g., for Hepatitis B, Hepatitis C, and Liver Cancer) that take into account the diverse Canadian liver disease community. CASL is also developing a Clinical Practice Guidelines Committee responsible for developing new clinical guidelines for Canadian HCPs. It is vital that a pan-Canadian Formulary aligns with current and evolving CPGs. To this end, the charitable sector could play an increased role in the HTA and HTR processes to ensure operational sustainability, to bring diverse perspectives to the table, and to provide regular communication channels with the clinician and research communities.

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

The Canadian Liver Foundation supports a process that leverages existing systems (e.g., CADTH's expert review committees) and reduces duplication of processes.

The Canadian Liver Foundation supports a health system that has a single publicly accountable management agency to secure optimal health outcomes for Canadians, including all Canadians living with liver disease.

The Canadian Liver Foundation supports improving the continuity of care (e.g., patients transitioning from the hospital to the community and vice and versa and transitioning from province/territory to province/territory).

The Canadian Liver Foundation supports transparency through communication and welcomes the opportunity to discuss a larger role in communicating in clear language to the diverse Canadian liver disease community.

The Canadian Liver Foundation recognizes a need to establish more effective and integrated IT systems in Canada to help healthcare professionals and others better understand and monitor prescription drug use and improve patient health. Importantly, IT systems must be easy for healthcare professionals to apply for reimbursement of drugs for their patients.

The Canadian Liver Foundation believes the goal of a pan-Canadian formulary should be improved patient health outcomes.

Canadian Organization for Rare Disorders (CORD)

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

The Canadian Organization for Rare Disorders (CORD) appreciates this opportunity to provide input for the consultation by the pan-Canadian Advisory Panel on a Framework for a Prescription Drug List on the nature of that list, or national drug formulary.

CORD is Canada's national network for organizations representing all those with rare disorders. CORD provides a strong common voice to advocate for health policy and a healthcare system that works for the 3 million Canadians with rare disorders and their families, since two-thirds of those with rare disorders are children. CORD works with governments, researchers, clinicians and industry to promote research, diagnosis, treatment and services for all rare disorders in Canada.

Frankly, CORD's initial reaction was to abstain from responding to this consultation. The Advisory Panel's stated task to explore approaches to "creating a proposed list of commonly prescribed drugs and related products" seemingly had no relevance to our rare disease population. Moreover, the staged approach starting with a small sample list as "proof of concept" in three common therapeutic areas (cardiovascular diseases, diabetes, and psychiatric illnesses) and "scaling up" would probably not get to even our most populous conditions for many cycles of review. Additionally, the proposed assessment criteria for the prescription drug list do not align well with potential considerations for specialized or rare therapies. Finally, the Panel does note that other pharmaceutical initiatives, such as the Drugs for Rare Diseases Strategy, was "out-of-scope" of the panel's mandate, albeit potentially informative.

However, given this last consideration, namely, that the concept of a list and the selection process could be applied to rare disease drugs, we decided it would be negligent NOT to respond and to put our reflections on the record. Moreover, we feel that specialty and targeted therapies for sub-groups of more common diseases have many of the characteristics of therapies for rare diseases, so while we will speak about rare disease patients and therapies, we believe many of our concerns are relevant to other therapies, especially those targeted at small populations.

With due respect to the intentions and composition of the Advisory Group, there is no doubt that the exercise and creation of a minimum Prescription Drug List, however provisional, would only disenfranchise and disadvantage the most vulnerable in Canada's healthcare system, persons living with rare disorders (PLWRD). As seriously, such a list will harm those who do not benefit from or are counter-indicated for "first line" or generic treatments for any condition; it will delay, limit, or deny access to specialized, combination, experimental, targeted therapeutics, and gene therapies. In short, the concept of a common Prescription Drug List is a concept that is not only outdated but detrimental to optimal treatment. As other developed countries move toward strategies to making the most highly effective innovative therapies more accessible to their patients, Canada is going backwards. Even if these specialized, targeted, and personalized therapies are available, there will undoubtedly be an application and review process. There is no doubt that many more Canadians who have the means will be driven to other countries to access their treatments.

The rare disease community, globally and in Canada, has worked strenuously and passionately to overcome the inherent and seemingly insurmountable obstacles of rare drug development. Thanks to the orphan drug acts (USA, Europe, Japan), there have been many more drugs developed and approved (over 600) for rare diseases but access is uneven. In Canada, we have fought for access, often on a drug-by-drug, patient-by-patient basis.

Importantly, drugs receiving an orphan designation are usually for severe, progressive or life-threatening conditions for which there are no other effective treatments or represent a significant improvement. In August 2021, Orphanet published a list of 204 Essential Medicines for Rare Diseases, compiled by an expert group under the auspices of the International Rare Diseases Research Consortium; that should be adopted by the pan-Canadian prescription drug list. If it included, at minimum, all the "rare disease" drugs approved by Health Canada, this would be a potential starting point toward addressing patient needs.

CORD proposes that an all-inclusive approach should apply not just for rare patients and diseases, and drugs but for all patients. If Health Canada has approved the drug as safe and effective, unless it has been removed, it should be included. While the pan-Canadian prescription drug list is being touted as facilitating access, it constitutes another barrier. After drugs are approved by Health Canada for safety and efficacy, they are assessed by the health technology agencies for cost-effectiveness, cost utility, and place in therapy, then negotiated by the panCanadian Pharmaceutical Alliance for lowest collective "willingness to pay", and then reconsidered by each public drug plan for budget impact. At each step, the ability of treaters to prescribe the most appropriate drug to their patients worsens. We cannot put one more impediment between the drug, the prescriber and patient.

CORD calls upon the Advisory Panel to follow the dictates in their own discussion paper. The first principle states that the proposed formulary should be "universal and integrated" which is defined as: "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)" (source: https://cadth.ca/sites/default/files/pdf/Pan_canadian_Formulary/CP0026-PanCdnFormulary-Discussion-Paper_FINAL_ForPosting.pdf).

Importantly, the purpose and audience for this proposed formulary are not clear.

This Discussion Paper argues that decisions on clinical efficacy "should be viewed in the context of 'benefit to patients and to the Canadian population as a whole.'" This is sadly an outdated and "out-of-context approach that ignores technological innovations and trends toward individualized healthcare and personalized medicine.

No advisory panel, no expert body, no stakeholder deliberation, and no public consultation should be allowed to determine what is needed by an individual patient. To that end, the acceptable option for a formulary is to include all approved treatments and, beyond that criteria, also provide a process for prescribers to access treatments that are individually necessary but not approved. Canada should be following the dictate of the World Health Organization and the United Nations in calling for "universal health coverage" applied in ways that "leave no one behind."

In sum, the proposition of a Prescription Drug List is an approach that is out of step with 21st century medicines and the emerging innovative therapies. If the goal is to equalize access for all Canadians, we need to explore much more effective strategies that are simultaneously focused on achieving individualized and personalized healthcare care as well as optimal and sustainable population benefits.

Canadian Partnership Against Cancer

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The Canadian Partnership Against Cancer thinks that the proposed principles, definitions and values to support the principles are very good. In particular, the discussion of equity throughout the paper is excellent and acknowledges that health inequities result from structural issues, such as policies, and are influenced by the social determinants of health. Equity in both financial access and physical/logistical access to medications is critical and has been considered and addressed well in the guiding principles. In addition, we agree with the idea that evidence used in developing the formulary should come from diverse populations, perspectives and experiences.

The Canadian Partnership Against Cancer has a couple of suggestions for additions to the definitions of two of the principles and associated values:

• We suggest that in the definition and values associated with the "Equitable" principle, there is a separate section that specifically discusses First Nations, Inuit and Métis. The experiences and perspectives related to accessing drugs are different for each of First Nations, Inuit and Métis populations compared to other populations experiencing health inequities and should be considered separately. In addition, it is important to take a Peoples-specific approach, so that the differing structures (e.g., NIHB for Status First Nations and Registered Inuit only) and experiences (e.g., living in remote areas) that currently impact access to drugs are acknowledged. It's very positive that OCAP principles are noted under the values for the "Equitable" principle, but it would be helpful to be more specific about the origins and use of OCAP principles and cite other research and data principles, even in footnotes.

• We suggest that in the definition and values associated with the "Inclusive, transparent, and fair process" principle, that First Nations, Inuit and Métis communities, organizations and governments be specifically named as stakeholders.

2. Do you agree with the proposed assessment criteria?

Yes

Please provide the reason(s) and suggested changes, if any.

Regarding the discussion of non-prescription drugs in this section of the discussion paper (page 20), the inclusion of non-prescription nicotine replacement therapies (NRT) as psychiatric drugs for nicotine addiction, is excellent and would have an impact on many diseases associated with tobacco use. In fact, prescription and non-prescription smoking cessation aids could also be considered oncology drugs.

When a person quits smoking, their cancer treatment becomes more effective, their quality of life improves and their chance of surviving increases. This makes smoking cessation support, including medications, a critical component of first-line cancer treatment and high-quality cancer care. Providing free smoking cessation medications to people at the time and place they receive cancer treatment would help more people quit smoking and contribute to achieving more equitable cancer care in Canada.

However, as we know from work funded by our organization (Canadian Partnership Against Cancer) on smoking cessation in the territories, requiring a prescription from a physician or nurse practitioner to access NRT under the proposed formulary could reduce access for people living in remote areas that don't have regular access to these prescribing health care professionals and increase inequities across Canada. In 2021, the NIHB changed its policy, no longer requiring a prescription for NIHB coverage of NRT, and allowed pharmacists to recommend NRT products for coverage. This removed an additional barrier to accessing NRT for people in remote areas. Still, in some places in Canada, remote health centres do not carry NRT on-site, and many rural and remote communities do not have ready access to pharmacies.

Therefore, we suggest that the formulary administration allow, or recommend to the provinces and territories to allow, a wide range of practitioners (including nurses and pharmacists) to prescribe non-prescription medications such as NRT.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

The Canadian Partnership Against Cancer agrees with the current approach regarding related products and notes that increasingly cancer drugs have companion tests that predict efficacy (e.g., Oncotype Dx).

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

Please see section b. below.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

The Canadian Partnership Against Cancer supports the proposed approach to expand to other therapeutic areas and then prioritizing remaining areas based on national health priorities. We also suggest including the health priorities of National Indigenous Organizations. We agree with the approach of creating working groups with rotating experts for each specific area (e.g., oncology).

We also suggest looking to the World Health Organization (WHO) Model List of Essential Medicines, 2021, to confirm that all prescription drugs on this list that are relevant to healthcare in Canada are prioritized on the pan-Canadian formulary. We note that bupropion, varenicline and nicotine replacement therapies were recently added to the WHO list.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

Options 2 and 3 do not appear to be mutually exclusive so the Canadian Partnership Against Cancer suggests pursuing both avenues. As indicated, option 1 has logistical issues that may make it infeasible.

5b. What criteria could be used to identify priority products?

For cancer drugs, prioritize curative treatments and those with a clear and clinically significant overall survival advantage (as opposed to progression-free survival).

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

No response provided

Canadian Pediatric Endocrine Group, Canadian Soc of Endocrinology and Metabolism

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

My specialty treats a very large number of orphan diseases, often with highly specialized medications. Page 7 'create a proposed sample list of commonly prescribed drugs and select related products ...) suggests that these patients will be under-represented. Table 1 should incorporate, somewhere, the notion of rare disease therapies.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The requirement for the availability of a biosimilar is very limiting for more recent therapies. It may make your list out of date particularly for the rare disease pediatric population.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

As I said above, I would remove the initial requirement for having a generic or biosimilar, but you could make this a requirement after a certain time period and remove it if not achieved - FOR ALL EXCEPT RARE DISEASE DRUGS - since this will be discriminatory if an investment in a biosimilar or generic is not deemed feasible.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

It is not clear if the criteria you list must be fulfilled in their entirety or in part. I think you are dreaming in technicolor if you think we have enough data for reduction of disease burden and QoL for some of the medications commonly used for Pediatric Endocrinology and rare diseases - it takes a huge sample size to adequately generate this data, which should actually include 'real world' data (and we know that registries are very difficult to use for more than safety because of biases and confounders). These evaluation criteria are only of use for very common diseases which will limit your formulary.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

See my comments above - there are many medications that should be included if we are to ensure equity with regards to rare diseases. However - see my caveats concerning the requirement of having generics or biosimilars.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

I would only say yes if you include rare diseases as a national health priority.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #3

Please provide the reason(s) for your choice.

I think that there is frustration that drug approvals by the FDA and the EMA have not been supported by HC and/or CADTH. International collaborations might be a way to move towards harmonization, particularly with our neighbor to the south. However, all options depend on whether the deciders have a good clinical knowledge base of the condition being treated, so any of these options would be okay if there were truly informed deciders. I laud your encouragement to get stakeholder involvement, but often the clinicians who would be most important to consult are too busy to participate. You have to be careful about the amount of paperwork you require of your evaluators, particularly if you want to hear from physicians who have very good clinical trial experience (often means they have the most experience with the disease or condition being treated) but of course they will also be those who interact the most with pharma and your procedures for COI declarations are very laborious and time consuming (last time I saw them you wanted exact dates of all the activities be they scientific ad boards, sponsored lectures, etc going back a ridiculous number of years).

Patient support groups MUST be included - and many of them have good organizations in the US (or Europe) but are missing or not necessarily as active in Canada.

5b. What criteria could be used to identify priority products?

You have a good list of characteristics but it is not clear how many of them must be fulfilled. Do you intend to have a scoring system? Some of the information takes too long to collect for a rare disease population - particularly real world data from registries. Does this mean these products will not be entertained? Most important to me is a novel therapeutic approach with demonstrated safety and efficacy and a clear support for the therapy by patients or their representatives because of the perceived benefits.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

I worry about the value for money in the sense that there are many things that are difficult to put a price on. Of course oncology medications are often a case in point - how do you place a value on 12 more months of life for the person and the family dealing with the cancer? I also do not know how to properly assess the pricing equations used by pharma, and this is a big problem for me. I can understand the need to recoup research and development costs, but I do not know what is a reasonable profit margin for a company. This has always made me uneasy when trying to measure cost versus benefit, particularly when you are comparing drugs coming from biggest pharma companies versus the mid-size versus the smaller, specialized companies.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

As I said above - use of a novel therapeutic approach, particularly if it improves safety and is at least non-inferior, or decreases the burden of the condition. Patient preferences should also have a high priority. I have been involved with MCDA through EVIDEM, and have used this methodology for assessing particular therapies. I can say that it is incredibly time consuming particularly if you do it well. Again, the scoring will require experts who 1)understand the condition being treated, 2) hopefully have interacted with patients and families dealing with the disease and 3) have the time to really review and digest the available evidence that is of good enough quality to give a reliable opinion. Next generation drugs pose a particular problem, given that clinical trials often have a 'non-inferiority' design. I have no suggestions for handling relative efficacies but certainly relative safety criteria should be important, as well as decrease in therapeutic burden - like long-acting preparations, a move from s/c to po, new pediatric formulations such as Alkindi Sprinkle which allows proper pediatric dosing and more stable formulation compared to traditional 5-10 mg tablets of hydrocortisone. Patient voice should also have a large weight. Patients speak with their feet, and if drugs are not perceived as useful, not easily administered or have an unacceptable side effect profile, no matter how well they performed in the pivotal trials, adherence will decline and/or drop-out rates will increase. Data should be available for all phase 3 trial participants on a longer term basis, and presented where possible.

8. 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 reviews)?

Next generation drugs pose a particular problem, given that clinical trials are often have a 'non-inferiority' design. I have no suggestions for handling relative efficacies but certainly relative safety criteria should be important, as well as decrease in therapeutic burden - like long-acting preparations, a move from

s/c to po, new pediatric formulations such as Alkindi Sprinkle which allows proper pediatric dosing and more stable formulation compared to traditional 5-10 mg tablets of hydrocortisone. I mentioned above how to handle the availability of biosimilars or generics.

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

Bravo but you have a very difficult mission ahead. The composition of your expert committee(s) will be very important. I will be curious to hear the opinion of INESSS about this initiative - and I hope you have/will have someone from there on your expert committee because as with international collaborations, I think that it is really important that this be a PAN-Canadian effort. I think that you really need good economists on your expert panel - with an understanding of the pharmaceutical industry and of healthcare economics. I presume that you do but you did not give any profiles in the group of names that you gave. You should also have a bioethicist, people with expertise in MCDA and clinicians from multiple PEDIATRIC and adult specialties as well as generalists, pharmacists, epidemiology methodologists, clinical trial experts and probably additional expertise as well. It would be nice to have someone from CORD. I suggest that when you post your list of names, you give a minimal bio so the public knows who these people are. I had to GOOGLE the people who contributed to your document to find their actual qualifications and profiles.

Canadian Pharmacists Association

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

Dear Panel Members,

The Canadian Pharmacists Association (CPhA) is the national voice of pharmacy, working to support pharmacists in delivering drug therapy, medication management and other vital health services to patients. Access to medication and pharmaceutical care are issues of great concern for pharmacists

across the country and we appreciate the opportunity to provide feedback on policy developments that have the potential to impact medication access, such as the proposed framework for a potential pan-Canadian formulary.

CPhA is supportive of the work the Panel has undertaken thus far in developing its recommended framework and we are pleased that the Panel includes the expertise of pharmacists. We agree with the guiding principles, and a staged approach to the formulary's development appears to be a sound and reasonable method to expand the list of medications from its initial sample. We further support the Panel's recommendation that a formulary work within existing processes and avoid duplication as work to develop a pan-Canadian formulary continues.

While we have no concerns related to the development of the proposed framework for a pan-Canadian formulary, we will take this opportunity to highlight several implications with respect to the use and implementation of such a formulary. Though we understand that it is beyond the scope of the Panel to make recommendations about the use of the proposed formulary, the implications associated with its use are of critical importance to Canadians, and these should be discussed and considered as early as possible in this process.

The context for a pan-Canadian formulary

CPhA strongly supports the idea that all Canadians should have access to the medications and pharmaceutical care they need. Recognizing the gaps in drug coverage across Canada, we support establishing a minimum standard of coverage for both public and private plans as well as establishing new common standards across the country that would ensure all Canadians have equitable access to some form of coverage in every jurisdiction. We would have significant concerns if the outcome of the pan-Canadian formulary contributed to a policy initiative where existing private plans no longer covered certain drugs or where individuals lost their existing coverage. Such changes could result in interrupted care if they are required to change their insurance provider and/or drug therapy.

Drug cost-cutting policies

Governments and insurers often move to seek savings on pharmaceutical drugs without fully considering the downstream impacts. CPhA is concerned that a pan-Canadian formulary could lay the groundwork for policies such as bulk purchasing, which can significantly restrict drug availability. Pharmacists see firsthand how patients respond to therapy differently. A drug that may work for one person may not work for someone else. Because bulk purchasing reduces the number and variety of drugs on the market to only those covered under a particular agreement, it can often result in limited therapy options for patients.

Bulk purchasing and other policies that reduce drug prices are important deciding factors for manufacturers who determine whether to keep drugs on the Canadian market. Such policies can also lead to drug shortages. For example, if there are limited number drug products available, should something occur along the supply chain, there is an increased risk of a shortage.

With these considerations in mind, CPhA would like to better understand how the federal government and others who have contributed to this draft framework plan to leverage it in pricing related discussions, and how they will consider broader supply chain impacts as part of that reflection.

Drug shortages

Further to the subject of drug shortages, CPhA continues to urge the Canadian government to enact policies to prevent and alleviate drug supply challenges. The risk of drug shortages increased throughout COVID-19 because of manufacturing and trade instability, and pharmacists have worked hard to mitigate supply issues and help their patients access the medication they need.

We strongly recommend that the issue of drug shortages be incorporated into the development of a pan-Canadian formulary and that the formulary be used as a tool to help secure the Canadian drug supply. For example, it could include a list of essential medications to monitor for supply chain risks and to help prioritize shortage mitigation efforts. Redundancies could therefore be built in for the list of essential medications to act as a safeguard in the event of a shortage.

Broader drug reform initiatives

With the aforementioned considerations in mind regarding pricing and our ongoing efforts to engage governments and those entrusted with government-related consultations such as CADTH, our association believes that there should be greater clarity on the government's policy objectives and a more coordinated effort to communicate how the many ongoing initiatives related to drug pricing and access are complementing or impacting each other. These include the ongoing consultation on a rare drugs strategy, the creation of a Canada Drug Agency, the PMPRB regulatory reform and broader efforts by governments to address prescription drug affordability. We would therefore strongly encourage the federal government to contextualize this specific consultation within a broader pharmaceutical policy lens and to convene a broader group of stakeholders to discuss and provide input on the government's drug policy objectives.

Conclusion

CPhA has contributed to numerous regulatory and policy consultations on pricing reform, drugs for rare diseases and pharmacare. We appreciate the opportunity to provide initial considerations to this process and we look forward to further opportunities to engage and understand the specific context in which a pan-Canadian formulary could be leveraged by governments.

Canadian Pulmonary Fibrosis Foundation

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

In general, Canadian Pulmonary Fibrosis Foundation (CPFF) agrees with the proposed principles and definitions.

Under the "Universal and Integrated" principle, and the Content Value of "Harmonization," we would like to caution against the removal of drugs from any provincial or territorial formulary in order to harmonize formularies nationally – unless the drug is removed and replaced, at the same time, with another, more effective medication.

Under the principle of "Sustainability," and in Content Values, we believe that value for money cannot be determined only by the cost of the drug itself and the cost associated with the administration of it, but rather in the context of health care resources in their entirety – including reductions in the costs of in physician visits, ED visits, hospitalization, palliative care and deaths. And, beyond the health care system, to "value" in continuing participation by the patient and their family as contributing members of society as a whole.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

In general, Canadian Pulmonary Fibrosis Foundation (CPFF) agrees with the proposed assessment criteria, with some caveats. In the case of "similar" drugs, those with similar cost, effectiveness, etc., the differences often lie in side effects and how tolerated they are by individuals. We believe there should remain a "choice" for patients of similar drugs. In the case of anti-fibrotics for instance, the two main medications have very different side effects that impact the daily life of patients in different ways. We believe individuals should be able to choose which drug, and thus which side effects, they can most easily tolerate in their lives.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

As noted, Canadian Pulmonary Fibrosis Foundation (CPFF) agree it makes sense to streamline the process for patients by including products/devices related to the optimum use of drugs in the national formulary.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

Yes. Especially using the first phase as a pilot and test and then revisit the process for feedback before continuing or adapting the process.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

Not certain. Canadian Pulmonary Fibrosis Foundation (CPFF) would need to know more about how national health priorities are determined – i.e. to help the greatest number of people, to help the sickest people, for children first, for prevention? Is cost/value the biggest consideration? Is there a political component to the determination of health priorities? If so, it should be discouraged. Where do vaccines fit into the priorities and/or formulary?

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #2

Please provide the reason(s) for your choice.

Option #2 seems to make the most sense for timely access to new medications. It could incorporate some of Option 1 and Option 3 within the new scoring system, whenever possible. (i.e. if another country is reviewing the same drug, there could be information sharing. A new drug that is under HC's priority reviews would be scored higher.)

5b. What criteria could be used to identify priority products?

Some thoughts:

Filling an unmet need (i.e. no current drug available)

Major clinical breakthrough

More accessible, easier to use, for patient – i.e. pill instead of IV

Substantial quality of life improvement by reducing side effects or inconveniences of current treatments

Availability of generic or biosimilar at much reduced cost

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Overall, Canadian Pulmonary Fibrosis Foundation (CPFF) are in agreement with the proposed evaluation criteria and the considerations for new products.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

Using the provided proposed criteria, Canadian Pulmonary Fibrosis Foundation (CPFF) would "weigh" them in the following order, with the first being most important and the last ones being the least important.

1. Clinical Benefit

2. Alignment with patient and societal values

3. Value for money. We think "Feasibility of adoption into health systems," is part of the value equation, since most things can be incorporated into health systems with feasibility being a matter of cost.

8. 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 reviews)?

It makes sense for a review to be undertaken at regular intervals – considering reports of adverse effects, usage, newer approved medications now available, etc. If the pan-Canadian formulary eventually replaces the provincial/territorial ones, workloads as noted in the question, would be vastly reduced – not increased.

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

The Canadian Pulmonary Fibrosis Foundation (CPFF) serves people living with pulmonary fibrosis and their families, health care providers and communities. Although incidence is rising, pulmonary fibrosis is considered a rare disease. A process is currently underway to address access to medications for rare diseases. We hope that the process is following many of the same principles outlined in the discussion paper on creating a pan-Canadian formulary and is just as transparent and offers the same opportunities for our input.

Canadian Skin Patient Alliance & Canadian Association of Psoriasis Patients

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

On behalf of the Canadian Skin Patient Alliance and the Canadian Association of Psoriasis Patients, we appreciate the opportunity to provide our feedback regarding the proposed approach for creating a national formulary. The CSPA and CAPP support the submission of several patient organizations coordinated by Save Your Skin Foundation (also an Affiliate Member of CSPA) and the Best Medicines Coalition. In this submission, we offer specific comments from the perspective of the skin patient communities in Canada.

It is clear that CADTH and the panel members have put a lot of thought into how to make the process principled, clear and flexible. The six principles included are indeed important. However, assessing these on their own may be less helpful than reflecting on how these may guide the operationalization of the process outlined in the discussion paper. The questions included as part of this consultation are clear but narrow. For this reason, the consultation gives rise to other important questions, which are identified in this submission.

We do have some specific comments on the principles articulated in the discussion document.

For example, consider the principle of equity. It is not clear from the robust discussion paper or the thoughtful presentation which community's needs will be prioritized to create a national formulary. The needs of the skin patient community are often diminished and disregarded in a society that is quick to brand skin concerns as cosmetic. We are concerned as a community that the development of a national formulary will leave skin patients behind and reinforce the misconception that our experiences do not matter as much as others.

For a formulary to be effective and high-quality, patient reported outcome measures should guide what is prioritized. The clarifications in the document do not explicitly include patient reported outcome measures. These should be articulated and co-developed with patient organizations and members of the relevant patient community.

Regarding sustainability, it is essential that the whole picture be considered. People with skin conditions spend a considerable amount of their disposable income on moisturizers and emollients, face and body washes that do not exacerbate their conditions, eye drops, wound care products, laundry detergents, clothing that doesn't irritate their skin, and many other non-prescription products. It is essential that a national formulary consider these direct costs to patients as well as direct costs to other parts of the healthcare system (e.g., emergency room visits and admissions for skin conditions that are not well treated) when considering the value of existing treatments and comparing that to the potential of a new safe and effective treatment option.

For a system to be efficient and timely, we need to consider a wider timeline. It is not enough to get a recommendation to list on a publicly-funded formulary, it is not until those medications are made available to humans that the process is complete. We must not get lost in the paper-based process.

Duplication throughout the several overlapping processes – and a perceived desire to ask the same question slightly differently – creates delay and jeopardizes our collective ability to take a solutions-focused approach to data. If the data does not exist at the time of review but the medication is promising for underserved communities, like the people living with more than 1,000 different rare dermatological diseases, we must embed a process to collect, analyze and report that data. The findings should be fed back into the review.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

For a community that is looking forward to many promising treatments, any initiative that serves to whittle down existing options or curtail access to new treatments would be widely regarded as a failure. An analysis of who will lose access to treatments should be conducted as part of the information gathering undertaken when creating a national formulary. For example, will people in a certain province or who rely on a certain federal drug plan lose access to important treatment options as a result of the creation of a national formulary for a specific area. This would be detrimental and is a very important consideration in light of the stated goal of a national formulary.

Will the national formulary created through the proposed process improve access to prescription drugs by increasing the options individuals have to create a tailored treatment plan that prioritizes addressing underlying disease mechanisms over symptom relief? For people living with skin, hair and nail conditions, the existing treatment toolkit does not yet include many options that target underlying disease mechanisms. We are looking forward to a growing pipeline of new and innovative treatments that benefit from research into the causes and drivers of skin disease, such as inflammatory conditions like atopic dermatitis (eczema) and alopecia areata. The dermatology treatment toolkit includes several drugs that were developed for other purposes like methotrexate (chemotherapy) and cyclosporine (organ rejection). These work well for some but for others, they are the only thing left to be used.

There are many new treatments for skin conditions that are restricted benefits, and these must be included. Further, creating a core list of the drugs that are already included on publicly-funded formularies risks creating a program that reflects the least common denominator. Where a provincial public drug program is available to all residents of the province, we note that the formulary often includes fewer drugs than other provincial formularies and urge the panel and decision-makers to not follow an approach that results in fewer drugs being available to patients with diverse needs and circumstances.

The process outlined by the panel does not clarify whether trade-offs will be required where there are multiple treatments for a given disease and how those will be decided upon. Consider the example of plaque psoriasis. There are several treatment options that target the diverse underlying mechanisms that drive the skin to grow 10 times faster than usual, resulting in “plaques” that give this condition its name. However, as it is a disease of the immune system, no given treatment will work indefinitely for a patient. Our immune systems are clever, and they will eventually outsmart the drug being used. For this reason, different treatments that work on different parts of the inflammatory process that drives psoriasis is essential for long-term management of the disease. If the process resulted in a smaller list of options available to people across Canada than is currently the case, this would be a disservice to the psoriasis community.

Like all skin patients, psoriasis patients are diverse. People have different skin tones (types), and hair textures. Despite important conversations in dermatology about the importance of diversity and inclusion, clinical trial participation continues to be dominated by people who identify as White (~85%). It is essential that treatment options be available as we learn more about their efficacy for different skin types and hair textures. This may mean that the formulary includes different treatment options, depending on the constantly-evolving real world evidence, or multiple formulations of the same active ingredient(s), such as ointment, gel and foam formulations to be used in scalp psoriasis.

It is also critical that treatments be available for them that permit them to make important life decisions, including around fertility and family planning. Older drugs that are most commonly included on formularies and widely used across the country such as methotrexate (for inflammatory skin conditions like atopic dermatitis, psoriasis and many others) are incompatible with pregnancy.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

As mentioned above in response to Question 1, people with skin conditions spend a considerable amount of their income on moisturizers and emollients, face and body washes that do not exacerbate their conditions, eye drops, wound care products, laundry detergents, clothing that doesn't irritate their skin, and many other non-prescription products. Where these are recommended by their healthcare provider as essential products to care for their skin, hair or nail condition, these should be considered for inclusion on the pan-Canadian formulary. For example, it is widely recognized that moisturizers are essential as part of the treatment and management of eczema or psoriasis, that eye drops are essential to the ability of people living with the impacts of Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis to retain moisture in their eyes that their body no longer produces, and that bandages and other wound care products are essential for people living with hidradenitis suppurativa, etc. Many patients live with a much higher burden on their finances because they need to use these products regularly in order to maintain their health, address stigma, or avoid exacerbating their conditions.

The Canadian Skin Patient Alliance and the Canadian Association of Psoriasis Patients would be pleased to provide more context about these products for skin patients.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No

Please provide reason(s).

They should not be included on the same list or subject to the same evaluation criteria. It would be difficult to imagine wig manufacturers being able to provide the same level of evidence as pharmaceutical companies, but people living alopecia areata who wish to purchase wigs may be otherwise limited to $500 lifetime maximum in coverage through private plans (if they have one).

4a. Do you support the proposed approach to expand to other therapeutic areas?

No

Please provide the reason(s) for your choice.

As mentioned above, it is not clear which community's needs will be prioritized to create a national formulary. The needs of the skin patient community are often diminished and disregarded in a society that is quick to brand skin concerns as cosmetic. We are concerned as a community that the development of a national formulary will leave skin patients behind and reinforce the misconception that our experiences do not matter as much as others.

Further, many skin conditions have comorbidities or impacts on other organ systems (e.g., scleroderma, Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis, lymphedema, lupus, etc.) and the proposed plan to create a national formulary must consider how people will juggle if some of their medications are included on a national formulary and others are not. For instance, how would benefits be coordinated between a national formulary, a provincial formulary (e.g., BC's PharmaCare program) and private benefits?

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

Skin, hair and nail conditions are consistently misunderstood and their importance diminished. This approach risks a disproportionate disadvantage to those in our patient community who do not have drug coverage and are not eligible for it.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

A fulsome appreciation of the options available for a specific skin patient community (e.g., people living with psoriasis) is needed in order to make best choices in context. There are some skin conditions, e.g., cutaneous lymphoma, where recent new treatments have not been recommended to be included in publicly-funded formularies in Canada. This assumes that options outlined on paper (e.g., phototherapy that a patient receives at a clinic 2-3 times per week for years on end) are available to all patients equally, which is not the case. This also puts a larger burden on often-under-resourced patient organizations to articulate the limitations of existing treatment options, information which does not always seem to be heard by the decision-makers. These decisions must better reflect the diversity of patients' experiences across Canada, which is not reflected in the criteria proposed above.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

Patients and patient organizations spend hours upon hours participating in these processes to the best of our abilities. We do it because it's important to us and to the patients and caregivers we serve. For organizations like the CSPA, which represents people impacted by over 3,000 conditions, and has a staff of 3 FTE, we are constantly engaged in submissions. We often work in collaboration with other organizations to share expertise and resources. For many organizations – including the CSPA and CAPP – no funding is accepted for developing advocacy positions, including patient input submissions. This puts extra strain on our lean resources.

Funding made available to patient organizations to participate would help offset our operating expenses and enable us to consult more deeply and widely than the options we currently use. This is especially the case for those organizations that receive no government funding to support this work (like CSPA and CAPP) and who do not benefit from significant community donations because they are not-for-profit organizations instead of charities (like CSPA and CAPP).

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

There are a number of off-label uses of a variety of medications to treat skin, hair and nail conditions. This is, in part, because of the limitations of the treatment toolkit for dermatology. Sometimes, these are older (cheaper) treatments, and sometimes they are newer (more expensive) treatments. We are interested to see how these issues are addressed in a national formulary and would appreciate a larger discussion on this topic.

Further, there is no mention of how access to treatments will be evaluated once a formulary is in place, which is vital to ensuring that the goal (better access) is met.

Canadian Society for Endocrinology and Metabolism and Division of Endocrinology and Metabolism, Western University

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

A criteria that is missing pertains to medications that are required to sustain life, even though the underlying condition may not be as frequent - thinking about adrenal insufficiency and hypothyroidism.

Also, it's important that medications are also available for pediatric population

Finally, it's not clear to me if the formulary is meant only for outpatient prescriptions,. and not for inpatients - please clarify

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Suggest to also reach out to various (sub) Specialty organizations so to identify more rare but vital medications, and where needed help to provide the required expertise.

it is not clear to me what the approach is for orphan diseases.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

I would keep in mind that it is important to try to try to have more than one product for each class/group of drugs. Over the last years, we (in endocrinology) have many times encounter backorders for a product that leave us completely scrambling for ongoing treatment for patients - would be happy to provide more info about this.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

I would keep in mind that it is important to try to try to have more than one product for each class/group of drugs. This limits issues when proeducts are on backkorder, or when patients are intolerant/allergic for a specific drug.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

In addition to national health priorities, I want to advocate for treatment for more rare conditions (orphan disease) - of which there are a lot. These patients should not be ignored.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #3

Please provide the reason(s) for your choice.

In the current climate, new drugs within our area are often not marketed in Canada because ' the market is too small'. linking to international partners may be the way to reduce that.

5b. What criteria could be used to identify priority products?

clinical requirement

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

add: essential for survival in individual patients.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No

If yes, how should weight be distributed among the proposed criteria?

While this system may work for commonly used drugs, it may inadvertently discriminate against orphan drugs/drugs used for more rare conditions.

8. 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 reviews)?

can't speak for others, but we as the Canadian Society for Endocrinology and Metabolism would be happy to identify experts to help out.

Key to include GPs and pediatricians in the process.

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

Might be an idea to create a forum discussion

Canadian Society of Hospital Pharmacists

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

These principles will help to ensure that this formulary will reflect the needs of Canada's diverse population. We are pleased to see that these principles are aligned with those in the Canada Health Act.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

To support the seamless transition of care for patients moving in and out of hospital settings, we suggest that the panel considers examining drugs listed on hospital formularies that may not be listed on existing public drug plans, as these would represent a gap in access. In hospitals, drugs are added to the formulary after a rigorous evaluation process and must be approved by a multidisciplinary committee, i.e., the Pharmacy and Therapeutics Committee. Scenarios do occur where patients are started on medications in hospital for valid reasons, but then face barriers to continuing that medication after they are discharged due to issues surrounding gaps in coverage.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

Criteria should include: ability to assist with the delivery or administration of a drug (e.g., needles and syringes for subcutaneous administration); necessary for the optimal use of a drug (e.g., spacer devices, nebulizers, blood glucose meters, lancets); ability to improve patient adherence to medication-use (e.g., blood pressure monitors, dosettes, pill-splitting/cutting devices).

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

The coverage of these related products should be linked to the specific drug or disease state where there is evidence for their use in optimizing patient care.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

The consideration of pharmacotherapeutic areas that have been shown to improve health outcomes in people made vulnerable by systemic inequities is particularly important to ensure equitable access to drugs for all Canadians.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

We agree with this approach; However, there must be flexibility in the prioritization process to allow for addressing new priorities as they arise, in a timely manner, e.g., drugs to treat COVID-19 during an evolving pandemic.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #2

Please provide the reason(s) for your choice.

Option #2 would be a reasonable choice. We feel that transparency is important for this type of initiative and predictability in the scoring system would be helpful for drug manufacturers to appropriately direct resources towards their submissions. This option would also provide the flexibility to address products meeting priority criteria to be reviewed in a timely manner. We would also like to note that it is also important to leverage work being done elsewhere to save on resources, as outlined in Option #3.

5b. What criteria could be used to identify priority products?

Criteria could include: a novel product that either provides significant health benefit compared to existing drugs or that fulfills a health need that hasn't yet been met; products that would improve health outcomes in people made vulnerable by systemic inequities; products that improve quality of life for Canadians.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

No additional comments.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

Weight should be distributed equally among the proposed criteria. In some cases, the clinical benefit of a product might be marginal but the impact on patient and societal values might be substantial. Conversely, the impact on a patient's quality of life might appear to be minimal, but the clinical benefit is significant. Therefore, one criterion should not be weighted more than another as the value of the product will be highly dependent on the disease state being treated.

8. 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 reviews)?

A regular cycle of 3-5 years to re-evaluate existing listed products would ensure that there is a planned and continued assessment of the formulary. Should resources be limited, prioritization could be given to products of a therapeutic class where major practice changes have recently occurred (e.g., new guidelines released, practice-changing evidence emerging from clinical trials).

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

Misalignment between hospital formularies and public/private formularies can lead to gaps in treatment for patients and drug wastage for the system. To improve continuity of care, there should be a standardized approach to review drugs listed on hospital formularies to prevent these gaps from occurring.

Hospital pharmacists are key players in hospital formulary decision-making and in ensuring that gaps in treatment for patients are minimized. We acknowledge that there are several pharmacists on your panel and encourage CADTH to continue to involve hospital pharmacists in future decision-making processes.

CANInsulin4All - T1International

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

We agree in part to the assessment criteria used in Table 2.

We agree with the criteria used to exclude medication from the proposed sample list if major safety issues have been identified by Health Canada.

We disagree with the assessment criteria used to flag medication for further review based on the third assessment criteria, "No longer best practice or standard of care for this therapeutic area," as we support evidence-based over consensus-based guidance. Therefore, we do not believe practice guidelines should be defined by best practice.

If we use Table 2 to assess all insulin types listed, best practice should not be a criteria for inclusion as prescribing patterns become very evident. This criteria impacts the safety and effectiveness of the insulin prescribed as it creates a large conflict of interest favouring the influence of the pharmaceutical industry. Individuals that are dependent on insulin deserve to have access to an insulin that best suits their body. Best practice does not necessarily allow for the distinction to be made.

It is evident best practice criteria was used to assess all three types of insulin listed; analog, human, and animal. Animal insulin was the only product that was excluded from the proposed drug list. Over 400 Canadian's are dependent on animal insulin. Although they are a small section of insulin users that require this particular type, they deserve to have the same access as other insulin users. Best practice criteria does not allow for this inclusion.

Animal insulin has been wrongly categorised in this formulary and this decision goes against recommendations of the parliamentary standing committee on health that insulin be funded and remain available in Canada. It is also the position of Health Canada that insulin is to be made available to people. Best practice criteria does not allow for this inclusion.

Our American advocates remind us that human insulin is being withdrawn from the market. Individuals are being forced to switch to a different insulin not because it is causing harm to their body but because of limited access. Best practices have influenced the amount of physicians who are willing to prescribe it, pharmacists are reducing or eliminating their stock as the price is substantially less than analog alternatives. Again, this is not based on evidence but influence from pharmaceutical companies. If this pattern continues we it is ensuring that people who are harmed or at risk of harm from analog insulins will not be able to receive funding for an insulin that will be more suitable for them (ie. human or animal insulins.)

Insulin is a drug that greatly impacts our membership but there are a number of other examples that are skewed by best practice assessment criteria. An example would be Vioxx, a drug used for congestive heart failure. Therapeutic Initiative sent out a warning that Pfizer had been omitting evidence of harm. After further investigation reports detailed the deaths of 60,000 Americans and 6,000 Canadians. This medication was listed on US formularilies but was manipulated as evidence through best practices.

What is most alarming about this assessment criteria is that best practice is not mentioned as a criteria for inclusion in the proposed sample list. This is a large problem in the formulary, but is not listed as the criteria used. The formulary even fails to define best practices. By having best practices list as criteria for assessment the formulary neglecting to meet many of the key principles mentioned in question #1.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

No response provided

Cystic Fibrosis Canada

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

Dear CADTH pan-Canadian Advisory Panel on a Framework for a Prescription Drug List,

Cystic Fibrosis Canada welcomes the opportunity to provide feedback to the pan-Canadian Advisory Panel on a Framework for a Prescription Drug List, as it directly relates to the Canadian cystic fibrosis community. Should the panel wish to refer to the broader patient group and health charities perspectives

on the proposed principles and framework, we refer to you the submissions of the Health Charities Coalition of Canada (HCCC), the Best Medicines Coalition (BMC), and Protect our Access, of which we are members.

Cystic fibrosis is the most common fatal genetic disease affecting children and young adults in Canada. There is no cure. Affecting approximately 4300 Canadians, cystic fibrosis a complex disease caused by mutations in the gene for the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR). There are over 2,090 known mutations. Cystic fibrosis has a tremendous impact on the people who live with it, their loved ones, and on society. Every week in Canada, two people are diagnosed with cystic fibrosis, one of them through newborn screening. Every week in Canada, one person with cystic fibrosis will die.

Cystic fibrosis causes various effects on the body, but mainly affects the digestive system and lungs. The clinical progression of cystic fibrosis can vary greatly from person to person, even with the same mutations. The most significant clinical impact is in the lungs, where patients have difficulty in clearing secretions, which in combination, with aberrant inflammation leads to persistent infections with cycles of inflammation that are ineffective in clearing infections. This leads to progressive scarring of the airways and a progressive and sometimes rapid decline in lung function. Pulmonary/ infection/ cardiovascular complications cause eighty percent of cystic fibrosis fatalities.

Stage 1 of the proposed framework prioritizes creating a proposed sample list of commonly prescribed drugs and related products for three therapeutic areas: cardiovascular disease, diabetes and psychiatric illness. While cystic fibrosis is a rare disease that is treated with many specialized therapies, which are not within scope of the proposed framework, there may be opportunity for Canadians with cystic fibrosis to benefit from the proposed staged approach. This includes drugs relating to diabetes, psychiatric illness, and any future staged implementation in respiratory, gastro-intestinal (GI), and other disease states that require treatments also used in managing associated symptomologies, as they relate to cystic fibrosis.

According to the Canadian Cystic Fibrosis Registry approximately 22% of Canada's cystic fibrosis population lives with Cystic Fibrosis Related Diabetes (CFRD). A unique type of diabetes, CFRD is a common complication for people with cystic fibrosis, especially as they age. The group of people living with CFRD is an important subset of Canada's broader diabetes population that can benefit from a pan-Canadian approach that includes diabetes medications and related products.

At the same time, anxiety and depression also negatively affect people with cystic fibrosis. In 2020, there were 605 individuals with cystic fibrosis (14% of all individuals) that were clinically diagnosed with depression or anxiety. Sixty-seven (67) of these diagnoses were children and 538 were adults, representing 4.1% of all children and 20% of all adults living with cystic fibrosis. Similarly, The International Depression/Anxiety Epidemiology Study (TIDES) showed rates of depression and anxiety among individuals with cystic fibrosis and their parents/caregivers in the range of 25%-40%.

It is noted in the consultation document that, "if the resulting panel recommendations are followed, a starting point would be to ensure that the most commonly prescribed drugs and related products currently available to some Canadians would be made available to all people living in Canada". As such, those in the Canadian cystic fibrosis community who live with these comorbidities should benefit from the proposed approach. Cystic Fibrosis Canada is well-positioned to work with CADTH and the advisory panel to measure the impact that these immediate interventions have on our population, as well as any future expansions to the pan-Canadian formulary that relate to people living with cystic fibrosis.

Cystic Fibrosis Canada is undertaking a comprehensive burden of disease study that will include the real socio-economic impact that cystic fibrosis has on individuals, families, and society in terms of time and money. As part of this study, we worked with cystic fibrosis clinicians, pharmacists, and patients from across the country to create an extensive medication list of medicines used to treat the disease itself (CFTR modulators) and its symptoms, and including both specialty and more commonly prescribed symptom management medicines. This list can be cross-referenced with the proposed common formulary drug list to capture any medicines that help Canada's broader patient population, as well as those within the cystic fibrosis population.

The Canadian Cystic Fibrosis Registry is another resource that can be used to measure utilization and impact that commonly prescribed symptom management drugs have on the Canadian cystic fibrosis population. The Registry was created in the early 1970s with the goal of monitoring important clinical trends in the Canadian CF population. It has played an invaluable role in helping to improve the quality and length of life of people with cystic fibrosis. Nearly all CF patients attend one of 41 accredited CF clinics (paediatric and adult) within Canada, making the Canadian CF Registry very complete and accurate – it includes data on virtually all Canadians with cystic fibrosis. It is a trusted and comprehensive source for understanding the clinical impact of cystic fibrosis in Canada, as well as the medical interventions and treatments that helped improve the median age of survival from under five years of age when the registry was started in the 1970s, to over 50 years of age in 2020.

Registry data was a key element in a request to the Drug Safety and Effectiveness Network (DSEN) from the Government of British Columbia to track the performance of a recently approved CF drug. We look forward to collaborating with CADTH to use real world data to measure the impact of drugs on the health and well-being of people living with CF, including on the design and implementation of the pan-Canadian Formulary.

Cystic Fibrosis Canada welcomes the opportunity to meet with CADTH and members of the advisory panel to discuss how the Framework for a Prescription Drug List could help Canadians with cystic fibrosis, and how we might help inform immediate and longer-term approaches to the creation of a Pan-Canadian Formulary that would benefit the Canadian cystic fibrosis population, in addition to larger populations impacted by this important work.

We will be in touch to arrange a meeting. Should you have any questions, please contact Kim Steele, Director, Government and Community Relations at advocacy@cysticfibrosis.ca.

Diabetes Canada

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Diabetes Canada asserts that national health frameworks should:

• Hold health in the highest esteem.

• Be equitable, with the attainment of health justice as the end goal.

• Be evidence-based.

• Be cost-effective and sustainable.

• Be progressive and timely.

• Be fair and transparent.

• Be patient-centred and respectful of choice.

As a member of the Health Charities Coalition of Canada, Diabetes Canada also espouses the Coalition's pharmacare principles of equity, timeliness of access, appropriateness of therapy, affordability, sustainability and patient partnerships. We recognize there is general alignment between the guiding principles laid out by the Advisory Panel and HCCC's and Diabetes Canada's values, however the principles must be applied thoughtfully and in the best interest of the patient. In any circumstance in which a principle is found to be at odds with one or more of the others, guidelines must be set in place to mitigate conflicts. It cannot be the public payer who, by default, has the strongest influence and dictates the prioritization of principles.

The goal of patient-centred policies is to improve patient outcomes and optimize their health potential. A 360-degree patient view should be used to develop, implement and evaluate health policies. In systems that are centred around patients, cost-saving measures are not sought at the price of limiting patient choice or removing agency over personal health management. A variety of outcomes and evidence needs to be considered when evaluating cost-effectiveness. At the heart of health policy must be the patient – they need to come first.

The COVID-19 pandemic has served to further expose the fissures in our healthcare system and more than ever highlights the need for an integrated approach to promote health and wellness. A pan-Canadian formulary, however well-developed it may be, is not a panacea and will not, in and of itself, achieve health equity. It cannot exist in a silo. Inserting a pan-Canadian formulary into the current system may further disservice those who do not have equal access to medications. Complementary policies and strategies that aim to address health system inequalities will be needed in order to support the success of any large-scale intervention. Efforts are required to address and correct systemic injustices that contribute to health inequity. Work around a pan-Canadian formulary cannot be carried out fulsomely without consideration to the broader context in which it is expected to function.

While it is not within the scope of the Advisory Panel to comment on healthcare generally, it must be recognized that a pan-Canadian drug formulary will not exist in insolation; rather, it will be part of a system. That system must be capable of containing and supporting such a formulary in order for it to be feasible. Healthcare in Canada at present is tremendously inequitable. A formulary will be of little to no benefit to a patient who has no access to primary, specialist or interdisciplinary care or whose provider doesn't have supports in place to facilitate deprescribing, for example. Equally, its benefit is limited if a patient struggles to afford good quality food, has difficultly securing stable housing or is precariously employed. Health systems changes will be required, as will bigger societal systems changes. Applying a health justice lens is necessary to bring about this needed change. Diabetes Canada implores CADTH to engage with patients and patient groups to further consider what broad system overhauls are needed to support a pan-Canadian formulary.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Many people with diabetes live with comorbid conditions and complications. Generally, we feel it is narrow in scope to look at antihyperglycemic medications and glucagon as a proof of concept for diabetes. It may be a proof of concept for blood glucose management, but not for people living with diabetes.

The Advisory Panel noted the following challenges in the proposed approach:

"A key limitation to this approach is that there might be drugs selected according to the panel's recommended principles for inclusion in the proposed sample list that are not included on some of the FPT formularies. That is, the various decision-makers who selected the drugs for the FPT formularies might have used different principles to determine what to include on the lists for their respective jurisdictions. In addition, there may be some population groups, such as pediatric patients, whose needs may not be fully met by the drugs on the proposed sample list. By not fully addressing the drug needs of these groups, inequities could be deepened or introduced." Both of these are real limitations to people living with diabetes. Pediatric populations living with diabetes having unique requirements that may get overlooked in the proposed system. Formulary listings for diabetes medications differ between jurisdictions and it is unclear from this proposed framework what the implications of this might be on access. This whole process must ensure that people's access improves, not diminishes. If there is any possibility that a patient could end up with worse coverage through a pan-Canadian formulary than they currently have (i.e., a medication or device that is covered in some jurisdiction is relegated to the red category for the pan-Canadian formulary), this can have a devastating effect on physical and mental health.

We are also concerned with some of the proposed formulary management practices. The Advisory Panel report states "if biosimilars and generics are available for a particular drug molecule, the panel felt that the least costly product could be selected and prioritized for listing. The panel supported the recommendation in the council report that encouraged both generic and biosimilar use, including generic and biosimilar substitution. Moreover, the panel considered that mechanisms such as reference-based reimbursement (e.g., limiting reimbursement to the lowest-priced drug in a category) could be used to ensure sustainability when the evidence shows that drugs within a given category treating the same condition (such as hypertension) are equally safe and effective." This policy would, in many cases, result in a non-medical forced switch, as most biosimilar antihyperglycemic agents are less costly

than their originator biologics. For reasons described in our position statement on biologic drugs and biosimilar insulins, Diabetes Canada does not support non-medical forced switches.

Reference-based reimbursement may also clinically disadvantage patients and decrease their ability and their clinician's ability to choose the medication that is the right fit. We are concerned that a patient would be limited to coverage of whatever medication is the least expensive option in the class, with consideration to nothing else. It is unclear whether patients will be able to choose their therapy within a class if all of the medications in the class have been included on the formulary. We also are uncertain at what stage biosimilar clauses and reference-based reimbursement mechanisms apply – when the formulary is being developed or when it has been implemented? Are these to become reimbursement policies? It is not clear.

Some medications are favoured by patients because they are easier to take for various reasons (e.g., combination therapy, BID dosing vs. QID dosing, oral medications vs. injectables). Will the medication cost always trump its benefits, when widely considered? Will criteria be applied requiring a stepwise procedure through lines of therapy? We are concerned a patient will need to 'fail' a certain medication to be eligible for another class or agent, which is not an effective or acceptable way to move through treatment options. Will there be exceptions criteria in place to allow for coverage to be tailored to individual circumstances? When it comes to the question of list refinement, Diabetes Canada is interested in knowing which organizations, people and processes would be involved in evaluating the drugs flagged for additional consideration. While we appreciate this was outside the scope of the Advisory Panel to determine, it is difficult to evaluate this process without giving this thought.

All this said, rudimentarily, it is not clear who would even be eligible for coverage under the pan-Canadian formulary. Will criteria be applied, and if so, what will they be? Will they be age and/or income-based, or incorporate other considerations? Again, while perhaps not the focus of the panel, it is challenging to evaluate criteria for inclusion and not wonder about criteria for reimbursement, as well as, very basically, who would receive coverage in the first place.

There are many unknowns when it comes to the framework and we recognize and respect this is due in no small part to the limits on the Advisory Council's scope in undertaking this exercise. CADTH was specifically tasked with proposing a process for creating a formulary and highlighting best practices for its management. We are aware that the work of the Council did not include:

• an 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

• the identification of governance structures to implement a potential pan-Canadian formulary (i.e., which organization or entity should oversee implementation of a potential pan-Canadian formulary or make funding decisions)

• a consideration of 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)

• the terms for coverage (e.g., patient contributions such as copayments or deductibles) and patient eligibility, including status

• a consideration of the interplay between public and private insurance plans (i.e., coverage as first and second payor)

• other ongoing pharmaceutical initiatives (e.g., Health Canada's Drugs for Rare Diseases Strategy).

And while we know it wasn't within the purview of the Council to consider the above, it does make it challenging to properly evaluate the framework and provide good quality feedback. It is extremely difficult the ascertain whether a pan-Canadian formulary will improve care without a much more complete and comprehensive overview. When we have no sense of who is intended to fund, administer or regulate the formulary, who will be eligible for coverage and under what conditions, whether this system is intended to be first payer public or some other model, and so on, we are very constrained in our evaluation of the framework, thereby limiting the usefulness of our feedback. Our impressions of the framework and responses to these questions might be wildly different with more information about eligibility, payers, etc.

We also know that, within the current system, the provinces are responsible for most of the public coverage of medications, with the federal government providing reimbursement for select groups (e.g., First Nation and Inuit people, veterans, members of the Canadian Armed Forces). We are unsure whether the assumption is that a pan-Canadian formulary would be plunked into the current system for the provinces to oversee. The formulary will not exist in isolation, yet there has been no information provided to show how it would be bridged into the bigger system. Since public drug coverage is highly impacted by provincial health budgets, would the provinces not then be the ones to determine what gets reimbursed? How would this then differ from our current system and in what ways would this be more equitable?

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

Any discussion about what should be included in a formulary should not be restricted to medication coverage. It must also include the medical devices and supplies that allow for optimal disease management. For people living with diabetes, these may include, but not be limited to, glucometers, continuous glucose monitoring systems, insulin pumps and their related components (e.g., infusion sets), test strips, lancets, insulin pens and pen needles or syringes.

Medication delivery is about both the drug and the device. Some equipment is essential to taking certain medications and should be covered (e.g., pen needles for the administration of a GLP-1 receptor agonist; test strips and an appropriate glucometer for the proper titration of an insulin dose). Many devices also have features that support accurate, safe dosing, like insulin pens with memory. A common-sense approach would provide a patient with the medication and the means to administer and properly track how to safely dose it.

Diabetes Canada publishes clinical practice guidelines for diabetes care in Canada. These guidelines have been widely accepted across the country and around the world as the professional standard for prevention and treatment of diabetes. Many public formularies presently offer access consistent with the guidelines, while others are outdated and do not align with current evidence-based recommendations. The Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada and other evidence-based guidelines, consensus statements and policy positions statements should be used to help inform the medications and related products that are included on the formulary.

Unfortunately, the definitions of evidence and best practice have, in many contexts, been weaponized against patients. Historically, the terms have been co-opted by various bodies and used to limit access to treatments. Health evidence is often biased toward particular outcomes and groups. There are many reasons for this, including the fact that certain populations are chronically understudied (e.g., children, minority groups) or underrepresented in research and that a great deal of research is funded by bodies with a conflict of interest. Randomized controlled trials, often considered to produce the highest quality of evidence, can be very narrow in terms of the outcomes that are studied (often clinical outcomes and usually limited at that). Real-world evidence is rarely included or highly considered in research assessments. Clinical evidence and its gaps must be contextualized to create public policy and should be expanded to include other types of important evidence. Patient-oriented research ought to be encouraged and incorporated into the evidence base that is used to form medication and associated product formulary inclusion criteria.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No

Please provide reason(s).

No, different evaluation criteria should be developed. Many diabetes devices and supplies are not included currently on public formularies, but are covered through other provincial programs (e.g., insulin pump coverage in Ontario is through the Assistive Devices Program). Processes ought to account for the different programs and reimbursement schemes that are currently in place for devices and supplies. There should be harmonization between medication and device/supply lists to ensure that the appropriate devices and supplies are available for the medications that are included on the formulary. Again, medication administration requires drugs and corresponding devices. For all people living with type 1 diabetes and many living with type 2, the ability to properly and safely use medication depends on supporting devices and supplies.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

Diabetes Canada's expertise is specific to diabetes medications, devices and supplies, but the majority of our constituents are also prescribed meds for comorbid conditions and diabetes complications, so would benefit from a similar process to get necessary medications on the formulary to support their overall health.

However, it must be pointed out that this system runs on the assumption that the correct decisions have been made on the currently established public formularies. Any systematic flaws in the public listing are perpetuated by the system. And any bias in the system is amplified in a national scheme. Very high-cost drugs are often not considered for coverage in general. Moderately costly drugs for people with diabetes are also rarely approved – it is untenable to do so because of the elevated rate of diabetes in Canada. The high diabetes prevalence in Canada serves ultimately to discriminate against people with diabetes.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

It is unethical to give preference to one disease state over another. All Canadians living with disease, whether it is diabetes, a related condition, a rare illness or other, should have the ability to access the treatments they need. One patient group should not be advantaged in any way at the expense of another. Canadian society will thrive when all of its citizens have an equal ability to achieve good health.

We are unsure about aspects of this question. Would a partially-complete pan-Canadian formulary would be implemented and then expanded? What are the barriers to developing a comprehensive and complete formulary? What are 'our' national health priorities – and according to what and whom?

The report mentions "in terms of expanding future work to other therapeutic areas, the panel proposed that a working group be formed." Of whom would this group be comprised? We know it would consist of "key members with rotating experts for each specific area", but who is this specifically? What organization/body would manage and oversee the working group? Where are patients, caregivers and patient groups in this process? This remains unclear.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

In the report, it states "assessments are currently conducted using a 'first-in, first-out' process based on when submissions are filed. These regulatory bodies typically use this process to manage the submission and review processes. Because of the potentially high volume of submissions and limited available resources, this method does not sufficiently allow for priority setting, which is an important for intentional, values-based resource allocation." Diabetes Canada is uncertain about the priorities being alluded to and is interested in knowing more about possible alternative options to the first-in, first-out process.

5b. What criteria could be used to identify priority products?

We are concerned that option 1 has the potential to be inequitable. The fairness of option 2 is questionable. Option 3 is a possibility, but information is lacking to be able to fully consider it. Overall, it is unclear which priorities are being addressed, what are the constraints that have led to the need for prioritization and which values-based decisions are already in place. Also, comparability between options is challenging as there is limited analysis offered behind each. Diabetes Canada strongly recommends CADTH explore and analyze the options further to determine feasibility and circle back with more details so a more thorough assessment can be offered by stakeholders.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Diabetes Canada generally agrees with the proposed evaluation criteria. This being said, we are concerned that limiting inclusion of therapies on a pan-Canadian formulary that are overcoming challenges with adoption will only further hinder their uptake and could undermine the adoption of new effective products. We recommend that the feasibility of adopting a therapeutic should be viewed as an opportunity to include emerging therapeutics supportive of ongoing improvements to patient care.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

Some objective measures might help eliminate or reduce some subjectivity behind processes. Diabetes Canada supports a governance model that is objective and takes into account authentic and regular patient input, that achieves the patient outputs described in the principles of the formulary and that is inspired by and improves upon existing models of patient inclusion and health technology assessments around the world. We are also interested in knowing more about the expert committee that would be responsible for evaluating and selecting products for the formulary. Who would form this committee and how would the patient voice be captured?

8. 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 reviews)?

Reassessment of formulary listings and re-evaluation based on changes to best practice guidelines and prescribing guidelines are important. Who would be assigned to do this work? How often would it occur? We recognize that changes to existing processes will require the input of many different stakeholders. Ultimately, Diabetes Canada supports an iterative process to manage workload while engaging all groups necessary to achieve a successful national formulary that is integrated within health systems and remains sustainable, modern, cost-effective and genuinely patient-centred.

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

According to Canadian Community Health Survey data from 2016, 44 percent of adults over the age of 20 live with one or more chronic conditions. Among the most prevalent of these is diabetes. Today, there are over four million Canadians who have been diagnosed with this progressive disease. Another 1.7 million people have diabetes and don't yet know it, while almost six million have prediabetes. Within the next decade, diabetes cases are expected to rise 27 percent. In 2022, someone new is diagnosed every three minutes.

Diabetes is a disease with no known cure to date. It can be managed with a combination of education, support, behaviour intervention and medication, but is a challenging condition to live with. Access to the right therapies is critical for people with diabetes. A large proportion rely on prescription medications to manage their blood glucose and avoid or delay complications, and for some, these therapies are life-sustaining. This is why Canadians have a such a huge stake in how and when appropriate medications are developed, procured, prescribed, dispensed and utilized in this country. Optimizing access to treatments like medications, alongside medication delivery systems and delivery support tools, helps provide people with diabetes the opportunity to achieve a better quality of life.

About diabetes

Diabetes is a disease characterized by elevated levels of glucose in the blood. Common symptoms of diabetes include extreme fatigue, unusual thirst, frequent urination

and weight gain or loss. Diabetes necessitates considerable daily self-management. Treatment regimens differ between individuals, but most include eating in a balanced manner, engaging in regular physical activity, taking medications (oral and/or injectable) as prescribed, monitoring blood glucose and managing stress.

Approximately 5-10 percent of people with diagnosed diabetes live with type 1 diabetes. Type 1 occurs when the pancreas does not produce its own insulin; to survive, daily exogenous insulin by injection or infusion is required. There are genetic and environmental factors thought to contribute to the development of this autoimmune condition, but very few effective, widespread prevention mechanisms in place at present.

About 90 percent of those diagnosed with diabetes live with type 2. Type 2 diabetes occurs when the pancreas does not produce enough insulin or the body does not effectively use the insulin that is produced. Treatment may include exogenous insulin, in addition to other therapies, like oral and/or other injectable medications. Typically, type 1 diabetes presents in children and adolescents, while type 2 develops in adulthood, though either type of diabetes can be diagnosed at any age. Those of advancing age, with a genetic predisposition, who are part of a high-risk population (African, Arab, Asian, Hispanic, Indigenous or South Asian descent, low socioeconomic status) and/or who are living with comorbid conditions, including obesity, are at increased risk of type 2 diabetes.

It can be quite serious and problematic for people with diabetes when blood glucose levels are not at target. Low blood sugar can precipitate an acute crisis, such as confusion, coma, and/or seizure that, in addition to being dangerous, may also contribute to a motor vehicle, school/workplace or other type of accident, causing harm. High blood glucose can cause weakness, nausea, vomiting, abdominal pain and other symptoms. Over time, glucose levels above target can irreversibly damage blood vessels and nerves, resulting in issues like blindness, heart disease, kidney dysfunction, foot ulcers and lower limb amputations. One of the goals of diabetes management is to keep glucose levels within a target range to minimize symptoms and decrease the risk of complications and consequences.

A third type of diabetes, gestational diabetes, is a temporary condition that occurs in pregnancy. When gestational diabetes is not well managed, the risk to the mother and child of developing various health issues increases significantly. Gestational diabetes is treated with behavioural interventions and medication, often insulin. It affects approximately two to four percent of all pregnancies (in the non-Indigenous population) and involves an increased risk of developing diabetes for both mother and child in the post-partum years.

Prediabetes is a state in which blood glucose rises to levels that are higher than normal, but not sufficiently high to constitute a diagnosis of type 2 diabetes. If left unaddressed and untreated, more than half of people with prediabetes will go on to develop type 2 diabetes within eight to 10 years.

The problem

Diabetes prevalence in Canada has increased by more than 50 percent since 2012. This distressing trend is being attributed in large part to the fact that Canada has an aging and ethnically diverse population, and is experiencing high levels of overweight and obesity, changing environments and a ubiquity of settings that promote sedentary and unhealthy behaviours. Once a disease of adulthood, type 2 diabetes is now being observed and diagnosed in younger cohorts, impacting people in the prime of life. At age 20, Canadians today face a 50 percent chance of developing type 2 in their lifetime. For First Nations Peoples, that risk is up to 80 percent and in some subgroups within this population, it is even higher.

With rates showing no sign of leveling or decreasing, Canada is facing a diabetes tsunami in the coming years. Rates of diabetes are alarming, with about 1 in 3 people living with diabetes or prediabetes today. By 2032, it is estimated that close to 14 million Canadians, or 33 percent of the population, will have diabetes or prediabetes. Similar trends are being seen around the world, making diabetes a global crisis of epic proportions.

The cost of diabetes

Diabetes treatment and care in Canada comes at a staggering cost in terms of financials, but also to human life. The all-cause mortality rate is twice that for those living with diabetes than without it. In a Statistics Canada survey, 80 percent of respondents reported living with at least one chronic condition in addition to diabetes. Diabetes contributes to 30 percent of strokes, 40 percent of heart attacks, 50 percent of kidney failure requiring dialysis, 70 percent of non-traumatic leg and foot amputations, and the largest number of cases of blindness in people under the age of 50. Every day, diabetes costs the healthcare system almost $50 million to treat.

A 2011 Statistics Canada survey showed that 32 percent of people with diabetes take three to four medications, 40 percent take five to nine medications and 12 percent take 10 medications or more. In a Diabetes Canada survey from 2015, 25 percent of all people with diabetes indicated treatment adherence was affected by cost. People living with type 1 diabetes can pay, on average, up to 17 percent of their annual income on diabetes, while people living with type 2 diabetes typically pay, on average, up to nine percent of their annual income on diabetes. Out-of-pocket costs that exceed three percent, or $1,500 of a person's annual income, are defined as catastrophic drug costs by the Kirby and Romanow Commissions on healthcare. By this definition, the majority of people with diabetes in Canada face catastrophic drug costs.

Many Canadians struggle to pay not only for their medications, but also the devices and supplies they need to maintain their health. High out-of-pocket costs limit access and can make diabetes self-management extremely difficult. There is significant variability in public coverage across jurisdictions, with each province and territory managing its own distinct formulary. Private insurance helps offset the cost of medications for many Canadians, but some are not fortunate enough to have insurance and illness can make it difficult to obtain.

A recent survey reported that 15 percent of Canadians with diabetes did not have private insurance to pay for their prescription medications, while 30 percent had no insurance coverage for the cost of

equipment or supplies to monitor blood glucose. About 18 percent of people with diabetes reported having difficulty getting insurance because of their disease. People who earn a low income are the most affected when it comes to difficulty obtaining insurance, compared to those earning a higher income.

Diabetes Canada's response

Diabetes Canada applauds CADTH for convening the pan-Canadian Advisory Panel on a Framework for a Prescription Drug List and undertaking the important task of developing a national formulary. Our hope is, that as one piece of the healthcare puzzle, it will help to improve access to necessary treatments for people living with disease. Once the Advisory Panel's report is complete, the recommendations will be useful to government policymakers to help support the conversations happening from coast to coast to coast around bringing a pan-Canadian drug list to life.

We are grateful for the opportunity to participate in this stakeholder consultation. Patient groups ought to always have a seat at the policymaking table. We also extend our thanks on behalf of the constituents we represent, those affected by diabetes. People with lived experience must be engaged in all consultations related to their care and their ability to manage health, and their influence and involvement should be equal to other parties in these consultations. Engagement should always be meaningful, and collaboration should be regular and ongoing. Expressly seeking out diverse representation within stakeholder groups is critical to solicit the viewpoints of those who are disenfranchised within our current healthcare system. We encourage CADTH to expand and tailor its consultations to ensure that marginalized and hard-to-reach populations are also given ample chance to make their voices heard. Targeted outreach to vulnerable groups to actively solicit their feedback is recommended to ensure the best possible representation of perspectives and lived realities.

Transparency in decision-making is paramount in stakeholder consultations. When patient and patient group feedback is requested and subsequently not used or accepted only in part, the reasons for this should be clearly and publicly communicated. We are glad to know that CADTH intends to organize a stakeholder session in the spring of 2022 to share the comments that will help refine the report and the key changes that will be incorporated. We look forward to hearing about the process through which those comments and key changes were identified and considered.

Diabetes Canada is a proud member of the Health Charities Coalition of Canada (HCCC), an organization dedicated to advocating for sound public policy on health issues and promoting the highest quality health research. The HCCC prepared a submission that member groups, including Diabetes Canada, contributed to. We support the perspectives contained therein. The following set of responses is to supplement the HCCC submission and is particularly relevant to the patient and caregiver community Diabetes Canada serves.

Diabetes is a heterogeneous condition that is broadly classified into categories, or types. The clinical features and etiologic classification of diabetes differ between types. Individual patient characteristics also contribute to the variation in how diabetes manifests, is experienced and must be treated. Type 1 diabetes, type 2 diabetes, gestational diabetes and prediabetes are each distinct conditions, with both shared, and unique, features and corresponding patient needs. Where it is relevant to the response in this consultation document, diabetes type will be specified; otherwise, the broad term 'diabetes' will be used to refer to the population of people living with metabolic disease characterized by hyperglycemia from impaired insulin secretion, malfunctioning insulin action or both.

About Diabetes Canada

A world free of the effects of diabetes is our vision. That's why we're working together to improve the quality of life of people living with diabetes. We're sharing knowledge and creating connections for individuals and the health professionals who care for them; advocating through public policy; and funding research to improve treatments and find a cure to end diabetes. For more information, please visit: diabetes.ca.

Diverse perspectives from members of CADTH's Patient and Community Advisory Committee

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

In January 2022, members of CADTH's Patient and Community Advisory Committee discussed the work of the pan-Canadian Advisory Panel on a Framework for a Prescription Drug List – specifically, the consultation for stakeholders to provide feedback on the Panel's proposed framework. There was support for a pan-Canadian formulary; a recognition that the work was complex, and encouragement for further involvement of patients, families, and the wider community. As voiced by two members: "Courage to those people who are involved in this project". "I feel very proud to be part of this. Thank you."

We did not aim to reach consensus. Instead, we noted a range of viewpoints and ideas, described in response to the specific prompts.

Support for the principles: "They are principles to be strived for." "The principles they've selected, I think, are all excellent "

The principles need to be firmly tied to actions taken to create and run a pan-Canadian formulary. Start by asking: "Have we met these principles? How are we going to measure how we've met them?" Give examples for each principle. "For equity, will the formulary work for children? For those homeless on the downtown eastside of Vancouver? For somebody with COPD who lives rurally? For someone with diabetes who lives remotely?" Be specific to the groups who are affected.

If provinces with many drugs on their formulary meet in the middle with provinces with fewer drugs; some individuals will lose out. Clearly identify who will lose out. Understand if this will create inequities. "Folks that are well-off have private drug plans. Many, many of the folks that I service do not have private drug plans. So, when they lose that large number of drugs that are covered now and they go down to here, they're without."

Add a principle to ensure "nothing is taken away".

Conversely, "Coming from a very small province, I worry a lot about what folks in Ontario, Alberta and Quebec and British Columbia would consider on their formulary, because we may not be able to afford that."

Make clear that equity does not mean equal. "Equitable can often be construed as when individuals have similar access".

Universality is limited if publicly funded formularies are aligned, but private drug plans are excluded.

Support for patients, people with lived and living experience, caregivers, and end users of the formulary to be named within the principle of inclusive, "because it impacts our lives and our potential deaths." However, the term collaboration implies 'patients as an external mechanism in the decision-making process. A formulary where patients are partners is warranted".

For the principle high quality, is it compared to an established standard? How is it measured? For sustainability, does this mean within a fixed budget? Or for drugs included to provide value for money? "Patients do not want to bankrupt the system. We are interested in ensuring Canada can care for our grandchildren, our great-great grandchildren."

Ethics of care will be important to deal with tensions with principles. Ethics of care recognizes human vulnerability, the implications of priority setting decisions on human lives, and prioritizes caring approaches. Consider and document how the panel will manage conflicting principles. Transparency of conflict is not sufficient

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

The process "opened my eyes to the need for mental health pharmaceuticals".

Add a mechanism to understand which drugs are established in clinical use but may not have been reviewed by a HTA body. A drug that has not been reviewed would "fall through the cracks".

If a drug is available to a subset to people, or with restrictions, how does this impact equity? Further explain how social determinants of health will be factored into decision-making. There are confounding variables e.g., biopsychosocial, that are independent to each patient. Take a patient centered care approach.

Consider long-term implications. For example, providing ACE inhibitors to diabetes patients free of charge can prevent kidney damage and prevent or delay kidney disease and further healthcare costs. Especially important for individuals under a certain income threshold.

Understand the impact on patients if limiting formulations (long-release, immediate release, gel vs pill vs patch). Suggest rules, with some exceptions. Exceptions or additional forms must be "quick and easy for doctors to figure out and fill out. Delays often result in a patient not taking the drug".

Completely agree to "current according to [clinical practice] guidelines." Further definition is needed as to what is current. For example, "diabetes drugs in the classes DPP4 are widely used; but are in yellow (flagged for consideration) rather than green. Sulfonylureas are cheap and listed, but they're no longer current." Review HTAs that don't align with best practices and what we know now about current practice when current knowledge is outdated. Clinical trials and real-world evidence are only good and meaningful if they correspond to drugs being used by people.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

Few people commented on this prompt. Agree to use same criteria for drugs and related products: "can't separate drug products from related products".

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

Build the system around the most vulnerable. "Who's not filling their scripts? Who's not accessing care right now? What therapeutic areas have the most patients who can't afford their medications?" Look at the familiar faces in the emergency room. "One gentleman we interviewed had 14 emergency room visits in one year. We met with him to find out why. Twelve of those visits were to get puffers. He couldn't afford his puffers. If we, as health care [providers], just gave him 12 puffers for the year, that would cost less than a thousand dollars. But what he cost us on 12 visits is incredible. It goes back to identifying the patient group gap".

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

Patients are best able to identify priority areas. Until partnership exists there's not going to be an adequate platform for patients to express their needs. Gaps will remain. "I am cautious and concerned about the use of the word expert committees unless they explicitly have on that committee, a disease specific patient expert that can attest to what their experiences are, where the gaps in service are, et cetera."

Over-the-counter drugs. "Aspirin is a drug people will go without because a bottle can be thirty dollars. And if you're on social assistance or you're a low-income working person with no benefits, you can't buy that".

What about drugs that are very expensive? "Can be beneficial to some people that are going through hoops when they're really ill."

"I have a bias, I'm a cancer patient, but almost half Canadians will get cancer sometime in their lifetime. A quarter of us will die from cancer. Cancer affects everybody in the country." More information on how oncology drugs and supported care drugs will be incorporated in the formulary are needed.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

A fair and predictable process is needed. "The first in, first out submission review process has its flaws, but at the same time, there are people who have been on a clinical trial and are waiting to see if this is going to become a standard of care."

"Agree with aligning with the Health Canada priority review process because there's a reason why that was designated in the first place."

Support for option 2 (clear scoring system to prioritize) with treatments that address unmet needs to be "bumped up a little bit higher".

Suggest a hybrid approach. "Let's say there were 10 reviews in a month. You could fill six or seven spots using the first in, first out and then designate three or four spots for priority drugs. For instance, a rare disease or a groundbreaking drug."

Support for working together at an international level, with similar countries in terms of affluence.

Consider how drug regulatory approval in Canada (as compared to US and Europe) and funding are tied before a patient can receive the drug. Consider the impact on those with progressive illness and when there are age caps. "I had five years to get progressively worse, whereas the drug could have stopped the decline to where I was five years ago. I'd be still walking." Might a shorter timeframe to funding impact pharmaceutical companies' ability to provide compassionate access when clinical trials end.

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

Patient and societal preferences: Avoid the term 'preference' because it is contentious. "Clear cut benefits or reduced harm, that's a reason...but because somebody prefers it?" Societal views can be diverse and in opposition. For example, the divide between vaccination against covid or public coverage of birth control. Explain how societal views will be known.

Clinical benefits Describe how prevalence (high or low) impacts inclusion. What might this mean for those with a rare disease? Is 'relevant health condition' needed? What would an irrelevant health condition look like? Patients to define 'clinically meaningful' outcomes. Scientists and patients may have differing ideas on what is meaningful.

Equitable access: Build around the most vulnerable patient. If you can ensure "equity for the person with least access, everything else falls into place."

Feasibility: Identify where and how infrastructure needs to be strengthened, rather than not fund a drug due to lack of infrastructure. For example, we found ways to incorporate freezers into the supply chain, rather than not purchasing Pfizer COVID-19 vaccines that required freezer storage. Consider how therapies are dispersed in different communities, rural and remote as well as bigger cities. Also consider seniors and those who might struggle with multiple medications and complex therapies.

Value for money: Explain why value for money is considered. "Why is money on the table? We're talking about people's lives and their health." Several members agreed value for money was important, the "reality of an affordable health care system", but as explained by another member "it can't be the be all end all, and it can't stop people from getting a drug or a therapy that they absolutely need."

Additional considerations; Ensure we're not putting barriers to care that will come up against new technologies such as gene therapies or personalized health care. Will the criteria "reconcile with the future? Is this a formulary for the past or is this going to carry us through?"

Ensure the agency and committee knows how to incorporate Indigenous way of knowing into decision making.

Consider online health records, analysis of social media posts by those with lived experiences, and other real world data sources, to inform decision making.

Explain what will happen for drugs prescribed off label. Will they be covered? For example, bevacizumab for macular degeneration.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

"I don't think that we're going to find a way out of a deliberative process with all of our various kinds of biases and worldviews and assumptions coming into the framework that tries to get rid of these, but never succeeds."

"It absolutely should be weighted, and I think it should be weighted in preference of patients."

8. 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 reviews)?

Discomfort with the term 'stakeholder' as it does not reflect Indigenous peoples or patients.

Patient perspectives needed for reassessments: “It can’t just be a data analysis”. Create a process so patients can view drastic decisions and have an opportunity to provide feedback prior to final decisions being made.

If delisting, allow grandfathering for those for whom the treatment works.

Improved health outcomes are the most important measure of success. “Did this drug improve my health at all? Did my quality-of-life change?”

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

No response provided

Eli Lilly Canada

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

CADTH pan-Canadian formulary

Questions for Stakeholder Input

Thank you for the opportunity to participate in the CADTH consultation on a pan-Canadian formulary.

Lilly Canada is the Canadian affiliate of Eli Lilly and Company, one of the world's largest research-based pharmaceutical companies. Our affiliate was founded in 1938 as a result of a collaboration between Eli Lilly and Company and Banting and Best, commercializing the production of insulin and making it widely available in the Americas.

Our work has broadened, and we now focus on diabetes, cancer, immunology, pain and neurodegeneration. Our products save and improve lives. Pharmaceuticals also save overall health care costs by improving health outcomes, reducing the need for surgeries, hospitalization, and extended care, and allowing people to return to work sooner. We unite caring with discovery to create medicines that make life better for people around the world.

Lilly employees work to discover and bring life-changing medicines to people who need them, improve the understanding and management of disease, and contribute to our communities through philanthropy and volunteerism. We employ approximately 325 people across the country.

Lilly's response to this consultation includes three components: an endorsement of the joint Innovative Medicines Canada and BIOTECanada consultation submission, commentary on the context surrounding a pan-Canadian formulary, and finally, technical responses on the questions posed by CADTH.

Yours sincerely,

Rhonda J Pacheco

President & General Manager

Eli Lilly Canada

Endorsement

As referenced above, Lilly endorses the joint submission made by IMC and BIOTECanada, in particular, the five principles enunciated in the submission: patient centred; access enhancing; predictable and transparent processes and appeals; expertise and stakeholder perspective in decision making; and excellence in HTA, as well as the commentary on the appropriate federal role in relation to provincial responsibilities for health. As will be expanded upon in the subsequent section, Lilly believes it important to recognize that the practical utility of a pan-Canadian formulary directly corresponds to the degree to which the construct is interoperable with and supportive of provincial jurisdictions.

Contextual Discussion

As previously articulated, the degree to which an additional layer of healthcare decision-making will be beneficial to health outcomes will be determined by the amount of support it provides to pre-existing mechanisms and systems. In this case, given a well-established system of provincially funded and managed formularies, as well as a robust private payer market, any pan-Canadian formulary initiative can only be deemed a success if it is designed to support and supplement those pre-existing apparatus.

Determining how best to provide this support through a pan-Canadian formulary is critical to the initiative; there is already a de-facto pan-Canadian formulary that has been created through the collaboration of the provinces on the pan-Canadian Pharmaceutical Alliance, as any medicine negotiated by that body will have, by necessity, received the assent of all provinces. If the product of this consultation process is to provide benefit to patients, careful consideration will need to be given to how the imposition of additional process is able streamline access to new and innovative products.

Finally, a general question for consideration is whether the proposed framework will be applied across all disease categories (e.g. oncology/non-oncology, drugs for rare diseases)?

As a technical note, it is unclear how patient perspective and HCP feedback was incorporated into the framework for the pilot or whether this was done consistently (i.e. detailing 'expert consultation'), and therefore, not entirely clear how this process will ensure an equitable approach that addresses smaller, perhaps more vulnerable populations or special circumstances without this input in the framework.

Technical Responses

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

As acknowledged by CADTH, some of the principles are in tension with others, for example, timeliness and equity vs. sustainability. A sense of how these principles would be ranked in the decision-making framework is recommended.

Comments on the 6 principles:

1. Universal and Integrated:

Lilly agrees that all Canadians should have access to the drugs they need regardless of their diversity characteristics.

2. Equitable:

Lilly agrees that there are discrepancies between provinces in listing criteria (and between public payers and private payers). We acknowledge that the pan-Canadian Pharmaceutical Alliance has, to a great extent, addressed many of these discrepancies. With respect to further work in the effort to make access more equitable, however, the most restrictive criteria shouldn't serve as the baseline reference.

3. Effective and High Quality:

Lilly agrees that listed drug products' benefits should sufficiently outweigh harms; should meet unmet health needs in the intended patient population and provide sufficient improvement to patient and caregiver quality of life.

For rare diseases, and diseases with high unmet need, it will be important to recognize as part of the process value that there are situations where preliminary data coming from phase I-II trials should be sufficient to make recommendations. We agree that including RWE in the process and evidence assessment is key.

There is a need to balance principle 3 with principle 6: To be efficient in decision making - there should be better acceptance of preliminary results (e.g. phase I/II trials).

4. Sustainable:

Lilly has no comment.

5. Efficient and timely:

Lilly agrees. Current timelines show that it can take up to 25 months from time of CADTH submissions

to listing. These delays impact access to important and life-changing medicines.

6. Inclusive/transparent/fair:

It is important that manufacturers are provided the opportunity to have open dialogue with HTAs before, during, and after the review process and to have the opportunity to appeal.

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

Products that are not listed on any of the identified public drug plans should not be automatically excluded from the list (as it is not always possible to ascertain the reason [e.g. clinical value, economic value, misalignment on price, etc.]).

Additionally, without any details on how existing private drug formularies would be impacted, it is not appropriate to focus strictly on the public market (and is misaligned with the guiding principles).

As an example, only one GLP-1 agonist is listed as a proposed product to include, while other GLP-1 agonists are reimbursed by private payers. Other GLP-1-agonists should not be automatically excluded, and a further review should be performed.

It is not clear how products having received different HTA recommendations (e.g. positive INESSS recommendation) but negative CADTH recommendation will be assessed.

It is unclear how subgroups (other than pregnant or breastfeeding) will be considered. There are products that are not as often used but have a high value to certain sub-sets of patients, will this be considered and if so, how? This is important to meet the stated goal of ensuring that the process "allow[s] the needs of individual patients or communities to be adequately identified or addressed" rather than take a population-based approach (page 10 in Discussion Paper)

3. (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 pan-Canadian formulary? Please provide details.

Lilly has no comment.

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

It would be difficult to gather the same level of evidence as for drugs.

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

More clarity on the methodological approach and potential execution (i.e. alignment with jurisdictional public and private plans and funding viability) would be required to be able to comment on expansion.

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

Lilly has no comment.

5. (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.

The first-in first-out submission review process allows fairness across drug manufacturers. There are already existing processes in place to reduce the time between Health Canada approval and the CADTH recommendation (aligned reviews between Health Canada and health technology assessment organizations).

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

To be consistent with the proposed principles, emphasis should be put on efficiency and timeliness of reviews versus prioritization of products. Core challenge with prioritization and / or scoring models is that they can be misaligned with the principle of equitable access to medication.

With regards to option 3 (international HTAs): there are several factors that would need to be considered (e.g. comparators, and standards of practice vary across countries).

6. Do you agree with the proposed evaluation criteria and the considerations for new products? Please provide the reason(s) and suggested changes, if any.

Principles make sense but the proposed execution is not clear.

Societal preferences: impact on the workplace should be considered (e.g. reduction of absenteeism, less disability, etc.).

7. 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?

Weighting of the evidence might be acceptable if all important factors from a societal perspective are considered and if the weighting is transparent. All stakeholders should be given the opportunity to comment on the distribution of weight across evaluation criteria (e.g. patient preference vs clinical benefit vs value for money).

8. 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 reviews)?

There are several issues to consider – the first is that companies have a finite capacity to manage formulary listing and other mechanical processes. Accordingly, if a pan-Canadian Formulary informed by this consultation is pursued, it should be designed in such a way that the addition of a product to any provincial or federal formulary automatically adds the product in an identical fashion to the pan-Canadian formulary.

Second, as it relates to the contextual issues discussed in section 2 above, serious consideration should be given to whether the resources required to manage a pan-Canadian Formulary, especially if it is duplicative of provincial formularies, could better be deployed to support health initiatives with more material outcomes.

Third, Lilly believes that a first in, first out system is the most equitable way to treat medicines. As different jurisdictions will have different system needs to best support population health, designing a prioritization system that allows for certain classes or therapeutic areas to be expedited will almost by necessity privilege one region of the country over another. If the formulary is to truly be "pan-Canadian," this sort of regional privilege will undermine cohesion and is likely to deter jurisdictions from subscribing.

Express Scripts Canada

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

We are in agreement with the 6 guiding principles and that the primary objective of a pan-Canadian drug list should be to provide access to essential medications to Canadians caught in existing drug coverage gaps. This list of individuals with drug coverage gaps would include but would not be limited to, part-time workers, new Canadians as well as under-served populations.

Other options to take into consideration include:

• A requirement to focus on harmonization by leveraging existing public and private drug programs to ensure that any new program facilitates the goal of closing the gap while maintaining access through existing programs.

• Any new program will require both public and private payers to make adjustments to their existing programs and will require collaboration moving forward.

• Acknowledging that the mandate is focused on the creation and management of the formulary and that funding is not a factor under consideration, we cannot lose sight of the importance of ensuring that Canadians have access to the drugs they need without undue financial hardship as a result of prescription drug costs.

As a frame of reference, Express Scripts Canada (ESC) is Canada's leading Pharmacy Benefit Management provider. We have over 25 years of experience delivering industry-leading services to large, complex, public and private sector insurance industry clients, including the Government of Canada.

Express Scripts Canada fully supports this proposed framework, and based on our positioning in the marketplace , we are in a unique position to provide expertise and any guidance that may be needed to understand the unique systems already in place that support clinical decisions for formulary listings as well as reimbursement of prescription drugs.

2. Do you agree with the proposed assessment criteria?

Yes

Please provide the reason(s) and suggested changes, if any.

We generally agree with the approach but would like to propose a few ideas for consideration if criteria is geared towards replicating or closely mimicking existing provincial formularies;

• This approach will only be effective if harmonization with other programs is achieved .As previously noted, this may still leave significant therapies inaccessible to Canadians.

• If the number of public formularies is arbitrary (i.e. 'all or most' public formularies), this may not reflect current evidence or standard of therapeutic practice. This may exclude products that are not currently listed on public plans.

• We would recommend that a re-evaluation of historic decisions be built into the model. Reconsideration for excluded drugs and products based on availability of additional research and new indications or potentially even generic or biosimilar alternatives.

• Consideration should also be given to the existing processes that support other 'public drug programs' outside of the general provincial formularies (e.g. NIHB, other provincial level programs e.g. Trillium, EAP, BC Special Authority)

For our private payer clients, ESC has been providing Formulary Management and Prior Authorization (PA) services for over a decade. Further, as the largest PBM for private payers, we leverage our data insights to inform our formulary management. We would be happy to provide insights and our benefit management expertise, to ensure a good understanding of how both private and public payer options can be balanced and leveraged.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

We agree with the inclusion of related devices on the formulary and have outlined some ideas for considerations.

• Consider products that are not currently listed on public formularies as many non-diabetic devices are not covered (i.e. aero chambers) and these criteria could perpetuate the problematic access to critical devices for special populations (e.g. pediatric patients).

• Devices should be evaluated in conjunction with the therapeutic options so that appropriate limits and approval criteria can be applied.

• Effective benefit management techniques should be considered. Such as quantity limits (e.g. diabetic test strips) based on prior therapies.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

Yes, related products should be included in the same list for drugs and have the same evaluation criteria applied to them. We are proposing that similar treatment and criteria be applied to digital therapeutics or apps / other 'related products' that may not necessarily be tied to devices but could be deemed critical for a patient's treatment/access (e.g. supplements).

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

Yes, we support the proposed approach to expand to other therapeutic areas that align with the national health priorities outlined in the discussion paper. The most scrutiny and most difficult decisions may reside in therapeutic areas where access is most prohibitive such as cancer and inflammatory conditions, where the population is smaller and drugs are more costly. We recognize that more prevalent conditions, like diabetes or cardiovascular conditions, are associated with therapies and inclusion decisions are clearer due to less costly therapeutics and larger supporting trials.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

Ideally, disease prevalence would be balanced with priorities based on disease severity, limited alternative options and patient impact. This further supports the proposed principles related to sustainability and access reflected in the discussion paper for products listed under specialized programs (e.g. Cancer and special drug programs).

We would also support considerations for lack of equity across provincial borders and underserved populations.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #2

Please provide the reason(s) for your choice.

Response:

Option 1: The first in first out process, currently in place today, may be problematic as not all products would be marketed in Canada at the same time as they receive approval.

Option 2: Our recommendation would be for the implementation of this option with the caveat that a clear and transparent scoring system would also include transparency in classifications. This scoring system should consider where limited patient populations are impacted.

Option 3: A model based on international collaboration would likely be very difficult to implement due to the uniqueness of the Canadian health care system. The general availability of drugs and coverage of alternative products would likely be different and would limit the applicability of the decisions.

5b. What criteria could be used to identify priority products?

The criteria to identify priority products could include the following:

• The availability of alternative treatments to already included on the universal list

• The assessment of therapeutic benefits relative to the alternative treatments

• High-risk or prioritized health conditions

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

We agree with the proposed evaluation criteria and considerations for new products, however we would like the following points to also be considered:

• Long-term thinking is difficult to define but it is significant and often not reflected in current formulary decisions.

• Preventative therapeutics like vaccines, or medications with longer-term effects are often not included, for example, medications used to treat obesity.

• Reevaluate drugs or products, which have received 'do not reimburse' recommendations from CADTH, where new clinical and cost effective evidence becomes available

• Some conditions currently classified as lifestyle choices (weight-loss, fertility) should be reclassified and recognized as medical conditions

• There should be equitable access (off-label use of drugs) to address DEI (diversity, equity and inclusion), for all Canadians despite of geographical location

• Consider the ability to collect and share data across all stakeholders and platforms to enable the collection of health outcomes and information to support decisions

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

We agree that the deliberative process should include weighting or a score from each criteria. Whichever approach is chosen, the methodology and weighting must be transparent to all stakeholders. It is difficult to assess any weighting/criteria if integration with other private/public programs are not under consideration. Any weighting/criteria should also consider any National health priorities.

8. 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 reviews)?

In order to ensure operational sustainability, the following measures should be taken into consideration along with the panel's recommendations:

• Ensure a consistent scoring system for all new drugs and products being evaluated

• Evaluate new indications as soon as they are approved

• Consider input from clinicians regarding prevalent disease states with common medications missing from public formularies

• Consider medications used to treat priority indications as identified through prior sections

• Explore expanding the indications under review

• There should be a prioritization system for listed products to be re-evaluated and we propose using the deliberative process that is being applied to evaluate any existing covered products

• Consider the patient and advocacy perspective

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

Any questions can be sent to:

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Fighting Blindness Canada (and on behalf of several other patient groups)

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

We would add that access to innovative medications is a critical aspect of these principles.

Under "universal and integrated" we would ask how "diversity characteristics" are defined?

Under "Equitable" we would suggest "equity recognizes that individuals have different circumstances that require variable allocation of resources to provide opportunities to achieve "improved" outcomes and across all stages of disease." (ex: palliative care)

2. Do you agree with the proposed assessment criteria?

Yes

Please provide the reason(s) and suggested changes, if any.

Yes, and we encourage that assessments against these criteria be performed in a way that is transparent, equitable and inclusive of the expertise of patients and their caregivers.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

If a related product is needed to diagnose or administer any medications on the potential pan-Canadian formulary then it should be included.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

The eligibility criteria should be applied to products as well as drugs. Some conditions (e.g. diabetes) rely on devices almost as much as on medications for day to day management and complication avoidance. Another example is respiratory inhalers. Evaluation should take into consideration the ease and technique of devices. This also needs to be a consideration when substituting brand name products with generics. Nonetheless, this approach should recognize and support the important role products can play in patient care.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

Yes, because it is equitable, transparent and consistent.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

Perhaps, but we would need a transparent way of determining what those priorities are. Decisions should not be based on current trends in healthcare and cannot be overly political, it must be nimble. It may make sense to start with therapeutic areas where the gaps in access are the most acute. However, problems may arise when a national priority may not include a drug for a less common disease, for example. There needs to be flexibility to cover precision medicines.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #2

Please provide the reason(s) for your choice.

Transparency is critical. System must be agile and adaptable, yet fair and consistently applied. No bureaucracy. There is a real need prioritize reviews where there is an unmet need.

5b. What criteria could be used to identify priority products?

• The population it serves: is it an underserved population?

• Does it reduce the number of uninsured Canadians?

• Is it serving those with less access (such as pediatric, women of reproductive age, low income households, minorities, etc.)

• Unmet needs

• Inclusion in clinical practice guidelines

Additionally, there should also be a process developed for stakeholders to recommend priority products.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Please focus on value as defined by patient health outcomes, including patient quality of life, as evidenced by both patient reported experience AND outcome measures, not just as defined by clinical outcomes at a population level.

Value and sustainability should be approached with a long-term lens - how does the product being reviewed impact patients and healthcare systems in the long term versus just the short term [ex: cost of the drug vs decreased hospitalizations, no need for future treatments, return to work, etc.]

We also want to consider the burden of disease in any evaluation. While on clinical treatment what psychological or emotional issues does a patient experience, are they able to return to normal activities such as school or work, full time or part time. Is there a reduction in the burden to the system when a patient receives beneficial medications and if so, what is the net cost? All these parts need to be factored into a decision to list a medication.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

Yes, but patients and patient caregivers should be among the experts consulted to arrive at the score.

8. 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 reviews)?

Prioritize based on risk and reward - look to address where there are the biggest gaps in equitable access as well as where there are unmet needs.

It is suggested that reviews conducted in other relevant jurisdictions be used here to minimize the workload.

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

We propose the following three guiding principles from our patient coalition:

• FOCUS ON ACCESS, NOT JUST AFFORDABILITY – balance efforts to lower drug prices with the value of bringing innovative medicines to impacted Canadians as quickly and as equitably as possible.

• PUT PATIENTS AT THE CENTRE OF DECISION-MAKING – benefits sought from this approach should be defined in terms of improving health outcomes for patients. Patients must be engaged meaningfully and continuously in decision-making.

• PRACTICE AGILITY AND CONTINUOUS IMPROVEMENT – apply real-world evidence, don't rely only on clinical trial data. Consider analysis done by comparable countries to expedite drug review. Recognize

that cost-benefit analysis will increasingly need to recognize that patient populations will decrease in size as therapies become more targeted. Take a systems approach in the establishment of the Canada Drug Agency and a pan-Canadian formulary. It cannot be considered in a silo separate from other related policies, levels of government and other agencies.

Our submission is on behalf of our patient coalition comprising of the following organizations:

ALS Society of Canada

Canadian Cancer Survivor Network

Canadian Hospice Palliative Care Association

Canadian Association of PNH Patients

Coalition Priorité Cancer au Québec

Colorectal Cancer Canada

Cure SMA

Cystic Fibrosis Canada

Fighting Blindness Canada

Lung Health Foundation

MitoCanada

Ovarian Cancer Canada

PROCURE – The Force Against Prostate Cancer

Québec Breast Cancer Foundation

The Leukemia & Lymphoma Society of Canada

Gastrointestinal Society

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The principles are a good starting point, but they are significantly incomplete and vague. Access to medicine is not simply creating a list of drugs. It's far more complex and nuanced.

The Context

• we recommend CADTH and the panel review the 2018 report of the Best Medicines Coalition on pharmacare and policy options as it includes the participation of a diverse group of patient organizations including the Gastrointestinal Society. This report also includes contributions from organizations that the panel referenced and consulted with, such as the Canadian Pharmacists Association and the Health Charities Coalition of Canada: https://bestmedicinescoalition.org/wp-content/uploads/2018/07/Better-Pharmacare-for-Patients_Evaluating-Policy-Options.pdf

• CADTH and the panel did not consult a diversity of patients and patient groups in the development of this discussion paper

• given the weight of health equity in the paper, it is puzzling that the panel's composition does not include health equity experts, perspectives from different Indigenous communities, and marginalized communities

• we recommend that they consult experts and representatives in these areas so that they can appropriately and accurately inform the decision-making processes

• there may be bias behind the development of the principles since the paper did not disclose information regarding the study design of the limited literature search and "focused internet search"

• there is no inclusion and exclusion criteria, and it did not share what databases and keywords they used to identify relevant material

• as a result, some of the resources found may not be fit-for-purpose, they lack diversity, and are not representative of the experiences and needs of all Canadians

• the goal and purpose of the formulary is unclear and needs to be explicitly defined

• we can infer that it might be to 'fill the gaps' to provide universal access, since the former seems to play a larger role in shaping the content and process values of the guiding principles; however, the process behind the formulary then evolves into those similar to HTA bodies for identifying new therapies

• this consultation opportunity for stakeholders lacks adequate notice, engagement, and accessibility

• engagement practices do not reflect Health Canada's and the Public Health Agency of Canada's Guidelines on Public Engagement, which state that "as a general guideline, the greater the potential impact on interested and affected participants, the higher the level of engagement recommended" (https://www.canada.ca/en/health-canada/services/publications/health-system-services/health-canada-public-health-agency-canada-guidelines-public-engagement.html)

• note that CADTH provided notice of the consultation in December 2021, at the beginning of the peak of COVID-19 infections, and then opened the feedback portal on January 11, with only one online information session on January 16 – which allows very little time for patient groups like ours, with limited resources, and who are busy meeting the needs of the patients who we serve

• limited to one-way online questionnaire

• a more appropriate alternative, given the nature of this topic affecting all Canadians, is to host virtual and interactive multi-stakeholder roundtables that include patients and patient organizations – that actually allows real-time interaction and questions, not like typical CADTH events that block the questions and control the discussion

• CADTH and the panel intentionally limited their work to only two of five elements, along with a list of exclusions

• this action appears arbitrary as all the elements and their counterparts are critical to one another and they provided no rationale for their limitations

• to separate them in the development of a pan-Canadian formulary may be a futile, incomplete, and ineffective exercise

• we recommend that CADTH and the panel revisit the formulary and incorporate considerations for all the elements, including the list of exclusions, and consult patients/patient groups so that it is comprehensive, fit-for-purpose, and evidence-based

• Principle 2: Equitable

• What does "close the gaps in access" (12) mean? What gaps are we looking at and from what lens do we identify these gaps? Are they:

_ gaps in coverage resulting from Canadians who are ineligible for public drug programs

_ gaps in coverage arising from out-of-pocket costs of underinsured Canadians (i.e., high premiums, coinsurance, and deductibles, and caps on coverage)

_ gaps resulting from variations in listing decisions across federal, provincial, and territorial public drug programs i.e., lack of coverage of take-home cancer medications in eastern Canada

_ only covering medications that the formulary leaders decide, and not listening to the needs of the individuals and the recommendation of their doctors (forcing round pegs into square holes)

• with the supporting value of "diversity data-driven" (12), it needs to incorporate active seeking of input from remote and marginalized communities, and to acknowledge the uniqueness of individuals even in homogenized communities

• Principle 3: Effective and high quality

• CADTH and the panel need to identify who will be responsible for continuously improving and monitoring the formulary and how this body will not reduce duplication among existing systems and processes

• Principle 4: Sustainable

• it is unclear how feasibility as a content or process value for this principle relates to assessing the impact of listing criteria (13), leading to truncated lists that will ultimately not meet the needs of the population

• Principle 5: Efficient and timely

• it is futile to highlight in this principle that it minimizes duplication of steps without providing evidence to support its claim; requires the inclusion of an assessment of the current healthcare environment (we know that our healthcare systems have way too many agencies/departments already, with unnecessary duplication, lack of efficacy, and excessive delays)

• Principle 6: Inclusive, transparent, and fair process

• this principle needs to include the following values: meaningful and accessible engagement

• please define the procedural fairness process for appealing decisions

_ see answer to question 2(b) for problems with lack of clarity in this approach

• add the following principles (see BMC Better Pharmacare Report for details on below):

• appropriateness of therapy and availability of a variety of therapeutic options as a principle

_ making only one or a select few drug products available can limit patient choice and access and decrease drug adherence

_ patients may stop taking/refilling their prescription because it is a less effective medication for them

• support innovation and the life sciences ecosystem

_ this would be harmonious with existing landscape i.e., life sciences strategy, rare disease, etc.

• timely access

_ reduce wait times and consider ways to address shortages in drug products and supplies

• affordability

_ recognize that high out-of-pocket costs occur because Canadians are either uninsured or underinsured (e.g., exclusions, cost-sharing, insurance plan limits)

_ this is crucial to include, since the paper only mentioned “affordable” twice and it was in the context of affordability for the payers of the pan-Canadian drug program

2. Do you agree with the proposed assessment criteria?

No

Please provide the reason(s) and suggested changes, if any.

• it is important to address that 11% of Canadians who do not have drug coverage are, in fact, eligible for public drug programs and they may not be aware of their eligibility due to gaps in awareness and accessibility of information and resources (http://innovativemedicines.ca/wp-content/uploads/2017/12/20170712-understanding-the-gap.pdf)

• there needs to be a collaborative approach to proactively engage individuals in Canada on the availability of public drug programs in their province or territory

• marginalized communities may require more support as they often face additional challenges in understanding and accessing the healthcare system (e.g., language and cultural barriers, and those struggling with their mental health)

• the assessment criteria do not include opportunities for patient input, and some processes direct further review to clinical communities only

• list refinement and reassessment also does not include patient input and it is unclear how this exclusion reflects practices of procedural fairness, especially as a guiding principle

• the assessment criteria must also capture real-world evidence, qualitative data, interviews and consultations, and various other types of information. Literature reviews often do not reflect these experiences (page 21 states that they are the source of supplementary information for formulary considerations)

• add that a variety of medicines in therapeutic areas can support greater adherence due to the range of available options for patients – we believe that increasing medication options allows physicians more tools to appropriately care for their diverse patients

• Appendix 2 of the proposed sample list of drugs may not address Canadians' diverse healthcare needs as it only includes non-proprietary names and does not provide information on the available manufacturers per drug product (can also prevent drug shortages), dosages, formulations, and administration

• another limiting factor is that the criteria eliminate the availability of medicines that have received Health Canada approval but received a negative recommendation from CADTH/INESSS and public drug plans have not listed

• recognize that barriers to access involve more than geographic location and includes socio-economic factors

• do not limit assessment to availability of biosimilar or generics as innovation can bring about more cost-effective options

• Formulary management practices

• we disagree with the approach of using generic and biosimilar substitution, therapeutic substitution and reference-based reimbursement as we have seen this go wrong and know it does not save money in the long run (Increased health costs from mandated Therapeutic Substitution of proton pump inhibitors in British Columbia. Alimentary Pharmacology and Therapeutics. 2009;29(8):882–891.)

• protect patients' continuity of care; patients who have achieved symptom control due to treatments may experience adverse reactions when they switch to other medications without a medical reason

• treatment decisions must rest between a patient and their treating physician and/or pharmacist

• see our report on patient experiences with the BC and Alberta non-medical biosimilar switch policy at https://badgut.org/wp-content/uploads/Biosimilars-in-AB-BC-Survey-Results.pdf

• Combination products

• their inclusion in the list should be based on clinical evidence and Health Canada approval, rather than listing status in public drug plans since doing so will still result in barriers to access

_ this also prevents timely access as public drug plans may eventually list some products into their formularies

• Non-prescription drugs

• the cost of over-the-counter medicines presents a significant burden on Canadians and CADTH and the panel must study and discuss this further in a separate forum with patients, caregivers, and patient groups

• Why does the assessment of relevant information specifically include safe use in pregnant and lactating women but not other factors?

• This is important to note but there are many other circumstances that can affect drug safety use (i.e., drug interactions, medical history). However, these are discussions between a patient and their healthcare provider as well as pharmacists.

• What is this criterion's role in affecting the assessment of a drug for the formulary?

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No

Please provide details.

• not at this time

• this section is unclear because it does not include specifics on the healthcare settings affected

• needs to include companion diagnostics, but this is a complex topic that is beyond the scope of the panel in this paper

• the panel should conduct a separate forum of discussion on this topic and include an assessment of current federal and provincial programs and services

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No

Please provide reason(s).

See answer above, under 3(a).

4a. Do you support the proposed approach to expand to other therapeutic areas?

No

Please provide the reason(s) for your choice.

We recognize that there are significant gaps in coverage for oncology medications, especially take-home cancer drugs in some jurisdictions, and appreciate their consideration in the expansion of the formulary but there are crucial issues that CADTH and the panel must first address before moving forward with expansion plans.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

Please provide information on what the "national health priorities" are, how they are determined, and those involved in this process.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

• this topic is beyond the scope of information available in the discussion paper and requires further study and multi-stakeholder consultations, especially including patients and patient organizations

• it is unclear why the panel is proposing approaches to establish a process for priority products since it contradicts the assessment criteria they developed (inclusivity)

• the assessment criteria specifically exclude products that public drug programs have not listed in their formularies, does not have an HTA review, and/or received a negative HTA recommendation

5b. What criteria could be used to identify priority products?

Please see answers above.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No

Please provide the reason(s) and suggested changes, if any.

• all processes behind the pan-Canadian formulary, including the proposed evaluation criteria, must not duplicate the work of other HTA bodies (i.e., "clinical benefit", "value for money") as Canada already has well established systems that conduct these assessments

• generic or biosimilar substitution (also known as non-medical switching for the latter) and reference-based pricing contradicts the considerations of equitable access

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

• unnecessary to create a new system since several initiatives, regulatory amendments, and processes for post-marketing surveillance of drugs and devices already exist

• e.g., CanReValue, Health Canada amendments to the Food and Drug Regulations and the Medical Devices Regulations (http://www.gazette.gc.ca/rp-pr/p2/2020/2020-12-23/html/sor-dors262-eng.html), CADTH's therapeutic reviews, provincial reviews, new CADTH Post-Market Drug Evaluation Program, and Choosing Wisely Canada

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

Please refer to the submission by Medicines Access Coalition – BC, as we are a member and are in full support of that submission.

We invite CADTH, the panel, and the Canadian Drug Agency Transition Office to engage patients and patient organizations on discussions regarding the pan-Canadian formulary. With our varied lived experiences, we can also provide suggestions on other ways we can address the healthcare needs of Canadians in an equitable, affordable, and timely manner.

GlaxoSmithKline Inc.

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

Dear Dr. King and Mr. Lefebvre:

On behalf of GlaxoSmithKline Inc. (GSK), I am pleased to provide feedback pursuant to the stakeholder consultation currently being undertaken by yourselves and the other members of the Pan-Canadian Advisory Panel regarding the proposed framework for developing a potential pan-Canadian prescription drug list, or formulary.

GSK – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. Consistently ranking as one of the country's top 100 R&D investors, GSK has a history in Canada that dates back to 1902.

In Canada, coverage for prescription drugs exists through an array of public and private drug plans. Canada's mixed system of public and private coverage generally works reasonably well to meet the needs of Canadians. However, as several recent reports have noted, depending on where they live and other factors, some Canadians do not have adequate prescription drug and vaccines coverage. In line with this public policy issue, the Advisory Panel has been tasked with an important mandate to help inform and advance the ongoing national discourse, which is ultimately aimed at ensuring all Canadians have robust access to prescription medicines – an objective that GSK firmly supports.

Fundamentally, GSK agrees that there is room to strengthen and improve the current system. However, it is unclear to us how and whether the framework proposed by the Advisory Panel would do that as there are critical – and indeed foundational – gaps in the consultation document put forward by the Panel, and in the information shared to date. Crucially, there is no mention or discussion in the paper of the funding mechanisms that would necessarily underpin any new national or sub-national formulary or formularies.

The paper also does not canvass the relationship between the proposed new formulary and existing provincial and territorial public formularies (or formularies managed by the federal government, for that matter). We understand that such topics are beyond the scope of the Panel's mandate and therefore are not part of this consultation. However, without addressing or even touching on these key questions, we are challenged to comment in a more meaningful way on the specific questions posed by the Advisory Panel.

That said, the Advisory Panel has helpfully noted certain key values and principles that would necessarily underpin any further work on a pan-Canadian prescription drug list. The values put forward by the Panel – namely "streamlined, timeliness, comprehensive, inclusive and data/evidence driven" – are values that resonate very much with GSK.

In particular, making data-driven decisions on which medicines to include in public formularies is key. If HTA (Health Technology Assessment) analysis is to form the basis of such formulary recommendations and decisions, then continued efforts and investments should be made to improve the quality, timeliness and utility of HTA reviews in Canada. Indeed, comparative analysis suggests that CADTH may be structurally more restrictive in its recommendations than some peer HTA jurisdictions, such as NICE (National Institute for Health and Care Excellence) in the UK.

Furthermore, the time lags that all-too frequently occur between HTA reviews, pCPA (pan-Canadian Pharmaceutical Alliance) negotiations, and provincial/territorial listings have become unacceptably long in Canada. Canada ranks near the bottom of the OECD (Organisation for Economic Co-operation and Development) 20 countries in time to listing, meaning that Canadian patients and their families do not have timely access to innovative medicines that is reasonably on par with other developed countries like the United States, the UK or Germany, for example (In 2019, the time from market authorization to first public reimbursement averages 526 days, whereas UK and Germany are able to do this in 317 and 299 days respectively).

Quite frankly, irrespective of what drugs are listed on what formularies, there needs to be much greater synchronization, planning and alignment between the various Canadian reimbursement bodies –

including Health Canada – to ensure that patients are not left waiting for access to life-saving and life-changing medicines. Additionally, going forward, it will be increasingly important to fully leverage the power of international collaboration.

GSK is encouraged to see the Advisory Panel referencing greater opportunities to work together at an international level to review and prioritize products collectively. By partnering with organizations like NICE or IQWiG (Institute for Quality and Efficiency in Health Care) there is an opportunity to not only make more efficient use of resources, but also to share ideas and best practices. International collaborations could also help accelerate the adoption and adoption of RWE (Real World Evidence) into HTA reviews and outcomes-based agreements in Canada; an area that the Advisory Panel has also rightly noted as an opportunity that requires further development. In short, innovative medicines also require innovative assessment and reimbursement practices. Leveraging outcomes data and RWE would foster access to new precision medicines and technologies.

Options for drug coverage within formularies are also key. No two patients are exactly alike, and variations between and across patient types can impact the effectiveness or tolerability of one medication compared to another. Therefore, any public formulary must be constructed with robust input from patients and their caregivers. It must also offer an appropriate range of options to patients and prescribers across all therapeutic areas.

In closing, the work of the Advisory Panel to identify ways of strengthening access to medicines for Canadians is commendable, even if the path proposed by the Panel to help achieve this requires further discussion and ultimately depends on policy and fiscal considerations that go well beyond simply establishing a pan-Canadian list of drugs. GSK appreciates the opportunity to participate in this process and welcomes further discussion.

H3 CONSULTING

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

One principle not acknowledged is that more than 60% of Canadians have drug coverage through employer-sponsored plans, and others own individual health insurance contracts. National policy cannot be made unless all Canadians are represented, and considering only provincial drug plans fails that test. There are important gaps in access within most private drug plans as well, including their voluntary nature. There is no limit on out-of-pocket expenses for about 85% of private drug plans (personal communication, Express Scripts Canada, 2020), and about 20% of private drug plans have annual limits at or below $100,000 (Telus Health, 2020).

Related to this and within the principle of 'inclusive, transparent and fair process' is the need for more participatory governance of the formulary. While political authority and accountability are required, the world is too complex, changes too fast, and the necessary expertise is too broad for control to remain solely with F-P-T Ministers and their bureaucrats. To the list of stakeholders provided, insurers and employers, and experts in medicine, pharmacy and drug policy (public and private) should be added as a resource pool on both management and governance levels.

Another important missing principle is affordability, which operates at the drug and plan level and in the short term and is therefore distinguished from sustainability (system-level and long-term). If out-of-pocket costs are too high or not graded to family income, a national formulary will become irrelevant. Cost-related non-adherence to drug therapy, now affecting about 5.5% of Canadians (Law et al., 2018), must also be addressed. For institutional payers, affordability means willingness to pay and for public plans, having the means to pay through allocated budgets.

The six proposed principles are all relevant and important, but how are they linked to those in the Canada Health Act? While political courage to consider revisions to an Act that is almost 40 years old has been missing, the formulary principles ought to be coordinated. Patients as well as policy and program leaders need to accommodate both sets. One set of principles should be sufficient for the entire health care system, and there is much to recommend the six proposed in the Discussion Paper.

Under 'universal and integrated,' I note the desire to align drugs with other health system goals. However, I am not aware of any goals articulated for our health care system in any province. I believe that is a major policy oversight, although out-of-scope for this investigation. Incoherence and access failures are likely to continue if that gap is not filled.

A further detail is that the principle of 'efficient and timely' should include explicit timelines as a process value. Germany has managed this since 2011, allowing one year from start to finish for new drug evaluation, including price negotiation with the manufacturer. If there is no agreement on price, then a three-month arbitration process occurs (Bonnett, 2020). The Canadian process takes much longer on average, and outcomes, i.e., listing and attached conditions, varies considerably by province. The whole process should be better integrated here, and more predictable for all parties.

Inherent in the six proposed principles is that the policy underlying the formulary must be actively managed, in order to stay effective, relevant, efficient, coordinated and inclusive. Health systems, technology and population needs are not static and immovable, and so formulary regulations, management and governance must keep up.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

As stated in my response to Q1, I don't believe any formulary review committee can properly evaluate access to medicines unless private drug plans are also included. The "assessment criteria" appear to be reasonable, but omitting private drug plans means the process is inadequate and the outcome is far less defensible. A "national" formulary must consider all sources of coverage and presumably be designed to benefit all Canadians, otherwise it will be irrelevant to the majority.

On this same point, private drug plans use different HTA than provincial plans because they need to consider productivity (presenteeism, absence and disability) and impacts beyond the publicly-funded health system. The decision to include, flag or exclude a drug must also consider economic and clinical criteria and perspectives that are relevant to private drug plan sponsors and members.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

All provincial and private drug plans should consider related products, but that alone will not be enough to ensure reimbursement on a consistent and equitable basis. The federal government, as the most likely source of top-up funding to ensure each province can adopt and sustain a national formulary, should also provide funding for related products. This should include pharmacogenomic (PGx) testing and companion diagnostics, when there is demonstrated benefit. These are more commonly part of the submission for high-cost drugs for oncology and some rare diseases. Used effectively, PGx testing can benefit payers and patients by avoiding the use of drugs that are unlikely to have the desired effects.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

All provincial and private drug plans should consider related products, but that alone will not be enough to ensure reimbursement on a consistent and equitable basis. The federal government, as the most likely source of top-up funding to ensure each province can adopt and sustain a national formulary, should provide this funding. That would include pharmacogenomic testing and companion diagnostics, when there is demonstrated benefit. These are more commonly part of the submission for high-cost drugs for oncology and some rare diseases. Used effectively, PGx testing can benefit payers and patients by avoiding the use of drugs that are unlikely to have the desired effects.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

Again, listing status and access under both public and private drug plans must be considered.

In addition to pregnant and lactating women, we should also be considering common comorbidities (the whole patient) to ensure that patients get access to all the drugs needed to manage their health. This is also an argument for integrating cancer and special drug programs AND rare disease drugs into the national formulary. For example, literature demonstrates that heart disease, diabetes, anxiety and depression are common comorbidities with cancer patients (Bonnett & Smofsky, 2018).

The Panel has proposed that DRDs be excluded. However, DRDs are the fastest growing class and the most challenging to evaluate, so I believe they should be included in a national formulary. Since 76% of new DRD sales are for oncology products (PMPRB, 2022), then it would be very difficult to include cancer drugs, but not DRDs.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

A greater priority than ranking diseases would be to understand and prioritize the needs of those who have no drug insurance, or those facing high drug costs relative to family income.

Q4b prompts me to ask other questions:

1. Have national disease priorities ever been identified? What are the ethical considerations of preferring one disease over another? If someone has comorbidities, would they get access to only drugs on the formulary but not to any drug that is not yet evaluated?

2. How long would it take to review the drugs on a comprehensive national formulary? Interest in prioritization suggests that launching a comprehensive formulary could take a long time. How long?

3. What happens to people with prior access to a drug that becomes ineligible under a new national formulary? PBO (2017) estimated about $4B of drug costs would become ineligible even if the QC formulary was used in a national pharmacare plan. These therapeutic needs do not disappear and may not be fully or immediately addressed by existing public drug plans. Let's avoid the OHIP+ debacle of transitioning patients back and forth as the government changed eligibility rules.

4. To shorten the review, could national listing be expedited when a drug is already listed on some number of provincial or insurer standard formularies? Could consideration of delisting or substitution with a reference drug for a lower-cost or lower-priority drug occur after the launch of the formulary?

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

All options will likely fail because they do not consider price negotiations by pCPA, private insurers and pharmacy benefit managers, and possibly HTA by INESSS or other provincial agencies. If these gaps can be solved, perhaps by integrating and broadening pCPA's work within the Canadian Drug Agency, then Option 1 might be the most practical. The entire long and winding trail to listing and access needs to be integrated and better managed.

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Regarding bullets 1 and 4, consideration should also be given to potential or proven impacts on workplace productivity, i.e., presenteeism, absence and disability. If employers are going to continue to pay billions for drugs, then a national formulary must also address their needs. Economic perspectives must be extended beyond the health system focus taken by provincial drug plans outside Quebec.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

I strongly agree with comments in the Discussion Paper about maintaining a formulary (p. 25). A structured process is needed for regular reviews of price and value, and to consider delisting. For example, France reviews their formulary every five years, and Switzerland evaluates one-third of its formulary every year (Commonwealth Fund, 2019 and 2020).

Again, "key stakeholders" must include employers, health insurers and private payer advisors and experts.

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

In the Discussion Paper under Prescribing Guidelines (p. 27), there is an important distinction to be made between the prescribing decision made by a health professional with the understanding and agreement of the affected patient (and sometimes the caregiver), and a provincial or private plan sponsor's willingness to pay. No payer wants to interfere in the patient's care, but the uncertain quality of prescribing decisions and potentially high-cost / low-value prescribing means the resultant choice should not automatically be paid or reimbursed. Prescribers need to understand and have ready access to drug price information in order to weigh available choices and choose the high-value option.

In Part 3, Reducing the Duplication of Processes (p. 27-28), active consideration should be given to a more integrated and consistent health technology assessment and reassessment. Separate processes between Quebec and the rest of Canada may be a political necessity, but there is little to justify separate HTA for public and private plans. While the clinical review should be very similar, the economic and budget impact evaluation will sometimes differ significantly. Recognizing the strong feelings that exist on this option, perhaps an integrated public-private process could be developed specifically for oncology drugs and DRDs. For the former class, this is particularly important because patients often need access to drugs not offered by their provincial program, i.e., non-IV cancer drugs are excluded or only available through a special access program in ON, NB and NL. In those provinces (and NS) those drugs are not fully covered like IV drugs, meaning that private drug plans often step in. Private insurers could pay the additional operating cost of CADTH according to their market share in order to include their perspectives in a national HTA process.

The references included in this submission are in short form. Full references can be provided on request.

Health Charities Coalition of Canada

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Health Charities Coalition of Canada (HCCC) recognizes and supports the existing alignment between CADTH principles and those of HCCC.

HCCC recognizes that a sustainable and modern formulary, that places principles of patient need ahead of cost containment, is an aspirational goal to be achieved through the integration of formulary decision making within the greater healthcare system.

HCCC recommends that point in time decisions influenced by competing principles of cost-effectiveness and patient need be viewed as opportunities for transparent patient engagement and issue identification for immediate or ongoing system change.

HCCC recommends that consideration be given to updating Principle 3: Effective and High Quality: An effective and high-quality national formulary is one that achieves better patient outcomes, comprehensive access to modern medicine and cost savings over what could be achieved by any one provincial or territorial formulary on its own.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

HCCC recognizes the benefits to a staged approach and efforts that have led to the pilot list of products.

HCCC notes that the success of the pilot will be determined by the impacts of any unmanageable changes to patient therapies and improved or loss of therapies.

HCCC would like to highlight that the creation of a national formulary is an opportunity to take into account information not previously considered as well as improve interfaces between formulary decisions and other aspects of healthcare. HCCC recommends that in parallel to exercises that nominate products from existing formularies, a new process also be considered that re-sets past decisions based on current healthcare considerations and principles that support holistic patient care.

HCCC recognizes that biosimilars are by definition not the same as biologics. This is reflected in the nature of the evidence required, and process for authorization by Health Canada which is distinctly different than that of generic drugs. Clinically, biosimilars and biologics are recognized as not being the same and substitution principles should be tailored accordingly to ensure that a switch will not jeopardize a patient's treatment stability due to immunogenicity. Ensuring that the right drug gets to the right patient at the right time must always be the core objective.

HCCC notes that the full plan (timelines, necessary steps, transitions, decisions, considerations, consultations etc.) that connects the creation of the pilot list to a functional national formulary is not clear.

HCCC notes that it is difficult to comment on discrete aspects of a plan to reach a national formulary without understanding the entirety of the approach.

HCCC recommends that a change management strategy should accompany any transition to a national formulary and a principle of avoiding any changes to therapy could/should/must be considered. (A 'grandfather' clause etc.).

HCCC recommends that principles should reflect opportunities to manage costs through modern procurement avenues/negotiations and include dynamic features to respond to marketplace cost changes in addition to cost savings from classic substitution of generics/biosimilars.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No

Please provide details.

HCCC supports the creation of new or additional criteria that can address both immediate needs for complementary therapies but also support a scalable to whole of person therapeutic approach.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

HCCC supports the inclusion of related products by making use of the most effective operational model (exiting lists or new/dynamic methods) necessary to achieve the patient outcomes identified in the principles.

HCCC supports changes to CADTH approaches that capitalize on this opportunity to establish a world leading HTA process inspired by the best practices of other jurisdictions while contemplating integration with national centres of clinical excellence and continuous/dynamic methods of incorporating modern medicine.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

HCCC recommends that the goal of achieving a truly universal and equitable national formulary is satisfied by achieving access to products that support all disease states and conditions.

HCCC recommends that therapeutic areas not be compartmentalized for prioritization as many patients, in particular aging populations, will face challenges across multiple therapeutic areas.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

HCCC supports on-going efforts and engagement to overcome any constraints that may be impeding a national formulary and that are contributing to the need to prioritize.

HCCC supports further engagement opportunities to clarify and determine the planning and operational consequences of setting priorities.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

HCCC recommends that CADTH explore and analyze the options further to determine feasibility.

5b. What criteria could be used to identify priority products?

HCCC supports clarity in the resource constraints that are contributing to the necessity of an option analysis and priority setting exercise.

HCCC recommends consideration be given to changing operational approaches to allow for a dynamic method of resource management and consultation on those constrains and metrics that are driving the need to engage in a priority setting dialogue.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

HCCC notes that values are a more appropriate term than preferences.

HCCC recommends that the feasibility of adopting a therapeutic should be viewed as an opportunity to include emerging therapeutics supportive of on-going improvements to patient care.

HCCC is concerned that limiting inclusion of therapies on a National Formulary that are overcoming challenges with adoption (feasibility) will only further hinder their uptake and could undermine the adoption of new effective products.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

HCCC recognizes the importance of a governance model to a successful national formulary.

HCCC supports a governance model that is objective and takes into account authentic and regular patient input.

HCCC supports the use of a governance model that achieves the patient outputs described in the principles of the formulary.

HCCC supports the use of a governance model that is inspired by and improves upon existing models of patient inclusion and HTA around the world.

8. 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 reviews)?

HCCC recognizes that changes to existing processes will require the input of many different stakeholders.

HCCC supports an iterative process to manage workload while engaging all groups necessary to achieve a successful National Formulary that is integrated within health systems and remains both sustainable and modern.

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

HCCC expresses its sincere appreciation for the opportunity to participate in this consultative process. We believe a National Formulary is an important component of a modern and patient focused healthcare system. We applaud the progress made to date and look forward to continued engagement.

HCCC proposes the following considerations in support of a successful National Formulary within the greater context of achieving an integrated patient outcome-based health care system:

• Changing the Conversation – Recognizing that Patient Centric Policy is Cost Effective

• Treating Patients as a Whole

• Rising above Jurisdictional Issues and Creating Systemic Solutions

• Embracing Change as Part of Preserving Canada's Healthcare Legacy

HCCC stresses that patients must be engaged as equal partners in all consultations and decision-making processes that affect their care. While this consultation represents positive progress, it remains difficult to assess elements of a pan-Canadian formulary in isolation of the other three components that are core to its implementation - that is: terms of coverage, financing and clear decision-making authority. We must capitalize on emerging opportunities to address the well-known gaps in our healthcare system. Now is the time to act as we recover from the impacts of the pandemic. HCCC looks forward to providing continued comment on the outstanding elements that are germane to the development of

a national formulary. We thank CADTH for this opportunity and the important contribution they make to our healthcare system.

About us:

The Health Charities Coalition of Canada is a member-based organization dedicated to strengthening the voice of Canadians, patients and caregivers by advocating for enhanced health policy and increased investment in health research.

Health Coalition of Alberta

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The Health Coalition of Alberta (HCA) would like to congratulate the Advisory Panel on their work to develop this proposed framework for a national prescription drug list. The principles put forward appear to align with those that have been suggested by patient groups, health charities and individuals in the past. These principles set the stage for a modernization of Canada's approach to providing publicly funded access to medications. Unfortunately, the process to develop the actual formulary reverts to a standard and typical cost analysis. The link back to the proposed principles is not demonstrated in the actual medication list and is weak at best.

The principles fall short in recognizing that national pharmacare is being developed for patients; patients are more than just another stakeholder in this process as we are the sole user of and reason for national pharmacare. Patient and caregiver lived experience should be embedded in all of these principles and inform all decisions made to create a national pharmacare plan. The lack of balanced and meaningful representation on the advisory panel by those who only identify as patients, caregivers or their representatives highlights the gap in recognizing the vital contribution patients must be allowed to bring to the development and decision-making process.

We also believe that improved care and health outcomes must be clearly defined as fundamental principles for this formulary with a focus on addressing unmet needs and inequities. Building a formulary with the goal to improve the lives of the most vulnerable Canadians will have an impact for all of us from coast to coast to coast.

While we recognize the principle of equity can be a challenge to operationalize, this is another glaring weakness of the proposed formulary. The process used to develop the prescription drug list cannot be labeled as equitable as it does not take into consideration the private insurance system. When upwards of half of all Canadians access their medications with funding from private insurance, a formulary that only considers public funding can in no way be equitable.

As members of the Best Medicines Coalition (BMC), we also support its submission and the additional principles put forward by its members. Recommendations of key importance to be added to this list of principles include: inclusive and comprehensive access; consistency and cohesion; and patient informed policy development. The Health Coalition of Alberta reiterates comments previously submitted by BMC asking for the expansion of the proposed principles.

2. Do you agree with the proposed assessment criteria?

No

Please provide the reason(s) and suggested changes, if any.

The Health Coalition of Alberta is greatly concerned about the lack of equity in the proposed prescription medication list. This surfaces in several instances in the assessment criteria.

How can this national formulary be considered equitable when there has been no assessment of medications funded by private insurance formularies? In fact, by not including them, this proposed list of prescribed medications helps to widen the gap between those who can afford private insurance and those who cannot. It actually supports a two-tier healthcare system in Canada.

The Health Coalition of Alberta has submitted recommendations to the Government of Alberta to ensure that participation in a national pharmacare program does not jeopardize the existing public funding of medications available to all Albertans. We support a program that will provide greater access to the medications patients need when they need them and that eliminates financial hardship. However, there does not appear to be any fulsome analysis of existing gaps in coverage.

In order to begin to address equity issues, an assessment needs to be done to determine who is not filling their prescriptions today and what are the reasons behind those choices. What treatment decisions are being made by health care providers based on insurance or public coverage vs prescribing the best medication to achieve the best patient-directed health outcome? How are medications dispensed? Is this done at all community pharmacies or specialized pharmacies or clinics that not all Canadians have access to and therefore, are not able to access recommended medications? These are all questions that do not appear to have been considered but should be guides to determining what medications should be included in a national formulary. If assessment criteria are built to consider the most vulnerable Canadian it will cause a ripple effect to improve access for all.

It is evident that the proposed assessment criteria are focused on the traditional approach to cost analysis and does not include measures to ensure all Canadians can access the medications required to manage their health. The criteria do not align with the proposed principles, demonstrate an unwillingness to develop a formulary that is a modern approach to providing benefit for the future and, are not centered on patients and their needs.

As members of the Best Medicines Coalition (BMC), we also support its submission and the additional criteria put forward by its members. Recommendations of key importance to be added to this list of criteria include: formulary breadth and depth; criteria to encompass future drugs to address unmet needs; define formulary scope; as well as timeliness and efficiency. The Health Coalition of Alberta reiterates comments previously submitted by BMC asking for the expansion of the proposed criteria.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

Although the phrase “pragmatic approach” is utilized in the discussion paper to describe the methodology to create the list of prescribed medications, it is not defined. Who determined this “pragmatic approach”? Was it based on patient needs, health outcomes, future unmet needs? Unfortunately, it appears that “pragmatic” was determined to be a simple analysis of existing public formularies that incorporate cost analysis as the primary assessment to determine if a medication is eligible for coverage. Without a clear definition of this “pragmatic approach” it appears evident that it is not one that is centered on the national pharmacare user – patients.

Another statement that highlights the lack of focus on patients is captured in the section about inclusion of products with restricted access.

"Although, it was outside the scope of the panel, members did recognize that current mechanisms of tiered restriction may work well for some of these drugs, but the workflow for clinicians could be considerably improved and streamlined. "

Why is the impact of workflow for clinicians of greater importance than the impact on patients, health outcomes, inequities, gaps, etc.? Each of these missing assessments align with many of the principles of the proposed prescribed medicines list but were not considered. Yet again, this demonstrates how the principles were not employed in the development of this formulary.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No

Please provide the reason(s) for your choice.

The Health Coalition of Alberta believes that all Albertans, and Canadians, should have equal, timely access to medications. Patient health outcomes can be improved by appropriate access to medication, particularly access to new, more effective drugs. An unfortunate reality in Canada is that access to medications can vary widely depending on a number of factors including where a patient lives, whether they have private insurance, are they disabled and their age.

The approach taken by the advisory panel is one that looks at cost and pre-existing public funding of medications only and does not assess what medications could have the greatest impact for Canadians. The social determinants of health, care gap analysis, a review of what prescriptions are not filled or refilled, or even simply asking Canadians what medications they would like to have publicly funded by a national pharmacare program do not appear to be considerations when determining where to begin or what next in the formulary development. Do Canadians even want a prescription medication list developed by therapeutic area or do they prefer one that is focused on helping the most vulnerable Canadians? The Health Coalition of Alberta recommends the advisory panel gain additional societal insights before finalizing the proposed formulary let alone recommending how to expand it.

We also recommend that a detailed impact analysis be conducted prior to any expansion of this formulary. It must demonstrate that national pharmacare has expanded and improved access to medications, achieved better health outcomes and what gaps were filled by the formulary. We also support BMC's recommendation that this type of detailed impact analysis must be conducted prior to the launch of any national formulary.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

See above

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

The Health Coalition of Alberta suggests a blended model of the three options proposed might be the best approach to ensure an equitable and efficient review process. Each option provides potential for success and we recommend that a critical analysis, that is centered on improving patients' lives, is conducted before any further decisions are finalized.

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The Health Coalition of Alberta believes Canada needs to shift to a relation-based model of care that is centered on patient needs to achieve healthy lives. We support shared decision-making between the health care team and educated and informed patients in order to make choices that will have the most impact. Therefore, we recommend "Alignment with patient and societal preferences" to adopted as the foremost evaluation criteria proposed. We also support criteria that helps to build a comprehensive formulary that is focused on clinical practice guidelines and real-world evidence to ensure appropriate medicines are funded.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

Although this is a can be viewed as a complex question, we believe it is one that needs to be proposed clearly and concisely to Canadians in order to capture societal views. The Health Coalition of Alberta believes in the value of each criterion with added emphasis on equity as a method to address gaps in care.

8. 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 reviews)?

Some suggestions to address sustainability of a national pharmacare program include achieving cost savings in streamlined, efficient administration instead of cost containment strategies that limit patient and provider access.

We also recommend the inclusion of a system to grandfather in patients with pre-existing medication access that may not align to this proposed list. The creation of a national pharmacare formulary must improve and expand access to medications for Canadians and not jeopardize patients' health by forcing a switch in medications in order to maintain funded access.

An appeals process is an essential component that appears to be missing from this proposal. Healthcare providers and patients must have the ability to request exemptions, special access and challenge denials of funding in order for this to be an equitable process.

Finally, the Health Coalition of Alberta recommends fulsome ongoing patient consultation is conducted during review, debate, development, and integration of new pharmacare strategies and programs. This process should employ a variety of methods in order to capture input from marginalized communities, indigenous peoples, individual patients as well as their representatives.

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

No response provided

HealthPRO Procurement Services Inc.

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

HealthPRO supports the proposed principles and definitions. They address a national approach to ensure equal access across geographic areas, a focus on patient equity through all demographics and a foundation in evidence and clinical outcomes.

Sustainability is an important principle to ensure not only financial sustainability but also to facilitate a robust drug pipeline in Canada. We need to ensure Canada remains a viable and desirable market for future new drug, generic and biosimilar launches.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

HealthPRO supports the proposed assessment criteria in principle, with reservations on the proposed formulary management practice with respect to selection of only one generic or one biosimilar for coverage. Please reference the following from the discussion paper: " If biosimilars and generics are available for a particular drug molecule, the panel felt that the least costly product could be selected and prioritized for listing".

Supply chain assurance is essential to ensure uninterrupted therapy for patients. In order to ensure sustainability and resiliency for drug therapy, contracting models that adopt diversified product listings and/or split contracts have proven successful in ensuring ongoing medication supply, both in Canada and other countries, such as the UK. This ensures retaining multiple suppliers, multiple product options within Canada and facilitates the ability to mitigate the impact of critical drug shortages when they occur. Maintaining a diversified market in Canada is also essential to ensure suppliers continue to consider Canada when planning global drug launches vs preferentially selecting other countries with better predictors of financial gain.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

Having related information in the same area facilitates communication, information sharing, and facilitates decision-making by providers.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #1

Please provide the reason(s) for your choice.

Suggest a hybrid approach with Option #1 guiding overall decision-making, however with the potential to utilize Option #2 as needed when new innovative therapies are launched (such as novel antibiotics) to help address antimicrobial resistance (AMR). This would improve market access for manufacturers who have had novel antibiotics approved in other countries and improve timely access to essential, new, and newer antibiotics for Canadians. Please refer to the December 2021 report completed by a collaboration between the Canadian Antimicrobial Innovation Coalition (CAIC) and McMaster University.

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

Hospital formularies also need to be considered when reviewing any drug products for inclusion in a pan-Canadian formulary. The transition of care for patients as they move between the community, in-hospital and out-patient care needs to be coordinated in such a way that there is no gap in treatment. There is a great opportunity to convene key hospital stakeholders to inform and ensure alignment with specialty practice areas. This will help to guide best practices and protocol-driven therapies within a pan-Canadian formulary.

Heart & Stroke Foundation of Canada

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

Heart & Stroke ("H&S") believes that a national formulary should be used as part of a process to create a national, universal Pharmacare system that can be integrated within the wider Canadian Healthcare system. These proposed principles and definitions will support the development of a successful national formulary. In particular, the principles of equity, transparency, and sustainability will be vitally important.

Equity: pharmaceutical access to our healthcare system is currently extremely inequitable, and COVID-19 related job losses and resulting loss in drug plan benefits have disproportionately impacted vulnerable groups, including women, racialized Canadians, and low-income Canadians. Efforts should be taken to include diverse stakeholder groups (not just the most vocal advocates). This formulary represents an opportunity to set a new standard for equity in healthcare.

Sustainability: almost all members of Canadian society will become users (or caregivers of users) in the healthcare system in their future. For example, heart disease and stroke affect 90% of the Canadian population. Members of the wider Canadian population are (usually silent) stakeholders in this system and the need for integrity and sustainability for future users must be prioritized. To carefully balance the values of users and Canadian society at large, the proposed principles require thoughtful and inclusive public engagement alongside the views and evaluation of experts.

Transparency: to ensure public trust in the process remains high, all Conflicts of Interest (COI) of all participants involved in formulary management must be minimized, and all information on COI must be publicly available.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

We agree with the assessment criteria starting point outlined on page 16 of the discussion paper – to "ensure that the most commonly prescribed drugs and related products currently available to some Canadians would be made available to all people living in Canada". This point is foundational to the development of a national, universal Pharmacare system.

Basing the initial phase of formulary development on current listing status of these medications across different Federal/Provincial/Territorial formularies in Canada is a reasonable initial approach. Further review and refinement of the list will be needed. An H&S expert reviewed the proposed cardiovascular formulary in detail and identified several medications for which the proposed classification does not reflect current clinical practice. For example, some medications will also have multiple indications across different therapeutic areas. Sodium-glucose cotransporter-2 inhibitors are included under the proposed Diabetes list but should also be considered as part of the Cardiovascular medications list, as they are used to treat some types of Heart Failure in patients without Diabetes. We look forward to more information about this list will be further refined in future.

H&S supports promotion of judicious use of biosimilars where possible to support the principle of sustainability, while acknowledging that there are circumstances where exceptions must be available for patients whose conditions are only controlled with drugs that are excluded from the proposed sample list.

Reducing barriers to non-prescription (Over the Counter, or OTC) drugs is important to equitable medication access. We agree with the inclusion of Acetylsalicylic acid in the formulary, as it is an important medication for treatment in cardiovascular disease and significant barriers currently exist to access for some patients.

Other national formularies have well-established processes that can be learned from as Canada moves towards a national formulary. As the only country with a universal healthcare system that does not include Pharmacare, Canada should make efforts to learn from other jurisdictions. We also recommend further consultation with stakeholders on formulary management best practices as part of the broader implementation plan.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

A national formulary should also include the medical devices and supplies that allow for optimal disease management. These related products should be evaluated for inclusion based on similar assessment criteria as new medications – clinical benefit, value for money, safety profile etc.

While new drugs and medical devices can provide improvement in clinical outcomes, this is not always the case, and they may have significant side effects that may not be detected until post-approval monitoring. Caution is required when determining eligibility of new products for a formulary. Patient advocacy is usually focused solely on one disease state and may not represent all diverse or underrepresented patient populations affected by a condition, so eligibility must be determined based on transparent processes and expert opinion, while acknowledging the lived experience and expertise of patients. New, related medications within a class should only be added to the formulary if there are clear benefits based on a certain set of pre-ordained criteria, as discussed in Question 6. Any listing decisions should be quantifiable using transparent, public analyses.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

One national formulary is the most streamlined option.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

Expeditious finalization of a national formulary across all therapeutic areas simultaneously is preferable to prioritization, as many individuals experience multiple chronic and acute conditions with complex interactions between their conditions. For example, CV outcomes are impacted by control of conditions such as diabetes, respiratory disease, kidney disease and infectious diseases, among others.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

Expeditious finalization of a national formulary across all therapeutic areas simultaneously is preferable to prioritization, as many individuals experience multiple chronic and acute conditions with complex interactions between their conditions. For example, CV outcomes are impacted by control of conditions such as diabetes, respiratory disease, kidney disease and infectious diseases, among others.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

We do not feel we have sufficient information to answer this question at this time. We recommend further comparative analysis of other countries' submission review processes, and consultation about constraints that impact prioritization/trade-offs. Whenever possible, international experience and cooperation should be leveraged to streamline and improve submission review, while being mindful of unique differences between countries.

5b. What criteria could be used to identify priority products?

If priority products are required, criteria should be transparent, use established metrics and high-quality data from extensive clinical trials including diverse and underrepresented populations.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

We agree with the proposed criteria, although we urge that further information on how these criteria are to be applied will be made available in a future consultation. Constraints such as financing mean

that there will be difficult trade-offs to be made in the future and clear, publicly available information on decision support tools are needed to navigate these challenges

It is worth noting note that clinical benefit is hard to determine in new drugs and post-market data is often essential in further establishing clinical benefits and safety profiles. Referring to the principles in Table 1, pressures of timeliness should not supersede the need for a strong evidence-base and adequate consideration of patient and societal values.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

We agree that the deliberative process should be quantifiable and transparent to all stakeholders. One example of potential scoring and weighting was provided in this discussion paper, but we encourage further comparisons between existing Health Technology Assessment processes across Canada and internationally. Canada has an opportunity to establish a new global gold standard for formulary management.

8. 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 reviews)?

Governance should be developed in a way that promotes patient and caregiver participation and input, however, an emphasis must be put on fostering processes that support transparent evidence-based decision-making and governance that considers the needs of the whole population (with a strong emphasis on equity, diversity, inclusion, and empowerment), rather than relying solely on the needs of any one group. The expert committee should contain experts from multiple fields, with very clear processes to minimize conflicts of interest and ensure transparency.

A cyclical revaluation/reassessment process that utilizes synergies within the health system and international collaboration is necessary to ensure a national Formulary meets the health needs of Canadians and aligns with the principles of the formulary on an on-going basis. Any national formulary must be adequately and sustainably resourced by the federal government as an integral part of a national universal Pharmacare program.

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

Heart & Stroke appreciates the opportunity to engage in this consultation, and we thank the panel for their work thus far.

There are many unanswered questions in this initial consultation, and issues identified as outside of the scope of this consultation (private/public funding, negotiation of drug pricing and budgets, governance structures, terms of coverage, interaction between the formulary and the Rare Disease Drug Strategy etc.). These issues are integral to any national formulary and cannot be completely considered

separately. We encourage and expect that CADTH to continue to engage with stakeholders in future phases of this work.

The adoption of a national formulary across Canada would streamline the new drugs approval process. The closer we align our systems with systems of other countries with similar national, universal healthcare systems, the more we will likely be able to ensure that our approach in Canada is based on best practices.

As we recover from COVID-19 pandemic, we are faced both with the inadequacies of our current patchwork of systems, but also an opportunity for transformation and renewal of our healthcare system, including adequate provision of medications that will improve the health of all people in Canada. The development of an equitable, comprehensive formulary represents a critical first step towards a historic opportunity to establish a national, universal Pharmacare system in Canada.

Individual Respondent 1

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The terms "streamlined" and "timeliness" need to be further defined, especially as they impact the addition of newly approved drugs. The effectiveness of these drugs is not well understood in the real world especially among populations where the drug was not tested. Similarly, little is known about either rare or long-term adverse effects. It takes about 3 years before the first new safety issue is identified.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The three step process as outlined on page 15 focuses on adding and maintaining the list but does not mention removing drugs from the list (although this is mentioned later on). Past experience has shown that removing drugs from a formulary is often very difficult and will probably require a different process from adding drugs to the formulary.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

As I noted above, particular caution needs to be applied when adding newly approved drugs to a list. Drugs typically show greater efficacy and fewer side effects in clinical trials than what is seen once they are marketed. Therefore, except in exceptional conditions (e.g., the antivirals for hepatitis C) significant caution should be used when deciding about adding newly approved drugs to a formulary.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No

Please provide reason(s).

Related drugs should only be added to the formulary if there are compelling reasons for using them, e.g., more convenient (backed up by clinical evidence showing that better convenience translates into better clinical outcomes) and/or lower cost. This is especially true where there are already multiple related products, e.g., ACE inhibitors.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

My answer is dependent on how national health priorities are set. Care needs to be taken to ensure that national health priorities are not based on the volume of lobbying by groups with conflicted interests, e.g., manufacturers of drugs, clinicians and patient groups with financial conflicts of interest.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

The first two of the options rely on data in new drug submissions. The currently available data shows that when Health Canada uses either its priority approval process or the NOC/c process that the majority of these drugs offer little to no additional therapeutic gain over exisitng products. The same conclusion applies to first-in-class drugs. Therefore, relying on the data available in the premarket stage is not a reliable way of determining significant therapeutic gain. In order for options 1 or 2 to be used, it should be shown that the available data reliably predicts therapeutic value in the majority of cases. Option 3 might be useful but existing data shows differences between the indications and/or safety concerns among national or supranational (e.g., EMA) regulators for the same drug. Therefore, international cooperation needs to take these potential differences into consideration.

5b. What criteria could be used to identify priority products?

Identifying priority products will require reforms to premarket clinical trials such that better data is generated, e.g., oncology products should only be approved based on surrogate endpoints if trials are underway to show improvements in either quality of life or overall survival; drugs for diabetes should only be approved if there are ongoing trials to show improved hard clinical outcomes; trials need to be focussed on the demographic groups that are going to be the highest users of the product, etc.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

As I have indicated previously clinical benefit is hard to determine in new drugs - benefits are greater in premarket trials than in real life and harms are greater in real life than in clinical trials. In determining clinical benefit these limitations of trials need to be taken into account.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

The weighting of the evidence may vary depending on the condition being treated, e.g., the weights for oncology products may be different than for products treating respiratory diseases.

8. 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 reviews)?

Products with the overall lowest score when they were added to the formulary should be re-evaluated the earliest since these are the ones with the least amount of evidence for adding them.

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

1. The Discussion Paper assumes that declaring a financial conflict of interest by various stakeholders is enough to ensure that the COI will not affect decision making but there is strong evidence to show that COI operates at a subconscious level. To the greatest extent possible people who are involved with the formulary process should be free of COI and at a minimum the majority of people on any committee should be free of COI as well as the chair and co-chairs. 2. Again there is strong evidence that clinical practice guidelines produced by committees where the majority of people have COI are of poorer quality than those produced by committees where a minority of people have COI. The level of COI on committees producing CPGs needs to be taken into account when deciding whether to use the CPG. 3. People with COI should be able to present their points of view but should not be involved in the actual decision making process.

Individual Respondent 2

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #1

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

No response provided

Individual Respondent 3

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

I feel like I must have missed some earlier publications? If this is, in fact, the first document that has been created to outline the framework for a potential pan-Canadian formulary, I believe it is sorely missing some important details. As I reviewed the document, I was searching for basic information regarding who is this formulary meant to serve? Is it meant to replace existing F/P/T and/or private

insurance formularies? Or will in work in parallel with existing formularies and, if so, how will its role be differentiated. Forgive me if I missed these details somewhere, but until I understand the basic intentions of this potential formulary, I find questions regarding what drugs should be listed on it to be irrelevant at the moment.

Individual Respondent 4

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

I agree in principle and only in part because, in practice and for some drugs, this approach might nor be optimal. There are certain drugs for example, where the generic product's effectiveness (when defined as how the drug performs in real life setting) differs from that of the reference drug. In order to ensure the quality of the product, RWD could be collected. Thus, the formulary could become a valuable way of collecting Real World Data and converting it into Real World evidence.

For similar reasons I have misgivings about reference based pricing. It was tried for hypertensives in BC some time ago. While I am not sure any longer and can find no literature to confirm this, what happens when practice guidelines or best clinical/medical practices change the drug of choice? How does a formulary become agile enough to take into account some of these points? I am not sure, but would like them to be discussed and considered.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

I have some issues around the definition and the matter stated in the document about continuous monitoring devices. It has become, pretty much, state of best practice for adequate glucose control to have CGM devices used. What can be done to consider such shifts right now, rather than deferring it to later. We are on the cusp of evolution in the treatment of Diabetes with drugs other than metformin for Type 2 DM and for CGM, particularly for Type 1 DM. And CGM for Type 1 DM is here already and to stay. Less common as yet for Tpye 2 DM, but on its way to become common.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

The optimal use for related products as noted under part a., above, should be considered. In part, the definition already covers related products as those necessary for optimal delivery. One could add optimal dosing and schedule of administration.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

With the comments under 1, 2 and 3, this can be applied to other areas. Some special consideration may need to be given to drugs used in oncology. Because, at present, many anticancer agents are not reimbursed or it takes too long to obtain "special permission", either particular consideration would have to be given for drugs that receive an NOC/c, or a "special permission" process needs to be developed to allow for prompt approval or otherwise, without falling into the temptation of denying automatically something only because it may take a bit longer to make a decision.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

I am not sure what this means really. Vaccines are a National Health Priority always. They belong to another category. Another category would be drugs for Alzheimer's Disease for example. There the issue is a bit more tricky and I do not have any suggestions that I would consider useful on a population basis.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

I am considering a combination of the three, depending on the case. A testing out of a case by case basis might provide a good perspective of how to combine the three or which process to settle on, or alternately, develop a scaled process where drugs are assigned to one or other option based on criteria to be developed.

5b. What criteria could be used to identify priority products?

Severity of disease, number of existing alternatives, quality of a generic or biosimilar, stage of disease, best medical practices. Or, for example if a new therapy comes to be for a disease that could be until then, managed by paliative care only, the drug should receive immediate priority.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

The only comment I need to add that the criteria provided should not be ranked.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

I noted above that the criteria should not be ranked. However, I have no objection to weighting. In this weigthing, given equal outcomes, cost or value for money should be left for the final decision to ensure that solid medicine and clinical science predominates in the decision.

8. 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 reviews)?

I am not sure. However, as I had noted above, there is here and opportunity to develop Real World Data and, as a consequence, Real World Evidence that can shed light on the issue/s and at the same time inform which drug or related product/s should be kept or removed from the list

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

There is also one other item that I wish to bring up: I thing consideration should be given to Indigenous Culture regarding Science when decision that would apply to our First Nations and Inuit Populations would apply.

Individual Respondent 5

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

agree there should be standardization particularly across programs like off label or special usage. should also be co-ordination with insurance companies around pre approvals. further, many physicians require fees for completing forms either per form, or a lump sum annual payment. a formulary is no good if a patient has to pay fees, and/or get multiple pre approvals which they can't afford.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

see previous comment

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

this approach would not necessarily cover diseases that are common, but in low numbers of the population

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #3

Please provide the reason(s) for your choice.

tired of waiting 2-5 years longer than the UK and US for drug approvals. also earlier treatment options can prevent disease progression. for example, Ocrevus for PPMS. by the time canada approved, I was too old to qualify. Had it been approved when US did, I would have qualified and my disease progression had a decent chance of stopping. as a result, I am more of a burden on the health care system going forward in terms of care and equipment costs, as well as the real possibility of losing my independence through a progression that may not have happened.

5b. What criteria could be used to identify priority products?

age limits, benefits of treating earlier rather than later (both monetary in reducing public costs, and prevention of disease progression).

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

re OTC drugs. Low dose Aspirin is not cheap any more, and is twice the price as in US. It's a common use drug that could still be out of the cost range of lower income people. should be part of formulary with a prescription. I'm sure there are other OTC drugs in this type of category.

It doesn't appear as if there were actual (non professional) patients on this panel. It's stated there were persons representing patients. There are lots of smart "real" patients out there that you could have involved. Not cool.

Individual Respondent 6

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

What standard of effectiveness will be acceptable?

Currently, RWE and clinical trials appear on the same level in their importance for inclusion. WOuld suggest emphasizing that clinical trials are crucial. Furthermore, would also emphasize the value of this formulary being an opportunity to incorporate randomized evaluations within the context of a national formulary, whereby drugs are constantly being tested through randomized evaluations against one another to determine optimal inclusion criteria onto the formulary, or determining their removal from the formulary. This should be under the control of the health system, and not reliant on the sponsoring company. Innovative strategies for randomization within the health system are now available, and could be considered for target conditions in the Canadian context as a pilot proposal.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The direction of listing (most/all provinces, then to national formulary) may be inefficient in some circumstances, and whether top-down decision-making about which drugs to include should be present for some products should be considered.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

Would strongly link 'public health priorities' with prioritizing therapeutic areas for consideration, sending a signal to industry as to what is important.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #3

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

Public health needs.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

Would do both MCDA and quantitative weighting, randomly assigned, and evaluate them for key metrics and determine which strategy is better.

8. 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 reviews)?

Embedding randomized research into health systems to allow for formulary modernization and constant re-evaluation, for all products.

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

You likely have noticed a theme with my comments. This is an incredible opportunity to create a learning health system in canada, with formulary content being the focus of determining which products are useful and which are not. Simple, straightforward randomized evaluations, within the context of healthcare, can be done to help decide which product is important to include, and relying on industry sponsors to conduct these evaluations should be a relic of the past.

Individual Respondent 7

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

Yes I believe this products need to be included

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #2

Please provide the reason(s) for your choice.

I don't believe option 2 has as many cons as the others

5b. What criteria could be used to identify priority products?

Those that Canadians are using the most

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

I don't know sadly

8. 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 reviews)?

I think there should be a prioritization system for listed products to be re-evaluated

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

Please do whatever you can to pressure the government to implement universal single-payer pharmacare for all please

Individual Respondent 8

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

See text at the end for a caution…perhaps the need for a qualifying paragraph…

With respect to the formal questions, I am comfortable defaulting to the final opinions of the Panel members in terms of the process and criteria described for the Formulary. My interest is in contexts and frameworks with the potential to optimize a sustainable response to the needs of the Canadian population, wherever they live, whatever their income, education or ethnicity. The technology to quite accurately project population needs and thus the required response, adjusted to individual circumstances for optimality does exist. What is missing is political will and vision. Timely access to safe, effective pharmaceuticals is one piece in the puzzle. Thus see comments at end (Sec. 9) about context for your questions and the project.

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

While I did read the report on implementing National Pharmacare several months ago, and understand the critical role a Pan-Canadian Formulary would play in the bigger Pharmacare picture, it is not clear in this Discussion Paper what if any difference a Formulary on its own would make relative to the current situation. I think the truthful answer is none. The paper says…

A potential pan-Canadian formulary could address issues that would support all people in Canada

— regardless of age, disability, gender, geography, race, or socioeconomic status, among other

characteristics — to have access to prescription drugs and select related products.

The goal of a potential pan-Canadian formulary is to include a broad range of safe, effective,

evidence-based drugs and related products that meet the health care needs of Canada's diverse

population.

And I agree it could under the right circumstances. But as I am sure all interested parties would agree, it is only within the context of some sort of national consensus if not plan that a Formulary would have a consequential impact on outcomes with respect to optimal pharmaceuticals access by Canadians. And as I am sure all parties will also agree, major challenges having to do with jurisdictions and costs are significant if not seemingly insurmountable barriers to achieving that end. The paper rightly acknowledges that 'terms of coverage' and 'financing' would need to be addressed for the potential of a Formulary to be realized, neither of which are within the scope of the Formulary panel. Regrettably provinces have too much authority for health policy in my opinion and as such we have nothing close to a national health 'system'. Until we have an electronic health record for every Canadian citizen/resident, we do not have a 'system'. Ironically we do not technically even have a single provincial or territorial 'system' if we apply that criterion.

I am not highlighting this reality to be discouraging but rather to encourage some qualification of claims and aspirations contained in the paper by acknowledging the significant contingencies upon which any utility coming from a Formulary is highly dependent. Several of the principles and values espoused in this paper are beyond the sphere of influence of a Formulary and would only be satisfied if all jurisdictions show the political will to come onside with both necessary policies and funding. Likely this reality is all too real for Panel members. So what? My point is that a paragraph may be necessary, clearly acknowledging that several of the aspirational values and principles relating to the impact of any Pan-Canadian Formulary are highly contingent on circumstances well beyond the scope of this process…like jurisdictional consensus on process and funding…but are included should the stars align. Otherwise they may give the naïve a false, unrealistic expectation.

On page 10, the paper states:

The panel acknowledged that the framework and process must allow for a strong focus on universal access — access for all people in Canada across geographic and cultural contexts. The panel noted that applying a population health perspective might put already disadvantaged populations further behind and not allow the needs of individual patients or communities to be adequately identified or addressed.

That is a truly regrettable and unnecessary statement and I suggest that it be removed/abandoned in any future publications. It appears that the panel were either erroneously informed or are harboring a very primitive understanding of 'population health'. While admirable when originally described in the Federal document "A New Perspective on the Health of Canadians" in 1974, its potential has been neglected in this country for no good reason. The adoption of an evolved Population Health framework in all Canadian jurisdictions is exactly what is required to ensure a true system…a 'System for Health'. It is not the place of the panel to educate Canadian decision-makers about the potential of a robust Population Health framework but it would be regrettable if it were to be discounted or disparaged out of ignorance in any national document when no Canadian jurisdictions have adequately explored its potential as have several European countries. And yes, partially as a consequence, those countries have individual electronic health records which ensures that the needs of all of their individuals are identified. So Population Health is not the problem but potentially the solution. The simple schematic below portrays the dynamic at the system level but also at the individual level, entirely feasible if an electronic record is in place.

Putting Population Health into Play

…."optimal response to assessed needs on a sustainable basis"…..

@ individual, population & system level

Societal Context

_ social values

_ policy and legislation

_ prevailing incentives (citizens, providers)

_ supply of resources ($, people, capital)

_ public expectations

_ technological feasibility

Need ----------'---------- Response

' why (access)

_ type (functional, medical, social) ' who (HR, community, etc)

_ scope (wellness to support to ‘ what (type – technology, drugs, etc)

treatment to dying) ‘

_ volume ‘ when (time dimension)

_ sequence (time dimension) ‘ where (locus –local, remote, etc)

_ locus ‘ how (constellation of who/what/when/

_ ‘agency’ for need (expressed, ‘ where; supporting infrastructure, etc.)

derived, unmet, assessed) ‘

,

Optimality

(from individual and system perspectives)

_ effectiveness

_ safety

_ appropriateness

_ accessibility

_ allocative efficiency (do right things)

_ technical efficiency (do things right)

_ system-level: quality, accountability and sustainability

Individual Respondent 9

1. Do you agree with the proposed principles and definitions?

No

Please provide the reason(s) and suggested changes, if any.

The proposed principles are inappropriate. The principle should be that the right patient should have access to the right drug at the right time at an affordable price. There should be no delays, access criteria or cost barriers restricting patient access.

2. Do you agree with the proposed assessment criteria?

No

Please provide the reason(s) and suggested changes, if any.

It's bureaucracy gone overboard.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

If a patient cannot properly use a medicine without a diagnostic test or a medical device, it's critical that the test or device is regarded as part of the therapy.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

If a patient cannot properly use a medicine without a diagnostic test or a medical device, it's critical that the test or device is regarded as part of the therapy and listed with the medicine.

4a. Do you support the proposed approach to expand to other therapeutic areas?

No

Please provide the reason(s) for your choice.

The areas for the pilot work are those where there is good agreement between all provincial formularies. The Panel is choosing an easy target. The work needs to focus on areas like rare diseases where there is a much greater divergence between provincial formularies.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

What is meant by "national health priorities"? If it means diseases that impact the most people, I do not agree. The focus should be on drugs where there are unmet needs, not those that provide the biggest bang for the buck.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

None of these options are ideal. Health Canada's priority reviews do not include every important new drug. To get a priority review requires manufacturers to submit an application and pay a substantial fee. A company may believe its drug should be prioritized but not want to apply and pay. Most importantly, Health Canada has limited resources with which to perform priority reviews. This means that an application for an important new drug may be rejected because Health Canada lacks the resources to perform the review at that time. If the Panel opts for this option, key drugs will be missed.

The other options have the potential to significantly extend the process, especially the option involving international collaboration. We all know that the more people involved, the slower the process.

Therefore, the current first in, first out process should be kept as the best option out of a poor selection.

5b. What criteria could be used to identify priority products?

The current first in, first out process should be kept as the best option out of a poor selection.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

With the exception of societal values, these are the criteria CADTH uses. CADTH does not take a societal view – just a health system view. I would like to see the whole system of assessing new drugs take a comprehensive societal view.

With regard to equitable access, this means to me fair and just access where patients receive the right drug for their health needs when they need it. The Panel mixes equitable access with equal access, but they are not the same thing. Equitable access includes equality, but equal access does not necessarily include equitable access. Equality can be achieved if every appropriate patient receives the drug they need, but it can also mean that no patient gets access, i.e. equal non-access.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No

If yes, how should weight be distributed among the proposed criteria?

Weighting is to complex and would obfuscate the process which should be transparent – not one hiding in the clouds of some esoteric process that only a few academics comprehend.

8. 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 reviews)?

While formulary evaluation sounds good, it is rarely done in Canada, because removing medicines from them is fraught with administrative and political issues.

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

The Panel has excluded the following:

1) Assessing current drug plan processes or expectations about whether or how coverage on existing drug plans might be impacted by a pan-Canadian formulary.

2) Identifying governance structures to implement a pan-Canadian formulary.

3) Considering the whole range of financing issues that will impact the implementation of a pan-Canadian formulary.

4) Terms for coverage such as patient copayments and patient eligibility for coverage.

5) Considering the interplay between public and private insurance plans.

Excluding these extremely important issues in working towards a common formulary makes the process simply a make-work activity. By assuming that the rare disease strategy will make things better for rare disease patients, where some of the greatest variation between provincial coverage exists, the Panel is naïve.

The issues around how a national formulary is paid for, including provincial support and patient contributions makes the work of the Panel Theatre of the Absurd. See https://www.thespec.com/opinion/contributors/2022/02/17/national-drug-plan-process-doesnt-add-up.html

Individual Respondent 10

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

In the appeal process in the table there is a statement under Open to Appeal: "The system should include a procedural fairness process in which stakeholders can engage to understand the rationale behind the decisions.." That sounds as though the only use of the appeal process is to present the rationale to those who appeal. It does not sound like a true appeal process.

When you say "cost-effectiveness models that incorporate a broader perspective that would include health care costs and implications in remote locations, not just populated areas." it does not sound as though improving life for the patient is a deep part of the statement. I also wonder what sort of deliberation would go into the design of the solution?

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The procedure seems logical. I worry about the variety of drugs available to patients in Canada in the future because the size of our market for some drugs would drop dramatically. That worries me.

Having 1 patient/public member as part of the deliberations would not satisfy most patients. Who speaks for the marginalized and vulnerable communities? How are they engaged and served? How did they contribute to this draft?

The patients I know who have any knowledge of CADTH and Drug Policy in Canada are extremely capable and sophisticated, so not representative of the very people who this plan will serve.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

I agree that in diabetes the expense of related products is a large factor in patients being unable to afford the treatment they need.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

It sounds like a logical idea and keeping things simple is important.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

Patients are not therapeutic areas and they do not define themselves by their 'therapeutic area'. Could you try to position this in a more human-centred way?

And many people fall into more than one 'therapeutic area'. How complicated will this make their lives? The majority with chronic illness have more then 1 condition.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

There are regional differences and this is a national program. We want all Canadians to have access to necessary medications

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #3

Please provide the reason(s) for your choice.

Option 3 is more open to change, and adds some life and fresh air to the structure we have now.

5b. What criteria could be used to identify priority products?

Benefit to patients and to the health of the public.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

What would happen to off-label use which is a huge boon to patients in the hands of expert or knowledgeable doctors?

I don't think patients and caregivers play an adequate role in drug evaluations now. This whole submission and plan is very top-down. Consultation with patients and caregivers are not the equivalent of seeing them as full partners with an important part to play.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No

If yes, how should weight be distributed among the proposed criteria?

The expert committees constituted by CADTH are composed of professionals and the included patient point of view is usually minimal. If the evidence from various types of experts were weighted how would it include the voices that make up equity/diversity/inclusion be heard at all? The experts and their organizations already have over 90% of the weight here.

The role of patients has changed as knowledge has grown and yet experts and PCHOs seem to leverage us when we're needed.

8. 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 reviews)?

Patients groups certainly have a workload in drug review processes though in a very narrow area, but they are not at the table. Only their proxy is there. This goes against modern thinking of the patient as a full partner that we have seen emerge with the free flow of information. Why did you even ask for patient input?

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

I don't feel that patients are seen as full partners in this process. There is only one public (patient?) member on the panel, and as a member of CDEC for the past 10 years he is far from an average patient. Health professionals and directors of health charities can also be seen as far more corporate in their views than average patients.

As a patient with chronic conditions that require some less common drugs I worry that financial pressure and Canada becoming a small market will limit my ability to be a successful self-manager of my conditions. I worry about financial pressure leading to people with diseases that are less common being limited in their choices of treatment.

At the same time I want an equitable system, and for all Canadians to be able to afford the medications they need for the good of our population, and long term sustainability.

It is well known that the person/entity who composes the survey gets the answers they want. I see no signs of patient input in this survey - we're referred to as therapeutic areas if at all.

This statement poses problems: “The panel supported the recommendation in the council report that encouraged both generic and biosimilar use, including generic and biosimilar substitution.” As a patient I want to know what medication I am taking at all times. When you mention listing the cheapest drug, and the discuss biosimilar substitution I wonder at what level that substitution is being considered. I don’t want to be subjected to every price change to know which biosimilar drug I am going to be taking every time I get a prescription refill.

Also the idea of creating clinical guidelines using the drug formulary as a starting point makes me uncomfortable.

Individual Respondent 11

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Would like to better understand what is included on public drug plans as I feel that there are significant gaps in coverage for children (e.g. compounded medications, Special access medications) or through special seperate provincially funded programs (e.g. rare disease, genetic/metabolic disorders, transplant, HIV, high cost drugs). Would also be curious about emerging therapies such as gene therapy. Many provincial payers do not adequately understand medication use in neonates, pediatrics and obstetrics to even have these as part of provincial plans. This is compounded by off label and sometimes off evidence use of medications in practice in these patient populations.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

Provided there is special consideration given to unique patient populations and small or no evidence base.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #2

Please provide the reason(s) for your choice.

This seems the most equitable and appears to address "unmet needs of population" which is currently an issue for patient populations described above.

5b. What criteria could be used to identify priority products?

Not entirely sure, but addition of commercial preparation unavailable otherwise (requiring risky compounding) would be of great safety benefit to all involved in medication use process for neonates/children/patients requiring enteral drug admin or those with swallowing difficulties

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Provided clinical benefit does not necessarily require rigorous evidence specific to underrepresented patient populations in drug development or post market studies.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

Unsure

8. 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 reviews)?

Adequate resourcing with individuals appropriate experiences and insight.In order for this to be timely and responsive it can't be done by individuals "off the side of desks"

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

No response provided

Individual Respondent 12

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

Principles :

Consider current access of proposed medicines via SAP (special access programs), EAP (exceptional access programs), provincial drug benefit programs and/or pediatric provincial drug benefit programs. Ensure that the proposed national list is comprehensive and provides equitable access.

Include pediatriac formulations (universality). Splitting tablets and/or alternative liquid suspensions may NOT provide accurate and safe dosing. Tablets and/or granules for pediatric use, e.g., new hydrocortisone formulations, will result in better patient outcomes.

Consider life-sustaining medicines, e.g., corticosteroid therapy for adrenal insufficiency.

Consider parenteral emergency formulations, e.g., injectable hydrocortisone, e.g., Solu-CortefTM and emerging auto-injector technologies, e.g., Twistject, Crossject ATRS1902, etc.) to treat suspected adrenal crisis. Shortages may also occur in hospital settings of normal saline, etc. Salt-wasting patients may require saline for IV administration.

Use up-to-date resources, e.g., Endocrine Society guidelines, updated product monographs, FDA reports for newly listed drugs. An example is uptodate where the most recent hydrocortisone formulations are available: https://www.uptodate.com/contents/hydrocortisone-systemic-drug-information (Note the inclusion of pediatric formulations.)

Ensure equitable access to medicines aligns with access to medical treatment in the pre-hospital and hospital settings, e.g., Solu-CortefTM administered by paramedics to treat suspected adrenal crisis.

Evidence-based principles: Consider the designation of medicines, e.g., CLEANMeds List, EML (World Health Organization), US Essential Medicines List, etc.

Evidence-based prescribing Guidelines and Timelines, e.g., STAT meds for acute care – See CSEM guidelines, CSEM (CAH guidelines), CPEG letter, CAEP letter, UK prescribing guidelines for Alkindi

Consider safety reports: Dangers with slow-release formulations (Medsask) and/or pediatric formulations causing harm (hydrocortisone buccal tablets) – Ensure safe pediatric formulations (accurate dosing), e.g., Alkindi Sprinkles, Acecort tablets

2. Do you agree with the proposed assessment criteria?

Yes

Please provide the reason(s) and suggested changes, if any.

Harmonization / Comprehensiveness: include ENDOCRINE-specific drugs, e.g., adrenal hormones

Consider treatment timeline, e.g., medicines for emergency use, CPSI, CAEP, ISMP Canada

Continuity of Care: First-line medicines should be used.

Assessment: Best route of administration and optimal clinical results – best patient outcomes with accurate and safe dosing

Therapeutic areas: Include adrenal hormones, e.g., corticosteroids, daily maintenance therapy, e.g., glucocorticoids, mineralocorticoids and emergency glucocorticoid, injectable hydrocortisone. (Consider for opioid-induced adrenal insufficiency, cancer treatment related adrenal insufficiency and post-dexamethasone therapy for COVID19 ARDS.)

Eligibility for drugs differs across the country. Prioritization may result from national clinical society guidelines and/or Health Canada health policies.

https://link.springer.com/article/10.1007/s40121-021-00500-z#citeas [Post-covid19 treatment (dexamethasone) and risk of adrenal insufficiency]

https://www.brit-thoracic.org.uk/media/455532/uhl-dose-advice.pdf (Prevalence/Priority Domains)

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

Eligibility should include the designation of Priority Medicines or Essential Medicines.

Consider CLEANMeds List and WHO/US Essential Medicines Lists (Consider review of international prioritization by indication. Consider prevalence domain and medication safety incidents related to delayed/omitted medicines, e.g., corticosteroids, glucagon, epinephrine, etc.

Collaboration with stakeholders (including clinical societies, patient support groups, national patient safety groups (CPSI, HealthcareCAN, ISMP Canada, HIROC, Canadian Medical Protective Association, Pharma, CPhA, CSHP, CLEANMeds, etc.) / Utilization of precautionary principle model.

https://www.pfizer.com/about/people/executives (Chief Patient Safety Officers representing Pharma)

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

Differentiate drugs for life or limb conditions, e.g., symptomatic rescue relief drugs, epinephrine, glucagon, hydrocortisone, relief inhalers, etc.

Contrast HRT (hormone replacement therapy) products with related parenteral (injectable) emergency products.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

Collaborate with Clinical societies to determine priority/prevalence domains to expand to other therapeutics areas, e.g., endocrine, oncology, etc.

Reduce socioeconomic burdens to patients with no/limited access to medicines and associated treatment. Sustain life, meet daily healthcare needs, optimize QoL by ensuring medicine and medical access throughout the circle of care.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

National stakeholders (health-related patient support groups, clinical societies, CIHI/CIHR, etc.) are able to provide needs assessment to ensure equitable access.

Suggested medicines to include on the National Formulary:

Corticosteroids, e.g., glucocorticoids, mineralocorticoids, pro-hormone corticosteroids

Consider collaboration with Translation Bureau of Canada (Termium database) to remove/correct translation miscues for medicines, e.g., normal saline, corticosteroids, etc.

Seek national uniformity with respect to medication terminology.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #2

Please provide the reason(s) for your choice.

Consider collaboration with health-related charities (patient support groups), clinical societies, e.g., CSEM/CPEG, CAEP, pharmaceutical and government patient advocates, health technology leads, e.g., CIOs, etc.)

A scoring system would prioritize newer first-line medicines to treat life or limb conditions. This would address the daily living and/or emergency medication needs of patients.

Elements of Option 1 and Option 3 should be incorporated into a global and holistic perspective, i.e., weave health technology and international components into the scoring system model.

5b. What criteria could be used to identify priority products?

Criteria: Prevalence/Priority Domains (Life or Limb Conditions)

Align with other National Pharma Lists, e.g,. Consider essential medicines

Harmonization / Comprehensiveness: include ENDOCRINE-specific drugs, e.g., adrenal hormones

Consider treatment timeline, e.g., medicines for emergency use, CPSI, CAEP, ISMP Canada

Consider: 1) Patient Safety Alerts (CPSI) 2) ISMP Reports 3) HIROC Reports 4) Canadian Medical Protective Agency Reports 5) Review DrugshortagesCanada reports for drug shortages

Continuity of Care: First-line medicines should be included.

Assessment: Best route of administration and optimal clinical results / Best patient outcomes with accurate and safe dosing

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

Evaluation Criteria:

Consider multi-disciplinary approach. Involve endocrinologists, e.g., for endocrine conditions and pediatric endocrinologists for consideration of pediatric formulations.

MCDA (multi-criteria decision analysis) / INCLUDE medication safety incidents through HIROC/ISMP Canada, Medical Protective Agency of Canada / Coroner or Medical Examiner Reports

Non-Binary and Gender Aspects:

Invite endocrinologists for recommendations re non-binary and gender aspects of medicine access.

Cultural (Indigenous Perspectives) e.g., Two-Spirited, Non-Binary Approaches to equal treatment (access to medicines and health treatment/technologies)

Gender: Access to sex hormones (e.g., testosterone, estrogen, etc.), pro-hormone (e.g., DHEA)

https://egale.ca/wp-content/uploads/2019/10/2-Intersex-Final-65-Reasons.pdf

Consider leveraging strategies where there is no access to life or limb or life-sustaining medicines in some regions, e.g., drug reimbursement for injectable hydrocortisone.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

The top distribution weighting:

-sustaining life (unmet life or limb clinical need), quality of life (unmet clinical need), clinical effectiveness, patient safety,

The overall benefit score should also consider equity and access components. Spending priorities must consider a higher distribution weighting for drugs that meet daily and emergent clinical needs and optimize quality of life for Canadians.

8. 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 reviews)?

Consider consortium with stakeholders to:

-monitor processes and provide feedback about the existing listed products

-provide feedback about re-evaluation of current products and novel emerging products

-provide feedback from clinical societies for therapeutic reviews (practice guidelines committees, e.g., CSEM Guidelines Committee)

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

Recommendations for medicines to be included on the Pan-Canadian Formulary:

Corticosteroids, e.g., glucocorticoids (hydrocortisone), mineralocorticoids (fludrocortisone), pro-hormone corticosteroids

(Pediatric formulations of hydrocortisone are lifesaving for corticosteroid-dependent pediatric patients, e.g., children with salt-wasting congenital adrenal hyperplasia, Addison's Disease, other primary or central forms of adrenal insufficiency.

Please note the historical MP support for constituents regarding access to corticosteroids for daily use and/or emergency treatment:

MP Ali Ehsassi (Willowdale) https://www.addisonsociety.ca/pdfs/newsletters/2019/summer2019.pdf

The Honourable Bob Rae (Former MP – Toronto Centre Rosedale) https://pm.gc.ca/en/news/backgrounders/2020/07/06/honourable-bob-rae

Relevant Reference Links:

https://academic.oup.com/jcem/article/101/2/364/2810222

https://ace-corporate.netlify.app/en/products/acecort/

https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/notice-alkindi-sprinkle.pdf

https://www.youtube.com/watch?v=VsJarxhWACY

https://solutionmedllc.com/

https://www.crossject.com/en

https://www.sec.gov/Archives/edgar/data/1016169/000156459021041202/atrs-ex991_19.htm

https://www.uptodate.com/contents/hydrocortisone-systemic-drug-information

https://list.essentialmeds.org/

https://www.fda.gov/media/143406/download

https://medsask.usask.ca/documents/drug-shortages-pdfs/hydrocortisone_shortage.pdf

https://www.gov.uk/drug-safety-update/hydrocortisone-muco-adhesive-buccal-tablets-should-not-be-used-off-label-for-adrenal-insufficiency-in-children-due-to-serious-risks

https://list.essentialmeds.org/?query=hydrocortisone

https://cleanmeds.ca/

https://list.essentialmeds.org/?query=fludrocortisone

https://www.patientsafetyinstitute.ca/en/newsalerts/alerts/pages/alertdetail.aspx?alertid=3943

https://www.healthcarecan.ca/

https://safemedicationuse.ca/newsletter/care-plan.html?utm_source=safemeduse&utm_medium=email&utm_campaign=smv12i09

https://www.hiroc.com/resources/risk-reference-sheets/failure-communicate-andor-respond-critical-test-results

https://www.cmpa-acpm.ca/serve/docs/ela/goodpracticesguide/pages/manage_risk/Medication_risks/using_medications_safely-e.html

https://www.pharmacists.ca/

https://www.ismp-canada.org/partners.htm

https://cshp.ca/company/roster/companyRosterDetails.html?companyId=42931&companyRosterId=71

https://egale.ca/wp-content/uploads/2019/10/2-Intersex-Final-65-Reasons.pdf

https://www.btb.termiumplus.gc.ca/tpv2alpha/alpha-eng.html?lang=eng&i=1&srchtxt=normal+saline&codom2nd_wet=1#resultrecs

https://www.btb.termiumplus.gc.ca/tpv2alpha/alpha-eng.html?lang=eng&i=1&srchtxt=CORTICOID&codom2nd_wet=1#resultrecs

https://caep.ca/wp-content/uploads/2019/12/EMSAdvisoryFINALGIEDIT.pdf

https://cpeg-gcep.net/system/files/cpen/CPEG%20AI%20Endorsement%20Letter%20with%20Signatures.en_.pdf

https://www.drugshortagescanada.ca/

https://www.drugshortagescanada.ca/ingredient/48?limit=20&discontinuance_limit=10&shortage_limit=10&allow_all_user_shortages=1&orderby=drug_dosage_form&order=desc

https://academic.oup.com/jcem/article/103/11/4043/5107759

https://jim.bmj.com/content/68/1/16.long

https://www.dorsetccg.nhs.uk/Downloads/aboutus/medicines-management/Other%20Guidelines/Diabetes%20and%20Endo%20Shared%20Care%20Guideline%20Alkindi%20March%202019.pdf

https://pedsendo.org/download/new-meds-and-tech-pes-dt-alkindi-long-version-final/

https://www.youtube.com/watch?v=VsJarxhWACY

https://link.springer.com/article/10.1007/s40121-021-00500-z#citeas

https://www.the-hospitalist.org/hospitalist/article/247932/endocrinology/opioid-induced-adrenal-insufficiency-hospitalist

https://www.mayoclinicproceedings.org/article/S0025-6196(18)30283-0/fulltext

https://canadiancriticalcare.org/resources/Documents/AMMI-CCCS-PHAC-clinical-guidance-Aug21-EN-FINAL.pdf

"If oral, IV and/or inhaled steroids are indicated for non-COVID-19 reasons (e.g., asthma or

COPD exacerbation, or stress dosing in someone on chronic steroids or with known adrenal

insufficiency), they should not be avoided." [86] [87] [88] [89] [90] [91] [92] [93]

https://www.asco.org/sites/new-www.asco.org/files/content-files/practice-and-guidelines/2018-management-of-irAEs-summary.pdf

"All patients need education on stress dosing and a medical alert bracelet for adrenal insufficiency to trigger stress dose corticosteroids by EMS."

https://www.brit-thoracic.org.uk/media/455532/uhl-dose-advice.pdf (Prevalence/Priority Domains and National Patient Safety Alerts)

https://link.springer.com/article/10.1007/s40121-021-00500-z#citeas

https://egale.ca/wp-content/uploads/2019/10/2-Intersex-Final-65-Reasons.pdf

https://www.pfizer.com/about/people/executives (Chief Patient Safety Officers representing Pharma)

https://www.endo-metab.ca/welcome-to-the-csem/committees#guidelines-committee

https://pedsendo.org/patient-resource/adrenal-insufficiency/

https://www.bmj.com/content/374/bmj.n1380

https://www.endo-metab.ca/guidelines-qi

https://www.endo-metab.ca/our-partners/community-partners

https://www.addisonsociety.ca/pdfs/medical-information-card.pdf

https://www.endo-metab.ca/drug-shortages-safety/drug-shortages

Thank you for the opportunity to participate in this consultation process with key stakeholders.

Kindest regards,

Gino Innamorato, OCT, M.Ed.

Individual Respondent 13

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #2

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

Recommendations for medicines to be included:

1) Corticosteroids (e.g. Hydrocortisone, fludrocortisone) for daily hormone replacement therapy

2) Corticosteroids (e.g. Solu-Cortef, injectable hydrocortisone) for emergency use

My son Arlo has Salt-Wasting Congenital Adrenal Hyperplasia. Currently there are no pediatric formulations for hydrocortisone in Canada. This is a life or limb condition. Pediatric formulations of hydrocortisone will provide safe and accurate dosing. Injectable hydrocortisone (future-use auto-injectors) will also be life-saving to treat emergency episodes of adrenal crisis.

Note from Member of Parliament:

Dan Vandal supports his constituent's request that the Pan-Canadian Advisory Panel on a Framework for a Prescription Drug List review access to these medications for children like their son Arlo.

Innovative Medicines Canada and BIOTECanada

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

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. 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.

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. 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 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).

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.

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.

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. 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. 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 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. 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, 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.).

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 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.

Insulet Canada

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No

Please provide details.

Improving access to diabetes technology is critical. However, related products, and how an individual responds to the products, are diverse and as such, it is challenging to develop a 'one size fits all' approach across both pharmaceuticals and medical technologies to determine device inclusion in the pan-Canadian formulary. At the forefront of any decision must be the impact on the well-being of the end-user, the person who uses the device daily, who faces the burden of managing a chronic disease. Every person living with diabetes should have the freedom to access the care, treatments, technology and information needed to successfully manage their disease, and reduce the likelihood of costly complications, and ultimately, achieve positive health outcomes.

Furthermore, the downstream implications of implementing stringent eligibility criteria need to be comprehensively considered. Canadians with diabetes must have sustainable access to innovative health technologies. Enforcement of any criteria and subsequent access impact needs to be considered in the context of a chronic and highly burdensome disease such as diabetes.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No

Please provide reason(s).

We do not agree that the same evaluation criteria should apply to related products. There are several fundamental differences between pharmaceuticals and related products (medical devices) and thus should not have the same evaluation criteria applied.

One example of a key difference between pharmaceuticals and medical devices is the pathway for obtaining regulatory approval and marketing authorization. Legislation governing medical devices in Canada classifies devices according to predetermined risk levels, with different regulatory requirements applying to each for approval by Health Canada. In this situation, applying the same criteria across drugs and related products will compromise the ability to facilitate informed and appropriate decision making.

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

No response provided

J.L. Glennie Consulting Inc.

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Summary of comments on reading the document:

- Note that taking a population health approach implies a commitment to creating special authorization processes, to provide a safety net for those who fall between the cracks from a criteria/eligibility perspective.

- It is interesting that there is no acknowledgment of medications as one of the tools in ensuring overall efficiency in the health system.

Lack of such acknowledgement continues to position drugs as a cost centre to government rather than an investment in the health system.

- Re: what standard of effectiveness will be acceptable?, real-world evidence, it will be important to provide formal direction on what kind of RWE is acceptable, how it will be used, how it is weighted in the process - both proactively in frameworks as well as within decision documents.

- re: How should the system operate?, there should be transparent performance standards at all levels of the process (i.e., HTA, pCPA, provincial listings), with a plan (i.e., resources, etc.) to address backlogs in each of these steps, as necessary.

- Appeals process is interesting - this needs to be fleshed out more and needs to include an opportunity for recourse outside of the decision making body.

- re: Transparency/"accountable to all people in Canada" - terminology like this ends up resulting in no real accountability. There need to be very clear and transparent lines of accountability, so that all stakeholders know who to engage with if issues arise.

- re: Table 6, does not acknowledge the fact that some patients may need access to table 6 drugs after they have failed other drugs; drugs to exclude is not defensible from an evidence perspective (i.e., what is the evidence to support the rationale for removing each of these drugs? Perhaps they need to be available on an exceptional basis?); make sure that things on list are not being used for rare diseases (e.g., Ubidecarenone for inherited metabolic diseases)

- re: value for money, capturing costs outside of the health system – this needs to be done/accepted within processes established

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Summary of general comments:

- In my mind, reference-based reimbursement is a tool of the past (i.e., prior to the advent of confidential prices/listing agreements via pCPA). Payers are effectively achieving consistent price levels within a class by virtue of confidential agreements that benchmark the price for an entire category. If a specific payer is not already doing this, then they are missing an opportunity for savings within their drug plan. The latter scenario should prompt a class review, to serve as the basis for consistent pricing within the category.

- re: tiered restrictions, Having transparent criteria + creating user-friendly, on-line mechanisms for MDs to make requests for restricted drugs will be key to success here.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

The value of related products goes beyond improving adherence. Most related products are integral to the appropriate use of a drug product and, hence, achieving the optimal response from that drug product. Suggest that the definition needs to include a focus on optimal drug use in order to achieve intended outcomes.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

- Related products are integral to the optimal use of the drug, so need to be made available through the same process/program that the drug is made available to ensure timeliness and alignment of therapeutic use of both products.

- However, to suggest that they need to be assessed in a manner that is the same as and independent of the assessment of the product may be creating unnecessary complexity. (For instance, separating out the evaluation of a companion diagnostic [CDxs] vs. drug - we've created HTA guidelines for that but have yet to see CADTH actually carryout such an assessment.) The related product and the drug product work in tandem to achieve the health outcome - separating out those evaluations makes no sense in most cases. Need to address this in a more pragmatic way that what has been proposed for CDxs.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

Summary of general comments:

- An alternative would be to look at drugs within a specified therapeutic area, so that you could get a critical mass of clinical experts and patient groups involved in the process. The challenge of looking at products solely on the basis of utilization patterns is that you get a wide swath of therapeutic areas with multiple clinical experts and patient groups involved, which makes the consultation process more complex. Perhaps a balance can be found between utilization factors and therapeutic area to make the on-going process more pragmatic.

- agree with including oncology and specialty areas

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

- Good luck trying to get the provinces to agree on national health priorities!

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #1

Please provide the reason(s) for your choice.

- Need to be careful re: inserting the priorities of payers as a rate-limiting step in the review process (NOTE: prioritization by jurisdictions does happen at the pCPA level, but that is after the evidence evaluation process is complete). There could be concerns re: anti-competitiveness and/or interference in the marketplace and would need to be assessed from a legal perspective, IMHO. We need to remember that other players (i.e., private payers, employers, etc.) rely on the outputs of HTA processes as well, so inserting jurisdictional priorities could alter the broader marketplace in unintended ways.

- re: Option 2, how are you going to get jurisdictions to agree to what product constitutes a priority? Regardless, all of this hinges on a company coming forward with a product and requesting prioritization.

- re: Option 3, perhaps as a very long term plan, but these initiatives take years so this approach would not be set up in a timely manner and would not be under Canada's control. Why would jurisdictions give up control to other countries whose health priorities are different from theirs? It will be challenging enough to get alignment within Canada on health priorities.

- also, need to have greater ability to add new info during the submission process (i.e., rolling submissions)

5b. What criteria could be used to identify priority products?

Summary of comments:

- All of this is contingent on jurisdictions collaborating on health priorities and agreeing that a long-term time horizon should be used. Getting provinces to collaborate is challenging at the best of times, and their time horizon is extremely short (i.e., fiscal year). Until drug plans are allowed (by Finance Departments) to approach investment in drug funding over an extended period of time (e.g., like capital projects), there will not be a shift to long-term thinking on the part of drug plan managers.

- Moving from a "push" (pharma submissions) to a "pull" approach to drug submissions and evaluations will be challenging, given that drug plans tend to be reactive to what is put in front of them, as opposed to proactive and thinking strategically about what they - and the broader health system - need from new drug therapies. A whole cottage industry would have to be built to get alignment on health/drug priorities within an individual province, let alone across the country.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

- There are a number of items in this list that traditionally have been afforded little to no value in the evidence evaluation process (e.g., frequency and mode of administration). If these are to become criteria for the selection of products for the new formulary, then they also need to be integrated into the evidence evaluation process to ensure alignment.

- There is an opportunity for real world data collection and evidence to demonstrate health and/or broad societal value of a new product.

- need to look at impacts beyond the drug budget (current focus), so that drug get credit for impacts in other areas of government spending (i.e., broad societal benefit aspect).

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

Summary of comments:

- Note that CADTH and its jurisdictional masters have traditionally been very resistant to moving towards an MCDA approach

- There is not a great deal of experience on the part of HTA bodies and/or decision makers re: MCDA, resulting in skepticism re: this method. Need for significant education and demonstration of value compared to current approach.

- The downside of the flexibility provided by MCDA is the lack of predictability re: the overall decision process, which is something that many stakeholders have come to depend on via the current pharmacoeconomics-based approach used to date. Again, will be important to create a road-map between the current approach and how it would be improved by moving to MCDA, as well as reassurance re: transparency and predictability of outcomes using the new approach.

8. 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 reviews)?

Summary of comments:

- Glad to see a very broad definition re: how reassessment could be done and what the purpose and/or outcome could be. Getting this down on paper is long overdue in our discussions re: re-assessment in this country.

- Important to be more transparent about what one of the key potential purposes/outcomes of a therapeutic review is - that is, potential cost savings either via delisting and/or renegotiation of prices.

Most of the areas identified are highly genericized categories with pCPA-based pricing caps already in place. One wonders whether this is where the focus of a therapeutic review should be vs. other therapeutic areas where evidence issues and/or potential cost savings could be more fruitfully addressed.

- Please be sure to look to European processes (e.g., France, Germany, Netherlands) for approaches to re-evaluation. These are typically founded in RWE-based listing agreements, which need to become part of the toolkit in Canada. You can't look at reassessment in isolation of the up-front evaluation process.

- Provinces have never invested enough in doing this work and it has always fallen of off the priority list at CADTH due to funding constraints; this will take more money in the system + a different kind of expertise vs. what is being use for other initial HTA assessment (i.e., RWE expertise is not the same as HTA expertise)

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

Summary of comments:

- Not clear what is meant by prescribing guidelines - those developed by jurisdictions or those developed by health professional societies (e.g., traditional clinical practice guidelines/CPGs)? If the latter, these have traditionally been ignored by HTA bodies/decision-makers and, in fact, relationships between decision-makers and CPG generators has been strained in the past. There needs to be more collaboration between these parties if CPGs are to be used.

- Why is it that the onus is on the clinicians who develop CPGs to consider the formulary? Should it not work both ways?

- CADTH is an animal of the jurisdictions, thus all jurisdictions would have to agree to any change in approach proposed in CADTH's processes.

- re: improving continuity of care, this is a prime example of why one cannot look at putting products on a formulary in isolation vs. other aspects of drug plan design and management. A very significant challenge that feeds into continuity of care problems is lack of policy alignment within a jurisdiction re: different funding pots for Inpatient vs. Outpatient drugs. A prime example of this is the policy gap for AML (acute myelogenous leukemia) drugs initiated in hospital (due to patient acuity) which the NDFP refuses to fund (in most cases) but then is funded once the patient continues their therapy on an outpatient basis. BOTH pots of money come from the same government department at the end of the day, but no one is willing take the reins and come up with a policy solution that makes sense for patients. These kinds of policy misalignment issues are asinine and also potentially explosive when they hit the front page of the Globe and Mail. (NOTE: there are non-oncology examples of this as well.)

Janssen / Johnson & Johnson

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

As concepts, Johnson and Johnson is supportive of the principles as outlined in the discussion document. Our concerns rest more on the potential application of the principles against an already complex reimbursement system and range of reviews, mandates, and processes.

Any framework impacting the availability of and access to medicines must place patients at the centre. This would be supported by a strong recommitment to health equity-based principles such as continuity of coverage and portability for citizens regardless of geography or employment status.

With respect to the principle of equity, the definition rightly notes that this should capture the reality of different circumstances of different individuals, and that the allocation of resources should be flexible to support the realization of equitable outcomes. The discussion paper also notes that any listing criteria should include drugs which can help address systematic health inequities. These considerations would have to be evaluated locally and made more explicit in formulary decision-making at the Provincial-Territorial level.

With respect to the principle of effective and high quality, J&J supports the intent that the formulary should aim to provide a high standard of access to innovative medicines for Canadians. However, it is challenging to reconcile this sentiment with further language referring to listing products against incidence and prevalence concerns (see p. 12). While this may not be the paper's intent, we recommend that care should be taken to avoid inferring that certain health conditions may not be deemed important or relevant based on those same considerations. Such an inference would also conflict with the included principle of equity

The discussion paper does contemplate scenarios where various principles may be at odds with one another:

"At times, the proposed principles may be in tension: for example, equity and timeliness may be in opposition with sustainability. In these cases, careful balancing will be required, accompanied by transparent justification for any trade-offs that are made." (p. 11)

Public trust and confidence in any drug listing process is an important consideration for policy implementation. This trust and confidence will depend on consistent and clear information, publicly available in an accessible manner, on the rationale and process used to balance principles.

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

From an implementation perspective, there may be challenges in reconciling the principle of equity with any assessment criteria dependent on "commonly prescribed drugs". Patients with less common conditions, or conditions where diagnosis presents unique hurdles (such as conditions depending on

access to specialized clinical knowledge, appropriate screening or testing) should not be placed at a disadvantage in any reimbursement policy.

The discussion paper emphasizes the importance of providing coverage for populations without suitable access to sufficient drug coverage due to historical, social or other contemporary inequities. This introduces important societal perspectives to coverage considerations which may not be present in the Canadian system at the current time. The challenge for the current public system will be to integrate this approach into the existing formulary paradigm, based on a narrower existing public drug plan perspective.

J&J agrees with the emphasis on providing sufficient options to mitigate any issues caused by drug supply shortages, to allow for patient and clinician preferences to be accommodated, and to address unmet clinical needs (see p. 27). We would encourage all parties to adopt a similarly clear commitment to the importance of ensuring and protecting patient choice in therapies under any formulary design.

In reviewing the sample list of drugs provided for a potential pan-Canadian formulary, we note the strong alignment with existing public formularies, which reflects the pan-Canadian output of requiring drug listings to be negotiated through the pan-Canadian Pharmaceutical Alliance. For this reason, the benefits of creating a parallel, roughly equivalent formulary are unclear. From a resource utilization and patient perspective, there may be early opportunities for existing public plans to "level up" their drug plan designs and eligibility to improve accessibility for patients in need of coverage in their respective jurisdictions (see note 1). Further, it is unclear from the discussion document how drugs with differing HTA recommendations by CADTH and INESSS would be managed.

Regarding the drugs identified as requiring further expert consideration, these tend to have more restrictive access criteria, including the need to satisfy additional requirements based on confirmatory testing or physician/specialist visits. J&J cautions that evaluating the criteria for a specific drug in isolation without factoring in the practical reality of the totality of clinical care faced by the patient may generate a highly limited or inaccurate assessment. This concerns also extends to the criteria of low utilization, as this may not be an appropriate measure as it could disadvantage patients with unique (medical, treatment, access, equity) challenges.

Note 1: See for example: Harmonization of Public Coverage Policies for Biologic Drugs in the Treatment of Rheumatoid Arthritis | CADTH. This CADTH Health Technology Review examined harmonization of various jurisdictional policies for reimbursing biologics for in the treatment of Rheumatoid Arthritis, and suggested all jurisdictions utilize the broadest possible criteria.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

As a science-based innovative manufacturer, we firmly believe in the importance of bringing new products to market and increasing the range of appropriate treatment options for patients and their prescribing physicians.

Based on evolving science, product definitions and criteria should reflect the realities of current and future therapeutic innovations anticipated to be authorized for the Canadian market. The entire area of personalized medicine, as a notable example, implies a much higher frequency of testing, through the use of companion diagnostics or genetic testing to match the right therapeutic interventions against the corresponding patient biomarkers. This is critical to adapt clinical treatments to each unique patient's situation and needs.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

Drug products have evaluation and implementation criteria that are typically not applied to other health interventions, including surgical interventions, diagnostics, and medical devices. Applying the same evaluation criteria for drug products to these other areas could create insurmountable barriers to patient access.

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

Given the focus on "commonly prescribed" drugs, this approach would tend to focus on general populations cared for by primary care physicians. However, as many therapeutic areas are increasing in overall complexity and health services requirements to treat patient needs, there will be limitations in how this approach could be broadly applied. J&J recommends a more holistic approach for therapeutic areas involving specialists, referrals etc. when considering a list of treatments that align with current standards of care.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

Given the constitutional separation of powers between federal and provincial/territorial government, and the expertise that has been developed at the provincial level in the review and listing of products, it is not apparent how Canada would appropriately develop "national health priorities" or where responsibility for developing these priorities would lie.

Different provinces, for example, might reasonably be expected to identify, fund and develop programming against unique priorities based on local factors and patient population needs, which may not align with a "national health priority". Conversely, a "national health priority" may not be accepted by all or even any provincial or territorial jurisdiction. Additional consideration and care must be taken to explore how the concept of a "national health priority" would be developed, defined, and accepted on a pan-Canadian basis and more importantly, how a national health priority would address needs for increased patient access to care.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

Almost two years into the COVID-19 pandemic, it is apparent that Canadians expect timely access to important innovative therapeutic options that offer the ability to improve their health and well-being. In modernizing and evolving the number of reviews, mandates, and processes, the intended result should be a more efficient system to support rapid, equitable decision-making grounded in the best available scientific information.

All of the presented options presume a continued level of delay in the review process and thus suggest the necessity of needing to prioritize certain drug submissions within that environment. Instead, we believe that our review system should aim for improved and predictable access to medicines for patients across the entire lifecycle of products, while avoiding the introduction of new layers of reviews, processes, or other barriers to patient care. If we can instead remove impediments to an expeditious review process, the need to prioritize submissions will be less necessary. It would also reduce the need for the potential arbitrary and socially difficult exercise of assigning priority amongst innovative medicines.

J&J is supportive of a practical and feasible approach that incorporates the required investment and capacity building at the pan-Canadian level to support the greater use of Real-World Evidence (RWE) data systems. Canada should be actively working to create and implement appropriate criteria for the use of RWE for both regulatory and reimbursement decisions. Greater collection of RWE data will support increased patient access, including by helping to inform HTA reviews with an improved evidence base for products.

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

In addition to our comments above, including with respect to assessment criteria (2), we would encourage greater consideration of the feasibility of adoption and clinical contexts for any given drug.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

J&J shares the panel's assessment of the shortcomings of the Multi-Criteria Decision Assessment (MCDA) approach. We affirm the importance of advancing a patient-centred deliberative process which is transparent and values-based to inform decisions regarding access to medicines inclusive of stakeholder perspectives. Utilizing a comprehensive process in this context is of fundamental importance – especially given the focus on diverse patient populations facing complex health and socio-economic challenges.

To support health equity, care must be taken to ensure that decisions do not have the unintended consequence of exacerbating current inequities and introduce a process that is overly reliant on mathematical equations and formulas. Such analysis may not only fail to address these issues but could result in over-emphasizing or de-emphasizing specific criterion without consideration to context.

Transparency in decision-making is enhanced by making any deliberations public, including their supporting rationale and related trade-offs, as well as assessing and incorporating other best practices for documenting individual decisions in a consistent, open, and accessible manner. J&J is supportive of value assessments anchored in clinical benefits for patients and the inclusion of multiple stakeholder perspectives. Rather than creating completely new deliberative processes and possibly adding to the complexity of the patient access pathway, there are early opportunities for reforms to existing processes to reflect these factors.

8. 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 reviews)?

Overall, J&J would recommend a careful examination of existing drug review processes to find efficiencies and opportunities to streamline reviews before introducing additional steps to an already complex and time-consuming access pathway for Canadians. There are available opportunities, as described across our various responses above, to evolve and streamline the current drug review process to improve access for patients and enhance the stakeholder experience.

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

February 25, 2022

Suzanne McGurn

President & CEO

Canadian Agency For Drugs and Technologies In Health (CADTH)

865 Carling Ave., Suite 600

Ottawa, ON Canada K1S 5S8

Submitted Via Electronic Portal

RE: Consultation on a Potential Pan-Canadian Formulary

Dear Ms McGurn:

Johnson & Johnson (J&J) welcomes the opportunity to provide the advisory panel and CADTH with our perspective on the current consultation regarding the Discussion Paper on a Potential Pan-Canadian Formulary.

While we are pleased to participate, we see opportunity to connect the outputs of this consultation with the important and fundamental elements of drug access pathways in Canada. It is impossible to adequately address key processes for a potential national formulary, such as evaluation, assessment criteria, and prioritization, without considering important and relevant areas deemed out of scope in this consultation, such as funding and eligibility. The outputs will also be constrained by the absence of any information on what potential role a national formulary might play in a system where provinces and territories are constitutionally responsible for public drug plan formulary decisions.

J&J recognizes the unique health policy context for this consultation, notably the ongoing COVID-19 pandemic and its continued impacts on the health and economic well-being of Canadians, on all levels of government, and our healthcare system.

The global life sciences industry has risen to the challenge and responded to the pandemic with a multitude of solutions. Likewise, we have seen the public service at its very best – innovating in real time to ensure Canadians get access to life saving vaccines and treatments. Partnerships between industry and government are working to safeguard supply chains and ensure that the healthcare system is adequately equipped to address the pandemic while continuing to offer services for patients who are living with other diseases and conditions. J&J is proud of its contribution to this effort, and we will continue to look for ways to collaborate with partners in the healthcare system.

Finally, J&J welcomes ongoing efforts by Health Canada to advance key policies impacting the life sciences sector, including the July 2021 Biomanufacturing and Life Sciences Strategy, and further work towards a National Strategy for Drugs for Rare Diseases. Stakeholder consultation has been a key component of this work, and we look forward to that constructive approach being carried forward.

Thank you for the opportunity to share our perspectives on these important issues. We are committed to continued partnership with the panel, CADTH and Health Canada and would be pleased to elaborate on our comments as this work proceeds into the future.

Sincerely,

Lesia Babiak

Head, Worldwide Government Affairs and Policy (Canada)

Johnson and Johnson

CC: Bonnie Kam, Director, Health Technology Assessment, The Janssen Pharmaceutical Companies of Johnson & Johnson

JDRF Canada

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

JDRF Canada agrees with the proposed principles and definitions. We emphasize that a potential pan-Canadian formulary should be universal and integrated. We also underscore that a pan-Canadian formulary should be equitable, closing gaps in access to prescription drugs and related products helping to reduce the burden of out-of-pocket costs.

The current patchwork of formularies by jurisdiction is problematic because it excludes segments of the type 1 diabetes (T1D) population through age, socioeconomic status, and geography. For example, a 26-year-old patient with T1D without private insurance in Ontario has full access to their drugs and related devices including but not limited to: an insulin pump, test strips, and continuous/flash glucose monitor. Out-of-pocket costs for these devices can total up to approximately $10,000 per year. However, if that individual chooses to move to Manitoba, their insulin pump is no longer covered, and they no longer have access to a reimbursed continuous/flash glucose monitoring system, which means they would likely have to pay out-of-pocket or risk changing their regimen, potentially leading to complications and hospitalizations, placing a burden on the healthcare system that could otherwise be prevented. We recognize that these gaps have been created from consequences of policy decisions that do not consider patient experience, creating an inequitable variation in access. Examining this from a national level to close the gaps is something JDRF wholeheartedly encourages and supports.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The proposed assessment criteria for the proposed sample list are comprehensive and ensures that existing drugs and related products are accessible to the T1D population. The provincial gaps will ideally be closed as a result of listing products that are on all identified drugs plans. The "flagged for further consideration" category should also consider what jurisdictions outside of Canada are covering, as part of the broader consultation with the clinical community prior to decision. We support that the excluded category lists products that are currently not listed or present safety issues identified by Health Canada.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

JDRF Canada is pleased that related products have been included as part of the pan-Canadian formulary as the standard of care for those living with T1D has changed drastically as a result of these new and emerging technologies. We would suggest that the qualification criteria include the following:

- Clinical benefit – what are the clinical benefits of these products? Do they help avoid short and longer-term complications, hospitalizations, emergency room visits?

- Patient experience – what is the patient experience of those who are using these products compared to those who do not? What are the quality of life implications for those who have access to these products? Are patients safer when they use these products? Are they able to better self-manage their disease?

- Psychosocial benefits – Do patients who have access to related products have improved mental health? Is stress and anxiety alleviated due to greater access to the related product?

We recognize that value for money is an important criterion that needs to be considered and recommend that the cost-effectiveness be measured, but emphasize that clinical benefit, which can also contribute to longer term cost savings, and patient experience should take precedence. It should also be recognized that given the rapidly changing technology, long term outcome measurements as classically defined in the medical literature are not necessarily available as the technology can become outdated prior to the data being available.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

We maintain that related products should be treated just as essential as drugs and should have similar evaluation criteria applied to them.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

As a national health organization that supports research and innovation, JDRF Canada supports the expansion into other therapeutic areas. Those living with T1D are susceptible to other conditions and complications. For example, T1D is often associated with autoimmune diseases such as: autoimmune thyroid disease (ATD), celiac disease (CD), autoimmune gastritis (AIG), pernicious anemia (PA) and vitiligo. Autoimmune thyroid disease is the most prevalent endocrinopathy among diabetic patients.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

Prioritizing other therapeutic areas based on national health priorities may not be feasible if those priorities are politically driven and change over the short term. In addition, national health priorities can be considered too broad to determine what the focus of expansion should be. Instead, we recommend that expansion be focused on prevalence and usage of specific drugs and related products.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #3

Please provide the reason(s) for your choice.

Opportunities to work together at an international level to review and prioritize products collectively is a way in which access can be accelerated since much of the review process would already be undertaken in the partner countries. In fact, there is a considerable gap in what is accessible for T1D patients in other countries as compared to Canada. For example, an artificial pancreas is a system made of three parts that work together to mimic how a healthy pancreas controls blood glucose, also called blood sugar, in the body. This has proven to be highly effective for T1D patients but no such specific system is available in Canada, while other countries have access to many options due to a faster, more effective review process. We are finding lag times of up to three years for devices that are available in the United States, but not in Canada. If international collaboration is the option that would accelerate the approval and consequently adoption of new drugs and devices most effectively, that would be our first choice.

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

We support the proposed criteria for the consideration of new products. We encourage that prioritization be given to equitable access, alignment with patient and societal values and clinical benefit. While feasibility of adoption into health systems and value for money are important considerations, we maintain that a patient-first approach should be adopted, and that system and fiscal constraints should not hinder a decision for product availability in Canada.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

We support a formal scoring tool for the deliberative process that is clear and transparent for each criterion and that involves an expert committee. The composition of the committee would need to best reflect the health needs of all Canadians and should include the patient voice that inform potential criteria of patient experience and quality of life benefits. We also feel strongly that the decision-making process and rationale for the decision are made available to all stakeholders. We also would recommend that national guidelines produced by each respective disease group association be considered.

8. 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 reviews)?

With the ongoing research and development in the T1D arena, a ramp up of reassessment would help patients gain greater access to drugs and related products that would help them live better lives. We would support this regular cycle of reassessment to ensure the latest and greatest drugs and related products are available in Canada. While this would put a greater strain on existing resources, a prioritization system like the Priority Review Process currently in place that allows for a faster review to make available promising products for conditions like T1D, that have high costs to the healthcare system, where there is a potential for complications and further disease and disability. It should also be recognized that the medical technology sector for Type 1 Diabetes may advance quicker than a standard 3-to-5-year life cycle.

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

We are concerned that the World Health Organization's Model List of Essential Medicines (EML) and the CLEAN Meds list are being used as a starting point for a national formulary because lists do not cover all the types of insulin that Canadians with diabetes commonly use. Insulin products on the EML are limited to human insulins and do not cover the insulin analogues used with insulin pumps, a preferred method of managing insulin therapy for tens of thousands of Canadians. If these lists are used without amendment, the formulary will not adequately meet the expectations and needs of Canadians, leading to public disappointment and loss of faith in the program.

To be workable in a Canadian context and to align with Canadian diabetes clinical practice guidelines, we would need at a minimum to see one long-acting insulin analogue and one rapid-acting insulin analogue added to the formulary, and ideally consider adding insulin adjunct therapies and newer insulins in development as they are approved by Health Canada and their clinical value is demonstrated.

It is critical that we ensure that the appropriate insulins are accessible to optimize outcomes and quality of life for all Canadians with diabetes.

About JDRF Canada

JDRF is the leading global organization funding type 1 diabetes (T1D) research. Our strength lies in our exclusive focus and singular influence on the worldwide effort to end T1D. JDRF works every day to change the reality of this disease for millions of people—and to prevent anyone else from ever knowing it—by funding research, advocating for government support of research and new therapies, ensuring new therapies come to market and connecting and engaging the T1D community.

LEO Pharma Inc

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

As a member of Innovative Medicines Canada (IMC), LEO Pharma Inc. supports the joint IMC and BIOTECanada response to this questionnaire. Moreover, LEO Pharma Inc. welcomes the opportunity to be a part of the dialogue in an area of importance to our fellow Canadians: Continued access to medications.

Whilst we have tried to provide constructive feedback below, LEO Pharma believes that it is critical to provide comments with context and a true understanding of the expected scope of national pharmacare policies. This would truly provide for meaningful consultation beyond simply a pan- Canadian formulary. LEO Pharma believes that it is also important to consider in consultation not just what will be covered via a formulary but also:

• How such a pan- Canadian formulary would fit into an already established private/ public model of drug reimbursement in Canada?

• How will the implementation change the betterment of patients who are not covered by existing drug reimbursement programs?

• What will be the terms of this reimbursement?

• What is the expected funding model?

CADTH has proposed principles to guide a potential pan- Canadian formulary: universality, equality, efficacy/high quality, sustainability, efficiency/timely, inclusivity/transparency and fairness. LEO Pharma is aligned with a principled approach and CADTH should be commended on applying this method to this exercise. We encourage that the principles be further refined to ensure they could be specifically applied to the overall scope of national pharmacare.

Overarchingly, like CADTH, LEO Pharma believes that patient centricity should be at the center of any principled approach. We believe all Canadians should have access to prescription medications and affordability should not be a barrier. LEO Pharma believes that patient choice should be included as part of the draft principles and values developed by CADTH. Patient choice is important and must be maintained as every patient and their respective condition is unique. Any pan- Canadian approach should strive to reflect the best and most comprehensive standards of coverage across the country. This is more resonant and specific to the Canadian environment than simply stating equality or universality as patient driven principles.

Another key principle to consider is collaboration. A high-quality formulary and pharmacare program must encompasses not just efficacy but expertise and stakeholder perspective in decision making. Pragmatically, for many therapeutic areas, the exact literature is not always available to support a review at the time it is needed- yet decisions need to be made. Hence it is important to consider the individuals involved as part of the principled approach. Engagement between decision makers and experts is critical and will lead to better decision acceptance, collaboration on individual drug reviews and overall,

the success of a pan- Canadian formulary. Collaboration will also help facilitate predictability and transparency.

Ultimately, any future developments towards a pan-Canadian formulary must ensure it does not create gaps in current drug reimbursement in order to adhere to the principle of being equitable.

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

LEO Pharma believes that a pan- Canadian pharmacare model must consider the following to guide its assessment criteria:

• Equality: Ensure that all Canadians have access to medication, provide choices and a full range of options based on the best health outcomes for Canadians, driven by value-based decision making, not cost;

• Monitor and evaluate the impact on patient outcomes, health spending, access to innovative therapies to ensure contribution to system sustainability;

• Pragmatism: Maintain current reimbursement structures and address gaps in care for those who cannot afford it;

• Reduce complexity: streamline review processes and implement timely decision making to ensure that there is no gap in access from either a time or jurisdiction perspective for Canadians;

• Respect provincial jurisdictions and autonomy;

• Take a holistic approach to healthcare;

• Future sustainability: Ensure future innovations are funded and foster an innovative and sustainable system which supports solutions for patients beyond medication;

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

Any decision-making framework should have at its core, patient centricity. Other questions that could be posed as part of the decision-making frame could include:

• Do we have the best options based on value to the overall system, or do we have the cheapest options?

• Do we have enough options knowing that not all patients may respond to a given treatment?

• How do we address changing or lack of evidence in listing, or maintaining a listing of a drug product?

• Do we consider short term measures or long-term sustainability of the healthcare system?

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

See response to Question 3A

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

As noted above, LEO Pharma believes that it is critical to assess this question within a framework of the expected scope of pan-Canadian pharmacare policies as opposed to a singular formulary.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

National health priorities tend to be broad at a federal level. Furthermore, access to medications is provincially mandated. Provincial governments need to maintain their autonomy as to what is important to them in a drug strategy given the differing priorities of provinces and needs of their constituents.

LEO Pharma believes that the most practical application of this initiative is to maintain flexible funding between the federal and provincial governments to ensure meaningful implementation of any new drug strategies and that national pharmacare policies provide guidance to provinces to help fortify the drug strategies they have in place.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

NA

5b. What criteria could be used to identify priority products?

NA

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

LEO Pharma believes that any adopted model in decision making should take into account and provide for choices and a full range of options based on the best health outcomes for Canadians, driven by value-based decision making, not cost.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

Overall, the deliberative process should remain flexible to address unique treatment needs in certain therapeutics areas and be able to evolve to accommodate innovative outcomes-based initiatives and development of real-world evidence.

There also needs to be appropriate weighting on the input from patients/ patient groups and clinician/ clinical groups and supportive direct dialogue with all involved stakeholders on the deliberative process in drug evaluation.

Finally, transparency should be given a weighting in the deliberative process. This should be CADTH lead and could include public disclosure of committee discussion and specific clinical feedback in order for fully visibility to the public.

8. 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 reviews)?

NA

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

Any changes to drug reimbursement system in Canada that would result in poorer patient access to medications than what is currently available or that will force a switch in medication will not be acceptable to most stakeholders.

In conclusion, LEO would like to re-iterate its stance that the goal of a pan- Canadian formulary and ultimately a pharmacare program should be two- fold. One, to expand medication access to a greater number of Canadians and two, continue to maintain medication choice and expand the number of therapeutic options for patients.

Life Sciences Ontario

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

Life Sciences Ontario is pleased to provide the following overarching comments related to the proposed national formulary:

-Many of the most fundamental questions related to the creation of a national formulary are explicitly excluded from the consultation document. It is difficult to provide informed feedback without first

understanding how a national drug list would be used, by whom, and under what conditions. Moreover, very few details are provided on how the proposed national formulary would integrate within existing coverage and reimbursement systems or impact other pharmaceutical policy initiatives. This is pertinent information that needs further clarification.

-It is not entirely clear what problem this exercise is trying to solve, given that the vast majority of Canadians have access to medicines benefits programs, or could have access to first-dollar coverage if they applied, and everyone has access to "catastrophic" drug insurance. Moreover, as health and pharmaceutical coverage remains a provincial responsibility, the most pragmatic approach would be to increase federal health transfers to the provinces, so they can close existing coverage gaps, reduce or eliminate co-pays, and expand their programs to cover more medicines than they currently do.

-A missing element in the proposed guiding principles for the national formulary is a principle for innovation and economic growth. The COVID-19 pandemic has made it abundantly clear that having a strong life sciences sector is critical for our health and economic security. It has also highlighted the importance of medical innovation and having access to as many different treatment tools as possible. Governments across Canada are now taking steps to build these capabilities and ensure that we are prepared for future challenges, e.g., the federal government's Biomanufacturing and Life Sciences Strategy, which has identified aligned governance (Pillar 1) and world class regulations (pillar 5) as priorities. In this context, any new pharmaceutical initiatives, such as a potential national formulary, should align with federal and provincial life sciences growth strategies and promote the adoption of a wide array of new health innovations.

- A logical next step in discussions regarding the creation of a new national drug formulary would be to convene a high-level, multi-stakeholder forum, to help advance dialogue and connect the dots between the many different but interconnected pharmaceutical policy issues and initiatives to ensure they align rather than work against each other. This could be done, for instance, by reconvening the work of the Health & Biosciences Economic Strategy Table (HBEST), which would help ensure an all-of-government approach and avoid siloed policymaking.

Thank you for the opportunity to provide input.

Sincerely,

Jason Field

President & CEO

Life Sciences Ontario

Lifescan Canada

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Lifescan Canada supports the principles that all people in Canada - regardless of age, income, ethnicity, or geography - should have access to the prescription drugs and related products they need, in an equitable manner, and that these should be of the highest quality and effectiveness available in a cost-effective way that is sustainable for the long-term.

Questions remain regarding the definition of "sustainable". Does that include operationally manageable? Financially sustainable for the long-term, etc? Also, how will the proposed list of products included in the recommendations be funded by the provincial governments and reflect a diverse population across Canada while addressing differing needs?

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Lifescan Canada supports a formulary design in the case of diabetes that is based on therapies as recommended for the treatment of diabetes in the Diabetes Canada Clinical Practice Guidelines utilized by Health Care Professionals across Canada and recognized as the standard of care. The drugs and related products included should provide strong clinical benefits in a cost-effective and responsible way that meet the needs of Canadians living with diabetes and their Health Care Professionals and empowers and engages patients to self-manage their conditions as much as possible.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

We agree with the inclusion of diabetes blood glucose meters, test strips and lancets as part of the pan-Canadian formulary project to aid in the monitoring and treatment of diabetes as a proportion of Canadians do not currently have adequate access to these products.

Coverage should enable patients to monitor their blood glucose according to the recommended testing frequency in the Diabetes Canada Clinical Practice Guidelines that has established the clinical benefits of doing so. Access for patients should be in line with the Guidelines and CADTH recommendations for coverage of diabetes testing supplies (as adopted by the Ontario Drug Benefit plan and other provincial and national health plans with similar criteria and coverage) that provides equitable access for all patients with diabetes in a long-term, cost-effective manner.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No

Please provide reason(s).

Lifescan Canada supports improving patient access to related products such as diabetes testing supplies that could potentially improve adherence with drug treatment and possibly health outcomes and quality of life for patients and their caregivers.

Related products meant to monitor adherence and clinical effectiveness of pharmaceutical drugs should be treated separately as they support the use of drugs and can potentially have a positive impact on patient adherence, clinical benefit, and cost-effectiveness of those drugs. These products can also have a positive impact on the efficiency and effectiveness of the healthcare system.

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #2

Please provide the reason(s) for your choice.

Lifescan Canada supports a clear and transparent process for evaluating new products and indications that includes all key stakeholders. Option #2 is preferred as it helps to address the inability to control when new product submissions are made and focuses on the specific needs and priorities of Canadians. International collaboration could slow the review process significantly and healthcare needs and priorities may vary widely from country to country depending upon demographics, disease prevalence, and healthcare funding.

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

We support the use of the proposed evaluation criteria and considerations of Alignment with patient and societal values, Clinical Benefit, Feasibility of adoption into health systems, and Equitable Access. Questions remain about how Value For Money would be evaluated in terms of what potion of the population is included in the analysis, pricing, funding, impact on quality of life for the patient and their caregivers, impact on the efficiency and effectiveness of the healthcare system, as well as long-term implications or cost reductions of treating a given disease and potentially avoiding more serious health complications in the future.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

No response provided

Lundbeck Canada

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The panel's proposed guiding principles on which a potential pan-Canadian formulary would stand are sound but the definitions fail to address certain imperatives. For instance, we believe an equitable framework should be one which aims at closing coverage gaps across Canada, while inclusivity involves that patient preference and healthcare professional choice be considered and not restricted. As such, a universal and integrated framework should aim at closing the existing drug and related products coverage gaps while ensuring Canadians maintain access to at least the same range of therapeutic options they rely on today. No Canadian should have worse access to medicines under a pan-Canadian formulary than they do today.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

A cornerstone of the proposed criteria involves comparing the listing status of medicines on existing public drug plan formularies and identifying gaps in access. The proposed framework should therefore focus on minimizing any disruption to existing listings and instead enhance access; a pan-Canadian formulary should reflect the best and most comprehensive standards of coverage across the country, for no formulary should be more restrictive than the one it seeks to replace. Under the proposed framework, the basis on which a medicine would be flagged for further review is excessively abstract and could diminish patient and clinician choice by restricting access to drugs currently available in certain jurisdictions; further context and details would be welcome.

Furthermore, current advancements in drug innovation are shifting treatment paradigms towards more targeted therapies. Expanding the proposed approach to areas such as oncology and orphan diseases might be too restrictive and create challenges in implementing the complex and individualized treatment algorithms required by these patient populations, to the detriment of optimal health outcomes.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

The same guiding principles we outlined in section 2 should be applied to related products, with the aim of informing best clinical practices & utilization, and with particular emphasis on preserving patient preferred choice of delivery devices & healthcare professional flexibility.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

The evaluation criteria for related products should account for patient and clinician preference and be conducive for a full range of delivery options be made available.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

Our feedback formulated in section 2 applies here.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #1

Please provide the reason(s) for your choice.

We believe that a drug evaluation system should be aligned with the health priorities of the Canadian population while recognising that processes & timing predictability are paramount to drug manufacturers. As such, aligning the HTA prioritization model with Health Canada's priority reviews would simultaneously cater to the needs of the Canadian patients and industry stakeholders alike. A scoring-based prioritization system therefore appear unnecessary given the prioritization processes already in place at Health Canada and would open the door to arbitrary and subjective assessment, while being detrimental to the predictability necessary to manufacturers.

We welcome the panel's acknowledgment of the need for transparency and collaboration between all stakeholders throughout the process.

5b. What criteria could be used to identify priority products?

While pharmacoeconomics remain fundamental in HTA evaluation and listing recommendation, the criteria used to identify priority files - and ultimately listing decisions - must be multi-factorial and look beyond basic financial considerations. For instance, the cost-saving impact of a given therapy

on institutional resources should be considered, along with the degree of therapeutic innovation in relation to the unmet medical need. Patient input must remain a key consideration. Given the fact each therapeutic field presents its own needs & challenges and needs flexibility in the weighting of these criteria is essential to ensure the best possible health outcomes.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Equitable access implies the framework should aim to enhance and close the existing gaps in coverage, not restrict medical innovations. 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 the government proceeds with a pan-Canadian formulary, it should always support full patient choice and clinical judgement. While cost considerations remain an unavoidable imperative in decision making, the analysis must factor-in long-term criteria and other factors including, but not limited to, reduction in hospitalization rates, patient preference and the opportunity for real-world evidence development.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

Equitable access implies the framework should aim to enhance and close the existing gaps in coverage, not restrict medical innovations by making cost considerations its primary focus. It must support full patient choice, clinical judgement and recognize that in many therapeutic areas, notably in mental health, a diversity of therapeutic and delivery solutions are required to achieve optimal health outcomes, to the benefit of all Canadians.

McMaster University

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

These are basically the principles used now for public plan formularies, which already adhere to the highest quality methods and practices.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

This is a reasonable starting premise for the sake of a draft. However, it ignores the role of formulary modernization.

The key over-riding principle of formularies (as for any resource that is not ubiquitously available to all at very low price) has to be cost-effectiveness. That is at the basis of equity, fairness, sustainability. Several of these tenets are violated for old products which no longer meet teh cost-effectiveness threshold and are using public dollars that have more value elsewhere. Also there has to be accepted the notion of a tiered formulary, with drugs that meet whatever is decided on as the common cost-effectiveness threshold (eg, $50,000 per QALY) being a general benefit, and drugs that might approach cost-effectiveness for a small segment of people, having restricted access. This is key to preserving sustainability and equity.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

It is a) naive to believe that adherence is simply a matter of making medications cheap. this is only a small component. I note that your background literature review is not systematic or high quality. in this area, have a look at Holbrook A, Wang M, Lee M, Chen N, Nguyen L, Garcia M, Manji S, Ford A, Law M. Cost-Related Medication Nonadherence in Canada: A Systematic Review of Prevalence, Predictors, and Clinical Impact. Systematic Reviews, 2021; 10 (11). https://doi.org/10.1186/s13643-020-01558-5.

b) also short-sighted to prioritize patient access as the primary principle of health care. Medications are not consumer goods, that can simply be purchased, and many Canadians have gone too far down the road of 'choice' in medications and 'wants' in healthcare. Medications have the strongest evidence base of any sector of healthcare. Clinicians and policy makers are in the business of providing the medications that patients NEED, not necessarily what they want. Delivery agents and devices should be treated like every other part of the assessment process. if the device is necessary to administer the drug, then the total package needs to be assessed for cost-effectiveness and price negotiation.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No

Please provide reason(s).

the answer, of course, is not necessarily. 'Related' products, particularly drugs in the same family, rarely share the same cost-effectiveness. Again as with all of these issues, these require KNOWLEDGE AND EXPERTISE in this area. this cannot be left to the general public to decide.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

I strongly support the principle that all medications proceed through the same process. There was never any historical rationale for having a separate process for considering cancer drugs, and these medications have been allowed on formularies at much lower value-for-money spent than other medications. This is, fundamentally, not equitable and is also not sustainable. Likewise, even drugs for rare diseases have to in the end adhere to the same principles.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

always come back to the most defensible process - what is the evidence that this product adds value for money spent compared to the alternatives or the standard of care that we are providing now.

'national health priorities' are too easily influenced by political and advocacy groups that are not representative of the population. National health priorities based on data on burden of illness, mortality rates, etc - that is a different matter. That is clearly part of the cost-effectiveness determination.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #1

Please provide the reason(s) for your choice.

all options are worth exploring, but Option 1 will be the most feasible moving forward.

5b. What criteria could be used to identify priority products?

there is already a system for this at the regulatory body, and I thought PMPRB is working on a model for this.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Again, the first and foremost principle is cost-effectiveness (value for money). In many cases, a more societal approach to cost-effectiveness is well argued but not yet as rigorously applied. Evaluation based on alignment of patient values will fail, miserably. Although it is not considered politically correct, physicians have a much better grasp on what is likely to help vs harm any particular patient and they are the only ones that have a wide experience of what multiple patients prefer. The current public notion that the individual patient is the ultimate judge of what is best for them in drug therapy, given their limited knowledge and expertise of the drug, its alternatives, the disease, prognosis, etc, has not been supported by the evidence.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

this is already done. 'Scores' persay are not required, but there has to be a clear understanding of cost per QALY, and how the cost/QALY stacks up against alternatives, how many people will be impacted, what is the budget impact going to be, how implementable is the decision and what is foregone by deciding to list this particular drug.

GRADE's Evidence to Decision process is excellent for making this decision-making transparent for all, and easier to vote on.

8. 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 reviews)?

Yes, the priority reviews that need to take place are those where the estimates of cost-effectiveness are unstable, or where the budget impact is large, or there is new important information that comes to light that throws the ongoing cost-effectiveness into doubt.

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

I was shocked that there were no Canadian drug policy experts with formulary evidence experience on this committee.

McMaster University

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Firstly, at the start of my feedback I want to acknowledge the excellent work that has been done here, this is a very good starting point. Having said that there is always room for improvement.

There are a number of statements that need to be more fully articulated, and in some cases consideration for removal as part of the first phase of the pan-Canadian formulary. I will articulate these points more formally in the final comments at the end of this document.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

In the question above you mention a three stage process, and then only present stage 1 or fail to label stage 2 and stage 3, looking further ahead on the questionnaire you do mention stage 2. It seems to me that a clearer statement that you are only asking about stage 1 here would be helpful. To keep my comments together I will address most of my feedback in the final section at the end of this document.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

It seems to me that processes used by CEDAC or pCODR would be a good starting point.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No

Please provide reason(s).

My guess is that in some cases this will be appropriate and in other cases it may not. As an example you might want to include some diabetes supplies (e.g. lancets, glucose sticks) but perhaps a different process for others (e.g. insulin pumps or insulin pens).

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

NA

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

No option for Yes in part. How will we deal with issues specific to certain provinces? National priorities do not always align with provincial needs.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #2

Please provide the reason(s) for your choice.

It seems to me that this would be the most open option, not limited by Health Canada guidance (option #1), nor encumbered by decisions within other jurisdictions that may have unique issues and challenges (Option #3). I also worry that option #3 would be a much slower and more cumbersome process, which is counter to being timely.

5b. What criteria could be used to identify priority products?

In option #2 you mention innovative products addressing an unmet need. I think the unmet need requires some sort of scaling and at the highest level (no available treatment for this condition) should take priority over definitions of “innovative”. Although I do think both aspects are important, to me a national formulary must always consider “unmet need” first and foremost.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

clinical benefit needs to be described in more detail. I saw in the document a reference to quality of life under clinical benefit (pg 23 of 43), but less on well-being that might be linked to accessibility whether financial or geographical. I think these dimensions should be included (perhaps you see this being rolled in under the equitable access label).

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

I would caution that weighting can be useful, but might also systematically bias certain types of products. I would suggest a thorough testing to see if under certain circumstances alternate weighting could be considered if it is identified that the default weighting is inequitable.

8. 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 reviews)?

It is unclear to me if this step should be tackled at this stage or be left until after the National formulary is in place. We may find that some adjustments are made to the formulary in the early stages and that may make some of these sustainability processes unnecessary. The priority now should be to get a National formulary in place to address those most at risk of having limited access to needed care.

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

I have noted a number of items that require clarification/updates.

Pg. 13 of 43 I note the comment under “sustainable” specifically “value for money” but note this value is heavily influenced by what it is compared to. Typically the default is either “the most commonly used” or “the cheapest” and is very much situation dependent. I would suggest making this an explicit statement. This limitation shows up again on page 24 of 43 under the same heading.

Pg. 13 of 43 I note the comment under “efficient and timely” specifically “timeliness”. It is unclear to me how you would measure this. I agree with this in principle but less clear on how we ensure this is accomplished. Perhaps tied to delays once submitted by the sponsor to the “National formulary”, with an appropriate window based on the nature of the product (e.g. shorter for an unmet need where no available treatment exists).

Pg. 19 of 43 Regarding reference-based pricing. This should include a process for those who have poor outcomes or adverse events related to the default product included in this reference based pricing scheme.

Pg. 24 of 43 Regarding “additional considerations” and “uncertainty of long term benefits and harms”. We know that uncertainty comes in different forms, some even beyond these types of uncertainty (e.g. structural uncertainty in modeling). It should be clearly stated which dimensions we are considering and what levels of uncertainty are acceptable as most long term models have some level of uncertainty.

Pg. 26 of 43 Regarding “health technology reassessment” I wonder how this would align with current provincial efforts. Should this process go above and beyond what provinces are currently doing, or dovetail/replace what they are already doing? I also question whether this belongs in the initial formulary offering or should be considered as a phase II process once we have had a 1-2 year trial run of the National formulary and better understand what works well and what needs adjustments.

Medicines Access Coalition - BC (MedAccessBC)

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

"Equitable" should include the equality of access as it relates to people being able to access care and if policies require steps to be in place such as filling out forms, up to date income tax reports, or fixed addresses, there is a lack of equality and this should be recognized and included.

Having listing criteria may not be equitable for all since not all have access to care so that listing criteria can be met. Meeting listing criteria often means the individual must have access to care providers and/or tests or other measures that are in the criteria and these themselves are prohibitive for some people, particularly those who do not have a family physician, which is a large proportion of people in Canada.

When using words like "effective and high quality," it should be individualized to the patient. Much of the wording that is used does not necessarily show recognition of patients and individuals, but speaks to populations and people in general. Furthermore, when terms such as "highest standard of health and patient experiences", it is unclear where these are derived and how these are defined. These terms, standards and outcomes are different for different individuals. To illustrate, what is adequate pain control with a particular dose of a particular medication may be determined as effective for one person, but to another person that level of pain control with a particular treatment and dose may be deemed inadequate and not effective. As with equitable access and effectiveness of treatment, these need to be defined from many points of views, including those of the patients in various circumstances and situations for it to have real impact and be applicable.

"Sustainable" needs to be defined from a patient health perspective and not speaking to costs and viability and feasibility. When you consider the pandemic that we are in, sustainable is not the target, it is the preservation of health, preservation of life, decreasing hospitalization and reducing mortality. The actions taken and the expenditures incurred have saved lives and preserved the economy and livelihoods. Isn't the control of symptoms, curing of diseases, and preventing negative health events something that is not looked at as doing it in a sustainable fashion. The goals and targets are about health and people and individuals. A National Formulary Framework should focus more on the people and not on sustainability. There should be a holistic focus and not just on the expenditures on medicines, but rather the outcomes, and value for money needs to take in to account the productivity, quality of life, and symptom free life aspects for people.

Where the term "inclusive" is used, there should be inclusion of being "comprehensive" in breadth and application when it comes to health and people.

When speaking to "transparency", there is a need to include "full disclosure" of stakeholders who are involved in decision-making processes and policy-making processes. Historically, it has been expressed that only those with commercial ties have bias, but in reality, everyone has a bias in some direction and to be transparent, those involved should provide full disclosure of their incentives and potential conflicts of interest including those who are in bureaucratic positions, including policy-makers, committee chairs, and members involved in making decisions or influencing decision.

2. Do you agree with the proposed assessment criteria?

No

Please provide the reason(s) and suggested changes, if any.

The proposed assessment criteria assumes that the current process does not include flaws, and it of course does. The current CDR and then pCPA process results in the provinces with some public plans listing a product and others that do not when we are all Canadians needing access to medicines. The people in the different provinces are not so different that each province should have different coverage. This current proposed assessment needs to look at a more inclusive approach that does not further amplify the flaws that exist in the current system.

The proposed assessment criteria should be reassessed to reduce duplication of work that has already been done and look for ways to improve the system so that the current flaws in the health technology assessment process are not perpetuated.

The inclusion of patient advocates and patients with lived experience should be included in stages 1, 2 and 3 where the value of the therapy can be properly understood and the impact to people with the affected conditions can communicate the value and benefits so a fair evaluation can take place.

The proposed approach focuses on high utilization therapies and conditions, the problem with this is that it will lead to the development of a biased process that may work well for common therapies and conditions and will not only fall short but may be detrimental for assessing low volume medicines or treatment of uncommon or rare conditions. There should be some sample of lower utilization drugs, and rare disease drugs, as well as low cost drugs and high cost drugs as part of the proposed initial assessment and sample list.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

Eligibility of products should be broad and comprehensive and should include any medicine as well as the related devices and processes which are necessary for administration of the treatment. Outside of blood products, drugs, medicines and related products should include all treatments that involve the administration of any chemical or treatment. All steps which are not diagnostic in nature performed by a physician should be considered as covered within a National Formulary of medicines including everything related to its administration. It is important that administration and required monitoring of a medicinal treatment is not omitted. The administration aspects relate to accessibility and equality. As an example, a drug product that requires Intravenous administration should be assessed not only as listing and coverage for the product, but must also include the cost and coverage of its administration. A specific example today is intravenous iron infusions, the molecule is listed in some provinces and many require prior authorization, but even so, many patients cannot afford or find access to a clinic where they can have the iron infused to them because the infusion service is not consistently available within provinces or across Canada. Some physicians may be able to have their patients receive an infusion in hospital and others without hospital affiliation cannot, and the waiting list for an infusion is long.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No

Please provide reason(s).

Related products are rather different from traditional medicines and therapies and therefore should have evaluation criteria that make sense and are applicable to the related products. For example, a drug product that requires administration by intravenous infusion may require an evaluation of the drug and of the administration process which is needed and how that would be funded so the treatment which is listed can actually be used and administered. Healthcare is not a one-size fits all and not only are individual patients unique in their needs and responses to therapies, many related products are unique and because they are difficult to even categorize together, they should not be evaluated the same way.

4a. Do you support the proposed approach to expand to other therapeutic areas?

No

Please provide the reason(s) for your choice.

There is a need to expand to therapeutic areas, but we disagree with the proposed approach. Input from patient organizations who have better visibility of the real needs of people should be involved in the expansion to other therapeutic areas. Expansion by using numbers and statistics where these are not comprehensive and have gaps in data collection will focus the attention on the wrong areas. There should be an approach that is guided by data collected, but also include patient experiences and patient organization perspectives which are more grass roots. Inclusion of practitioner input and not just researchers and HTA experts will be important as frontline experience and impacts need to be included as there is expansion to other therapeutic areas. There is a chance to improve on the current assessment process when creating a National Formulary and inclusion of the “right” areas require more consultative input from those who experience it, rather than the aggregate data we are able to collect in databases in Canada which are devoid of necessary patient data, particularly patient health related quality of life data

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

Needs vary by jurisdiction and because each province runs its hospital system differently, therapeutic areas may have different priorities in different provinces. The people are not that different, but how healthcare is administered is different. As an example, there is variation in the number of ICU beds per capita in each province making different priorities when ICU is involved, etc.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

A combination of Option 1 and Option 2 is needed to properly serve Canadians. The process by Health Canada is not sufficiently transparent and involves little input from patient organizations and clinicians. A transparent approach which is clear and publicly known with engagement points for clinicians, patients and patient organizations will help to ensure an effective prioritization. Prioritization by those who are researchers, bureaucrats, and policymakers do not include the actual needs and concerns of the people and patients. Clinicians and patient organizations have better and timely visibility of current needs and priorities. It would be difficult for an individual patient to prioritize, but their input can be channeled through patient organizations, ideally through a combination of patient organizations or patient organization coalitions so that there is not a bias towards one particular disease state or patient population. Transparency is key since there are many biases possible when making priorities when it is not a first in first out approach.

There should be some recognition of first in first out since there is much investment made to submit a file and strides taken to submit a file early. From a perspective of ensuring a constant pipeline of new products which contribute to the health of Canadian, whether it is large or small, are beneficial to Canadians and should receive a fair and timely review. This is to say, first in first out should not be completely ignored, but priorities must also be set for files where the impact to Canadians appears to be significantly high. High impact may be a combination of significant impact to health improvement and affecting a large proportion of the population.

5b. What criteria could be used to identify priority products?

In general, the criteria is a combination of significant impact to health improvement (eg. reducing mortality when there was no therapy which reduce mortality before) and affecting a significantly large amount of the population (eg. positive impact to all those who are at risk of being infected by COVID-19). Spelling out the specific metrics and parameters will take significant consultation and deliberation and involves pricing and expenditure considerations of the therapeutic area. That is if there is a product which is being assessed in an area where there is large economic expenditure and this therapy can reduce the spend significantly, then it should be a criteria to consider it a high priority.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

When including Value for Money, there needs to be careful consideration of this so that it is not only about cost savings or cost avoidance or cost containment. Health of people is a long-term consideration and most assessments done today are siloed considerations focusing on drug budgets and expenditures rather than looking at long-term impacts on people, patients, and productivity. What is missing is a focus on long-term impact and impact on the productivity of people who need access to medicines. The cost has often been based on cost of the medicine and its administration and side effects. The benefits to the person with respect to quality of life, productivity and well-being are often omitted.

Feasibility of adoption into the healthcare system needs transparent definition and be inclusive of those people who have less common conditions and rare diseases. Feasibility drops low when we look at

therapies that are low volume or costly, and these should not be the only drivers of feasibility, which they often are. Feasibility should be omitted since healthcare is not something we should assess whether it is feasible or not. Again, as mentioned before, many of the steps we took and the expenditures we incurred would not be considered "feasible" when assessed in the realm of this kind of evaluation of medicine coverage.

What is also challenging is who will be the judge of whether something is "feasible or not feasible", this type of assessment has too much subjectiveness associated and has no place in the consideration of healthcare and treatment with medicines. If something is deemed not feasible for adoption into the current health system, perhaps it is an indicator that our health system has a flaw if the therapy is deemed and demonstrated to be beneficial to patients or people.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

A multicriteria decision analysis (MCDA) would help with the deliberative process as long as the analyses and criteria are transparent, fair and applicable. This will mean that the MCDA derived must be robust and represent the needs and requirements of patients. There may be need to have several versions of MCDA since in different circumstances, there is need for different weighting and criteria. The same analysis cannot be done for all areas of treatment, for example, how we analyze and make decisions and the criteria used for oncology conditions, compared to rare diseases, acute treatments and chronic conditions need different analyses and weighting of criteria.

Healthcare cannot be standardized where the same system or approach is used for all patient populations, diseases, and age groups. This means there needs to be some ability to adjust and tailor decision analyses to the needs of the patients and the therapy.

A pan-Canadian formulary expert committee needs to be carefully chosen to have sufficient representation that all perspectives are provided and must include patients with lived experience as well as patient organization representatives. The same way that a practitioner for such a committee may be chosen due to the diversity of people and conditions they are exposed to, so should the patient and patient organization representative. This is difficult to find since patients with lived experience would only have experienced 1 or 2 conditions and cannot represent a diversity of conditions, but can provide a patient perspective. Similarly, if a patient group representative is from a particular disease area, that person may also not be able to provide a diverse perspective and may be biased towards a single disease area. Therefore, it is encouraged to have broad representation through patient organization coalition representatives, or multiple representatives and have clinicians who are diverse in practice as an example.

8. 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 reviews)?

To ensure operational stability and not be wasteful of resources, reassessment of those therapies which have been listed already, should only be reassessed if there is a complaint or reason to do so. It should not be a routine process just so the therapy is reassessed because some arbitrary deadline or due date is set. Reassessment of a therapy that is not listed, but there is call for reassessment due to new needs identified, or new evidence, or new insight from non-formulary use should have a process for reassessment. There should be transparent process and eligibility for reassessment and a balance and representative committee that reviews products for reassessment and sets priorities and identifies the most appropriate pre-determined transparent process. There needs to be a different process for different category of therapies and conditions. Not all therapies should be reassessed the same way to be considerate of the variety of patient needs and impacts in different disease states and patient populations.

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

Medicines Access Coalition – BC (formerly The Better Pharmacare Coalition) has been effectively advocating for appropriate and timely access to evidence-based prescription medications through the BC PharmaCare program and federal agencies since 1997. With a renewal of the Coalition in 2020 and a new name which more effectively reflects our mandate, we aim to be the leader in advocating for better access to medicines in BC by providing a unified voice of many patient care organizations. We are now known as MedAccessBC and have expanded our scope and activities to more effectively meet the needs of our coalition members and improve the health of British Columbians which often requires us to take action at a federal level, such as feedback and submissions we have provided to CADTH and its programs and services, PMPRB, and other national organizations.

MedAccessBC's current member organizations represent more than two million BC patients, caregivers and advocates. We achieve our mandate by providing education and awareness, interacting with stakeholders who participate or influence the decisions directly affecting the access to medicines including, policy makers, government, researchers, health practitioners, public and private health payers, benefit managers/consultants, pharmaceutical manufacturers, and others who play a role in the access to medicines.

On behalf of the members of MedAccessBC, we welcome the opportunity to provide a written submission sharing our views on CADTH framework for developing a potential pan-Canadian prescription drug list or formulary. We recognize the importance and need for all Canadians to have fair and equitable access to medicines and that it should include fair prices for medicines which are affordable for Canadians. A standard formulary for all Canadians that results in a reduction of coverage or access would not be acceptable. A universal national formulary should improve the current access to treatments and not add more delay or additional bureaucratic processes that are not an effective use of limited resources.

There is strong concern that a framework and process to developing a national formulary will result in increased duplication of work as we have already seen duplication among CADTH, CDR, PMPRB, pCPA, and the provincial medicine reviews each province also undertakes.

We emphasize the importance of ensuring a healthcare landscape that ensures Canadians have consistent access to new and breakthrough medicines as well as participate and gain benefit from clinical trials involving new drug therapies. Early access to innovative and life-saving medicines in parity with the rest of the world ensures Canadians are able to achieve a high level of quality of life and life expectancy, contributing to the success of Canada as a whole. Patients and patient organizations who focus on the health and well-being of people and Canadians as a first priority have perspectives on the

proposed framework for developing a potential pan-Canadian prescription drug list or formulary, which may be different from those who are regulators, create policies, plan budgets or are employed by for-profit corporations.

We would like to point out that and highlight the following as you consider the input and responses to the questions CADTH has provided and requested responses.

- Since the context of this framework for developing a potential pan-Canadian prescription drug list or formulary is not entirely clear with respect to how and if a National Pharmacare program will be developed, it is very difficult to provide informed responses.

- There are too many issues and questions which are not answered with respect to a National Pharmacare program making it impossible to effectively answer the questions posed.

- Context for this framework for developing a potential pan-Canadian prescription drug list or formulary is missing

- For transparency and to mitigate potential for conflict of interest, the multidisciplinary advisory panel (the panel) should produce disclosures of their affiliations and representation to properly understand the motivation and potential biases of the panel members. Bias is not necessarily a bad thing and different perspectives and biases are important to be considered when dealing with issues of health where there are many stakeholders and situations. Without disclosure, there is a significant loss of transparency. Transparency is key when putting together such a framework that will have dramatic national impact and cost implications for Canadians.

- A national formulary is a very complex issue with many implications and consequences affecting the future availability of treatments, use of treatments, and research in addition to the health and well-being of Canadians. Therefore, steps in developing and formalizing framework and review processes and decision-making require broad consultation across disease groups, stakeholder groups, jurisdictions and ministries. In general, Health Canada has recognized the different between disease groups which is the genesis for the NOC/c priority review process. Unmet medical needs, innovative activities, disease populations and numerous other factors must be considered to determine the most appropriate approach to ensure the broadest access to as many patients as possible to medically necessary drugs. A hybrid approach may be required.

- Reduced access to therapies for any Canadian compared to what individuals have today should not occur, and if it does occur, there must be transparency and careful scrutiny of why an individual cannot access their therapy under a national formulary when it was accessible provincially in the past

- A national formulary should fill in gaps which exist with current provincial public coverage and should not increase complications and increase barriers or delays in access. Nothing in the current framework speaks to the aspect of ensuring timely access to new therapies. This added layer of review and assessment sounds like it will add delays to access to therapies for people, evaluation focused on ensuring this is not the case should be part of the initial implementation.

- The concept of only listing the lowest cost version of a therapy which was mentioned in the discussion paper is not workable since this is how we run into drug shortages. There needs to be recognition that listing only the lowest cost alternative will lead to situations where that drug supply runs out and there is no other supply or a more costly supply.

- Formulary listing and drug pricing are often linked and cannot be separated, the discussion paper does not go into any detail about that aspect which is an important part of a formulary framework. However, once pricing is involved or volume discounting, the implication become enormous and affects the introduction of new therapies and medicines in Canada as well as clinical trials and research in Canada. Therefore, before going further with the framework, the issues with PMPRB guidelines changes must be resolved and be compatible and in alignment with National Formulary needs and goals.

- Many of the guiding principles listed in the discussion paper are contrary to the consequences of some of the PMPRB Guidelines changes. When considering the guiding principles that this Panel used, Universal and Integrated, Sustainable, Equitable, Efficient and Timely, Effective and high quality, Inclusive, transparent and fair process and looking at the PMPRB Guidelines and the changes to be implemented, they contradict these principles. A National Formulary will work in concern with PMPRB and those stakeholder organizations which are involved in pricing. If these are at odds, it prevents moving forward in an integrated and cohesive manner and may be wasteful of taxpayer resources.

- With the introduction of a National Formulary, it is indicative of the need to update the Canada Health Act to include the public coverage of medicines used to treat diseases. There may be a need to develop the National Formulary Framework along with an update or addendum to the Canada Health Act to include universal coverage of medicines for the people of Canada. There is currently a lack of equality and access to medicines in Canada. This is seen with BC having available drug coverage for every British Columbian through the Fair PharmaCare program which is income based with a deductible, this universal coverage is only in BC and no other province provides available public coverage for every one of their residents. However, BC also has a public listing of drugs which is smaller than most other provinces, that is many drugs listed in other provinces are not listed in BC, many examples can be produced if needed.

Merck Canada Inc.

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

On behalf of Merck Canada Inc. (Merck), we are pleased to provide input into the consultation on the proposed framework for a potential pan-Canadian formulary. Our submission is complementary to that of our industry associations, Innovative Medicines Canada (IMC) and BIOTECanada, and aims to provide supplementary observations and recommendations.

Merck is a global biopharmaceutical company with a diversified portfolio of prescription medicines and vaccines. For over a century, Merck has been developing treatments for many of the world's most challenging diseases in pursuit of our mission to save and improve lives. We have discovered medicines for heart disease, osteoporosis, diabetes, tuberculosis, HIV and many hard-to-treat cancers. We are also now expanding our presence in the rare disease space to help some of the most vulnerable Canadians.

Merck supports policies and measures that improve patient access to new medicines and provide more equitable drug coverage across the country. However, the proposed pan-Canadian formulary framework raises several issues that need to be more examined and considered before the federal government moves forward with this initiative, including:

1. Clarity regarding the problem the pan-Canadian formulary is intended to solve

2. Considerations for how the pan-Canadian formulary would work in practice

3. Concerns around more limited and delayed patient access to new medicines

4. Pharmaceutical policies should aim to support a strong life sciences sector

1. Clarity regarding the problem the pan-Canadian formulary is intended to solve

The discussion paper for this consultation does not clearly define the problem that a pan-Canadian formulary is intended to solve. This makes it challenging to provide meaningful input on whether the proposed approach is the appropriate one to take.

The discussion paper includes a very short background section that hints at challenges this initiative might be intended to address, such as lack of coverage and the affordability of drugs. However, given that a formulary is simply a list of medicines, it is unclear how it could solve these issues. Having a medicine listed on a formulary does not mean that you can necessarily access it. For individual beneficiaries, affordability depends on whether you are covered by a drug plan and whether you are able to pay the premiums, deductibles and co-pays associated with that plan. As well, affordability issues for beneficiaries could be exacerbated if needed medicines are not on the formulary.

If we want to make drug coverage more equitable across the country, we need to address the real challenges. Based on a 2017 Conference Board of Canada report, less than 2% of Canadians are uninsured (Understanding the Gap, Conference Board of Canada, 2017: https://www.conferenceboard.ca/temp/3e7c1666-82b1-4784-89d4-9aa64ae4c776/9326_Understanding-the-Gap__RPT.pdf). We have to therefore start by closing the remaining gaps. We also know that many Canadians opt not to enroll in public drug programs even though they are eligible. We probably need to educate these Canadians to encourage them to enroll in drug plans as well as address financial barriers that may be dissuading them from enrolling, such as high premiums, deductibles and co-pays. These financial challenges may also explain why certain Canadians choose not to fill some of their prescriptions due to cost. Ultimately, more work needs to be done to better understand these problems, including collecting the right data, to come up with the right solution. That said, these challenges will not be solved by establishing a single pan-Canadian formulary.

Finally, it is true that a national formulary could help increase consistency of coverage across the country. However, studies have shown that there is already high concordance among the provincial formularies (PMPRB, Alignment Among Public Formularies in Canada, Part 1: General Overview, October 2017: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1327&lang=en), in part due to the coordination of the pan-Canadian Pharmaceutical Alliance (pCPA). It is therefore unclear why a national formulary would

be needed and whether it could and should be implemented to address remaining discrepancies that exist among Canadian public drug programs.

2. Considerations for how the pan-Canadian formulary would work in practice

The consultation scope is very narrow and excludes many crucial aspects that are needed to understand how the proposed framework would work in practice. Specifically, we don't know how a national formulary would affect the current coverage of Canadians, how it would fit within the existing reimbursement system, who would be responsible for funding and managing it, the impact on private plans and the link to other ongoing initiatives, including the national rare disease strategy and the Biomanufacturing Life Sciences Strategy. The formulary is being developed in a vacuum and it is impossible to provide specific and meaningful input without understanding how it fits into the broader picture and its implications.

3. Concerns around more limited and delayed patient access to new medicines

We are concerned that a pan-Canadian formulary would lead to the lowest common denominator, as certain public drug plans could decide to only reimburse medicines included on the national list. We need to ensure that any new initiative does not remove the coverage already available to Canadians but rather aims to improve the status quo, which is already multi-layered and challenging for patients to access. Specifically, new pharmaceutical policies should aim to promote and support patient and clinician choice of treatments rather than overly focusing on a population-based approach, which appears to be the case for this initiative according to the discussion paper.

Nonetheless, if governments decide to move forward on a pan-Canadian formulary framework, we strongly recommend that oncology and rare disease medicines be excluded from the initiative. These are specialized medicines that require tailored approaches and expert clinical reviewers to help develop appropriate reimbursement recommendations. With regard to rare disease medicines more specifically, new review and reimbursement mechanisms could be adopted as part of the evolving national rare disease strategy.

Further, we strongly recommend that this initiative not include private plans, which cover two thirds of Canadians. These plans generally provide broader and more timely access to new medicines compared to public plans and this level of access should not be compromised (Coverage of new medicines in private versus public drug plans in Canada 2009-2018, Canadian Health Policy, 2019: https://www.canadianhealthpolicy.com/product/coverage-of-new-medicines-in-private-versus-public-drug-plans-in-canada-2009-2018-2/?brief=yes).

Finally, we need to be careful not to further delay the reimbursement of new medicines in Canada. The current drug reimbursement process in Canada is already very complex and lengthy, which means Canadians already face very long timelines before access treatments they need. For instance, an IQVIA study shows that reimbursement timeline of oncology medicines is worsening, taking more than 1.5 years from Health Canada's approval to a first provincial listing (IQVIA, Market Access Metrics Database, September 2021). We are concerned that the proposed formulary framework would further delay access by adding an unnecessary step that duplicates existing processes (e.g., HTA reviews at CADTH and at the provincial level).

We are entering an exciting new period of research in the field of precision medicine. Many of the newest treatments hold significant potential to improve quality of life and end suffering for many Canadians with cancer and rare diseases. We should be focused on finding solutions that accelerate access to these new medicines.

4. Pharmaceutical policies should aim to support a strong life sciences sector

The pandemic has demonstrated the importance of having a strong life sciences sector. This industry is crucial not just for its contributions to economic activity in Canada but also in helping protect Canadians from serious health challenges such as COVID-19 and other serious diseases and conditions.

Pharmaceutical policies should therefore strive to support the sector. In particular, approaches to formulary management should encourage continued medical innovation and the introduction of new medicines. This will help ensure that Canada remains a priority market for launching new medicines and investing in health research. In this regard, several countries are adopting new life sciences strategies and changing their drug reimbursement process to better support the sector. For instance, the United Kingdom's HTA agency NICE recently launched a consultation to improve its review process, with the goal of better supporting patients and ensuring it can play its part in "ensuring the UK remains a first-launch country for important and promising new health technologies" (https://www.pharmatimes.com/news/nice_launches_public_consultation_for_process_review_1362777).

Final remarks

We believe the federal government can play an important role in helping improve Canadians' access to medicines and drug coverage. In particular, the federal government can increase health funding to the provinces and territories so they can address coverage gaps, reduce co-pays and deductibles and expand the scope of their formularies. In this regard, we commend the federal government for recent steps taken in this direction, including the sizeable investment provided to PEI to bolster its pharmacare program. As well, we hope that the investments targeted towards a national rare disease strategy can also be allocated to the provinces to help them strengthen their coverage of orphan medicines.

Thank you again for the opportunity to provide feedback. We look forward to working with all levels of government, patients, and other health stakeholders to work on solutions that provide more equitable drug coverage and accelerate access to new medicines to address the current and future health needs of Canadians.

Please do not hesitate to contact me for further information about our views.

MS Society of Canada

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

The Multiple Sclerosis (MS) Society of Canada appreciates the opportunity to provide feedback on a potential pan-Canadian formulary. We appreciate the amount of work that the panel has untaken thus far. While we agree with the goals to be achieved through the integration of formulary decision making within the greater health care system, we have concerns about how some of the guiding principles will apply to different patient populations.

The definition of "Effective and High Quality" in the discussion paper states: "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." How is the benefit to patients determined? Approximately 90,000 Canadians live with MS, and every person will respond differently to each of the disease modifying therapies (DMT) for MS. A medication that works well for one person with MS may not have the same effectiveness in another Canadian living with MS. It is important that a pan-Canadian formulary consider the unique needs of all patient groups.

The "Efficient and Timely" principle as outlined has a high degree of complexity that seems counter to the stated goal to get the right drug to the right patient at the right time. The patient perspective must be considered in terms of timeliness. For people living with MS, timely access to the right medication can make a significant clinical impact on slowing the progression of the disease.

The definition of the "Sustainable" principle states: "The people of Canada should benefit from a formulary management system that maintains its own viability and supports long-term development and vision." This implies that a formulary system is independent of other health and social systems, whereas we would purport that investing in a robust and comprehensive formulary management system will have positive outcomes on many social determinants of health for patients that will support sustainability across multiple systems. For example, there is a direct impact on reduced hospitalizations for Canadians living with MS who have timely access to DMTs.

The "Value for Money" content value under the "Sustainable" principle also states that formulary decisions should consider the cost-effectiveness of drugs to maximize benefit for unit of expenditure. How is cost-effectiveness determined? Health outcomes must be inclusive of the broader social determinants of health and not limited to drug budgets. Without access to early or effective treatment, individuals are at high risk of hospitalization due to acute disease activity, absenteeism from employment, the requirement for family or paid care among other needed programs and services that accompany disease progression – all of which carries significant financial impacts on health and social systems.

The discussion paper also states: "The process of selecting drugs and related products for a potential pan-Canadian formulary would, ideally, consider not only clinical effectiveness and cost-effectiveness but also access to treatment" (Page 10). The selection of drugs and related products should consider the patient perspectives and outcomes with equal weighting to cost and clinical effectiveness with the aim to improve health outcomes for patients.

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

As noted in the discussion guide, there are many presumptions made and limitations noted in the process. The three selected therapeutic areas include a set of drugs that are commonly or universally included in the identified FPT drug formularies. Although we understand this is a starting point and guide, there is concern that making this broad presumption in a process does not take into consideration the current challenges with prescribing and reimbursement criteria that Canadians face in accessing drugs. Thus, the foundation of the process is flawed.

Many diseases and health conditions have multiple therapeutic options; however, they will have differing utilization rates based on prescribing criteria. First-line treatments will have a higher utilization than second- or third-line treatments. Patients who are unresponsive to higher utilized treatment must switch to a second- or third-line therapy to achieve optimal therapeutic benefit. Lower utilization within this context therefore may not translate to 'demonstration of sufficient clinical benefit'. Should the pan-Canadian Formulary expand its listing to include therapeutics for MS, this assessment criteria process may cause additional access to treatment issues related to the current approach to treating MS, which is an escalation treatment approach.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

To fully assess this question and provide an answer, more information is needed as highlighted in commentary in the other questions. For example, in Question 1, "The panel noted that applying a population health perspective might put already disadvantaged populations further behind and not allow

the needs of individual patients or communities to be adequately identified or addressed." (Page 10). This statement is not reflected in the process outlined, so we would need to understand this and other points more fully before being able to respond to this question. It is an important statement, and this philosophy needs to be reflected in the principles and throughout the implementation of the formulary. It is difficult to ascertain where and how this is integrated into both the principles and approach to creating the formulary.

Specific to MS, we have concerns surrounding the selection of drugs given the high number of Health Canada approved DMTs. Provincial and territorial formulary listings differ in drug coverage and reimbursement criteria, furthermore, generics and biosimilars are replacing innovator medications based on cost containment. It is unclear how the selection process will impact access to treatments for a disease such as MS, which requires access to the full range of DMTs due to the significant heterogeneity of the disease.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

How will national health priorities be defined and determined? More information is needed to determine if this would be important and relevant. Health priorities need to be reviewed holistically due to the significant burden of disease in many chronic health conditions.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

We are unsure at this time and would need more information, time, and resources to fully explore the options. Because MS is a disease that has numerous therapies already on the market, some MS therapies may not get prioritized in the outlined submission review processes and would discourage investment of pharmaceutical companies in Canada. No two people living with MS have the same disease course, which is why it's critical to have access to have the current full range, and newly approved DMTs on the market. What works for one person won't necessarily work for another person and time matters with MS. Access to the right medication at the right time is critical to preserve brain health.

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

In theory, we agree with the proposed criteria, though it is not clear how the evaluation criteria will differ from what is currently taking place in provinces and territories. A fair assumption is that the same issues provinces and territories face when making decisions about their formularies will occur at the federal level. Patient experience is routinely requested by provincial and territorial decision makers; however, it is perceived that the ultimate decision about public coverage for a new drug is reduced to cost containment versus innovation or improved efficacy.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

We are supportive of processes that are inclusive of the lived experience and weigh their perspectives in an equitable way to other evidence. Due to the complexity of this process, it is difficult to provide thorough commentary on the proposed criteria and its subsequent weighting.

8. 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 reviews)?

We are supportive of an iterative process that is inclusive of all stakeholders including people with lived experience. The acknowledgement of the context (e.g., resources/capacity) for each of the different stakeholders to be included is critical.

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

The MS Society of Canada is appreciative of this opportunity to provide feedback. The complexity of this proposed process and being able to adequately assess and understand and provide feedback now and in the future is challenging for many patient groups who do not have access to the same resources that are available to both industry and government. Layered on with this complexity is the disconnect to the multitude of out-of-scope elements that were outside of the mandate of this committee. Patient groups' capacity to analyze the information provided has also been further hindered because of COVID-19, which has added additional strain on organizational resources. These challenges are a reality that need to be considered in the context of this consultation.

Neighbourhood Pharmacy Association

1. Do you agree with the proposed principles and definitions?

No response provided

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. Do you agree with the proposed assessment criteria?

No response provided

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.

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3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

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.

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

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 Que_bec formulary which is the most comprehensive in Canada.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

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.

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

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. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

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. 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 reviews)?

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.

Novartis Pharmaceuticals Canada Inc.

1. Do you agree with the proposed principles and definitions?

No

Please provide the reason(s) and suggested changes, if any.

INTRODUCTION:

On behalf of Novartis Pharmaceuticals Canada Inc. ("Novartis"), we appreciate CADTH committee's work to date and thank you for the opportunity to participate in this current consultation on the Potential Pan-Canadian Drug Formulary.

As a preliminary comment, we find it difficult to respond to all questions in isolation due to the opacity of many crucial parameters deemed out-of-scope for this specific consultation. This comment applies to every question raised by this consultation. We therefore look forward to being an active partner in future discussions which we hope will be more inclusive of these crucial issues.

Discussions about the Potential Pan-Canadian Drug Formulary must take a comprehensive approach, which includes ensuring that all current and future generations of Canadians continue to have access to the best available medicines. All Canadians, without exception, deserve and expect a healthcare system that improves patient outcomes and quality of life while reducing the disease burden.

Novartis, as a member of both Innovative Medicines Canada ("IMC") and BIOTECanada, agrees with, and fully supports, the response submitted by these stakeholders.

Question 1:

Novartis' position has been and remains that no patient should be left behind. All Canadians should have access to therapies they need when they need it. This should be the overarching goal and guiding principle surrounding policy related to the Potential Pan-Canadian Drug Formulary. We believe this goal to be compatible with the core foundation of our current multi-payer system of both public and private insurance that we currently have in Canada. The particular focus of the Potential Pan-Canadian Drug Formulary should however be Canadians that currently have limited or no access to the medicines they need.

2. Do you agree with the proposed assessment criteria?

No

Please provide the reason(s) and suggested changes, if any.

The Potential Pan-Canadian Drug Formulary must take a comprehensive approach. This includes ensuring that current and future generations of Canadians have access to the best available existing and upcoming medicines.

Our position is that equity demands that all products, including new therapies, be listed immediately after HTA approval at the latest. We believe this reform to be a solution to all issues raised in this consultation. For instance, for existing therapies, the assessment criteria are reasonable but not pragmatic. It is unclear how products 'flagged for further consideration by experts' would be reviewed

and prioritized. It will be imperative to provide more information on how this would be executed, because it appears that the products falling into this category are, by definition, more likely to have inequitable access across jurisdictions.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

We believe equitable, timely and facilitated access to be the ultimate priority. In order to align with the stated principles of "universal and integrated" and "equitable", there must be a mechanism for all patients to have access to the related products that would enable the optimal use of drugs.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No

Please provide reason(s).

As stated above, we believe equitable, timely and facilitated access to be the ultimate priority. This requires flexibility to be built into the design of a new process, similar to the private market where "flex benefits" have become the standard. Likewise, digital health care solutions should be used and encouraged to support a more personalized approach to formulary design. Canadian companies in particular are at the forefront of health tech solutions. Our leadership in this field should be leveraged to provide Canadians with leading edge, world class therapies to manage their specific health care needs.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

Not all patients are the same. Once the out-of-scope parameters are more clearly defined and guiding principles established, it will be imperative to expand into other therapeutic areas to reflect this diversity. Access to the medicines in a timely manner should be the priority, and there is no reason to alter this guiding principle based on therapeutic class

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

Solutions should be identified to enable timely access to novel therapies for all patients. There needs to be a commitment to ensure that resources are available to review all products in a timely manner so as to minimize unnecessary delays for patients. We do not support prioritization at the expense of another novel therapy being waitlisted or deprioritized. Rather, we maintain that all products, including new therapies should be listed immediately after HTA approval at the latest. This is the only true solution to the issues underlining this question.

5b. What criteria could be used to identify priority products?

As per our response to 5a, there should not be a requirement for priority criteria

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No

Please provide the reason(s) and suggested changes, if any.

Canada already has a complex system for drug reimbursement. We are concerned that including another inert step in the process will not improve equity while risking further delays for patients. If this committee really is to make equitable access its guiding principle, it should strive to simplify processes rather than add new layers to an already complex one

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No

If yes, how should weight be distributed among the proposed criteria?

No. See above for rationale.

8. 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 reviews)?

Our position is that all products, including new therapies should be listed immediately after HTA approval at the latest. This would involve less resources and processes while considerably accelerating equitable access for all Canadians. We would welcome multistakeholder discussions on strategies and developing solutions for ensuring equitable access to therapy for all Canadians.

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

No response provided

Pfizer Canada ULC

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Pfizer Canada supports the comments provided by Innovative Medicines Canada (IMC) and BIOTECanada (BTC) for the CADTH pan-Canadian formulary initial framework consultation. Pfizer Canada provides additional context here:

Fundamentally, Pfizer is supportive of a goal to improve access to prescription drugs and related products to all people in Canada. However, by providing feedback to this consultation, Pfizer is not explicitly supporting the concept of a pan-Canadian Drug Formulary, as presented by CADTH, to achieve those goals.

Pfizer Canada is aligned with the guiding principles of equity, sustainability, and effectiveness in access to treatments for all Canadians. We are supportive of the proposed principles towards timely and inclusive processes. However, we strongly suggest that further efforts need to be taken to better understand the current gaps in the Canadian system, including evaluating several of the out-of-scope items identified by the panel. Furthermore, if the proposed formulary is to be integrated within the current mixed system of public and private coverage, it should include drugs reimbursed publicly across all Canadian provinces and territories to limit bias, risks, and gaps and at the same time, it should not create any additional gaps or discrepancy in any of the Canadian provinces.

Integrated should mean preserving the benefits that Canadians have access to through the existing private and public sector programs. Any new initiative should be focused only on filling the small uninsured gaps and not lowering the access denominator for other Canadians. One should be also careful in establishing boundaries to mitigate potential movements from existing benefit programs towards a new national formulary.

2. Do you agree with the proposed assessment criteria?

No

Please provide the reason(s) and suggested changes, if any.

Pfizer Canada supports the comments provided by IMC and BTC for the CADTH pan-Canadian formulary initial framework consultation. Pfizer Canada provides additional context here:

Fundamentally, Pfizer is supportive of a goal to improve access to prescription drugs and related products to all people in Canada. However, by providing feedback to this consultation, Pfizer is not explicitly supporting the concept of a pan-Canadian Drug Formulary, as presented by CADTH, to achieve those goals.

For any potential pan-Canadian formulary, it should start with the most inclusive provincial formulary and grow from there. It should not work from the lowest common denominator or start fresh. The formulary should include drugs reimbursed publicly across all Canadian provinces and territories to limit bias, risks, and gaps and at the same time, it should not create any additional gaps or discrepancy

in any of the Canadian provinces. As part of the assessment process, consultation with clinical experts was included in the framework, however it is important to note that clinical guidance, especially in areas of emerging science, can be very subjective among clinical experts. Taking a broad approach to clinical consultation will allow for more fulsome feedback. Patient's voice should be taken into consideration too in the process of the assessment.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No

Please provide details.

Pfizer Canada supports the comments provided by IMC and BTC for the CADTH pan-Canadian formulary initial framework consultation. Pfizer Canada provides additional context here:

The decision on the inclusion of related products should be driven by the medical necessity to use those devices/products as well as a strong clinical judgment to decide on the inclusion in a drug plan. The design would be best if it was focused on providing maximum flexibility to health care workers to express their clinical judgment in the decision to prescribe with a minimum required eligibility criterion for reimbursement.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

Pfizer Canada supports the comments provided by IMC and BTC for the CADTH pan-Canadian formulary initial framework consultation. Pfizer Canada provides additional context here:

We suggest that related products should be listed in the same list and have the same evaluation criteria to respect consistency in the criteria required for a product to be reimbursed.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

Pfizer Canada supports the comments provided by IMC and BTC for the CADTH pan-Canadian formulary initial framework consultation; and reinforces the following point: The formulary should include drugs reimbursed publicly across all Canadian provinces and territories to limit bias, risks, and gaps and at the same time, it should not create any additional gaps or discrepancy in any of the Canadian provinces.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

Pfizer Canada supports the comments provided by IMC and BTC for the CADTH pan-Canadian formulary initial framework consultation; and reinforces the following point: The ultimate purpose of Canada's system of reviewing and enabling access to medicines must meet the current and future health requirements of Canadians at a world-class standard, and fully involve patients in decision making.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

Pfizer Canada is supportive of the current approach of first-in, first-out to reflect maximum transparency on the process, and we ask CADTH to not move away from this approach. Any alternative approach might raise questions as to how files are being selected for priority review and what are the drivers behind that, which would enlarge the equity gap. We believe that CADTH should instead focus on removing barriers to patient access in order to reduce the time to listing and accelerate access to innovation which would help address unmet medical needs.

5b. What criteria could be used to identify priority products?

Pfizer Canada supports the comments provided by IMC and BTC for the CADTH pan-Canadian formulary initial framework consultation; and reinforces the following point: Inclusion of a multi-criteria decision analysis approach (MCDA) is an encouraging advancement as well as embedding the patient voice throughout the decision-making process. All efforts to broaden decision making beyond primarily cost considerations is of value.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Pfizer Canada supports the comments provided by IMC) and BTC for the CADTH pan-Canadian formulary initial framework consultation. Pfizer Canada provides additional context here:

A patient centric evaluation criterion that would ensure a meaningful clinical benefit should be privileged. Incorporating the use of Multi-Criteria Decision Analysis (MCDA) and imbedding the patient voice throughout the decision-making process should be considered. We believe that these recommendations should be more broadly considered within the existing Canadian Health Technology Assessment (HTA) processes, and not just considered as part of this proposed pan-Canadian Formulary. For instance, the MCDA allows decision makers to explicitly weigh certain value components of importance to

Canadians that may not be adequately captured in a more traditional HTA evaluation. Additionally, we are supportive of convenience being a criterion that favorably influences a decision to fund. Within the current HTA system, convenience is often overlooked – despite the obvious benefits to the patients and the potential to reduce healthcare resources within the institutional setting.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

Pfizer Canada supports the comments provided by IMC) and BTC for the CADTH pan-Canadian formulary initial framework consultation. Pfizer Canada provides additional context here:

A transparent and consistent framework for a decision-making process is preferred. We caution that a process of weighing the evidence or providing a score for criteria can become complex and is often subject to debate and subjective opinion. Taking into consideration the complexity of the process, we suggest the necessity to align ahead of time with all stakeholders since transparency and equity are key when making a decision. Fundamentally, Pfizer is supportive of a goal to improve access to prescription drugs and related products to all people in Canada.

8. 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 reviews)?

Pfizer Canada supports the comments provided by IMC and BTC for the CADTH pan-Canadian formulary initial framework consultation. Pfizer Canada provides additional context here:

Fundamentally, Pfizer is supportive of a goal to improve access to prescription drugs and related products to all people in Canada. However, by providing feedback to this consultation, Pfizer is not explicitly supporting the concept of a pan-Canadian Drug Formulary, as presented by CADTH, to achieve those goals.

In general, very clear, detailed, consistent, and transparent guidelines are always preferred to ensure operational sustainability. We believe any initiative undertaken, should utilize and build off the current system in place – rather than seek to create additional bureaucratic burdens on the system. Furthermore, we do not see this as an effective way to re-evaluate currently reimbursed products since there are already thorough review processes in place from Health Canada, HTA and the provincial drug plans. Lastly, since financials were out of scope from the presented framework, we cannot cover all optimization areas required to ensure the best way to address the challenge CADTH is facing.

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

Pfizer Canada ULC is the Canadian operation of Pfizer Inc., the world's leading pharmaceutical company. Pfizer's product portfolios span the spectrum from Rare Diseases, Internal Medicine, Inflammation and

Immunology, Oncology, Vaccines and Hospital products. We are dedicated to discovering medicines and vaccines to help people lead longer, healthier, and more productive lives.

Pfizer Canada appreciates the opportunity to provide feedback to the discussion paper on the potential pan-Canadian Drug Formulary. Fundamentally, Pfizer is supportive of a goal to improve access to prescription drugs and related products to all people in Canada. However, by providing feedback to this consultation, Pfizer is not explicitly supporting the concept of a pan-Canadian Drug Formulary, as presented by CADTH, to achieve those goals.

Pfizer Canada is struck that most of the out-of-scope elements of the consultation are fundamentally integral to the creation and effectiveness of a pan-Canadian Formulary initiative. This includes how a potential pan-Canadian formulary could impact current drug coverage for Canadians, how it could impact the current mix of public and private coverage, funding and governance considerations, terms of coverage and other ongoing pharmaceutical initiatives. We strongly believe that without these real-world and operational elements incorporated, it is incredibly difficult to provide adequate feedback on the proposed pan-Canadian Formulary. Therefore, while Pfizer has attempted to provide answers to the questions posed in the consultation, our feedback is limited by these significant gaps.

Additionally, Pfizer Canada believes that further examination and clarity is needed on the specific targeted populations that would benefit from the proposed formulary. The consultation identified several different (and overlapping) populations (part time workers, self-employed or contract workers, women, young people, and new immigrants) who may have very disparate needs from the healthcare system, and, in turn, this proposed formulary. We stress that more effort needs to be put towards understanding the breadth of the access issues for Canadians across the country. For instance, the 2018 Health Care in Canada Survey (HCIC) , conducted by McGill University researchers, presents a starkly different perspective than the one presented in this discussion paper. Findings in this study indeed confirm that many Canadians "do not take their medications as directed", however, the most reported reasons for non-adherence were a patient's forgetfulness and the patient's sense of wellbeing on that day. In contrast, costs of therapy, lack of access and/or lack of understanding of the benefits of their therapeutic treatment were rarely cited as the causes for the poor adherence. This suggests that a proposed pan-Canadian Formulary that seeks to provide better funding and access to medications for all Canadians, may not be a solution addressing much of the root issues affecting non-adherence.

Pfizer Canada is firmly in support of a "fill the gaps" type model that addresses the specific needs of the populations, which may mean different solutions for different populations based on but not limited to geography, ethnicity, and age. As such, we believe that any national initiative should in no way alter the quality of access to existing drug programs in the public and private systems. Furthermore, regional differences in public and private plan designs may create unique challenges that may not suit a one-size fits all formulary option. We believe that collaboration and partnership with the provinces, private insurance providers and industry, among other stakeholders are essential to finding appropriate solutions for those Canadians who are either un-insured or under-insured.

Pfizer Canada was, however, very encouraged to see the panel consider certain advancements, including incorporating the use of Multi-Criteria Decision Analysis (MCDA) and imbedding the patient voice throughout the decision-making process. We believe that these recommendations should be more broadly considered within the existing Canadian Health Technology Assessment (HTA) processes, and not just considered as part of this proposed pan-Canadian Formulary. For instance, the MCDA allows decision makers to explicitly weigh certain value components of importance to Canadians that may not be adequately captured in a more traditional HTA evaluation. We applaud the panel for recognizing that convenience should be a criterion that favorably influences a decision to fund, and that in the context of

overutilized institutional care (particularly as a result of the pandemic), the use of products that reduce reliance on institutional care should be incentivized through increase access more than ever before. Both components are not currently valued within the current CADTH HTA review process.

Finally, Pfizer Canada expresses caution to the panel on the use of prioritization models as these can often limit options for patients and get in the way of providing truly patient-centric care and would contradict with the equity concept.

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

Pulmonary Hypertension Association of Canada

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

The principles are well thought out and comprehensive. The challenge will be in reconciling the inevitable tensions that exist between them.

2. Do you agree with the proposed assessment criteria?

Yes

Please provide the reason(s) and suggested changes, if any.

This process appears to be a logical and fair place to start - we must start somewhere, even if the results are imperfect.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

The definition and/or criteria to determine the eligibility of related products should be expansive and include products essential to the administration/delivery of therapy and the effective management of daily life. The harms/side effects associated with the administration of treatment should be minimized and improve both health outcomes and quality of life for patients. Even basic and inexpensive products - such as gauze and saline - may be necessary for preventing serious health complications but inaccessible to vulnerable segments of the population.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

Greater integration of the approval and funding process for drugs/devices is good for patients by reducing delays to access and increasing consistency and equity.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

We support seeing the expansion of a pan-Canadian formulary to include special access drugs but we find it difficult to comment on this process without consideration for how it intersects with the proposed Rare Disease Drug Strategy.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

"National health priorities" is a political concept that is bound to change with the election cycle and exclude many patients with significant unmet needs.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #2

Please provide the reason(s) for your choice.

Our preference is for a combination of options #2 and #3. Option #2 provides the greatest control and still provides flexibility to adapt as priorities may change. We also would like to see the ability to piggyback on international evidence and believe the benefits of option #3 can be integrated into option #2 to reduce redundancies and speed up access for Canadian patients.

5b. What criteria could be used to identify priority products?

The scoring system should focus on prioritizing therapies that address unmet needs (as determined by patients and their caregivers) and/or represent significant therapeutic advancement.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

All of these criteria are important and this process will test our ability to reconcile the tensions present in the framework's principles.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

Alignment with patient preferences, value for money (with an emphasis on societal benefits beyond direct/indirect health care costs - i.e. return to work for patients/caregivers), and long-term thinking

should all be given weight to ensure that clinical uncertainty or financial feasibility aren't used as barriers to restrict access to patients, especially patients from small disease populations with limited treatment options.

8. 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 reviews)?

Reassessment of existing products is an important part of ensuring a sustainable system. The prioritization process applied to the expansion of the formulary could be applied to help manage resources and ensure that patient preferences, unmet needs, and therapeutic advancement are being prioritized.

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

No response provided

REACH Community Health Centre

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

Today I am addressing my letter to you as the co-chair of the Advisory Panel on a Pan-Canadian Formulary and I hope you will share it with your colleagues. I have read the report and recommendations and commend you and your co-panelists for the work you've done to develop a framework that will help guide discussions in the future. However, I wanted to raise a concern about the approach the panelists took to the issue of listing or not listing insulin products, and more specifically the decision to exclude pork insulin.

The supply of and access to animal-sourced insulin products was the subject of a two-day hearing by the Parliamentary Standing Committee on Health (HESA) in 2003, as well as the subject an Expert Panel on Insulin conducted in 2008. I appeared before HESA during its hearings and also was a member of the Expert Panel. Both HESA and the panel recommended Health Canada take steps to support ongoing access to both beef and pork insulin for those who were unable to safely manage their diabetes using recombinant DNA insulin options.

These recommendations reflected a growing acknowledgement within Canada and internationally that a subgroup of Type 1 and Type 2 diabetics are unable to safely or effectively use human or analogue insulins in the management of their conditions. For this reason, Elwyn Griffiths (Health Canada) wrote the World Health Organization in 2007 about the efforts Canada had made "to ensure Canadian patients with diabetes have an uninterrupted supply of safe and effective animal-sourced insulins". In the same correspondence, Mr. Griffiths requested that the WHO designate animal insulin an essential medicine but was told the WHO did not distinguish insulin species or type on the Essential Medicines List at that time.

Health Canada has "formally recognised that there are indeed some Canadians who need animal-sourced insulin not only to manage their diabetes, but in fact to maintain their lives." There have been no investigational studies to determine why this is the case, but it is a situation that Health Canada takes seriously and has prompted it to act to ensure ongoing access to animal insulin products within the terms of its mandate. Since 2006, Wockhardt UK Ltd. has supplied the Canadian market. At that time, Dr Pierre Charest, then Director General of the Biologics & Genetic Therapies Directorate, assured the company that the authorization of Hypurin pork insulin "generated relief to many Canadian patients with diabetes and their families." He wrote that many provinces had listed pork insulin on their formularies (some under special access) and indicated that the Directorate had also urged those provinces which had not yet done so to consider listing pork insulin on their formularies in order to make it more accessible to Canadian diabetes patients.

Ongoing access to animal insulin products has been the subject of numerous reviews and policy developments in Canada and many other countries since the 1980s. In 2002, the Cochrane Collaboration undertook a review of available evidence comparing the safety and efficacy of animal and recombinant human insulin products. With few exceptions, the group wrote, the studies – 70% of which were sponsored by insulin manufacturers – were of "poor methodological quality" and had failed to investigate essential endpoints such as mortality, morbidity and health-related quality of life issues. The evidence did not show any therapeutic or clinical advantage of recombinant human compared with animal insulins and only 40% of the studies reviewed provided information about adverse effects. Cochrane concluded that the introduction of recombinant human insulin should serve as an example of "pharmaceutical and technological innovations that are not backed up by sufficient proof of their advantages and safety." Despite these cautions, recombinant human insulin products are recommended for inclusion in the Pan Canadian Formulary, thereby providing options for those who are able to safely use them.

The Cochrane review prompted Health Canada, the FDA and other regulators to require Eli Lilly (and Novo Nordisk) to upgrade the labels on human insulin with this warning: "a few patients who experienced hypoglycaemic reactions after being transferred to Humulin have reported that these early warning symptoms were less pronounced than they were with animal-source insulin." There are very few patients in Canada currently using pork insulin, in part because few are aware that it is available. Yet it is clear that a safe and effective option is essential for those who may experience hypoglycaemia unawareness, allergic reactions to recombinant insulin brands or other reported problems.

For these reasons, I was surprised that the Advisory Panel had recommended that pork insulin be excluded from the proposed formulary. A decision not to list pork insulin on a national formulary would undermine efforts to safeguard ongoing access for those who are unable to safely use human and analogue insulin products. I urge you to reconsider the decision to exclude this important option in the insulin portfolio and to engage with officials within Health Canada's Biologics & Genetic Therapies Directorate for advice and guidance.

Roche

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

At a very high level and broadly, Roche supports the proposed principles; however to realize these principles or to fully appreciate/understand the intent of them without addressing items deemed out of scope, it is difficult to provide a complete and comprehensive answer. It is unclear how specifically these principles could be addressed through a pan-Canadian formulary, in isolation. More needs to be done than just developing a national formulary, including addressing the healthcare infrastructure and capacity across Canada to ensure that all Canadians receive the right care at the right time in the right place. We would welcome additional context and further discussion on how specifically these elements could be addressed and feel they are likely best considered through direct discussions with provinces.

The principles behind the formulary may at times be in tension with the goals of ensuring Canadians are able to access treatment. For example, for individuals diagnosed with rare conditions, the data may not be deemed as high-quality or robust due to the challenges of conducting clinical trials in these settings. Patients with rare conditions are at the forefront of our minds as we consider these particular principles and how they tie in with the National Strategy for Drugs for Rare Diseases. The principles should foster improvements in patient access, especially for individuals where there is significant unmet need.

Core principles should ensure that patients are at the center and that the systems and processes meet the current and future health requirements of Canadians, and fully involve patients in decision making. Any decision-making process should be informed by the best available clinical expertise and should allow for direct engagement between decision makers, manufacturers, and other relevant stakeholders. Access to treatment should be enhanced and support patient choice as well as clinical judgment.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The concept of starting with a sample list and moving to address the addition of new products seems reasonable. However, the process could be streamlined by eliminating the need to go through a full assessment (as per Table 2) of each of the products by therapeutic area. The emphasis should be on the assessment criteria for new products to be added to the national formulary and ensuring consistency to avoid potential loss of access to treatment. Clear timelines for assessment of new requests or reviews should also be outlined, to ensure timeliness of this process and support patient access.

The intention of Stage 1 is to establish a baseline formulary from treatments that are already on the market. For many years, new treatments have gone through a rigorous process of health technology assessment by CADTH and/or INESSS (and pCPA) prior to being added to provincial formularies. Therefore it could be assumed that the decisions to make these products available on provincial formularies are aligned with many of the key principles identified for the national formulary, and this has been confirmed with provincial comparisons showing almost 100% concordance.

Prior to this centralized review, provinces may have had their own expert committees. Therefore, by selecting products that are listed on at least 1 provincial formulary (or some similar approach), it should not be necessary to re-assess each product based on effectiveness, safety, or other factors. To go through a full assessment of these characteristics for each product requires significantly more resources. In this approach the only assessment criteria would be whether or not the product is currently approved and available for use in Canada and whether it is listed on at least one provincial formulary. As noted in the first question, patient / clinician choice and continuity of care should also be a key consideration. An additional assessment criteria could be added to exclude products that have major safety issues as identified by Health Canada, though it is unlikely a significant number of these therapies would still be on the market. It is worth noting that relatively few drugs were excluded in the sample list based on applying the assessment criteria in Table 2. For products that are listed as special authorization, the broadest criteria could be used in the context of a national formulary. This approach would reduce the risk of patients losing access to treatment as a result of inconsistencies across formularies.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

Roche agrees with the pan-Canadian formulary panel to include related products that improve patient access and improve adherence with drug treatment is important. However, for the inclusion of related products to a potential pan-Canadian formulary, it is also important to establish criteria for what would be considered related products. In some cases, related devices may be needed for the administration of the treatment (e.g. use of a spacer and mask for inhalers in young children) whereas in other cases the devices may inform the administration of a treatment or management of the underlying condition (e.g. glucose test strips to inform diabetes care or diagnostic tests to ensure optimal treatment selection). A related device should be defined as one that is necessary in order for the patient to be able to administer a product or inform the appropriate use of a product that is on the formulary per any specific criteria required for reimbursement. In cases where there is evidence of benefit from receiving the treatment, then any related product which is required in order for the patient to be able to receive that treatment should be made available in order to ensure patients are able to realize that benefit. The value of the related device in these cases is that it will lead to patients receiving the treatments they require.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

Related products, as defined in the previous response, should not be evaluated separately given that they are deemed to be necessary in order for patients to benefit from a drug listed on the formulary or necessary to appropriately manage treatment. The panel should consider automatically including related products for drugs that have already gone through evaluation to be included on the formulary. Table 3 in the discussion paper may be used to choose between multiple brands or types of related products as long as they serve a similar purpose of optimal use of any drug listed on the formulary. In

this case, the panel should further consider balancing choosing related products based on Table 3 for inclusion on the formulary, while also ensuring patient choice and preference is maintained.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

Roche supports the principles of universality and an integrated approach to all products. As noted in question 2, with the current pan-Canadian approach, the concordance rates between the provinces for all drugs is close to 100%, including oncology and specialty products. Although not in scope, the key intraprovincial differences in specialized drug programs and oncology are not the assessment, recommendations and funding, but the infrastructure and design of the different provincial healthcare systems, and patient eligibility considerations. For example, the specialized program in Ontario to fund products for HIV, cystic fibrosis and others was designed to bridge the gap in the outpatient setting as well as the patient eligibility gap. The same outpatient gaps exist in oncology with oral medications, and this varies by province, irrespective of formulary coverage decisions. Therefore how the National Formulary will be implemented is important in the consideration of specialty and oncology products.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

The current approach proposed in the consultation document suggests that older therapies would be assessed by first selecting key therapeutic areas and then identifying and evaluating products within each of these categories. However, as per our response to Question 2, a more simplified approach could avoid the need to prioritize by therapeutic area by establishing a baseline formulary from existing sources. In this way the focus could shift to adding new therapies. For new therapies, priority should be based on need (patients, population, and healthcare system needs). This would include treatments for conditions in which there are currently no effective treatments or conditions in which time to treatment has a significant impact on outcomes.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

Roche recommends the harmonization of existing prioritization methods to facilitate a shorter path to access for innovations promising to alleviate burden of disease and impact on the system. We suggest prioritization could begin concurrently with Phase 3 clinical trial design consultations with Health Canada and carry forward through Regulatory review, HTA, and pCPA negotiations. We suggest it would benefit Canadians to forgo scoring files as they come in but rather score files against key priorities ahead of time, collaborate on clinical trial design to meet those priorities, and carry this forward through all steps on the access pathway. We believe an additional National Formulary prioritization scheme has the potential to spend resources on a redundant process and lead to delays in patient access.

5b. What criteria could be used to identify priority products?

Many prioritization models already exist, we suggest choosing one that focuses on criteria such as, unmet medical need, impact on individual health, impact on population health, and impact on the healthcare system (please see answer 5A for more details).

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

Roche supports the additional criteria of equitable access and long-term thinking. Under the criteria of 'Alignment with patient and societal preferences', it is important that 'burdens to persons' includes clinical, emotional, physical, societal and economic burden to capture the broad value of health technologies. With six criteria to consider, it is important to provide clarity how those criteria would be assessed and traded-off if conflicts were to arise. Roche advocates for an inclusive and flexible deliberative process using principles and established criteria.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No

If yes, how should weight be distributed among the proposed criteria?

In Canada, a multiple-criteria deliberative process is currently employed by HTA agencies and provinces. Currently, each criterion is not formally weighted and scored, and therefore can be described as a "qualitative MCDA". While Roche appreciates that a more "quantitative" MCDA approach may improve the transparency and consistency of HTA decisions, there exists a number of challenges. In other HTA markets there have been a number of pilots, but there has not been wide adoption of quantitative MCDA. This low adoption of a more formal quantitative MCDA has been attributed to stakeholders' discomfort with a "formulaic or mechanistic" approach, methodological issues, and practical challenges, especially with MCDA decision rules. Roche supports a deliberative approach that provides flexibility in decision making, including greater consideration for patient voice.

8. 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 reviews)?

As part of a 2019 consultation, CADTH proposed a reassessment framework to monitor and re-evaluate drugs once they have been funded. At that time, Roche provided input into the framework and is supportive of a lifecycle approach. Formulary modernization is an important part of an effective pharmacare system for assessing and managing health technologies to achieve better outcomes and value for Canadians. Reassessment, especially in specific cases that support funding on the condition of reassessment, is in line with Roche's mission to accelerate patient access to innovative therapies.

We believe that HTR should incorporate reassessments mandated as a condition of funding for products in specific circumstances, i.e. a conditional pathway. This mechanism could incorporate RWE or outcomes-based agreements, and would be intended to support accelerated patient access to therapies that show promising benefits.

Formulary modernization and RTM will be resource-intensive and therefore will need a prioritization process to manage capacity issues. Therefore RTM should be limited to only a limited number of products that show promising benefit in an area of high unmet need, exhibit high clinical and economic uncertainty, and where the value of removing the uncertainty is high enough for adoption/disinvestment decisions. It is important that a data-enabled healthcare system is developed through appropriate investment in data infrastructure to enable automated execution and high-quality data to inform these HTRs and better decisions. We suggest a collaborative approach that includes manufacturers, HCPs, patients/patient groups to develop principles and priorities (e.g. developing the data infrastructure).

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

As noted in the first response, providing input is difficult in this situation where the use of the National Formulary is unknown. We realize that the wider healthcare context such as the role of the formulary, its relationship to existing formularies, and how access under existing plans might be impacted is out of scope; however many of these issues are key matters of importance for stakeholders. In addition, as there are currently many initiatives around pharmaceutical policy in Canada such as Canada's Biomanufacturing and Life Sciences Strategy, the National Strategy for Drugs for Rare Diseases and the development of a Canadian Drug Agency underway; a holistic perspective is key to ensuring the broader goals of ensuring all Canadians have access to the drugs they need, regardless of their characteristics, are met.

Provinces are responsible for the delivery of health and pharmaceutical coverage in Canada. Given these provincial responsibilities, 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. As such, we see the most practical manifestation of a pan-Canadian formulary as a voluntary or non-binding list that reflects the federal government's best advice to the provinces regarding the highest standards of coverage.

Sandoz Canada

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

Sandoz Canada is very appreciative of the work conducted by the committee and would like to thank you for the opportunity to provide input. Overall, Sandoz Canada agrees with the proposed principles. However, the procedures for how these principles should be more detailed to better understand how they will be implemented. By a more comprehensive approach, it would be easier to respond to the consultation process with a more in-depth knowledge. The scope of the mandate should have been more comprehensive to fully capture the drug needs of the population with an open consultation process as a first step to better define the sample. As such we look forward to being an active partner in future discussions.

Sandoz Canad,a as a member of Biosimilars Canada and Canadian Generic Pharmaceutical Association (CPGA), fully supports the response submitted by these industry groups.

Sandoz Canada recommends that priority be given to the following three principles:

1. “Sustainable” – Generics and biosimilars offer cost-savings that supports the long-term vision and feasibility, as well as value for money for a proposed pan-Canadian formulary. Making prescription drugs more affordable and accessible is the key value proposition of Canada’s generics and Biosimilars. We support the recommendations in the Final Report of the Advisory Council on the Implementation of National Pharmacare for mandatory generic substitution policies to encourage patients and prescribers to choose the most cost-effective therapies. We are pleased to see the commitment to emphasize the use of generic and biosimilar products, as they provide safe and effective treatments that are cost effective.

2. “Efficient and Timely” – The current patchwork of requirements needs to be optimized to avoid delays. Existing systems should be leveraged where possible to reduce costs and the potential for delays. It is important to ensure the approach does not duplicate industry and government resources.

3. “Universal and Integrated” – we support a universal and integrated approach to expand prescription drug access to those who currently lack access. We recommend that hospital products be included on the proposed formulary to ensure improved continuity of care between hospital and community pharmacy settings. We also recommend that oncology products be included as this is a therapeutic area that currently has significant disparities in access between jurisdictions.

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

Without additional information on the parameters deemed out-of-scope for this consultation, it is difficult to respond to this question in a detailed manner.

We support maximizing the use of cost-saving products through policies requiring well-controlled physician-supervised biosimilar switching and generic substitution when these products are available, as recommended by both this Panel and the Advisory Council on the Implementation of National Pharmacare.

Our position is that generic and biosimilar medicines must be added to the formulary without delay following market authorization by Health Canada in order to create the budget headroom to fund innovative new treatments and increase patient access.

As noted by the panel, Sandoz agrees that the drugs selected from the proposed sample list would not be able to fully meet the drug needs of the groups excluded by this sample. Therefore, by omitting these groups, inequities could be deepened or introduced.

That said, we believe it is important to include oncology medications and other medications that are started in hospital to ensure that access to medicines is equitable and to support the principle of continuity of care. Many patients initially receive medications in hospital and then continue the medication at home in the community.

Other examples include chronic diseases, such as arthritis, MS, dermatological/ophthalmological/ inflammatory digestive diseases, etc., which have a high societal impact (e.g. absenteeism, quality of life, ability to work or require the help of a caregiver, etc.).

Additionally, it is important to keep in mind that the system should be efficient to guarantee that patients have rapid access to the drugs. Therefore, it would be beneficial to ensure the approach does not duplicate industry and government resources.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

In order to align with the stated principles of “universal and integrated” and “equitable” there must be a process that allows for the inclusion and access to related products to ensure optimal usage. The processes and/or criteria must be transparent and flexible to ensure that patients have access to the related products without further barriers, which forms the basis for the establishment of a national formulary. This would include, for example, ongoing testing needed for appropriate monitoring and patient adherence.

However, in any process and/or criteria there should be no unnecessary clinical re-evaluation.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

If the drug meets the evaluation criteria, then any devices / testing needed for the patient to effectively use the drug must be listed on the formulary.

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

There are certain products – such as oncology and HIV drugs – that are not funded as a regular benefit on all drug plans. Additional analyses may be needed to determine whether these products are covered in other ways. The Panel suggests that these products should be included in a national formulary, and Sandoz Canada supports their inclusion. We believe it is important to ensure access to medicines is equitable and to support the principle of continuity of care when patients initially receive medications in hospital and then continue the medication at home in the community.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

Any expansion should be based on medical needs and sustainability, patient access and cost-saving, such as the availability of generic and biosimilar medicines.

Specifically, we believe that Oncology should be prioritized as this is a therapeutic area that has one of the greatest disparity in access between jurisdictions. Therapeutic areas where cost-saving biosimilars are available should be prioritized to support sustainable access. In addition to Oncology, these therapeutic areas include diabetes (already included on sample list), arthritis, irritable bowel disease, dermatology, MS and ophthalmology.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

Sandoz Canada recommends a combination of Option #1 and Option #2 be adopted. Option #1 is aligned with the current HTA process, and the inclusion of Option #2 would help to address unmet medical needs.

Although option#3 may have the potential for being inefficient, there are regulatory procedures (ACESSUK, where one dossier is submitted and approval is granted in all countries, such as Australia, Canada, Singapore, Switzerland, UK) in development that can be efficient.

Generic and biosimilar medicines must be added to the formulary without delay following market authorization by Health Canada in order to clear budget headroom to fund new treatments and increase patient access.

5b. What criteria could be used to identify priority products?

Cost-saving biosimilar and generic medicines should be automatically identified as priority products. We support a streamlined approach for the additional of biosimilars and generics whereby standardized and accelerated listing criteria is employed.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

Sandoz agrees with the proposed evaluation criteria and recommends that priority emphasis be given to the proposed evaluation criteria Value for Money.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

Without additional information on the parameters deemed out-of-scope for this consultation, it is difficult to respond to this question in a comprehensive manner. The Panel's intended meaning for "integration into other systems" is not clear and we would appreciate clarification.

Value for Money criteria should be given priority.

8. 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 reviews)?

Clear timelines with expedited/automatic listings should be available for biosimilar and generic medicines. Biosimilar switching policies should be implemented and new products should be applied to the policies when available to maximize potential savings.

The pan-Canadian Pharmaceutical Alliance (pCPA) has identified several measures that support sustainability on page 8 of its Biologic Policy Directions & pCPA Negotiations document and its September 2019 Biosimilars Review Process and pCPA Negotiations Update. Both documents can be accessed at https://www.pcpacanada.ca/biologics-biosimilars.

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

• While Sandoz Canada is supportive of efforts to improve drug coverage for Canadians, we caution against the pursuit of risky tendering schemes with unknown savings results that could threaten the current and future supply of cost-saving generic and biosimilar products in Canada.

• The COVID-19 pandemic has highlighted the need to strengthen Canada generic and biosimilars pharmaceutical manufacturing capacity and the international pharmaceutical supply chain.

• The generics market in Canada faces high inflation, like others, downward pressure on pricing and a complex regulatory regime. Combined, these elements are increasing the fragility of the domestic industry.

• By limiting the number of suppliers for a given medicine, tendering increases the risk of drug shortages and could lead to higher prices in the long-term as manufacturers are forced out of the market. If the chosen supplier or suppliers have production or other issues, alternatives to meet patient needs may not be available.

• Care must be taken to ensure that the potential benefits of a national formulary are not undercut by pricing schemes that reduce the current and future availability of cost-saving generic prescription medicines.

• A national formulary should avoid "tiering" where certain drugs are "preferred" over / prior to reimbursement of other medicines.

• We support the recommendations in the Final Report of the Advisory Council on the Implementation of National Pharmacare for the implementation of biosimilars switching policies to encourage patients and prescribers to choose the most cost-effective therapies, and increase patient and prescriber awareness about the benefits and the science behind biosimilar medicines.

• Patients should have consistent access to drug products when moving from a hospital to community setting, and vice-versa.

Saskatchewan Health Authority& RxFiles

1. Do you agree with the proposed principles and definitions?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

Yes

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

Yes

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

Yes

Please provide the reason(s).

This prioritization should also take into account the risks associated with populations that require therapies that fall outside of the national health priorities. These populations and potential risks should be acknowledged.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #3

Please provide the reason(s) for your choice.

1. improve efficiencies as mean more timely access to therapies

5b. What criteria could be used to identify priority products?

1. need based on equity and patient outcomes such as preventing hospitalizations or mortality.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

drug effectiveness and safety based on the most recent evidence

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

It depends on the drug- equal weighting with a range for e.g. 20-25% so that context can be taken into account

8. 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 reviews)?

Link into academic detailing groups that exist across the provinces- not all provinces. in Saskatchewan the RxFiles is funded by the Ministry of Health and plays a key role in reviewing evidence and bringing into front line practitioners.

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

Please consider the role of current academic detailing programs and how they can tie into your process (opportunity to leverage skills, partnerships, etc.)

Save Your Skin Foundation, on behalf of the signatories listed

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

In reviewing the proposed principles and definitions, we, as patient representatives, are governed by a vision, and set of values as outlined below that were developed by patients at a patient consultation in 2015.

OUR VISION:

All people residing in Canada have timely, consistent, equal and equitable access to the safe and effective drugs, treatments and medications, as well as the information, diagnostics, care and support that they need, without conditions. This is part of a broader vision for every person to have equal opportunity to access all social determinants of health. We also recognize the Indigenous worldview and Ownership, Control, Access and Possession (OCAP) principles that underpin them.

OUR VALUES:

Respect for people who access the health system and their support team

Meaningful and ethical engagement of people who access the health system including engagement in health systems planning, decision making, implementation, knowledge transfer and exchange, monitoring and evaluation, systems redesign.

Universality, equity and equality recognizing diversity and accommodation.

Accountability framework for all health systems processes and health policy.

Transparency and information sharing in all health systems processes and health policy decisions.

Support for health innovations.

Excellence in health systems and health policy including recognition of the importance of integrating best practices in evidence based qualitative and quantitative medicine.

Capacity building and mentoring.

Social Justice, to address the social determinants of health, and ensure that all people have access to optimal healthcare.

Recognition of the Indigenous worldview and Ownership, Control, Access and Possession (OCAP) principles that underpin them.

##

Based on the above, we submit that there are significant differences in the core values espoused by the patient community and those that were used in this initiative.

We submit that the promotion and awareness of this stakeholder engagement was significantly lacking. We also submit that undertaking this consultation solely through online form-based submission process with guided questions, rather than an open format, or the option for written submissions is not supported by our values. In any case, as described below, the complexity of the issues raised in the questions require a fulsome consultation, allowing patients and their representatives to discuss these issues in a comprehensive manner, including members from diverse disease groups, and health equity experts.

PROCESS RECOMMENDATIONS FOR CONSULTATION AND MEMBERSHIP SELECTION

Recommendation 1: Undertake an open consultation with diverse patients and their representatives through appropriate and accessible fora, including health equity experts.

Recommendation 2: Engage in a separate fulsome Indigenous consultation, as determined and managed by Indigenous stakeholders, especially given that the diseases chosen as the proposed sample list by CADTH affect Indigenous populations significantly.

ADVISORY COMMITTEE COMPOSITION AND SELECTION PROCESS

The Advisory Panel composition included:

• 2 co-chairs (a physician and a caregiver member)

• 1 ethicist

• 1 former Assistant Deputy Minister–level drug plan lead

• 1 nurse practitioner and 1 registered nurse

• 1 representative of a national health charity

• 2 pharmacists

• 5 physicians (generalists and specialists).

The Advisory Panel members are described as having been recruited from across Canada and representative of diversity across gender, culture, race, and geographic area. The panel is further described as bringing together members with a range of expertise and experience, including health care providers (nursing, pharmacy, and medicine), persons representing those with lived and living experience, persons working with Indigenous and other communities often made vulnerable through a combination of social and economic policies, and individuals with backgrounds in ethics, health policy, and drug plan leadership.

The Advisory Committee did not, however, include patients and patient representatives at all. This is particularly ironic, given that it excludes those most likely to benefit from this initiative i.e., patients from diverse populations who experience lack of access, or inadequate access, due to health inequities. Just as there are diverse healthcare representatives included in the panel, there are many diversities in patient populations and their representatives, that provide broad experiences and points of view. In

looking at the current representation of the panel, at most 7% represented populations targeted by this initiative (i.e., patients) while at least 43% were composed of physicians.

It also excluded health equity expertise such as Women's College Hospital's Equity Mobilizing Partnerships in Community (EMPaCT) group. Thus, a comprehensive group of persons representing those with lived experience was not on the Panel.

Recommendation 3: To rectify this, conduct broad, open consultations with members of these groups who request to be engaged in such consultations in accordance with the Health Canada and PHAC Guidelines for Public Engagement.

Although there was a member of the Panel from an Indigenous community, it is our understanding that this is not considered to be a process in keeping with Indigenous OCAP principles. A comprehensive group of persons working with Indigenous communities were not on the Panel. In addition, diverse Indigenous populations are required since Indigenous peoples are not monolithic and homogenous.

Recommendation 4: Engage Indigenous health and related leadership to develop and undertake a fulsome Indigenous consultation. Refer to Recommendation 2 above.

CADTH selected the Advisory Panel members with advice and guidance from its federal, provincial and territorial funders. These are not the only stakeholders who have the knowledge and expertise required to provide fulsome advice on the topic of a pan-Canadian formulary. Other relevant stakeholder groups including patient groups should have been included.

Recommendation 1 above will address this omission, at least to some degree.

##

CONTENT OBSERVATIONS AND RECOMMENDATIONS

On page 7 of the Discussion Paper, CADTH identifies 5 elements that must be addressed to develop a potential pan- Canadian formulary. CADTH was engaged, however, to support only 2 of these elements: (1) to develop processes for creating a list of drugs and related products and (2) to highlight best practices for managing a formulary.

Observation: One cannot delink these two elements from the other three.

In fact, even these 5 are not comprehensive in determining the potential for a pan-Canadian formulary. One must consider the entire healthcare environment within which these elements are situated. As an example, a list of mental health drugs, however comprehensive, is purely theoretically available unless we recognize and ameliorate the dearth of psychiatrists available to prescribe them and monitor their use, not only in rural and remote communities but even in urban settings. In addition, some drugs must be prescribed by a hospital staff physician, or recommended by a provincial psychiatric hospital regional coordinator, adding further complexities to an already convoluted system.

In addition, access is limited by long wait-times that also need to be addressed, as well as the tension between population health analyses and individual-level patient health.

Obviously, the entire concept of a pan-Canadian formulary is also theoretical without the agreement of provinces, since they have the responsibility and jurisdiction for healthcare delivery and public drug reimbursement plans. There is no point in developing frameworks for which there is no commitment to implementation even in theory, let alone on the basis of federal government recommendations.

Recommendation 5: Rather than developing lists of drugs, we suggest analyzing gaps in drug access in the public system of each province/territory and assist in filling them. A pan-Canadian group of stakeholders including patients and patient representatives can help identify these gaps and develop solutions to fill them that the federal government can provide, with provincial agreement. For example, on page 8, one of those gaps mentioned is the unaffordability of drugs that prevented 5.5% of people in Canada from taking one or more prescribed medications, mostly for treating psychiatric health conditions. Mental health stakeholders can assist in this endeavour. Another example of a gap in public drug access, in Ontario and in some Atlantic provinces, is that take home cancer drugs are not provincially covered and this would be an extremely important area to cover. People with lack of access or inadequate access due to health inequities also need help with deductibles and copays.

##

SPECIFIC COMMENTS ON PROPOSED PRINCIPLES AND DEFINITIONS

The first question that arises in attempting to analyze and comment on the principles in the Framework is the actual purpose of this framework. It is very difficult to analyze principles without context.

The "Goal" described does not fit the definition in the Cambridge Dictionary of a goal, as an "aim or a purpose." The Goal described in the discussion paper is an intention to create a formulary that reflects the health needs of diverse populations. This does not tell us the aim or purpose of this list.

There are already lists in each province/territory of publicly reimbursed drugs. It is unclear for what purpose this new list will be used. It lacks a goal.

Recommendation 6: The Goal must be rewritten and reframed to explain its purpose in order to allow a comprehensive analysis of the Proposed Framework and its Principles and Definitions. Without this, it is not feasible to provide an analysis of the Framework in terms of whether the principles, approach and elements of the Framework will in fact achieve these goals. It also makes it difficult to know what other recommendations to make to ensure that the Framework is actually required and, if so, that it has all the elements needed to be successful.

On page 10 in the last paragraph, there is a reference to making prescriptions more accessible, especially for those who currently do not have access for reasons beyond their control, including both historic and contemporary inequities. If this is the actual Goal it should be included in the "Goal" section. It must also be clear that the list would only cover people who cannot access the public system in their province for any reason and that no list can provide fewer drugs than the drugs available in the province where the person lives. It should also be a list that actually provides people with the most comprehensive list of drugs provided on provincial lists. It should also be clear that the goal would be to have the participating provinces/territories administer the programme.

Recommendation 7: Definitions are required throughout including the definition of "evidence-based "e.g., from where will they get this evidence; will it include real world evidence; what will it include, and what is meant by "diverse populations"?

Turning to the specific details under "Guiding Principles" in Table 1, we submit the following:

Recommendation 8: Under "Universal and Integrated," definitions are needed. What is meant by "universal?" What is meant by "Integrated?" Who will make the determination about what prescription drugs patients need? This is provincial jurisdiction and should be a decision between the doctor and the patient. This must be made clear in this principle.

Recommendation 9: Under "Equitable," this principle should include "equal" as well as "equitable." Equal would lead to all people getting the same drugs no matter in which province they live based on the best practice for a comprehensive drug list, which should be a compilation of drugs covered on all public drug plans across provinces/territories as a start. That said, there will need to be a plan to review the lists on a regular basis. There is a reference to monitoring under the principle "effective and high quality", but the continuous improvement commitment does not have a process that is defined or offer concrete metrics. This is required.

Under "effective and high quality," the definition of "highest standard of health and patient experiences" is not patient determined and therefore not meaningful for the patient. This criterion needs to be defined from many points of views, including those of the patients for it to have any meaningful impact.

Recommendation 10: The process of developing patient reported outcome measures should be the first step in determining the "highest standard of health." These will be different for diverse patient groups and patients at different stage of disease. Patient experience is not the same as patient outcome.

The definition of clinical values does not state that patients in specific disease groups and their healthcare providers will determine clinical benefit. Who will be making those decisions? Any analysis that does not include them as meaningful members of that decision making process is not acceptable and will not provide necessary information.

Evidence-based decisions are important but the definition of "evidence" as "a solid and defensible understanding of acceptable evidence that includes clinical trials and real-world evidence" requires further elaboration.

Recommendation 11: Each word in this phrase above requires definition and an explanation of who will be making these determinations. It is well known that there is no accepted pan-Canadian definition of real-world evidence and real-world evidence of many different kinds is held in both public and private databases. Which sources of real-world evidence will be used? In addition, there is no reference to a commitment to ensure the sources of real-world evidence will be monitored for protection of personal information and data. There is no description of the role of patients and their representatives and healthcare providers in this process which must be meaningful.

Quality improvement is definitely a mandatory part of any process. There is no explanation of timing; definition of modernized, evaluated, improved. There is also no description of who will be engaged in this quality improvement process. There is no description of the role of patients and their representatives and healthcare providers in this process which must be meaningful.

The pace of innovation, the growth of precision medicine and the use of companion diagnostics, as well as the growing understanding of the role of genetic testing among other dynamic enhancements across the healthcare system require ongoing monitoring and evaluation and continuous quality improvement. The existence of these advancements must be considered seriously in the list of guiding principles and are missing from Discussion Paper's proposition.

Recommendation 12: Based on the factors described above, a multi-stakeholder group should be created to develop and undertake a transparent and continuous monitoring and evaluation process for quality improvement, keeping pace with the rate of innovation.

Recommendation 13: Under "Sustainable," this entire section requires rewriting. The definition of what is sustainable depends on the stakeholder group making that decision. A topic in the virtual consultation referred to in Recommendation 1, must include a discussion about sustainability from the patient perspective.

Recommendation 14: Since patient representatives and health equity experts were not part of the Panel there must be a fulsome consultation including these groups to discuss their concepts of feasibility, long-term thinking and value for money. It is far too complex to include the broad base of issues that must be discussed to use this limited approach of a written submission to explore them meaningfully. A recent example of concerns that lead to this conclusion is the unilateral decision by CADTH that value for money for cancer drugs was reduced to a cost per QALY threshold from $100,000 to $50,000 with no discussion or evidence-based explanation for this decision.

Under "efficient and timely," we certainly support the minimization of duplication of steps across all government processes. We are not at all convinced that the Panel that was unilaterally selected can ensure this definition can be achieved given the very limited mandate it had. To actually achieve this definition requires provincial government engagement and support, and even at the federal level it will require a much broader cross-ministry and agency analysis and review. We would gladly engage in meaningful multi-stakeholder consultation to discuss the steps that will be required and the changes in several government departments, agencies, and organizations that will allow minimization of duplication and seamless access to drugs as required.

Recommendation 15: Convene a multi-stakeholder, multi-jurisdiction, diverse patient representative consultation to discuss the steps required for the minimization of duplication and seamless access to needed drugs. Expertise in areas including health equity, health economics and ethics must be included.

Under "inclusive, transparent and fair process," these are mandatory but the mandate of building a list of drugs in a silo from all of the other areas of the healthcare system including those under provincial jurisdiction and removed from the challenges people face with filling their prescription due to social determinants of health is simply unrealistic and will not lead to any truly meaningful outcomes.

Recommendation 16: This principle must apply far beyond this individual project, the mandate of which is not as comprehensive as it needs to be, in order to be successful for patients. We specifically note that "health organizations" are included in the list. These must include patient driven organizations and those that work directly with patients, as well as range of diverse disease groups. These groups should not be handpicked but there should be a call out for the positions including eligibility requirements to which interested patients and their representatives can apply. The entire process must be transparent.

2. Do you agree with the proposed assessment criteria?

No

Please provide the reason(s) and suggested changes, if any.

Turning to the specific details under "Staged Approach" we submit the following:

Recommendation 17: Definitions are required including what a "sample list" means; what "commonly prescribed drugs" mean; is this analysis pan-Canadian, and how? Does this include publicly and privately covered, and drugs paid for out of pocket?

Recommendation 18: Definitions are required under "Other Key Elements." For what purpose are you selecting, evaluating and making recommendations? This goes back to the problem of the lack of clarity of the overall Goals of the entire Framework.

Turning to the specific details under "Assessment Criteria" as part of Table 2, we submit the following:

PRODUCTS LISTED

These criteria are not broad enough to ensure that drug coverage gaps will be filled. Gaps result in part from the fact that each province/territory as jurisdiction to determine its own public reimbursement systems including the list of drugs covered; criteria and conditions for reimbursement and deductibles/ copays that are the responsibility of the patient. They are also responsible for setting application criteria for reimbursement including documentation required to be completed by healthcare providers and the applicant patients, e.g., Trillium Drug Plan in Ontario.

Recommendation 19: Rather than looking at a list of drugs solely, the project must be far more wholistic and tailored to the gaps in each province. In some cases, the gaps may well be the lack of necessary drugs but not always. Just focusing on this is in a vacuum will not go far enough to enhancing access for the most likely to be in need of assistance.

Recommendation 20: We do not need a new list. Rather, a compilation of the drugs already covered in all provinces/territories as a single list will be a good first step. See Recommendation 9. All restrictions on these drugs should be analyzed and removed unless a list of healthcare providers and experts in the area approve them. This will lead to more than solely equitable access (discussed below) but equal access for people no matter where they live. Companion devices, tests or diagnostics, including companion diagnostics should also be included as part of the assessment criteria, as they are co-dependent technologies. Recommendations from this Panel must include these as part of the budget for drugs to ensure appropriate access for each drug is provided should be added.

The range of precision medicine technologies that enable precision medicine is very broad and includes medicines, e.g., targeted cancer medicines therapeutics, immunotherapies, gene-therapies, cell-therapies, imaging devices, in-vitro diagnostic tests including genetic and genomic tests, digital health technologies, including clinical decision support tools, digital diagnostics and remote monitoring tools, Artificial Intelligence such as risk-predictive algorithms and gene editing technologies such as CRISPR-Cas9.

EQUITABLE ACCESS

Equitable access is far broader than age, substance use and other examples listed. Health inequities encompass a broad range of socio-economic factors that cross ministries in the provinces and federally. Education and training, employment, housing, social networks, race, sex, gender, poverty are included.

Recommendation 21: These long-term factors require multi-stakeholder, multi-jurisdictional and inter-ministerial cooperation. This Panel should be recommending this type of process. In the meantime, the Canada Drug Agency (CDA) should obtain recommendations from the patient populations experiencing these inequities in each province to determine the gaps they experience in access and should have within its mandate to develop a process to fill these gaps with provincial/territorial support.

BIOSIMILAR AND GENERIC DRUGS

The availability of these drugs should not be a criterion for assessment. While we entirely support the use if these drugs where available and appropriate, we are also entirely in support of research and development of new, innovative drugs and other treatments, that should also be accessible to patients based on healthcare provider and patient decision making.

Recommendation 22: Remove the criterion of availability of biosimilars and generic drugs.

OTHER AVAILABLE INFORMATION

This is vague and therefore it is difficult to determine what comments to make. Much more explanation is required.

Recommendation 23: Provide a fulsome explanation of what "other available information" is an assessment criterion.

Turning to the key discussion points on page 19 of the Discussion Paper, we submit the following:

LIST REFINEMENT

This is a necessary part of all such processes but the manner in which, the content of such reviews and the stakeholders engaged in so doing is a topic for consultation with broad stakeholders including patients and patient representatives. See Recommendation 1.

FORMULARY MANAGEMENT PRACTICES

We strongly disagree with the Panel conclusion on the use of least costly products including generics and biosimilars wherever available.

Recommendation 24: Where appropriate as determined by the patient and healthcare provider, these products should certainly be selected. Other options should also be available that are determined by the patient and healthcare provider based on all relevant information about the patient and his/her situation.

PRODUCTS WITH RESTRICTED LISTING STATUS

The fact that this issue is outside the jurisdiction of the Panel exemplifies the problem of such a limited siloed mandate for this Panel.

Recommendation 25: All relevant factors including restrictions are relevant to this entire exercise, and should be added to the Panel's mandate.

COMBINATION PRODUCTS

Combination products are often used and are very important to be considered. Further clarification is required on what is meant by "the flagged component will need to be further assessed and may require additional review of the combination product itself" on page 19 of the discussion paper, prior to our being able to provide additional input.

Recommendation 26: Remove this from proposition.

Turning to the discussion of non-prescription drugs and related products on page 20 of the Discussion Paper, we submit the following:

NON-PRESCRIPTION DRUGS

This requires an entirely separate consultation and set of considerations. Over the counter (OTC) drugs place additional responsibility on patients related to cost and information about safety and efficacy. Decisions about what drugs to be considered OTC are also within provincial jurisdiction and managed separately from prescription drugs. Filling the gap in access to these drugs would certainly assist those unable to afford them.

Recommendation 26: CDA must have in its mandate the determination of a process for consideration of access to non-prescription drugs, and make recommendations.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No

Please provide details.

We responded "no" for the reasons listed below:

RELATED PRODUCTS

The definition of what is intended in this category is too vague to answer. If it is referring to diagnostics, we have commented in Recommendation 20. This consultation does not provide an appropriate forum to determine such definitions and criteria.

Recommendation 27: CDA must convene a multi-stakeholder group including patients and their representatives to define specifically what it means by related products.

Recommendation 28: After a definition is established, the appropriate patient groups impacted by the definition should be convened to provide advice on next steps.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No

Please provide reason(s).

The definition must first be determined. See Recommendations 27 and 28.

4a. Do you support the proposed approach to expand to other therapeutic areas?

No

Please provide the reason(s) for your choice.

This work should not be expanded until all of the issues raised in this submission have been resolved.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

This work should not be expanded until all of the issues raised in this submission have been resolved.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

We have selected "none" for the reasons below:

FIRST-IN, FIRST OUT SUBMISSION REVIEW PROCESS

This is a very complex issue that also requires broad consultation across disease groups, stakeholder groups, jurisdictions and ministries. In general, Health Canada has recognized the different between disease groups which is the genesis for the NOC/c priority review process. Unmet medical needs, innovative activities, disease populations and numerous other factors must be considered to determine the most appropriate approach to ensure the broadest access to as many patients as possible to medically necessary drugs. A hybrid approach may be required.

Recommendation 29: The Health Canada and PHAC Guidelines for Public Engagement require the highest level of consultation for the issues of greatest importance to the public. This falls under this highest level and the broadest consultation is therefore required. Given that this issue is within provincial jurisdiction, their perspective must also be solicited.

5b. What criteria could be used to identify priority products?

See comments above, in subsection (a). These present some criteria but are not intended to be exclusive.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No

Please provide the reason(s) and suggested changes, if any.

We have selected "no" for the following reasons:

PROPOSED EVALUATION CRITERIA FOR NEW PRODUCTS

It is premature to determine these until the other issues set out in this submission are considered and addressed. We have already made comments on equitable access and the need for equal access as well. Filling gaps in each province should be the key consideration as the first step. Real-world evidence issues must be resolved as one of the additional considerations.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No

If yes, how should weight be distributed among the proposed criteria?

We have selected "no" for the following reasons:

DELIBERATIVE PROCESS

This is again a huge issue on its own that cannot be simply resolved by a written submission. This requires a broad consultation with expert advice on deliberative processes including health economists.

There are many different processes for analysis, all of which have strengths and weaknesses, about which even seasoned health economists and health technology groups disagree.

In addition, some health economists support processes that not only consider value based on Quality Adjusted Life Years and health system savings, but also broader societal benefits, which must be considered.

Recommendation 30: See Recommendation 1, and ensure expert advice on deliberative processes, including health economists, health equity experts and ethicists are included.

8. 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 reviews)?

This is not an issue for patients and patient groups to solve. Surely, Health Canada and CADTH should provide appropriate resources and time required to conduct a comprehensive consultation and develop and implement appropriate recommendations to resolve this fundamental issue of access to necessary medications by diverse patients.

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

Yes.

PART 3: REDUCING THE DUPLICATION OF PROCESSES

Patient groups strongly support this proposal. We already have obvious duplication between CADTH's mandate and the provinces' mandates in that some provinces have retained their drug review processes although the commitment was made to dismantle them once CADTH was up and running.

This process itself of developing a list of drugs when each province has already created a list, is profoundly duplicative.

Recommendation 31: A full review of government processes at all levels must be undertaken to reduce red tape, and duplication of processes is required. The siloing of this process with its limited and incomplete mandate actually adds to duplication rather than being part of the solution to it. A seamless system requires this review. That will improve continuity of care and ensure transparency as well. Ongoing transparent monitoring and evaluation, involving patients and patient groups, must be conducted.

DATA

The Public Health Agency of Canada (PHAC) is stewarding a process to develop a pan-Canadian Data Strategy.

Recommendation 32: To avoid duplication of data approaches, including patient data privacy, real-world evidence, clinical trial data referred to in the discussion paper, PHAC must be included in this initiative and lead in ensuring a consistent non-duplicative data strategy.

ENSURING CONTINUITY OF CARE

Patients and patient groups strongly support processes that ensure continuity of care.

PROJECT ORBIS

Health Canada has joined a group of other regulators convened by the U.S. Federal Drug Agency. These types of international collaboration provide effective, efficient, timely processes for reducing the time to access for medically necessary treatments. The CDA should champion, and potentially assist in navigating, the development of further international collaborations in health technology assessment and other processes to reduce duplication and enhance time to access for necessary treatments.

This represents an example of the broader mandate that CDA should be given to fill gaps, and avoid duplication of current processes.

SIGNATORIES TO THIS SUBMISSION

Kathleen Barnard, Founder and President, Save Your Skin Foundation

Martine Elias, Executive Director, Myeloma Canada

CONECTed, a network of national patient oncology organizations

Antonella Scali, Executive Director, Canadian Psoriasis Network (CPN)

Rachel Manion, Executive Director, Canadian Skin Patient Alliance (CSPA) and Canadian Association of Psoriasis Patients (CAPP)

Erin Boudreau, Director, Government/Stakeholder Relations & Quality Assurance, Institute for Advancements in Mental Health

John-Peter Bradford, Chief Executive Officer, Life-Saving Therapies Network (LSTN)

Servier Canada Inc

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

Servier's position supports the Stakeholder Feedback of Innovative Medicines Canada (IMC) and BIOTECanada, as captured in their parallel response on these Proposals. Servier would like to provide feedback, that could not be appropriately addressed using the proposed template of questions.

Considering the evolving changes in Canadian policy, the complexity in the drug funding and access procedures, we believe the current Feedback Process focusing on a potential pan-Canadian formulary should be considered from a more comprehensive perspective, which requires multi-stakeholder policy dialogue to address pharmaceutical innovation and access in Canada. We believe this could not be addressed by completing set of questionnaires. That said, Servier has taken this opportunity to comment on important points.

As a first observation, a clear role for a pan-Canadian formulary has yet to be defined. As a centrally developed drug list, a pan-Canadian formulary would be implemented and used within the different Canadian systems of funding. This needs to be taken into consideration when assessing the proposed principles and definitions from the consultation document. Considering the current Canadian systems of private-public funding, and the existing formularies within this system, the addition of any pan-Canadian formulary could unintentionally impact the access and coverage to drugs that patients are currently taking. In this context, the federal government's role may be to provide their best advice to provinces for standards of coverage. Consequently, further discussion and reflection are required to provide additional comments under a broader consultation process.

Overall, we agree with the broad principles of enhancing patient access and decision making that is based on best available evidence and meaningful stakeholder engagement processes. The following core principles are central to support patient access: being patient centered in meeting their needs, enhancing access in view of patient choice and clinical judgement, supporting predictable and transparent review and appeal process, while involving decision makers, manufacturers, and other stakeholders. Decision making must also remain flexible to address unique treatment needs in certain therapeutic areas.

In addition, we would like to attract your attention to the use of Canadian Heath Technology Assessment reports, and more specifically cost-effectiveness outcomes embodied by the ICER, a value measure that needs attention in its interpretation. It is an important topic of debate when it comes to applying it to decision making as ICERs carry an amount of uncertainties that needs to be taken into consideration in their interpretation and therefore, to narrow the ICER to a single numerical value is misleading and restrictive. The knowledge behind ICERs was developed decades ago and worth using along with an understanding of its benefits, flaws and biases. ICERs are born out of various assumptions and one must consider a range of potential values and assumptions for its interpretation. Additional controversy and challenges are associated with recent changes in the informal thresholds used for oncology medicines and these thresholds are causing prejudice in price negotiation process. Formulary decisions should not be overly driven by cost considerations but rather should emphasize and reflect the value that innovative medicines bring to Canadians.

Servier supports efforts to make prescription drugs more affordable and more accessible, while preserving the needed access for all Canadians. We appreciate CADTH committee's work and are looking forward to further dialogue and consultations.

Sun Life Financial

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

While we conceptually agree with the proposed principles and definitions, we feel that it is important to consider the ways in which the principles may come into conflict with one another. Consideration should be given to how each one would be ranked/prioritized.

We recommend prioritizing effectiveness and high quality, sustainable followed by universal and integrated.

2. Do you agree with the proposed assessment criteria?

No

Please provide the reason(s) and suggested changes, if any.

We believe that there are limitations with the assessment criteria selected. Specifically, they may not be appropriate for all disease states found in locations across Canada. For example, increased incidences of cancer or certain rare diseases in some provinces versus others.

In addition, the proposed assessment criteria for the sample list is guided mostly by the requirements of the current public drug plans. The assessment criteria should be expanded to include the requirements of Canadian employers who fund private drug plans.

These requirements include providing medical supports for employees on disability and helping to provide return to work support for employees when appropriate. Employers fund prescription drugs that keep employees healthy and productive, and that minimize absences from the workplace.

There has been an assumption made by the panel that the drugs existing on today's public formularies are cost effective and therefore the pan-Canadian formulary should draw upon these for the proposed list of covered drugs. We believe it is important to have any assumptions on the drugs validated to determine if they are the most appropriate before they are factored into the design.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

We support related products being covered as part of the establishment of a national formulary. For example, aero chambers are used to help make inhalers deliver medication more effectively.

We are agnostic as to whether the coverage is noted specifically on the formulary or through some other mechanism.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

As the remaining therapeutic areas are prioritized, we believe that the principles of diversity, equity and inclusion should be included to ensure the differences in disease prevalence across the country are accounted for. Mental health and disability are focus areas for Sun Life and our clients. We encourage the government to place priority here when considering the list of national health priorities. Prioritization efforts should also consider the experiences of both private and public payers to capture the needs of all Canadians. We encourage the government to focus on these areas when considering the list of national health priorities.

The proposal to include cancer and special drug programs in the pan-Canadian formulary is interesting as typically these programs are funded partially or entirely by the public plans. Cancer programs vary substantially across the country. There have been changes to the types of products covered with the advent of oral cancer products, as an example. In certain jurisdictions such as Ontario, IV chemotherapy is primarily funded by the provincial program. Other jurisdictions have a program that covers a mix of IV and oral products.

The variations in public plan coverage for cancer, using only those programs as the basis for assessment criteria will leave a large void in the number of products reviewed and potentially included in a pan-Canadian National Formulary. It may be helpful to consider the unique nature of cancer drug coverage when developing final recommendations.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #1

Please provide the reason(s) for your choice.

At Sun Life, we continue to review our processes to ensure that we are operating efficiently. We also monitor the latest therapeutic advancements to provide supports to patients as quickly as possible. In addition, employers across Canada want their employees to be healthy and to have access to the treatments they need to be part of their workforce.

In line with these points, we support option 1 as outlined in the consultation guide. It is important that private plans are aligned with the process Health Canada takes and this option provides for a predictable process to identify advancements that would benefits Canadians.

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes

Please provide the reason(s) and suggested changes, if any.

We support the idea of having a deliberative process that includes transparent scoring for criteria. Specifically, we recommend prioritizing value for money, equitable access, and clinical benefit as the highest weighted criteria.

We also encourage the government to include the perspectives of both public and private payers when considering criteria. This can be addressed through the inclusion of both groups as part of the Expert Committee.

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

We support the idea of having a deliberative process that includes transparent scoring for criteria. Specifically, we recommend prioritizing value for money, equitable access, and clinical benefit as the highest weighted criteria.

We also encourage the government to include the perspectives of both public and private payers when considering criteria. This can be addressed through the inclusion of both groups as part of the Expert Committee.

8. 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 reviews)?

As we have noted in the Rare Disease Strategy consultations, we believe that it is important for the government to establish a central coordinating body. Consideration will need to be given to the role that the various players in the space play including CADTH, the pan-Canadian Pharmaceutical Alliance, the Canada Drug Agency, the Patented Medicines Pricing Review Board, private payers, and provinces in relation to the coordinating body.

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

We recognize that the scope for this consultation was limited, however, we believe it is important to identify the connectivity between some of the out-of-scope items and the success of a national formulary.

Specifically, it will be important to ensure that current drug plan processes are all factored into the design of a formulary. This would include the interplay between private and public drug plans and ensuring no disruption in access for patients.

As we noted above, a strong governance structure that considers all players in the space will be a critical component of implementation.

Finally, as we work closely with Health Canada on a range of other initiatives, including the Rare Disease Strategy, it will be important to understand the ways in which a national formulary is part of these other streams of work. We want to ensure that any unintended impacts for plan members and sponsors are identified and mitigated.

This would include ensuring that the potential for the implementation of a pan-Canadian formulary resulting in a loss of coverage for Canadians is avoided as any loss of coverage would have a substantive impact on their health and wellbeing. The implementation criteria (i.e., mandatory, optional, as a base) will need to be clearly agreed-upon early on in development as this can have further repercussions.

We recognize that this is the first stage of the process. We also appreciate that the linkages to Health Canada's work on broader prescription drug issues may not be clearly identified yet. We hope that our submission has demonstrated our expertise and key elements that will need to be considered as this work continues. We look forward to continuing to be part of this process and would be happy to continue to share our experience and expertise as you further refine your approach to the pan-Canadian formulary.

Takeda Canada Inc.

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No response provided

Please provide the reason(s) for your choice.

No response provided

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

Consultation on a Proposed Framework for a Potential Pan-Canadian Formulary

Takeda's Recommendations to Ensure Canadians get Access to the Right Medications at the Right Time

February 25, 2022

Takeda Canada Inc. (Takeda) is making this submission in response to the call for input on the Canadian Agency for Drugs and Technology in Health (CADTH) Discussion Paper on a proposed framework for a potential pan-Canadian formulary.

Executive Summary:

While Takeda recognizes that the Discussion Paper focuses on certain in-scope elements of a potential pan-Canadian formulary, linkages to existing drug plans, provincial and territorial jurisdiction over health care, and the impact on patients – including those with rare diseases – need to be considered in exploring a potential pan-Canadian formulary.

Takeda's response focuses on the following high-level recommendations:

1) Address gaps within the system while respecting the autonomy of the provinces and territories

2) Support increased and equitable access to rare drugs for Canadians

3) Align and coordinate drug policy initiatives under a clearly understood objective supported by the provinces and territories

Takeda is pleased to provide feedback on the CADTH Discussion Paper on a potential pan-Canadian formulary. As a leading company in rare disease, with a clinical pipeline in which ~50% of our products have orphan drug designation, Takeda plays a valuable role as a pharmaceutical partner that brings a unique perspective to this important discussion. It is through collaborative discussions with all levels of government, industry, patients, healthcare providers and other stakeholders that we can work together to support Canadians with a strong healthcare system that includes timely screening, diagnosis, and access to the right innovative medications at the right time.

Takeda is grateful for this opportunity to share its feedback in the form of a written submission. While Takeda appreciates the important elements that were in-scope such as: exploring guiding principles, developing a sample list of commonly prescribed drugs and establishing criteria and a transparent process that could expand the formulary list – there were critical components that were deemed out of scope. Key elements such as: governance structure, funding and terms for coverage, and patient eligibility need to be better explained by both CADTH and the government in order to provide substantive feedback.

Takeda supports the Innovative Medicines Canada/BIOTECanada submission – particularly the recommendations on the core principles. These principles are to support robust patient access, regardless of policy mechanism: 1) Patient Centered; 2) Access Enhancing; 3) Predictable and Transparent Processes and Appeals; 4) Expertise and Stakeholder Perspective in Decision Making; 5) Excellence in HTA.

In addition to the industry submission, Takeda is pleased to offer its reflections on the Discussion Paper with the following high-level recommendations:

4) Address gaps within the system while respecting the autonomy of the provinces and territories

5) Support increased, equitable and timely access to rare drugs for Canadians

6) Align and coordinate drug policy initiatives under a clearly understood objective supported by the provinces and territories

Addressing gaps in healthcare while respecting the autonomy of the provinces and territories:

Like most stakeholders, Takeda believes that all Canadians should have equitable access to the medications they need – regardless of income, age, or postal code. Takeda is supportive of a universal national pharmacare system that leverages the strengths of the current mixed public-private model. Generally, Canada's mixed system of public and private coverage works well to meet the needs of Canadians by providing high quality prescription drug coverage for most Canadians. A recent review undertaken by the Patented Medicines Pricing Review Board demonstrated that formulary listings for 307 CDR-reviewed medicines are relatively consistent across most of Canada's public drug plans.1 That said, gaps within the system do exist. According to the December 2017 Conference Board of Canada report entitled "Understanding the Gap" the proportion of uninsured Canadians in Canada is 5.2 per cent.2 Takeda encourages governments to continue working towards filling existing gaps in coverage. Much like we have seen recently in Ontario with the announcement of an advisory panel to explore making benefits portable for Ontarians working in industries like hospitality and the gig economy.3

However, there needs to be a recognition that the provinces and territories have constitutional responsibility for health care, including pharmaceutical coverage. In doing so, the provincial and territorial drug plans maintain their own formulary lists and associated listing criteria.

The foundation of the Canadian health system is provincial and territorial autonomy to best address their local needs. For example:

Quebec –in 1997 introduced a private-public drug coverage system that requires all employers to provide private drug coverage for their employees.4 Those who do not have private insurance are required to contribute to an insurance-style drug plan from the provincial government with premiums that are geared to income with annual ceilings.

Ontario –in 2018 launched OHIP+ to support children and youth 24 years of age and under who are OHIP-insured but are not covered through a private plan. 5

Prince Edward Island –in August 2021 signed the first federal/provincial agreement to accelerate the implementation of a universal pharmacare program. 6

While all three examples are distinctly different, they do address the realities of their respective provincial health care needs. Provinces and territories, backed by their Constitutional authority have been asking for Canada Health Transfers that respect their jurisdictional autonomy. The same must apply to any pan-Canadian formulary, and at this point, it is unclear how engaged provinces and territories are in this process and exactly how such a formulary would be implemented. Simply put, from a provincial and territorial perspective, what problem are we looking to solve, do provinces and territories recognize that problem, and is there a willingness for federal intervention to help address that problem?

Support increased, equitable and timely access to rare drugs for Canadians

As a pharmaceutical leader in rare disease, Takeda understands the importance of targeted, personalized medicine. Rare diseases impact about 1 in 12 Canadians, two-thirds of whom are children.7 Innovations in healthcare have shifted from "one-pill-fits-all" to a more tailored approach. As a result, patients who may have been presented with minimal options for their less common or rare disease in the past are increasingly seeing more treatments available for their condition. With these innovations, patients are seeing better outcomes. As such, formulary decisions should be timely and not be overly driven by cost considerations but rather should emphasize and reflect the value that innovative medicines bring to Canadians and the broader health care system.

Takeda is encouraged by the federal government's commitment to a rare disease strategy. The focus of a pan-Canadian formulary should complement the work of the federal rare disease strategy and patients with rare diseases. In fact, rare disease has been highlighted as an option in national discussions as we have heard from provincial jurisdictions such as Ontario.8

While Takeda recognizes that Health Canada's Drugs for Rare Diseases strategy is ongoing, we believe that a strategy for rare diseases needs to be considered as part of the discussion on a potential pan-Canadian formulary, especially since many of the key issues noted in the Background section of the Discussion Paper are issues that are felt to a substantial degree by patients and families dealing with a rare disease. These are often the patients that fall through the "cracks" in the healthcare system. Takeda has recently released the Strategies for Rare Diseases: International Landscape Report as a tool to help advance discussions on a national strategy for rare diseases and we commend the federal government for its commitment to this strategy and the funding allocated in support of it.9

Align and coordinate drug policy initiatives under a clearly understood objective supported by the provinces and territories:

These unprecedented times have reinforced the importance of Canadians having access to the right medications at the right time and in the right place. During the pandemic, the pharmaceutical sector in partnership with governments and other stakeholders have been agile in addressing urgent needs and challenges. Takeda encourages governments to continue this spirit of collaboration as we move beyond the pandemic to address other health care challenges.

It is promising that within the past few years the federal government has made progress on several pharmaceutical policy related initiatives such as the Canada's Biomanufacturing and Life Sciences Strategy10 and a National Strategy for Drugs for Rare Diseases 11. Takeda also appreciates that the federal government has delayed implementation of the Patent Medicine Pricing Review Board (PMPRB) regulations to July 1, 2022 to allow the federal government to further engage stakeholders on the application of these amendments within the changing pharmaceutical landscape. That said, the impending PMPRB changes already have, and will continue to have a destabilizing impact on the broader life sciences sector, Canada's ability to attract clinical trials and ultimately jeopardize patients' access to new medicines.12

As government moves forward with pharmaceutical and health initiatives – such as a potential pan-Canadian formulary – it is imperative that they are not done in silos or fragmented, as the initiatives are highly interconnected in nature. Takeda is encouraging CADTH and the Advisory Panel to work collaboratively with Health Canada, FPT governments (bureaucratic and political), the Canadian Drug Agency, and other key stakeholders to take a more holistic approach to healthcare systems and pharmaceutical policy. A key recommendation regarding next steps would be to incorporate the potential pan-Canadian formulary with other major policy initiatives into a more comprehensive, multi-stakeholder policy dialogue or forum to address pharmaceutical access and innovation in Canada, including a rare diseases strategy. This forum could connect the many interrelated, but disparate policy streams currently being discussed in isolation within a whole-of-federal government approach.

The challenge associated with CADTH's mandate to build out recommendations for a potential pan-Canadian formulary is certainly recognized, and Takeda appreciates the work that went into the development of the Discussion Paper. However, there are several questions that require clarity to substantively provide input on this initiative, such as: exactly how this formulary could be used, what tools would be leveraged by the federal government for implementation, what impact analysis will be done to assess access to existing and new innovative medicines, what is the problem being solved from

a provincial and territorial perspective, and finally, how this initiative fits within existing pharmaceutical policy initiatives such as a strategy to support rare drugs. Takeda would like to thank CADTH for the opportunity to comment and look forward to further dialogue and policy to help shape the future of Canada's healthcare system.

Legal Disclaimer

This submission and any other engagement in consultations with this matter are without prejudice and are not intended and should not be interpreted as supporting any prescribed outcome or legislative reform. Takeda continues to have concerns about the legality of the Patented Medicines Regulations, as amended, related Draft Guidelines, which are the subject of an ongoing legal challenges.

Reference links:

1. https://www.canada.ca/en/patented-medicine-prices-review/services/npduis/analytical-studies/formularies-part3-medicines-assessed.html

2. https://www.conferenceboard.ca/temp/2fcebaaf-285e-4fcb-9984-85e24c252a5f/9326_Understanding-the-Gap__RPT.pdf

3. https://www.ontario.ca/page/portable-benefits-advisory-panel?utm_campaign=%2Fen%2Frelease%2F1001523%2Fontario-working-for-workers-by-moving-towards-expanding-health-and-wellness-benefits&utm_term=public&utm_source=newsroom&utm_medium=email

4. http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=5&file=1996C32F.PDF

5. https://news.ontario.ca/en/release/48686/making-prescription-drugs-free-for-people-65-and-over

6. https://www.canada.ca/en/health-canada/news/2021/08/government-of-canada-and-prince-edward-island-accelerate-work-to-implement-pharmacare.html

7, https://www.canada.ca/en/health-canada/services/licences-authorizations-registrations-drug-health-products/regulatory-approach-drugs-rare-diseases/about-drugs-rare-diseases.html

8. https://ipolitics.ca/2019/11/21/elliott-says-ontario-doesnt-want-full-pharmacare-overhaul-urges-focus-on-drugs-for-rare-diseases/

9. https://www.takeda.com/4ae35c/siteassets/en-ca/home/newsroom/strategies-for-rarediseases/strategies-for-rare-diseases----international-landscape-report--dec-2021-en.pdf

10. https://www.ic.gc.ca/eic/site/151.nsf/eng/00019.html

11. https://www.canada.ca/en/health-canada/programs/consultation-national-strategy-high-cost-drugs-rare-diseases-online-engagement/what-we-heard.html

12. https://lifesciencesontario.ca/wp-content/uploads/2020/02/Research-Etc.-PMPRB-Survey-02-03-20.pdf

The Canadian Arthritis Patient Alliance

1. Do you agree with the proposed principles and definitions?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The proposed principles are well accepted throughout the Canadian healthcare system. An additional principle should be added, patient centered. Currently so much in healthcare is focused on the system. We need to focus on the person receiving care and what is best for them in meeting their needs and improving health outcomes. There are many claims around being patient centered but not in practice, depending on the perspective the definition of what patient centered means can very different.

The panel membership does not represent the principles proposed in the discussion paper. There is no patient lived experience or representation from marginalized populations (at least that is obvious) which is unacceptable for a project like this. It would be useful to understand why these perspectives were not included in the panel, and further, how these perspectives will be sought out in addition to the opportunity to provide this type of submission, which for many individuals, is not accessible.

This discussion paper addresses extremely complex processes and health policy which makes it very challenging for most patients – this means people with lived experience of a health condition(s) - to be able to contribute. There is more that is out of scope for this project than what is in scope. It is very challenging to provide input into one piece of pharmaceutical policy and ignore all the other systematic barriers to Canadians being able to access the medicines they require.

A number of years ago the Federal government launched a National Pharmaceutical Strategy and produced a comprehensive report (2006). A great deal of time and energy went into this work but only pieces of it moved forward. One of the proposed principles here is 'timely and efficient,' which always seems to be a struggle in the policy world. Canada needs to stop trying to reinvent the wheel, many countries have a national pharmacare program. We can learn from others who have successfully implemented one as well as taking into consideration the extensive work that has already been done in our country.

This current work needs a vision, what will be accomplished? There are serious inequities to accessing medications in Canada. Those who are privileged to have private insurance plans are able to receive what their healthcare provider deems necessary to treat their medical needs. The panel seems to represent this particular population, and even though they may feel they serve the interests of others, not having those voices on the panel is a missed opportunity. Canadians who rely on a public drug program are at the mercy of a complex, difficult to navigate, convoluted broken system that has not been meeting the needs of Canadians for decades. As a result, this work needs to address the process of accessing medications and not just the list of medications on a formulary.

2. Do you agree with the proposed assessment criteria?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

The proposed assessment criteria seem reasonable. It makes sense to exclude drugs that Health Canada has safety concerns with, but it could further the gap between what patients can access who

have private coverage and those who are more vulnerable and rely on public drug programs. In addition, assessment criteria need to explicitly consider unique populations, such as pregnancy and lactation. Although this was noted as a step in the process or reason for using a criterion, it did not clearly become an assessment criterion. Women of childbearing age are diagnosed with a range of health conditions and are often limited by the evidence when choosing among therapeutic options. It is important to consider this specific gender lens when assessing medications therefore it is recommended that this be explicitly noted as a criteria in order to ensure prioritization of treatment choices for vulnerable populations.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

The criteria needs to be flexible to meet the diverse needs of patients as everyone responds differently to treatments depending on their disease, co-morbities and other drugs they may be taking. If the product listed on the formulary is not working for the patient there should be alternative options. If the product is in short supply, other options need to be available. As an example, during the pandemic, people living with inflammatory arthritis have experienced issues accessing their medications because the drugs may or may not have shown to be effective in treating the effects of COVID-19. For example, we know that lupus patients were being limited or denied refills on their hydroxycloroquine even though there was no evidence or effectiveness in treating COVID-19. Alternative drugs to treat Lupus are not listed on public formularies leaving some patients with little or no treatment options.

The criteria listed seem appropriate, however, as with anything, the absolute devil will be in the details. For example, the proposed criteria of 'alignment with patient and societal preferences' – how will this information be collected and decided? Currently one may argue that CADTH has processes related to this, but it is questionable how much this is weighted in decision making. Will the criteria be equally weighted for decisions to be made about what goes on the formulary list, or will they each be weighted separately? And if the latter, it's important to know what that weighting will be.

We have often seen research evidence used to determine societal values and often evidence is incomplete or use methodologies that do not adequately capture the range of patient experiences. Input directly from people with lived experience is crucial to balance out the approach and ensure patient needs are adequately represented and considered in decision making.

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

Related products should be listed in the same list with the same evaluation criteria applied. People living with Rheumatoid Arthritis are experiencing issues accessing Actemra as it has been shown to be effective in treating COVID 19, if not for considerable effort by our clinicians to switch patients from the IV indication to subcutaneous administration many patients would not have been able to remain on a drug that was working to treat a serious and disabling disease clearly demonstrating that multiple drug options are necessary.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

Answered in 3 a

4a. Do you support the proposed approach to expand to other therapeutic areas?

No

Please provide the reason(s) for your choice.

There is a lot in the discussion paper that is out of scope, more than what is in scope. It is difficult to pull one thing out of healthcare without taking into consideration the entire health ecosystem or an individual's life, which should include impact on health services, long/short term disability, long term care and the real world impact on someone's life. These latter impacts may include the abilities to accomplish daily activities of living, care for children and be employed. "Value for Money" needs to be seen in the most inclusive and broadest sense. For example, drugs are just one part and a large percentage of drugs are paid by private payers and out of pocket by patients which are never included in health spending reporting. The proposal needs to be part of a larger Canadian conversation about health and the healthcare system generally.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

The remaining therapeutic areas should not be prioritized based on national health priorities but on the number of Canadians affected by the disease or condition which is how the panel identified the initial three disease areas. We have facts on numbers of people with diseases and annually costs – drug and healthcare wise to Canada and these should be taken in to account. History has clearly shown that it is very challenging for all provinces to agree on pan Canadian initiatives (in fact in the inflammatory arthritis space, not all public formularies even cover the same medications), how are the provinces engaged throughout this work to help with the practical aspects of adopting a pan Canadian formulary.

We also need to be mindful that if we are going to rely on 'information about safe use in pregnant and lactating women,' this is directly connected with ensuring that more diverse populations are included in clinical trials moving forward or cohort studies are funded once a medication comes to market. This particular population is often excluded from studies (which we saw widely happen with COVID-19 vaccine development), and which then puts these populations at risk when decisions are made based on available data. We are not saying data from studies is not important – but we need to do more to either fund cohort studies (real-world) of individuals in these populations or encourage this (where reasonable) from the point of designing clinical trials.

The working group noted must also include representation from people with lived experience. They are experts and deserve to be part of a conversation about which drugs are selected for inclusion in the formulary.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

Option #3

Please provide the reason(s) for your choice.

The principle of equity and fairness needs to be a top consideration when considering additions to the formulary. Canada, with so many independent health systems and within those systems too many silos that don't communicate with each other, already has too many inequities that inhibit access to care and negatively impact patient outcomes. We need to be very careful not create additional barriers to treatment. This includes streamlining the timelines for listing a medication and ultimately affects when a patient can access a needed therapy.

Option 3 proposes working together at an international level to review and prioritize products collectively. On the surface, at a time when resources often seem constrained, this makes sense. While in some instances, Canada might be unique based on its population (for example, some diseases such as MS and Crohn's disease have higher numbers in Canada than other countries), in general this approach to collaboration and best use of resources appears to be an idea worth exploring.

5b. What criteria could be used to identify priority products?

The criteria proposed are alignment with patient and societal values, clinical benefit, feasibility of adoption into health systems, and value for money, all seem reasonable. We might add that prioritizing vulnerable populations, such as pediatrics, pregnancy, and lactation, could also be a new criteria.

As stated before though, the fine details matter, and is of utmost concern with respect to 'patient and societal values.' An example to illustrate this right now is the clash between immunocompromised individuals' values and those of policymakers and a large part of the population who simply are hoping/wishing the COVID-19 pandemic is over and abandoning a number of evidence-driven protections that are currently in place. Simply put, which 'wins' out here – patient or societal values, who decides, and how will these criteria be weighted? And until policymakers see qualitative evidence on par quantitative evidence that decision makers prefer to use, saying that patient and societal values will be on equal footing with these other criteria, is likely not being completely transparent.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

Yes-in part

Please provide the reason(s) and suggested changes, if any.

See our response above in 5b – it is really directly aligned with this response.

Another consideration is who is making the decisions about identifying new products. As we know from current CADTH processes (which it's unclear from this proposal about whether or not these will be used), the public members are often few and don't necessarily understand what it's like to live with

a particular condition. While these members may have experience in debating and making decisions, we know as patients ourselves that: 1) there is always a power imbalance in any room where you are identified as a patient or public member. No matter your credentials, you are often seen as not being at the same level as perceived 'experts' in the room; and 2) it is simply not fair to expect these individuals to represent the voice of all patients, no matter how well intentioned the committee or organization is. So as per our other comments, howe these actually gets done needs a serious think and needs operationalization input when the time is appropriate. While it may not seem this is the time to bring up these details – these do need to be considered as part of this exercise.

Creating the framework for a national formulary represents an opportunity to improve the current state of patient engagement within our health care system. If the pandemic has demonstrated anything, it's that we need to hear directly from a broad group of people directly affected by decisions or risk further erosion of trust in government decision making processes. Directly related to this is the question of how can government better support patient organizations to be able to contribute the patient perspective?

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

Yes

If yes, how should weight be distributed among the proposed criteria?

We have highlighted this in some of our other responses as being something that needs to be considered. This is extremely difficult to answer – as patients ourselves, we see many decisions being driven in healthcare by the economic benefit, which is important to help us build sustainable systems for all Canadians. However this isn't the only thing that needs to be considered. We also see in our current systems that patient input can appear to have little affect on decisions – as we've highlighted previously that qualitative evidence doesn't appear to be seen as robust as evidence for example, from randomized controlled trials. We encourage an approach that considers some flexibility. Maybe in some instances where there are very few options for patients and a great need for new ones, this actually means being more mindful of potential clinical benefit for a smaller number of people who could really benefit. We know this is not a robust response, but there is concern that always having certain criteria weighted higher than others creates inequities for some disease areas.

Also, weighting of evidence or scoring is deeply affected by which stakeholders are involved in making the decisions. Patient organizations and people with lived experience are often only one – maybe two – voices in a larger discussion where interests inherently lie as actors within the health care system. Weighting of evidence or perspectives can only be viable if there is robust engagement of communities directly affected by the decision. In this regard, CADTH has to evolve substantially in its efforts to engage patient organizations and people with lived experience.

8. 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 reviews)?

Unlike the current drug review process in Canada, patients living with the disease/condition impacted by the drug under review should be engaged throughout the entire process not just as an afterthought

or spending hours and extensive resources providing a patient input submission that may or may not be considered by the review committee. The review committee needs to see the impact that the disease has on real patients and hear the hopes that the new drug has for a better health outcome. Unfortunately, clinical trials don't always measure and capture the outcomes that are important to patients often due to their strict eligibility criteria, they leave out important subsets of the population (as we have witnessed first hand with people living with inflammatory arthritis being excluded from COVID19 vaccine trials). Having patients living with the disease that the drug under review is intended to treat could potentially bring forward real world impact that would otherwise be missed. Additionally, looking beyond randomized controlled trials is also important. While we understand these trials provide the most robust evidence, much work has also been done to indicate the populations in clinical trials are sometimes not entirely representative of a population living with a disease. As such, observational cohorts can also provide evidence based on patients who live with other comorbidities and who are often more representative of the actual population. These other resources that provide real world evidence should be considered.

Evaluating the impact on patient access and outcomes from the initial three therapeutic areas is critical. A detailed impact analysis of the proposed framework and the proposed sample lists should be conducted and released publicly. There should also be multiple opportunities to continue to engage, beyond these types of submissions. There should be more than one webinar opportunity and outreach to patient communities and organizations. t

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

No other comments

The Hospital for Sick Children Research Institute

1. Do you agree with the proposed principles and definitions?

No

Please provide the reason(s) and suggested changes, if any.

Principle: Whose needs should be prioritized?

The report provides only superficial recognition that equity issues should be addressed. The report's presentation of equity issues is limited to discussing equity in access and equality in health outcomes thereby failing to apply a suitable EDI framework to all phase of the work. Whose needs should be prioritized should be determined by proactively identifying vulnerable and/or underserved populations with unmet health needs, such as children, young adults, indigenous communities, women, low income groups, homeless, rural and other groups. There is no mention of applying validated equity frameworks such as the PROGRESS framework (O'Neill et al., J Clin Epi, 2014) that are currently in use by some HTA agencies in Canada. A process value that seeks to use data to only identify inequities in access is insufficient.

Principle: What standard of effectiveness will be acceptable?

The content value, for Clinical benefit, "Listed drug products should address relevant health conditions, by incidence and prevalence" is very concerning. Prevalence using what data source -- a claims database for a drug plan that serves predominantly seniors? Unless incidence and prevalence estimations are stratified according to vulnerable populations that display unique health conditions and unique health needs, e.g. children, then the process reflects a form of prevalence-incidence (Neyman) bias: exclusion of individuals with less frequent disease in the data source resulting in a systematic error in the estimated importance of that class of medications. It is biased and inequitable to structure the formulary or make listing decisions based on prevalence of the population as a whole. This only serves to reinforce limitations of current public drug plans that fail to meet the needs of vulnerable populations, see for example, https://cichprofile.ca/module/3/section/5/page/publicly-funded-drug-coverage/ and https://www.youtube.com/watch?v=72sudlK-ABk .

Principle: Who should benefit from the potential pan-Canadian formulary?

Content value: value for Money

Cost-effectiveness from which payer perspective? A formulary or restricted public health payer perspective is not recommended as it ignores the equity-efficiency trade-offs and fails to consider spillover effects and benefits to family members and caregivers that are only captured by a societal paper perspective. Increasingly HTA agencies are including societal perspectives for cost-effectiveness analysis of medications and this is also recommended in guidelines, such as the US Washington Panel.

2. Do you agree with the proposed assessment criteria?

No

Please provide the reason(s) and suggested changes, if any.

Stage 1 of the process, "Consideration included those therapeutic areas involve drugs with the highest utilization, which diseases are the most significant and growing in prevalence, and which conditions account for high numbers of clinician visits and/or hospitalizations in Canada" is a violation of equity principles as it ignores the medication needs of vulnerable and minority groups, particularly children and patients with rare diseases. While expedient, there is no ethical justification for using population-wide prevalence as an acceptable criterion for national formulary building or expansion.

The panel appears to recognize that using FPT formularies may omit some drug classes but stops short of acknowledging that these plans are not designed to serve the needs of all segments of a population. The vast majority of claims in FPT formularies are for seniors. The panel further recognizes that " there may be some population groups, such as pediatric patients, whose needs may not be fully met by the drugs on the proposed sample list" and "additional steps would be needed so that drugs can be added to the proposed list" but does not provide any details of how this will be done. Deferring attention to classes of medications that address unmet needs to "when the sample list undergoes further review or refinement" reflects the panel's bias that the needs of current FPT formulary beneficiaries, i.e. seniors, be prioritized. In considering which drugs should be added to meet the needs of vulnerable populations, identifying these needs and gaps should not be incidental, but requires thoughtful systematic planning using a suitable EDI-framework.

The report paradoxically states that the proposed assessment criterion that a product would be listed if it appears on all or most FPT formularies will address inequity. In fact, this approach will only serve to reinforce inequities currently built into FPT formularies that exclude many vulnerable groups by design. If vulnerable patient groups and the medications they require are systematically omitted from all formularies then equity cannot be achieved. It is incorrect to claim that omitted products are only omitted due to reasons of safety or ineffectiveness.

With regard to Formulary Management Practices, the report fails to recognize that biosimilars are distinct from generics. Mandatory switch polices for biologics such as infliximab have been opposed by patients and clinicians for patients who are well managed on originator biologics. Such a substitution policy should not be considered without input from patient groups and prescribing physicians.

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

Yes

Please provide details.

The prioritization of products for diabetes reflects the panel's bias toward adult diseases covered in most FPT formularies. In fact, asthma is far more prevalent in children who also require spacers and nebulizers.

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

No

Please provide the reason(s) for your choice.

Expansion should not be governed by a drug class-first approach. Rather, a patient-based approach that is intended to serve the medication needs of identified patient populations, particularly those that are not served or well served by existing public drug plans, should be implemented. A careful, planned approach to expansion that adheres to a valid equity framework is essential.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No

Please provide the reason(s).

There are several aspects of this section of the report that are flawed and require significant revision. First, it would be biased to use claims or utilization data from FTP plans that systematically exclude segments of the population. The panel proposes to secondarily supplement this process with "literature reviews" to address needs of vulnerable populations. This is insufficient. These populations must be identified first to ensure their needs are met.

The panel seems to recognize that there are "disparities in the representation of sex, race, and ethnicity in evidence-based formulary management and drug utilization review processes." However, they propose to address this only if data are available. If data are available, they then propose to take the same flawed prevalence-based approach that will essentially weight each vulnerable group according to its proportion of the population as a whole. It's critical that the needs of each identified vulnerable group be considered independently, and not as function of their proportion of the whole population.

The focus on "national health priorities" is concerning. There is no single uniform set of priorities. Priorities vary by region, by sociodemographic and sociocultural factors, by ethnicity, and many other factors. A single set of national health priorities cannot be imposed on a population as diverse as ours.

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

None of the options are appropriate, i.e. using a drug-first or produt-first model would be inequitable.

5b. What criteria could be used to identify priority products?

An approach that prioritizes products or medication classes is inappropriate and biased. Rather, prioritization should place emphasis on distinct patient groups and their needs.

The proposed criterion, “alignment with patient and societal values” is problematic. Whose values? They are highly variable across groups as described above.

The panel dwells on “equitable access” but fails to recognize the greater importance of equitable listing.

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

No response provided

ViiV Healthcare

1. Do you agree with the proposed principles and definitions?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

2. Do you agree with the proposed assessment criteria?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

3a. Do you have suggestion(s) on a definition and/or criteria to determine the eligibility of related products that could be included on a pan-Canadian formulary?

No response provided

Please provide details.

No response provided

3b. Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them?

No response provided

Please provide reason(s).

No response provided

4a. Do you support the proposed approach to expand to other therapeutic areas?

Yes-in part

Please provide the reason(s) for your choice.

The proposed approach for expanding to other therapeutic areas is described as a checklist. Without addressing the key question regarding terms of coverage (who this is for), there is insufficient amount of information shared to weigh in on whether the approach to expand to other therapeutic areas is appropriate. There is no mention of funding mechanisms within the existing systems, the relationship or impact to existing provincial formularies, and whether access will be changed or integrated with current plans. It will be important to identify and prioritize life changing medicines to be added as part of the expansion. For example, HIV remains an incurable disease today and transmission remains

common in many vulnerable populations despite major advances in treatment and prevention. Without adequate access to suppressive treatment options over a lifetime, patients are subject to higher chance of opportunistic infections, and disease progression will eventually lead to AIDS and ultimately death. The Advisory Panel may want to consider defining what a life changing medicine may be and include this as part of the expansion and prioritization process to provide Canadians timely access to a robust selection of medications.

4b. Should the remaining therapeutic areas be prioritized based on national health priorities?

No response provided

Please provide the reason(s).

No response provided

5a. Which option could be adopted as an alternative to a first-in, first-out submission review process?

No response provided

Please provide the reason(s) for your choice.

No response provided

5b. What criteria could be used to identify priority products?

No response provided

6. Do you agree with the proposed evaluation criteria and the considerations for new products?

No response provided

Please provide the reason(s) and suggested changes, if any.

No response provided

7. Should the deliberative process include weighting of the evidence or a score for each criterion?

No response provided

If yes, how should weight be distributed among the proposed criteria?

No response provided

8. 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 reviews)?

No response provided

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

No response provided