Response to the Discussion Paper *Building Toward a Potential Pan-Canadian Formulary*

Diabetes Canada

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Introduction

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.[1] Among the most prevalent of these is diabetes. Today, there are over four million Canadians who have been diagnosed with this progressive disease.[2] Another 1.7 million people have diabetes and don't yet know it, while almost six million have prediabetes.[2] Within the next decade, diabetes cases are expected to rise 27 percent. In 2022, someone new is diagnosed every three minutes.[2]

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 to10 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 to 95 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. Among other things, 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)[3] 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.[4]

The problem

Diabetes prevalence in Canada has increased by more than 50 percent since 2012.[2] 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.[5] For First Nations people, that risk is up to 80 percent and in some subgroups within this population, it is even higher.[5]

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.[2] By 2032, it is estimated that close to 14 million Canadians, or 33 percent of the population, will have diabetes or prediabetes.[2] 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.[6] In a Statistics Canada survey, 80 percent of respondents reported living with at least one chronic condition in addition to diabetes.[7] 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.[8,9] Every day, diabetes costs the Canadian healthcare system almost $50 million to treat.[9]

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, as part of their treatment.[10] In a Diabetes Canada survey from 2015, 25 percent of all people with diabetes indicated treatment adherence was affected by cost.[11] 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.[11] 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.[11] About 18 percent of people with diabetes reported having difficulty getting insurance because of their disease.[11] People who earn a low income are the most affected when it comes to difficulty obtaining insurance, compared to those earning a higher income.[11]

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 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. Policymaking bodies should expressly seek out diverse representation within stakeholder groups 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 receive their feedback is recommended to ensure the best possible cross-section 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 for this consultation 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 itself, 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.

Discussion questions from *Building Toward a Potential Pan-Canadian Formulary*

1. **Do you agree with the proposed principles and definitions? 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 HCCC, 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 the 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 patients – 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 was 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 prescribing or 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[12] lens is necessary to bring about these needed changes. Diabetes Canada implores CADTH to engage with patients and patient groups to further consider what broad system overhauls are required to support a pan-Canadian formulary.

2. **Do you agree with the proposed assessment criteria? 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 could 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 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 Advisory 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 Panel'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 Advisory Panel 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 payer).
- Other ongoing pharmaceutical initiatives (e.g., Health Canada's Drugs for Rare Diseases Strategy).

While we know it wasn't within the purview of the Advisory Panel 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 have the potential to be quite 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?

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.**

   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, pen needles and 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, relevant 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 various 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 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.

b) Should related products be listed in the same list for drugs and have the same evaluation criteria applied to them (see Table 3 in the discussion paper)? Please provide the reason(s). Note that this question pertains only to evaluation of related products; there will be an opportunity to comment on the proposed criteria for evaluation of new drugs in question 6.

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. To reinforce the point, 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.

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

Diabetes Canada's expertise is specific to diabetes medications, devices and supplies, but the majority of our constituents are also prescribed medications 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.

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

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.**

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.

b) 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? 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? 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.

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.

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[10] Statistics Canada. 2011 Survey on Living with Chronic Disease in Canada. Custom data request.

[11] Diabetes Canada. 2015 Report on Diabetes: Driving Change. Toronto, ON: CDA; 2015.

[12] *"The health justice framework builds on…principles of health equity. Health justice requires a regulatory and jurisprudential approach that consistently and reliably considers the health ramifications of judicial and legislative decision making. [There is an] urgent need for robust measures that address the deleterious effects of economic, societal, cultural, environmental, and social conditions, as well as the policies and legal systems that have devastating effects on health.*

[The] knowledge of social determinants of health should be integrated into the policy-making and judicial decision making processes. Policies, laws, and social structures must anticipate, and be designed to mitigate, the effects of socioeconomic inequality and the social determinants of poor health. Equally important, health justice requires the development of laws and policies that prevent health inequity and increase individual capability."
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