Pan-Canadian Biosimilars Consultation Process: 2019 Online Survey Questionnaire

A pCPA and CADTH Partnership

Electronic Consent

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Policy Frameworks

1. What is the most significant barrier to the updating of biosimilars and why?

The most significant barrier to the updating of a policy on the use of biosimilars is effectively adopting a patient-centered approach that prioritizes the needs and safety of people living with diabetes, and people with other diseases that may be affected by the policy transition. Health care providers and people living with diabetes need to have an opportunity to make a joint informed decision about treatment options without being restricted by a policy transition that does not consider individual circumstances and characteristics.

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2. **What steps can be taken to address that barrier by policy-makers or others?**

While considering financial constraints and policy development, patients need to remain at the center of health policy decision-making. This entails acknowledging the patient perspective as a unique knowledge source, and meaningfully engaging patients early and frequently in the policy development process. To accomplish this, it is essential to develop and publicly state a transparent policy outlining how patients will be involved in the initiative and how that process will consider patients' perspectives.

Further, while developing health policy, it is important to move beyond concerns of clinical trials and cost-effectiveness, and to consider significant real-life patient experiences that include a range of structural and psychosocial aspects that affect patients' lives, treatment, care, and environment. These include, but are not limited to, caregiver support, overall well-being (including mental health and distress), employment, socioeconomic status, education, etc.

Finally, to assess the benefits of adopting a patient-centered approach, it is important to develop a robust monitoring and evaluation framework for patient engagement. Monitoring and evaluation should be continuous throughout the patient engagement process.

3. **Beyond "New Starts Only," attendees at the CADTH consultation discussed four policy frameworks: tiering, quotas, switching, and tendering. Rank these from most to least desirable and describe the reasons why for your most and least desirable option.**

Diabetes Canada has the following concerns about the four policy frameworks:

1. *Tiering:* The appropriateness of medications available to a specific patient would depend on the composition of each tier and the criteria for advancing to the next tier. The criteria for advancing to a tier 2 medication needs to be based on the best available evidence as well as account for individual patient circumstances and characteristics.
2. *Quotas:* The proportion of people allocated to a particular biologic drug or biosimilar in a particular region is likely to be arbitrary and does not consider individual patients who may require additional deliberation after the quota has been met. This system does not account for individual patient circumstances and characteristics.
3. *Non-medical switching*: The policy framework needs to account for individual patient circumstances and characteristics. Health care providers should be permitted to support patients not to switch if they believe the patients have characteristics or circumstances, temporary or otherwise, that would contribute to some lability in his/her diabetes care or negatively impact other health outcomes.

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4. *Tendering:* Tendering consists of payers using a competitive bidding framework to purchase medicines from a small number of successful bidders, without accounting for patients' experiences and perspectives. This potentially could require patients to switch multiple times to different products as tendering agreements change.

Diabetes Canada believes that health care providers and people living with diabetes need to have an opportunity to make a joint informed decision about treatment options. Biosimilar insulins are a safe and effective treatment option for all people living with type 1 diabetes and those people living with type 2 diabetes who require insulin. Insulin-naive patients can be encouraged to initiate treatment with a biosimilar insulin. The decision to switch a patient from a reference biologic drug to a biosimilar insulin should be based on joint patient and health care provider decision. Diabetes Canada believes that forced non-medical switching from a reference biologic drug to a biosimilar insulin, without consideration of individual factors is not in the best interest of people living with diabetes.

If patients are a priority, most policies can be developed and implemented in a way that is patient centric. Policies that do not consider the unintended consequences for patients are careless and misdirected. It is essential that patients be included in the development, implementation, and evaluation of health policies.

4. How should an exceptions policy for a biosimilar policy framework be developed?

An exceptions policy should be developed by policy-makers, health care providers, and patients. It should allow health care providers and patients to jointly request for an *exceptional Special Authority authorization*, which would allow patients to remain on their established therapies. Health care providers should have the ability to support people living with diabetes not to switch to a biosimilar from the reference biologic drug, if they believe the patients have characteristics or circumstances, temporary or otherwise, that would contribute to some lability in his/her diabetes care or negatively impact other health outcomes. If needed, to facilitate this process, people living with diabetes should be informed to provide sufficient detail and context to their provider to request an *exceptional Special Authority authorization*.

Governments and private insurers have the responsibility to swiftly and diligently respond to submissions requesting an *exceptional Special Authority authorization*, as to not delay patients' access to therapy based on their personal circumstances and needs. In the case of a claim rejection letter, an explanatory statement should be provided for an *exceptional Special Authority* denial within an appropriate time frame.

5. **At the November 18 in-person biosimilar consultation event, it was noted that manufacturers may be able to match the price of biosimilars and that this, rather than the policy options that were discussed, might be a preferred approach. On the other hand, it was also noted that improving biosimilar uptake is important for generating competition, ensuring long-term sustainability of the biosimilar market in Canada, as well as enhancing patient choice. What is your organization's perspective on this issue and why?**

   Diabetes Canada believes that patients ought to benefit from the opportunity to access reference biologic products provided at the same price as biosimilar products. This provides people living with diabetes additional treatment choices, that is not driven by non-medical based policy.

Education and Information Support

6. **Are there gaps in the currently available education and information support with respect to biosimilars? If yes, what are they? What type of organization or group is best positioned to fill them?**

   There are gaps in the currently available education and information support including:

   - There are people living with diabetes who have reported being unaware of the current policy proposals taking place with respect to the use of biosimilars. This indicates that if a forced non-medical switching policy were to take effect, there are people living with diabetes who would be ill informed and likely unable to make a seamless transition.
   - Some health care providers are largely unfamiliar with biosimilars and/or reluctant to prescribe them in treatment-naïve patients and/or patients currently managed on reference biologic drugs. This limits the acceptance of biosimilars by patients, as it is related to the comfort of health care providers educating patients and prescribing biosimilars. Other barriers to prescribing biosimilars include: safety and efficacy concerns, patient opinions, and how cost savings from the use of biosimilars are distributed.
   - Patients sometimes mistakenly call biosimilars 'generic' versions of reference biologic drugs; however, biosimilars are similar to, but not identical to the reference biologic drug. This implies that there may be a knowledge gap among people regarding the differences and use of reference biologic drugs and biosimilars.

   To increase the acceptability and uptake of biosimilars by health care providers and patients, both groups need to receive consistent, concise, and clear educational materials from a trusted

and credible external source such as a health technology assessment (HTA) organization or a health group. This would help dispel any misinformation regarding biosimilars.

7. **Thinking about the tools and resources that you are aware of that support education and information about biosimilars, which are the most and least helpful and why?**

   The tools and resources that Diabetes Canada is aware of that support education and information about biosimilars includes print materials that are distributed through provincial government websites, hospitals, and primary care. The tools and resources that support education and information about biosimilars should also include online and digital resources such as webinars, podcasts, and interactive infographics; that could be distributed through a range of alternative outlets such as social media platforms (e.g., Facebook, Twitter, Instagram).

8. **Which stakeholders should be responsible for developing or preparing educational and information support material on biosimilars? Would the provider/source depend on the type of information?**

   The stakeholder responsible for developing or preparing educational and information support material on biosimilars would depend on the nature of the information and the intended audience. Two stakeholder types that could be responsible for developing or preparing educational and information support material on biosimilars include HTA organizations and health groups. HTA organizations are entirely or nearly entirely publicly funded entities that focus on delivering evidence on the clinical and cost effectiveness of health technologies including medications, devices, and supplies. Health groups act as patient and caregiver advocates or represent health professionals and engage in multiple activities including writing clinical practice guidelines, funding research, speaking at conferences, educating patients and caregivers, and authoring policy research reports and position statements.

9. **How well do you believe that existing educational information about biosimilars is being disseminated? Could anything be done differently or better to enhance distribution?**

   To enhance the distribution of existing educational information about biosimilars a comprehensive education and communications strategy should be developed and implemented, including, multiple media sources beyond just print materials distributed in hospitals or through primary care. Educational information should be developed based on a set of prespecified criteria and standards, to help dispel some of the misinformation and improve consistency and quality of material. Online and digital tools and resources are becoming increasingly important such as webinars, podcasts, and interactive infographics. Further, it is important to consider alternative distribution channels that could be much better leveraged, such as social media

platforms (e.g., Facebook, Twitter, and Instagram) and non-conventional health care settings including retail pharmacies.

Collection and Use of Real-World Evidence and Monitoring

10. What types of outcomes data or measures are the most important to capture for biosimilars?

Due to the complex manufacturing processes of biopharmaceuticals, biosimilars are not identical to their reference biologic products or between two different biosimilar manufacturers. This may result in slight differences resulting in differences in adverse events and/or immunogenicity between the originator biologic product and biosimilar. As such, post-market surveillance is essential to capture, detect, and assess effectiveness and adverse effects from biosimilars, with particular emphasis on effects not recognized prior to licensing and sub-populations. Post-market surveillance is also important in detecting other unexpected changes to a drug's safety profile. Post-market surveillance systems should account for the following:

- Post-market surveillance requires the active participation of a variety of stakeholders including patients, patient groups, health care providers, pharmacies, and pharmaceutical companies.
- A post-market surveillance system needs to be readily available and easy to use for patients given the current partial reliance on patients for spontaneous reporting of adverse events.
- Health care providers should be trained to actively report into a pharmacovigilance system, in order to report any adverse reaction to a biosimilar and track clinical outcomes associated with switching. Further, given the extrapolation of indications that may occur for biosimilar drugs, the indication for which the biosimilar was prescribed should be collected during adverse event reporting to identify potential at-risk populations for a specific adverse event.
- Health care providers should actively monitor the proportion of patients who remain established on a therapy, those that switch to a biosimilar, and those that switch to a biosimilar and switch back to a biologic drug.
- Health care providers should actively monitor the proportion of patients who file for an *exceptional Special Authority authorization,* the approval or rejection of their application, and their outcomes.
- Patients and patient groups should have the opportunity to provide input that conveys their experiences with the biosimilar policy.

11. If a mechanism is established to capture, analyze, and report on outcomes related to biosimilars, what criteria or conditions should be in place to make the information useful for stakeholders and policy makers?

If a mechanism is established to capture, analyze, and report on outcomes related to biosimilars, following the implementation of a policy on the use of biosimilars, a report should be published 6, 12, 18, and 24-months after implementation. This would continual engender trust with patient and providers; and provide stakeholders of interest and policy-makers with the evidence needed to make real-time changes to the policy as it evolves in the Canadian context.

12. How could real-world evidence from other jurisdictions with more experience with biosimilars be used to support policy decisions in Canada?

Real-world evidence from other jurisdictions with more experience with biosimilars can be used to inform policy decisions in Canada. Real-world evidence from other jurisdictions can help to:

- Determine the ideal length for the time-to-transition period, which would provide health care providers and patients with sufficient time to learn about biosimilars and decide if they need to file for an *exceptional Special Authority authorization*.
- Develop an effective monitoring strategy which incorporates key outcome measures that have been proven essential for a policy evaluation of this nature.
- Determine if the pre-implementation cost-effectiveness aligns with the post-implementation cost-effectiveness of this health policy.
- Consider modeling studies that assess the potential intended and unintended effects of this health policy using real-world evidence from other jurisdictions.

Questions About Reinvestment

13. What should be a priority for the reinvestment of savings generated by the use of biosimilars and why?

Diabetes rates have risen significantly in Canada over the past few decades and health care costs have correspondingly skyrocketed. Funding decisions related to health systems and services are increasingly being made in an environment of limited fiscal resources. The increased uptake of biosimilars as a cost-saving alternative to high-cost biologic drugs is intended to maximize savings for local and national health care economies. However, the increased uptake of biosimilars and potential cost savings depends on several factors including:

- Patients and health care providers' knowledge and acceptance of biosimilars,
- Cost of biosimilars,

- Insurer coverage,
- Policies around interchangeability, automatic substitution, and switching, and
- Any unintended consequences.

This question infers that there will be cost saving through the use of biosimilars, however, this is not unequivocally the case. While the costs of medications on the public formularies are not transparent, some cost differences between reference biologic drugs and biosimilars are negligible. If cost savings are incurred by the use of biosimilar insulins, they should be reinvested to help people living with diabetes reduce their risk of complications and improve their health outcomes by increasing access to care and life-sustaining medications. Specifically, cost-savings can be reinvested into:

- Public and private drug formulary budgets, to allow for the addition of new medications coming in to the market place, and in doing so, expand patient medication options to manage their condition.
- Specialized care for some people living with diabetes such as children, emerging adults, and pregnant women. Specialized care allows people living with diabetes to manage their diabetes at an optimal level through the use of an interprofessional team, which could include the primary care provider, diabetes educator, dietitian, nurse, pharmacist, and other specialists.
- Supporting ongoing post-market surveillance of biosimilars to establish long-term safety and efficacy profiles in the post-marketing phase.
- Funding of new innovative therapies.

Other

14. Is there anything that you haven't been asked that you would like to comment on with respect to biosimilars?

People living with diabetes have a large stake in the drug policy environment, because it impacts their ability to access therapies, including medications, that allow them to sustain life and also optimize their health outcomes. Diabetes Canada welcomes that biosimilar insulins offer additional treatment choices for people living with diabetes and may be the preferred option for some. However, we also believe that the decision to use a reference biologic drug or a biosimilar insulin must be made jointly by patients living with diabetes and their health care providers. A biosimilar should not be considered as interchangeable with its reference biologic drug with no regard for the person or clinical context. Medical switching should occur only with explicit knowledge and consent from patients and their health care providers. When a patient's

characteristics or circumstances contribute to lability in diabetes care, and a switch could exacerbate that lability, a switch in medical treatment may not be advised.

For more information please refer to Diabetes Canada's policy position on "Diabetes, Biologic Drugs, and Biosimilar Insulins":
https://www.diabetes.ca/advocacy---policies/our-policy-positions/diabetes,-biologic-drugs,-and-biosimilar-insulins

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