CADTH

Biosimilars Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	**Semglee (insulin glargine biosimilar)** **Diabetes mellitus, type 1 and 2**
Name of the Patient Group	**Diabetes Canada**
Author of the Submission	**Ann Besner**
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Introduction

Biologic drugs come from living organisms or from their cells and are often made using biotechnology.

They are used to treat diseases and medical conditions including anemia, diabetes, inflammatory bowel disease, psoriasis, rheumatoid arthritis, hormone deficiency, and some forms of cancer.

A biosimilar is a drug demonstrated to be highly similar to a biologic drug (known as the reference biologic drug) that was already authorized for sale by the regulatory body, Health Canada. Biosimilars are approved based on having no clinically meaningful differences compared with the reference biologic drug product in terms of safety, purity, and efficacy. Biosimilars may enter the market after the expiry of reference biologic drug patents and data protection.

To help inform the advice that you provide to CADTH and that will be shared with the pan-Canadian Pharmaceutical Alliance and participating jurisdictions making a funding decision, please consider the following:

A. Awareness About Biosimilars

1. How familiar are you with biosimilars? (Please specify: very familiar, somewhat familiar, not at all familiar.) Please provide aggregate data, if available.

   To inform this patient input submission, Diabetes Canada solicited Canadians' feedback through a survey that was administered online in November 2018. A total of 50 people participated in the survey on biosimilar medications and Semglee. The sample consisted of 32 people living with type 1 diabetes, 6 people living with type 2 diabetes, and 12 caregivers to people with diabetes.

Of those who responded to this question (n=36), 6 said they were “very familiar” with biosimilar medications. All of these people are living with type 1 diabetes. Another 20 respondents said they were “somewhat familiar” with them (11 living with type 1 diabetes, 2 living with type 2 diabetes and 7 caregivers) and 10 said they were “not at all familiar” with them (6 living with type 1 diabetes, 3 living with type 2 diabetes and 1 caregiver).

2. If you are familiar with biosimilars, how was this information obtained (e.g., from health-care provider, patient organization, government or not-for-profit organization, industry, general website, other [please specify])? Please provide aggregate data, if available.

The following table summarizes where information on biosimilars was obtained among those who said they were “very familiar” or “somewhat familiar” with them (n=23) (note: respondents were permitted to provide as many answers as were relevant to them):

Information source	**Percent of respondents** (rounded to the nearest whole number)
Health-care provider	35
Patient organization	9
Government organization	9
Not-for-profit organization	0
Industry	22
General website	61
Other	22

The top two information sources for all respondents (those living with type 1 diabetes, type 2 diabetes and caregivers) were general websites and health-care providers.

Several respondents expanded on their answers, providing the following details regarding their information sources on biosimilars:

- “*Diabetes Canada*”
- “*Google scholar, peer-reviewed journals*”
- “*Endocrinologist, Diabetes Daily, FB [Facebook] bloggers, pharmacy*”
- “*Google and drug sites*”
- “*A few people [with] type 1 I know online have spoken about it*”
- “*Education centre*”

- "*Family members in health sector, adertising [sic]*"
- "*Diabetes Facebook groups*"
- "*Advertisements, especially on Twitter. Diabetes-related websites*"
- "*Research studies*"

3. To what degree are you aware of any biosimilars that would treat your condition? (Please specify: aware, not aware.) Please provide aggregate data, if available.

Of the 23 people who responded to this question, 83% or 19 respondents said they were aware of biosimilars to treat diabetes – 13 with type 1 diabetes, 2 with type 2 diabetes and 4 caregivers. The remaining 4 respondents were not aware of any biosimilars to treat diabetes.

B. Treatment Options

1. If you are using a biologic, have you discussed with your doctor about being switched to a biosimilar? (Please specify: yes, no.) Please provide aggregate data, if available.

A total of 28 respondents said they had experience with insulin glargine (13 were taking it and 15 were previously on it). Only 4 respondents said they had talked to their health-care provider about the possibility of switching to an insulin glargine biosimilar medication to treat their diabetes, 2 living with type 1 diabetes and 2 caregivers to people living with diabetes. The other 24 people who responded to this question reported not having had any discussion with their health-care provider about a switch.

2. As a biosimilar is considered to be effective and safe by the regulatory body, how important would each of the following factors be in your decision to start treatment with a biosimilar rather than the reference biologic drug: (1) head-to-head clinical trials showing no significant difference in efficacy and safety, (2) evidence from (post-approval) long-term monitoring of effectiveness, (3) side effects, (4) other (please specify).

Survey respondents were asked to list the factors most important to them in deciding whether or not to start treatment with a biosimilar rather than the reference biologic drug. No head-to-head clinical trials have been done on biosimilar medications for diabetes, nor is there any significant body of post-market surveillance data available on diabetes biosimilars to date, so people were not asked to comment on either of these.

A total of 28 people provided feedback on factors they consider to be important in their decision to start on, or switch to, a biosimilar. Many of the respondents said that the efficacy and safety information of biosimilars is essential to have when making a decision. Others indicated cost

and/or whether the biosimilar would be covered through their insurance plan as important information to know when considering biosimilar initiation. Possible risks and side effects associated with the biosimilar were also mentioned as key factors in the decision-marking process. People were interested in knowing not only about the benefits of the biosimilar over the reference biologic medication, but the benefit (if any) to switching (where applicable). Respondents additionally wanted to know about the mechanism of action, the extent to which testing has occurred and other people's experience with biosimilars (relative to biologics).

The following describes what was most important to patient and caregiver respondents, in their own words:

- "*What are the side effects, where is it made/sourced from, is it as effective, does it cause the same negative effects, is it cheaper*"
- "*What it is exactly, if there are any risks, does it work the same way, what is the cost*"
- "*How much testing has gone into it? Side effects experienced by a large test population. Cost. Paid for by ODB [Ontario Drug Benefit program]? Equivalency to [other types of insulin]. Where produced - in Canada or elsewhere?*"
- "*How similar are the drugs. Are there any side effects to the biosimilar medication. How have patients using this new medication typically responded in terms of blood sugar control"*
- "*What is it? How does it work? Do you use with a pump? Effects on glucose management*"
- "*That it wouldn't cause me to have a lot of lows*"
- "*Would need a lot of information on the insulin and the benefits of changing. It is very challenging to make the change."*
- "*In [sic] would never [switch]…It would be very stressful for me.*"

C. About the Biosimilar Under Review

1. For patients who have experience with a biosimilar, how did you access the biosimilar under review (e.g., clinical trials, a special access or support program, private insurance, public drug plans, other)?

There were no respondents who reported having tried Semglee, the biosimilar under review. One respondent said that the person for whom he/she provides care is currently on Basaglar, another insulin glargine biosimilar. A second person, living with type 1 diabetes, said he/she was previously on Basaglar, but is not taking it anymore. Neither person specified how Basaglar was accessed.

2. If you were initiated on a biosimilar, please describe if there were any benefits or side effects experienced with the biosimilar.

The person living with type 1 diabetes who reported experience with an insulin glargine biosimilar said he/she did not find it to be as effective, but that there were no side effects associated with it. There were no comments provided by other survey respondents.

3. If you were switched from the reference biologic drug to a biosimilar, please describe any benefits or side effects experienced with the reference biologic drug compared with the biosimilar.

The person who was previously on an insulin glargine biosimilar reported that it was cheaper than the reference biologic, which he/she cited as beneficial. There were no further comments provided by survey respondents.

D. Accessibility Considerations

1. Do you have access to a support program with the biosimilar? What aspects of the support program do you find to be beneficial?

Support programs do not exist for diabetes biosimilar medications. Therefore, this question is not applicable to the submission.

2. If you were previously on a reference biologic drug, does the biosimilar provide a similar support program?

Support programs exist for insulin glargine, but not for insulin glargine biosimilars to date.

E. Additional Comments (Optional)

Diabetes is a chronic, progressive disease with no known cure. Type 1 diabetes occurs when the body produces either very little or no insulin. Type 2 diabetes occurs when the pancreas does not produce enough insulin or the body does not effectively use the insulin that is produced. Diabetes requires considerable self-management, including eating well, engaging in regular physical activity, maintaining a healthy body weight, taking medications (oral and/or injectable) as prescribed, monitoring blood glucose and managing stress. Poor glucose control is serious and problematic. Low blood glucose can precipitate an acute crisis, such as confusion, coma, and/or seizure that, in addition to being dangerous themselves, may also contribute to a motor vehicle, workplace or other type of accident causing harm. High blood glucose over time can irreversibly damage blood vessels and nerves, resulting in blindness, heart disease, kidney problems and lower limb amputations, among other issues. The goal of diabetes management is to keep glucose levels within a target range to minimize symptoms and avoid or delay complications.

Many of the survey respondents provided comments about the impact diabetes has had on their lives and the lives of their families. The following are some testimonials:

- "*The greatest impact for my first 25 years with diabetes was low blood sugars and the fear that created for those around me and the planning I had to do to avoid them…In recent years, I am finding it harder to bounce back from things—a cold that takes a healthy person 7-10 days to kick takes me six weeks*." (40-54 year old person living with type 1 diabetes for over 20 years)

- "*It has been tough – it is not easy to control, and it puts a lot of stress on loved ones.*" (25-39 year old person living with type 1 diabetes for 6-10 years)

- "*Because of poor control of my blood sugars… I have kidney disease…and leg ulcers…I'm on disability and my wife just retired last year and we have no health insurance; its [sic] very stressful.*" (55-69 year old person living with type 1 diabetes for over 20 years)

- "*It has affected meal planning and it affects how I feel physically.*" (40-54 year old person living with type 2 diabetes for 3-5 years)

- "*Positive: it has made me more aware of what I eat [and] made me more active. Negative: it's never out my mind. I have to constantly think about what is happening in my body. I have to inject insulin before I put any food in my mouth. I have to poke my fingers. Some nights I wake up low. My family worries that I won't wake up one morning. Diabetes has cost me financially as well.*" (40-54 year old person living with type 1 diabetes for 11-20 years)

- "*It is a 24/7 job on top of my actual job. It is hard at times to handle all the counting carbs and checking blood sugar and injections. It is expensive, I had to take a job that I really did not want to be doing just for the benefits…It was a huge adjustment for myself and for my family.*" (25-39 year old person living with type 1 diabetes for 3-5 years)

- "*I live the nightmare daily.*" (40-54 year old person living with type 1 diabetes for over 20 years)

- "*[It affects] how I eat, making sure to always take my meds. Feeling dehydrated when I wake up in the morning. Side effects from some of the meds.*" (55-69 year old person living with type 2 diabetes for 3-5 years)

- "*I have had type 1 for over 18 years now. I have experienced many highs and lows, pun intended, during this time. There have been countless nights that I've lost sleep due to my*

blood glucose levels being too high or low. I've had to change my plans or miss work because I'm not legally allowed to drive with a low blood glucose or because my blood glucose has been too high for several hours and I have ketones or because I have to go to yet another doctor appointment. I have become a pin cushion with permanently burst blood vessels on my legs and scars on my fingers. It has made it so that I have to have a full medical done every time that I renew my license. I felt very alone when I was first diagnosed and lost a lot of friends because they thought I was contagious. There was also a lot of stressed [sic] places [sic] on my parents for the first few years after my diagnosis. I was still very young and they had to do all the carb counting, insulin dosing, bg [blood glucose] testing, and injections for me. They were the ones that had to deal with my mood swings when I was low and force me to drink juice when I was still half asleep. It has made my parents and sisters all very good at giving needles. I have become the trendy hashtag for a sugary treat. Despite all that, T1D [type 1 diabetes] has also taught me a lot about myself and allowed me to meet many people that I wouldn't have without my disease. I wouldn't be the person I am today without my diagnosis." (25-39 year old person living with type 1 diabetes for 11-20 years)

- "*It has affected every aspect of our lives: our child is under 5 and was diagnosed at 14 months. She currently uses a pump. We count every one of her carbs, ensure her ratios and basal rates are working to keep her blood glucose stable. We are constantly thinking about where her blood glucose level might be, checking her, making adjustments by increasing insulin or treating with a fast acting carbohydrate. We are up every night to check on her. We are in almost constant contact with her school caregivers and anyone who is temporarily watching her. It is all day, everyday.*" (caregiver to a person under the age of 14 living with diabetes for 3-5 years)

Diabetes is a disease that requires intensive self-management. Diabetes Canada's 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada highlight the importance of personalized care when it comes to the pharmacologic management of the condition. Specifically, after initiating healthy behaviour measures, the guidelines recommend selecting diabetes treatment modalities based on a patient's degree of glycemic control and various other considerations. To achieve optimal blood glucose levels, individualization of therapy is essential. This includes careful consideration of medication selection, route of administration (oral, injection, pen or pump), frequency with which someone monitors blood glucose and adjusts dosage, benefits and risks that the patient experiences and/or tolerates, and lifestyle changes the patient is willing or able to make. Our survey responses reinforce the message that different people with diabetes require different medications/treatment modalities to help effectively manage their disease. Their unique clinical profile, preferences and tolerance of therapy should direct physicians to the most appropriate choice and combination of treatments for their disease management.

Diabetes Canada recognizes that biosimilars offer additional treatment choices for some people living with diabetes, may lower costs for patients and insurers and may increase access to needed medications for patients. The decision to use a reference biologic or a biosimilar must be made jointly by patients living with diabetes and their health-care provider, and patients should be provided with all relevant information to make an informed choice. A biosimilar should not be automatically considered as a substitute or interchangeable with its reference biologic, given insufficient data to confirm equivalence and the potential for changes in patient therapy. Neither should patients be forced to switch their treatment regimen without consent, given the lack of supporting information on the effect of switching from a reference biologic to a biosimilar.

Diabetes Canada recommends that there be post-marketing surveillance and safety reporting for biosimilars to ensure information about effectiveness and side effects is collected in a consistent manner.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

There was no assistance from outside Diabetes Canada to complete this submission.

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

There was no assistance from outside Diabetes Canada to collect or analyze data used in this submission.

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In Excess of $50,000

Please find attached a list of organizations who have provided financial support to Diabetes Canada, along with the amounts given.

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Ann Besner
Position: Manager, Research and Policy Analysis
Patient Group: Diabetes Canada
Date: December 4, 2018

Financial Contributions to Diabetes Canada (updated 2017)

Constituent/Name	Funder range ($)
AstraZeneca Canada Inc	350,000+
LifeScan Canada Ltd.	350,000+
Novo Nordisk Canada Inc	350,000+
Sanofi Canada	350,000+
Sun Life Financial	350,000+
Eli Lilly Canada Inc	250,000-349,999
Ascensia Diabetes Care	175,000-249,999
Janssen Inc	175,000-249,999
Medtronic Of Canada Ltd	175,000-249,999
Dairy Farmers Of Canada	100,000-174,999
Merck Canada Inc	100,000-174,999
WEIGHT WATCHERS	100,000-174,999
Abbott Diabetes Care	50,000-99,999
Canola Council Of Canada	50,000-99,999
Insulet Canada Corporation	50,000-99,999
Knight Therapeutics Inc.	50,000-99,999
Manulife Financial	50,000-99,999
Nestle Health Science	50,000-99,999
RBC Foundation	50,000-99,999
The Bank of Nova Scotia	50,000-99,999
Abbott Nutrition	25,000-49,999
BD Medical Diabetes Care	25,000-49,999
Beer Canada	25,000-49,999
Dexcom Canada	25,000-49,999
Dynacare	25,000-49,999
Heartland Food Products Group	25,000-49,999
McNeil Consumer Healthcare	25,000-49,999
Rexall Foundation	25,000-49,999
Roche Diabetes Care	25,000-49,999
SaskCanola	25,000-49,999
Auto Control Medical Inc	5,000-24,999
Bayer Pharmaceuticals	5,000-24,999
Boehringer Ingelheim (Canada) Ltd	5,000-24,999
Canadian Association of Optometrists	5,000-24,999
Canadian Produce Marketing Association	5,000-24,999
CHICKEN FARMERS OF CANADA	5,000-24,999
Edelman Canada	5,000-24,999
EOCI Pharmacomm Ltd.	5,000-24,999
Euro Harvest Bakery Wholesalers	5,000-24,999
Farleyco Marketing Inc	5,000-24,999
ForaCare Technology Canada Inc.	5,000-24,999
Holista Foods	5,000-24,999
InBody Canada	5,000-24,999
Innovative Medicines Canada	5,000-24,999
Ipsen	5,000-24,999
Jays Care Foundation	5,000-24,999
mdBriefCase Group Inc.	5,000-24,999

Montmed	5,000-24,999
Myelin & Associates	5,000-24,999
Novartis Pharmaceuticals Canada Inc	5,000-24,999
Ontario Pork Council	5,000-24,999
Original Energy Sales	5,000-24,999
Paladin Labs Inc	5,000-24,999
Pharmasave Drugs (National) Ltd	5,000-24,999
Prime Strategies Inc.	5,000-24,999
PULSE CANADA	5,000-24,999
Royal College Of Physicians And Surgeons Of Canada	5,000-24,999
Tykess Pharmaceuticals	5,000-24,999
Urban Poling Inc	5,000-24,999
Valeant Canada LP	5,000-24,999
VitalAire Canada Inc	5,000-24,999