

## BC Biosimilars Policy and Advocacy Update – October 2019

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### Introduction

On May 27, 2019, the Government of BC introduced Phase 1 of its new Biosimilar Policy. We have been working on a number of initiatives to ensure we are providing information and support to patients who will be affected by this policy. In addition, we continue to stay engaged with government as we monitor and track the impact of this policy on patients in BC. This update provides a report on recent activities, an analysis of the impact to date of this initiative, and some potential patient-focused alternative solutions.

**Biologic drugs are highly complex:** Biologic drugs come from living organisms or from their cells. They are generally larger and more complex in composition than chemically produced pharmaceutical drugs.<sup>1</sup> They have transformed the way we treat many complex conditions, including Crohn’s disease, ulcerative colitis, diabetes, rheumatoid arthritis, cancer, osteoporosis, psoriasis, HIV, multiple sclerosis, growth deficiencies, and many more.

**Biosimilars are not the same as generic drugs:** A biosimilar is a biologic drug that is highly similar to a biologic drug that was already authorized for sale. Generic drugs are small molecules that are chemically synthesized and contain identical medicinal ingredients to their reference products. A biosimilar and its reference biologic drug can be shown to be highly similar, but not identical.<sup>1</sup>

### Preferred Policy Options

There are previously established options that BC could have implemented, such as:

1. **Negotiating a lower, confidential net price for the originator biologic:** this would allow physicians and patients the option to either switch or remain on their current biologic at the same (or less) cost as the biosimilar, thereby achieving savings for the government equal to or greater than the biosimilar and avoid mandatory switching of stable patients. **We believe this is the best patient centric option and that it will result in the required cost-savings.**
2. **Manitoba’s tiered biologics reimbursement policy:** on August 15, 2018, Manitoba Health, Seniors and Active Living implemented a tiered biologics reimbursement policy that only applies to new patients (biologic naïve) and existing patients that have previously been trialed and deemed unresponsive to biologic therapy. MB had already provided a model that BC could have adopted but chose not to.

<sup>1</sup> Health Canada: Biosimilar biologic drugs in Canada: Fact Sheet. [www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html#a3](http://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html#a3)

## Our Recommended Approach for the Use of Biosimilars

1. **We strongly urge all provinces to reject non-medical switching** and commit to a patient-focused, evidence-based approach that ensures the best possible outcome for everyone. Preferred policy options exist that can achieve similar savings targets without forcing stabilized patients to switch biologics.
2. **Patient-Physician choice must be respected and preserved.** Recent surveys show that patients strongly believe that the biologic medicine used to treat their disease should be a clinical decision made in consultation with their physician, on an individual patient basis.
3. **We support fair, responsible, and patient-focused policy for funding biosimilars.** We recognize that biosimilars present a valuable opportunity for cost-savings in public drug budgets, and as such support their uptake in a responsible, patient-centred, and evidence-driven manner; however, there are alternatives that protect continuity of patient care that can also achieve cost-savings.
4. **Patient support continuity must be protected.** Forcing patients to switch to a biosimilar without appropriate information and support can lead to sub-optimal outcomes and responses to treatment. This is an especially important consideration in disease areas with limited therapeutic options upon potential failure of switching treatment to a biosimilar. It is further perpetuated in Canada by an associated change in healthcare professionals delivering their medications and training through proprietary patient support programs.
5. **A robust monitoring system must be in place** to capture a patient's response after switching, as well as to accurately capture any adverse reactions or changes in disease activity in the following months/years. A streamlined system to ensure that patients who experience loss of disease control after switching have timely access to the therapy that is right for them is essential. Monitoring should review overall impact to the healthcare system including resource utilization and impacts on patients which may affect their out of pocket expenditures and additional visits to healthcare practitioners, etc.

## CADTH Information that should halt policy decisions until the end of 2019

There is currently an ongoing consultation in place on biologic and biosimilar use, the recommendations of which could be important to inform provincial direction on biosimilar policy. It would be prudent for public jurisdictions to wait for finalizing of these recommendations. The pan-Canadian Pharmaceutical Alliance (pCPA) asked the Canadian Agency for Drugs and Technologies in Health (CADTH) to examine how to improve the use of non-oncology biosimilars in Canada, similar to a previous process on oncology biosimilars led by Cancer Care Ontario. Stakeholders will discuss which policies public payers could introduce to increase appropriate use of biosimilar treatments and reduce the overall cost burden.

- the CADTH project on Utilization of Biologics and Biosimilars for Inflammatory Conditions is now reporting an expected completion date of December 1, 2019
- in the meantime, CADTH has posted an "In Brief" document, which is essentially a summary of their October 2018 report on International Policies on the Appropriate Use of Biosimilar Drugs
- CADTH has posted, "Tools for patients and healthcare providers designed to share information on biosimilar drugs." Please see here: [www.cadth.ca/tools/biosimilar-drugs](http://www.cadth.ca/tools/biosimilar-drugs) Quote from the patient hand-out about switching: **Question:** If a biosimilar is available for one of my drugs, should I switch? **Answer:** It depends. Your pharmacist cannot automatically substitute a biosimilar in the same way that they can substitute a generic drug. However, you and your care team may decide together that switching is an option in your specific case. Maybe you are starting on the drug for the first time, or maybe you are doing well and are closely monitored, or there could be any number of reasons why switching might or might not make sense for you."

## Canadian Association of Gastroenterology & Crohn's and Colitis Canada

October 24, 2019 (Toronto, ON) – The Canadian Association of Gastroenterology and Crohn's and Colitis Canada today announced a joint statement that has been accepted for publication in the *Journal of the Canadian Association of Gastroenterology*.<sup>2</sup> The paper, entitled Joint Canadian Association of Gastroenterology and Crohn's and Colitis Canada Position Statement on Biosimilars for the Treatment of Inflammatory Bowel Disease, was co-authored by Canadian gastroenterologists including: Drs Paul Moayyedi, Eric Benchimol, David Armstrong, and Grigorios I. Leontiadis.

Using the GRADE approach, authors reviewed evidence comparing biosimilars (available in Canada) to originator biologics for the treatment of patients with inflammatory bowel disease. They evaluated efficacy, safety, cost, and acceptance by patients.

Ultimately, this important joint statement made the following recommendations:

- patients may be started on a biosimilar if they have active disease and have not been exposed to that biologic previously; this is with the understanding that the price differential between the originator biologic and biosimilar is significant
- non-medical switch is not recommended for patients stable on biologic treatment
- automatic substitution from a biologic to its biosimilar is not recommended

Dr. Paul Moayyedi, Audrey Campbell Chair of Ulcerative Colitis Research at McMaster University said “there are a number of position statements from various organizations but none of these provide an explicit literature search or assessment of the quality of evidence of a defined clinical question according to GRADE criteria. We felt that this was critical in demonstrating the evidence base for our joint position.”

“Gastroenterologists across Canada and indeed government and private payers need to understand the evidence, or lack of evidence on this topic. Based on what we learned, we cannot recommend a non-medical switch policy for patients stable on biologic treatment,” added Dr. Grigorios Leontiadis, Associate Professor of Medicine, Division of Gastroenterology at McMaster University.

Crohn's and Colitis Canada released their own Position Statement in early September. “Opposition to a non-medical switch policy affecting patients with Crohn's and colitis has been irresponsibly characterized as an emotional reaction to change. This work invalidates this portrayal and firmly indicates to policy makers that non-medical switch is not in the best interest of patients as this may result in worsening of disease in some patients,” says Mina Mawani, President and CEO of Crohn's and Colitis Canada. “We are hopeful that this joint statement gives government pause and opens up discussion toward alternate policy interventions.”

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<sup>2</sup> To learn more, the Joint Statement is available here: <https://crohnsandcolitis.ca/News-Events/News-Releases/Joint-Statement-from-the-Canadian-Association-of-G>

## Biosimilars Patient Forum, Vancouver, September 30, 2019, Summary

On September 30, 2019, the Gastrointestinal Society and the Canadian Society of Intestinal Research (CSIR) hosted a patient forum in Vancouver funded entirely by the CSIR from bequest revenue. Representatives from the Gastrointestinal Society, the CSIR, the Better Pharmacare Coalition, and the Pharmaceutical Services Division (PSD) of the Ministry of Health presented.

- **Gail Attara** provided introductory remarks that included an overview of the GI Society and the CSIR and provided some details on information and resources available on the [www.badgut.org](http://www.badgut.org) website. Patients were also invited to check out the [www.biosimilarioptions.ca](http://www.biosimilarioptions.ca) website for information regarding biosimilars.
- **Dr. James Gray** provided an overview of inflammatory bowel disease (IBD) and some of the treatment options that are currently available for patients. He also shared that Canada is a bit of a hotbed for inflammatory bowel disease around the world, relative to other countries. Biologic drugs are important because they suppress the inflammation and thereby control the symptoms associated with IBD.
- **Gail Attara** played the GI Society's video on **Biologics and Biosimilars**, available online at [www.badgut.org/biosimilars](http://www.badgut.org/biosimilars)
- **Dr. Eric Lun**, Executive Director, Drug Intelligence Outcomes and Strategy, Pharmaceutical Services Division, Ministry of Health, provided the rationale behind the **Biosimilars Initiative** and the public policy context around how BC's policy was developed.

### Summary:

- of the top 10 most expensive drugs that PSD funds, three of them are biologics (infliximab, adalimumab, and etanercept). The total cost for those three drugs is around \$185.57 million, or roughly 17% of total PSD expenditures, placing significant financial pressure on PSD
  - "Essentially, we're viewing the biosimilars as therapeutically equivalent to the originator, but there are differences."
  - overall, Canada's uptake of certain biosimilars is much lower (roughly 8%) than the average for OECD countries
  - two key objectives:
    - to provide patients better support by improving the sustainability of our healthcare system
    - offer additional savings to allow funds to be used for other medications
  - Health Canada expects no differences in both efficacy and safety following a change of routine use between a biosimilar and a reference product
  - BC also looked at what other provinces are doing and how they view biosimilars
  - the provinces formed a negotiating alliance in 2010, called the panCanadian Pharmaceutical Alliance (pCPA), which supports the use of biosimilars and seeks to improve the uptake as much as possible
  - lots of consultation took place; however, not all of those consulted agreed with the policy
- **Tijana Fazlagic**, Executive Director, PSD, provided a roll-out of the Biosimilars Initiative and described follow-up efforts to monitor and evaluate its impact.

### Summary:

- PSD launched Phase 1 of the Biosimilars Initiative on May 27, 2019, with the goal of switching patients using originator biologics to their biosimilar versions by November 25, 2019:
  - Enbrel® (etanercept) for rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis to Erelzi™ or Brenzys® (biosimilar etanercept)
  - Remicade® (infliximab) for rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis to Inflectra® or Renflexis™ (biosimilar infliximab)
  - Lantus® (insulin glargine) for diabetes to Basaglar™ (insulin glargine biosimilar)
- in Phase 2 (September 5, 2019 - March 5, 2020), the Initiative will switch patients using Remicade® (infliximab) for Crohn's disease or ulcerative colitis to Inflectra® or Renflexis™ (biosimilar infliximab)
- during each switch period, PSD will cover both biologic and biosimilar versions of the affected drugs, to allow time for patients to discuss the switch with their prescriber
- after the switch periods end, PSD will cover only the biosimilar versions of etanercept, infliximab, and insulin glargine for the affected indications

- based on the evidence available and on the Health Canada position, no difference is expected between efficacy and safety of biologics and biosimilars
- in the event that there are medical reasons for which a patient may need to remain on the originator product, the Ministry is allowing an opportunity for a physician to submit an exceptional coverage request (special authority)
- prescriber and pharmacist fees of \$50 and \$15 respectively have been introduced to support the patient having an extra conversation with each of these healthcare practitioners about the switch, but the fee is not dependent on the patient actually switching
- monitoring and evaluation is in place to look at the at the number of patients being switched, what kind of requests are being submitted for exceptional coverage, and monitoring to see what develops
- prescriber and ER visits and hospitalizations will also be tracked
- ongoing Health Canada monitoring will take place under its adverse drug reaction reporting, but it's important to keep in mind that Health Canada's ability to monitor the safety of marketed health products depends on healthcare professionals and consumers reporting adverse reactions
- as of September 15, 2019, the total number of patients switched to a biosimilar is about 4,000, with the majority for the diabetes and inflammatory arthritis indications, and there have been 400 requests for special authority for the patient to not switch, but PSD could not say whether these were approved or denied.
- PSD expects to save about \$96 million over three years and the savings will be directed to provide drug coverage and to improve patient care, including:
  - coverage for Jardiance® (empagliflozin) for diabetes patients
  - adding Taltz® (ixekizumab) for psoriatic arthritis
  - adjustments to coverage for patients with rheumatoid arthritis
- Phase 2 also includes a nursing support fee for gastroenterologists when a nurse is present in the care of IBD patients, then the gastroenterologist can bill the extra fee for nursing support (and then pay the nurse for his or her assistance); this is \$60 per patient, billable every six months
- Phase 2 also provides coverage for a fecal calprotectin test, which is used to monitor disease progression in IBD patients
- **Dr. Alan Low** provided some additional perspective on the policy from the perspective of a pharmacist and he advised patients to ensure they talk to their doctor and their pharmacist ASAP and to not wait until the end of the six-month transition period.
  - pharmacists can get a one-time reimbursement (\$15) for the time they spend advising their patients re: this transition, so patients should not hesitate to ask them about it
  - Dr. Low stressed the importance of getting good information from a reliable source and described the impact of the nocebo effect as being when something that shouldn't have a negative effect brings about a negative effect because of the way it is communicated or implemented
- **Dr. Ganive Bhinder** also touched on patient support programs in Canada and pointed out that they are unique compared with other jurisdictions in the world. It is important to ensure that those continue to be provided with similar services to the originator program when patients are switched to a biosimilar.
  - some of the published studies re: impacts of switching to a biosimilar were reviewed and discussed – overall, they indicate switching does not create significant issues for most patients
  - however, even though switching is safe for most of the people, most of the time – there must be an allowance made for exceptions
  - for example, in Denmark, after a nationwide non-medical switching policy approximately 20% did not switch
  - monitoring is also key: fecal calprotectin testing is a great tool for monitoring intestinal inflammation
- **Patient Discussion:** the following is a summary of the key concerns expressed directly by patients (the event was filmed) at the recent policy forum along with the transcript response from PSD, where applicable:
  1. **Grandfathering of existing patients:** new patients who are starting a biologic for the first time could start on biosimilars to save costs rather than getting patients who are stable on originator biologics to switch.

*PSD Response: we actually tried that first and didn't get the [hoped for] amount of uptake [and it] was too low and based on the data and the experience of other countries, switching is safe and there's no problems with that.*

2. **Immunogenicity:** why force someone to mess with a treatment that is working? Especially when switching back and forth may lessen the long-term effectiveness of the original biologic.

*PSD Response: the evidence to date suggests that this isn't a concern for most patients but that is why having exclusions is so important – for patients that shouldn't be switched. Also, even originator biologics change slightly with every batch manufactured so there are changes over the years in what a patient receives.*

3. **Monitoring:** a lot of the studies have been done in Europe; however, Canada and BC specifically have unique populations. Also, there are very few studies in ulcerative colitis.

*No response.*

4. **Health risk:** why take the risk to switch a patient who is stable and using a biologic that is effective? What if they are anxious and upset and nervous about switching – would that be a reason for their doctor to not switch them?

*PSD response: that would be taken on a case by case basis.*

5. **Exceptions:** what if you are a patient who is one of those exceptions to the rule? It is no comfort to a patient who does not do well with the switch to tell them that they are the exception. There are no defined exemption criteria.

*PSD response: special application can be made if there is a specific reason to make an exception.*

6. **Exceptions:** why are there so few exceptions? Are physicians being pressured to switch their patients?

*PSD response: physicians are not being pressured.*

7. **Multicultural make-up of BC:** BC is very multicultural and has people from around the world living here – how do we know studies from Europe will be applicable?

*PSD response: BC looked at studies from around the world – not just Europe. And special authority is available if needed.*

8. **Cost:** ultimately, this is really about saving money, not about providing better care.

*PSD response: BC will be able to pay for more drugs and provide more services for IBD patients with the money that is being saved.*