

British Columbia, May 2019

"British Columbia (B.C.) is following evidence-based results from a number of international jurisdictions that have over 10 years' experience with these innovative drugs."

"B.C. is leading the country by promoting the widespread use of biosimilars, which have been proven to work just as safely and effectively as higher priced biologics. To date, Canada is far behind European jurisdictions."

-Adrian Dix, Minister of Health, May 17, 2019



Alberta, December 2019

Health Minister Tyler Shandro cited European biosimilars experience to defend his forced switching policy against arguments of Canadian gastroenterologists not to switch IBD patients...



Tyler Shandro 🚱 @shandro - Dec 12, 2019

David, a decade of experience in Europe, with 90 studies on switching to biosimilars that tell us switching is safe. That's why BC NDP Minister @adriandix agrees. And Crohn's & Colitis UK. And Dr. D'Haens of European Crohn's and Colitis Org. crohnsandcolitis.org.uk/news/new-

We welcome increased availability of effective treatment options for patients and understand the importance of the wise and careful use of NHS resources. Crohn's and Colitis UK has been working in the field of biosimilars to provide patient information and support since 2014 and is familiar with the evidence to date which reinforces the fact that biosimilars are as safe and effective as the reference products. The introduction of biosimilars for adalimumab brings potential opportunities for both patients and the NHS. However, it is vital that patients are fully informed about all the treatment options available to them and commissioners and health professionals adopt the principles of shared decision making. At a time when services are thinking about new contracts, we would also hope that patients' views are proactively sought and that things that matter to patients, including excipients, device and homecare packages, are given due consideration. 99

Sarah Berry, Health Policy and Public Affairs Officer, Crohn's & Colitis UK



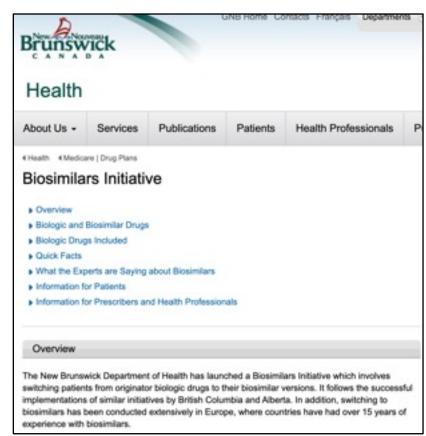
🦓 David Shepherd 🕜 @DShepYEG · Dec 12, 2019

"We provided the Alberta gov't with an evidence-based counterargument against a non-medical switch for patients with IBD, fully supported by Canadian gastroenterologists and yet they still went ahead.

New Brunswick, April 2021

"This biosimilars initiative follows similar policies implemented by British Columbia and Alberta over the past 2 years, where tens of thousands of patients in each province were safely switched from an originator biologic drug to a biosimilar. Switching to biosimilars has also been conducted extensively in Europe, where countries have had over 15 years of experience with biosimilars."

"Biosimilars are just as safe and effective as the originator versions, as demonstrated by the experiences in British Columbia, Alberta and Europe."



Information for Prescribers and Health Professionals
 Overview

Overview

The New Brunswick Department of Health has launched a Biosimilars Initiative which involves switching patients from originator biologic drugs to their biosimilar versions. It follows the successful implementations of similar initiatives by British Columbia and Alberta. In addition, switching to biosimilars has been conducted extensively in Europe, where countries have had over 15 years of experience with biosimilars.

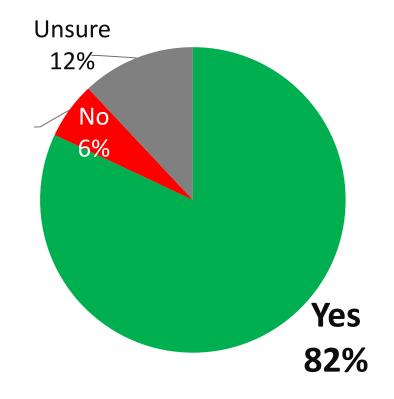




Real-World Evidence of Safe Use (and Switching) Builds Confidence

- The mere absence of negative data (i.e. problems) is not satisfactory to build confidence with physicians.
- Switching data/studies that show positive patient outcomes will do this.

Should Switching Studies Be Conducted Before Automatic Substitution?
Canadian Survey, Oct. 2017



The Forced-Substitution policies of some Canadian provinces more closely resemble the substitution policies of **Eastern Europe**....



ESTONIA: Permitted. Patient can refuse and pay price difference out-of-pocket.



LATVIA: Non bio-naπve patients can refuse and pay cost difference; the physician can prevent substitution. Others must use cheapest product.



POLAND: Permitted, pharmacists are to discuss with patient.

Canadian Op-Eds, 2019-2021



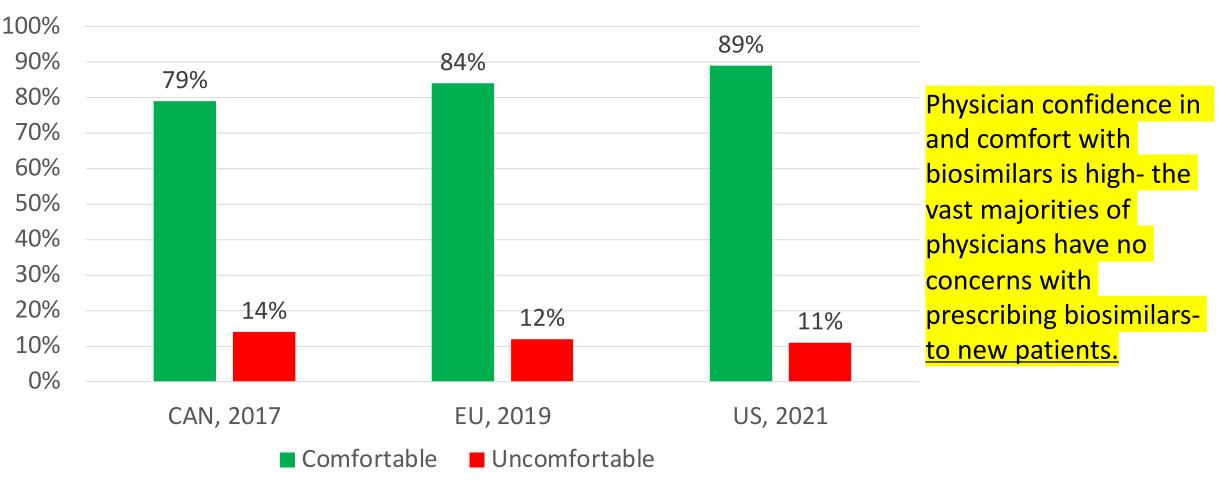






Surveys Have Shown Physicians Have <u>High Confidence in Biosimilars:</u> They Are Very Comfortable Prescribing Biosimilars to New Patients





Issues Arise With the Non-Medical Switching of Biologics

- Treatment plans are not "one size fits all."
- A patient often has to try several different medicines before finding the one which stabilizes their condition.
- Changing treatment may change the control a patient has over their condition.
- If a medicine is working for a patient, most doctors don't think it is a good idea to switch from one biologic to another for cost reasons only.

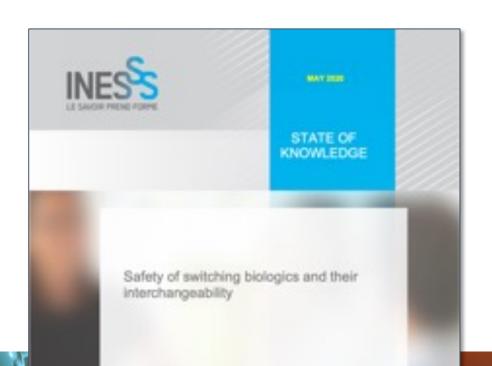


Canadian Physician Groups Opposed Non-Medical Switching

 Canadian Gastroenterologists issued statements opposing forced-switching policies enacted in Alberta and British Columbia. "Non-medical switching in patients being treated with a reference biologic is generally not accepted by learned societies and the consulted clinicians."

"Safety of switching biologics and their interchangeability",
 INESS Report (Quebec), May 2020





Canadian Patient Groups Also Strongly Opposed These Policies



Patients, NDP call on province to reconsider upcoming change to not cover biologic drugs

MOIRA WYTON Updated: January 15, 2020



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Members of Crohn's, colitis community protest potential non-medical switch policy

VOICES UNHEARD

IBD patients say they weren't consulted on forced switch to biosimilars

Dec 16, 2019

'Back at square one:' B.C. Crohn's patient struggles with forced transition to biosimilar medication

More than 12,000 people in B.C. have switched to biosimilar medications since the province announced it would stop funding three drugs

GLENDA LUYMES Updated: February 9, 2020

Takeaways

- Canadian patients and physicians have strong concerns with forced-substitution policies. Survey data has borne these concerns out.
- Contrary to the assertions of forced-switching proponents, these policies represent a stark contrast with those of Western Europe.
- The European experience in particular shows that forced-substitution is not necessary to achieve high uptake and savings.
- Government policies incentivizing the use of one particular product distort the treatment-decision making process and may create pushback from physicians and patients.
- Expanding (rather than restricting) physician/patient choice reimbursing multiple products competing on a level playing field has contributed to the success of biosimilars in Europe.

For More Information, Read our GaBI Whitepapers:

"Policy Recommendations for a Sustainable Biosimilars Market: Lessons from Europe"

- Michael S Reilly, Esq,
 Professor Philip J Schneider, MS, FASHP, FASPEN, FFIP
- GaBI Journal, Volume 9 / Year 2020 / Issue 2

"US Biosimilars Market on Pace With Europe"

- Madelaine Feldman, MD FACR; Michael S Reilly, Esq,
- GaBI Journal, Volume 9 / Year 2020 / Issue 4

"A Critical Review of Substitution Policy for Biosimilars in Canada"

- Michael S Reilly, Esq; Professor Philip J Schneider, MS, FASHP, FASPEN, FFIP
- GaBI Journal, Volume 10 / Year 2021 / Issue 3

Available at www.gabi-journal.net

