



Analysis of Biosimilars Policies: The European, American, and Canadian Landscape

Michael Reilly,
Executive Director, Alliance for Safe Biologic Medicines
June 28, 2022



Introduction

Michael Reilly, ESQ
Executive Director, Alliance for Safe Biologic Medicines
2010-Present

- Associate Deputy Secretary at the U.S. Department of Health and Human Services (HHS) from 2005-2008
- Responsible for policy development and implementation, regulatory oversight for issues involving CMS and the FDA.
- Senior Advisor to the Assistant Secretary for Public Affairs and the Assistant Secretary for Planning and Evaluation at HHS from 2002-2005

Biosimilars Working Group

**ASBM is also a member of the
Canadian Biosimilars Working Group:**

[Alliance for Safe Biologic Medicines](#)

[Canadian Council of the Blind](#)

[Canadian Organization for Rare
Disorders](#)

[Canadian Society of Intestinal Research](#)

[Crohn's and Colitis Canada](#)

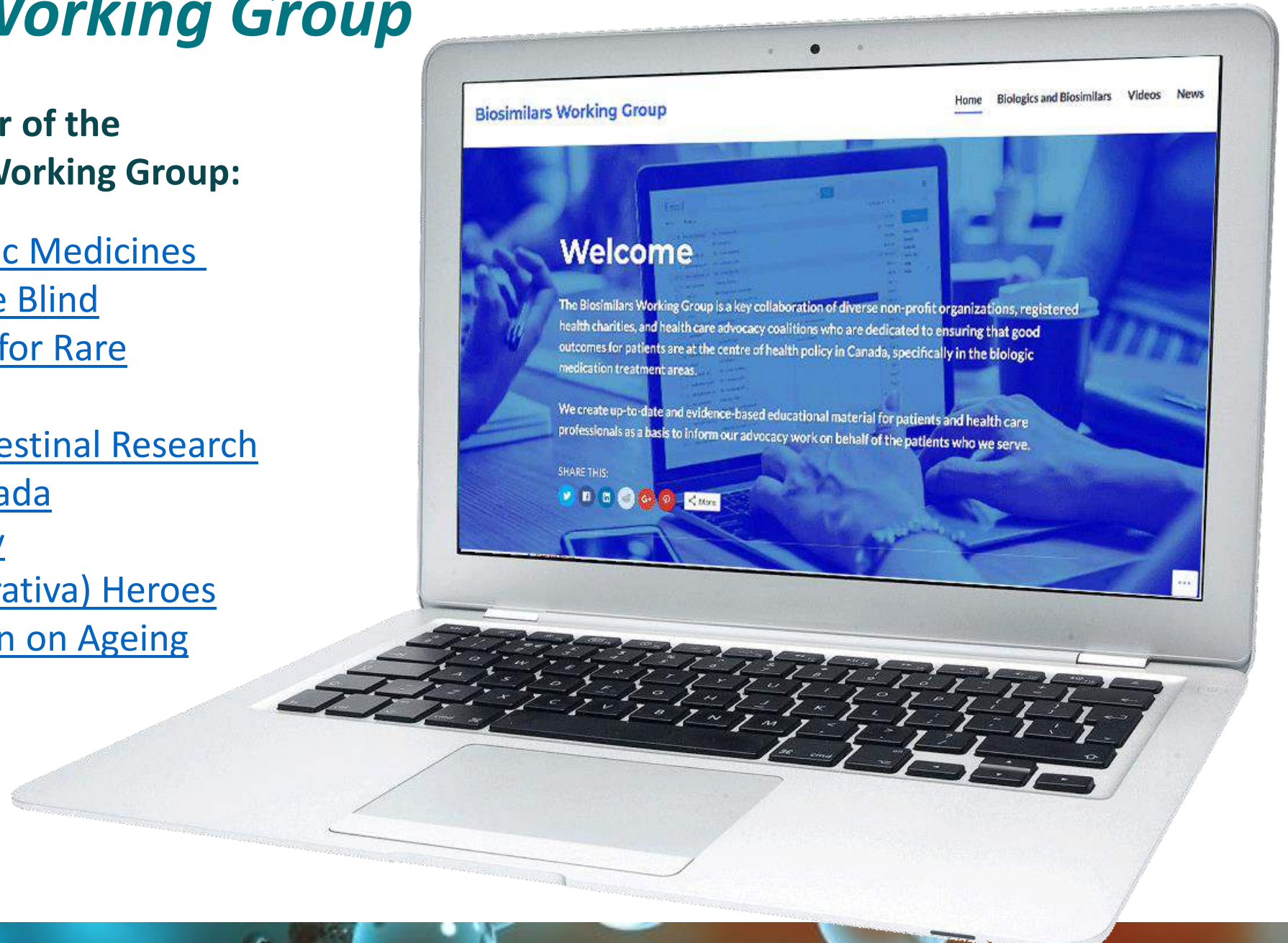
[Gastrointestinal Society](#)

[HS \(hidradenitis suppurativa\) Heroes](#)

[International Federation on Ageing](#)

[MedAccess BC](#)

biosimileroptions.ca



Joint PMPRB Comments: February 14, 2020

February 14, 2020

Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

Submitted electronically to PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Re: PMPRB DRAFT Guidelines

Dear Board Members,

As advocates representing millions of Canadian patients, the Alliance for Safe Biologic Medicines (ASBM) appreciates the opportunity to comment on the PMPRB's new Draft Guidelines. ASBM is a global alliance of patient advocacy organizations and physician societies, working to promote patient-centered biosimilar policies worldwide. The Gastrointestinal Society is one of our leading Canadian members, and represents as many as 6 million Canadians with irritable bowel syndrome (IBS), more than 9 million with functional dyspepsia, as many as 8 million with chronic acid reflux (GERD), and an additional 233,000 suffering from chronic inflammatory bowel disease (Crohn's and ulcerative colitis).

We are keenly aware of the importance to these patients we represent of improving access to new and innovative life-improving and life-extending therapies by ensuring affordability of medicines. However, pricing policies alone do not guarantee access; other factors contribute as well. Ensuring that new medicines available to patients in other advanced countries are launched in Canada as well is among these key factors.

It is our view that while well-intentioned, the new Draft Guidelines have a strong potential to upset this critical balance, by disincentivizing manufacturer investment in product launches and dissuading applications or subsequent indications in Canada thereby jeopardizing, rather than promoting, patient access to such therapies.

In its budget for 2017, the Canadian Government [laid out a vision](#) for Canada to become a global leader in innovation. Pursuant to this objective, the Government established an Economic Strategy Table (EST) for the Health Biosciences Sector, which published its [recommendations](#) in September 2017, setting a goal of "doubling the size of the sector by 2025 and becoming a global leader in innovative technologies."

June 29 Webinar: “Key Factors for Successful Uptake of Biosimilars: Europe and US”

- Tomorrow ASBM & GaBI will present a webinar which discusses the factors contributing to the success of biosimilars in Europe and the U.S.
- This is the first in a series of webinars presented by ASBM and GaBI this year.

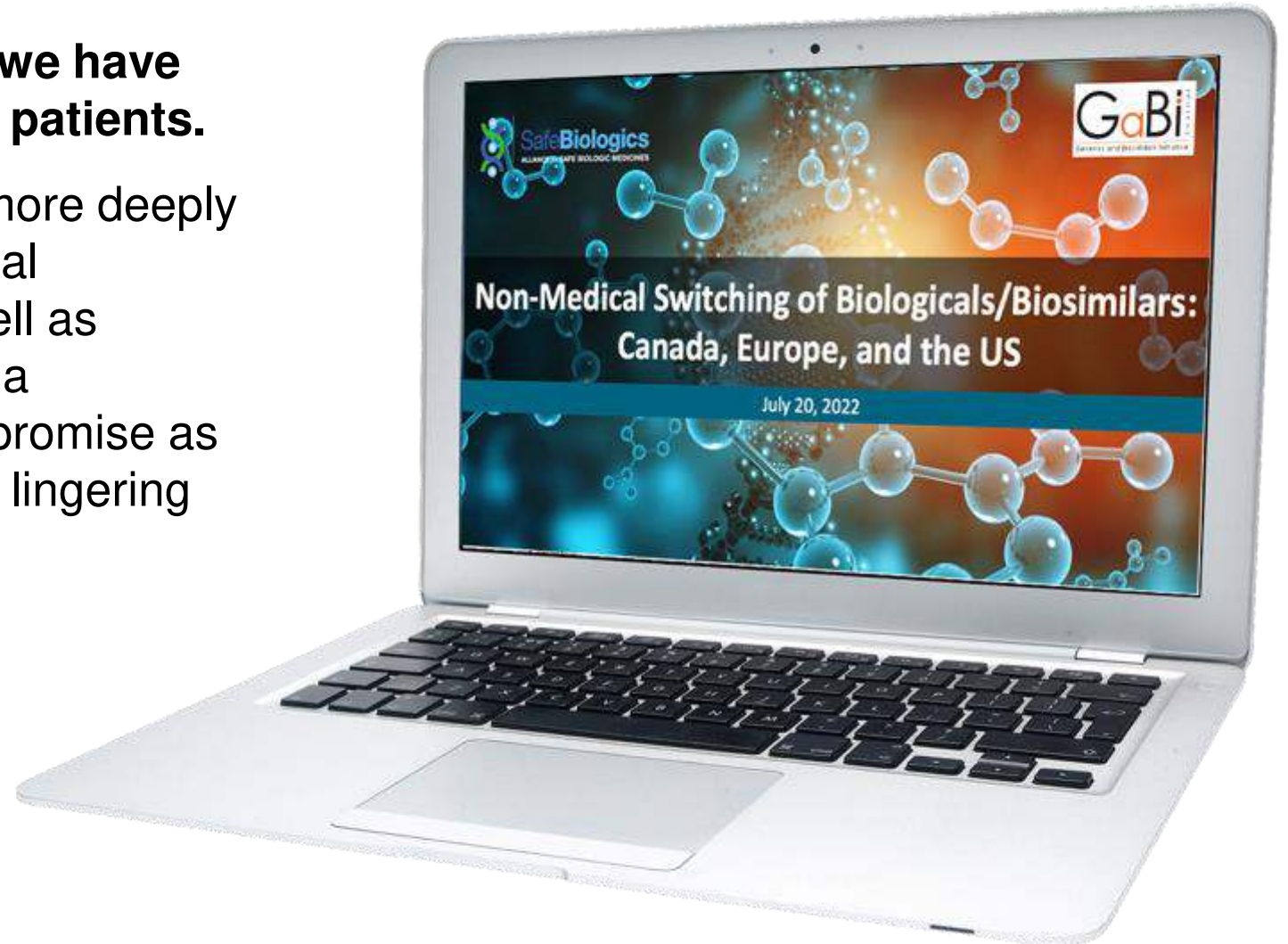
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Non-Medical Switching Webinar: July 20th

Non-Medical Switching is a concern we have seen across our surveys and among patients.

Our next webinar (July 20th) will delve more deeply into physician concerns with non-medical switching and forced substitution- as well as discussing how the FDA designation of a biosimilar as "Interchangeable" shows promise as an effective means of addressing these lingering concerns for most physicians.



Europe Enjoys High Biosimilar Uptake Rates and Savings

Biosimilar Uptake Varies Throughout Europe by Country and Product (Usually 20-80% range):

Total Biosimilar Volume: Denmark: 63%; UK: 45%; Germany 40%; France 34%, Belgium and Switzerland tied at 14%.

Filgrastim/Pegfilgrastim: 16 European countries had > 90% biosimilar utilization in 2018, Ireland was just 27%.

Anti-TNF biosimilars (adalimumab, etanercept and infliximab): Norway and Denmark had 81% and 96% biosimilar uptake, respectively, while every other country's utilization was less than 50% .



Variations are influenced by government involvement, reimbursement structures and tender procurement policies.

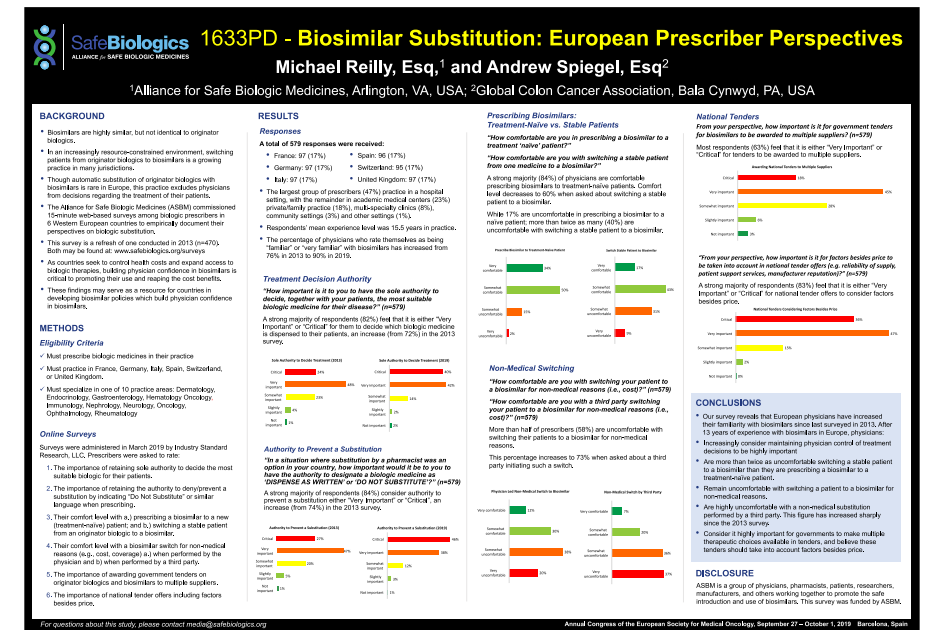
Biosimilar Policy in Europe: A Collaborative, Patient-Focused Approach

- **Regular multi-stakeholder consultations held by European Commission in Brussels.**
- Discussions about switching are made collaboratively between health care providers and patients.
- Education of patients to build trust in biosimilars has been a priority.
- Savings attributed to biosimilars are being visibly reinvested into the system- more healthcare workers, etc.



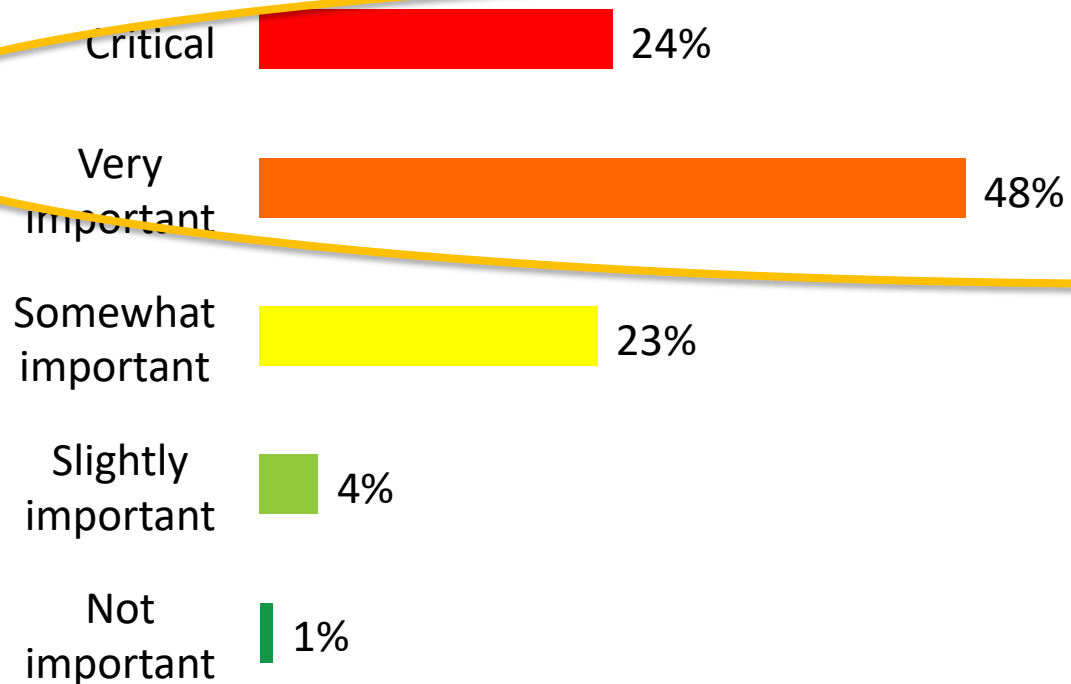
Survey Presented at ESMO Congress 2019

- An update of a prior survey in 2013
- The survey findings were presented at the European Society of Medical Oncology 2019 Congress in Barcelona, Spain.
- The European physicians took great pride in their approach, which is very patient-focused.
- ***Notably, as familiarity and comfort with biosimilars increased, so did the importance to physicians of maintaining control of treatment decision.***

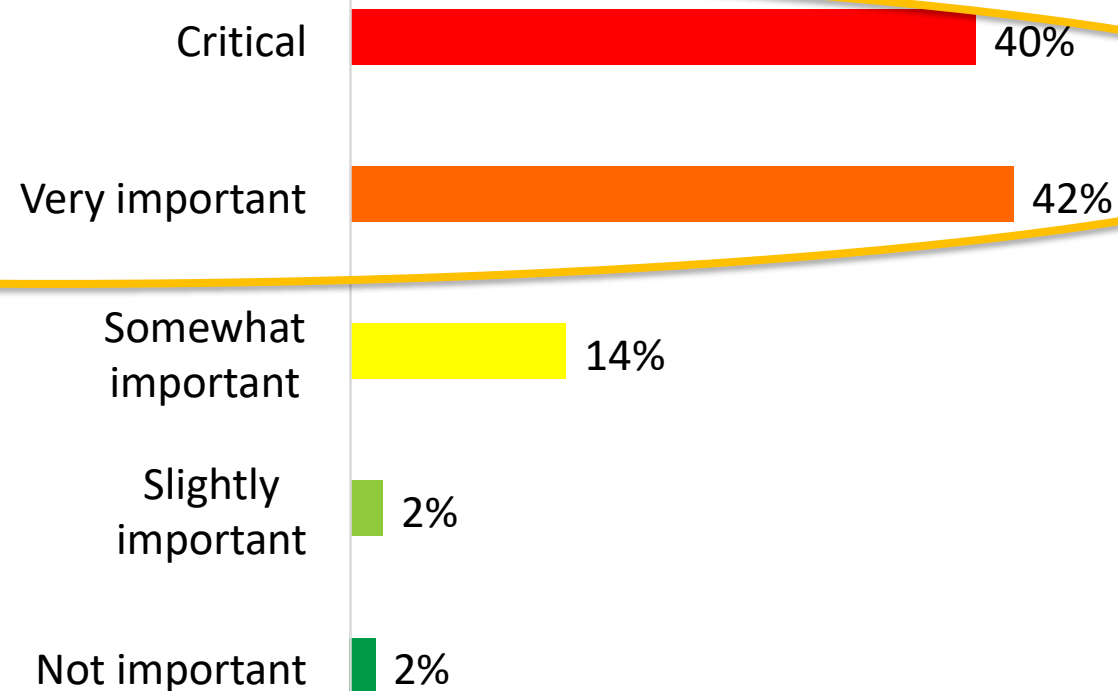


European Surveys (2013 vs. 2019): Importance of Physician/Patient Control of Treatment Decisions

Sole Authority to Decide Treatment (2013)



Sole Authority to Decide Treatment (2019)



82% feel that it is either “Very Important” or “Critical” for the physician & patient to decide which biologic medicine is used, an increase (from 72%) since 2013. Those considering this “Critical” nearly doubled from 24% to 40%.

“Policy Recommendations for a Sustainable Biosimilars Market: Lessons from Europe”

- Generics and Biosimilars Initiative Journal (GaBI Journal). Published in: Volume 9 / Year 2020 / Issue 2
- Authors: Michael S Reilly, Esq, Professor Philip J Schneider, MS, FASHP, FASPEN, FFIP
- Analyzed the different approaches to biosimilar policy across Europe
- OBJECTIVE: identify principles which can be applied to develop an efficient and sustainable biosimilar market.



The European Whitepaper Identified “Must-Have” Principles, Critical for Countries to Achieve Biosimilar Success:



1. Physicians should have the freedom to choose between off-patent originator biologicals and available biosimilars and to act in the best interest of their patients based on scientific evidence and clinical experience.
2. Tenders should be designed to include multiple value-based criteria beyond price, e.g. education, services, available dose strengths, and provide a sufficient broad choice (multi-winner tenders versus single-winner tenders) to ensure continuity of supply and healthy competition.
3. A level playing field between all participating manufacturers is the best way to foster competition; mandatory discounts which place artificial downward pressure on manufacturers do not engender a sustainable market environment.

Outliers: Norway and Denmark

- Even in Norway with a national tendering system, physicians retain the prescription choice among all available products but are strongly encouraged to choose the lowest priced product for new patients.
- Only Denmark, following a transparent process, will solely reimburse the winning product, except in rare substantiated circumstances.
- **Critically: No European country has stopped reimbursement of an originator product through an arbitrary government fiat as occurs in the Alberta and British Columbia forced-switching policies.**



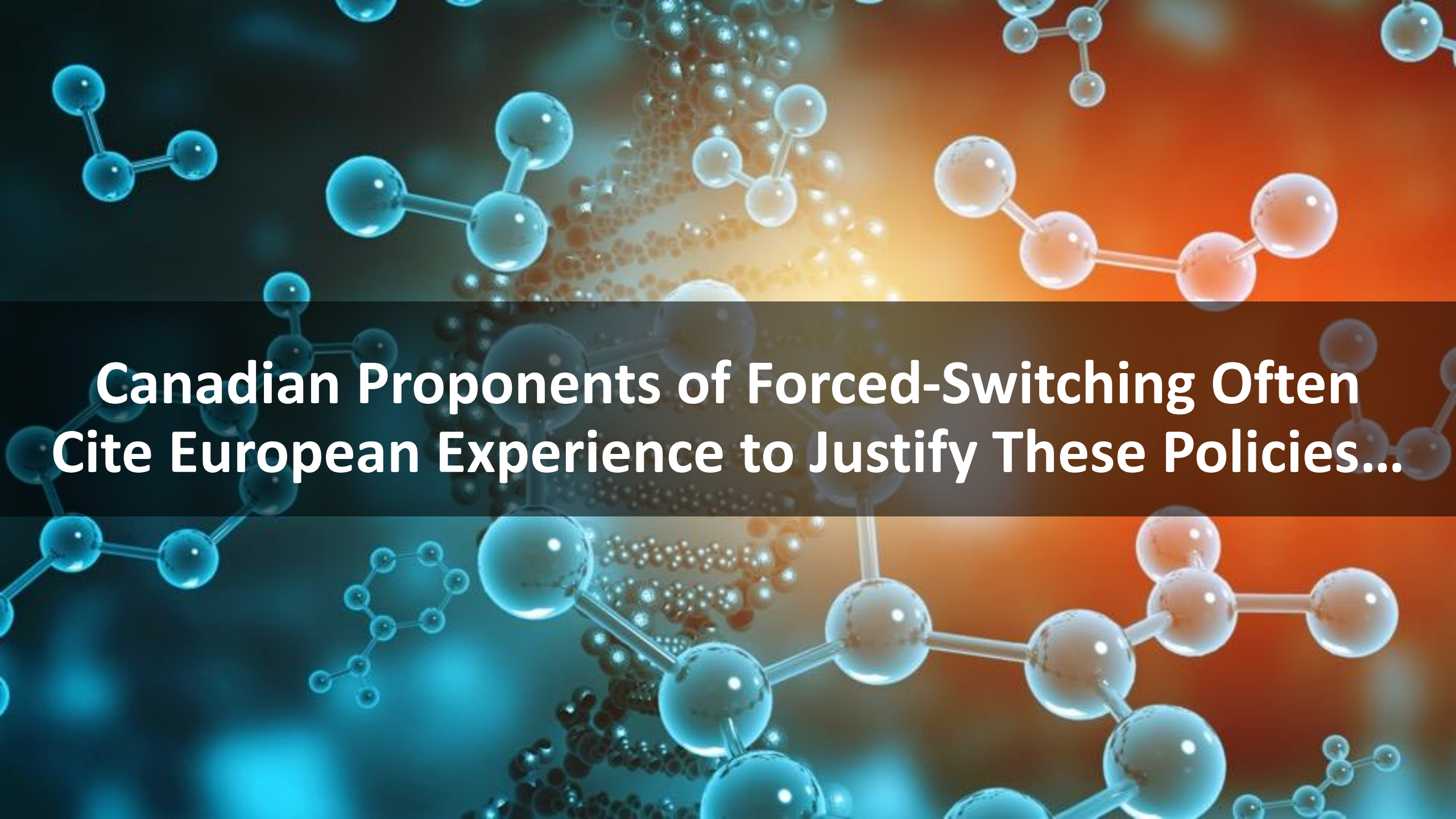
While Europe is Viewed as the Leader in Biosimilar Adoption, the U.S. is Catching Up...

- **U.S. biosimilar market shares are catching up with European uptake rates:**
- **80% for filgrastim biosimilars, 70% for trastuzumab and bevacizumab biosimilars, and 55% for rituximab biosimilars.**
- Infiximab biosimilars have had the most limited adoption, with approximately 20% market share.



The background of the image is a complex, abstract representation of molecular structures. It features a central vertical axis with a bright, glowing yellow and orange light source. Radiating from this center are various molecular models, including ball-and-stick structures and dense clusters of spheres. The color palette transitions from deep blue on the left to bright orange on the right, with a dark grey horizontal band across the middle. The overall effect is one of scientific complexity and dynamic energy.

And Then, There's Canada...

The background features a complex arrangement of molecular models. Some are simple diatomic or triatomic molecules, while others are more intricate, resembling a DNA double helix or a branched polymer. The spheres representing atoms are semi-transparent and have a blue or cyan tint. A bright, glowing orange-yellow light source is positioned in the upper-middle section, creating a radial gradient and casting a warm glow over the scene. The overall composition is layered, with some molecular structures appearing in the foreground and others receding into the background.

**Canadian Proponents of Forced-Switching Often
Cite European Experience to Justify These Policies...**

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-biosi...

“ 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. ”

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 counter-argument 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.”



The screenshot shows the New Brunswick Health website. The header includes the New Brunswick Canada logo and navigation links for Home, Contact, Français, and Departments. The main navigation bar lists About Us, Services, Publications, Patients, and Health Professionals. The page title is "Biosimilars Initiative". A list of links includes Overview, Biologic and Biosimilar Drugs, Biologic Drugs Included, Quick Facts, What the Experts are Saying about Biosimilars, Information for Patients, and Information for Prescribers and Health Professionals. The "Overview" section is highlighted, and the text below states: "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."

The background features a complex arrangement of molecular models. A prominent DNA double helix is visible in the center, rendered with a glowing orange and yellow core. Surrounding it are various other molecular structures, including linear chains and branched networks, depicted with translucent blue and white spheres connected by thin rods. The overall color palette transitions from deep blue on the left to a warm orange on the right, creating a sense of depth and scientific focus.

What Are the Experiences of Patients in Europe, British Columbia, and Alberta?

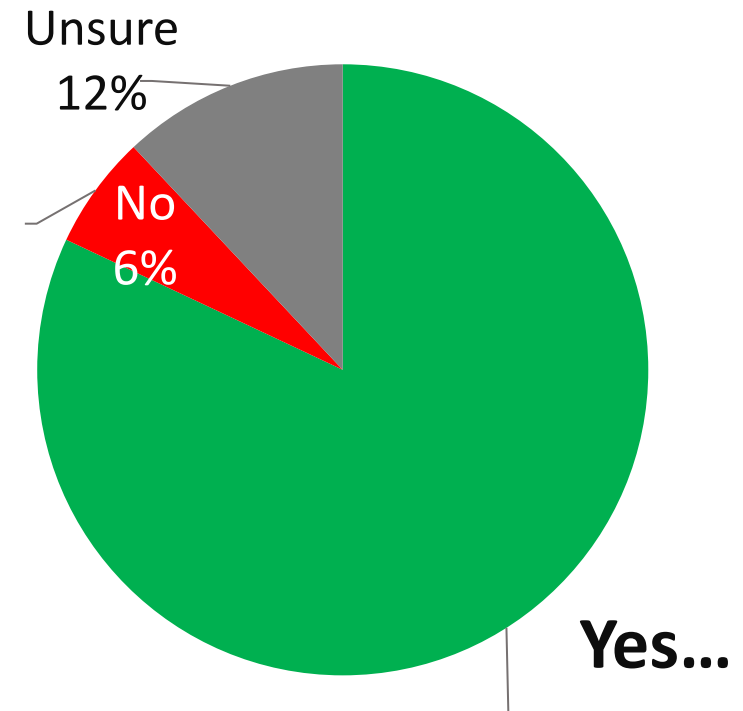
The background of the slide is a complex, abstract representation of molecular structures. It features a central vertical axis with a bright, glowing yellow and orange light source. Radiating from this center are various molecular models, including ball-and-stick structures and dense clusters of spheres. The color palette transitions from deep blue on the left to bright orange on the right, with a central band of white and yellow light. The overall effect is one of scientific complexity and dynamic energy.

We Don't Know- That's the Problem

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-naïve 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

VANCOUVER SUN

Op-Ed

Michael Reilly: Forcing patients to switch to biosimilars puts them in uncharted waters

Michael Reilly
Jun 24, 2019 • June 24, 2019 • 4 minute read • [Join the conversation](#)

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OPINIONS POINTS DE VUE

11 septembre 2021 16h54

Les politiques de substitution forcée mettent le Québec sur la mauvaise voie

Partager

MICHAEL REILLY
Directeur général de l'ASBM (Alliance for Safe Biologic Medicines)

TELEGRAPH-JOURNAL

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GUEST OPINION

Forced-substitution medication policy puts N.B on the track

NIAGARA FALLS
REVIEW

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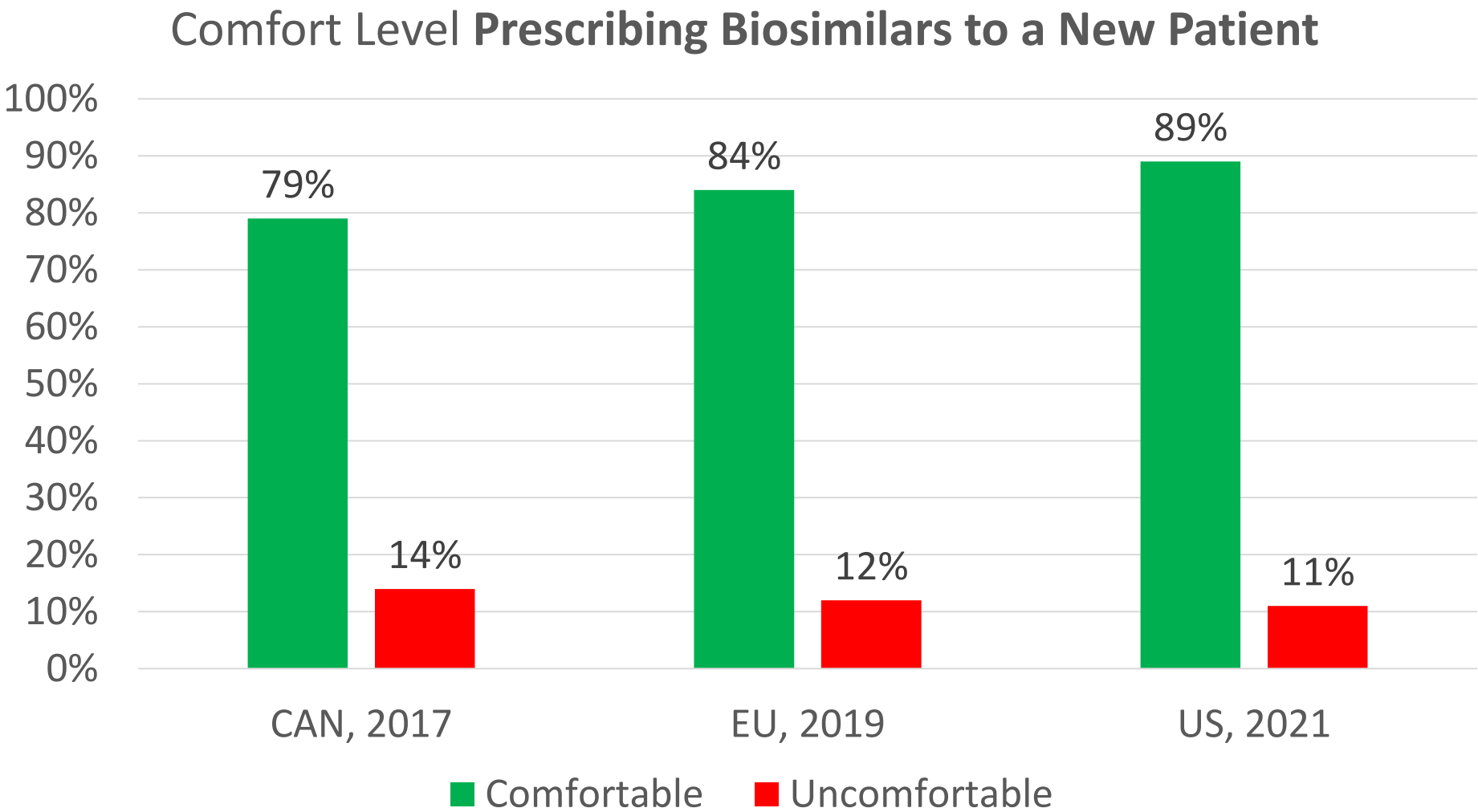
CONTRIBUTORS OPINION

Forced-substitution policies for biologic medicines would put Ontario on wrong track

Biosimilars are highly similar to the originator medicines they copy, but unlike generics, they are not exact copies, Michael Reilly writes.

By **Michael Reilly**
Wed., Oct. 6, 2021 | 3 min. read

*Surveys Have Shown Physicians Have High Confidence in Biosimilars:
They Are Very Comfortable Prescribing Biosimilars to New Patients*



Physician confidence in and comfort with biosimilars is high- the vast majorities of physicians have no concerns with 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




The screenshot shows a news article header with logos for the Canadian Association of Gastroenterology and Crohn's and Colitis Canada. The article is dated October 24, 2019, and is titled "Joint Statement From The Canadian Association Of Gastroenterology And Crohn's And Colitis Canada". The text of the article states that the organizations recently announced a joint statement accepted for publication in the Journal of the Canadian Association of Gastroenterology. The statement is titled "Joint Canadian Association of Gastroenterology and Crohn's and Colitis Canada Position Statement on Biosimilars for the Treatment of Inflammatory Bowel Disease" and was co-authored by Drs Paul Moayyedi, Eric Benchimol, David Armstrong, and Grigorios I. Leontiadis. The article also mentions that the authors used the GRADE approach to review evidence comparing biosimilars to originator biologics for the treatment of inflammatory bowel disease, evaluating efficacy, safety, cost, and acceptance by patients.



The image shows the cover of a report from INESS (Le Réseau Québécois). The cover is primarily white with a blue vertical band on the right side. The INESS logo is at the top left. The date "MAY 2020" is printed in green on the blue band. The title "STATE OF KNOWLEDGE" is printed in white on the blue band. The main title of the report, "Safety of switching biologics and their interchangeability", is printed in a smaller font at the bottom of the cover.

Canadian Patient Groups Also Strongly Opposed These Policies



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

MOIRA WYTON Updated: January 15, 2020



Arthritis patient Wilma Ritter speaks at the Federal Building on Wednesday, Jan. 15, 2020, in front of other Albertans with chronic illness who are devastated by the UCP government's decision to switch from biologic to biosimilar medications. *ED KAISER / POSTMEDIA*

< Home



EDMONTON | News

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

GLENDALUYMES 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

