SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

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

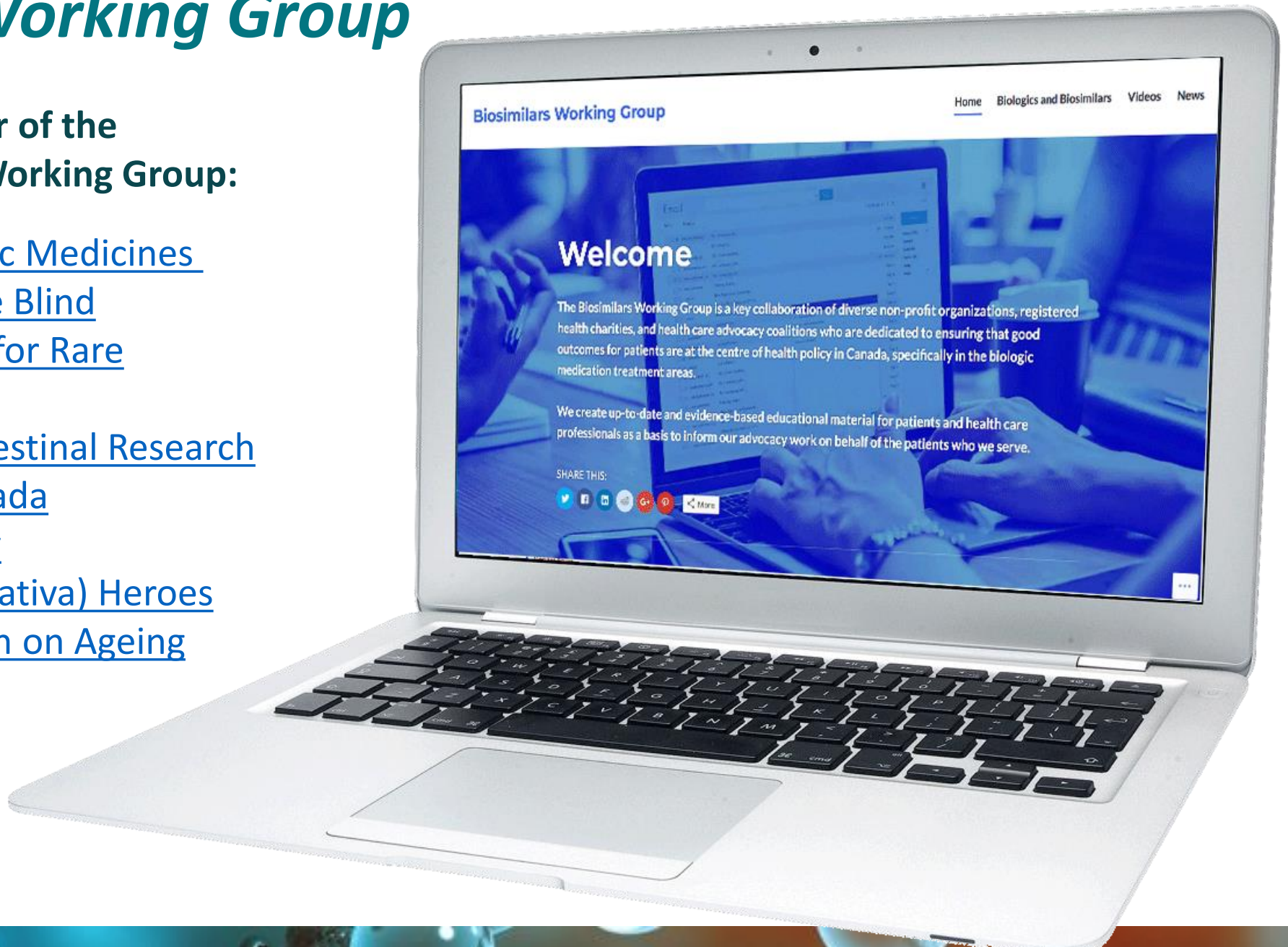
- Associate Deputy Secretary at the U.S. Department of Health and Human Services (HHS) from 2005-2008
- Responsible for policy development and implementation, regulatory oversight for issues involving CMS and the FDA.
- Senior Advisor to the Assistant Secretary for Public Affairs and the Assistant Secretary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

Biosimilars Working Group

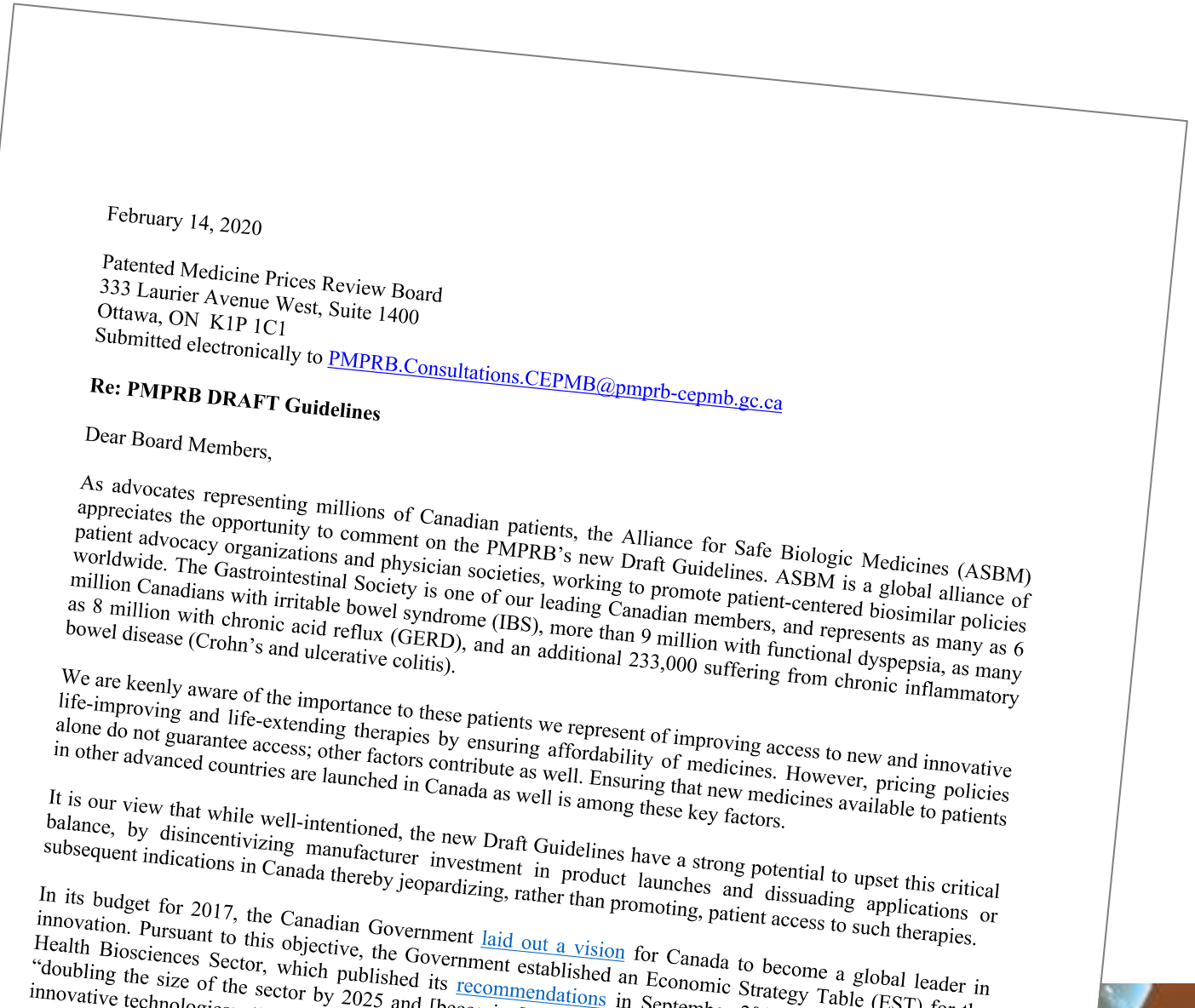
ASBM is also a member of the Canadian Biosimilars Working Group:

[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]

biosimilaroptions.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 [illegible] "doubling the size of the sector by 2025 and [illegible] innovative technologies

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

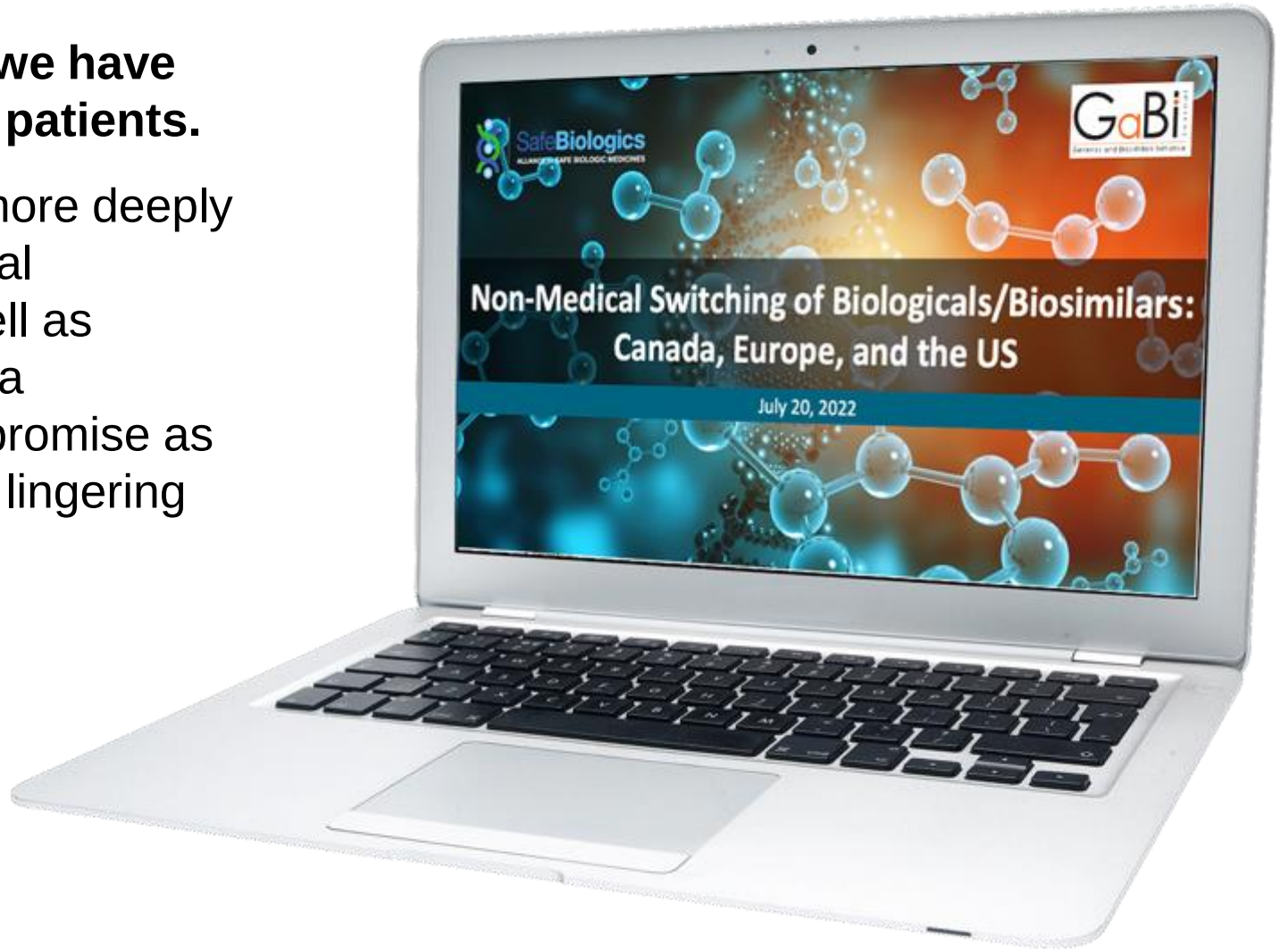
- Tomorrow ASBM & GaBI will present a webinar which discusses the factors contributing to the success of biosimilars in Europe and the U.S.
- This is the first in a series of webinars presented by ASBM and GaBI this year.

REGISTER

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% .

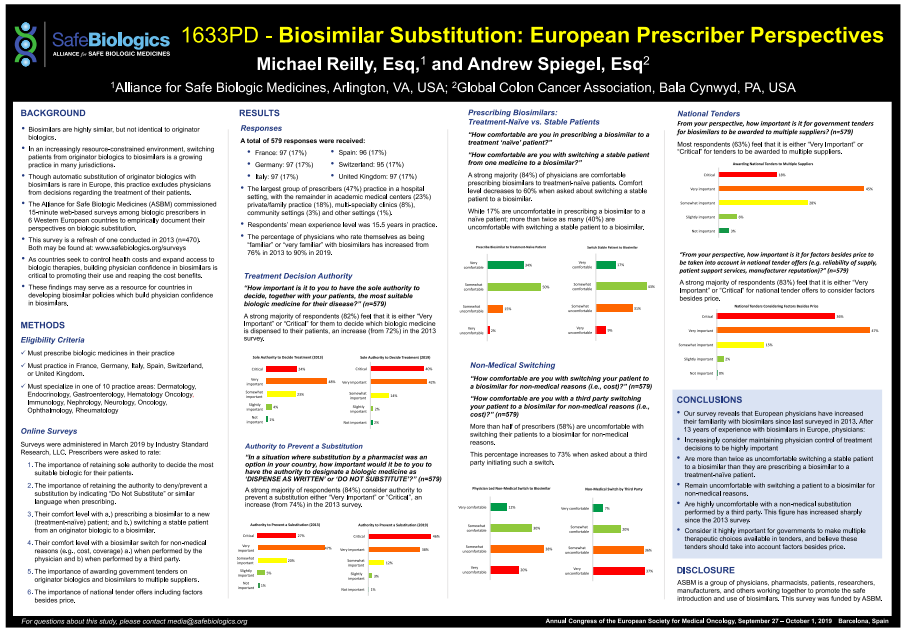
Variations are influenced by government involvement, reimbursement structures and tender procurement policies.

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.***



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1633PD - **Biosimilar Substitution: European Prescriber Perspectives**

Michael Reilly, Esq,[1] and Andrew Spiegel, Esq[2]

[1]Alliance for Safe Biologic Medicines, Arlington, VA, USA; [2]Global Colon Cancer Association, Bala Cynwyd, PA, USA

BACKGROUND

- Biosimilars are highly similar, but not identical to originator biologics.
- In an increasingly resource-constrained environment, switching patients from originator biologics to biosimilars is a growing practice in many jurisdictions.
- Though automatic substitution of originator biologics with biosimilars is rare in Europe, this practice excludes physicians from decisions regarding the treatment of their patients.
- The Alliance for Safe Biologic Medicines (ASBM) commissioned 15-minute web-based surveys among biologic prescribers in 6 Western European countries to empirically document their perspectives on biologic substitution.
- This survey is a refresh of one conducted in 2013 (n=470). Both may be found at: www.safebiologics.org/surveys
- As countries seek to control health costs and expand access to biologic therapies, building physician confidence in biosimilars is critical to promoting their use and reaping the cost benefits.
- These findings may serve as a resource for countries in developing biosimilar policies which build physician confidence in biosimilars.

METHODS

Eligibility Criteria

- ✓ Must prescribe biologic medicines in their practice
- ✓ Must practice in France, Germany, Italy, Spain, Switzerland, or United Kingdom.
- ✓ Must specialize in one of 10 practice areas: Dermatology, Endocrinology, Gastroenterology, Hematology Oncology, Immunology, Nephrology, Neurology, Oncology, Ophthalmology, Rheumatology

Online Surveys

Surveys were administered in March 2019 by Industry Standard Research, LLC. Prescribers were asked to rate:

1. The importance of retaining sole authority to decide the most suitable biologic for their patients.
2. The importance of retaining the authority to deny/prevent a substitution by indicating "Do Not Substitute" or similar language when prescribing.
3. Their comfort level with a.) prescribing a biosimilar to a new (treatment-naïve) patient; and b.) switching a stable patient from an originator biologic to a biosimilar.
4. Their comfort level with a biosimilar switch for non-medical reasons (e.g., cost, coverage) a.) when performed by the physician and b) when performed by a third party.
5. The importance of awarding government tenders on originator biologics and biosimilars to multiple suppliers.
6. The importance of national tender offers including factors besides price.

RESULTS

Responses

A total of 579 responses were received:

- France: 97 (17%)
- Germany: 97 (17%)
- Italy: 97 (17%)
- Spain: 96 (17%)
- Switzerland: 95 (17%)
- United Kingdom: 97 (17%)

- The largest group of prescribers (47%) practice in a hospital setting, with the remainder in academic medical centers (23%) private/family practice (18%), multi-specialty clinics (8%), community settings (3%) and other settings (1%).
- Respondents' mean experience level was 15.5 years in practice.
- The percentage of physicians who rate themselves as being "familiar" or "very familiar" with biosimilars has increased from 76% in 2013 to 90% in 2019.

Treatment Decision Authority

"How important is it to you to have the sole authority to decide, together with your patients, the most suitable biologic medicine for their disease?" (n=579)

A strong majority of respondents (82%) feel that it is either "Very Important" or "Critical" for them to decide which biologic medicine is dispensed to their patients, an increase (from 72%) in the 2013 survey.

Authority to Prevent a Substitution

"In a situation where substitution by a pharmacist was an option in your country, how important would it be to you to have the authority to designate a biologic medicine as 'DISPENSE AS WRITTEN' or 'DO NOT SUBSTITUTE'?" (n=579)

A strong majority of respondents (84%) consider authority to prevent a substitution either "Very Important" or "Critical", an increase (from 74%) in the 2013 survey.

Prescribing Biosimilars: Treatment-Naïve vs. Stable Patients

"How comfortable are you in prescribing a biosimilar to a treatment 'naïve' patient?"

"How comfortable are you with switching a stable patient from one medicine to a biosimilar?"

A strong majority (84%) of physicians are comfortable prescribing biosimilars to treatment-naïve patients. Comfort level decreases to 60% when asked about switching a stable patient to a biosimilar.

While 17% are uncomfortable in prescribing a biosimilar to a naïve patient; more than twice as many (40%) are uncomfortable with switching a stable patient to a biosimilar.

Non-Medical Switching

"How comfortable are you with switching your patient to a biosimilar for non-medical reasons (i.e., cost)?" (n=579)

"How comfortable are you with a third party switching your patient to a biosimilar for non-medical reasons (i.e., cost)?" (n=579)

More than half of prescribers (58%) are uncomfortable with switching their patients to a biosimilar for non-medical reasons.

This percentage increases to 73% when asked about a third party initiating such a switch.

National Tenders

From your perspective, how important is it for government tenders for biosimilars to be awarded to multiple suppliers? (n=579)

Most respondents (63%) feel that it is either "Very Important" or "Critical" for tenders to be awarded to multiple suppliers.

"From your perspective, how important is it for factors besides price to be taken into account in national tender offers (e.g. reliability of supply, patient support services, manufacturer reputation)?" (n=579)

A strong majority of respondents (83%) feel that it is either "Very Important" or "Critical" for national tender offers to consider factors besides price.

CONCLUSIONS

- Our survey reveals that European physicians have increased their familiarity with biosimilars since last surveyed in 2013. After 13 years of experience with biosimilars in Europe, physicians:
- Increasingly consider maintaining physician control of treatment decisions to be highly important
- Are more than twice as uncomfortable switching a stable patient to a biosimilar than they are prescribing a biosimilar to a treatment-naïve patient.
- Remain uncomfortable with switching a patient to a biosimilar for non-medical reasons.
- Are highly uncomfortable with a non-medical substitution performed by a third party. This figure has increased sharply since the 2013 survey.
- Consider it highly important for governments to make multiple therapeutic choices available in tenders, and believe these tenders should take into account factors besides price.

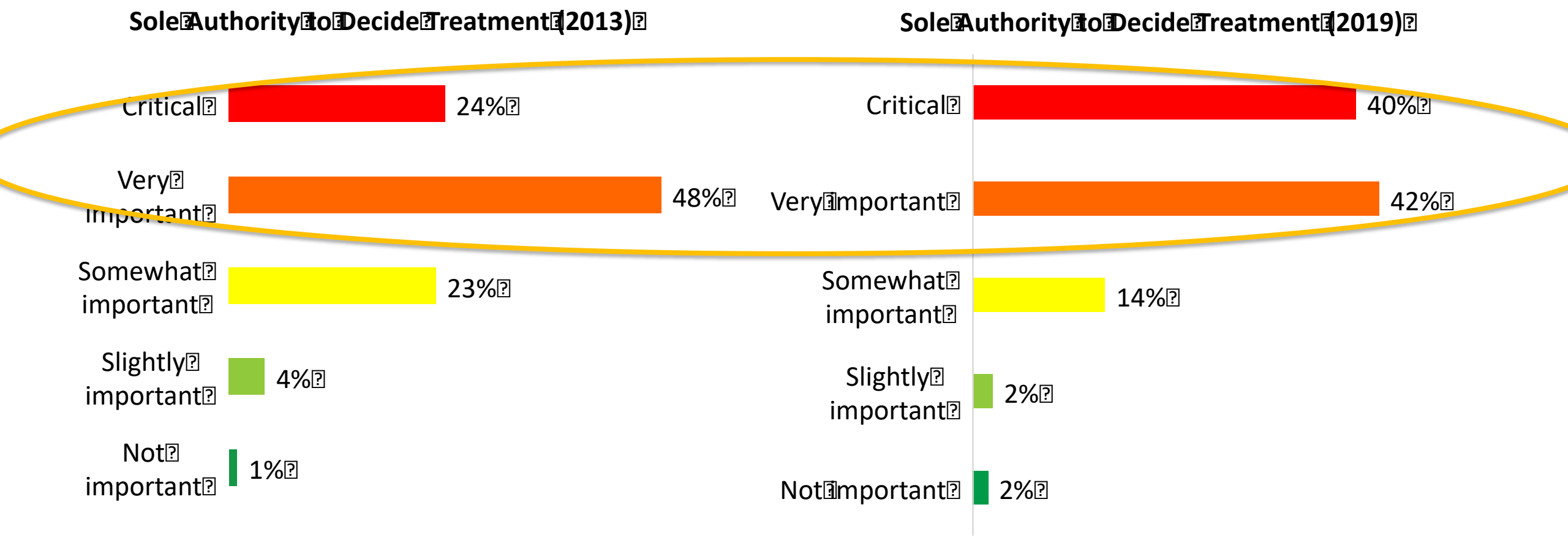
DISCLOSURE

ASBM is a group of physicians, pharmacists, patients, researchers, manufacturers, and others working together to promote the safe introduction and use of biosimilars. This survey was funded by ASBM.

For questions about this study, please contact media@safebiologics.org

Annual Congress of the European Society for Medical Oncology, September 27 – October 1, 2019 Barcelona, Spain

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



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
- <u>OBJECTIVE: identify principles which can be applied to develop an efficient and sustainable biosimilar market.</u>

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.

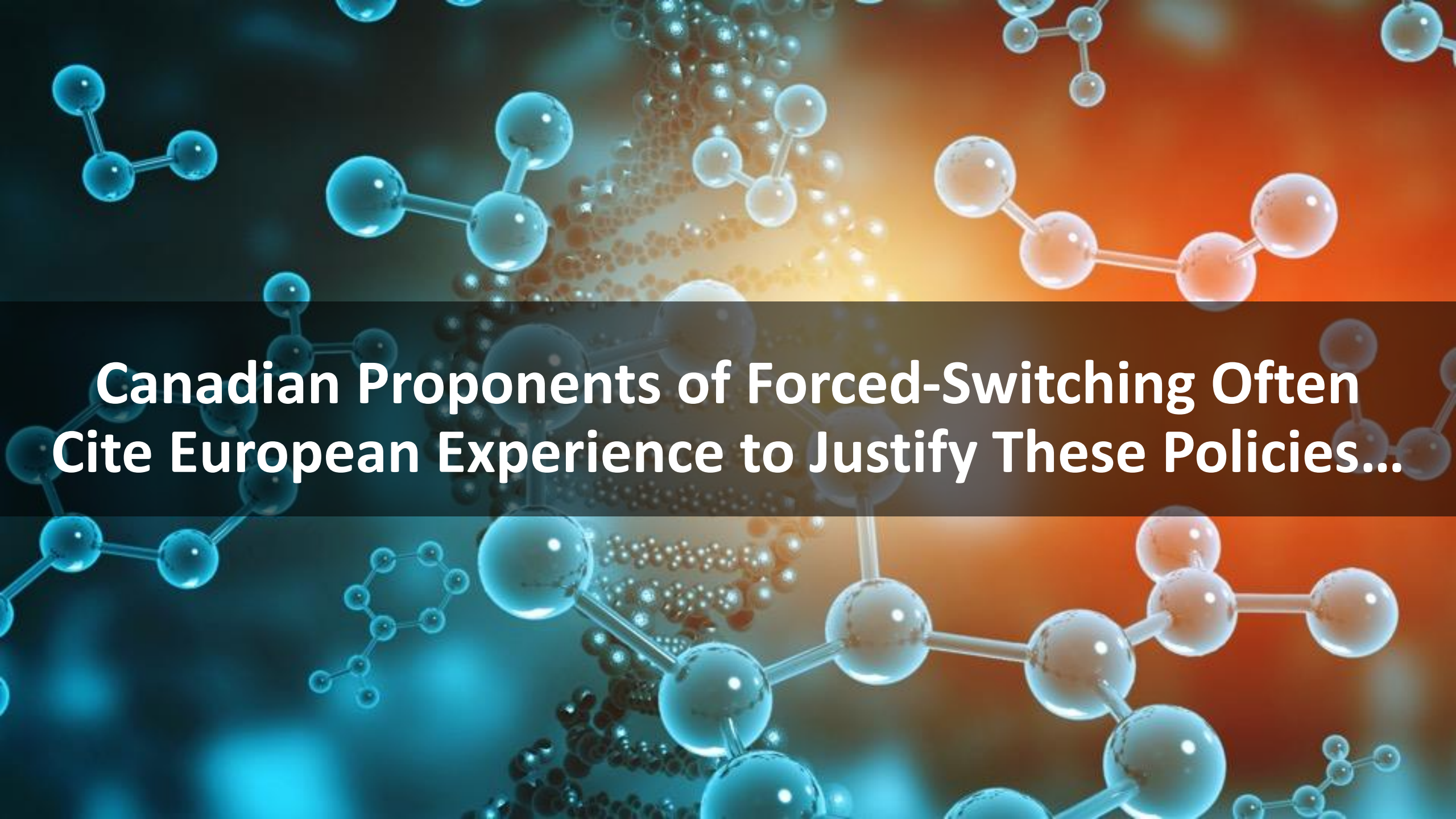
- **Critically: No European country has stopped reimbursement of an originator product through an arbitrary government fiat as occurs in the Alberta and British Columbia forced-switching policies.**

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.
- Infliximab biosimilars have had the most limited adoption, with approximately 20% market share.

2 https://accessiblemeds.org/resources/press-releases/study-finds-us-generic-and-biosimilar-savings-totaled-record-338-billion


And Then, There’s Canada…



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

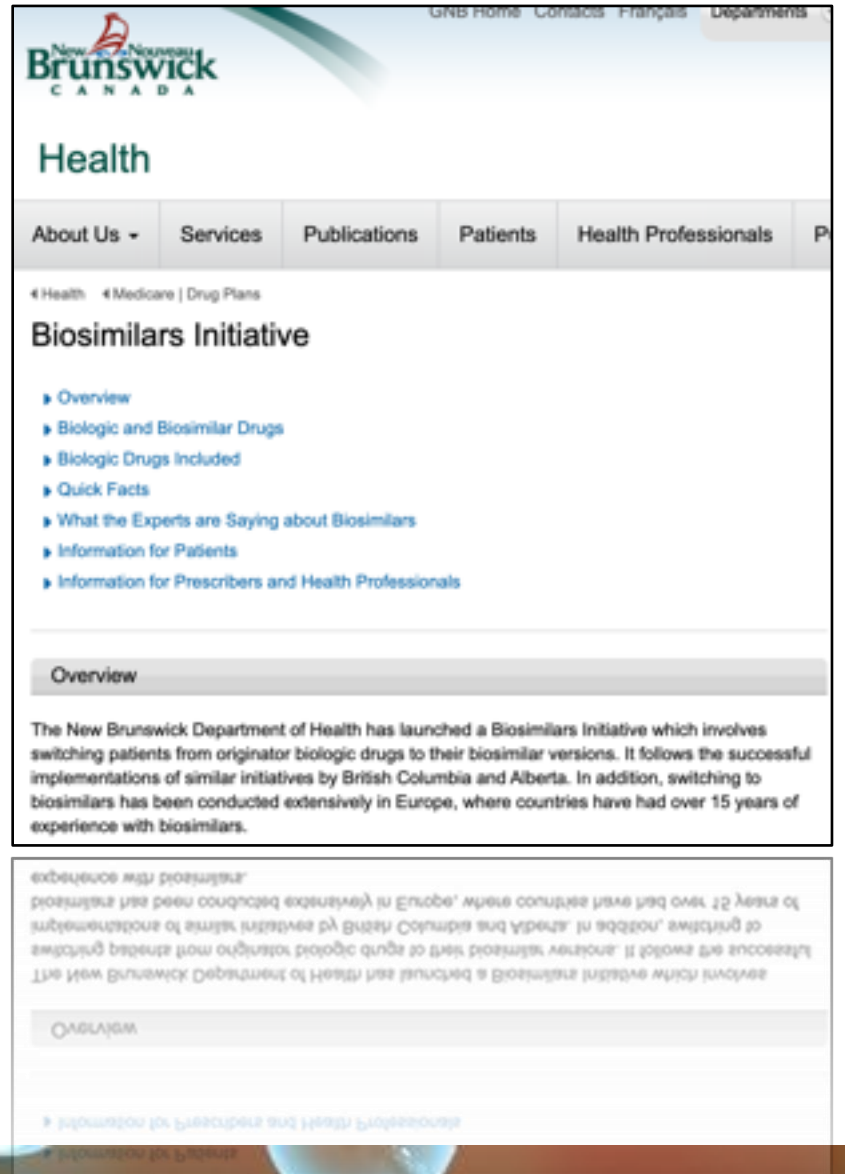
Alberta, December 2019

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

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."



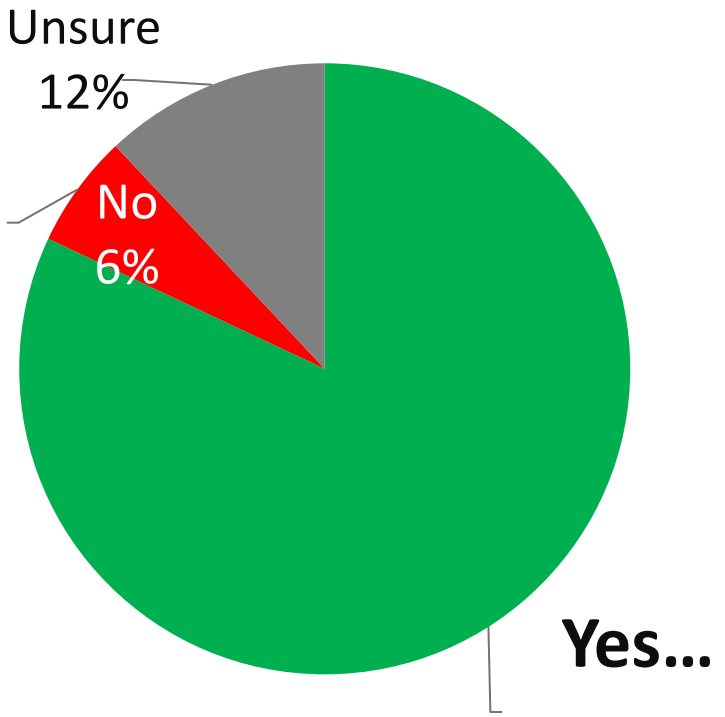
What Are the Experiences of Patients in Europe, British Columbia, and Alberta?


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.**
- **<u>Switching data/studies that show positive patient outcomes will do this.</u>**

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)


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GUEST OPINION

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


NIAGARA FALLS REVIEW

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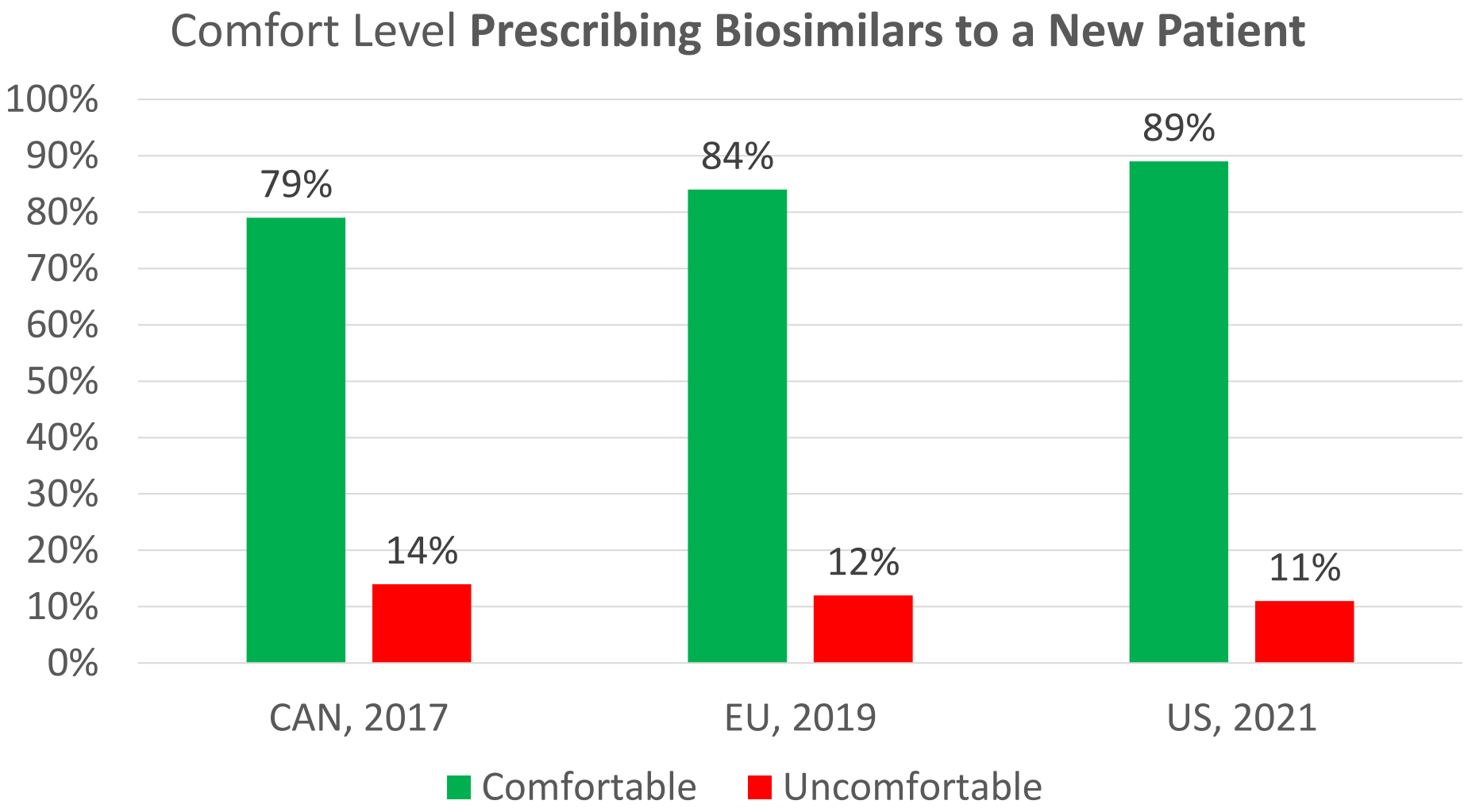
Forced-substitution policies for biologic medicines would put Ontario on wrong track

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

MR 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

Canadian Association of Gastroenterology | L'Association Canadienne de Gastroentérologie

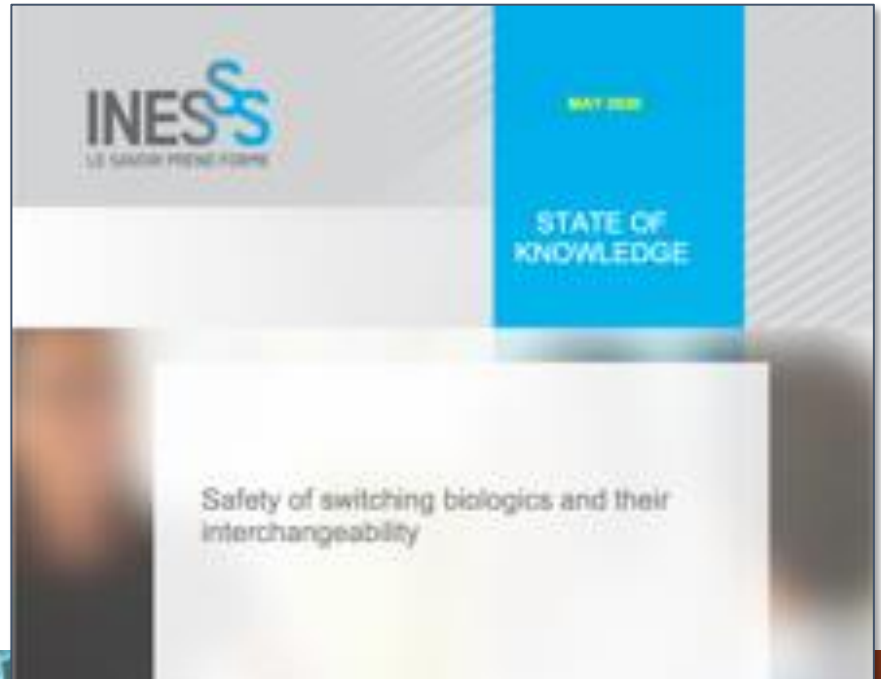
Crohn's and Colitis Canada | Crohn et Colite Canada

News | October 24, 2019

Joint Statement From The Canadian Association Of Gastroenterology And Crohn's And Colitis Canada

The Canadian Association of Gastroenterology and Crohn's and Colitis Canada recently announced a joint statement that has been accepted for publication in the Journal of the Canadian Association of Gastroenterology. 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 esteemed 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.



Canadian Patient Groups Also Strongly Opposed These Policies

EDMONTON JOURNAL

NEWS OPINION SPORTS BUSINESS ARTS LIFE OBITS CLASSIFIEDS

NEWS POLITICS FEATURED: CORONAVIRUS CANNABIS OBESITY

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

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CTV NEWS

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

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