SafeBiologics
ALLIANCE *for* SAFE BIOLOGIC MEDICINES

The Current Biosimilars Landscape: What is Contributing to Gaining Market Share?

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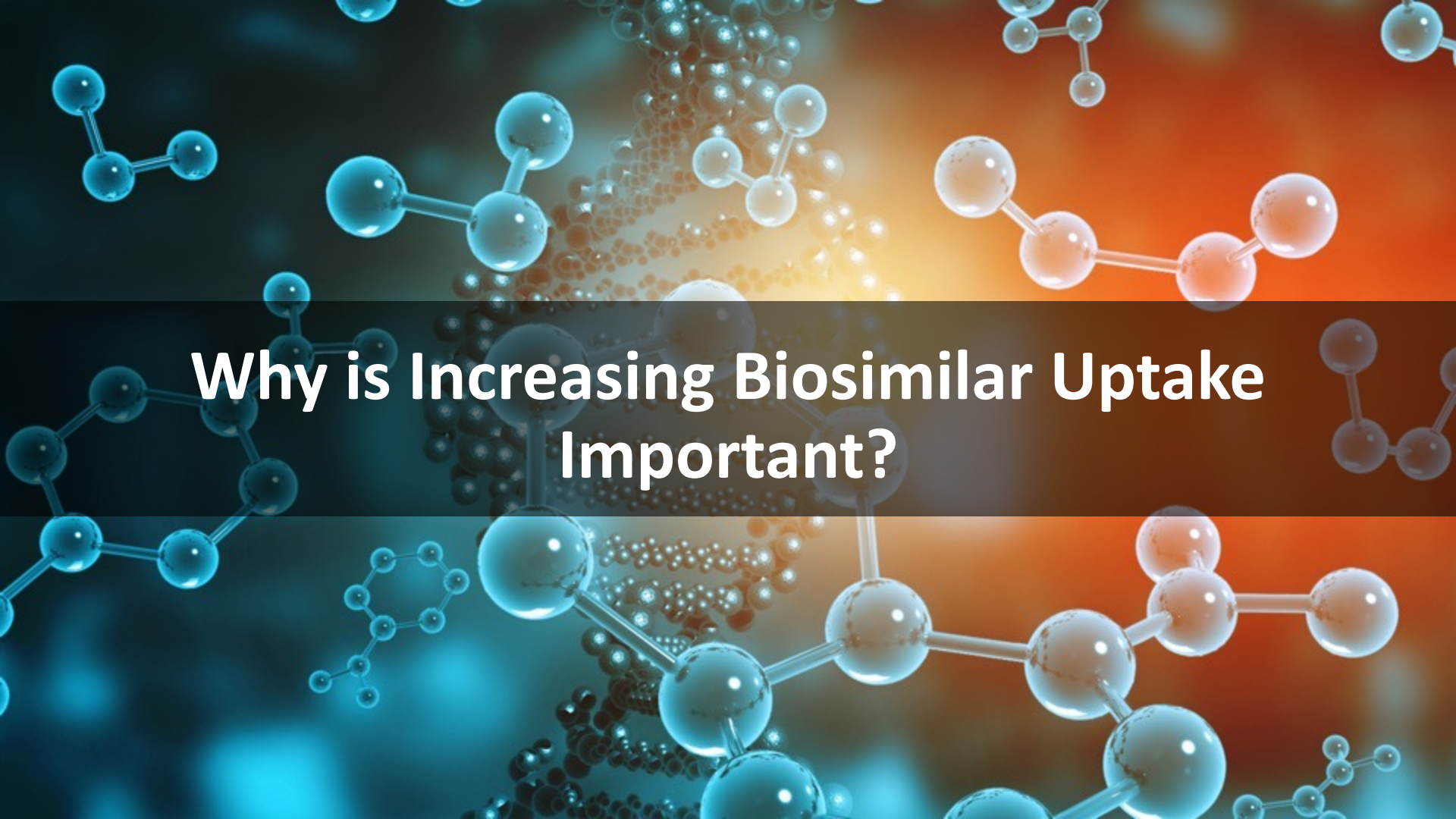
The Biosimilars Market: Key Questions

Why is Increasing Biosimilar Uptake Important?

What Factors Increase Uptake?

What Challenges Exist?

How to Address These?


Why is Increasing Biosimilar Uptake Important?

Potential Savings to U.S. Market: RAND 2022 Study

- Savings estimated to be **$38.4 billion or 5.9% of projected total U.S. spending on biologics from 2021 to 2025,** according to a new RAND Corporation study.

- More aggressive biosimilar uptake and competition could trigger larger cuts, with **savings estimated to be as large as $124.5 billion from 2021 to 2025 under the most-optimistic scenario**.

- The study estimates that most of the expected savings from biosimilars would be caused by **downward pressure on the brand-name biologics they compete with, rather than lower biosimilar prices**.

Chain Drug Review

Biosimilars could generate $38.4 billion in savings over five years

January 10, 2022 by Chain Drug Review

PRINT PDF EMAIL

NEW YORK — Biosimilar drugs could drive down prices for expensive medicines used to treat illnesses such as cancer and rheumatoid arthritis, with savings estimated to be $38.4 billion or 5.9% of projected total U.S. spending on biologics from 2021 to 2025, according to a new RAND Corporation study.

However, Biosimilar Discounts are Lower than Generic Discounts

- Typically biosimilars in the U.S. have a discount of 15-35% off the price of the reference product.
- By contrast, generic versions of small molecule drugs typically launch with an 80%-90% discount over the originator.
- In Europe, biosimilar discounts can be somewhat higher (30-50%) after **availability of multiple products** drive prices down.

Note: In the case of a sole tender, however, this price competition can favor the originator manufacturer at the expense of biosimilar market (Norway example)

What Factors Increase Uptake? (European Case Study)

“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 Paper examined findings and recommendations of five previous studies and reports on biosimilar sustainability in Europe.

2014: GfK Market Access/European Generics Association (EGA) (now Medicines for Europe)

2015: European Federation of Pharmaceutical Industries and Associations (EFPIA)

2016: Simon & Kucher/ Medicines for Europe report: "Payers' price & market access policies supporting a sustainable biosimilar medicines market."

2018: IQVIA; Advancing Biosimilar Sustainability in Europe; commissioned and funded by Pfizer.

2019: Patch Consilium study "Towards a sustainable European market for off-patent biologics", commissioned and funded by EFPIA.

medicines for europe
better access. better health.

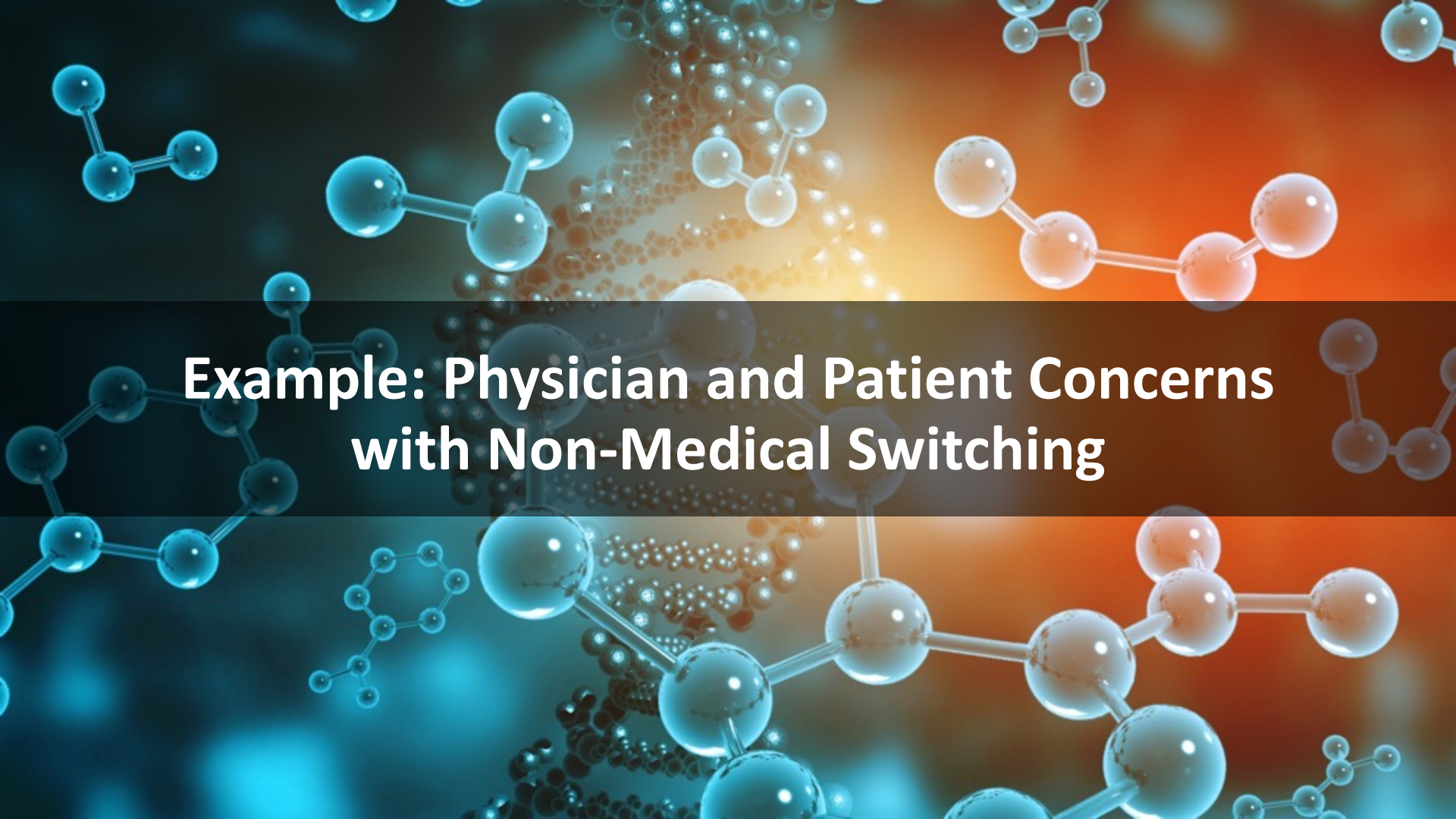
efpia
European Federation of Pharmaceutical Industries and Associations

IQVIA

Identified Three "Must-Have" Principles:

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.


What Obstacles Exist for Increasing Biosimilar Uptake?

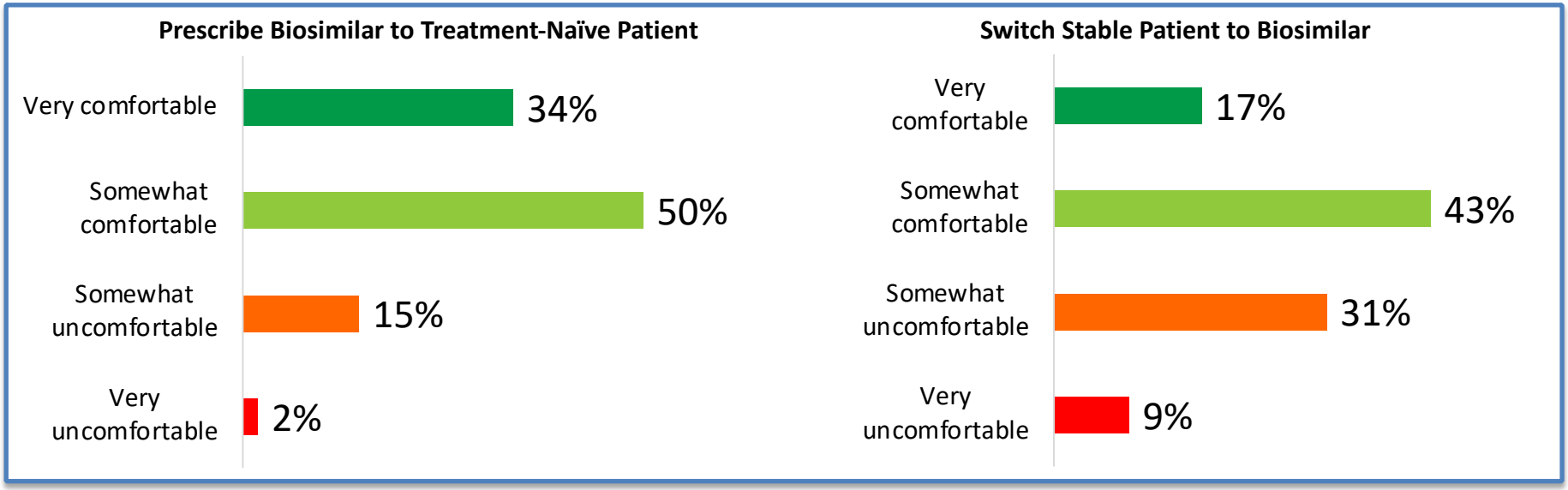


Example: Physician and Patient Concerns with Non-Medical Switching

EU Survey: Prescribing Biosimilars: Treatment-Naïve vs. Stable Patients

Q: "How comfortable are you in prescribing a biosimilar to a treatment 'naïve' patient?"
Q: "How comfortable are you with switching a stable patient from one medicine to a biosimilar?"

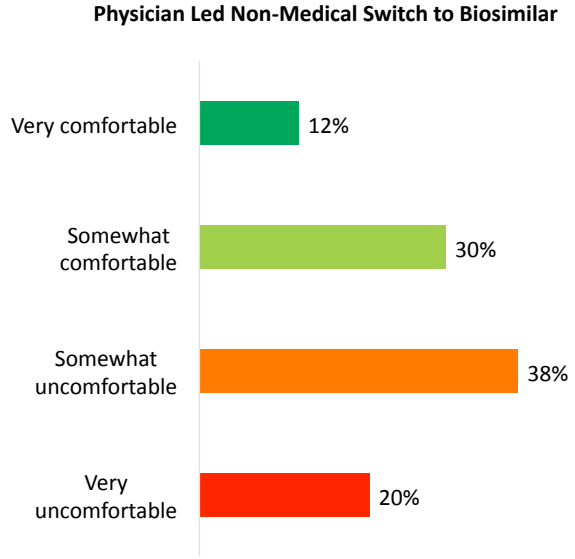
A strong majority (84%) of physicians are comfortable prescribing biosimilars to treatment-naïve patients. Comfort level decreases to 60% when asked about switching a stable patient to a biosimilar.

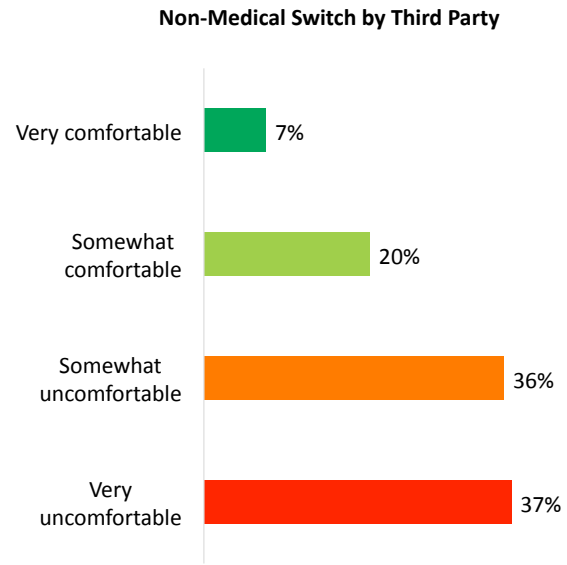


Strong Discomfort With Third-Party/ Non-Medical Switching

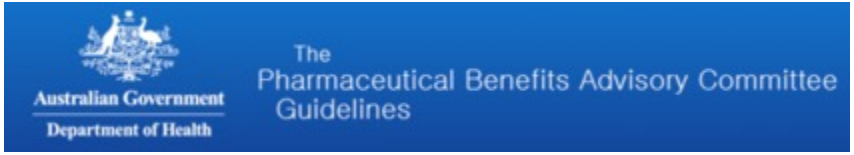
Q: "How comfortable are you with switching your patient to a biosimilar for non-medical reasons (i.e., cost)?" (n=579)
Q: "How comfortable are you with a third party switching your patient to a biosimilar for non-medical reasons (i.e., cost)?" (n=579)

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 .**





Case Study: Australian Biosimilar Substitution Policy

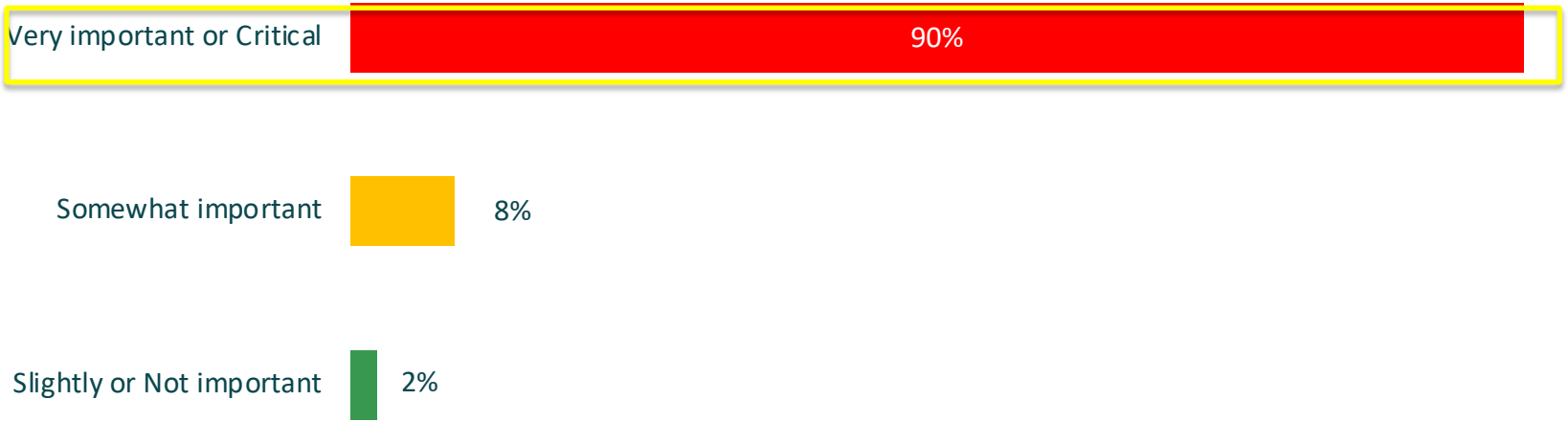


- On May 26, 2015, Australian Health Minister Sussan Ley announced that Australia would become the first nation in the world to allow so-called “automatic” substitution of biosimilars by pharmacists in place of the biologic prescribed by a physician.
- In Australia this is referred to as “**a-flagging”**
- This move came at the recommendation of Australia’s Pharmacy Benefits Advisory Committee (PBAC)- the government payor, not the regulatory agency (Therapeutic Goods Administration).
- This made substitution an economic non-medical decision rather than a safety decision.

2016 Australian Survey (n=160): Importance of decision authority to choose biologic is dispensed to patient?

Question

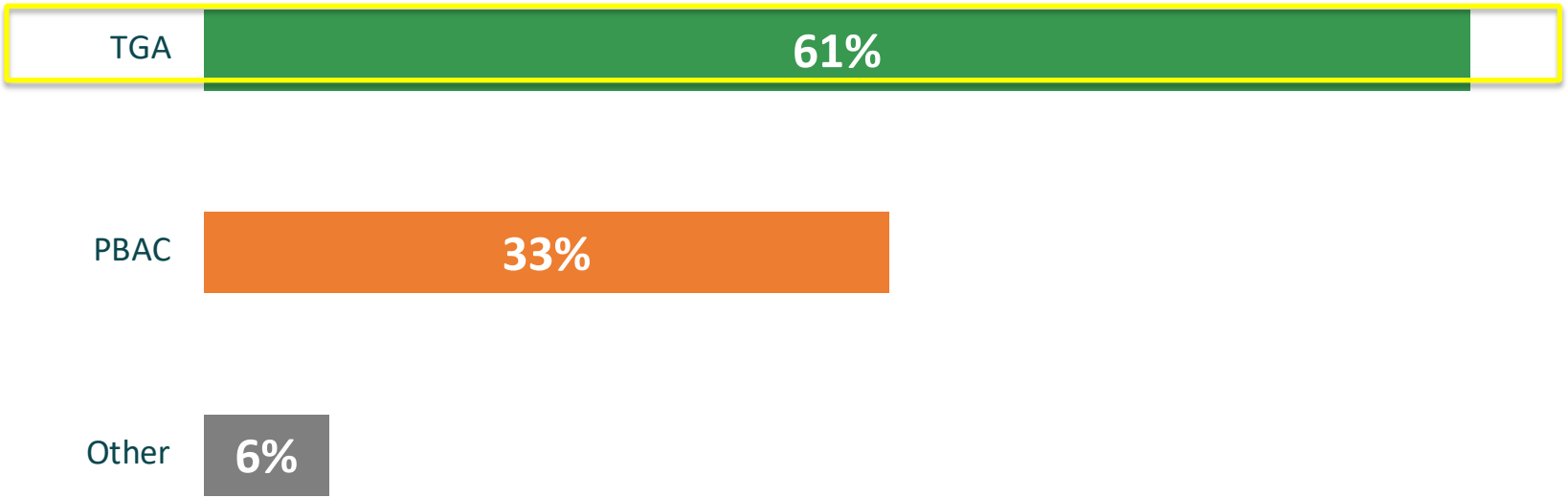
"How important is it for you, as the prescribing physician, to have the sole authority to decide, together with your patient, the most suitable biologic medicine that is to be dispensed to your patient?"



Australian Survey: Substitution Decision?

Question

"Which body do you believe should be responsible for providing the primary advice to Government that a product is suitable for pharmacy level substitution?"

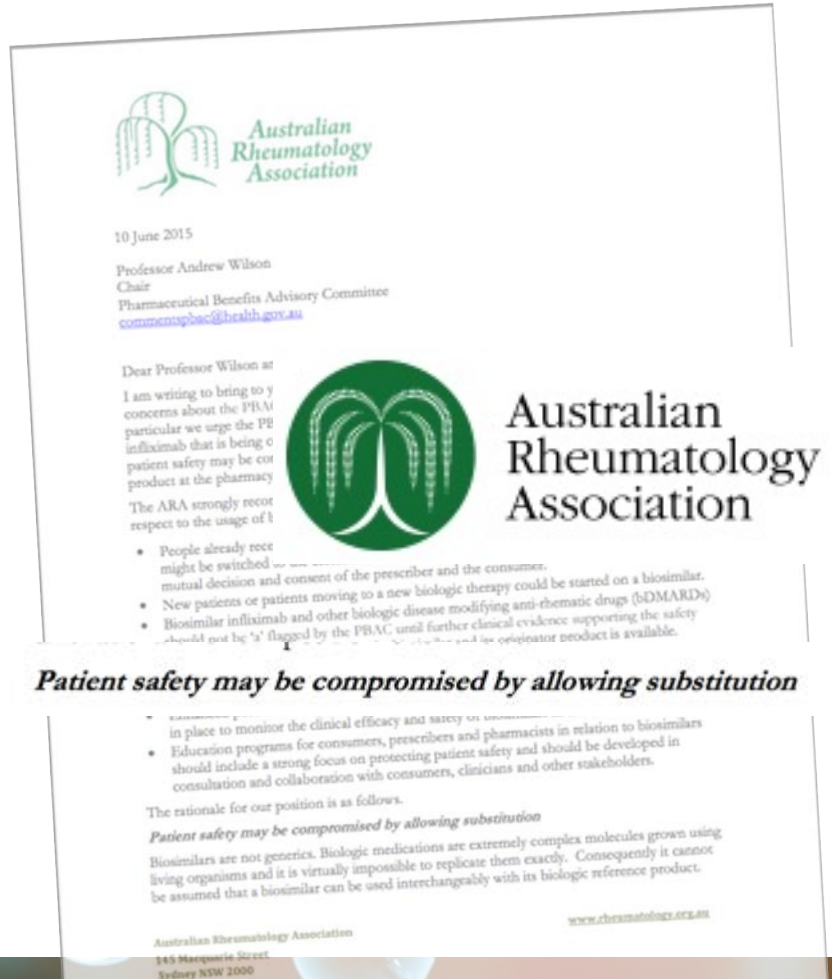


Physicians Asked for Data

In February 2016, the Australian Rheumatology Association called for **a robust pharmacovigilance program** to be set up for the REMICADE (infliximab) biosimilar INFLECTRA

Dr. Mona Marabani (ARA):

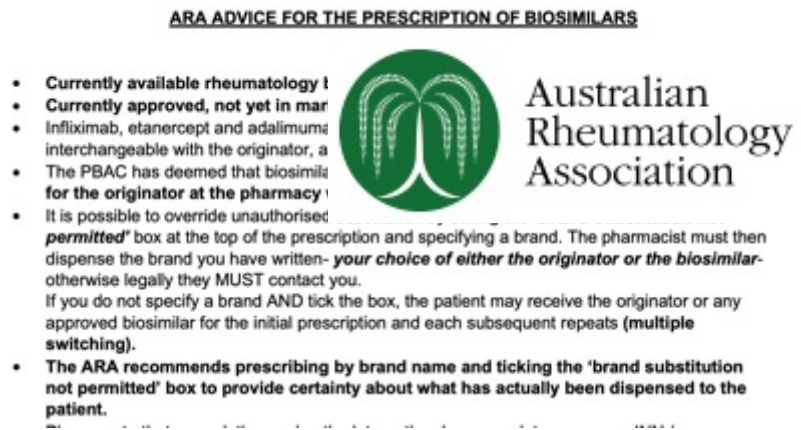
- "The ARA wants to see biosimilars successfully introduced to the Australian market, but we have expressed concern with respect to substitution and extrapolation of indications because the evidence is just not there … We are hopeful that collection of data, if done comprehensively, may go some way to establishing an evidence base which is so sorely needed"



Preventing Automatic Substitution

To prevent automatic substitution, physicians have to check a box “brand substitution not permitted” when prescribing. **The Australian PBAC believed that the physicians would not take this extra step.**

Yet, as of July 2020, the ARA still advises its members:



ARA ADVICE FOR THE PRESCRIPTION OF BIOSIMILARS

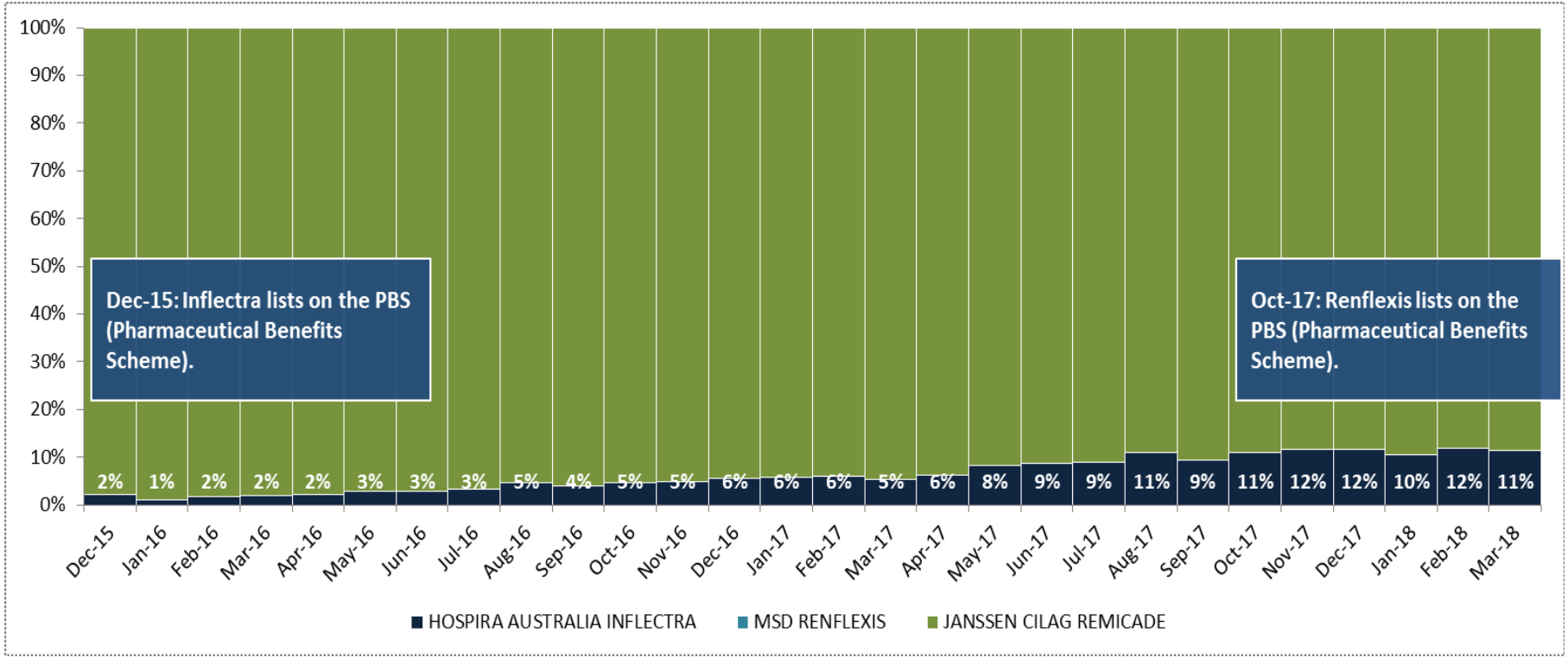
- **Currently available rheumatology b**
- **Currently approved, not yet in mar**
- Infliximab, etanercept and adalimuma
  interchangeable with the originator, a
- The PBAC has deemed that biosimila
  for the originator at the pharmacy
- It is possible to override unauthorised
  permitted box at the top of the prescription and specifying a brand. The pharmacist must then dispense the brand you have written- ***your choice of either the originator or the biosimilar-*** otherwise legally they MUST contact you.
  If you do not specify a brand AND tick the box, the patient may receive the originator or any approved biosimilar for the initial prescription and each subsequent repeats **(multiple switching).**
- **The ARA recommends prescribing by brand name and ticking the ‘brand substitution not permitted’ box to provide certainty about what has actually been dispensed to the patient.**

Australian Rheumatology Association

“If you do not specify a brand AND tick the box, the patient may receive the originator or any approved biosimilar for the initial prescription and each subsequent repeats (multiple switching). **The ARA recommends prescribing by brand name and ticking the ‘brand substitution not permitted’ box to provide certainty about what has actually been dispensed to the patient.”** – *July 2020 ARA Advice for Prescription of Biosimilars*

This practice led to slow biosimilar uptake in Australia as many physicians checked “Brand Substitution Not Permitted”…

Dec 2015 to Mar 2018



Source: IMS Audits data (Australia only); Market Share is measured as share of dosage unit sales (this is to account for compounding)

May 2021: Australia Announces Forced Switching of Stage IV Metastatic Cancer Patients; Patient Advocacy Orgs Push Back.

- Avastin (BEVACIZUMAB) was withdrawn from Australia's Pharmaceutical Benefit Scheme (PBS) as a biosimilar was added.

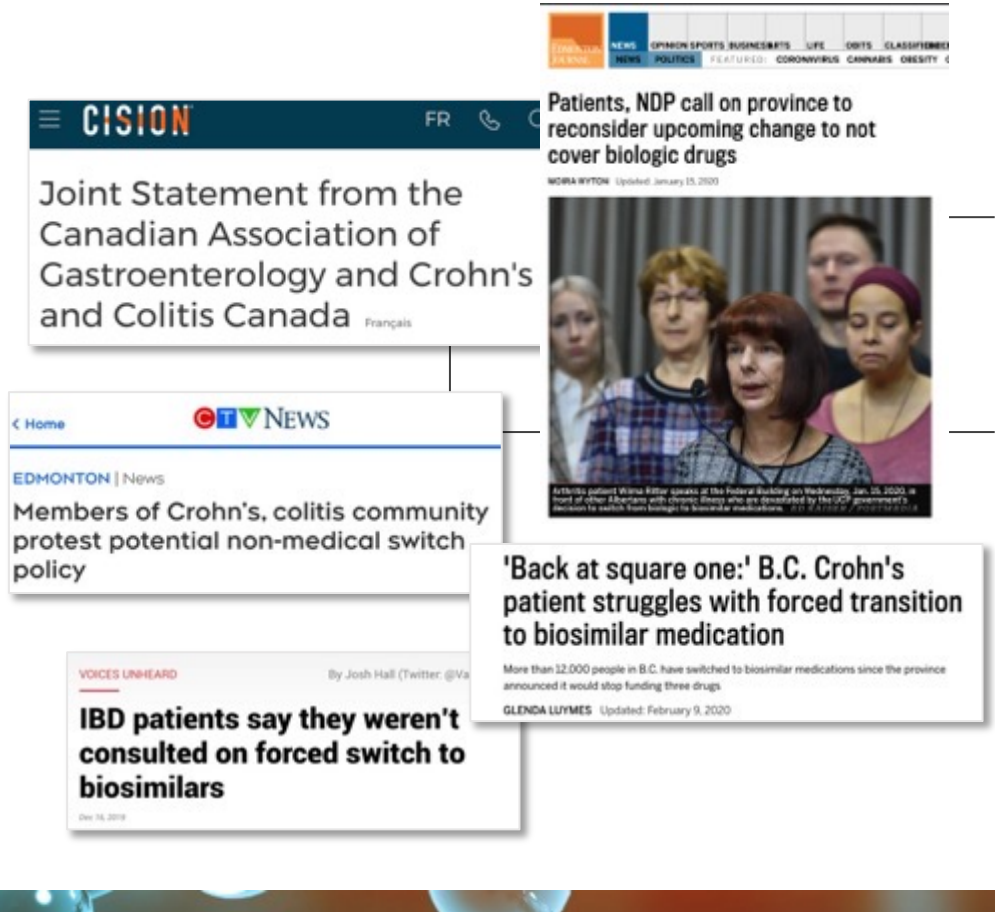
- Bowel Cancer Australia issued a Patient Alert for Australia's metastatic cancer patients:

> "The introduction of biosimilars was intended to increase treatment options, but reality suggests the impact will be the opposite…Policies that directly impact patients need to consider patient circumstances and preferences."

Australian patients have organized an e-petition to Parliament, urging reversal of the decision.

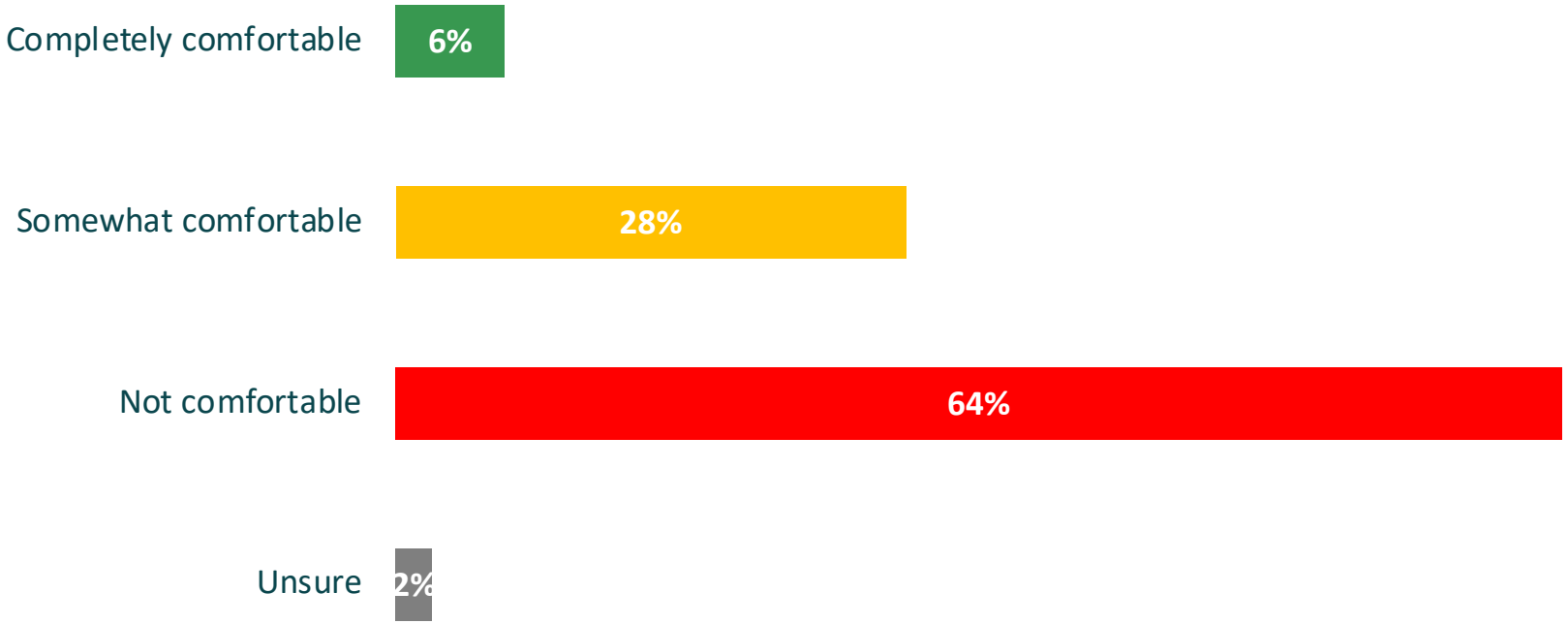
Case Study: Forced-Switching in Canada

- British Columbia and Alberta about 50,000 patients from their current medicines (chosen by the patient and physician) to the government-chosen biosimilar.
- Affected patients include those with ankylosing spondylitis, diabetes, plaque psoriasis, psoriatic arthritis, rheumatoid arthritis, Crohn's disease, and ulcerative colitis.
- Canadian Gastroenterology Association and IBD Patient Groups issued a joint statement of opposition to forced switching.



Physician Comfort Level with Third-Party Switching to a Biosimilar

Canadian Survey, Oct. 2017

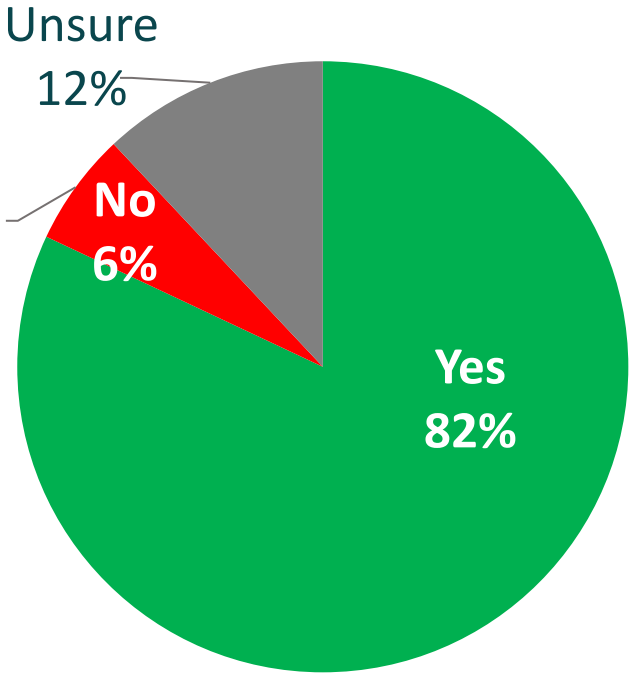


2017 Canadian Survey: Need for Switching Studies?

"While provinces have the authority to determine interchangeability and automatic substitution of medicinal products, Health Canada advises against this practice in the case of biosimilars.

Prior to deciding whether automatic substitution should be allowed by a pharmacist or payer,

Do you believe studies should be conducted that measure the effects of switching on patient safety and product efficacy?" (n=403)



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

- Generics and Biosimilars Initiative Journal (GaBI Journal). Published in: Volume 10 / Year 2021 / Issue 3
- Authors: Michael S Reilly, Esq, Professor Philip J Schneider, MS, FASHP, FASPEN, FFIP
- Analyzes the biosimilar substitution and reimbursement practices in Canadian provinces and comparing them to those in Europe and the U.S.

Available at:

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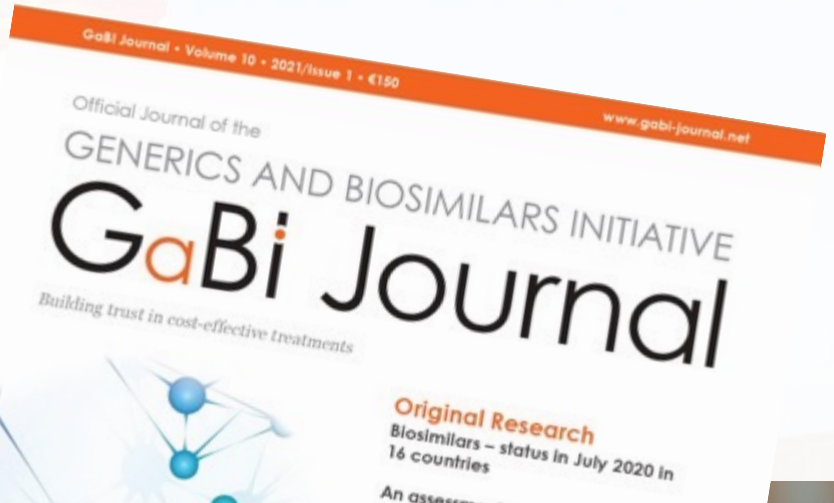
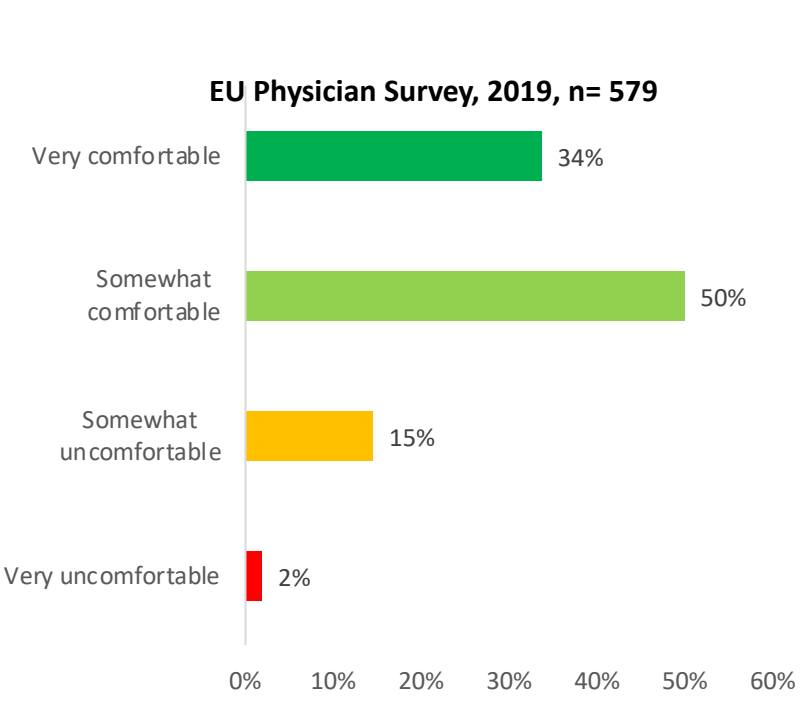
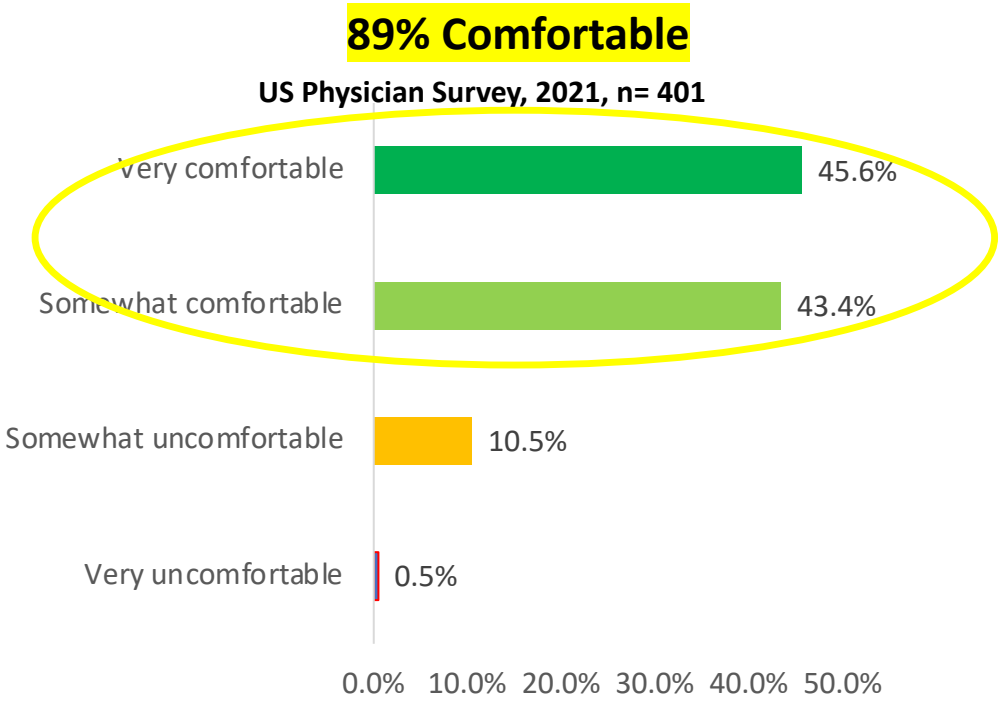


Addressing Physician and Patient Concerns with Automatic Substitution: US Case Study

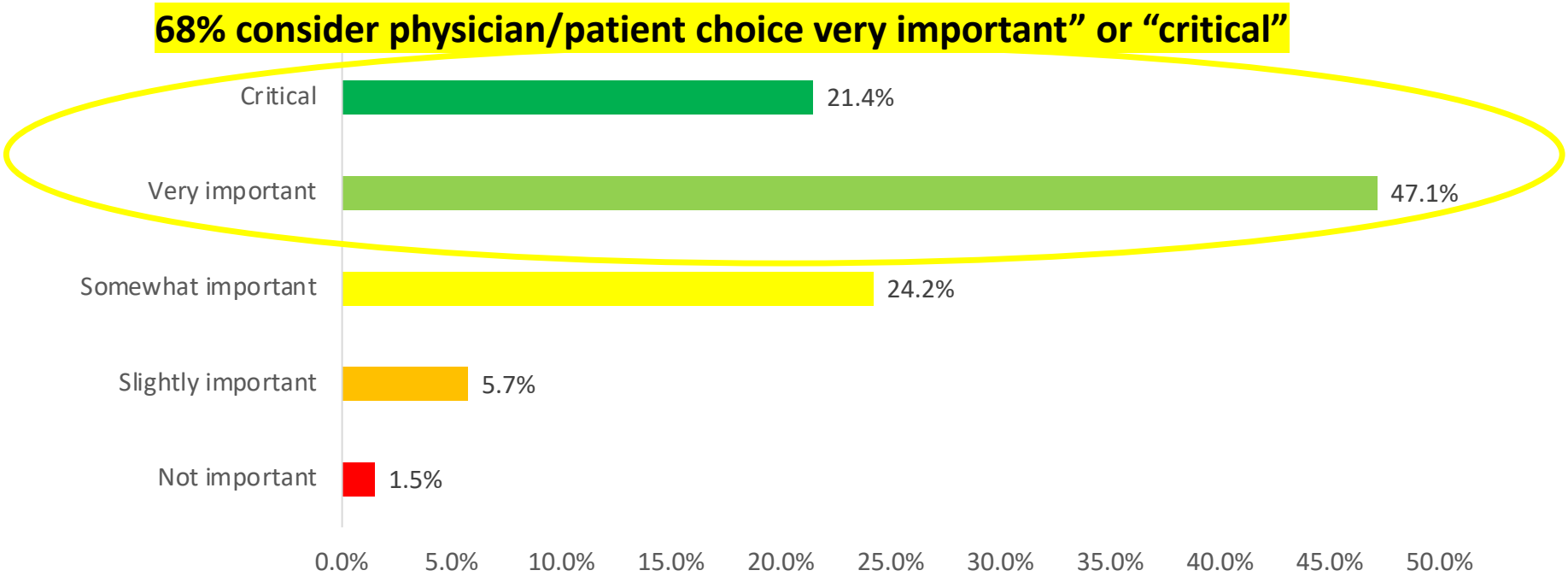
US Survey (2021): US physicians are highly comfortable with prescribing biosimilars- comfort level is comparable or higher to that of European physicians.





US Survey (2021): Treatment decisions should rest with physician and patient, not third-parties.

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=401)



“Interchangeability” (US-Specific Standard)

US-Specific higher regulatory standard. More data is required, including switching studies.

An “INTERCHANGEABLE” Biosimilar :

1) Must be a **biosimilar** (“highly similar” to reference product).
2) Must have **same clinical result** expected as with reference product.
3) Must create **no additional risk to patient** when switching back and forth between itself and reference product.
4) **May be substituted for the reference product without the intervention of the prescriber.**

Interchangeability Guidance (FDA, 2017)

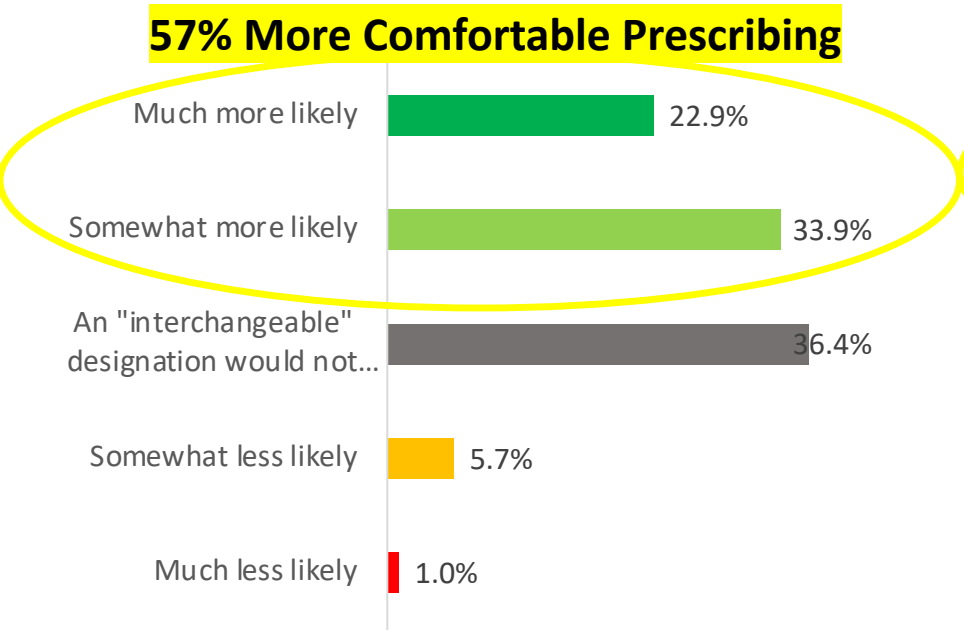
Many US physician groups offered comments supportive of the interchangeability guidance.

These included:

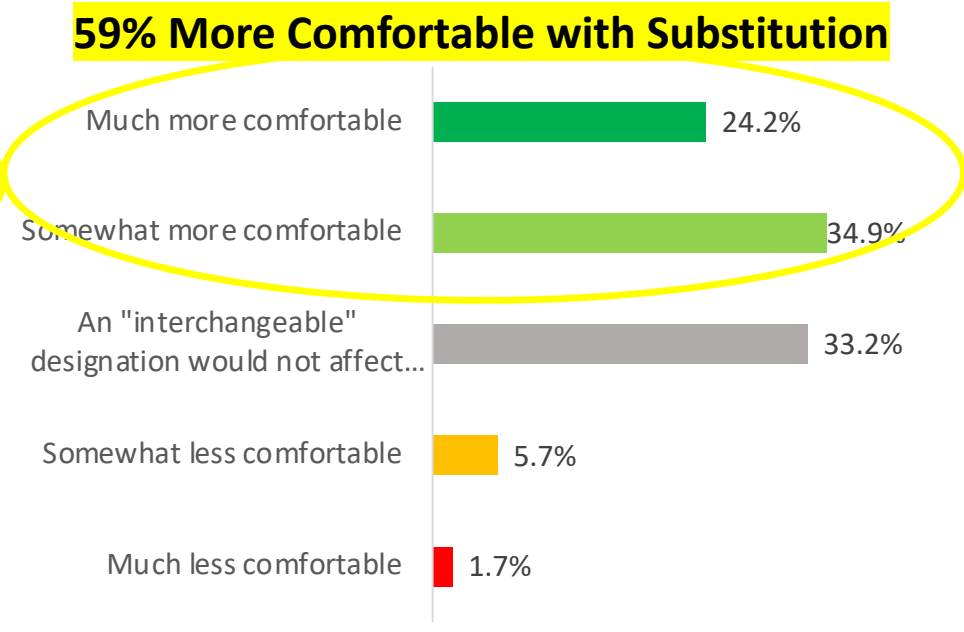
- American Association of Clinical Endocrinologists
- American College of Rheumatology
- American Gastroenterological Association
- Biologics Prescribers Collaborative
- Coalition of State Rheumatology Organizations

US Survey: Interchangeability increases physician comfort with prescribing biosimilars, substitution for a majority of U.S. physicians.

Does a biosimilar carrying an interchangeable designation make you more or less likely to prescribe it? (n=401)



How does knowing a biosimilar carries an "interchangeable" designation affect your comfort level with pharmacy substitution of the biosimilar? (n=401)




Increasing Uptake in the US

US Biosimilars Market: A Snapshot

- 33 Approved, 21 are on the market.
- Biosimilars launch at wholesale acquisition cost (WAC) 15% to 37% lower than their reference products and up to 40% below the reference product's average sales price (ASP).
- **In the US, biosimilars have gained significant share in the majority of therapeutic areas in which they have been introduced:**
- 80% for filgrastim biosimilars, 70% for trastuzumab and bevacizumab biosimilars, and 55% for rituximab biosimilars.
- Rituximab and infliximab have had the most limited adoption, with approximately 20% market share.
- As more become available, the increased competition has **driven down prices of both biosimilars and innovator biologics.**

FDA U.S. FOOD & DRUG ADMINISTRATION

According to the FDA's Janet Woodcock, the savings from biosimilars was $2.5 billion in 2019, and **more than three times that much in 2020**.

Price: A Key Factor in Boosting Biosimilar Uptake

As in Europe, as more and more biosimilars launch in a given product class, competition drives prices downward, discounts increase, and biosimilar market share goes up:

- **First U.S. filgrastim biosimilar launched with 15% discount over its reference product. Today, with increased competition, its discount has increased to 35% and it has now attained a majority market share (55%).**
- **First U.S. rituximab biosimilar launched at a 10% discount over its reference product. A few months later the second launched at a larger, 24% discount to compete.**
- **As it becomes routine to have 3, 4, or 5 biosimilars approved for a reference product we expect this trend- and savings- to continue.**

Paying Physicians and Patients to Switch? Controversial Ideas to Increase Biosimilar Uptake in the U.S.

Congress: ASP +8% Legislation

Proposes to increase the reimbursement rate for biosimilars, effectively giving physicians a 33% bonus to prescribe biosimilars. Has received pushback from physicians and patient advocacy organizations who feel it undermines the physician-patient relationship and distorts the treatment-decision process.

CIGNA: $500 Debit Card

Health insurer pays patient $500 to switch to a biosimilar. OPPOSED by the American Medical Association and American College of Rheumatology, who support legislation to outlaw this practice.

Takeaways

- Europe remains the leader in the in biosimilar approval and commercialization but the **U.S. market is catching up and poised to overtake it.**
- **Physicians worldwide are confident in biosimilars but wary of forced switching of stable patients for non-medical (cost) reasons.** This practice has received pushback from physicians and patients, and can undermine biosimilar uptake.
- **The European and U.S. experience shows that forced substitution is not necessary to achieve high uptake and savings, though this may take time**. In both markets, competition between multiple reimbursed products has created downward pricing pressure and savings. **As biosimilar discounts increase, so does uptake.**
- **Multiple products competing on a level playing field** contributed to the success of biosimilars in Europe. Government policies incentivizing the use of one particular product distort the treatment-decision making process and may create pushback from physicians and patients.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