

REAL WORLD CONSIDERATIONS FOR THE USE OF BIOSIMILARS IN RHEUMATOLOGY: WHAT DO AUSTRALIAN PHYSICIANS THINK?

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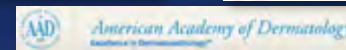
The Alliance for Safe Biologic Medicines (ASBM)

ASBM is an organization consisting of patient, physician, research and manufacturing organizations devoted to promoting the safe introduction and monitoring of biosimilar medications

- Steering Committee composed of patient and physician groups
- Advisory Board of physicians, researchers, pharmacists, and patients
- More than 60 member groups on five continents



STEERING COMMITTEE



Problem Statement

Biologic medicines have revolutionized the treatment of rheumatology. As patents for these medicines expire, similar versions of these medicines, known as biosimilars, are beginning to enter the marketplace.

Given that these medicines are similar, but not identical to the original medicine they are based on, what are some of the considerations for their use in clinical practice?

Gathering the Perspectives of Providers Around the World



All surveys available at www.SafeBiologics.org



Sharing Data With Regulators, Stakeholders



In February 2017, ASBM held a series of meetings to share these findings with Australian regulators and policy makers, as well as pharmacy, physician and patient organizations:

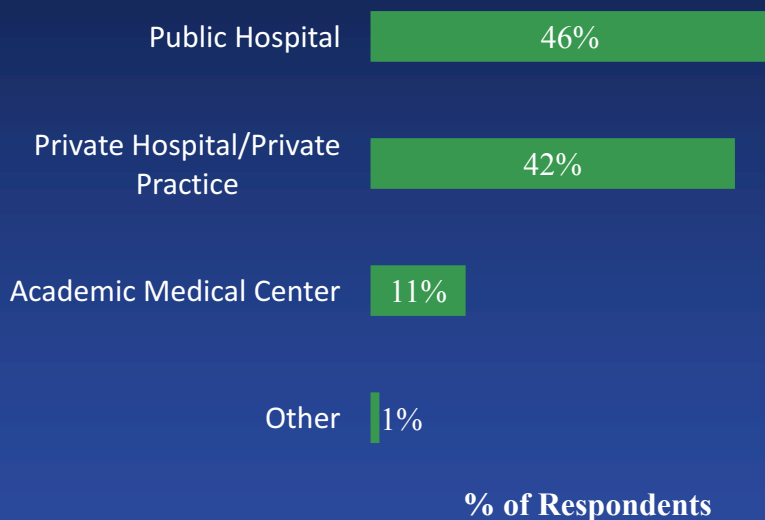
- Australian Department of Health
- Therapeutic Goods Administration
- 3 Senior Health Ministers in Parliament
- Arthritis Australia
- Australian Diabetes Society
- Consumer Health Forum
- Crohn's and Colitis Australia
- Australian Rheumatology Association
- Gastroenterology Society of Australia
- Pharmacy Guild of Australia
- Medicines Australia

Methodology

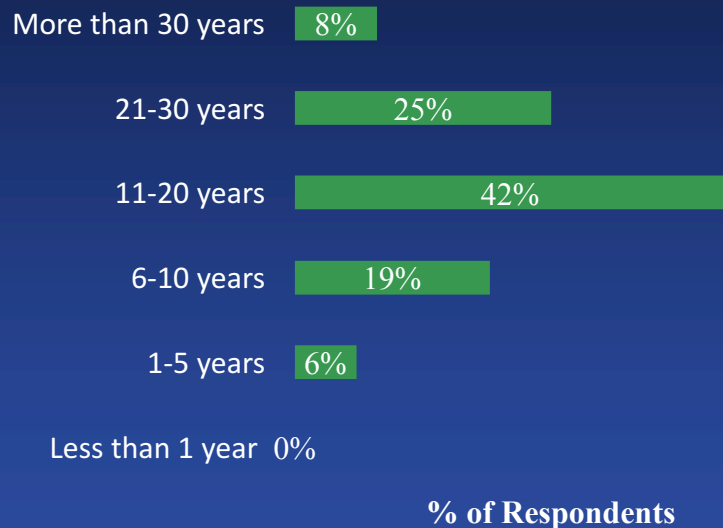
- 160 prescribers
- 15-minute web-based survey
- All participants practice in Australia
- Participants recruited from large, global panel of healthcare professionals
- Participants screened as follows:
 - Specialize in one of 7 therapeutic specialties, including: Dermatology, Endocrinology, Gastrointestinal, Nephrology, Neurology, Oncology, Rheumatology
 - Must have been in practice for 1 year or more
 - Must prescribe biologic medicines in their practice
- Participants received a standard cash stipend for their time
- Data collected in June, 2016
- Study was sponsored by ASBM and administered by Industry Standard Research, LLC

Setting and Experience

Practice Setting

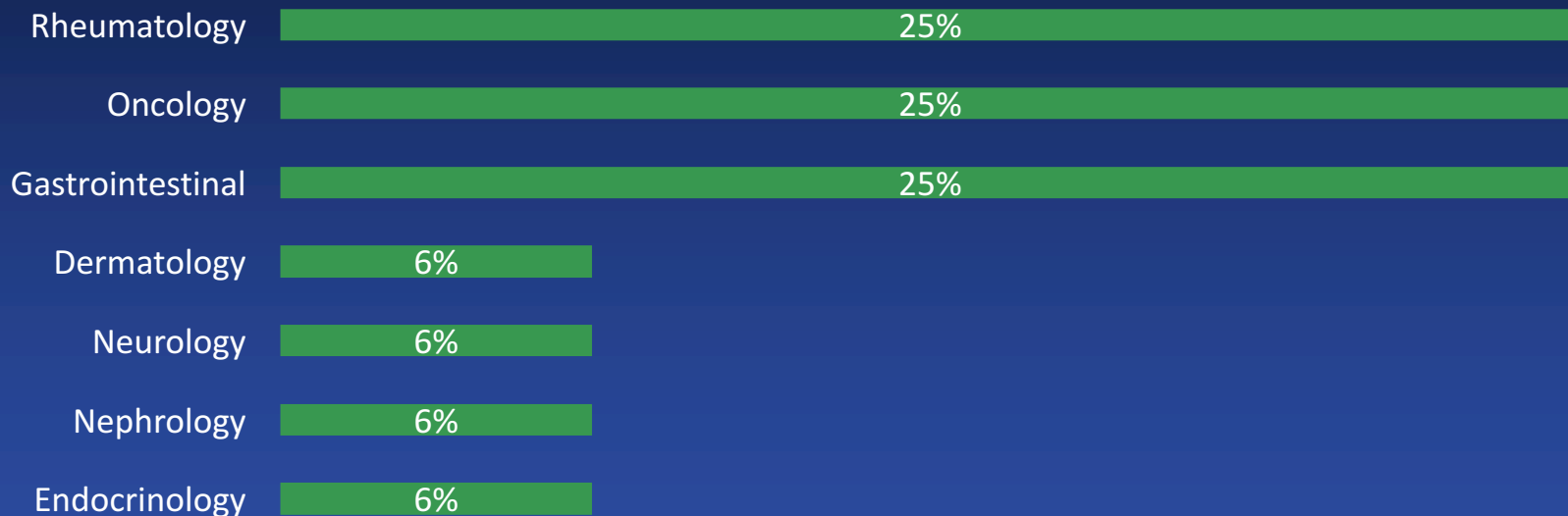


Years in Practice



Therapeutic Specialty

“Please indicate your primary practice area or therapeutic area in which you practice.”



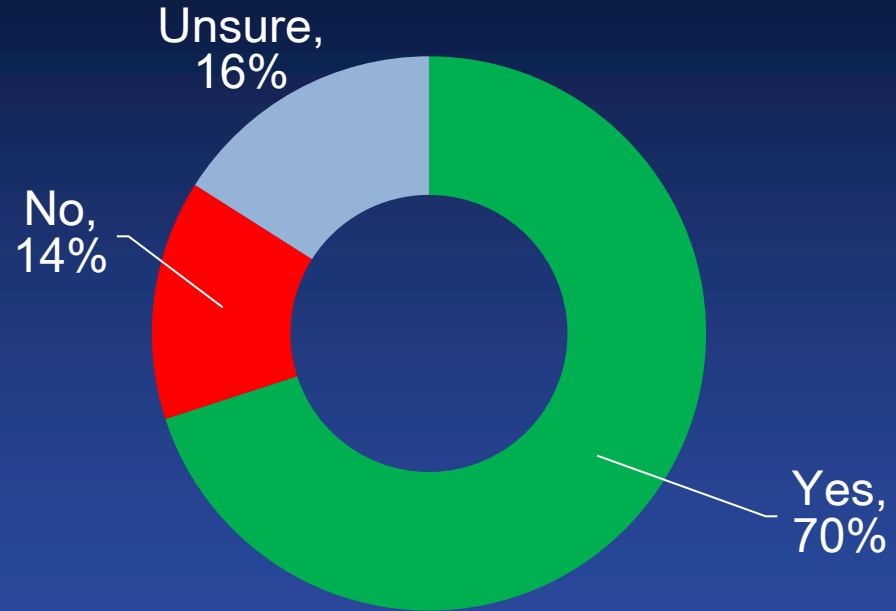
% of Respondents

Approval Process



Awareness of Biosimilar Approval Process

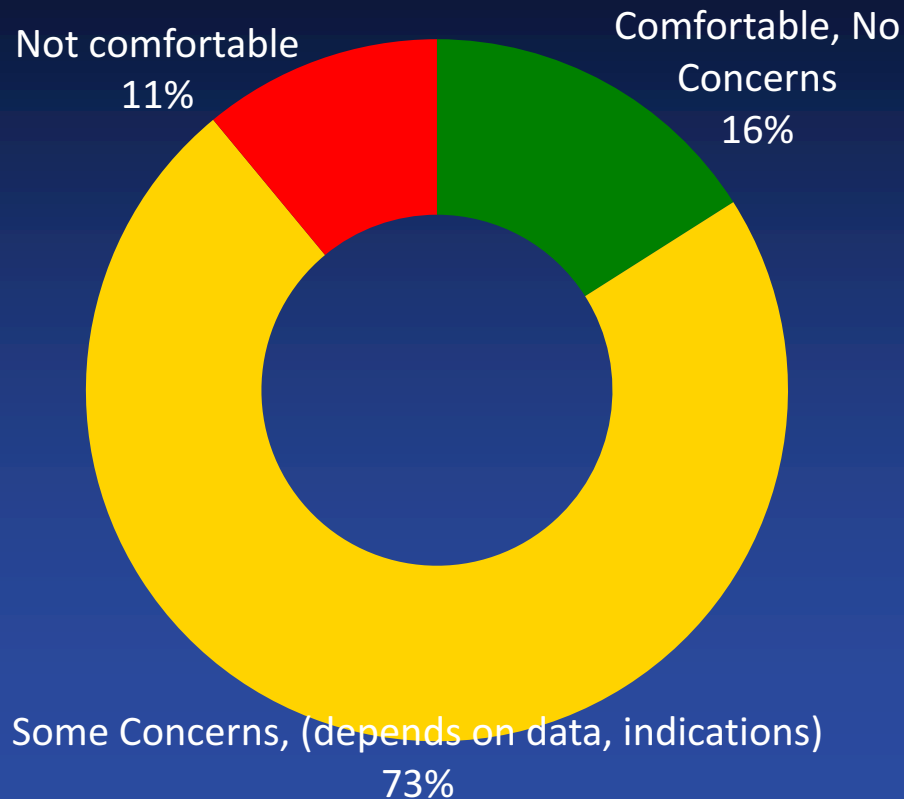
- Question
 - “Are you aware a biosimilar medicine may be approved for several or all indications of the reference biologic medicine on the basis of clinical trials in only one of those indications/fewer indications than the reference biologic is approved for?”



Comfort with Approval Based on Indication Extrapolation

Question:

- “How comfortable are you/would you be prescribing a biosimilar medicine where it has been approved for several or all indications of the reference biologic medicine on the basis of clinical trials in only one of those indications/fewer indications than the biosimilar medicine is approved for?”



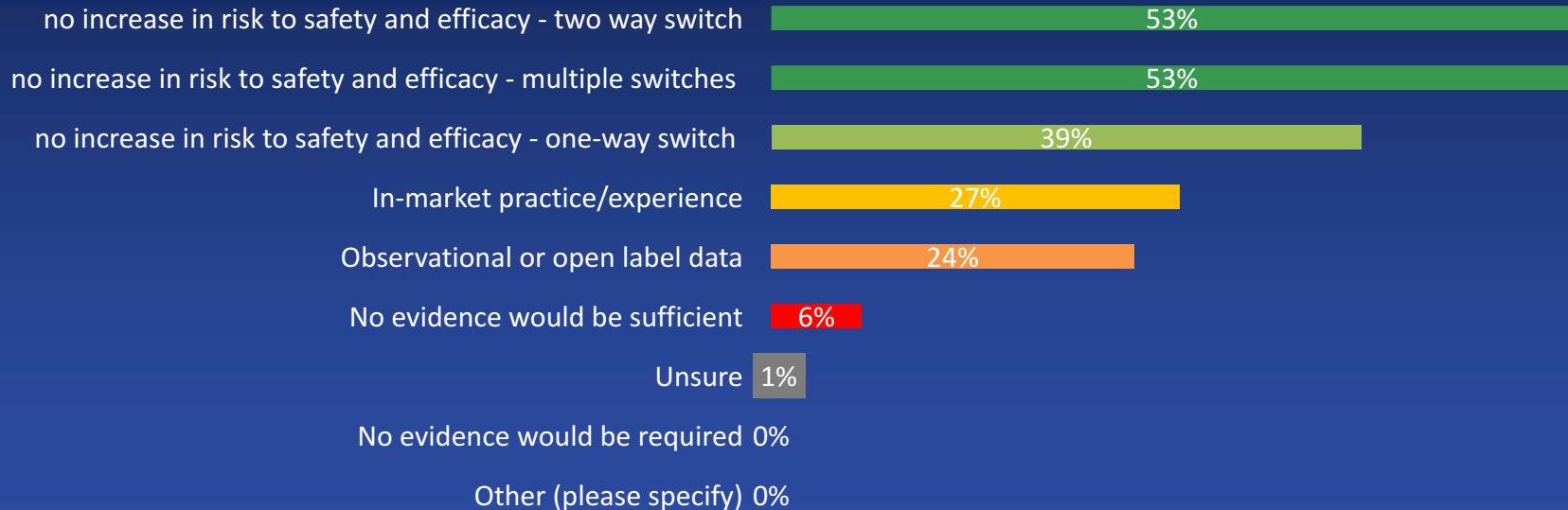


Pharmacy-Level Substitution

Australian Survey: Sufficient Evidence for Substitution?

Question

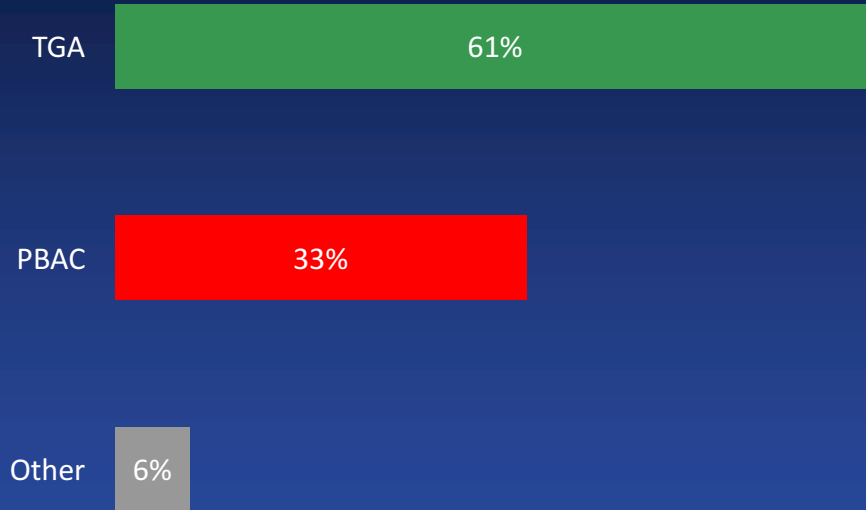
“What evidence would you regard as sufficient to be supportive of the PBAC’s conclusion that a biosimilar product is suitable for pharmacy level substitution? Select all that apply.”



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?”



Consistent with Physicians Wanting 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”



How Important is Notification of Which Medication Is Dispensed?



85% of Canadian physicians consider it "very important" or "critical"



77% of EU Physicians consider it "very important" or "critical"



80% of US physicians consider it "very important" or "critical"

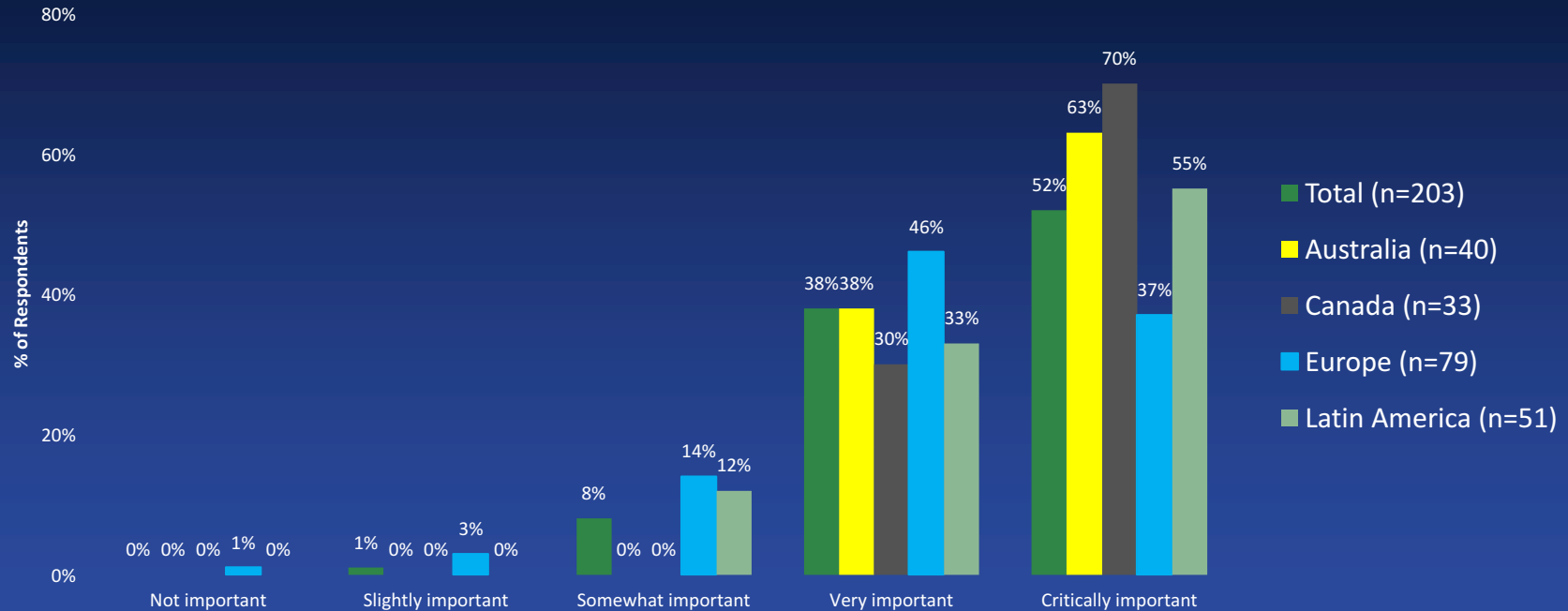


89% of Australian physicians consider it "very important" or "critical"



87% of Latin American Physicians consider it "very important" or "critical"

Rheumatologists: Importance of notification





Naming of Biosimilars

Distinct Naming Proposals Internationally

Both the WHO and US FDA have proposed four-letter suffixes be appended to the International Nonproprietary Name (INN) of biologics and related biosimilars. The WHO calls this suffix a “Biological Qualifier” (BQ). Goals include:

CLEAR PRODUCT IDENTIFICATION - Distinguishable from reference product, and other approved biosimilars.

CLEAR COMMUNICATION - between physician, patient and pharmacist

CLEAR PRESCRIBING & DISPENSING - Helps prevent inadvertent and inappropriate substitution.

BETTER PHARMACOVIGILANCE - proper attribution of adverse events.

INCREASED MANUFACTURER ACCOUNTABILITY - suffixes tied to manufacturer/facility

Australian Results are Consistent With Those of Physicians Worldwide



79% *of Canadian
physicians support Health Canada
issuing distinct names. (2014)*



66% *of US physicians support
FDA issuing distinct names. (2015)*



94% *of Latin American
Physicians consider WHO's BQ Proposal
to be "useful" in helping patients receive
the correct medicine. (2015)*



76% *of Australian
physicians support TGA issuing
distinct names (2016)*

Summary

- Australian prescribers of biologics want data demonstrating that substitution can occur without loss of safety and efficacy.
- Indication extrapolation is a particular area of concern for prescribers, that needs to be addressed during approval and/or through post-market surveillance.
- Notification in the event of a biosimilar substitution is highly important to prescribers.
- Australian prescribers overwhelmingly support the TGA issuing distinct naming for all biologics including biosimilars.
- As regulators seek to bring the health and economic benefits of biosimilars to patients, building physician confidence is critical to the success of this effort.
- We encourage all of you to read the full study at www.safebiologics.org/surveys



SafeBiologics

ALLIANCE *for* SAFE BIOLOGIC MEDICINES

Thank You For Your Attention

Questions?

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