

Real World Considerations for the Use of Biosimilars in Oncology: What Do Australian Physicians Think?

Michael Reilly, Esquire, Harry L Gewanter, MD, FAAP, FACR, and Andrew Spiegel, Esquire

Alliance for Safe Biologic Medicines, Arlington, VA

Introduction

- Biologic therapies for oncology have significantly improved the outcomes of patients with cancer.
- The expiration of patents for a number of originator oncology biologics has led to the development and regulatory approval of similar versions of these medicines, known as biosimilars.
- Since biosimilars are not identical to the originator biologic, there are a number of considerations for their use in clinical practice.
- The Alliance for Safe Biologic Medicines (ASBM) conducted web-based surveys to understand how Australian oncologists feel about the use of biosimilars in their practice.

Methods

- ASBM conducted 15-minute, web-based surveys among 160 Australian physicians.
- Surveys were administered in June 2016 by Industry Standard Research, LLC.

Eligibility criteria for oncologists:

- ✓ Must have been in practice for at least one year
- ✓ Must prescribe biologic medicines in their practice

Topics included:

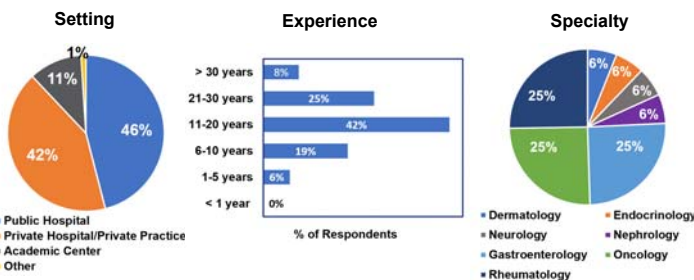
- Importance of prescribing authority
- Acceptability of biosimilar substitution
- Importance of notification



Results

Demographics of Australian Prescribers

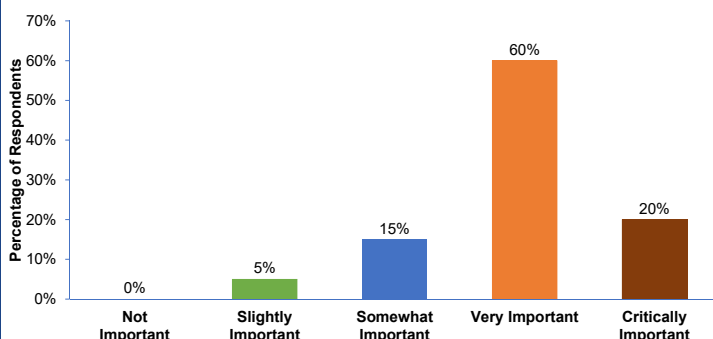
- Most prescribers (88%) were from the hospital setting.
- Most (94%) had at least 6 years in clinical practice; 42% with 11–20 years.
- Oncologists comprised 25% of the prescriber population.



Survey Responses From Australian Oncologists

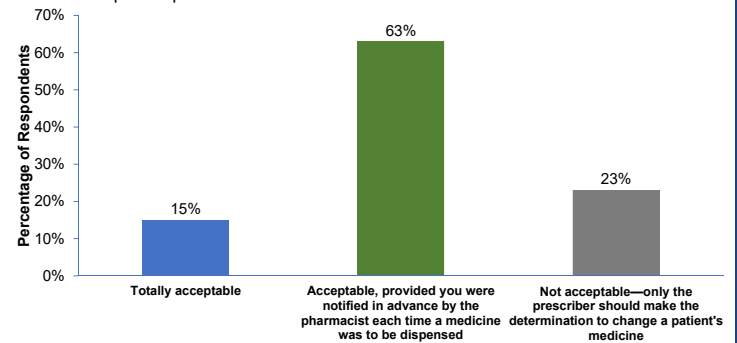
How important is it for you, as the prescribing physician, to have the sole authority to decide, together with your patient, the most suitable biologic medicine that is to be dispensed to your patient?

- Most (80%) respondents feel that it is either "Very Important" or "Critically Important" for them to decide which biologic medicine is dispensed to their patients.
- Oncologists from other regions provided similar responses: 80% from Latin America, 78% from Canada, and 66% from Europe replied "Very Important" / "Critically Important" to this question.



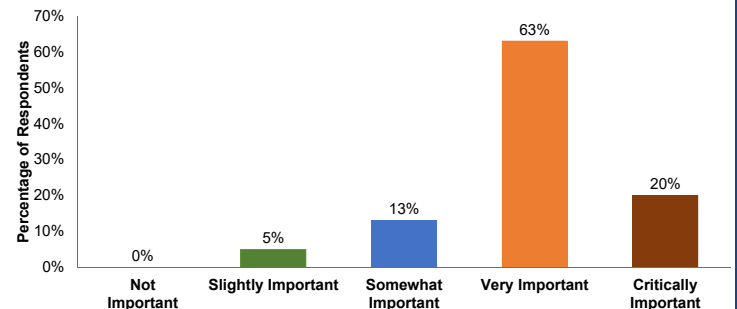
If a reference biologic and its biosimilar(s) have been approved for pharmacy-level substitution and your patient has a chronic disease - how acceptable would it be for you if a pharmacy switched between the reference biologic and its biosimilar(s) as the prescription is refilled over time?

- Approximately two-thirds of respondents (63%) believe that pharmacy-level substitution is acceptable, provided that they are notified in advance.
- Oncologists from other regions were more likely to respond that pharmacy-level substitution is not acceptable: 79% from Latin America, 57% from Canada, and 53% from Europe compared with 23% from Australia.



How important would it be for you to be notified by the pharmacist that your patient has received a biologic medicine other than the one you prescribed (eg, if the pharmacist substituted a reference biologic medicine for its biosimilar)?

- Most (83%) respondents feel that it is either "Very Important" or "Critically Important" that they be notified if the prescribed biologic medicine has been substituted.
- Oncologists from other regions provided similar responses: 76% from Latin America, 80% from Canada, and 70% from Europe replied "Very Important" / "Critically Important" to this question.



Conclusions

- Our survey provides important insights into how Australian oncologists feel about their role in prescribing biologics for their patients.
 - Most believe that the prescriber and patient should decide on whether the patient receives an original biologic or a biosimilar.
 - Most believe that they should be notified of biologic substitution at the pharmacy.
- When a biologic substitution occurs, it is important to accurately trace which biologic medicine a patient receives.
- This can be achieved through the use of distinguishable non-proprietary names as well as notification and documentation of any substitutions that occur after a medicine has been prescribed.
- Policies that facilitate accurate tracking of biologic substitution, such as the use of distinguishable non-proprietary names, can help increase physician comfort with biosimilars and ultimately increase biosimilar utilization in Australia.

ASBM Position Statement

- ASBM supports the use of a distinguishable, meaningful, and user-friendly suffix related to the biologic manufacturer, added to the end of a shared root name. This will enable biologics to be distinguished from each other while ensuring a clear link to the reference product. We believe that a memorable suffix is preferable to a random series of characters, as it will minimize confusion, while enabling a connection to the biologic manufacturer, facilitating traceability and accountability.
- Many healthcare professionals and patient and professional groups, including ASBM, support a unification of naming conventions across regions to facilitate patient safety with this important class of medicines.

Disclosure

- The 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, Amgen Inc., and AbbVie Inc.