What's in a Name?
Distinguishable Naming and its Role in PV for Biosimilars: What do Australian Physicians Think?

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Introduction

- Biologic medicines are large, complex molecules that are made from living cells.
- Biosimilars are similar to approved biologics—it is not possible to manufacture exact copies of biologics.
- The ability to monitor a patient's response to a medicine and track any adverse events are important components of clinical care. Similarly, the ability to determine how a medicine behaves in a patient population over time is an important part of monitoring real-world drug effectiveness.
- Tracking the use of medicines using their name is one way to achieve these public health priorities.
- Clear product identification is essential to distinguish between biologics and biosimilars.
- The Alliance for Safe Biologic Medicines (ASBM) utilized web-based surveys to gather the perspectives of Australian prescribers in order to provide insights for regulators and policymakers as they draft policies regarding biosimilars.

Objectives

- Determine prescribers' familiarity with biosimilars/biosimilars approval process.
- Gather prescribers' perspectives on the importance of distinguishable naming for biologics.
- Determine how Australian physicians identify biologics in patient records and in adverse event (AE) reports.

Methods

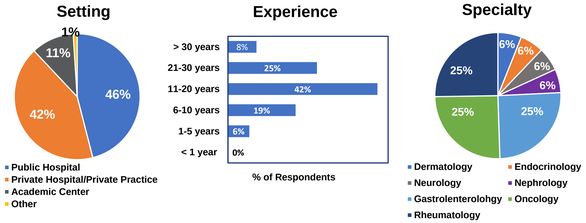
- The ASBM conducted web-based surveys among 160 Australian physicians.
- Surveys administered in June 2016 by Industry Standard Research, LLC.

Web-based survey

- ✓ Must have been in practice for at least one year
- ✓ Must prescribe biologic medicines in their practice
- ✓ Specialize in one of seven therapeutic specialties:
  - Dermatology
  - Endocrinology
  - Gastroenterology
  - Nephrology
  - Neurology
  - Oncology
  - Rheumatology

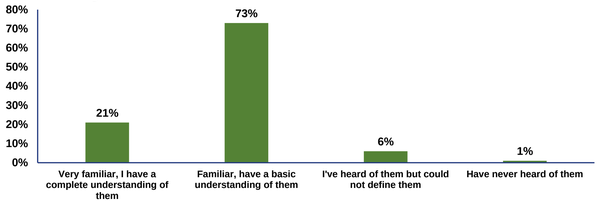
Results

Prescriber Demographics



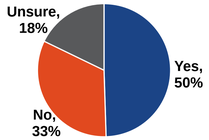
- Most prescribers (88%) were from the hospital setting.
- Most (94%) had at least 6 years in clinical practice; 42% with 11–20 years.
- Rheumatologists, oncologists, and gastroenterologists comprised 75% of the prescriber population.

Familiarity With Biosimilars



- Nearly all (94%) respondents considered themselves either "Familiar" or "Very Familiar" with biosimilar medicines.

Awareness of Biosimilars Approval Process



- 50% of respondents believed that biosimilars and originator products are approved through the same regulatory process.

Impact of Names for Biologic Medicines

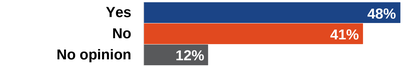
If two biologic medicines have the same non-proprietary scientific name, does this suggest to you or imply that:

… the originator medicine and its biosimilar medicine are approved for the same indications?

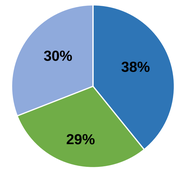
…the medicines are identical?

…a patient could be switched from a reference biologic medicine to its biosimilar medicine during a course of treatment and expect the same result in terms of safety and efficacy as with either of the medicines?

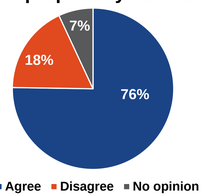
…a patient could be switched on multiple occasions from a reference biologic medicine to its biosimilar medicine during a course of treatment and expect the same result in terms of safety and efficacy as with either of the medicines?



Distinguishable Naming

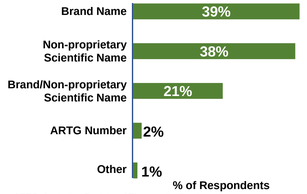


Requirement for Distinguishable Non-proprietary Names

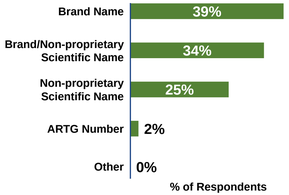


- The majority of respondents (76%) believe it is important for the Therapeutic Goods Administration (TGA) of Australia to require distinguishable non-proprietary names for biologics and biosimilars

How do you identify biologics in Patient Records?



How do you identify biologics in AE Reports?



ARTG: Australian Register of Therapeutic Goods

Conclusions

- Regulatory authorities acknowledge the need for distinguishable names for biologics and biosimilars.
- The results of our survey demonstrate that distinguishable non-proprietary names are important to Australian physicians who prescribe biologics.
- The use of distinguishable nonproprietary names will enable prescribers to accurately monitor efficacy and adverse events and will facilitate ongoing pharmacovigilance by regulatory authorities.
- These data have been shared with the Australian Department of Health, TGA, and senior Health officials in Parliament, to highlight educational challenges, which if properly addressed, can help 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.

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