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ASBM Biosimilars

Australian Prescribers and Biosimilars

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METHODOLOGY

Study 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

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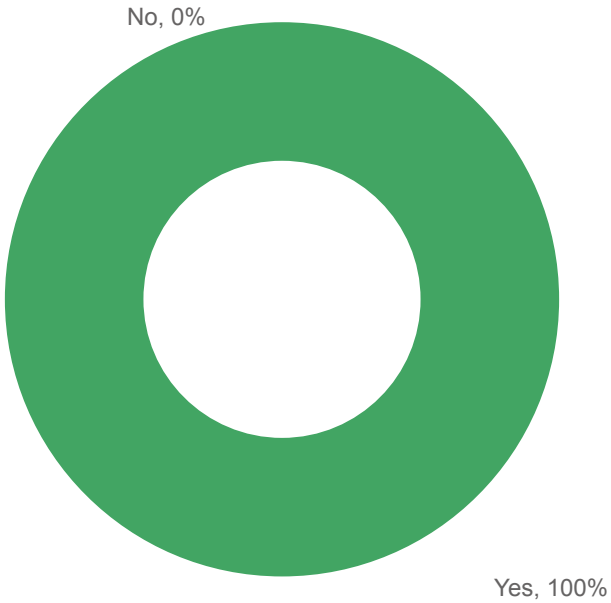
SAMPLE CHARACTERISTICS

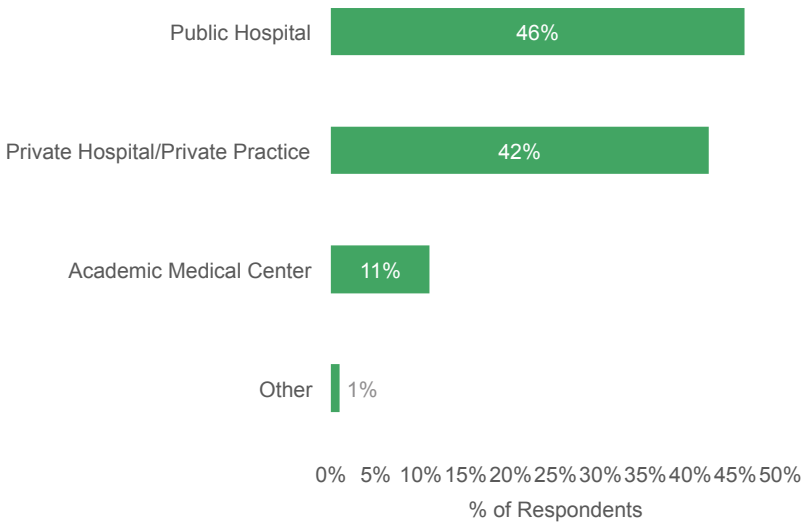
Prescribe biologics?



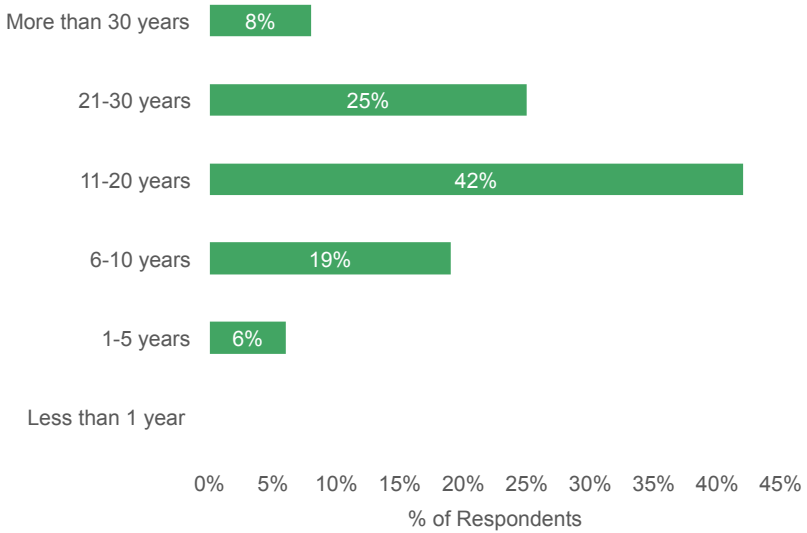
- Question
  - “Do you prescribe biologic medicines in your practice?”

Setting and experience

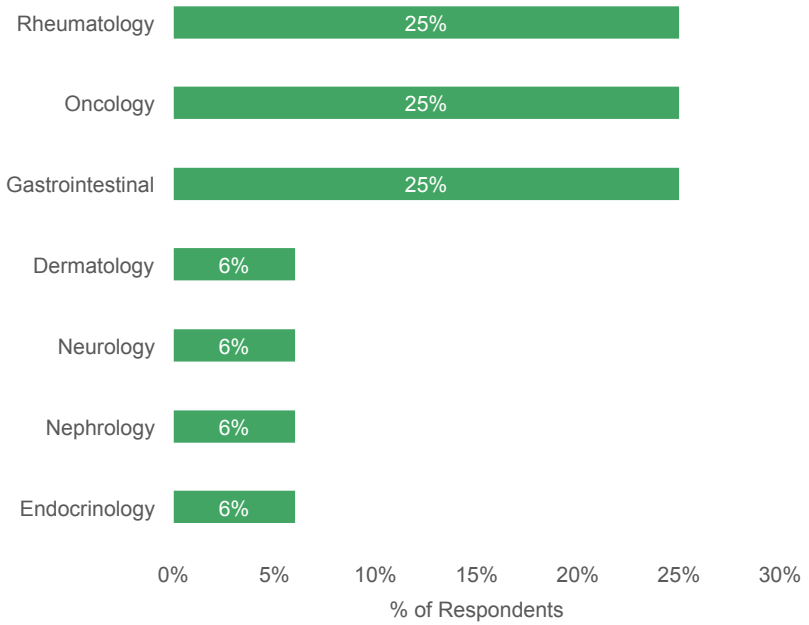
Practice Setting



Years in Practice

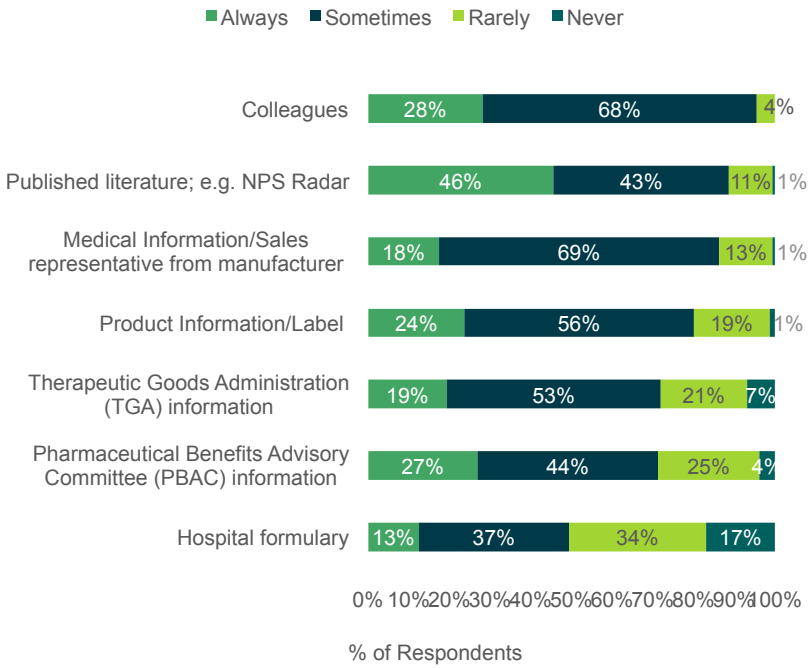


Therapeutic specialty



- "Please indicate your primary practice area or therapeutic area in which you practice."

Use of information sources



- Question
  - "How often do you use each of the following sources to learn about the details of a medicine for prescribing and monitoring?"

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EXECUTIVE SUMMARY

Executive Summary
Biosimilars familiarity

- Nearly all (94%) of surveyed prescribers consider themselves either Familiar or Very familiar with biosimilar medicines.
  - That said, 50% believe biosimilars and originator products are approved through the same regulatory process.

Executive Summary Reporting and Naming

- Brand name (39%) and non-proprietary scientific name (38%) are used in about equal frequency when recording in patient records.
- 48% Always or Sometimes include batch numbers when reporting adverse events.
- 76% believe TGA should insist on distinct non-proprietary scientific names for all biosimilars and reference products.
  - Respondents are split as to whether biosimilars should receive an identifying prefix, suffix or completely unique name.

Executive Summary Substitution

- Convincing evidence for a PBAC recommendation for substitution is varied but respondents generally agree that the data should be robust.
- 61% of respondents believe TGA should be responsible for recommendations on pharmacy-level substitution compared to 33% for PBAC.
- 90% of respondents believe it is Critical or Very important that the prescriber and patient hold the ultimate decision for which biologic is dispensed.
- 89% believe it is Critical or Very important that they be notified in the event of a pharmacy-level substitution.

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Biologic medicines are therapeutic proteins produced using living cells. The active substances of biological medicines are larger and more complex than those of non-biological medicines. A biosimilar medicine is a biological medicine that is developed to be similar to an existing biological medicine (the 'reference medicine'). Biosimilars are not the same as generics, which have simpler chemical structures and are considered to be identical to their reference medicines.

STUDY INTRODUCTION

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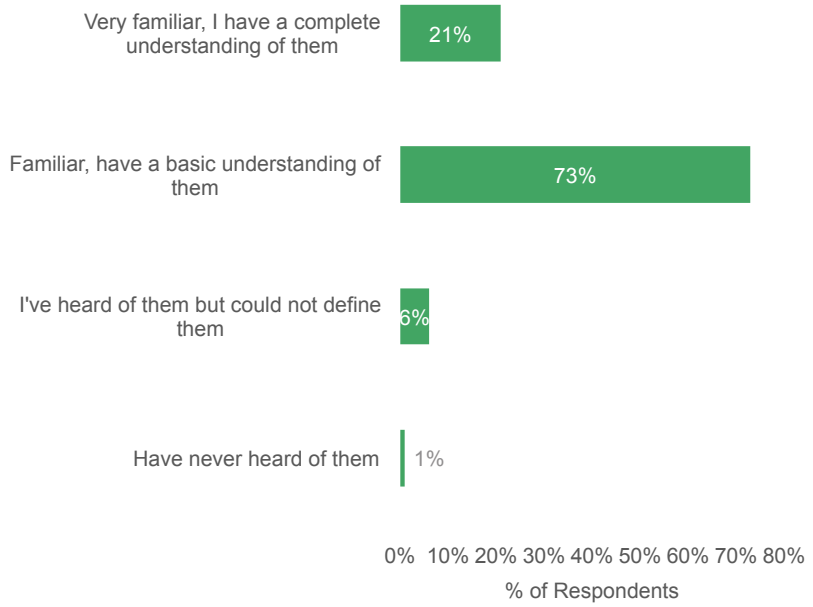
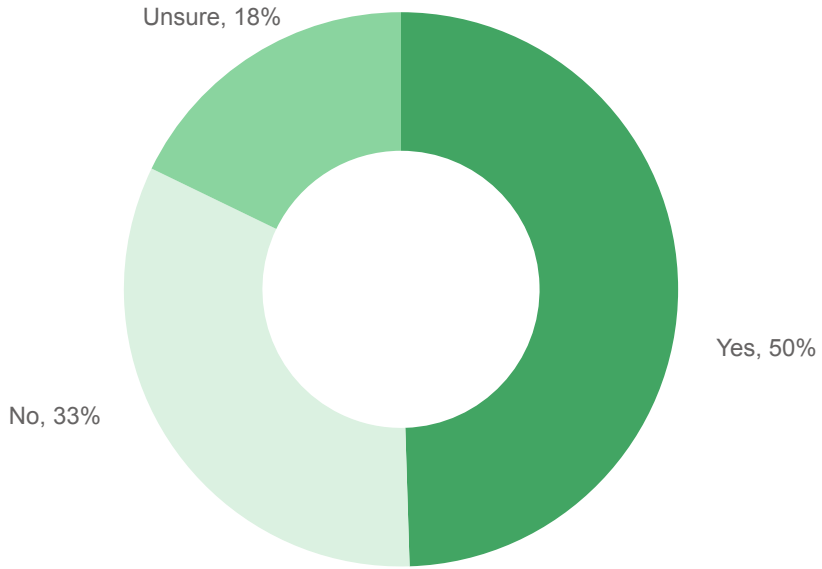
BIOSIMILARS FAMILIARITY, KNOWLEDGE, ATTITUDES AND BELIEFS

Familiarity with biosimilars



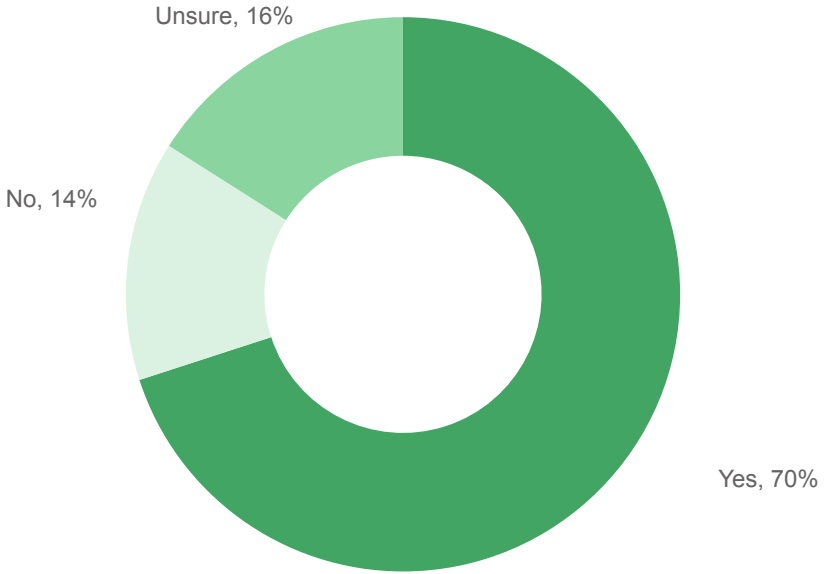
- Question
  - "How familiar are you with biosimilar medicines?"

Awareness of biosimilars approval process



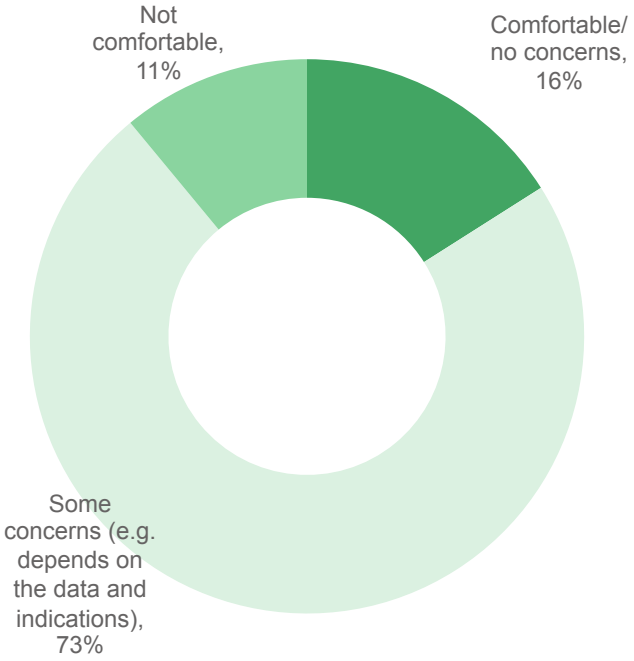
- Question
  - "Is it your understanding that all biosimilar medicines go through the same regulatory process for approval as the original reference biologic medicine?"

Awareness of biosimilars approval process



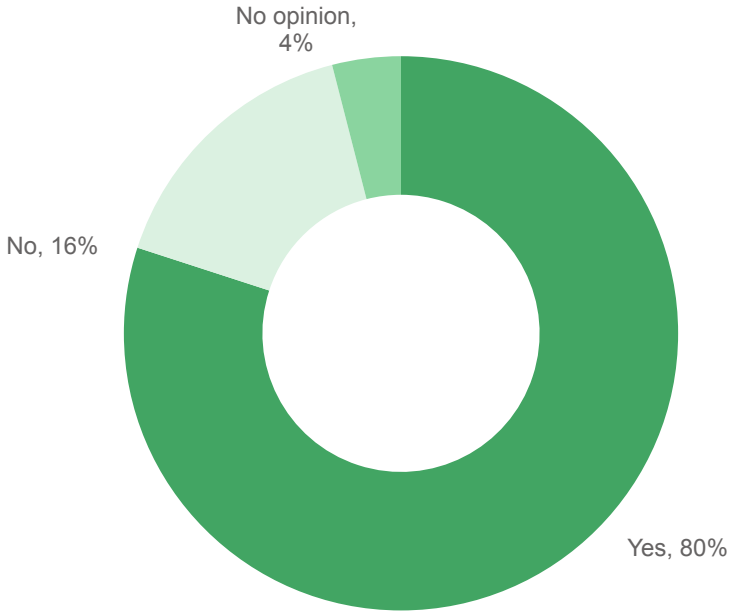
- Question
  - “Are you aware a biosimilar medicine may be approved for several or all indications of the reference biologic medicine on the basis of clinical trials in only one of those indications/fewer indications than the reference biologic is approved for?”

Comfort with biosimilars approval process



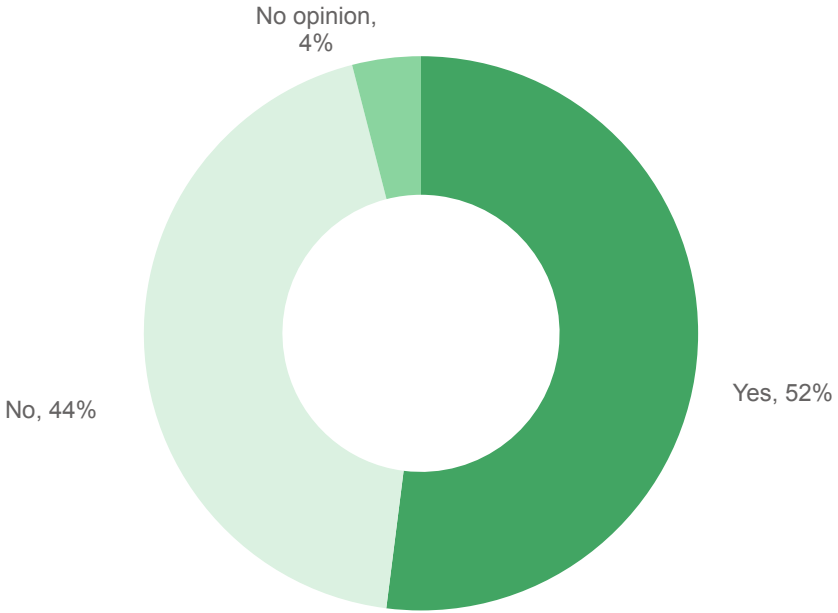
- Question
  - "How comfortable are you/would you be prescribing a biosimilar medicine where it has been approved for several or all indications of the reference biologic medicine on the basis of clinical trials in only one of those indications/fewer indications than the biosimilar medicine is approved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

Approved for the same indications?



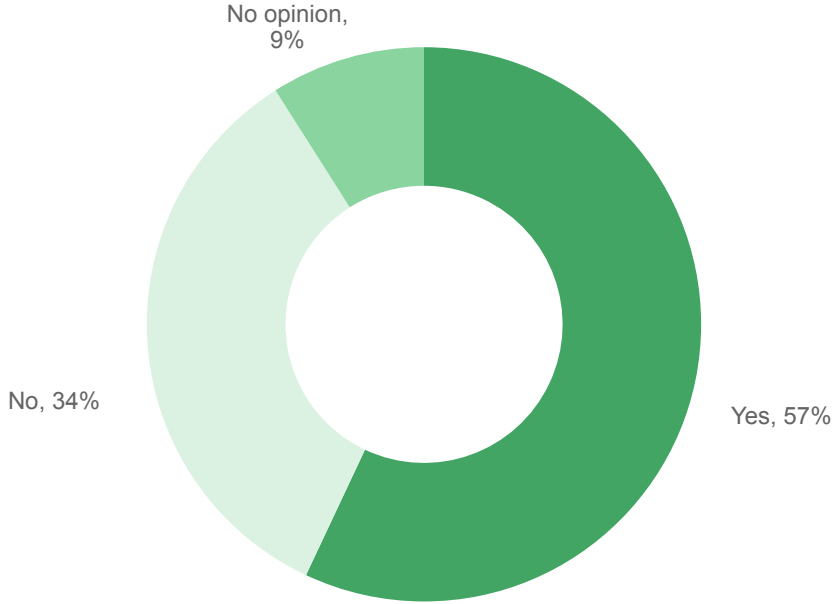
- Question
  - "In Australia all biologic medicines must have a non-proprietary scientific name (e.g. infliximab, trastuzumab) and a brand name (e.g. Remicade; Herceptin) upon approval. If two biologic medicines have the same non-proprietary scientific name, does this suggest to you or imply that::
  - …both the originator medicine and its biosimilar medicine are approved for the same indications?"

Identical?



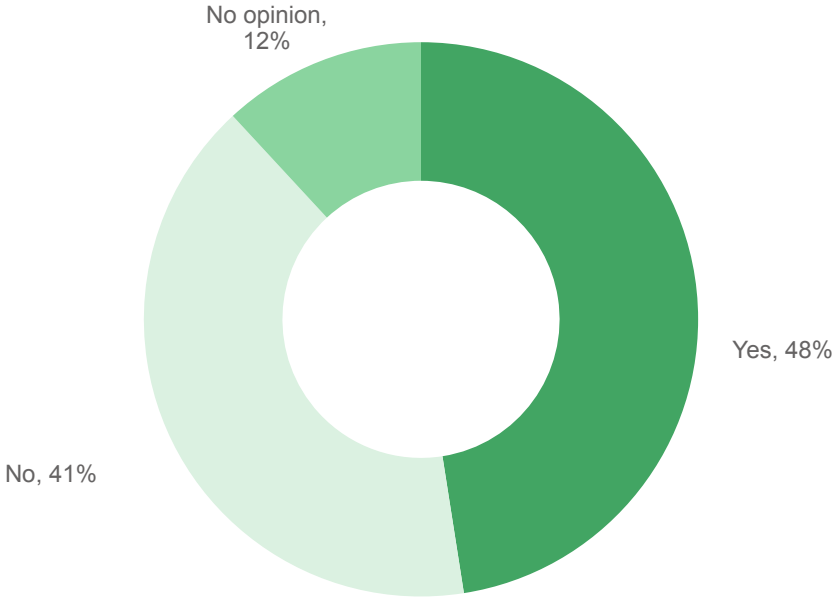
- Question
  - "In Australia all biologic medicines must have a non-proprietary scientific name (e.g. infliximab, trastuzumab) and a brand name (e.g. Remicade; Herceptin) upon approval. If two biologic medicines have the same non-proprietary scientific name, does this suggest to you or imply that::
  - …the medicines are identical?"

Switching



- Question
  - "In Australia all biologic medicines must have a non-proprietary scientific name (e.g. infliximab, trastuzumab) and a brand name (e.g. Remicade; Herceptin) upon approval. If two biologic medicines have the same non-proprietary scientific name, does this suggest to you or imply that::
  - …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?"

Switching



- Question
  - "In Australia all biologic medicines must have a non-proprietary scientific name (e.g. infliximab, trastuzumab) and a brand name (e.g. Remicade; Herceptin) upon approval. If two biologic medicines have the same non-proprietary scientific name, does this suggest to you or imply that::
  - …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? "

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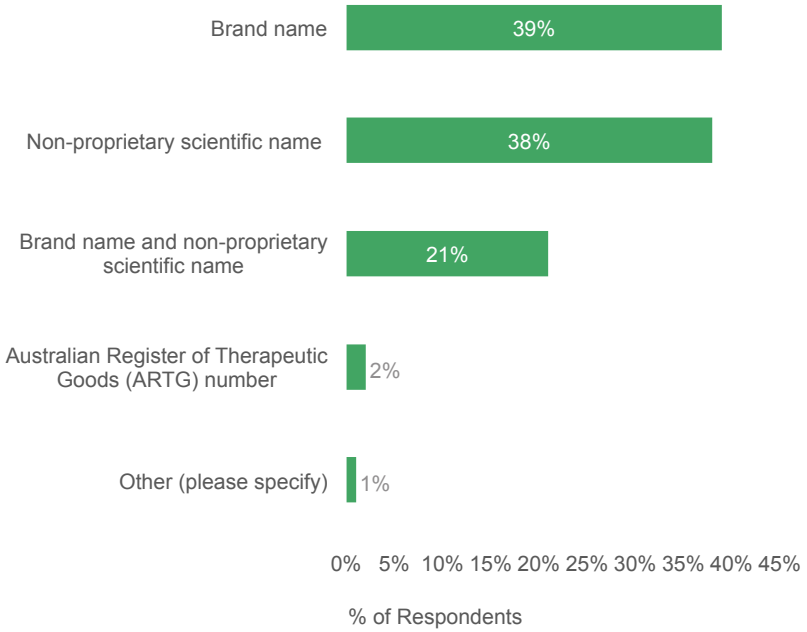
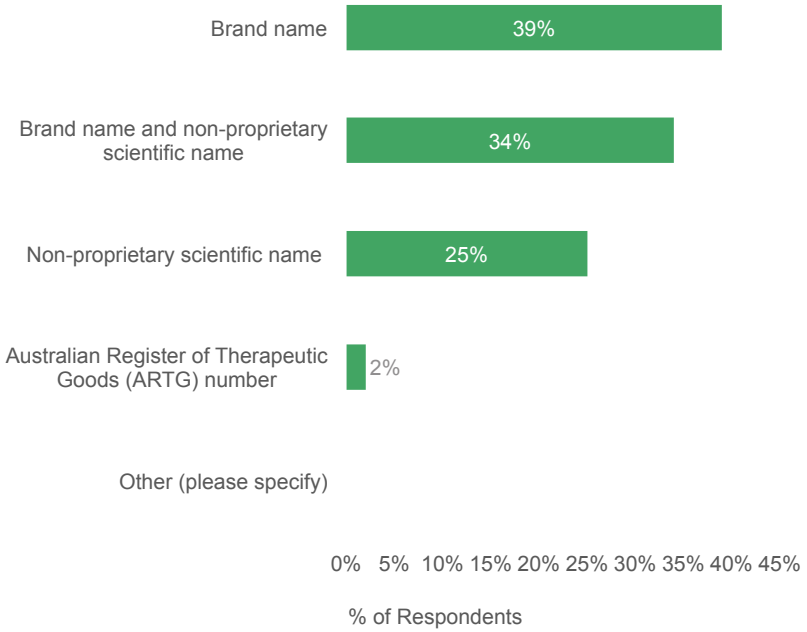
REPORTING AND NAMING FOR BIOLOGICS AND BIOSIMILARS

How biologics are identified



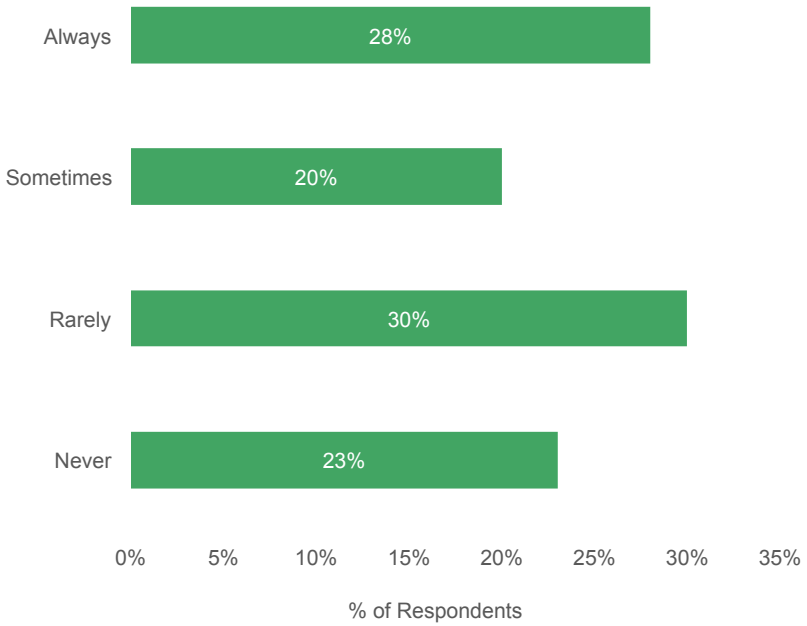
- Question
  - "When you prescribe a biologic medicine/make an entry on a patient record, are you likely to identify the medicine by:

How biologics are identified – Adverse events



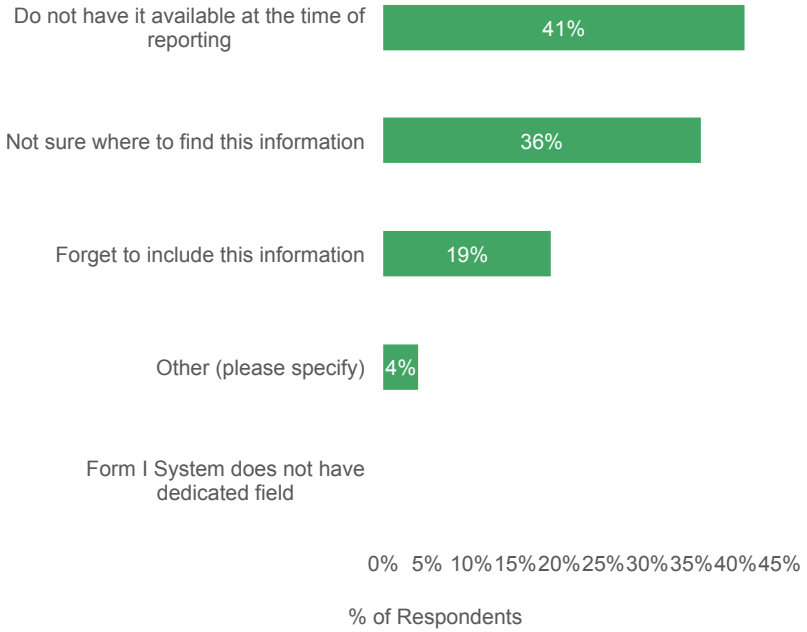
- Question
  - "In the context of identifying a biologic for the purposes of reporting an adverse event, how do you identify the medication?"

Batch numbers?



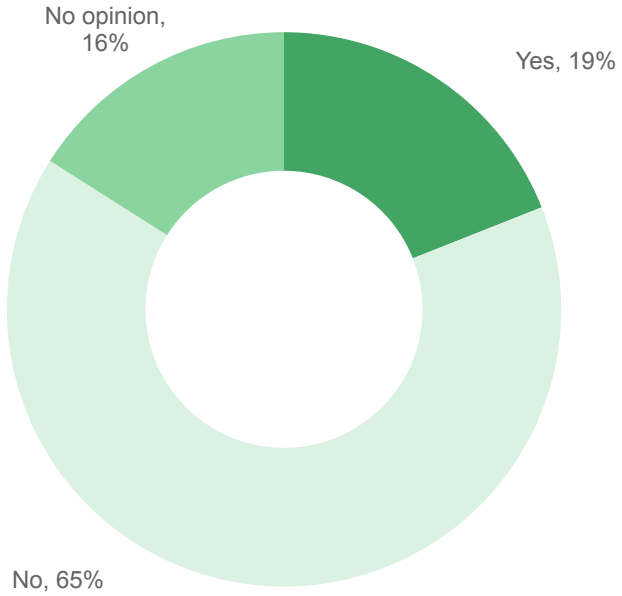
- Question
  - "How often do you include the batch number when reporting adverse events?"

Batch numbers?



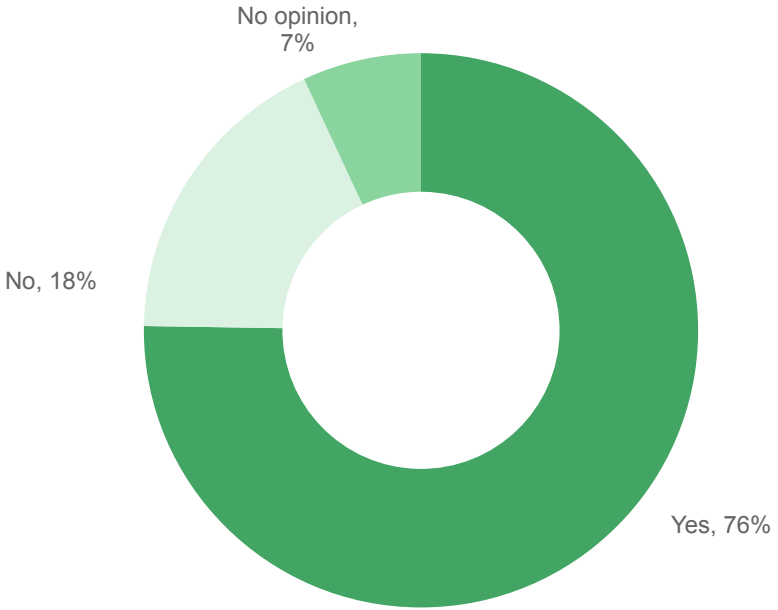
- Question
  - "Wat are the main reasons for not reporting the batch number?" (n=116)

Loss of efficacy an AE?



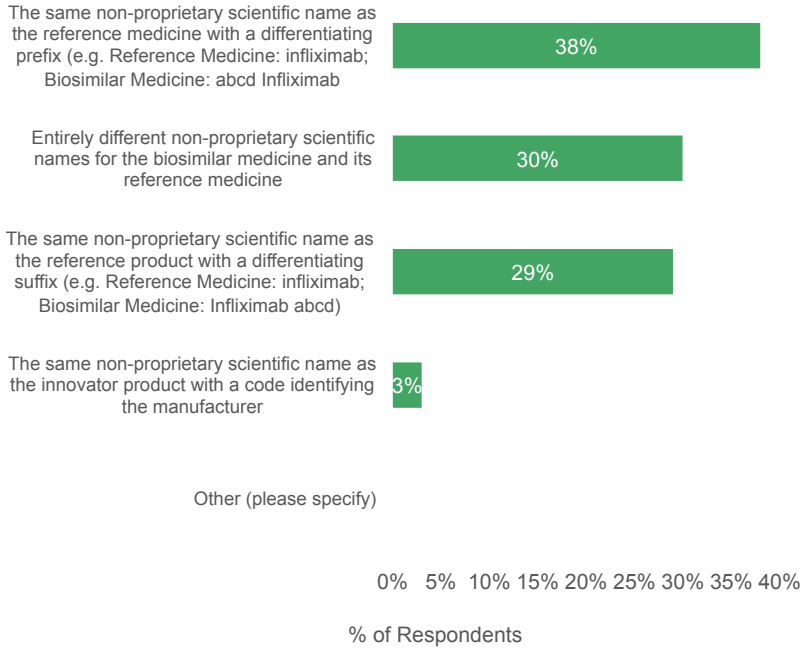
- Question
  - "Do you consider that a loss of efficacy is a reportable adverse event?"

Naming



- Question
  - "In your opinion, should the TGA insist on a distinct non-proprietary scientific name for every biologic or biosimilar medicine that it approves?"

Naming



- Question
  - "In your opinion, what is the best way for the TGA to differentiate a biosimilar medicine from its reference biologic medicine?"

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SUBSTITUTION ATTITUDES & BELIEFS

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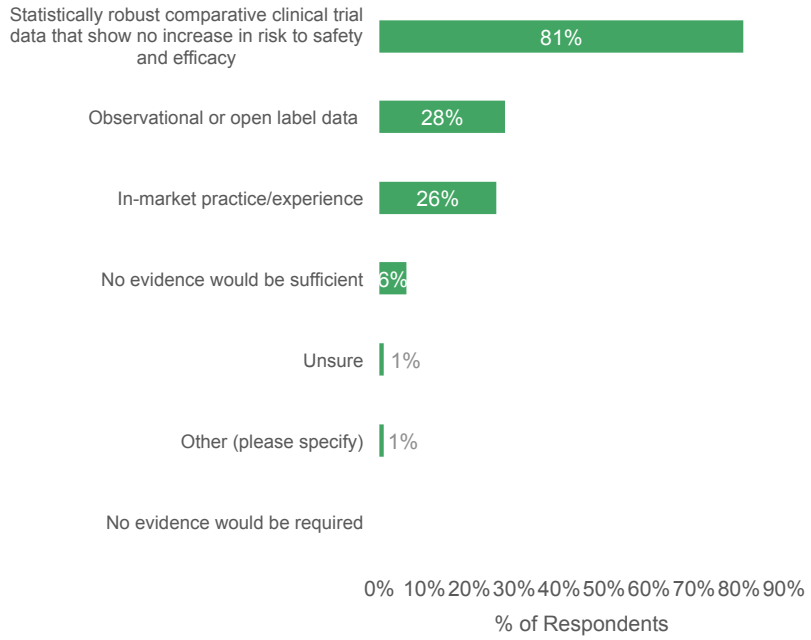
The Pharmaceutical Benefits Advisory Committee (PBAC) has indicated that it will consider pharmacy level substitution of biosimilars for reference biologic medicines on a ‘case by case basis’. Where a product is deemed suitable for pharmacy level substitution (a process known as “a” flagging), a patient can be switched by a pharmacist from the reference biologic medicine to the biosimilar medicine and from the biosimilar medicine back to the reference biologic medicine. This could potentially be done on multiple occasions.

INTRODUCTION TO SUBSTITUTION

Sufficient evidence for substitution

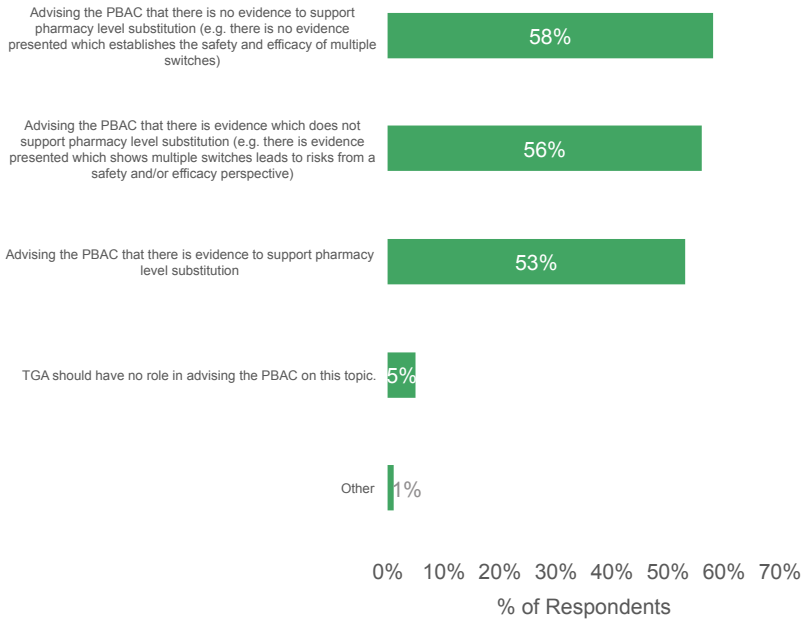
- Question
  - "What evidence would you regard as sufficient to be supportive of the PBAC's conclusion that a biosimilar product is suitable for pharmacy level substitution? Select all that apply."

Sufficient evidence for substitution



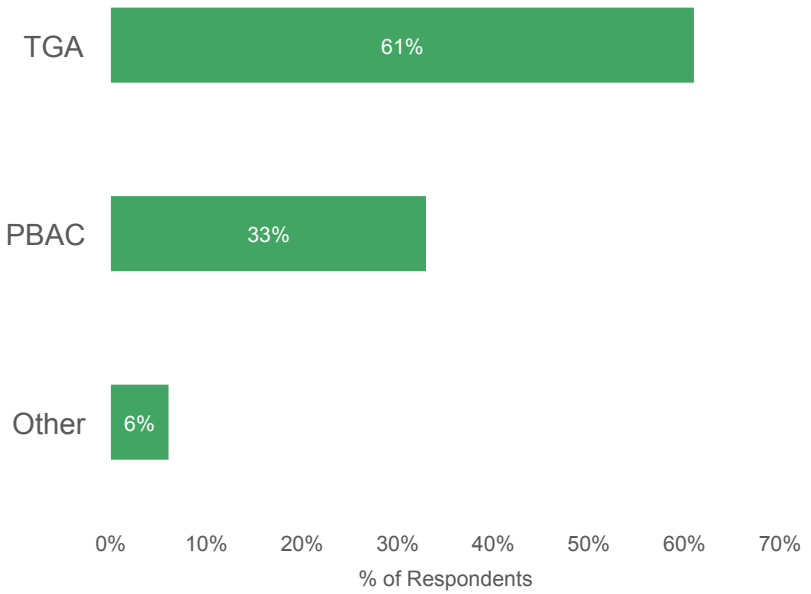
- Question
  - "Where there is more than one biosimilar medicine to a single reference biologic, what evidence would you regard as sufficient to conclude that one biosimilar is appropriate for pharmacy level substitution for another biosimilar? Select all that apply."

The role of the TGA



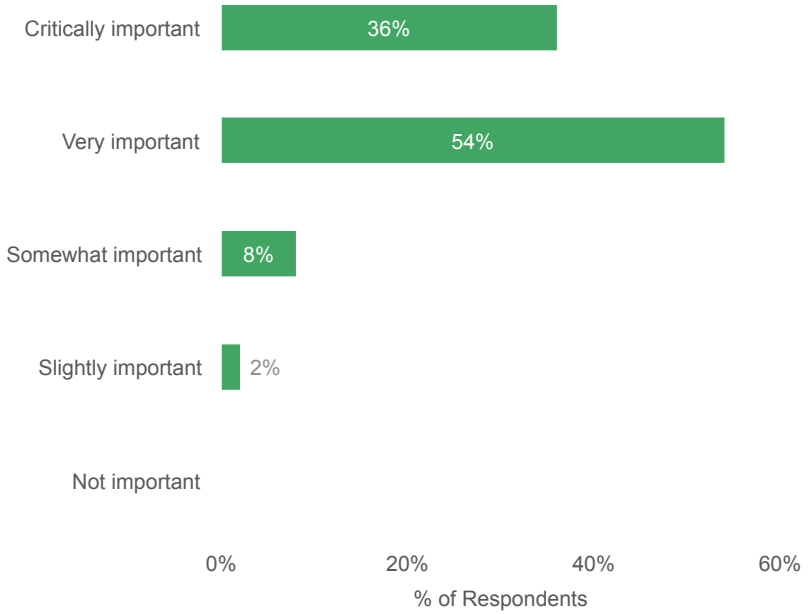
- Question
  - "In Australia, biologics and biosimilars are approved nationally by the TGA. What role, if any, do you believe the TGA should have in advising the PBAC on the suitability of a product for pharmacy level substitution? Check all that apply."

TGA or PBAC for substitution



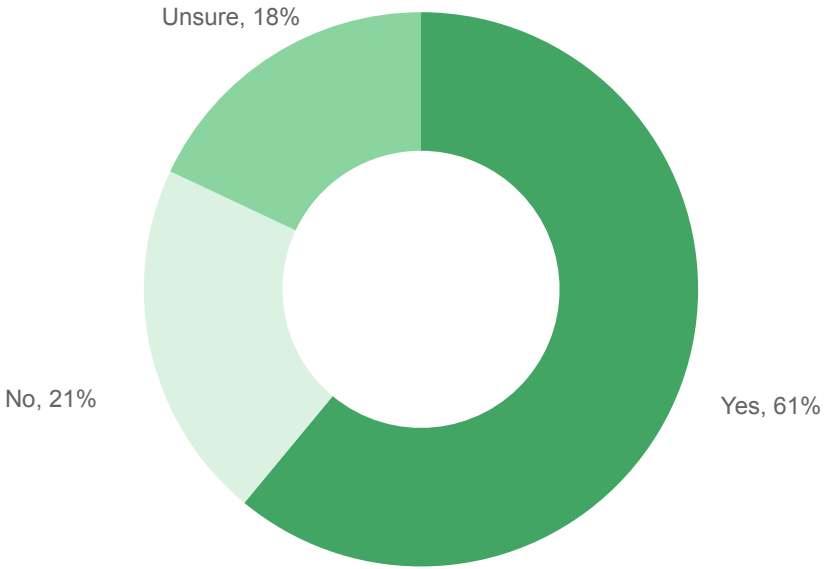
- Question
  - "Which body do you believe should be responsible for providing the primary advice to Government that a product is suitable for pharmacy level substitution?"

Importance decision authority



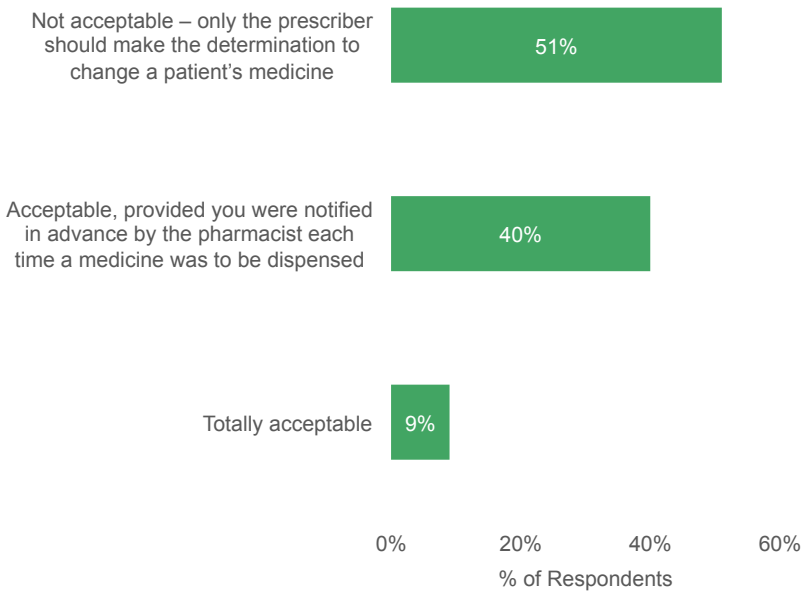
- Question
  - "How important is it for you, as the prescribing physician, to have the sole authority to decide, together with your patient, the most suitable biologic medicine that is to be dispensed to your patient?"

Prescription software capability



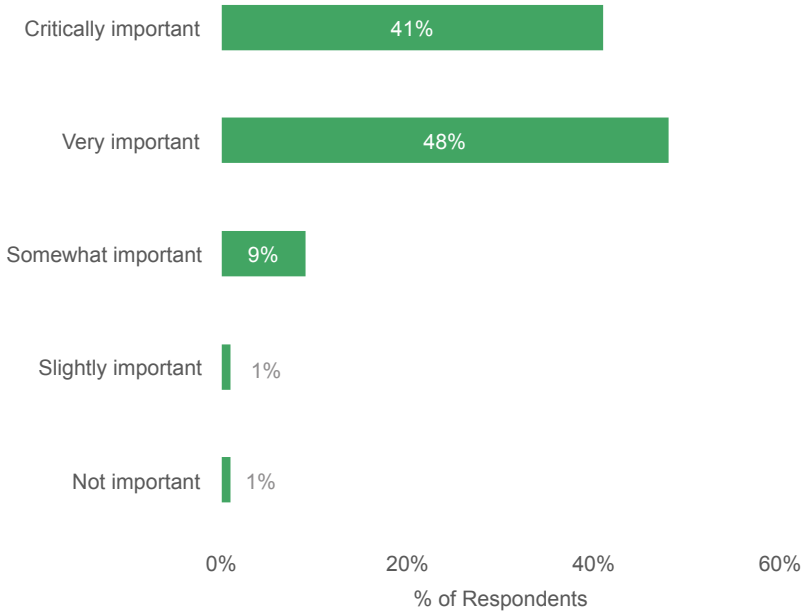
- Question
  - "Does your prescription software/documentation include a 'brand substitution not permitted" box?"

Acceptability of substitution – Chronic disease



- 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?"

Importance of notification



- Question
  - "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 (e.g. if the pharmacist substituted a reference biologic medicine for its biosimilar)?"