



Smarter questions • Smarter answers

Biosimilars Naming and Labeling

A Study of U.S. Pharmacists

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ASBM

METHODOLOGY

Study methodology

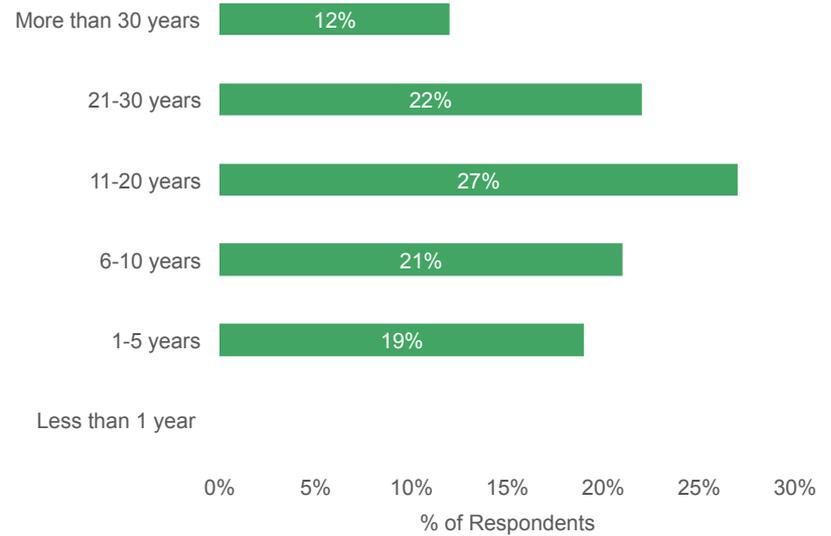
- 401 pharmacists
- 15-minute web-based survey
- All participants based in the U.S.
- Participants recruited from large, global panel of healthcare professionals
- Participants screened as follows:
 - Must be employed in either Hospital / Health System pharmacy or Retail pharmacy setting
 - Must dispense biologic medicines
 - Must have been in practice as a pharmacist for 1 year or more
- Participants received a standard cash stipend for their time
- Study was sponsored by ASBM and administered by Industry Standard Research, LLC

Sample characteristics

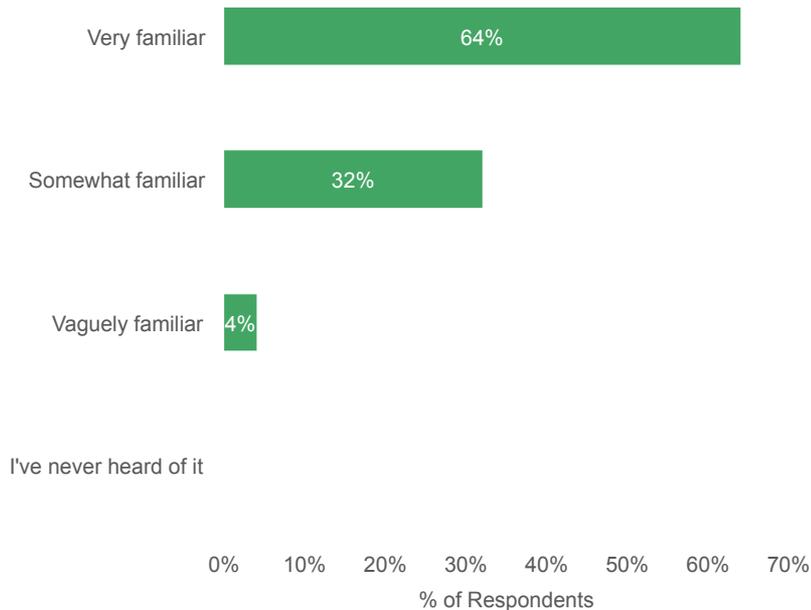
Practice Setting



Years in Practice

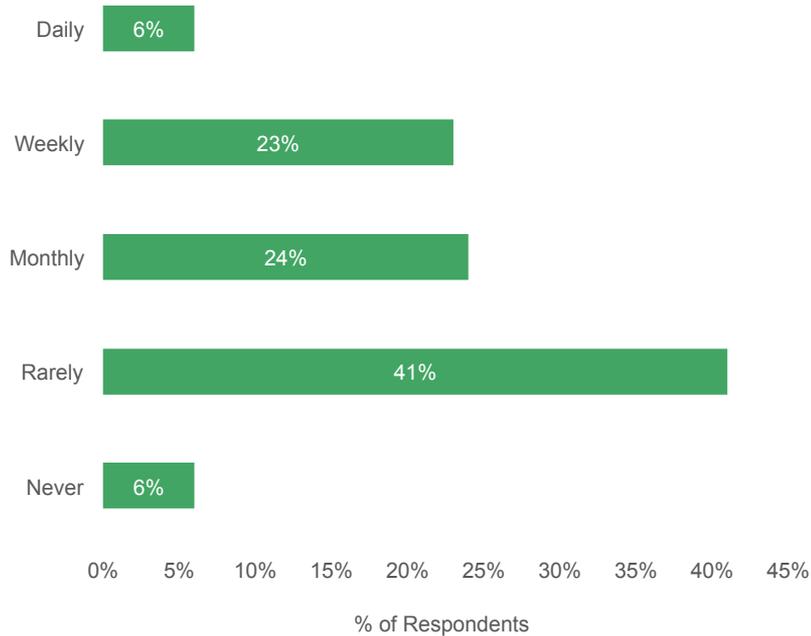


Familiarity with Orange Book



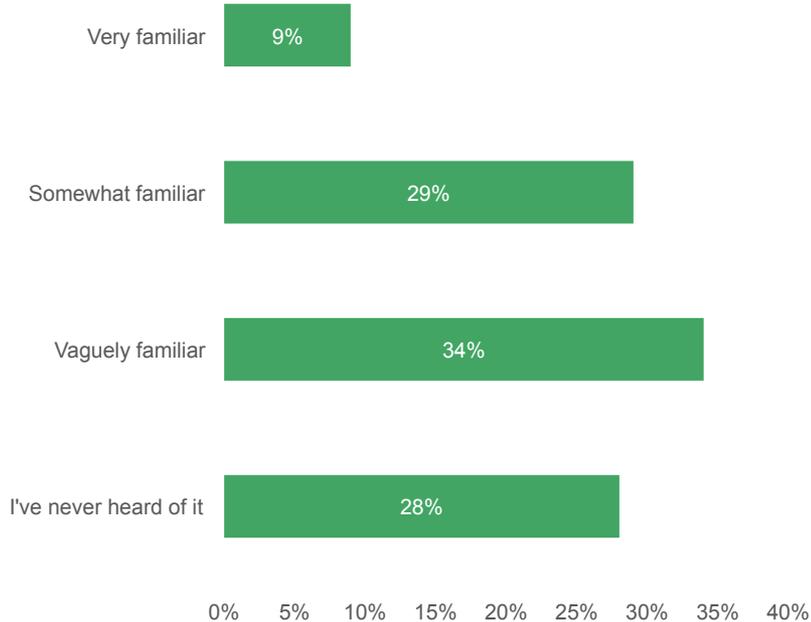
- Question
 - “How familiar are you with the “Orange book”, that is, the resource for Approved Drug Products with Therapeutic Equivalence Evaluations?”

Frequency of Orange Book use



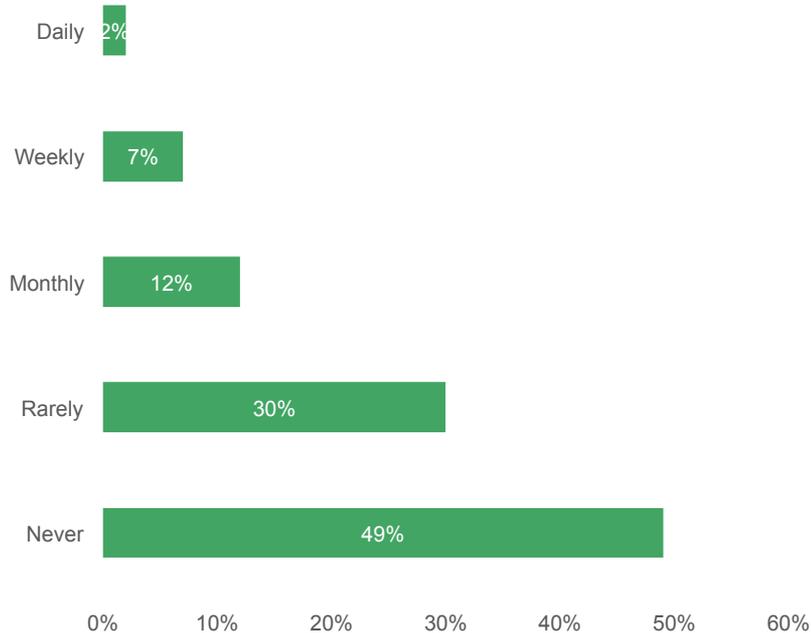
- Question
 - “How often in your work do you use or refer to the “Orange Book”?”

Familiarity with Purple Book



- Question
 - “How familiar are you with the “Purple Book”, that is, the resource for Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations?”

Frequency of Purple Book use



- Question
 - “How often in your work do you use or refer to the “Purple Book”?”

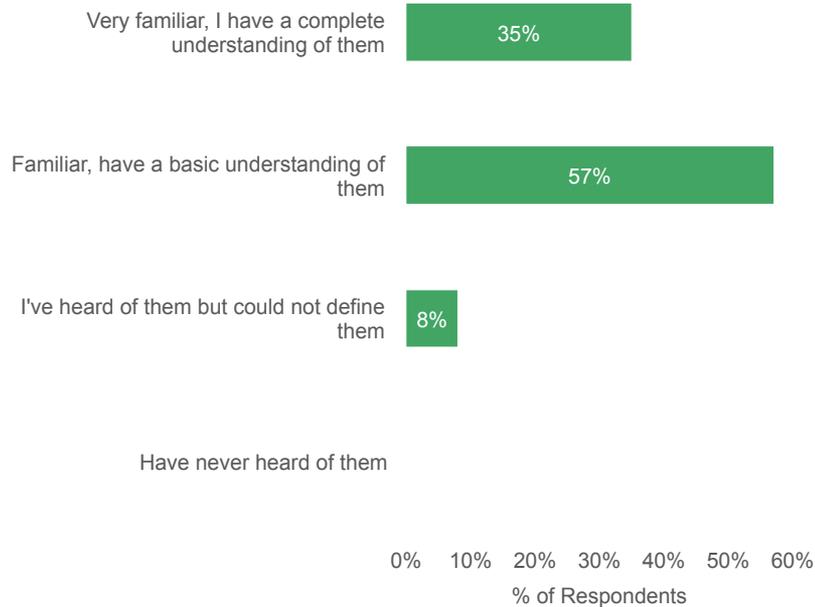


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U.S. Pharmacists

BIOSIMILARS KNOWLEDGE

Familiarity with biosimilars



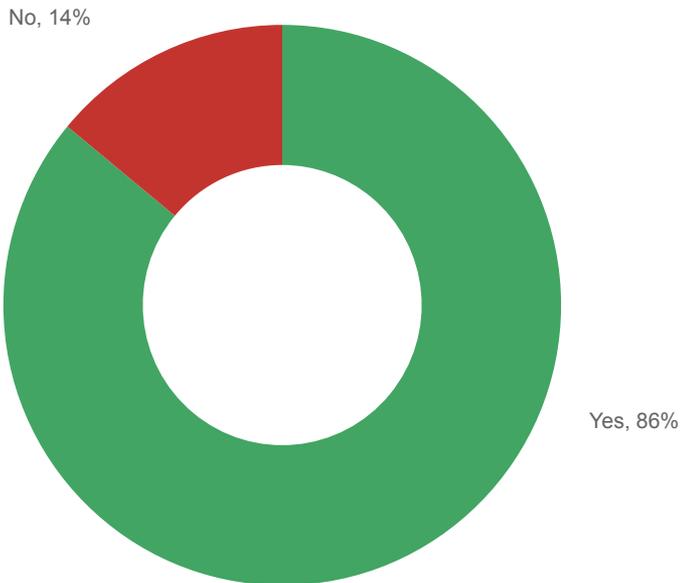
- Question

- “Biosimilar medicines are intended to be copies of already approved biologic medicines. They are referred to as “biosimilar” rather than “generic” because they will be similar, but not identical to the product they copy. How familiar are you with biosimilar medicines?”

- Segment Difference

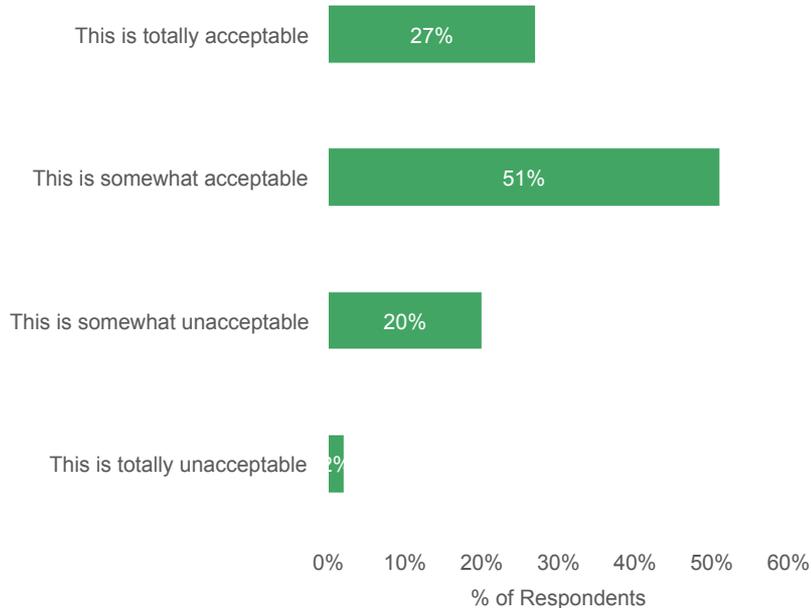
- Hospital pharmacists are more likely to be “Very familiar...” with biosimilars than retail pharmacists. 44% vs. 23%

Awareness of biosimilars approval process



- Question
 - “Originator medicines are approved by the US Food and Drug Administration based on an evaluation of clinical data that demonstrates a medicine is safe and effective for the specified indication and data must be provided for every indication. The approval pathway for biosimilars is different than for originator medicines. Are you aware a biosimilar medicine may be approved for several or all indications of the reference product on the basis of clinical trials in only one of those indications?”
- Segment Difference
 - Hospital pharmacists are more likely to respond “Yes” than retail pharmacists. 91% vs. 78%

Acceptability of biosimilars approval process



- Question

- “How do you feel about the fact that a biosimilar medicine may be approved for several or all indications of the reference product on the basis of clinical trials in only one of those indications?”

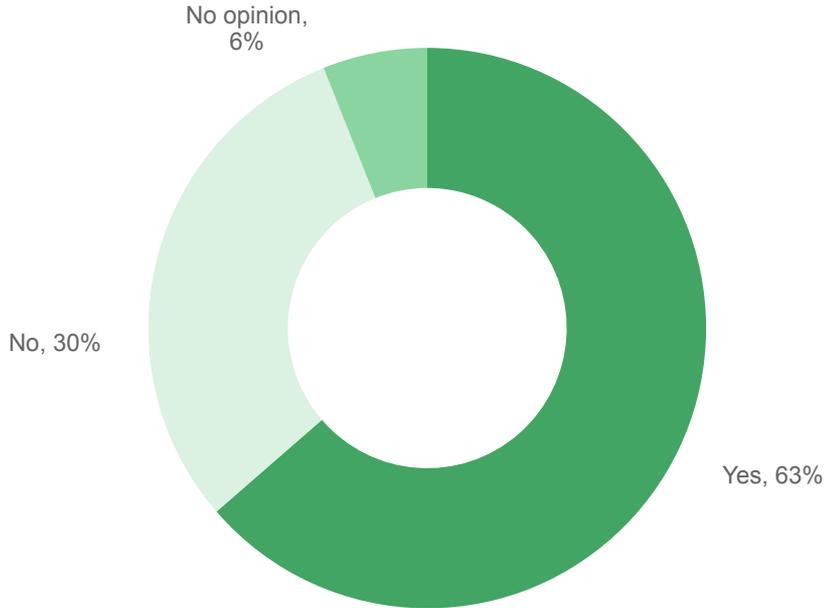


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U.S. pharmacists, biosimilars and

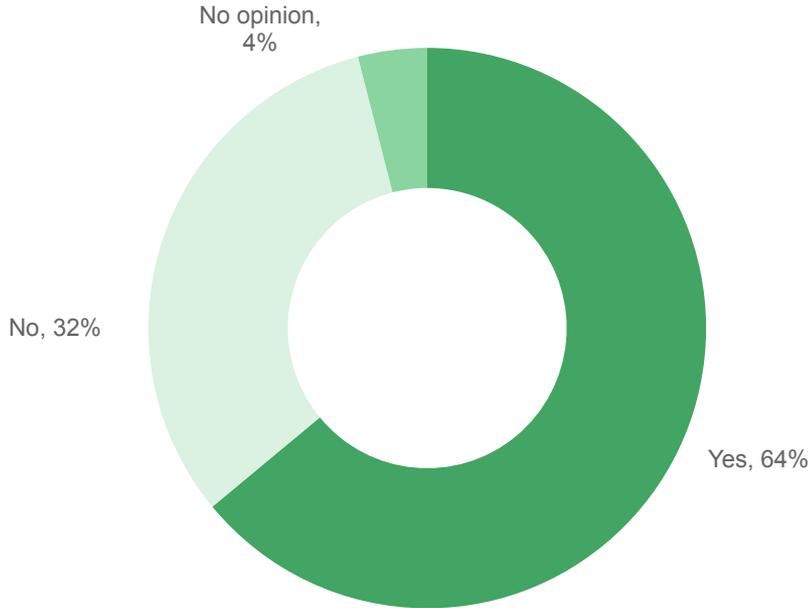
NAMING

Same name = identical?



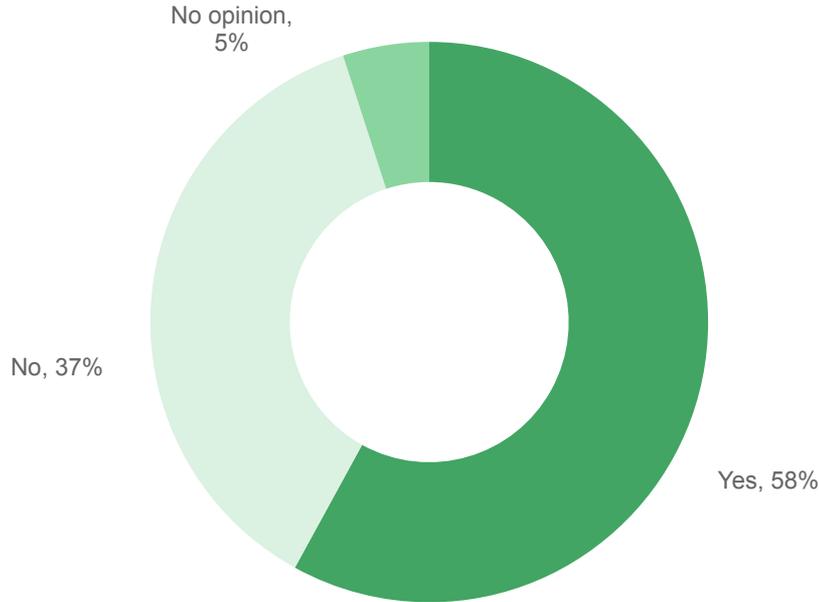
- Question
 - “If two biologic medicines have the same non-proprietary scientific name, does this suggest to you or imply that the medicines are identical?”
- Segment Difference
 - Hospital pharmacists are more likely to answer “Yes” than retail pharmacists. 68% vs. 57%

Same name = same result?



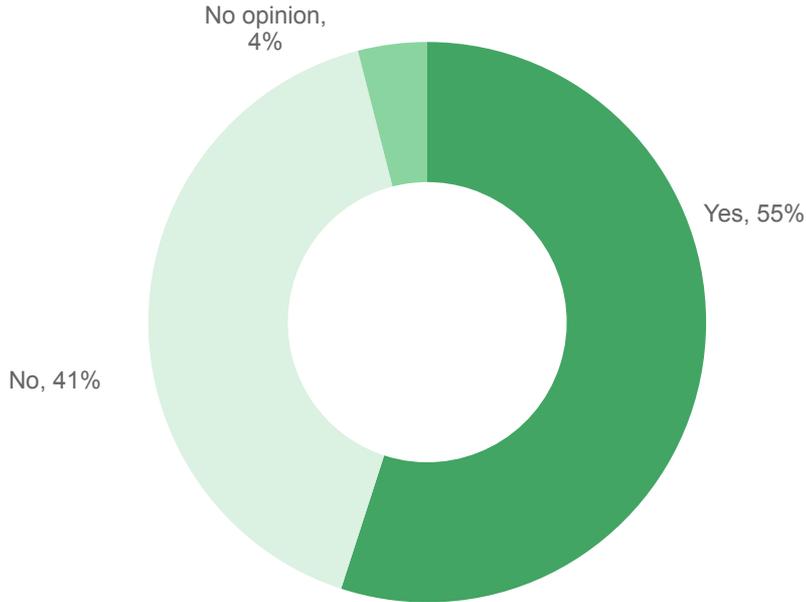
- Question
 - “If two biologic medicines have the same non-proprietary scientific name, does this suggest to you or imply that a patient could receive either biologic product and expect the same result?”

Same name = safe switching during treatment?



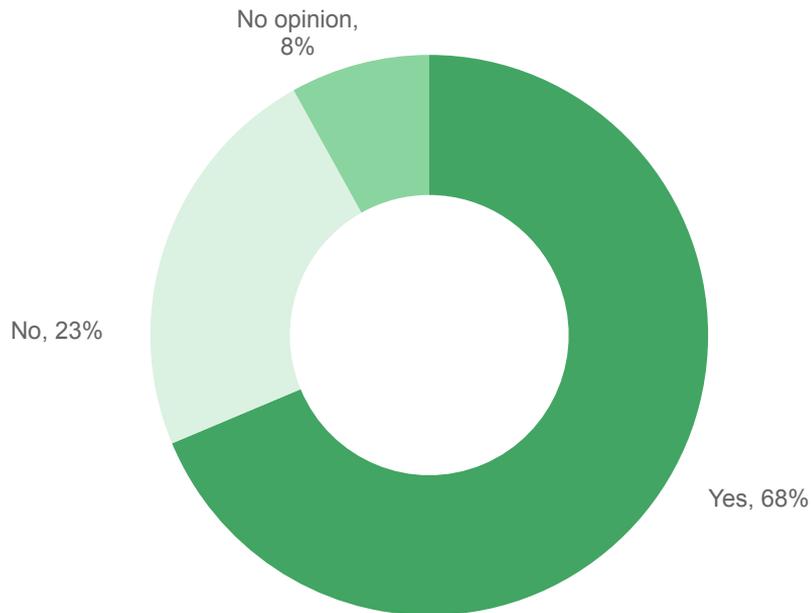
- Question
 - “If two biologic medicines have the same non-proprietary scientific name, does this suggest to you or imply that a patient could be safely switched from a reference biological medicine to its biosimilar during a course of treatment and expect the same result as with either of the products?”

Same Name = Approved for the same indications?



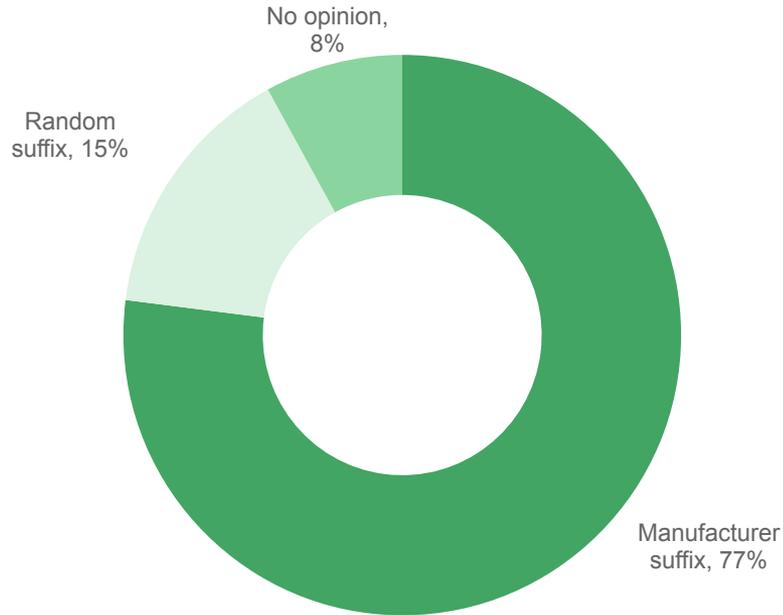
- Question
 - “If two biologic medicines have the same non-proprietary scientific name, does this suggest to you the medicines are approved for the same indications?”

Should FDA require distinct names?



- Question
 - “The FDA has proposed a new policy that would require every biologic – whether originator or biosimilar – to have a distinct non-proprietary scientific name. In your opinion, should the FDA require a distinct non-proprietary scientific name for every biologic product – whether originator or biosimilar – approved by them?”

Representative or random suffix?



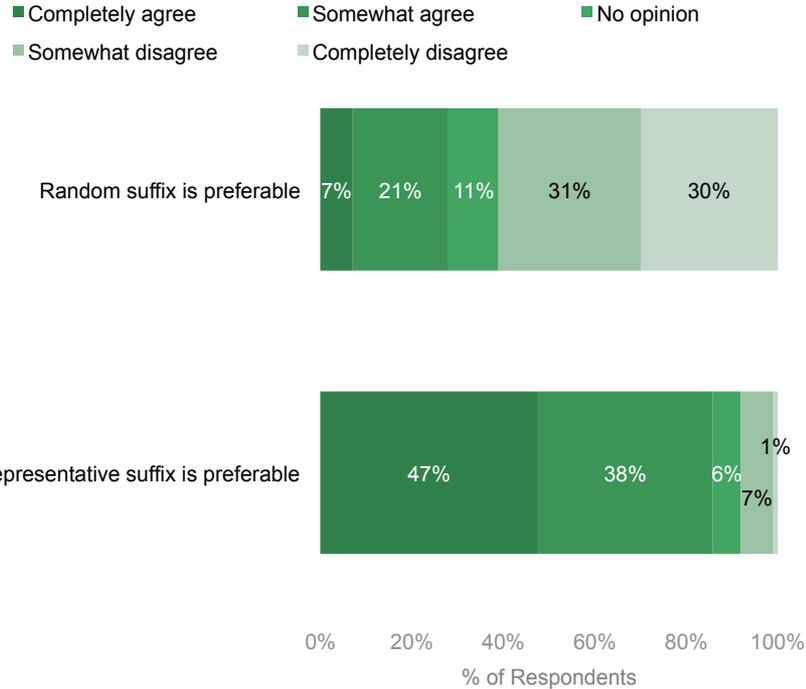
- Question
 - “The FDA has proposed a policy that would require the use of a distinct non-proprietary scientific name for all products, whether originator or biosimilar. This is intended to aid the process of pharmacovigilance and accurate prescribing and dispensing of medicines. In March of 2015, the FDA approved the first biosimilar product for the U.S. market. The product currently carries the scientific name “filgrastim-sndz.” In the case of filgrastim-sndz, the suffix “sndz” is intended to identify Sandoz as the manufacturer of the product. More recently, the FDA has proposed a further change to the naming of biologic products. In the case of filgrastim-sndz, the name would become “filgrastim-bflm,” where the suffix carries no meaning and is not indicative of the product’s manufacturer. For future product approvals, which of the following would you prefer?”

Why representative / random?

- See verbatim responses in attached MS Word file.



Suffix content



- Question
 - “For purposes of accurately identifying the medicine, a representative suffix – for example, one that resembles the manufacturer name – is preferable.”

- Question
 - “For purposes of accurately identifying the medicine, I prefer a suffix that is a random 4-digit string of characters.”

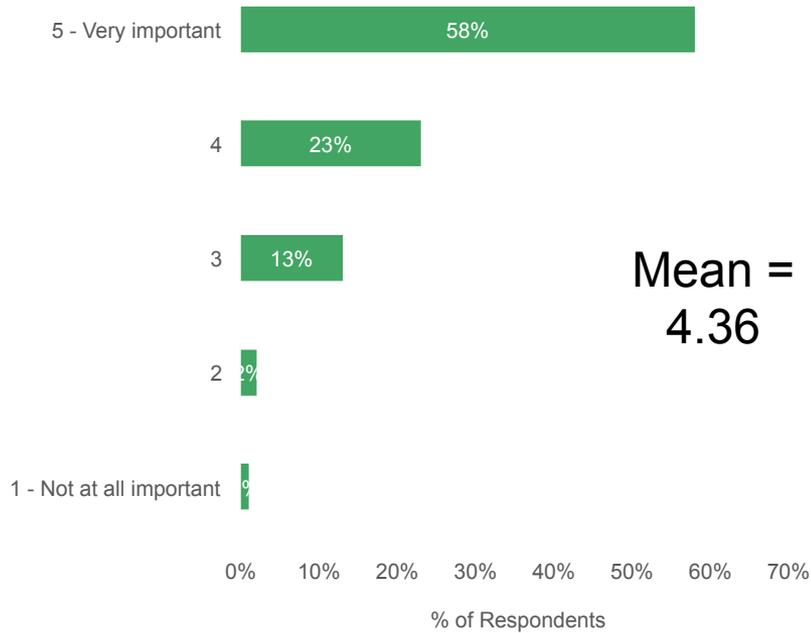


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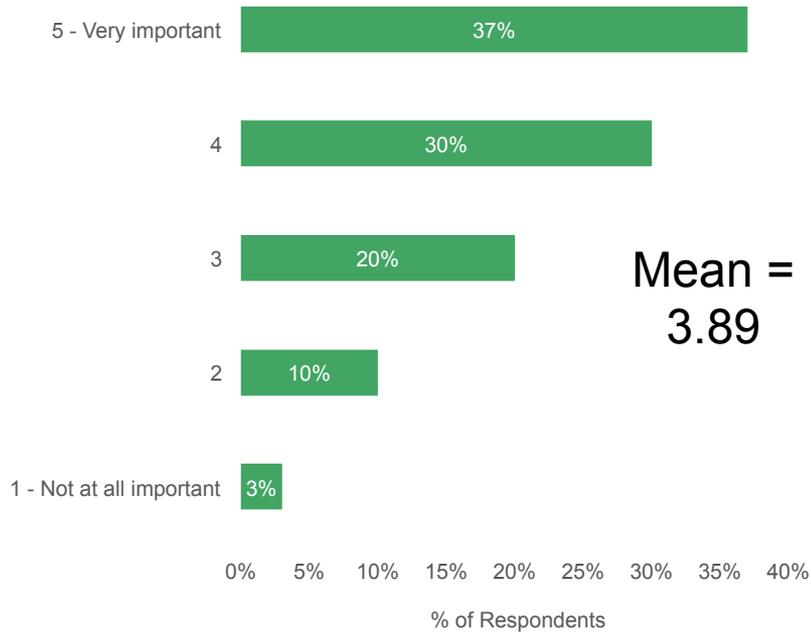
LABEL CONTENT

Indicates biosimilar



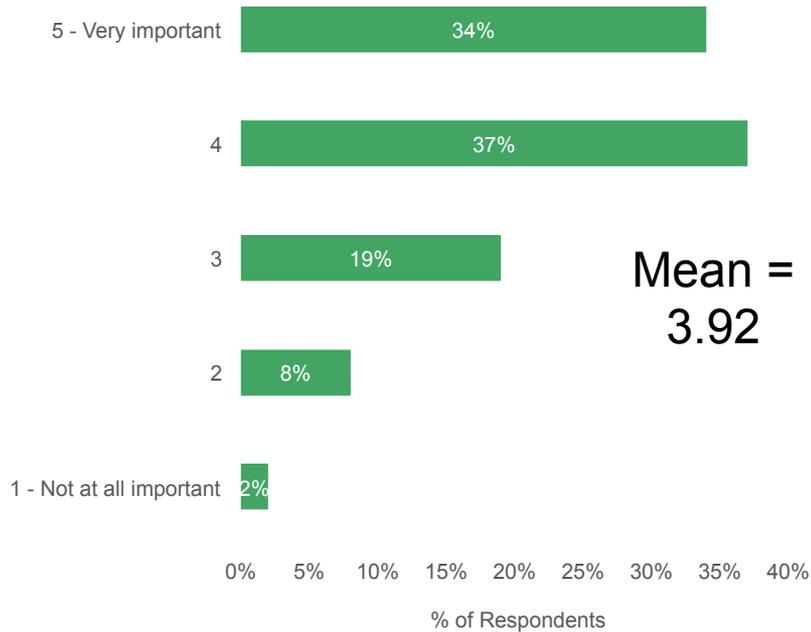
- Question
 - “How important is it that a product label for a biosimilar clearly indicates that it is a biosimilar?”

Defines biosimilarity



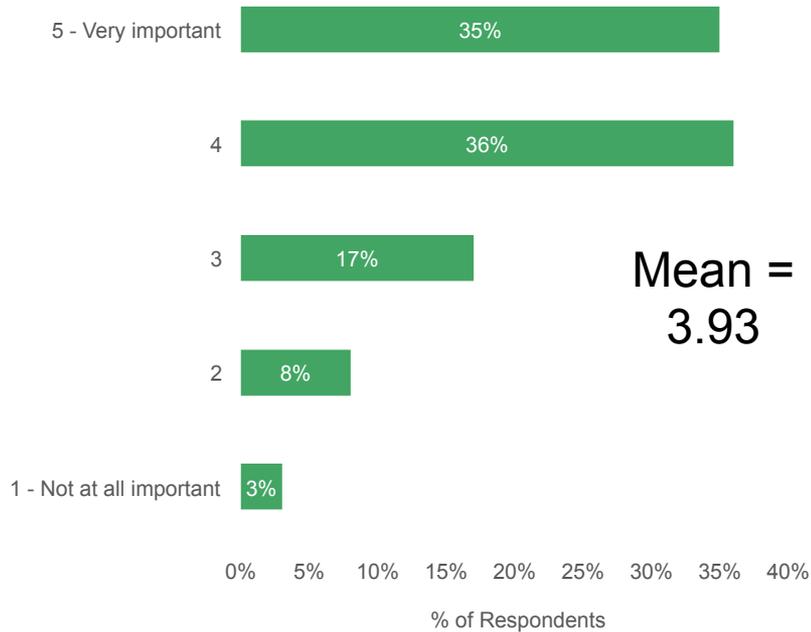
- Question
 - “How important is it that a product label for a biosimilar defines what biosimilarity means?”

Analytical data



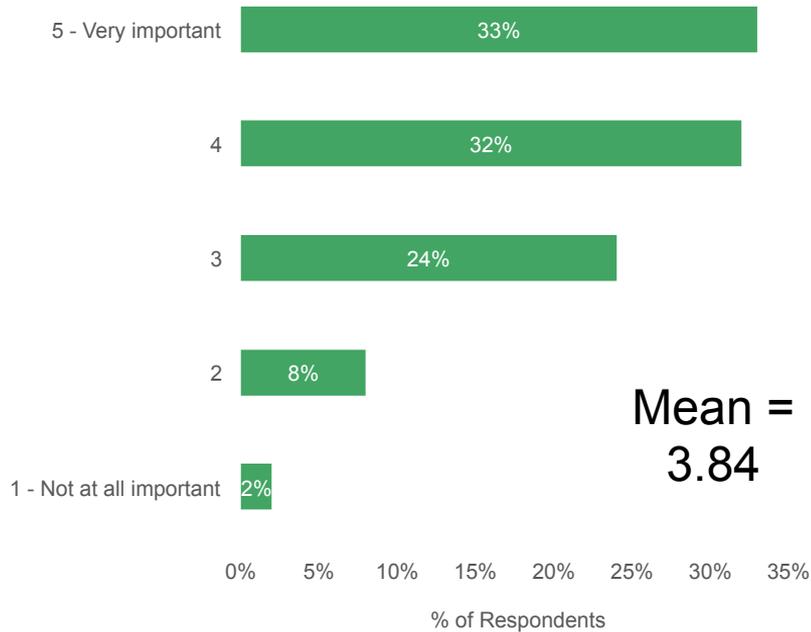
- Question
 - “How important is it that the biosimilar label includes the analytical data developed by the biosimilar sponsor to demonstrate its analytical similarity to the reference product?”

Clinical data



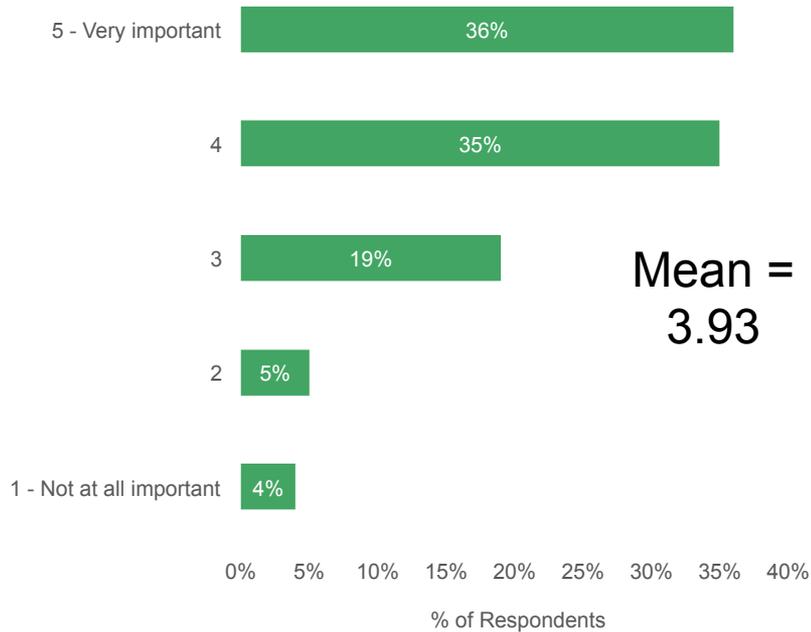
- Question
 - “How important is it that the biosimilar label includes the clinical data, if any, submitted to FDA by the biosimilar sponsor to demonstrate that it is highly similar to the reference product?”

Post-marketing data



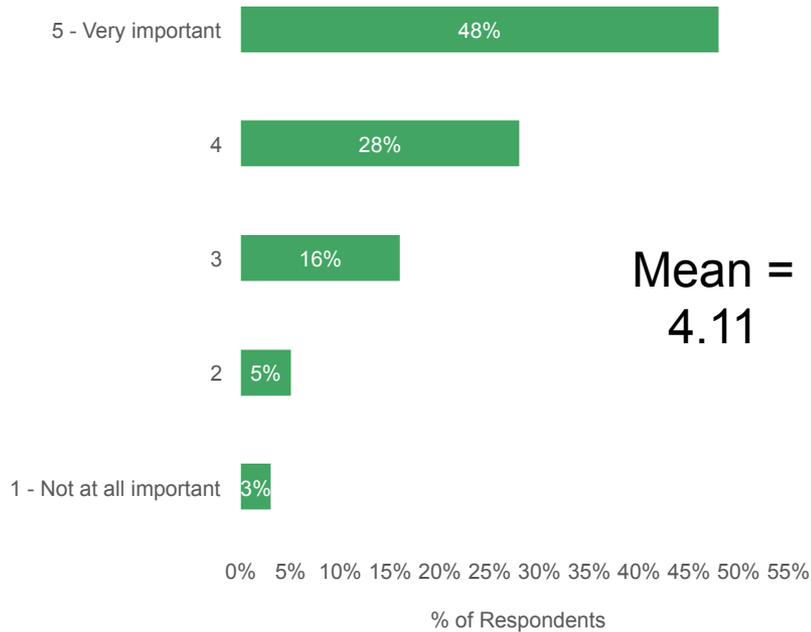
- Question
 - “How important is it that post-marketing data related to the biosimilar be added to the biosimilar label?”

Reference brand name



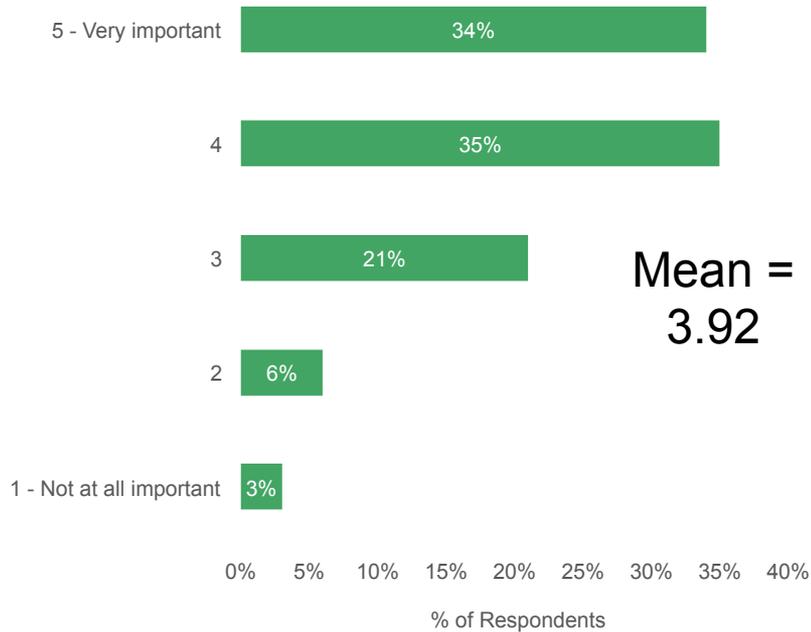
- Question
 - “How important is it that the label mentions the reference product by brand name so as to clarify the precise relationship between the originator product and the biosimilar product?”
- Segment Difference
 - Retail pharmacists have a higher average rating of importance for this than hospital pharmacists. 4.14 vs. 3.79

Approved and non-approved indications



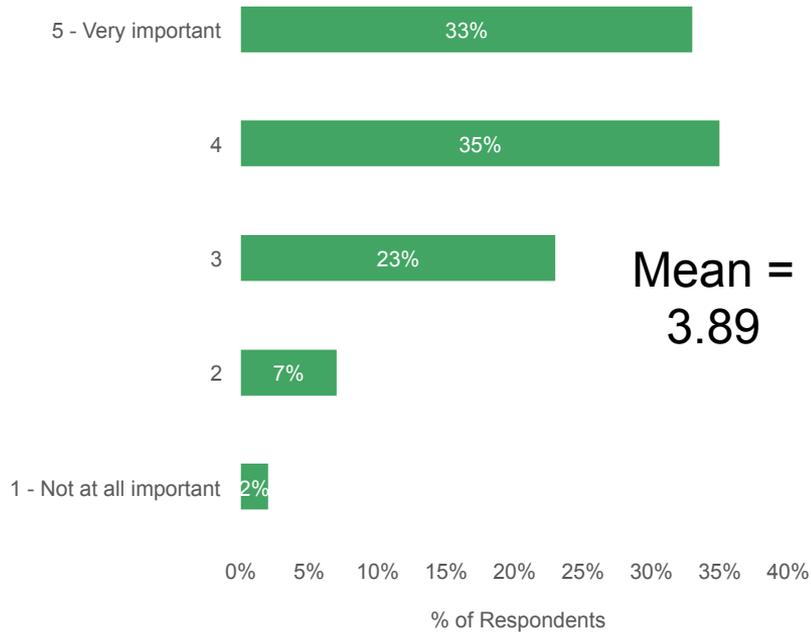
- Question
 - “How important is it that the label explicitly states that specific indications or conditions of use that are approved for the originator product are NOT approved for the biosimilar product?”
- Segment Difference
 - Retail pharmacists have a higher average rating of importance for this than hospital pharmacists. 4.32 vs. 3.98

Originator vs. biosimilar data



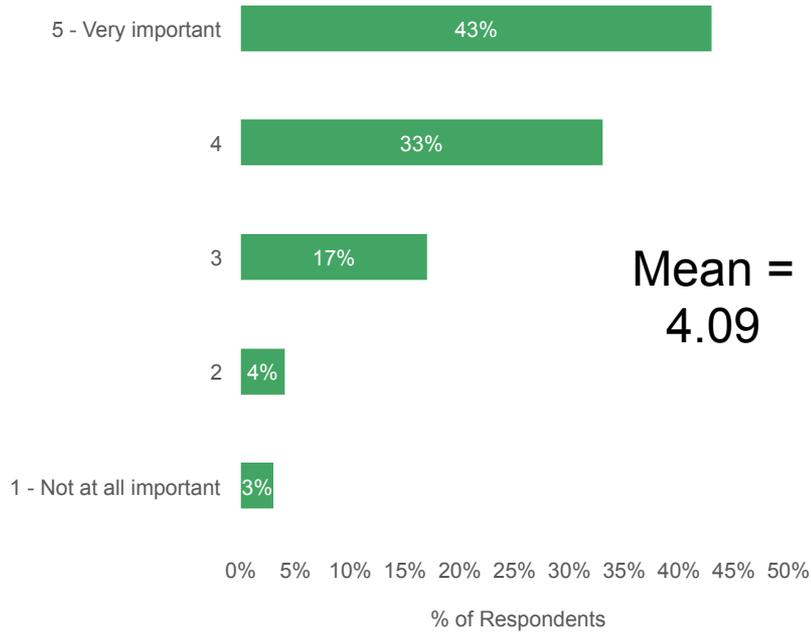
- Question
 - “How important is it that the label clearly distinguishes those data generated by the biosimilar sponsor from those generated by the originator sponsor?”

Clinical similarity



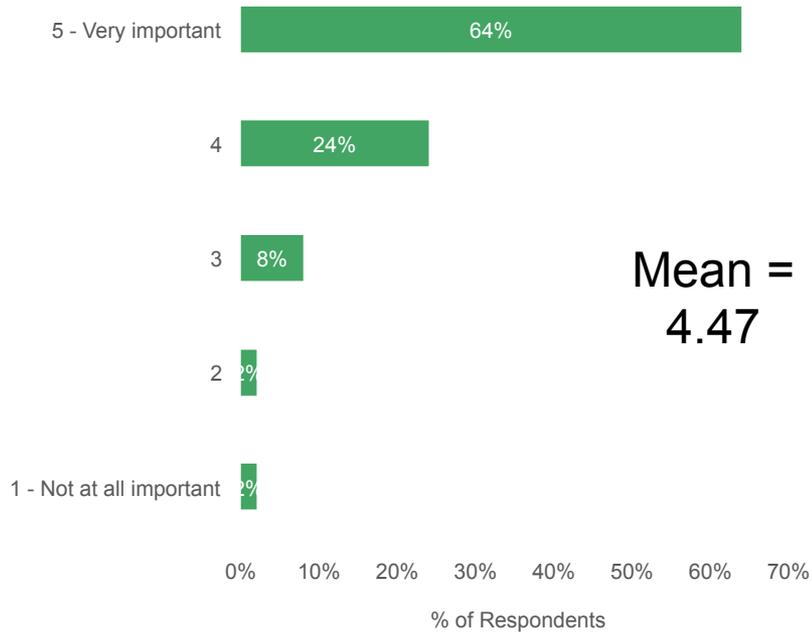
- Question
 - “How important is it that the label includes all relevant clinical similarity data, including clinical immunogenicity findings, from the biosimilar product development?”

Data source



- Question
 - “How important is it that the label makes clear which indications were studied by the biosimilar sponsor and which indications were approved based on extrapolation from studies in other indications?”

Interchangeability / Substitution



- Question
 - “How important is it that a product label clearly indicates a biosimilar is or is not interchangeable, meaning it may be eligible for automatic substitution by a pharmacist depending on the state in which the prescription is written?”

Questionnaire



ASBM Pharmacist
Survey