Increasing Success and Sustainability of Biosimilar Markets: Physician Perspectives

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SafeBiologics
ALLIANCE *for* SAFE BIOLOGIC MEDICINES

BACKGROUND

- Biologic medicines are highly-effective products used to treat serious and chronic conditions including rheumatoid arthritis, psoriasis, ulcerative colitis, Crohn's Disease, and cancer.
- Biosimilars are highly similar, but not identical, to the originator biologics on which they are based. They offer new treatment options for patients at reduced cost and promote price competition between products.
- The high cost of biologic therapies incentivizes payers to change coverage policies in order to switch patients to lower-cost (or more profitable) products.
- While biosimilars are safe and effective medicines, treatment plans are not universal and are developed over time by physicians and patients. Patients often try multiple products before finding one which stabilizes their condition.
- Accordingly, physicians and patients have expressed concerns about unnecessarily switching between biologic medicines, particularly when the patient is stable and well-treated on their current medicine.
- The U.S. FDA has attempted to address these concerns by creating a designation of "interchangeable" to a biosimilar which has demonstrated that a patient can be repeatedly switched between it and its reference product and expect the same result, without additional risks, as a patient who was not switched.
- A 2019 report[1] from the FDA Task Force on Drug Shortages also emphasized the importance of maintaining multiple suppliers. It recommended **"promoting sustainable private sector contracts (e.g., with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs."**

OBJECTIVE

- The survey empirically documents attitudes of 401 U.S. prescribers of biologics from 12 specialties on: biosimilar safety and efficacy; prescribing biosimilars to patients; switching patients to biosimilars; third-party switching of patients for cost/coverage reasons; payer reimbursement practices; preferred biosimilar access scenarios including the availability of multiple sources for a class of biologic medicine; and implications of FDA interchangeability.
- This survey is part of a series of physician surveys covering 13 countries since 2011. These including surveys of U.S. physicians in 2012, 2015 and 2019.
- These surveys may be viewed at www.safebiologics.org/surveys.

METHODOLOGY

- In September 2021, a web-based quantitative survey was conducted of 401 practicing U.S. physicians. All prescribe biologics.
- Participants were drawn in roughly-equal proportion from 12 specialties in which biologics are routinely prescribed and were provided an honorarium for their time.

RESULTS

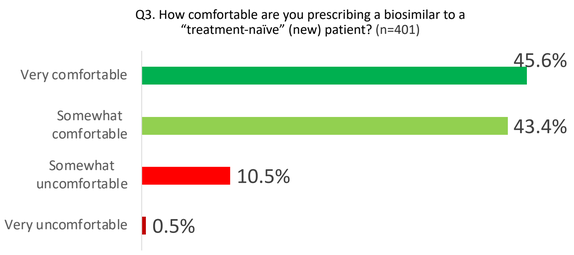
U.S. PHYSICIAN CONFIDENCE IN BIOSIMILARS IS HIGH

- 92% of respondents expressed confidence in the safety and efficacy of biosimilars:

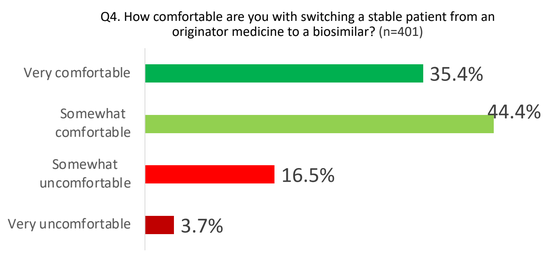
Q1. How would you describe your personal confidence level in the safety and efficacy of biosimilars? (n=401)

- 89% would prescribe a biosimilar to a new (bio-naive) patient. 80% are comfortable switching a stable patient to a biosimilar themselves:

Q3. How comfortable are you prescribing a biosimilar to a "treatment-naïve" (new) patient? (n=401)



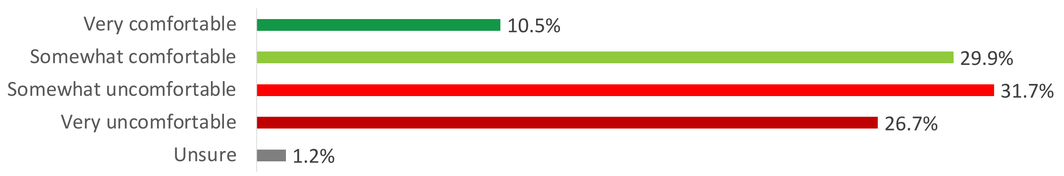
Q4. How comfortable are you with switching a stable patient from an originator medicine to a biosimilar? (n=401)



CONTROL OF TREATMENT DECISIONS: VERY IMPORTANT

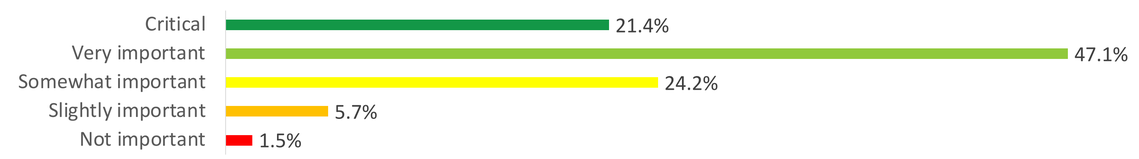
- A majority (58%) are uncomfortable with third-party substitution for non-medical reasons (e.g. cost, coverage):

Q15. How comfortable are you with a third party switching your patient to a biosimilar for non-medical reasons (i.e., cost or coverage)? (n=401)



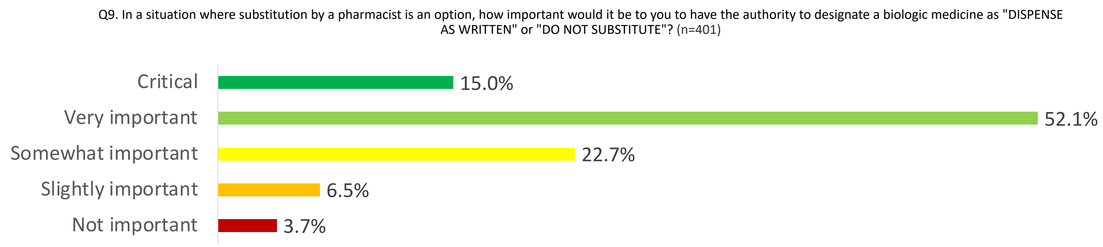
- 69% of US physicians surveyed consider it "very important or critical" that patients and physicians decide the most suitable biologic to use- be it the originator or one of the biosimilars to that product.

Q13. How important is it to you to have the sole authority to decide, together with your patients, the most suitable biologic medicine for their disease? (n=401)



- 67% of respondents consider it "very important" or "critical" that they're able to prevent a substitution they feel is inappropriate:

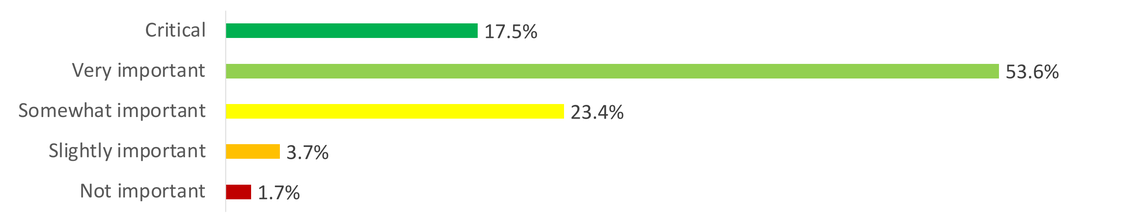
Q9. In a situation where substitution by a pharmacist is an option, how important would it be to you to have the authority to designate a biologic medicine as "DISPENSE AS WRITTEN" or "DO NOT SUBSTITUTE"? (n=401)



AVAILABILITY OF MULTIPLE PRODUCTS: VERY IMPORTANT

- 71% considered it highly important that payers (public and private) should reimburse multiple products in a given class- including originator and biosimilars:

Q17. How important is it that payers such as health insurers and government agencies have the formulary flexibility to reimburse multiple products in a particular class, including originator products and biosimilars? (n=401)

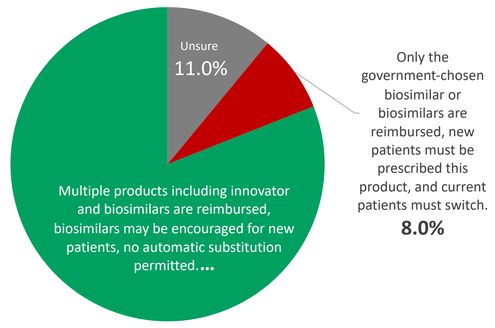


- 74% considered it highly important that payers consider factors other than cost when determining coverage.

MULTIPLE PRODUCTS: PREFERRED BIOSIMILAR ACCESS SCENARIO

- 81% believe their patients would be best served under a biosimilar access scenario popular throughout most of Western Europe- in which biosimilars and originator products are both reimbursed, biosimilars may be encouraged for new patients, but automatic or pharmacy-level substitution is not permitted.
- Only 8% supported an access scenario implemented by several Canadian provinces, in which only a preferred, government-chosen product is reimbursed and to which both new and stable patients must be switched. 11% were unsure.

Better Access Scenario for Your Patients?

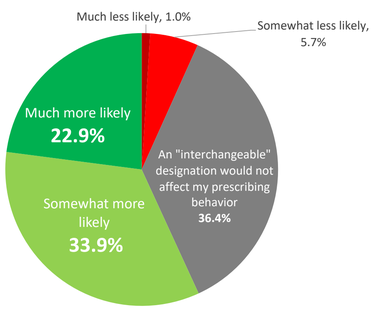


Q20. From your perspective, which type of access scenario would better serve your patients? (n=401)

MORE DATA = MORE CONFIDENCE, COMFORT WITH SWITCH

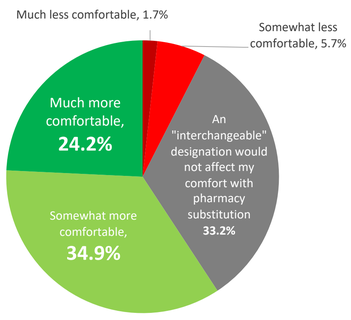
- An FDA designation of "interchangeable" (meaning additional data has shown that repeated switching between originator and biosimilar will provide the same result without additional risks relative to unswitched patients) makes 57% of physicians more likely to prescribe the interchangeable biosimilar.
- An "interchangeable" designation also makes a majority (59%) more comfortable with a pharmacy-level substitution of the interchangeable biosimilar in place of the prescribed originator product.

More Likely to Prescribe?



Q5. Does a biosimilar carrying an interchangeable designation make you more or less likely to prescribe it? (n=401)

More Comfortable with Substitution?



Q6. How does knowing a biosimilar carries an "interchangeable" designation affect your comfort level with pharmacy substitution of the biosimilar? (n=401)

MULTIPLE SUPPLIERS: A KNOWN SUCCESS FACTOR

- In addition to the 2019 FDA Report[1] a meta-analysis of five studies from a range of stakeholders was conducted by the authors, to identify principles which can be applied to develop an efficient and sustainable biosimilar market. Availability of multiple suppliers and the ability for physicians to choose among these were among the "must-have" success factors identified.

1 *Drug Shortages: Root Causes and Potential Solutions, U.S. Food and Drug Administration, October 2019.*

2 *Policy Recommendations for a Sustainable Biosimilars Market: Lessons from Europe; Generics and Biosimilars Initiative Journal (GaBI Journal). Published in: Volume 9 / Year 2020 / Issue 2*

CONCLUSIONS

- U.S. physicians are highly comfortable prescribing biosimilars, and with switching patients to a biosimilar themselves.
- Despite this, a majority maintain that they, with their patients, should have sole control over treatment choices including- especially the decision to switch a patient who is stable on their current biologic.
- Accordingly, a majority continue to have concerns with third-party-initiated non-medical switching (e.g. cost, coverage, greater profit, manufacturer rebates).
- More data increases physician confidence in a biosimilar and increases their comfort level with biosimilar substitution by a third party. The FDA designation of a biosimilar as "Interchangeable" (requiring additional data to demonstrate safe switching) shows promise as an effective means of addressing these lingering concerns for most physicians.
- In addition, strong majorities believed that payers should reimburse multiple biological products in a given class, including the originator along with its biosimilars; and that both private and public payers should consider factors other than cost when determining coverage.
- The existence of multiple suppliers for a product not only expands physician choice and promotes price competition, it helps avoid drug shortages due to supply chain disruptions. Physicians agree with the FDA's assessment which identified multiple suppliers as necessary to a successful biosimilar market. This is also consistent with analyses by many disparate entities of success factors for biosimilar markets generally, and of European biosimilar markets specifically.

DISCLOSURE: 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.