



Biosimilar Adoption in the United States

Although biosimilars have been widely adopted in highly regulated markets, including Europe, Canada, Australia, and Japan, the first biosimilar drug in the US market was introduced last year. In 2013, the global market for biologics was \$200 billion, with an estimated size of \$386 billion in 2019. The biosimilar sub-sector creates substantial opportunity for the US pharmaceutical industry, so understanding market perceptions and adoption challenges is a major focus for generic drug companies.

Clarkston Consulting partnered with the Babson College Management Consulting Field Experience (MCFE) team to analyze the biosimilar market, and evaluate perceptions and biosimilar awareness among prescribers, pharmacists, and patients. The purpose of the analysis is to provide recommendations to biosimilars manufacturers on the fastest and most effective route to widespread adoption.

Approach and Methodology

The Babson MCFE team conducted extensive primary and secondary research on the topic, which included a survey of 348 US citizens. Of those surveyed, the distribution of consumers with and without medical industry experience* was relatively even. Regarding biosimilars, consumers' primary concerns were efficacy, naming protocol, safety monitoring and producing standards.

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* Medical industry experience was defined as having studied or worked in the pharmaceutical, insurance, or healthcare industries.

Study Results

The survey found that many individuals are not aware that other drug options exist. Sixty-eight percent (68%) have never heard of biosimilars—and one-third of those individuals had medical industry experience. Furthermore, unsurprisingly, 90 percent of respondents have never asked their doctors about alternatives to the biologic drugs that they currently take (Exhibit 1).

Participants were also asked to rate their likelihood of switching from a biologic to a biosimilar. The cost savings achieved from biosimilars played a major role in their decision-making process, raising respondents' likelihood of switching from 27 to 50 percent. The greatest inhibitor appears to be the lack of information available on biosimilars (Exhibit 2).

This lack of information could be influencing consumer perception of biosimilar safety. Of the people likely to switch, 56 percent believe biosimilars are safe, and no one thought they were unsafe. Of the people that were unlikely to switch, only 17 percent consider biosimilars safe, while 22 percent consider them unsafe (Exhibit 3).

Medical professionals also seem to have reservations about biosimilars. When asked if they trust the safety of biosimilars, 43 percent were unsure; 59 percent of consumers were unsure (Exhibit 4). In comparison, 87 percent of medical professionals trusted the safety of generics.

The results highlight the importance of biosimilar education, particularly regarding product safety, to ensure adoption in the United States.

The team also conducted focus groups and expert interviews, which yielded similar insights—few consumers had heard of biosimilars. The majority would consider biosimilars for cost savings, but said that brand names mattered more as the severity of their condition increased. The experts interviewed correlated the lack of biosimilar awareness to their absence on formularies, and subsequently, why they are not discussed with patients.

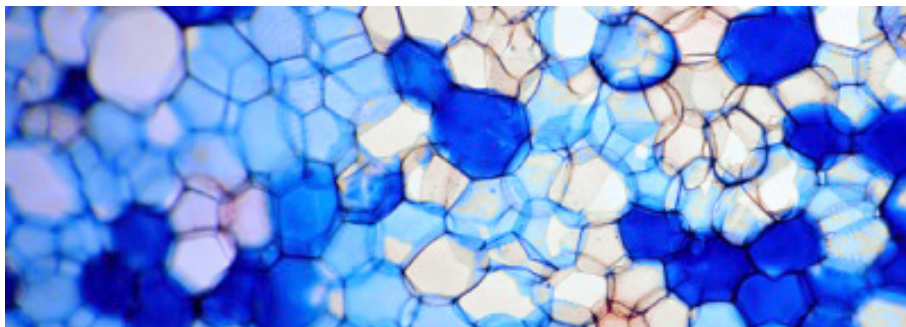


Exhibit 1: Have you ever asked your doctor if there was an alternative for a biologic drug that he or she has prescribed to you?

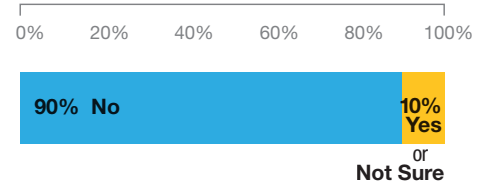


Exhibit 2: What would be the primary inhibitor of you using Biosimilars?

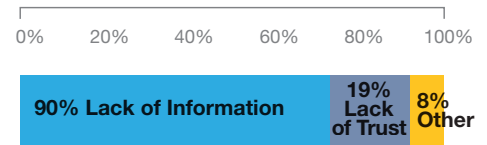


Exhibit 3: Would you switch from a Biologic to a Biosimilar?

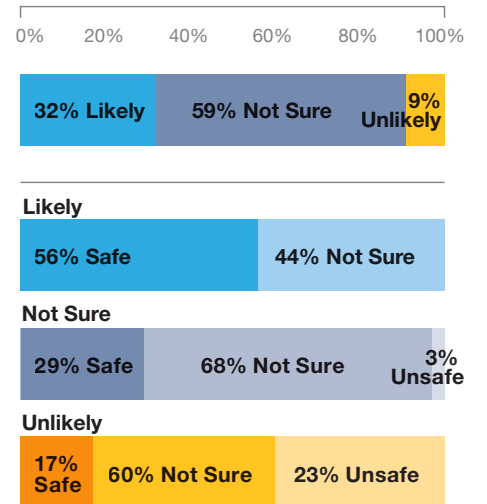
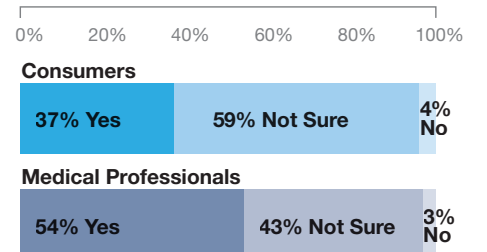


Exhibit 4: Do Consumers & Medical Professionals trust the safety of Biosimilars?



Market Concerns

Since biosimilars are new to the US market, regulatory concerns will likely affect market growth. The FDA has yet to issue guidance on naming biosimilars in comparison to their reference product. Currently, biosimilars are labeled with the International Proprietary Name (INN), followed by a four letter suffix that indicates the drug's manufacturer. Brand name drug makers want biosimilars to have unique names, arguing that unique names allow easier adverse events tracking and side effect reports filings. Unique names would also minimize confusion among patients or accidental substitution among patients and pharmacists. Biosimilar manufacturers argue that "different names may confuse physicians and pharmacists, who could have difficulty sorting out whether medicines are really the same as they try to verify dosing and regimens. As they see it, brand-name drug makers are trying to thwart substitution."¹ Having the same INN implies interchangeability, which would expectedly increase the rate of market penetration for biosimilars.

The second market concern involves prescribing information. The FDA allowed the first approved biosimilar to share prescribing information with the originator biological drug. If this practice sets the precedent, physicians may lack important data about the actual biosimilar. Some industry organizations, however, argue that physicians receive accurate and transparent data to make prescribing decisions and protect patient safety.

Finally, the Centers for Medicare and Medicaid Services (CMS) categorizes biosimilars for a specific reference product under the same category, imitating molecule generics, which means that reimbursement is based on the weighed average of a biosimilar's sales price. Innovator companies argue against these payment codes for various reasons. First, having the same payment code for all biosimilars could impede safety tracking. Second, since doctors will be reimbursed at one price regardless of the biosimilar, the categorization could compromise optimal patient care. Doctors may choose the cheapest option even though their patient is stable on a different biosimilar. Finally, the rule could deter competition by forcing companies to compete on price instead of value. Additionally, within the rapidly changing payer landscape, consumers are pushing for lower prices while pharmacies gain more negotiation power in the market.

Recommendations for Pharmaceutical Companies

1 Brand Biosimilars

Biologic companies should consider manufacturing, or partnering with a manufacturer, to produce a biosimilar based on their original biologic. Consumers will be more willing to adopt biosimilars when the treatment is affixed to a reputable brand. This tactic will also minimize potential cannibalization between biologics companies and emerging biosimilar companies.

2 Push Biosimilars onto the Formulary

Create (or expand) an internal department within companies that is responsible for managing payer relationships and pushing biosimilars onto formularies. A key factor in determining sales volumes for biosimilars will be where they lie on insurance formularies. Development of formularies are based on evaluations of efficacy, safety and cost; in other words, the drugs that exhibit the greatest value. Considering consumers' price-sensitivity, the affordability of biosimilar options will be critical in driving sales.

3 Market Biosimilars Directly to Prescribers

While increasing consumer awareness of, and interest in, biosimilars would be ideal, prescribers must be knowledgeable and supportive of this alternative first. Additionally, the physicians ultimately decides which drugs to prescribe. Educating prescribers can be achieved through conferences and workshops, as well as educational programs run by regulatory agencies.



Conclusion

With increasing biosimilar development and FDA approvals in the United States, companies understand the opportunity that biosimilars can bring to the industry and the healthcare system. Despite substantial market size projections, pharmaceutical companies will need to closely monitor the regulatory landscape, and develop strategies that will not only address pending regulations, but also ensure timely commercialization and adoption. Companies that leverage their current manufacturing capabilities and brand recognition while managing consumer, provider and payer perceptions will quickly gain market share.

For More Information

To learn more about our research or how we work with life sciences companies, please visit our **website**.

References

- ¹ Silverman, Ed. "FDA Approves First Biosimilar Ushering in a New Era of Treatments." Wall Street Journal online. March 6, 2015.



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