The Perfect Storm for Biosimilar Marketing

By Robert M. Rifkin, M.D., FACP

Accounting for nearly a quarter of new drug approvals in the United States from 2010-2015, biologic agents have grown to have an increasingly important role in clinical care, particularly in oncology. However, biologics also significantly contribute to rising healthcare costs, representing 38% of overall prescription drug revenue in 2015.[i]

Pressure to reduce healthcare costs associated with biologics is one of the forces driving the rapid expansion of biosimilars, which are biological drugs that are very similar to already approved "reference" biologics in terms of potency, safety, and efficacy.

The Biologics Price Competition and Innovation Act (BPCI) authorized the U.S. Food and Drug Administration (FDA) to create a new regulatory approval pathway for biosimilars. The streamlined 351(k) approval path was designed to introduce competition among manufacturers, with the goal of achieving greater patient access and lower drug costs. An analysis from the RAND Corporation estimates that the introduction of biosimilars could reduce spending on biologics by $54 billion between 2017 and 2026.[ii]

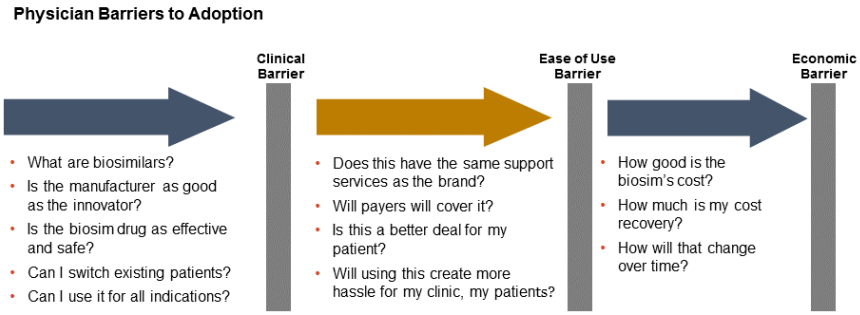
Barriers to Success in the U.S. Market

In March 2015, filgrastim-sndz (Zarxio; Sandoz/Novartis) was the first biosimilar to receive FDA approval. Since then, 11 biosimilar drugs have been approved by the FDA. In fact, the FDA just approved pegfilgrastim-jmdb (Fulphila; Mylan/Biocon) as the first biosimilar to Neulasta (pegfilgrastim). In the announcement, FDA Commissioner Scott Gottlieb, M.D. said “This summer we’ll release a comprehensive new plan to advance new policy efforts that promote biosimilar product development…We want to make sure that the pathway for developing biosimilar versions of approved biologics is efficient and effective, so that patients benefit from competition to existing biologics once lawful intellectual property has lapsed on these products.”[iii]

Expectations for biosimilar market growth are high with the pending loss of patent protection for many high-value biologics. Currently, there are more than 60 biosimilars in development as part of the Biosimilar Product Development (BPD) Program for some 20 reference biologics.[iv]

While there is tremendous excitement about the potential clinical and economic benefits that biosimilars represent, there are still regulatory, reimbursement, and competitive barriers that could limit the market potential. These include regulatory issues associated with naming, interchangeability and switching; uncertainty regarding payment rates and reimbursement; and notably, lagging stakeholder education. These barriers have slowed the development of the U.S. market; however, the success of biosimilars in the European Union demonstrates that they are not insurmountable.

Biosimilar Manufacturers will Need to Overcome Several Physician Barriers to Adoption



Key to Commercialization is Stakeholder Education

The biosimilar commercialization dilemma is how to differentiate a product that is essentially the same. In order to promote adoption with patients, physicians and payers, biosimilar manufacturers must clearly articulate benefits beyond simply being a lower cost alternative. Commitment to education was a central theme in ASCO's recent statement regarding biosimilars. Published in the *Journal of Clinical Oncology,*[v] the statement focused on the value of biosimilars in oncology and highlighted the importance of prescriber and patient education.

While the reduction of drug costs is a significant benefit, commercialization of a biosimilar is different than generics where competition is based primarily on price. It is also different than a branded drug where the product is the focus of differentiation. Successful biosimilar commercialization requires a well-defined go-to-market strategy that blends proven aspects of branded pharmaceutical marketing and clinical education programs that can be implemented quickly. This starts with fully understanding the timing of 351(k) regulatory process and employing a unique strategy that encompasses the needs of the multiple stakeholders, enabling them to be comfortable switching from an originator to a biosimilar.

McKesson is focused on supporting manufacturers with a commercial strategy that optimizes patient access and enables physicians, pharmacists and other healthcare providers to care for patients throughout their treatment journey. Unless physicians truly understand both the clinical and economic implications of biosimilars, they are unlikely to prescribe them for their patients.

According to the review article, "Major lessons learned from Zarxio's U.S. launch: the start of a biosimilar revolution," adoption has been slow but steady – growing from 2 percent market share in December 2015 to 15 percent by the end of 2016.[vi] The analysis suggests that much of this growth was driven by Sandoz aggressively promoting Zarxio with an emphasis on physician education via journals and digital content, educational events and meetings, and detailing by the

sales force. The adoption of Zarxio has also been accelerated by favorable formulary coverage decisions. As more biosimilars come to market and demonstrate clinical and economic benefits, payers are beginning to expand and increase biosimilar coverage and in some cases, exclude their reference biologics.[vii],[viii]

Ultimately, both clinical education and marketing activities will be needed to educate physicians and payers about product nomenclature, product attributes, and comparisons to reference drugs. Additionally, ongoing education and patient-centric support is critical to helping patients navigate their treatment journey and improving patient outcomes. Further, an innovative, easy-to-navigate Hub program can differentiate between competitive products, creating preference among providers and patients based on their experience with and perception of support services available.

Building on the Success of Biosimilars in Europe

More than 700 million patient days on biosimilar treatments have been documented over 10 years of clinical experience within the European Union.[ix] According to the European Medicines Agency (EMA), evidence shows that biosimilars approved through EMA can be used as safely and effectively in all their approved indications as other biological medicines.

Since creating a regulatory pathway for biosimilars in 2004, the European Union has approved more than 30 biosimilar drugs. In fact, when Zarxio was the first biosimilar approved in the U.S., it was already available in more than 60 countries.[x] An analysis by the European Generic Medicines Agency in 2009 estimated that biosimilars generated €1.4 billion in savings in the EU that year.

The European Union has made significant progress in raising stakeholder awareness and the continuous education of providers, payers, and patients has been critical to EU biosimilar acceptance. The involvement of regulatory agencies in the education process, as evidenced by the Biosimilars Guidelines[xi] jointly released by the European Commission (EC) and the EMA, not only reinforces the importance of these products, but also serves as a source of non-branded education.

Biosimilars: Increasing Access and Reducing Costs

Biosimilars have been bringing value to the U.S. healthcare system by increasing access to drugs that are needed and by decreasing costs. By the end of 2018, more biosimilars are expected to be approved and there is a robust pipeline of biosimilars in development. Combining the growing acceptance of the clinical value of biosimilars with continued cost containment pressures, we are entering the perfect storm for biosimilar marketing. To successfully navigate this storm, biosimilar makers must have a well-defined commercialization strategy focused on educating providers, payers, and patients and providing value-add patient support services to improve access.

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[i] Express Scripts, 2015 Drug Trend Report.
[ii] Biosimilar Cost Savings in the United States, Initial Experience and Future Potential **DOI:** 10.7249/PE264
[iii] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm609805.htm

[iv] https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=cder&id=CDER-RRDS-Number-of-biosimilar-dev-programs-in-BPD-Program
[v] Lyman G, et.al., J Clin Onc, March 2018

[vi] Sarshad, M, Major lessons learned from Zarxio's US launch: the start of a biosimilar revolution, Generics and Biosimilars Initiative Journal (GaBI Journal). 2017;6(4):165-73., **DOI:** 10.5639/gabij.2017.0604.035

[vii] United Healthcare, Formulary ID Number 00018044, Version 14 Y0066_170602_215911_FINAL_M53.05 Approved

[viii] CVS Caremark Performance Drug List, June 1, 2018

[ix] A van den Hoven. Biosimilar medicines: practical EU experience and perspectives. Sept 12, 2017. 2017 AAM Biosimilars Council Conference. http://biosimilarscouncil.org/wp-content/uploads/2017/09/BIO17-Agenda.pdf.

[x] https://www.sandoz.com/news/media-releases/fda-approves-first-biosimilar-zarxiotm-filgrastim-sndz-sandoz

[xi] Biosimilars in the EU: Information guide for healthcare professionals. European Medicines Agency. http://www.ema.europa.eu/docs/en_GB/document_library/Leaflet/2017/05/WC500226648.pdf. Updated April 27, 2017. Accessed September 1, 2017.