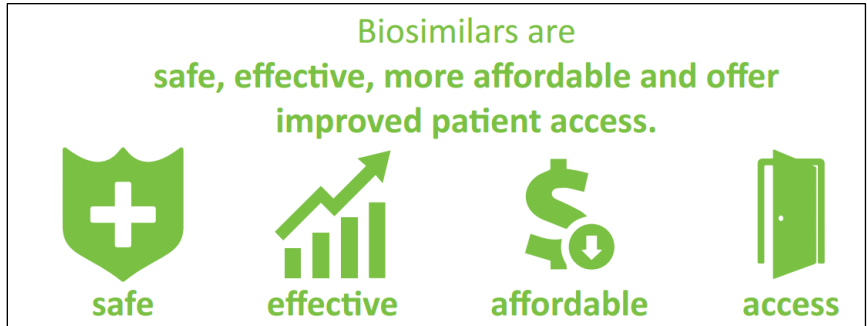


Biosimilars: A Safe & Effective Option for Patients

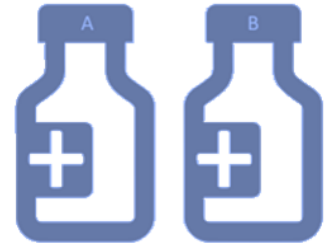
What are Biosimilars?

- A **biosimilar** is a biologic medicine that is highly similar to a previously approved brand biologic medicine (known as “**reference products**” or “**brand counterparts**”) currently on the market in the United States.
- Biosimilars are safe effective alternative versions of reference products with scientifically comparable quality, safety and efficacy.
- Biosimilars are subject to rigorous testing and review by the U.S. Food & Drug Administration (FDA), as well as monitoring after they are made available to patients in the U.S.
- The process for developing biosimilars is complex; and companies that manufacture biosimilars are committed to providing safe, effective products to patients.



Biosimilars at a Glance

- Biologic medicines are costly. While only 2% of the U.S. population uses them, biologics account for 40%¹ of prescription drug spending in the United States, which reached a record \$425 billion in 2015.²
- Like generic drugs, which saved the U.S. health care system \$227 billion dollars in 2015, biosimilars have the potential to increase competition in the market, which will help lower the cost of biologic medicines and increase patient access to biopharmaceutical advances that increase the quality and length of their lives.
- Biosimilar usage and approvals continue to grow in the United States, enabling more patients to have access to these safe, effective treatments and improved health outcomes.



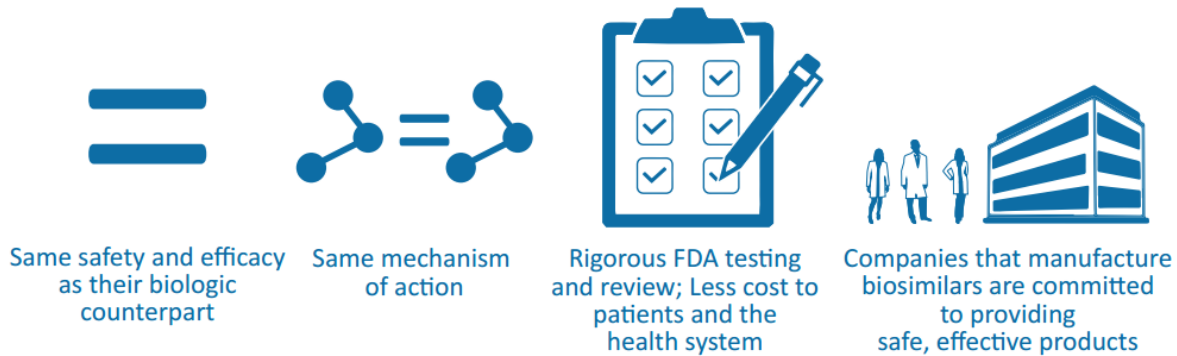
Current estimates suggest that consumers could save as much as \$250 billion during the first 10 years of biosimilar availability.¹

Biosimilar Access and Savings

- Most new biologic medicines entering the market are expensive and highly specialized. Prices continue to climb, with some treatments costing tens of thousands of dollars per year.³
- Biosimilars have the potential to help lower the cost of branded-biologic medicines and increase access to biologic medicines by creating increased competition in the market. That provides patients with more treatment options and significantly lower costs not only for patients, but also for providers and the healthcare system.
- Biosimilars will positively impact the most vulnerable patient groups – including those with low incomes, senior citizens, and patients with multiple chronic diseases – by increasing accessibility and reducing out of pocket costs.

Biosimilar Safety & Efficacy

- FDA-approved biosimilars have the same mechanism of action as the approved brand biologic counterpart – meaning the biosimilar works the same way as the reference product.⁴ The FDA requires biosimilar manufacturers to adhere to the same safety monitoring requirements of brand biologic manufacturers.⁵
- More than 10 years of biosimilars patient-use in the EU has shown no difference in health outcomes between patients who use a biosimilar and those who take the original branded biologic medicine.⁶



Biosimilar Approval in the U.S.

| Approval Date | Biosimilar Product | Brand Product | Patient Population |
|--------------------|---|---|---------------------|
| March 6, 2015 | Filgrastim-sndz/Zarxio* (Sandoz) | Filgrastim/Neupogen (Amgen) | Oncology |
| April 5, 2015 | Infliximab-ddyb/Inflectra* (Celltrion/Pfizer) | Infliximab/Remicade (Johnson & Johnson) | Autoimmune |
| August 30, 2016 | Etanercept-szszs/Erelzi (Sandoz) | Etanercept/Enbrel (Amgen) | Arthritis/Psoriasis |
| September 23, 2016 | Adalimumab-atto/Amjevita (Amgen) | Adalimumab/Humira (AbbVie) | Arthritis/Psoriasis |
| April 24, 2017 | Infliximab-abda/Renflexis (Samsung Bioepis) | Infliximab/Remicade (Johnson & Johnson) | Autoimmune |

* Denotes products that have reached market.

- To date, the FDA has approved five (5) biosimilars in the United States. These medicines treat patients suffering from rheumatoid arthritis, Crohn’s Disease, cancer, psoriasis and other conditions. More than 60 additional biosimilars are in development.⁸
- In Europe, 20 biosimilars are available in at least eight therapeutic areas.⁹ Biosimilars are available in more than 60 countries worldwide.¹⁰

References

1. The \$250 Billion Potential of Biosimilars. Available at: <http://bit.ly/2d2Mbix>. Accessed May 31, 2017.
2. Prescription Drug Spending Hits Record \$425 billion in U.S. Available at: <https://bloom.bg/2pKG4CA>. Accessed May 31, 2017.
3. Why Are Biologic Drugs So Costly? Available at <http://bit.ly/2pPHyT>. Accessed May 31, 2017.
4. Lenery SJ, Ricci MS et al. FDA’s Approach to Regulating Biosimilars. *Clin Cancer Res*. 2017 April 15;23(8):188-2-1885. Epub 2016 Dec. 29.
5. Information on Biosimilars. Available at: <http://bit.ly/2mpq1bl>. Accessed May 31, 2017.
6. The Impact of the Entry of Biosimilars: Evidence from Europe (p.3). Available at: <http://hbs.me/2pzfb5p>. Accessed May 31, 2017.
7. FDA approves Amjevita, a biosimilar to Humira. Available at: <http://bit.ly/2mD5XUm>. Accessed May 31, 2017.
8. Biosimilars Implementation: Testimony of Janet Woodcock, M.D. to the U.S. House of Representatives February 4, 2016. Available at: <http://bit.ly/2nmE2bc>.
9. Biosimilars in the EU: Lower Costs, Increased Patient Access. Available at: <http://bit.ly/2nmy0HX>. Accessed May 31, 2017.
10. Factsheet on Biosimilar Medicines. Available at: <http://bit.ly/2bFnrt0>. Accessed May 31, 2017.