Paving the Way for Biosimilars

What is the Biosimilars Council?

The Biosimilars Council, a division of the Association for Accessible Medicines (formerly known as the Generic Pharmaceutical Association), works to ensure a positive regulatory, reimbursement, political and policy environment for biosimilar products. It also seeks to educate the public and patients about the safety and effectiveness of biosimilars.

Since its establishment in 2015, the Biosimilars Council has focused on issues facing the biopharmaceutical industry, including education, patient access, the regulatory and reimbursement environment, federal and state legislation and legal affairs. Biosimilars hold the key to ensuring affordable access to biologic-alternatives medicines for all consumers. The Biosimilars Council exists to educate, advocate and promote the development of these products.

What is a Biosimilar?

Biosimilars are safe, effective alternative versions of existing biologic medicines (known as "reference products") with scientifically comparable quality, safety and effectiveness. Biologic medicines are often the only treatments available for serious illnesses, like cancer or genetic disorders, but they come at steep expense to patients, taxpayers and insurers. Many biologics cost tens of thousands of dollars per year per patient — some as much as $200,000.[1]

The biosimilar development process is complex and companies that manufacture biosimilars are committed to providing safe, effective product to patients. Biosimilars provide important market competition, which can help lower the cost of high-priced biologic drugs and increase patient access to important, lifesaving medications. Biosimilars undergo rigorous testing by the Food and Drug Administration (FDA), similar to the review of their reference products.

Research has found no differences in health outcomes between patient populations on biosimilars versus their branded biologic counterpart. To date, the FDA has approved 28 biosimilars and launched 17 in the U.S. to treat patients suffering from conditions such as rheumatoid arthritis, Crohn's Disease, cancer, and psoriasis. Biosimilars could lead to over $54 billion in savings over the next ten years, giving 1.2 million patients access to needed medicines.

Who Does the Biosimilars Council Represent?

Member organizations include any company or stakeholder organization working to develop biosimilar products with the intent to compete in the U.S. market. 2020 Biosimilars Council members:

Updated September 2020

What Resources Does the Biosimilars Council Offer?

The Biosimilars Council works to educate policymakers, stakeholders, patients and the public, supporting events and policy briefings. It also hosts an annual Biosimilars Council conference, "GRx+Biosims," which seeks to convene industry leaders, U.S. government officials, patient and consumer advocates, and clinicians and academic experts to discuss key areas of focus.

The Biosimilars Council also provides information and resources on its website: http://biosimilarscouncil.org, including press releases, videos, infographics, an educational handbook and an up-to-date list of FDA approved biosimilars and launches. These materials help patients, providers, policymakers and health experts understand what biosimilars are, why they are important, how they can improve patient access and how they can save the United States billions of dollars.

Where Can I Learn More About the Biosimilars Council?

To learn more about biosimilars and the Biosimilars Council, visit http://biosimilarscouncil.org/ and follow us on Twitter, Facebook, LinkedIn and YouTube for the latest updates on biosimilars.

References

1. Forbes. The World's Most Expensive Drugs. Available at: http://bit.ly/2oYciwv. Accessed April 28, 2017.