**http://www.fda.gov/foresee/sitelogo.gif**

FDA.gov

[**FDA Overview of Biosimilar Products**](http://fdabiosimilars.e-paga.com/) [disclaimer icon](http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)    
This continuing education (CE) course provides an understanding of biological products and biosimilar products and a description of FDA’s general approach to the development and approval of biosimilar products. The target audience for this course is healthcare professionals, including physicians, physician assistants, nurses, nurse practitioners, and pharmacists.

[https://www.biosimilarsresourcecenter.org/wp-content/themes/BiosimilarsResourceCenter/img/logo.png](https://www.biosimilarsresourcecenter.org/)

<https://www.biosimilarsresourcecenter.org/>

[](http://www.biosimilarsforum.org/)

<http://www.biosimilarsforum.org/>

[](http://www.amgenbiosimilars.com/)

<http://www.amgenbiosimilars.com/amgen-and-biosimilars/amgens-biologics-story/>

**Merck Biosimilars – Biosimilars Clarified**

There is a lot of information out there about biosimilars. At Merck, we want to bring clarity to that information. We want to create a place for patients and caregivers to get the information they want and need. We believe that the more patients know, the more they can be in charge of their health. This Web site is here to help answer your questions, which is why we chose a question-and-answer format. To explore a topic, please select a question. For additional information, just click the links.

https://www.merckclarifiesbiosimilars.com/

**Pfizer Biosimilars**

**Pfizer**, one of the world's premier innovative biopharmaceutical companies, is committed to bringing high-quality **biosimilars** to patients, providers, and payers, with nearly 10 years of experience with **biosimilars**, 3 marketed **biosimilars** outside the United States, and 4 **biosimilars** in late-stage clinical development.

<http://www.pfizerbiosimilars.com/>

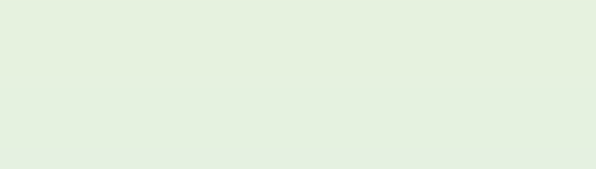
BiosimilarsCME.org

[**www.biosimilarscme.org**](http://www.biosimilarscme.org)

**BiosimilarsCME.org** offers educational opportunities and resources to help clinicians improve their knowledge and competence in the use of biosimilars across multiple therapeutic areas.

[](http://www.biosimilarscouncil.org/index.php)

<http://www.biosimilarscouncil.org/pdf/GPhA-biosimilars-handbook.pdf>



<https://safebiologics.org/about-us/>



[Biosimilar Drugs - National Kidney Foundation](https://www.kidney.org/sites/default/files/02-10-6762_HBE_Biosimilars_Booklet_v2.pdf)

[*https://www.kidney.org/.../02-10-6762\_HBE\_****Biosimilars****\_Booklet\_v2.p*](https://www.kidney.org/.../02-10-6762_HBE_Biosimilars_Booklet_v2.p)*...*

**Biosimilars** are not generic versions of biologics. 1 (See Figure 1.) The active ingredient in a generic small molecule drug is a single molecular structure and…



<https://www.sandoz.com/our-work/biopharmaceuticals/information-patients>

BIO

Biosimilars Myths & Facts

For more than a decade, BIO has called for open, transparent, and science-based dialogue regarding biosimilars. More recently, we played a leading role in the effort to establish a pathway for the approval of biosimilars. Many of our members are global leaders in the development and commercialization of biosimilars.

<https://www.bio.org/articles/biosimilars-myth-vs-fact>

**PhRMA - Biosimilars**

A biosimilar is exactly what its name implies — it is a biologic that is “similar” to another biologic drug already approved by the FDA. Under U.S. law, a biosimilar is approved based on a showing that it is “highly similar” to an FDA-approved biological product, known as a reference product. It may not have any clinically meaningful differences in terms of safety and effectiveness from the reference product.

<http://www.phrma.org/advocacy/research-development/biologics-biosimilars>

**AJMC – Biosimilars Essentials**

*The American Journal of Managed Care* is the leading peer-reviewed journal dedicated to issues in managed care. [**AJMC.com**](http://www.ajmc.com/) distributes healthcare news to leading stakeholders across a variety of platforms. Other titles in the franchise include

<http://www.ajmc.com/essentials/biosimilars>

**AMCP**

**Biosimilars Collective Intelligence Task Force**

Biosimilars represent an opportunity to bend the cost curve for specialty drugs. AMCP believes the public and health care community’s adoption of biosimilars will be enhanced if we can assure them that biosimilars are being actively monitored for safety and effectiveness.

Managed care organizations have devoted significant resources to develop an infrastructure that makes possible active surveillance of biosimilars in distributed research networks (DRNs). AMCP plans to marshal these resources for the important public health benefit inherit in monitoring biosimilar safety and effectiveness, using ongoing sequential analyses to compare biosimilars to their innovator product.

Below are links describing the science behind data consortiums, and why AMCP is engaging data consortium, managed care specialty drug experts, researchers and industry in our launch of the AMCP Biosimilars Collective Intelligence consortium before the first biosimilars hit the market

<http://www.amcp.org/BBCIC/>

**Premier Inc. - BIOSIMILARS:ARE YOU READY?**

Biosimilars Success in the US: Will Physicians Rule the Road?

As the high cost of new biologic medicines sends U.S. healthcare costs soaring, payers are anxiously anticipating the introduction of biosimilar medicines – biological products, approved by FDA because they are highly similar to an already FDA-approved biological product. However, there is one stakeholder whose influence over biosimilar adoption may be underestimate

<http://www.actionforbetterhealthcare.com/biosimilars-101/>

<http://offers.premierinc.com/SPJ_Demo.html>

**Arthritis Broadcast Network (ABN)**

*Arthritis Consumer Experts today announced the launch of the Biosim•Exchange*

Arthritis Consumer Experts today announced the launch of the **Biosim•Exchange** – the first central resource in Canada for consumers to find timely, fact-based information on biosimilars safety and effectiveness and report on public and private health insurance formulary policy or listing decisions on biosimilars.

<http://arthritisbroadcastnetwork.org/2016/10/new-online-forum-improve-biosimilars-education/>

**CVS**

[**Biosimilars**](http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/default.htm)

* Highly similar to an FDA-approved biological reference product
* No clinically meaningful differences in safety and effectiveness
* Only minor differences in clinically inactive components allowable
* Cannot be automatically substituted for reference product

[**Interchangeable**](http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/default.htm)

* Biosimilar to an FDA-approved reference product
* Meets additional standards for interchangeability
* May be substituted for the reference product by a pharmacist without intervention of the prescribing provider

<http://insights.cvshealth.com/basics-about-biosimilars>

**National Council of State Legislatures**

State laws and legislation related to biologic medications and substitution of biosimilars: <http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx>

**American Society of Hospital Pharmacists**

Articles and guidelines relating to biosimilars: <http://www.ashp.org/menu/PracticePolicy/ResourceCenters/Emerging-Sciences/Biosimilars.aspx>

**International Alliance of Patient Organizations**

An Information and Advocacy Toolkit for Patients' Organizations: This toolkit provides patients’ organizations with up-to-date, evidence-based information on the science, technology and regulatory information relevant to biological and biosimilar medicines, as well as tips on advocacy.

<https://www.iapo.org.uk/biosimilars-toolkit>

[http://app.propatient.com/img/logo.png](http://app.propatient.com/)

<http://app.propatient.com/visits/library>

go to site, and then click in:”Biosimilars for Rheumatoid Arthritis: What Do I Need to Know?”