Global Biosimilar Policies

A closer look at safety, efficacy and regulation

Biosimilars FORUM

Our Members Represent the Majority of Biosimilars Makers in the United States

What are Biosimilars?

No difference in safety & efficacy

Biosimilars are created using living cells

Typically administered via injection or infusion

Conditions treated:

- Cancer
- Arthritis
- Crohn's Disease
- Psoriasis
- Kidney conditions
- More…

Became available in Europe in 2006

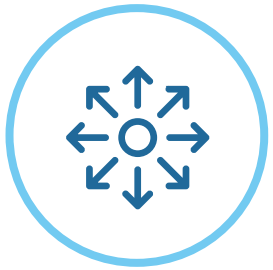
BPCIA signed into law in 2010

The first biosimilar launched in the U.S. in 2015

The Biosimilars Forum

We are a nonprofit dedicated to expanding patient access to life-saving biosimilar drugs. We work with policymakers and stakeholders to create public policies that encourage biosimilar awareness and education and increased use.

Lower prescription drug costs for millions of Americans that need them



Increase access to lifesaving, lower-cost treatments

Educate patients, providers, employers, and payers on the safety and efficacy of biosimilars

Engage with the Administration and lawmakers to implement policies that promote biosimilars

Work with regulatory bodies to advance biosimilars

Lay of the Land

The biosimilar market in the U.S. remains sluggish

- The U.S. has approved 36 biosimilars to 11 reference biologics, but only 21 approved biosimilars are on the market
- In the EU today, more than 60 biosimilars are approved for more than 15 reference products
- If uptake increases, biosimilars could save more than $133 billion by 2025

2% of all prescriptions are for biologic drugs

40% of all prescription drug spending is for biologic drugs

The United States Regulatory Framework

The BPCIA created an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product.

- The abbreviated licensure pathway does not mean that a lower approval standard is applied to biosimilar or interchangeable products than to originator biological products.

- The ability to rely on FDA's previous finding regarding the reference product to support approval of the biosimilar product allows for a potentially shorter and less costly drug development program.

- The data package required for approval of a biosimilar or interchangeable product is extensive
  - Biosimilar applicants submit data from analytical, nonclinical, and clinical studies to support a demonstration of biosimilarity with the reference product.

Biosimilars Regulatory Agencies Around the World

- Biosimilars are **SAFE**
- Biosimilars are **EFFECTIVE**
- Biosimilars are **HEAVILY REGULATED**

FDA

Health Canada Santé Canada

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Current Biosimilars Forum Initiatives

- Engage FDA, CMS, HHS, and the Administration on pro-biosimilar policies
- Influence policymakers and regulators
- Educate patient and provider health care groups on biosimilars
- Inform the public and industry on biosimilars via media outreach

Thank you!

Biosimilars
FORUM