



Global Biosimilar Policies

A closer look at safety, efficacy and regulation

Biosimilars

F O R U M



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



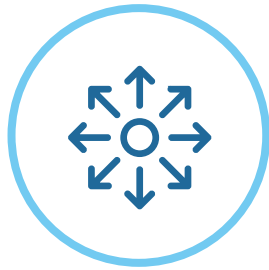
The first biosimilar
launched in the
U.S. in 2015

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**



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