



# 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



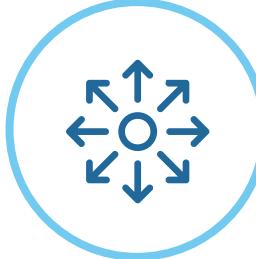
The first biosimilar launched in the U.S. in 2015

# The Biosimilars Forum

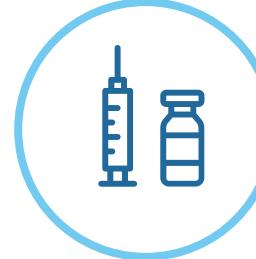
We are a nonprofit dedicated to expanding patient access to life-saving biosimilar drugs. We work with policymakers and stakeholders to create public policies that encourage biosimilar awareness and education and increased use.



**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



# 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!