BIOSIMILARS POLICY IN THE U.S.

BIOLOGICS VS BIOSIMILARS

Biosimilar approval was established by the Biologics Price Competition and Innovation Act (BPCIA) of 2009

BIOLOGICS COME FIRST

- Large, complex molecules derived from living cells
- Examples: insulin, growth hormone, and monoclonal antibodies
- Have a unique manufacturing process

BIOSIMILARS COME LATER

- Similar but not the same
- Approval after biologic exclusivity periods expire
- Manufacturing process can cause differences

OUR POLICIES

1

Ensure patients get the medicines their doctor intended

2

Create regulations reflecting the uniqueness of biologics

KEY FACTORS IN POLICIES

MAKE SCIENCE-BASED DECISIONS

Science and clinical evidence must be at the foundation of all decisions

Science-based, regulatory reviews should determine if biosimilars meet interchangeability standards

KEEP THE FINAL DECISION WITH THE DOCTOR

Patients should receive the medicine their doctor intended and prescribed

Only interchangeable biosimilars should be eligible for automatic substitution by pharmacies

MONITOR PATIENT SAFETY

Small changes in biological medicines' manufacturing processes can cause difficult-to-predict changes in safety and efficacy

GUARANTEE IDENTIFICATION AND TRACEABILITY

Biologics and their biosimilars should have unique names

WHAT'S NEXT? + HELPFUL RESOURCES

Biologics are approved under one of two pathways:

- Section 351 of the Public Health Service Act
- Section 505 of the Food Drug & Cosmetic Act

Beginning in 2020, 505 biologics will also be classified under the 351 pathway

State substitution legislation should cover all biosimilars

HELPFUL RESOURCES

www.lilly.com
www.lilly.com/who-we-are/key-issues/biosimilars