BIOSIMILARS POLICY IN THE U.S.

BILOGICS VS BIOSIMILARS

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

BILOGICS 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

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

WHY ARE BIOCLOGICS AND BIOSIMILARS IMPORTANT?

1. Ensure patients get the medicines their doctor intended
2. Create regulations reflecting the uniqueness of biologics

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