THE BIOSIMILARS PATHWAY 101

Original biologic medicines are sometimes followed by similar medications called biosimilars, which are meant to increase treatment options and lower costs. Biosimilars are approved through a process detailed in the ***Biologics Price Competition and Innovation Act of 2009.***

The Biologics Price Competition and Innovation Act of 2009 outlines the information needed to qualify as ***one of two types of biological medicine:***

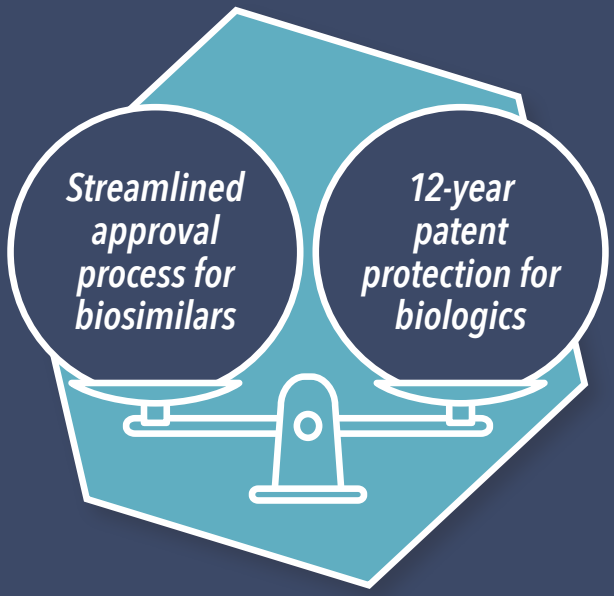
BIOSIMILARS

- ✓ "Highly similar" to the original product
- ✓ No "clinically meaningful differences" from the original biologic in safety and efficacy

INTERCHANGEABLE BIOSIMILARS

- ✓ Meet standards for traditional biosimilar
- ✓ Undergo additional evaluation to meet added requirements
- ✓ Can be substituted for the original biologic by a pharmacist

The Biologics Price Competition and Innovation Act of 2009 was designed to balance innovation with the need for lower-cost treatment options.



Along with regulatory guidance from the Food and Drug Administration, The Biologics Price Competition and Innovation Act of 2009 provides a roadmap for how biosimilar drugs can be approved and become available to patients fighting cancer, arthritis, skin conditions and other diseases.

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