BIOSIMILARS POLICY IN EUROPE

BIOSIMILARS POLICY AND REGULATORY FRAMEWORKS SHOULD:
Reflect specificities of biological medicines and ensure patients get the medicine their doctor intended and prescribed.

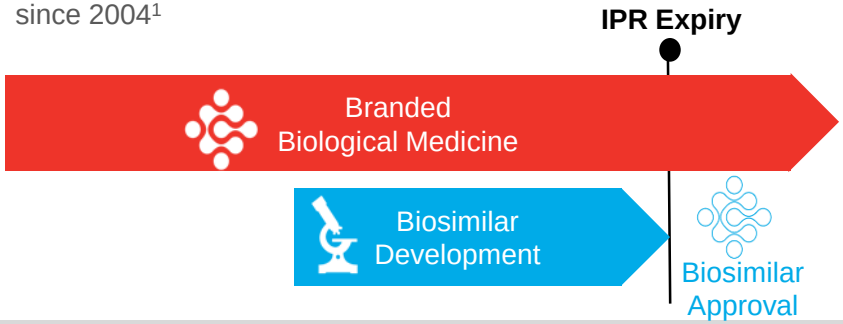
DEFINING BIOLOGIC MEDICINES AND BIOSIMILARS

BIOLOGICAL MEDICINES:

- Large, complex molecules
- Have a unique manufacturing process

BIOSIMILAR MEDICINES:

- Approved after branded biological medicines' intellectual property rights (IPR) expire
- Not generics
- Similar to, but not the same as, approved branded biological medicines
- Regulated by a specific EU biosimilars framework since 2004[1]



KEY FACTORS IN POLICIES FOR BIOLOGICAL MEDICINES

MONITOR PATIENT SAFETY

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

MAKE SCIENCE-BASED DECISIONS

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

Regulatory reviews should determine if biosimilars meet approval standards

KEEP THE FINAL DECISION WITH THE DOCTOR

Patients should receive the medicine their doctor intended and prescribed

Non-interchangeable biosimilars should not be automatically substituted

GUARANTEE IDENTIFICATION AND TRACEABILITY

Biologics and their biosimilars should have unique names

For more information, visit these helpful resources:
www.lillypad.eu | www.lilly.com | www.lilly.com/who-we-are/key-issues/biosimilars

[1] Directive 2003/63/EC and Directive 2004/27/EC: European Medicines Agency Regulatory Guidelines (CHMP/437/04)

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