BioPharma Solutions

Biosimilars

Global Terminology, Strategy & Pathways

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Biosimilar Definition

- **Highly similar to the reference product**
- **No clinically meaningful differences**
  - Differences in raw materials or manufacturing processes between biosimilar and reference product may require pre-clinical tests or clinical trials
- **Does not equate to "Me,too" or 2nd generation biologicals**
- **Provisions for generic medicinal products may not be sufficient for biological medicinal products**

US Regulatory Pathway

- **The Patient Protection and Affordable Care Act and Biologics Price Competition and Innovation Act (BPCI Act)** ***(signed March 23, 2010)***
- **Scientific Considerations in Demonstrating Biosimilarity to a Reference Product** ***(draft FDA guidance)***
- **Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product** ***(draft FDA guidance)***
- **Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009** ***(draft FDA guidance)***

Biologics Price Competition and Innovation Act (BPCI)

- **Creates an abbreviated licensure pathway for biological products**
- **Section 351(k) of the Public Health Service Act**
- **Similar to the Abbreviated New Drug Application process in Section 505(j)**

351(k) Application Requirements

- Is biosimilar to a reference product
- Utilizes the same mechanism(s) of action for the proposed condition of use as the reference product
- Condition(s) of use proposed in labeling have been previously approved for the reference product
- Has the same route of administration, dosage form, and strength as the reference product

EU Regulatory Pathway

- Directive 2001/83/EC, as amended (2004/27/EC)
- Guideline on Similar Biological Medicinal Products Containing Biotechnology-Derived Proteins as Active Substance: Non-Clinical and Clinical Issues
- CHMP Guideline on similar biological medicinal products

Application Requirements

- CTD Module 3 – Quality
- CTD Module 4 – Non-Clinical (Cross reference)
- CTD Module 5 – Clinical (Cross reference)
- Integrate Comparability Exercise to demonstrate the biosimilar and reference product have similar quality, safety and efficacy profiles.

Interchangeability/Interchangeable - US

- Biosimilar to the reference product
- Produces the same clinical result in the patient population
- May be substituted for the reference product without the authorization of the health care provider

Interchangeability/Interchangeable - EU

- Interchangeability is outside of the EMEA authority
- May be different meanings based upon the territory

Thank you!

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