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The US-FDA interchangeability guidance for biosimilars

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The US Biologics Price Competitionv and Innovation Act of 2009 (BPCI Act) was enacted on March 23, 2010. The BPCI Act created an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product. Interchangeability is the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. This automatic substitution by the pharmacist allows reducing the health care cost and allows wider access of more patients to these high quality medicinal products. The Presentation will address the Regulatory requirement of the US-FDA Guidance to Industry entitled: "Considerations in Demonstrating Interchangeability with a Reference Product" published in January 2017 and setting the details of the clinical study needed to demonstrate that interchangeability leads to the same clinical outcome in any given patient with no increased safety - or decreased efficacy concerns.

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