Dr. Dr. Michel Mikhail, J Bioanal Biomed 2018, Volume 10
DOI: 10.4172/1948-593X-C2-040

Dr. Dr. Michel Mikhail

International Expert in Biosimilars, Global Expert in Regulatory Affairs, Germany

Biosimilars interchangeability: The draft guidance in the USA

In the USA only interchangeable products can be substituted for the reference product by a pharmacist without the intervention of a health care provider. The interchangeability regulation is in the form of guidance: Interchangeable biologics must be biosimilar to the reference biologic.If administered more than once, data must show the safety and efficacy risks of switching. If not administered more than once, justify the omission of a switching study. The clinical data must demonstrate switching risk in all of the reference biologic's licensed conditions of use.The data must support the "totality of the evidence" and "reduction of residual uncertainty". Switching study design is defined and described in the guidance. Guidance describes what is insufficient to demonstrate interchangeability. The use of post-marketing data from a biosimilar. The presentation and design attributes must be the same to enable substitution. The impact of biosimilar interchangeability in the USA will be more than positive. Where will an interchangeable biosimilar have the most impact? An interchangeability rating may result in the perception that the product is superior in quality to other biosimilars.How will payors react? Likely competitor response

Biography

Michel Mikhail has more than 25 year's pharmaceutical industry experience. He is an Expert in Biosimilars, involved in the global development and worldwide regulatory approval of blockbuster monoclonal antibodies medicines and involved in shaping the EU biosimilars guidelines and their review, the WHO guidelines, ICH guidelines and now in the US-FDA biosimilars guidelines. He is a Chartered Expert in Pharmacology-Toxicology, a chartered Clinical Expert as well as a Chartered Analytical Expert. He is a Member of the Expert Committee of the Government Federal Institute of Risk Assessment (BfR) Germany and served as a Member of the Expert Committee for Toxicology of the United States Pharmacopoeia (USP).

mikhailm2001@aol.com

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