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Biosimilars Interchangeability in the USA: The Final US-FDA Guidance to Industry

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Abstract:

Biosimilar Interchangeability: The newest regulation 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 US-FDA interchangeability regulation is in the form of a 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

Final FDA guidance on demonstrating interchangeability of biosimilar drugs omits two appendices that were in the draft; does not use the term, "fingerprint-like"; and refers to "residual uncertainty" only once. So-called switching studies must be performed to assess safety and efficacy when alternating between a biosimilar and its reference product, and sponsors referring to products not licensed in the US "should provide adequate data and information to establish a 'bridge' between the non-U.S.-licensed comparator and the U.S.-licensed reference product," according to the guidance. The impact of biosimilar interchangeability in the USA is expected to be more than positive. An interchangeability rating with automatic substitution at Pharmacy level may result in the perception that the product is superior in quality to other biosimilars. So far no interchangeability approval was granted by the US-FDA.

Biography:

Dr. Michel Mikhail has more than 25 years Pharmaceutical Industry experience and track record of achievement in R & D and International Regulatory Affairs in large multinational Research-based pharmaceutical Companies, Biotech Companies as well as in the Generic industry. Dr Mikhail is an Expert in Biosimilars. He has been involved in the Global Development and Worldwide regulatory approval of Blockbuster Monoclonal antibodies Medicines. He was 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. Dr. Mikhail served as member of the Expert committee of the Government Federal Institute of Risk Assessment (BfR), Berlin, Germany and served as member of the Expert Committee for Toxicology of the United States Pharmacopoeia (USP), Washington D. C., USA.

Publication of speakers:

1. Dr Dr Michel Mikhail: Biosimilars – Hurdles and challenges from development to a successful launch. Pharmind 77, Nr. 5, 668-672 (2015)
2. Dr Dr Michel Mikhail: Pre-Filled Syringes Conference. 2016 Prefilled syringes Forum: strategic development, safety & Regulatory compliance and commercialization Case Study Presentation: US-FDA Warning Letter and Regulatory Implications. April 4-5, 2016, Racket club, Philadelphia PA
3. Dr Dr Michel Mikhail Global regulatory Challenges and current hot topics in the Regulatory World. Published on LinkedIn on September 10, 2015, updated in 2016.
4. D. Palmer, M. Mikhail, j. O'Connell, B. Dogan, JB Flinders, T. Catka, J. Lee, Ch. Askew: Beyond Immune Checkpoint Inhibitors to Personalized Medicine: Planning and Conducting Trials of the Latest Immunotherapies Immunotherapy White Paper Inventiv Health Clinical; published in March 2017
5. M. Mikhail, B. Dogan, M. Martinez, T. Catka: The New Clinical Trials Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use is to be rolled-out in 2018…Are you ready? White Paper Inventiv Health Clinical; March 2017

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