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Some considerations about biosimilar safety

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Statement of the Problem: Biosimilar safety is an important step to be approved. Biosimilar safety is related with the adverse drug reactions as a result of their pharmacological actions and immunogenicities. The purpose of this study is to describe some considerations about biosimilar safety such as naming, immunogenicity, manufacturing, pharmacovigilance, interchangeability, labeling, preclinical studies, clinical studies and post-approval studies.

Methodology & Theoretical Orientation: Naming of biosimilar is an important step to differentiate biosimilar from the reference product as a part of safety. Biosimlars are proteins having capacity of inducing immune response that may be humoral or cellular. Small manufacturing alterations in the source materials or production process of any biologic product may lead to changes in molecular structure and potentially its biologic effects. Pharmacovigilance planning include efforts beyond post marketing spontaneous reporting and designed for enhancing and expedite the biosimilar manufacturer's acquisition of safety information. Biosimilars, to be approved interchangeable, it must meet a higher standard by producing the same clinical result as the reference product in any given patient. The labeling is important to decide whether a specific adverse event/safety issue for biosimilar is already identified as a risk or could be a new potential safety issue. Preclinical studies used animal models to preliminarily assess toxicity, including immunogenicity. Clinical studies include an assessment of immunogenicity and PK or pharmacodynamics (PD). Finally, the need for post-approval studies to establish efficacy in indications was not studied during the approval process and long-term safety studies.

Findings: Biosimilar is a new pharmaceutical product and its safety approval is very important.

Conclusion & Significance: Naming of biosimilar is an important step for safety and immunogenicity study is important for safety assessment. Biosimilars, to be approved interchangeable, must meet a higher standard and preclinical studies, clinical studies, post-approval studies, must be achieved.

Recommendations: Reaching to unified name, standard definition for biosimilar and close guideline and demonstration of other aspects about biosimilar safety is recommended.

Biography

Samer M Al-Hulu is an Assistant Professor of Microbiology, completed his PhD from Babylon University, College of Science, Iraq. He has published more than 14 papers in microbiology field. He trains at Ministry of Health at Laboratory of Babylon Maternity and Children Hospital. Currently, he is working at Al-Qasim Green University, College of Food Science, Iraq.

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