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Biosimilars: Challenges in safety and risk management

Asif Mahmood
Pfizer, USA

Advances in biotechnology have ensured a world of opportunities for biosimilars to enter the market and serve the needs of patients in a cost-effective manner. However, pharmacovigilance and risk management for biosimilars present a significant challenge that arise from their unique characteristics as biologics as well as from their differences with the reference innovator products. Traditional PV processes may not incorporate sufficient provisions to meet the particular requirements for biosimilars. While a biosimilar and its reference drug can show similar efficacy, it can exhibit a different safety profile with respect to the nature, seriousness or incidence of reported adverse events (AEs). Therefore, there is a need to clearly identify the specific product associated with the AE. Hence, product naming is an important consideration for biosimilars traceability. The potential for immunogenicity represents an important safety concern with all biologics, including biosimilars. The nature and severity of immunogenic reactions may differ from those observed for the reference innovator and immunogenicity data from the reference product may not be directly extrapolated to the biosimilar. Given the relatively small number/size of clinical trials required for regulatory approval of biosimilars, full characterization of the immunogenicity profile of a biosimilar may not be established at the time of regulatory approval. Continued post-marketing surveillance of biosimilars is critical for effective risk management. Also, the unique nature of biosimilars requires a labeling approach that combines data on the reference product with data specific to the biosimilar due to differences in their source materials, manufacturing processes and impurities. Finally, the safety specifications in the RMP of a biosimilar should include the identified and potential risks of the reference innovator product as well as risks identified from studies on the specific biosimilar product..

Biography

Asif Mahmood has diverse leadership experience as a health services professional with significant accomplishments in all aspects of pharmacovigilance, clinical development, medical affairs, regulatory affairs, primary health care, project management & international health programs. He is currently working as Disease Area Cluster Lead for Biosimilars & Drug Delivery Devices at Pfizer. His past experience includes working as Associate Vice President PV and Therapeutic Area Head (Rare Diseases) for Sanofi Genzyme, working as Senior Director & Director for vaccines PV at Sanofi Pasteur and working as Medical Consultant for Apotex Inc., Canada. Prior to joining industry, he has worked as Joint Executive Director for Pakistan Institute of Medical Sciences, Registrar of the Post-graduate Medical Institute PIMS and as Deputy Director General of Ministry of Health, Pakistan. He has also worked on various primary healthcare, public health, and health planning & development programs as well as on World Food, UNICEF; WHO & JICA assisted programs on drug safety, emergency preparedness and primary healthcare.

Asif.Mahmood@pfizer.com

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