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Biosimilars: challenges in safety and risk management

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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.

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