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Biosimilars role as therapeutics

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Biosimilar products are very complex molecules and, therefore, cannot be treated the same as conventional generic drugs. There is a need to comprehensively test biosimilars during the production process and always in comparison with an appropriate reference product. Although a variety of assays are available, they may not be adequate to reliably predict the safety and efficacy of a biosimilar product. The validation and standardization of assays will be crucial for future testing and regulation of biosimilars. The regulatory approval of biosimilars will require much more than the demonstration of pharmaceutical equivalence and pharmacokinetic bioequivalence associated with conventional generics. In the post-PRCA era, the immunogenicity of recombinant therapeutic proteins has become a significant safety concern. Ultimately, only clinical studies and post-authorization pharmacovigilance to monitor potential immunogenicity will provide definitive evidence for product comparability to the innovator product with respect to safety and efficacy. Yamanaca factor play important role in diagnosis. As manufacturing and clinical experience with the first biosimilar products accumulates, existing EMEA guidelines for the market approval of biosimilars will be revised to include the latest developments and new guidelines will be developed for other biosimilar product classes. Outstanding issues will need to be resolved, including substitution, naming and labeling. Unique naming for all biopharmaceuticals would likely help to differentiate these products, which would facilitate accurate prescribing, dispensing and pharmacovigilance. The labels of the approved biosimilars are nearly identical or are very similar to those of the reference product. A more transparent label that included relevant clinical data for the biosimilar, i.e., the data included in the EPAR, would help clinicians make informed treatment decisions. Physician awareness of potential differences between biopharmaceuticals and biosimilars and the impact on safety and efficacy is critical for patient safety. Entry of biosimilars in the market will require transparent, unbiased dissemination of information to prescribers and other healthcare professionals. Clinicians need comprehensive information on biosimilars, and biopharmaceuticals in general, to make informed treatment decisions.

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