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Biosimilars: Regulatory considerations

B P Nagori
Lachoo Memorial College of Science & Technology, India

Biosimilars also known as follow-on biologics are biologic medical products whose active drug substance(s) are made by a living organism or derived from a living organism using recombinant DNA or controlled gene expression methods. They have been independently developed after the patent protecting the original product has expired. In general, it means that the biological reference medicine must have been authorized for at least 10 years before a similar biological medicine can be made available by another company. Biosimilars are intended to have the same mechanism of action as the original biological medicines and are designed to treat the same diseases as the innovator's product. Successful development and commercialization of a biosimilar product requires the integration of regulatory strategy, clinical strategy and trial design as well as commercial and market access considerations. Companies looking to develop biosimilars aim to minimize the developmental cost without sacrificing the product quality. They must also address the challenges involved in developing and commercializing biosimilars and identifying the investigators and patients for clinical trials. Regulation of biosimilars is evolving rapidly because of increasing pressure for lower cost versions of biological medicines and continuous improvement in the involved technologies. Recently a number of countries have issued the guidance addressing the regulation of biosimilars and the content of biosimilar applications. WHO also has issued guidelines for regulatory authorities that are seeking to develop standards for biosimilars. This presentation will highlight the present status of regulatory considerations for bio¬similars.

Biography

B P Nagori is presently working as Professor and Director at Lachoo Memorial College of Science & Technology, Jodhpur, India. He has a blend of 31 years of experience in teaching, research, development & administration. He is recipient of the Principal of the Year 2010 Award conferred by APTI. He was invited as speaker at Analytica Acta-2011: 2nd World Congress on Analytical & Bioanalytical Techniques organized by OMICS Group at Sanfrancisco. He designed a branch in MPharm (Pharmaceutical Management & Regulatory Affairs) for the first time in the country with his background knowledge of pharmacy, management and law. His areas of interest include pharmaceutical management, regulatory affairs, IPR, TQM, medicinal & pharmaceutical applications of various gums and institutional management. Under his guidance, 7 scholars are pursuing PhD, 5 have submitted PhD and 2 have been awarded PhD. He is serving as the Vice President (Central) of APTI and was the founder Dean of Faculty of Pharmacy, Rajasthan University of Health Sciences, Jaipur.

bpnagori@bsnl.in