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Biosimilar regulations in India: Current scenario

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Biosimilars are designated as "Smilar Biologics" in India. EMA has clear defined guidance for the regulations of Biosimilars. US and India are developing the regulations of Biosimilars. Developing bioimilars regulatory policy is a challenge to Indian authorities because it is utmost important to create balance in between serving quality, safe drug which is affordable and has easy access to people. Currently the final draft of similar biologics regulatory policy is under review by the government and stake holders. It is expected to finalize this document in this year. Apart from recombinant therapeutic proteins, it is proposed to include vaccines and blood products under the category of Similar Biologics in India. For the regulatory approval of similar biologics in India, complete CMC (Chemistry, Manufacturing and Control) data in comparison with reference biological product (RBP) i.e. innovator product would be needed to establish the similarity. Toxicity study in relevant animal model with the same route of administration in comparison with RBP would be needed. Immunogenecity study in animals is also suggested. With respect to human studies PK &PD study in human is required. If PD marker is not there then Confirmatory Clinical trial in comparison with RBP would be needed. Immunogencity study in human is also required. Labeling of similar biologics in India would by as per the trade name given by the manufacturer. There is no clause for data exclusivity. The above mentioned regulatory requirements for approval of similar biologics in India are for the biosimilars that are manufactured in India and are marketed in India. However, if biosimilars are manufactured in India for exports purpose and not for domestic market then only CMC data establishing proof of similarity with reference biological product is needed.

Biography

Smita Singhania, Ph.D. has 20 years of Post Ph.D. work experience in the field of Bio-Pharmaceuticals encompassing R&D, Academics, Pharma Regulatory Approval, Clinical Research and Intellectual Property Management. Dr. Smita is actively involved in the development of biosimilar regulations in India along with Indian policy makers. Dr. Smita is WHO, Geneva expert for the development of Influenza Vaccine, member of OECD – Working Party in Biotechnology, She has worked at Senior management position at key Indian multinational Pharmaceutical Companies, Mabpharm – Biotech JV of Cipla, Zydus Cadila, Bharat Biotech International etc. She is Adjunct Professor, Biotechnology at University of Pune and ex-member Board of Studies for MBA –Biotechnology program of Pune University. She is co-investigator in PCT application on Rota virus vaccine formulation patent and herbal water formulation patent, publications in International and national journals. Dr. Smita is invited speaker multiple international and national symposia including WHO, OECD, IBC-China, FICCI, DBT, UGC, DST, BCIL, Bangalore Bio India etc

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