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Recent trends in the discipline of biosimilar medicines

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Biotechnology has facilitated the discovery of treatments for some of the most severe diseases known to man – worldwide. Now days in market, patients have access to many biotechnology drugs and vaccines, and medical science is working to grow that number every day. Biologic medicines are made in living organisms to produce proteins to treat various diseases, often by genetically modifying cell constructs or cell lines. When exclusive rights like patents for the first generation of approved biopharmaceuticals got either expired or are about to expire, the market is opening for generic versions, referred to as 'biosimilars' (European Union) or 'follow-on protein products' (United States). These are also called as similar biological medicines. Some of these are already on the market in Europe. Biosimilar medicine is similar to biological medicine which has already been authorized as the 'biological reference medicine'. The active ingredients of both biosimilar medicine and biological medicine are similar and are used in general at the same dose to treat the same disease. Since biosimilar and biological reference medicines are similar but not identical, so the name, appearance and packaging of a biosimilar medicine differ to those of the biological reference medicine. A biosimilar manufacturer must commence pre-clinical and clinical studies so as to present pertinent data which establishes the quality, safety and efficacy of the product, as well as its similarity with the reference product. Biosimilars are still new and emerging market. Regulatory guidelines and standards are still being developed in some countries and they are constantly evolving as technology develops.

Biography

Upendra Nagaich has completed his PhD from Jiwaji University, MP, India. He is the Founder Secretary of Society of Pharmaceutical Education & Research (SPER), a well established registered society of pharmaceutical sciences. He is the Founder Editor of Journal of Advanced Pharmaceutical Technology & Research (JAPTR), a renowned pharmacy research journal indexed in SCOPUS and PubMed etc. and published by Medknow Publications (A Part of Wolters Kluwer Health, USA). He has in his credit various awards few of them Young Pharmacy Teacher, Young Performer Award etc. He has published more than 30 papers in international and national journals of repute and serving as an editorial board member of various reputed journals.

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