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Future of next generation biosimilars

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Although the breakthroughs in biologicals have been groundbreaking, the future of health care is not just about new molecules. It is also about the new and exciting frontier of biosimilars, also known as 'follow-on biologics'. Over the past two decades, biologics have revolutionized patient management in multiple disease states, including solid tumors, hematologic malignancies, autoimmune diseases, and hormone deficiencies. Patents that expired or are soon to expire have provided a great opportunity for companies to make copies or 'generic' versions of these drugs. The most recent trend has been to pursue drugs for diseases that most commonly afflict the aged and for leading causes of death like CVD, cancer and stroke. Few very important differences between biosimilars and small molecule generics like difficult and expensive to get them approved, complicated and challenging to manufacture, and generally have a short shelf life. A biosimilar may be perceived to have a low risk of immunogenicity given the mechanism of action established for its originator counterpart. However, if it is produced using a novel expression system, this risk may be changed due to the introduction of impurities. Though FDA and EMA have their own definition of biosimilar product, the concept is subject to the strict definition of the authorizing agencies in a tightly regulated market. A "biobetter" (second-generation or next-generation) biological/biologic is a biologic that has been structurally and/or functionally altered to achieve an improved or different clinical performance. These are intended to improve performance of the first-generation product while preserving the mechanism of action, but are not considered biosimilars. In February 2012, US FDA issued three highly anticipated documents providing guidance on its biosimilar approval pathway. This guidance set forth FDA's current thoughts on 'key scientific and regulatory factors involved in submitting an application for biosimilar products'. In Sept 2013, EMA approved the first biosimilars Inflectra, a biosimilar medicine to the reference medicinal product, Remicade® (infliximab). With the approval of the "first wave" of Biosimilars around the world, it is readily apparent that Biosimilar mAb are quickly becoming the "next generation of drugs" across many regions of the world. This landmark regulatory approval has opened the door to approval of biosimilars of other products nearing or passed their patent expiry dates. Future studies to demonstrate similarity, future studies will have efficient study models (smart approach) to tackle the high cost and complexity by running simpler and smaller trials of comparative clinical trials. Despite some challenges and few potential problems of developing and manufacturing such complex molecules, therapeutic development of lower cost Biosimilars will inevitably enter the drug market in the near future, increasing the market competition and patients' access to the more cost-effective therapies that they may not have otherwise. In an effort to ensure patient safety and to address issues of micro-heterogeneities between biosimilars, including the potential for immunogenicity, robust clinical development programs must be required for each new agent. Each marketing application should include studies supporting the use of the agent in target disease states and patient populations, as well as a robust post-marketing pharmacovigilance plan. Apart from that there is also a need of enhancing the 'biological experience' for physicians/prescribers and for that adequate physician education, sufficient clinical data and appropriate reimbursement services for physicians will result in greater use of biologicals and biosimilars.

Biography

Kamlesh Patel has more than 13 years experience in Indian pharmaceutical industry and worked from small to large sized Indian and MNC prior to his current role as General Manager - Medical Affairs and Head Pharmacovigilance in Abbott HealthCare, India. He played instrumental role in new product ideation, establishing PV department from scratch, developing regulatory strategies to ensure faster approvals, late phase clinical development program as a part of KOL engagement, launching innovative products, formulation of advocacy across multiple therapy areas and training more than 200 medical colleges of India on PV. He was a key person in planning, developing and implementation of the core medico marketing projects/initiatives across therapy areas along with developing and implementing process of ethics and compliance.

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