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Biologics versus biosimilars: Are they similar molecules? Do they share similar drug safety profile?

Biologics are medicines made from living cells through highly complex manufacturing processes. Biologics are important treatments for a number of cancers or chronic diseases. Biosimilars are highly similar to an already approved biologic molecule with differences (may be minor) in clinically inactive components. As biologics differ from small-molecule drugs due to their size and complexity, multifaceted manufacturing process, and their potential for immunogenicity, biosimilars cannot be considered "generic versions" of currently approved biologics. Although comparative studies are needed to generate substantive evidence in terms of quality, safety and efficacy, stringent pharmacovigilance procedures are required to detect potential differences in safety signals between biosimilars and their reference products. Unlike small molecule generics, a biosimilar approval requires clinical studies to ensure that small manufacturing changes have not altered the therapeutic efficacy of the biological drug. Post-marketing pharmacovigilance becomes even more critical in case of biosimilars as there is limited information available regarding them. Additionally, the effect of such biosimilars on diverse patient populations with respect to the dosage and duration of therapy needs to be closely monitored. Due to these reasons, biosimilars are required to undergo same pharmacovigilance regulations as its reference product. In my presentation, I would like to present before the audience the risks that the biosimilars could potentially bring in terms of immunogenicity and interchangeability of small molecules compared to the innovator's biologic molecule. Since biosimilars are many times cheaper than innovator's biologic molecules, we should not be discouraged in developing biosimilars but should be cautious with its characteristics and requires thorough evaluations. This would ultimately help the needy patient population.

Biography

Nipom Deka is a Physician with 7 years of valuable experience in various departments of Medicine, Surgery, Accident & Emergency and Orthopedics in India & abroad. In 2007, he started his career in Pharmaceutical Industry as a Clinical Investigator for a Phase II trial. Eventually, he moved into Pharmacovigilance joining as a Pharmacovigilance Physician. Over a period of time, he had the opportunity to lead and manage teams of Medical Reviewers & Drug Safety Associates (DSA). Besides working on streamlining & process improvement initiatives, he was actively involved in delivering training on Pharmacovigilance to DSA's & Physicians in various Organizations, he has been associated with. He was also involved in setting up of Pharmacovigilance units in various country offices in Asia, Africa & Middle East for multiple pharmaceutical companies. Having worked in Pharmacovigilance for more than 10 years, he has gained experience in areas including signal detection, benefit-risk assessment, risk management plan and various process improvement initiatives. In his current role in Amgen, he is providing leadership to the Pharmacovigilance teams in various affiliate offices in Asia Pacific region. As a member of Strategic Leadership Team, he contributes to develop and maintain compliant safety systems working closely with cross functions.

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