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The role of pharmacovigilance in biosimilars

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Biosimilars are the biological products which are facsimile of their innovator biopharmaceuticals. By 2020, all major biological products will be at the verge of losing patency and the market of biosimilar can be one among the fastest-growing biologics sector. The quality control of biosimilar agents are not same as their innovator biopharmaceuticals as there are changes either in production, packaging, storage, and distribution process; even minor changes in biopharmaceutical properties may enhance their immunogenicity and lead to autoantibodies production. The classical example being the epidemic of pure red cell aplasia that occurred due to minor changes in the manufacturing of Eprex by Johnson in 1998. Even though Biosimilar are affordable and cost effective and may have comparable efficacy to biologics but their adverse effects varies; pharmacovigilance plays an important role in monitoring these adverse events associated with a particular marketed biosimilar. Since the biosimilar are used for rare diseases and pre-clinical trials are conducted in limited no of patients; they should be monitored on long term basis for their safety in the post marketing setup, which can be accomplished by pharmacovigilance. Major challenges are faced by pharmacovigilance for biosimilars which include: Traceability, limited data from general practitioners and public pharmacies, underreporting and difficulty in causality assessment and concomitant medications. Certain measures to be taken to be followed to overcome these challenges are collection of the name of the medicinal product and the batch number for traceability and maintaining drug and disease-based registries which have shown to be important tools for the post-marketing collection of safety data for biosimilars in general. This illustrates the crucial role of Pharmacovigilance in assessing the safety and gaining additional knowledge for Biosimilars.

Biography

Imran Maniyar has completed his MBBS from Yenepoya Medical College, Mangalore and is now pursuing his PG In Pharmacology in JJM Medical Davangere. At present he is involved in two research paper.

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