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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, which occurred is 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 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.

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Expression of human neonatal Fc-receptor (FcRn) in Escherichia coli: A novel strategy

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Neonatal Fc-receptor plays an important role in maintaining the serum half-life of antibodies. This unique function had been explored in various studies in order to improve the pharmacokinetics of human immunoglobulin G (hIgG) in vivo. FcRn is composed of a α-chain which non-covalently associates with a β-chain, named β-2-microglobulin (β2m). Studies had shown that the α-chain contains several interaction sites to the Fc segment of IgG, while β2m is important for the proper folding of FcRn. Genetic expression of FcRn has been conducted in many eukaryotic tissues, ranging from mammalian tissue to yeast, and also prokaryotic organism. Study designed by Andersen had shown the production of functional FcRn in bacteria. However, protein refolding step is required to ensure the native activity of FcRn. In this study, we have demonstrated a novel expression strategy by using bacterial system, which produces the functional α-chain of FcRn. Expression vector that carries the cDNA of α-chain was transformed into expression host, Rosetta-Gami 2. The bacterial culture was grown under 22°C for 16 hours after induction in terrific broth with addition of sodium chloride (NaCl), glucose and betaine. The α-chain was expressed as soluble supernatant after sonication and centrifugation. The results of ELISA have indicated the native affinity of the α-chain towards hIgG and also retained its unique pH-dependent binding to the antibody. Our study proposed that the binding of FcRn to IgG may remain active in the absence of its β-chain. Further study will be conducted to confirm this finding.

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