Comparative testing and pharmcovigilance of biosimilars

Noghayin Mega Ehigie
University of Benin, Nigeria

The expansion of scientific knowledge in drug safety is attributable to greater awareness and academic interest. Academic centers of pharmacology, pharmaceutics and pharmacy generally have played an important role through the teaching, training research, policy development, and clinical research. (Ethics committees institutional review boards) and the clinical services they provide in many medical institutions particularly in the developed world. Adverse Drug Reaction (ADR) monitoring is recognized as an essential quality activity. Hence, Biosimilars (also known as biopharmaceutics in the USA) is targeted and designed to have active properties similar to one that has previously been licensed, the need for extensive comparability testing will be required to demonstrate that follow on biopharmaceutics has a comparable profile in terms of quality, safety, efficacy as the reference product. As any changes in the manufacturing process can alter the product capability and effects. This research is focused on the analytical tests to demonstrate comparability and similarity of a biosimilar product to a reference drug with respect to protein content, activity, physiochemical integrity, stability, impurities and additives, as well as immunogenicity are discussed, keen monitoring and inspection of resemblance drugs and its adverse effects as pharmcovigilance and all drug safety issues are relevant to everyone whose life is touched in anyway by medical intervention.

Biography

Noghayin Mega Ehigie is a Lecturer in the department of pharmaceutical pharm technology and obtained his Bachelor of Pharmacy Degree (B Pharm) in year 2008 and Doctor of Pharmacy (pharm D) and Master degree in Pharmaceutics in 2012 all in University of Benin. He has 3 publications and 2 journal articles.

Notes: