The Interchangeability of Innovator and Generic Drugs

L Tutunji

Drug Products with Therapeutic Equivalence Evaluation (Orange Book)[2]. Generic drugs offer a powerful approach to cost savings for the patients. As a result patient compliance to the treatment increases [1, 2]. In the year 2008 alone, generic drugs accounted for 69% of all prescriptions dispensed in the USA, yet only 16% of the cost in US dollar were spent on such prescriptions [2].

All prescriptions and over-the-counter generic drugs marketed in the USA must meet standards set by the US FDA. In approving a new generic drug for marketing, the FDA concludes that it is therapeutically equivalent to its corresponding reference product (usually the innovator product, but may be sometimes another generic product if the innovator product was withdrawn). The US FDA thus believes that therapeutically equivalent drug products can be substituted with full expectation that both drugs will produce the same clinical response.

L Tutunji,2017, The Interchangeability of Innovator and Generic Drugs, MOJ Bioequivalence & Bioavailability.