doi: 10.4172/2153-2435.10000S1

Joint Meeting

2nd World Congress on Bioavailability & Bioequivalence: Pharmaceutical R & D Summit-2011

International Conference on Pharmaceutics & Novel Drug Delivery Systems

The development of the use of generic products in Indonesia; does it increase or decrease and how is the role of bioequivalence study to ensure the quality of the products

Yahdiana Harahap

University of Indonesia, Indonesia

Because of the increasing health cost in Indonesia thus in order to fulfill public's needs of affordable drugs, substitution of innovator products with good quality generic product is needed. The price difference of generic product with its innovator is significant because it can reach ten to eighty times. To anticipate the high price of innovator product, Generic Drug Policy was launched in 1989: principally to the expansion of drug coverage for the community, ensuring availability of essential drugs, assuring the safety, quality and efficacy and affordable prices to the public. But the availability of essential generic drugs in health facilities has only reached 69.74% of the targeted 95%. The budget for generic drugs in the public sector amounted to 14.47% with a target equal to 2 USD per capita. Generic prescription drugs at health center has been at 90%, but in government hospitals 66% and in private hospitals 49%. Based on that condition, the government made the strategic policy such as Revitalization of Generic Drug Use among others Ministry of Health Decree 2010: Generic drug use in public health care facility is mandatory, Government Decree 2009: Pharmacists are allowed to substitute a brand name drug for its generic with physician and/or patient approval, and Bioequivalence study to ensure interchangeability for safety, efficacy, and quality. The Bioequivalence study must be performed in independent Bioequivalence laboratory, fulfill GLP and ICH-GCP aspects, must be accreditated with ISO 17025:2005/2008 from National Accreditation Committee or already has acknowledgement from National Agency of Drug and Food Control Republic of Indonesia.

Biography

Yahdiana Harahap received his education in Indonesia with BSc degree (1987) at Department of Pharmacy Faculty of Mathematic and Natural Sciences University of Indonesia. She obtained her MS (1994) and PhD (2003) in Pharmaceutical Chemistry at Department of Pharmacy Faculty of Mathematic and Natural Sciences Institute Technology Bandung. She then worked as Head of Public Service Center at Department of Pharmacy, University of Indonesia. Now she is the Head of Bioavailability and Bioequivalence Laboratory at University of Indonesia, member of BA-BE working group Indonesia and also as the Bioequivalence expert at National Agency of Drug and Food Control Republic of Indonesia.