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Professor Rezvi Sheriff Auditorium
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OP 1

Requirement for bioequivaience and biowaiver data for regulatory decision making: a comparative study of regulatory authorities

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Introduction and objectives: Requirements of Drug Regulatory Authorities (DRAs) on bioequivalence (BE) data and Bio Pharmaceutics Classification System (BCS) based biowaiver (BW)for generic drug registration are not uniform. This study compared dossier format, acceptance of BE and BW data during solid oral generic drug approval process by selected DRAs representing countries with different industrial, economic and social development.

Method: The selected DRAs were European Medicines Agency(EMA), Food and Drug Administration(USFDA) in United States, Health Canada(HC), Japanese Pharmaceuticals and Medical Devices Agency(PMDA),Singapore Health Sciences Authority(HSA), Malaysian National Pharmaceutical Control Bureau(NPCB), Korean Food and Drug Administration(KFDA),Central Drugs Standard Control Organization(CDSCO) in India, Australian Therapeutic Goods Administration(TGA) and former Cosmetics, Devices and Drugs Authority(CDDA) in Sri Lanka. Data collection was based on the information available in the public domain and personnel communications during 2013-2015.

Results: International common technical dossier format (CTD) is used by all jurisdictions except Japan and Sri Lanka which use their own dossier formats. Except Singapore, Japan and Sri Lanka, other jurisdictions require BE data as a principle for registration of all solid oral generic pharmaceutical products. Singapore requires BE for all prescription only medicines (PoM) and Japan requires BE for first approval of all generic drugs. Australia requests BE or justification for not submitting BE, for all PoMs and for over the counter (OTC) medicines excluded in the list not requiring BE. Sri Lanka requested BE only for antiepileptic drugs and narrow therapeutic index drugs up to 2014 and for antibiotics from 2014.

US, Singapore and India allow BW only for BCS class 1 drugs, and EMA, Canada and Korea allow BW for BCS class I and III drugs. A drug list for which BW can be applied is published by Malaysia. Not submitting BE can be justified based on BCS based dissolution data on case by case basis in Australia. Sri Lanka does not apply BW.

Conclusions: All jurisdictions studied request BE data for registering generic drugs to varying extents and most accepted BCS based BW except Sri Lanka. We recommend that National Medicines Regulatory Authority (former CDDA), Sri Lanka should expand the BE requirement list and accept BCS based biowaiver in registration of generic drugs.

OP 2

Factors associated with Adverse Drug Reactions (ADR) in a cohort of Sri Lankan patients with non-communicable chronic diseases

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Introduction and objectives: Adverse drug reactions (ADRs) are a major problem in medication use. Objective of this study was to describe the factors associated with ADRs in a cohort of Sri Lankan patients with non-communicable chronic diseases (NCCDs).

Method: This is a prospective observational study conducted in a tertiary-care hospital. In-ward patients with NCCDs were recruited systematically using the admission register in the ward as the sampling frame. All ADRs occurred during the index hospital admission and the 6-month period following discharge were detected by active surveillance. Details were recorded using ADR reporting form, developed based on the publication of Clinical Center, Pharmacy Department, National Institute of Health.