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Comparative study of regulatory guidelines - bio analytics

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Rapid growth in pharmaceutical spending is a worldwide phenomenon. According to a study, spending on pharmaceuticals in OECD (organization for economic cooperation & development) countries has an increase by an average of 32%in 1998 & in 2003 it was more than U.S$450billon. The regulation of pharmaceuticals aims to control manufacturing standards, quality, efficacy & safety of drugs, labeling & information requirements, distribution procedures and consumer prices. Here comes the role of drug price control, as India is known for it's reverse engineering, we are now current net exporter of quality & cheap generic drugs across the global market & India is a global competitor in advanced life sciences. Price control mechanisms for pharmaceutical products are a common form of intervention in many countries to control the costs of healthcare. The principal methods employed in many countries include pharmacoeconomics, various forms of reference pricing, comparator pricing, restrictions on dispensing and prescribing, and reimbursement restrictions. Canada uses the two-tiered pricing system based on negotiated prices while France follows new price notification procedure - to be set up with reference to prices based on a European average. The present work deals with impact of regulations pertaining to economy of pharmaceuticals.

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Registration of generics and requirements for dossier compilation in South Africa

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South Africa is the only country in the African region which is having strong regulations for the registration of medicines like major countries USA, Australia and Europe. Implementation of Common Technical Document (CTD) increased the stringency of the rules unlike other countries in African region. The market of Pharmaceutical products in generic version has increased in the many folds over a decade in South Africa. This has led to the reduction of costs to the insurance systems and for health care system of the government bodies. The South African regulatory body Medicines Control Council (MCC) is responsible for the selecting the medicines which are having properties like Safety, Quality and Efficacy. The safety data is obtained from two sources like pre-clinical studies and clinical phases. The Quality data indicates the stability of product since from starting of first step of synthesis to final product in the final packaging form which is ready sell, at different storage conditions. The Efficacy indicates the expected benefit will infact happens in the clinical application. The balance between the risks and benefits are over weighed in this study. The paper presents the requirements for the registration procedure for generics in South Africa and the compilation of dossier are Chemistry Manufacture and Control (CMC) Requirements, Stability Requirements, Labelling requirements and Bio equivalence Requirements.

Biography

I Mahesh. E pursuing II M. Pharmacy in Regulatory Affairs in JSS college of Pharmacy, JSS University, Mysore. I have done my B. Pharmacy in Visveswarapura College of Pharmacy, Rajiv Gandhi University of Health Sciences, Bangalore. I have presented many presentations in various National conferences and International conferences held in India. I have published few review articles.