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Pharmacovigilance system in India: Scope and limitations

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Use of medicinal products is not completely safe and sometimes it may lead to harmful effects in the body known as the Adverse Drug Reactions (ADRs). Pharmacovigilance is a system that improves the safe and rational use of medicines. WHO defines Pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems". The basic aims of Pharmacovigilance are improvement in patient care and safety, to contribute in the assessment of benefit, harm, effectiveness and risk of medicines and to promote education and clinical training on rational and safe use of medicines. India is becoming a major hub for clinical trials but the Pharmacovigilance system in India is still in its infancy. Although "Pharmacovigilance programme of India for assuring drug safety" was launched in 2004 but it has yet not been implemented effectively. Discrepancies exist between the provisions of Schedule Y and Central Drugs Standard Control Organization (CDSCO) guidelines for ADRs reporting. Need therefore exists to critically review the present Pharmacovigilance system in the country. This paper presents an overview of the current regulatory framework for Pharmacovigilance in India and discusses its limitations. Further, recommendations are provided to formulate a comprehensive and vibrant Pharmacovigilance system in India to protect country's population from the potential harm of the new drugs.

Biography

Mr. Diwakar Yadav is presently pursuing M. Pharmacy in Pharmaceutical Management & Regulatory Affairs branch at Lachoo Memorial College of Science & Technology, Pharmacy Wing, Jodhpur, India.

General comparision of patent system in SAARC countries

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The present study deals with the process of obtaining a patent in South Asian Association for Regional Cooperation (SAARC) nations. A patent is a form of intellectual property which consists of a set of exclusive rights granted by a sovereign state to an inventor or their assignee for a limited period of time in exchange for the public disclosure of an invention. The present work depicts on the procedure for granting patents, the requirements placed on the patentee, and the extent of the exclusive rights which vary widely between countries according to national laws and international agreements. A patent application must include 1 or more claims defining the invention which must meet the relevant patentability requirements such as novelty and non-obviousness. The exclusive right granted to a patentee in most countries is the right to prevent others from making, using, selling, or distributing the patented invention without permission. Paris Convention, WIPO (World intellectual property organization) and PCT (Patent co-operation treaty) programs have all played an important role in the field of patent information. The Centre's holdings of foreign patent literature are meager and need to be strengthened by acquiring them mainly from the U.S.A., France, Japan, Italy and Switzerland which are the top nations responsible for introducing new drug substances. Recently, there also has been a considerable increase in the number of patent grants from south Asian countries. The main aim here is to compare the patenting system (i.e. patent laws, patenting procedure, and requirements for filing a patent) in SAARC nations.

Biography

E.Bhargav is a presently a student of JSS College of Pharmacy, JSS University Mysore. He has completed his B.Pharm from JSS College of Pharmacy, Mysore. He is presently pursuing his M.Pharm in Industrial Pharmacy in the same college. His areas of research are Novel drug delivery systems, Novel Drug development and Formulation Research and development.

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