



PHARMACOVIGILANCE AND INDIAN PHARMACEUTICAL INDUSTRY

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ABSTRACT

Indian pharmaceutical industry is third largest industry in terms of volume and thirteen largest in term of value. The market is dominated mainly by branded generic drugs which contribute nearly 70-80% of the market. It has also emerged as a hub for the clinical trials and drug development process with a frequent increase in new drug delivery system, devices and chemical entities. Pharmacovigilance is the science and activities related to the collection, detection and assessment of the adverse event data. The major aim of Pharmacovigilance is the evaluation of the benefit-risk profile of the drug for better efficacy and safety for use in patients. Pharmacovigilance has been known to play a key role in the rationale use of drugs by providing information about the adverse drug reactions occurring in patients. Nowadays, drug safety gains more and more significance within “traditional” activities of pharmaceutical companies: safe data collection, safe processing of the data, safe evaluation and assessment of reports, safe submissions to authorities, safe overview of time frames for periodic reports, safe signal monitoring, safe management of risks of medicinal products.

KEYWORDS: Pharmacovigilance and Indian pharmaceutical industry

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