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Why do we need pharmacovigilance in India?

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According to various estimates, Adverse Drug Reactions occur in 10-20% of hospital inpatients, account for 2-6 % of all hospital admissions, and are among top 10 causes of death in inpatients. Overall incidence of serious ADRs is about 6.7 % and for fatal ADRs it is 0.32%. 15-20% of hospital budget may be spent dealing with drug complications. 30% to 60% of ADRs are preventable. More than 121 medicines were withdrawn for safety reasons in last 40 years- 33% within 2 years of marketing, 50% within 5 years. Tests in animals may not predict human safety. In clinical trials, patients are few, selection is narrow, indications are limited and time is brief. Therefore, information about rare but serious adverse effects, chronic toxicity, use in special groups and drug interactions often are incomplete or not available. Pharmacovigilance helps by early detection of unknown ADRs, detection of increase in frequency of ADRs, identification of risk factors and possible mechanisms underlying ADRs, estimation of benefit/risk, dissemination of information and taking necessary actions e.g., ban/withdraw the drug, insert suitable warnings, restrict use, modify OTC/prescription only status. Why do we need Pharmacovigilance in India? There are differences in ADRs between countries because of differences in drug availability, use, genetics, diet, pharmaceutical quality, use of alternative medicines, OTC availability of "prescription only" drugs, multiple systems of healthcare. Moreover, Indian Pharmaceutical industry is worth more than Rs. 90,000 crores & growing at 12-14% per annum. India is the global clinical trial hub and there is almost simultaneous global introduction of new medicines.

Biography

Ratinder Jhaj has completed her MD (Pharmacology) and DM (Clinical Pharmacology) from PGIMER, Chandigarh. She is currently working as an Associate Professor in the department of Pharmacology All India Institutes of Medical Sciences, Bhopal. She is also the Coordinator for the newly designated ADR Monitoring Centre under Pharmacovigilance Program of India at All India Institutes of Medical Sciences, Bhopal. Her research interests lie mainly in the field of Pharmacoeconomics including Pharmaco-economics, Pharmacovigilance, Rational Drug Use and Prescription Audits. She has 18 national and international publications and has been a resource person for many workshops on Clinical Pharmacology, Research Methodology, Essential Medicines and Pharmacoeconomics.

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