P Senthil Kumar, J Pharmacovigilance 2014, 2:5
http://dx.doi.org/10.4172/2329-6887.S1.015

OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Conference and Exhibition on
Pharmacovigilance & Clinical Trials
October 27-29, 2014 Hyderabad International Convention Centre, India

Pharmacovigilance; need of the hour: Risks and management

P Senthil Kumar
KMCH College of Pharmacy, India

The word Pharmacovigilance can be divided into 'Pharmakon' and 'Vigilance'. In Greek Pharmakon means 'a drug or medicine' and the word 'Vigilance' has been derived from a latin word 'Vigilare', which means 'to watch'. WHO defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects of marketed medicines or those under trial. The drug regulatory agencies have the responsibility of having a well-established pharmacovigilance system to monitor adverse reactions of drugs, during the drug development phase and later during the life time of a marketed drug. It collects, records, codes ADEs/ADRs, analyses and assesses the reports, promotes the safe use of drugs and creates appropriate structures and means of communication needed to perform its tasks. The information collected during the pre-marketing phase of a medical drug is inevitably incomplete with regard to possible adverse reactions. Tests in animals are insufficiently predictive of human safety. Information about rare but serious adverse reactions, chronic toxicity, use in special groups (such as children, the elderly or pregnant women) or drug interactions is often incomplete or not available.

Ethical Concern: Not reporting a serious unknown reaction is unethical. 'To know of something that is harmful to another person, who does not know, and not telling, is unethical'.

Cost: In USA over 770,000 people are injured or die each year in hospitals from adverse drug events (ADEs), which may cost up to $5. 6 million each year per hospital depending on hospital size. Pharmacovigilance is needed for the prevention of drug-induced human suffering and to avoid financial risks associated with unexpected adverse effects. WHO programme for international drug monitoring started in 1968 and is located in Uppsala, Sweden. Governance and Reporting Structures of India is PVPI (Pharmacovigilance programme of India) and National Pharmacovigilance Center, Central Drugs Standard Control Organization, Government of India.

Risk Management: Ensure availability and management of funds, Conduct frequent training and awareness of Pharmacovigilance, Detect and respond to under reporting of Adverse Drug Reactions, Ensure quality of filled ADR forms, Proper supervision of functioning of the centers, Feed back to the Health Care Professionals.

drsenthilkumarp@gmail.com