Recent Research in Science and Technology 2011, 3(12): 33-34
ISSN: 2076-5061
Available Online: http://recent-science.com/

Pharmacovigilance

Suneel.I.Majagi* and P.A.Patil

*Department of Pharmacology, J N Medical College, Nehru Nagar, Belgaum- 590010 India

A report on the 'National Symposium on Pharmacovigilance – 2011' held at KLE University's JN Medical College, Belgaum on 12th April 2011

Pharmacovigilance is an activity that is of international significance. Until recently, pharmacovigilance has been confined mainly to detection of adverse drug events that were previously either unknown or poorly understood. Its main purpose was to contribute to a scientific understanding of the safety profile of drugs and to advise national regulatory authorities. Adverse Drug Reactions (ADRs) results in 0.3% to 7% of hospital admissions & forms 4th to 6th leading cause of death among hospitalized patients. Despite awareness, practicing doctors do not report ADRs due to their busy schedule. Hence there is a need for alternative approach to identify, analyze & report the ADRs in order to minimize the incidence. There is also a need to establish Pharmacovigilance centers across the country.

Objectives of Pharmacovigilance activities are to detect, assess, understand and prevent the adverse effects or any other drug-related problems. This conference brought together top pharmaceutical, biotechnical and regulatory representatives in a forum that addresses the key issues of the industry. The in-depth program covers the i) Detection, analysis and prevention of adverse drug reactions with case studies and industry experiences. ii) Understanding and learning the latest information, tools and knowledge to update with the currentand future market. iii) Analyzing latest developments in pharmacovigilance which would shape any organization's risk management strategy. K.L.E.University's Jawaharlal Nehru Medical College, Belgaum, Karnataka, India, Regional Medical Research Centre, Belgaum, [as part of ICMR Centenary Celebrations], Indian Pharmacological Society, and IPS, Belgaum Branch jointly organized national symposium on Pharmacovigilance. It aimed at disseminating information and to discuss and debate controversial issues in the continuously evolving field of pharmacology. There were 230 participants from different healthcare institutes of India. Y.K.Gupta National Co-ordinator, Pharmacovigilance programme of India, (AIIMS, New Delhi) in his key note address spoke on "Pharmacovigilance Programme of India (PvPI): for safer medicine for Indian Population". The goal of this programme has been to provide safer medicines for the Indian population. However, the program is faced with many challenges. The number of patients in India is quite sizeable and the issues sometimes conflict between the need to provide access to medicines versus the need to provide safer medicines. On this occasion he announced the sanction of Pharmacovigilance Centre to the J.N.M.C. Belgaum. In his address he highlighted the importance of establishing pharmacovigilance centers in the medical colleges throughout India. The National Pharmacovigilance Centre at New Delhi is collaborating with the World Health Organization. Now the MCI (Medical Council of India) is regularizing Pharmacovigilance Centres in Medical Colleges. In the Inaugural address C.K.Kokate, (K.L.E University, Belgaum) explained the history of Indian pharmaceutical industries and compared the Indian status with those of other developing and developed countries. He also requested all the doctors to report adverse drug reactions, so that the database regarding adverse drug reactions can be strengthened which is a need of the time.

Neelima Kshirsagar (ICMR, Mumbai) spoke on "Post marketing surveillance studies". Manufacturers should take a more proactive approach to drug safety rather than maintaining defensive tactics. This calls for a heightened level of product stewardship and recognition of responsibility to public and environmental health. B. Sesikeran (NIN, Hyderabad), spoke on "Safe limits of Nutrients" At present there are no specific limits on the levels of vitamins, minerals or other micronutrients which may be contained in supplements or fortified foods sold under food law, nor are there rules on the range of vitamins, minerals or other nutrients that they may contain. Anand Harugeri (Astra Zeneca Pharma India Ltd) spoke on "Case Handling Process in Pharmaceutical Industry". A remarkable increase in use of drugs is seen in almost every country. Modern medications tend not only to be expensive but also add appreciably to the cost of health services. The medical, social and economic consequences of drug utilization are equally important issues, which need evaluation from time to time. It is necessary to ensure that drug use in a community is congruent with drug needs and confers maximum therapeutic benefits and minimal adverse reactions. A therapeutic audit is required at all levels of the therapeutic chain to ensure safe and effective medical care. Medical doctors, pharmacists and public are requested to assess both the risks and benefits of drugs in a broad perspective. M.S.Ganachari (KLES College of Pharmacy, Belgaum) spoke on "ADR monitoring - our experience". He elaborated on ICMR sponsored multicenter study on implementation and evaluation of ADR monitoring programme conducted for a period of 3 years. He explained about establishment of an ADR reporting system with the help of yellow card and ADR drop boxes. Supriya Bhalerao (Nayar Hospital, Mumbai) spoke on "Issues in safety reporting of traditional medicines". She explained about ayurvedic concepts of ADR, safety and the need for Pharmacovigilance. She also elaborated the present issues in safety monitoring of traditional medicines which involve challenges in detection, assessment, prevention of ADRs and recommendations to overcome them.

Received: Sept 12, 2011; Revised: Oct 20, 2011; Accepted: Dec 02, 2011.

*Corresponding Author

Suneel.I.Majagi
Department of Pharmacology, J N Medical College, Nehru Nagar, Belgaum-590010 India

Tel: +91-0831-24094082; Fax: +91-0831-2470759
Email: suneelmajagi@yahoo.co.in

India's Drugs Control Department within the Ministry of Health & Family Welfare initiated the establishment of a nationwide network to build a comprehensive pharmacovigilance data system. The National Pharmacovigilance Advisory of the Director General of Health Services and the Drug Controller General of India (DCGI), who functions as the member secretary of the Committee. Based at the Central Drugs Standard Control Organization, NPAC was assigned the primary responsibility of setting up the system to monitor the pharmacovigilance programme throughout the country. The National Pharmacovigilance Programme for India is sponsored by the World Health Organization (WHO) and is funded by the World Bank.

In the panel discussion resource persons discussed the on-going pressing concerns faced in drug safety, addressing the risks, timeline and budget constraint, whilst effectively tackling key challenges in overcoming trials agreement and site contract negotiation hurdles.