Barna Ganguly, J Pharmacovigil 2017, 5:4 (Suppl)
DOI: 10.4172/2329-6887-C1-029

Challenges of pharmacovigilance programme in Indian set up

Barna Ganguly
Pramukhswami Medical College, India

Origin of pharmacovigilance in India goes back to 1986, when a formal adverse drug reaction (ADR) monitoring system consisted of 12 regional centers, each covering a population of 50 million. India is a hub for clinical trials flooded with more than 6,000 licensed drug manufacturers and 60,000 branded formulations. Though Pharmacovigilance plays a significant role in clinical research and practice, yet there is an immense gap in understanding its importance in such areas. The Pharmacovigilance Programme of India was launched with an objective to safe guard the health of people of India. While major advancements in this discipline have taken place in Western countries, implementation and compliance still remain as challenge in India. So, it is important to address various challenges of pharmacovigilance. In India, the events are not properly reported due to lack of time, low motivation and ignorance. Lack of continuing medical education on pharmacovigilance and dearth of drug information and updates particularly at the level of primary health centres and private practitioners lead to underreporting of ADR. The practice of self-medication and use of traditional medicines pose other challenges as adverse events in such cases often go unreported. In addition, there are lacunae like lack of communication among healthcare professionals, shortage of trained personnel and inadequate training on pharmacovigilance at undergraduate level. Another challenging area of ADR monitoring is with that of clinical trials where there are always certain risks for the participants in such trials, which involve healthy volunteers and patients. The safety of the trial subjects is the sole responsibility of the investigator. She should conduct the trial strictly abiding by Indian GCP guidelines and ICH-GCP Guidelines if the requirement is by USFDA or EU regulatory agencies. Different kinds of research (epidemiological studies, post marketing surveillance, other pharmacovigilance studies, clinical trials and product development) have their own particular scientific requirements and specific ethical challenges. These can be addressed by incorporating changes like making pharmacovigilance reporting mandatory at all levels and introducing pharmacovigilance inspections. Intensive training should be given in all aspects of pharmacovigilance to various stake holders including the patients, efficient system of communication, creating a clinical trial database for SAEs and ADRs for signal detection and access to relevant data for various stakeholders. Thus it can help in proper implementation and compliance of the programme.

Biography

Barna Ganguly has completed her MBBS (1987) from Calcutta University & MD - Pharmacology (1994) from Aligarh Muslim University, Aligarh. She has also done her PG Diploma – Bioethics (2012-13) IGNOU, supported by ICMR – NIH (USA). Presently, she is working as Professor and Head of Department of Pharmacology and Head of UNESCO Bioethics Unit of Gujarat under UNESCO Chair in Bioethics, (University of Haifa), in P S Medical College, Karamsad, Gujarat, India. She has a total of 24 years (approx.) of teaching experience and collaborated with several publications at various national and international levels with authorship in chapter of book in CRC publication. She has presented posters and papers at all levels of conferences and received scholarships from PRIM & R Conferences and 12th World Congress with full scholarships from NIH. She is a life member of six associations, was President of Society of Pharmacovigilance India in 2014-2015 and reviewer of many journals. She is a Member of International Forum of Teachers of Bioethics, UNESCO. Her area of interest is Clinical Pharmacology and Bioethics.

barnaganguly@rediffmail.com
barnag@charutarhealth.org

Notes: