



Pharmacovigilance: Aggregate reports

Inder Makhija

CRO Industry, Mysore

Pharmacovigilance is science and activities relating to detection, assessment, understanding and prevention of adverse events including the off-label use, medication errors and occupational exposure of medicinal products. Pharmacovigilance applies throughout the life cycle of a medicine equally to the pre-approval stage as to the post-approval. The scopes of pharmacovigilance is to improve patient care and safety in relation to the use of medicines, and all medical and paramedical interventions; to evaluate the benefit risk profile of medicinal product with the help of periodic benefit-risk evaluation report (PBRER), periodic adverse drug experience report (PADER) or developmental safety update report (DSUR); encourage rational and more effective (including cost-effective) use; and to promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public. The source of pharmacovigilance data are pre-clinical studies, clinical studies, spontaneous adverse reaction reporting, epidemiological studies, published articles, literatures and case reports. All health care workers, including doctors, dentists, pharmacists, nurses and other health professionals must report all suspected adverse reactions to drugs especially when the reaction is unusual, potentially serious and clinically significant. Patient's condition is an adverse drug reactions evaluated by analyzing patients medical history, underlying disease, temporal relationship between drug and events and by studying the effect of dechallenge and rechallenge of medicinal product. Studies conducted in developed countries have consistently shown that approximately 5% of hospitalised patients are admitted into hospital as a result of an ADR and 6-10% of in-patients will experience a serious ADR during hospitalisation. Even these startling figures don't represent the whole picture. These studies generally excluded ADRs caused by overdose, drug abuse, or therapeutic failures. The cost to most countries for managing adverse drug reactions is considerable. For now establishment of

validated pharmacovigilance system is need of hours as no medicinal product is entirely or absolutely safe for all people, in all places, at all times. These goals can be readily achieved only with the collaborative efforts and contributions from the key partners in the area of pharmacovigilance. Inputs from a variety of sources such as government, academia, pharmaceutical and medical associations, health professionals and the media will help towards achieving improved management of risks associated with the use of medicines. The emerging priority of pharmacovigilance system is to detect early unsuspected potential risk; use of existing data as feedback for the drug discovery process; to ensure regulatory compliance to prevent punitive action; raise awareness; mass treatment regimens and drug resistances. In conclusion, pharmacovigilance is essential part of public health program but encounters some crucial challenges. There is a need for better integration of pharmacovigilance into clinical practice and public policy. When adverse effects and toxicity appear they should be analyzed and communicated effectively to an audience that has the knowledge to interpret the information.