



PHARMACOVIGILANCE: REGULATIONS AND DRUG SAFETY MONITORING

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ABSTRACT

Pharmacovigilance is to describe the processes for monitoring and evaluating ADRs. It is the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications, biological products, blood products, herbals, vaccines, medical device, traditional and complementary medicines with a view to identifying new information about hazards associated with products and preventing harm to patients. Adverse drug reactions experienced with use of a medicinal product may result in significant morbidity and mortality. The ultimate goal of pharmacovigilance is to ensure safe use of medicines, minimizing the risks related to the medicinal product and maximizing the benefits. To understand the pharmacovigilance, a high level of expertise is required to rapidly detect drug risks as well as to defend the product against an inappropriate removal. The current global network of pharmacovigilance centers, coordinated by the Uppsala Monitoring Centre, would be strengthened by an independent system of review. Today many pharmacovigilance centers are working for drug safety monitoring in this global pitch, however, at the turn of the millennium pharmacovigilance faces major challenges in aspect of better safety and monitoring of drugs. It is important to monitor safety during the post-approval period and throughout the entire lifecycle of the medicinal product to arrive at the actual of the medicinal product and take necessary measures to minimize risks.

KEYWORDS: Pharmacovigilance; ADRs; Morbidity; Monitor; risk-benefit profile; etc.

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