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Pharmacovigilance: A brief outlook

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The drug safety monitoring is now the mandate area of interest for Regulatory Authority; Ethics committee and Pharmaceutical/bio-pharmaceutical companies. Every drug is associated with beneficial as well as undesirable or adverse effect. Nuremberg code 1947 and the thalidomide tragedy of 1960's lead to stringent ethics and regulations. Previously the benefit/risk ratio for drug(s) under study and marketed drug(s) were not transparent to Regulatory Authorities and safety of patient was not on priority. The drug safety issues were globalised, strengthen and systematized after the establishment of 1964 Declaration of Helsinki; World Health Organization (WHO) Programme for International Drug Monitoring in 1968; birth of ICH - International conference on harmonisation 1990 and 1996 - ICH GCP guidelines released. Adverse drug reactions (ADR) are the common clinical problem. The hospitalization due to ADRs in some countries is about 15.1%. In addition, 10-20% of the hospital inpatient suffers from ADRs. Appropriate and effective monitoring of ADRs, i.e. Pharmacovigilance, is the only best way to safeguard the public health. ICSRs originating from solicited and unsolicited categories are submitted to Regulatory Authority in the form of CIOMS and MedWatch 3500A Drug. The ICSRs submission to Regulatory Authority depends on causality relationship with suspect drug and the expectedness. Serious unexpected adverse drug reactions (SUSARs) are expeditable to Regulatory Authority. The spontaneous reporting system (SRS) is the first and most widely used method to report ADRs in spite of under-reporting as a major limitation. Based on those reported cases signal is generated.ADRs which are assessed as special terms are by default considered for signal analysis. The safety monitoring of drug is assessed by benefit/risk ratio analysis by submission of PBRER/PADER as per Regulatory timelines. The severity of under-reporting of ADRs is considerably high; it estimates that only 8% of ADRs are reported. There are many factors associated with under reporting of ADRs; categorized as personnel and professional characteristics of healthcare professional and their knowledge and attitude to ADR reporting. Under-reporting can be significantly improved by appropriate educational intervention.

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