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Novel approaches of risk management in Pharmacovigilance

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The importance of pharmacovigilance in assessing the safety of a marketed medicine is increasing in the recent years owing to the high profile safety issues with widely used drugs. In response many strategies to improve the collection, integration and analysis of data related to post marketing drug safety are initiated like medicines and health care products regulatory agency which operates yellow card scheme for health care professionals, patients and carers to report suspected Adverse Drug Reactions. The similar scheme was also developed by the US Food and Drug Administration in which the records are stored in adverse event reporting system (AERS) and vaccine adverse event reporting system (VAERS). Pharmacovigilance is a critical component for determining the benefit to risk ratio of treatment. A major change in the approach to drug safety surveillance after marketing has been introduced in the form of risk management planning. The action plan includes calling for additional pharmacovigilance in the form of active surveillance, epidemiology studies, further clinical studies and drug utilization studies. Additional risk minimization activities include additional educational material about the medicine and its use, training programs, restricted use of the medicine. A formalized risk management plan is mandatory for most marketing authorization application which helps in improving the safety of medicines.

Biography

T Priyanka is pursuing her fifth year PharmD from Annamacharya College of Pharmacy. She was University topper in PharmD, fourth year results. She has presented a poster on knowledge, attitude, perception among pharmacy and non pharmacy students in the conference held by Indian Association of Colleges of Pharmacy. She has attended a module held at SR University. She was a delegate at the conference held at RIPER on the future opportunities of PharmD.

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