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The periodic safety update report: A role in Pharmacovigilance

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The Periodic Safety Update Report (PSUR) is a document that allows a periodic comprehensive assessment of the safety data of a manufactured drug or biological product worldwide. The main focus of the reports is Adverse Drug Reactions (ADR). It is submitted to the regulatory authority at set intervals and it provides an update on post marketing experiences both nationally and globally. PSUR is required to be submitted by the marketing authorisation holders (MAH) and has to include the summary details of all ADRs reported along with critical evaluation. A thorough literature search and cross referring of all relevant PSURs is mandatory to discover the similar safety concerns elsewhere in the world. As per the requirements of Schedule-Y of Drug and Cosmetic Act, the PSURs are required to be submitted to the office of DCGI every 6 months in the first 2 years & annually for the subsequent 2 years. The sources of the PSURs may include spontaneous notifications from the healthcare professionals/patients, MAH sponsored clinical studies, literature, ADR monitoring by the regulatory authorities, epidemiological databases etc.company Core Datasheet is an important tool of reference safety information based on which the reported ADRs are classified. One PSUR is submitted/active substance/all dosage forms/all formulations. PSUR is the important source to identify the new signals, to determine any change in the benefit risk profile and to communicate with the regulatory authority. It is an indicator for the need for risk management initiatives and a tracking mechanism to monitor the effectiveness of such initiatives.

Biography

Swetha ES has completed her undergraduate degree from Al-Ameen Medical College, Bijapur affiliated to RGUHS, Bangalore. She is presently pursuing her postgraduate degree in S. S. Institute of Medical Sciences and Research Centre, Davangere. She has completed various preclinical and clinical studies namely, evaluation of antidepressant and anti anxiety activities of Angiotensin Receptor Blockers and Xanthine Oxidase Inhibitors and Drug utilization studies in MICU. Presently she is engaged in a clinical study to see the difference with morning and evening doses of Montelukast in seasonal allergic rhinitis patients. She has published 4 papers in reputed journals till now.

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