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Pharmacovigilance: An Empowerment in Safe Utilization of Pharmaceuticals

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Abstract : Pharmacovigilance (PV) is a rapidly growing discipline in pharmaceutical industries as an integral part of clinical research and drug development over the past few decades. PV carries a breadth of scope from drug manufacturing to its regulation with safer utilization. The fundamental steps of PV not only includes data collection and verification, coding of drugs with adverse drug reactions, causality assessment and timely reporting to the authorities but also monitoring drug manufacturing, safety issues, product quality and conduction of due diligence. Standardization of adverse event information, collaboration of multiple departments in different companies, preparation of documents in accordance to both governmental as well as non-governmental organizations (FDA, EMA, GVP, ICH) are the advancements in discipline of PV. De-harmonization, lack of predictive drug safety models, improper funding by government, non-reporting, and non-acceptability of ADRs by developing countries and reports directly from patients to the monitoring centres respectively are the major road backs of PV. Mandatory pharmacovigilance reporting, frequent inspections, funding by government, educating and training medical students, pharmacists and nurses in this segment can bring about empowerment in PV. This area needs to be addressed with a sense of urgency for the safe utilization of pharmaceuticals.

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