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JOHP

**Journal of Hospital Pharmacy**  
**An Official Publication of Bureau for Health & Education Status Upliftment**  
(Constitutionally Entitled As Health-Education, Bureau)

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## **Present Era of Drug safety in India: Recent Insights**

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### **Abstract**

Good Pharmacovigilance Practices (GVP) are a set of measures drawn to promote the role of pharmacovigilance in European union (EU). Good Pharmacovigilance Practices is a growing Scenario in India Since 2016, with an aim to give platform to the industry with good practices in pharmacovigilance, in order to make them competent to avoid adverse drug reactions. A large number of Adverse Drug Reactions (ADR) are evaluated by clinical trial study of drugs, but in case of any reaction, which occurs after prolong time in a specific individual or specific population remains not detected for a long time. Pharmacovigilance (PV) is a scientific Investigation which deals and keeps regular vigil on the drug around its life period. In our country Indian Pharmacopoeia Commission (IPC) and other regulatory authorities like National Coordination Committee (NCC) via the Central Drug Standard Control Organization (CDSCO) warmly synchronize and control the Pharmacovigilance activities. In order to improve a potential Pharmacovigilance (PV) system in India, Pharmacovilance Program of India (PvPI) was planned and enforced by the Indian government by year 2010. The backbone of this system is exact detection and evaluation reporting of ADR. Anyone can report such as- Clinician, Nurses, lay person, pharmacist and other healthcare professionals by filling the suspected ADR reporting form available online or offline to the nearest centres available (regional, zonal and peripheral centres) in their local or

national language. As long as Indian geographical distribution and large population and mobile network connectivity is good, a toll free number and the mobile app is also a good source for reporting of ADR. All the suspected reported ADRs are collected and processed at the centres in Vigi-flow software. Regional, National, zonal and peripheral centres are responsible for Signal detection, Risk evaluation and Mitigation strategies (REMS) which are reported to CDSCO and World Health Organisation (WHO) for the required regulatory action. The final decision of CDSCO-WHO is passed by a suitable media source for the advancement of health of society.

**Keywords:** CDSCO, World Health Organization, Pharmacovigilance, Adverse drug reaction, Indian Pharmacopoeia commission

**Abbreviations:** ADR-Adverse Drug Reaction, PV-Pharmacovigilance, CDSCO- Central Drug Standard Control Organisation

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Website: <a href="http://www.journalofhospitalpharmacy.in">http://www.journalofhospitalpharmacy.in</a>	
Received on 8/09/2020	
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