

## **Pharmacovigilance Programme of India**

Adverse drug reaction (ADR) is one of the leading causes of morbidity and mortality worldwide. The consequences of ADRs burden the healthcare system with increased cost of therapy and prolongation of hospitalization. According to WHO, Pharmacovigilance is defined as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem”. Pharmacovigilance Programme of India (PvPI) is Government of India’s flagship drug safety monitoring programme which collects, collates and analyses drug-related adverse events and recommends regulatory measures to the Central Drugs Standard Control Organization for implementation.

The Pharmacovigilance Programme of India (PvPI) was operationalized in July 2010 by the Ministry of Health and Family Welfare, Government of India with the mission to safeguard the health of Indian population by ensuring that the benefits of use of medicine outweigh the risks associated with its use. The All India Institute of Medical Sciences (AIIMS), New Delhi was established as the National Coordination Centre (NCC) for PvPI. Later on, Ministry of Health and Family Welfare, Government of India on 15<sup>th</sup> April 2011, recasted this programme and shifted the National Coordination Centre from AIIMS, New Delhi to Indian Pharmacopoeia Commission (IPC), Ghaziabad. The Materiovigilance Programme of India (MvPI) and Hemovigilance Programme of India (HvPI) are also under the umbrella of PvPI.

Pharmacovigilance is based on sound scientific principles and is an integral part of clinical practices. This discipline needs to develop further to meet the demands of public health for which continuous monitoring of drugs is essential. Such monitoring will help in assessing, monitoring and detecting adverse effects of drugs, their interactions, taking corrective intervention, selection of safer drugs for rational prescribing etc

Recognising the strength and progressive journey of PvPI in the area of Pharmacovigilance and Public health, World Health Organization (WHO) HQ, Geneva on July 18, 2017 has bestowed upon India the honour as the “**WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services**”. PvPI as a WHO-CC provides scientific support to countries in Asia and beyond for Pharmacovigilance

in Public health Programmes such as tuberculosis, neglected tropical diseases, vector-borne diseases, HIV-AIDS, Adverse event following immunisation (AEFI) and other regulatory issues.

This stable pharmacovigilance system has enabled us to collect, collate and analyze data scientifically. Thus evidence-based information is utilized for appropriate regulatory decision by the CDSCO such as changing/updating package-insert, issuing drug alerts, and signals.

### **Scope and Objectives of PvPI**

1. Create a nation-wide system for patient safety by ensuring drug safety
2. Identify and analyse new signals from the reported cases.
3. Analyse the benefit-risk ratio of marketed medications.
4. Generate evidence-based information on safety of medicines.
5. Support regulatory agencies in the decision-making process on use of medications.
6. Communicate safety information on use of medicines to various stakeholders for preventing/minimizing the risk.
7. Collaborate with other National Centres for exchange of information and data management.
8. To organize and sensitize the stakeholders for celebration of national Pharmacovigilance Week from 17<sup>th</sup> to 23<sup>rd</sup> September every year.
9. Provide need-based training and consultancy support to other National Pharmacovigilance Centres across the globe.
10. Promote rational use of medicines.
11. Emerge as a Centre of Excellence for Pharmacovigilance Activities.

For further details about PvPI, please visit the website [Pharmacovigilance Programme of India \(PvPI\) Updates - Indian Pharmacopoeia Commission \(ipc.gov.in\)](http://www.ipc.gov.in)