

STATUS OF PHARMACOVIGILANCE PROGRAM OF INDIA

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INTRODUCTION

India is emerging rapidly as a hub of global clinical trials and drug discovery & development, result of which Indian pharmaceutical industry is valued around Rs. 90,000 crores with an annum growth rate of 12 – 14 %. Several new drug molecules and medical devices are introduced in the Indian market every year which needs to be monitored for any Adverse Drug Reactions (ADRs) not only during the drug development process but also after it is marketed. There is no medicine which is free from side effects. Majority of known ADRs are preventable with judicious use of medicines, while many are still unknown even though that medicine has been in clinical use for several years. Hence, it is imperative to monitor the pharmacotherapy/medicines for both the known and hitherto unknown side effects.

Indian published literature on pharmacovigilance suggests that there is a need for a robust pharmacovigilance programme in India. Need becomes more important considering its large population with vast ethnic variability, geographical conditions, different disease prevalence patterns, practice and faith in different indigenous systems of medicines and varying socioeconomic status.

WHO defines pharmacovigilance as the Science and activities relating to the detection, assessment, understanding and prevention of adverse drug reactions. Information collected from healthcare providers and patients on the adverse effects of medications, biological products (vaccines, blood products), herbal and traditional medicines is furnished in the ADR monitoring form.

In June 2010, Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services under the aegis of Ministry of Health & Family Welfare, Government of India in *collaboration with Indian Pharmacopodia Commission, Ghaziabad* initiated a nation-wide pharmacovigilance programme for protecting the health of the patients by assuring drug safety with well defined goal with predestined road map to ensure its future growth and progress. Ultimate goal of the program is to ensure that the benefits of use of medicine outweigh the risks and thus safeguard the health of the Indian population. In general the prime activity of the Pharmacovigilance Program of India (PvPI) is to collect, collate and analyze data on adverse drug reactions to arrive at an inference to recommend regulatory interventions, besides communicating associated risks to healthcare professionals.

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Objectives of the PvPI

- To monitor Adverse Drug Reactions in Indian population
- To create awareness amongst health care professionals about the importance of ADR reporting in India
- To monitor benefit-risk profile of medicines
- Generate independent, evidence based recommendations on the safety of medicines
- Support the CDSCO for formulating safety related regulatory decisions for medicines
- Communicate findings with all key stakeholders
- Create a national centre of excellence at par with global drug safety monitoring standards

In year 2010, 22 ADR Monitoring Centers were established under this programme. The programme is coordinated by the Indian Pharmacopoeia commission, Ghaziabad as a National Coordinating Centre (NCC) under the supervision of a Steering Committee. Steering Committee recommends procedures and guidelines for regulatory interventions. Drugs Controller General (India), New Delhi, chairs the eight member steering committee and Officer-in-Charge (New Drugs), CDSCO, New Delhi acts as its member secretary. In addition, Steering Committee and Strategic Advisory Committee along with Signal Review Panel,

Core Training Panel and Quality Review Panel administer and monitor the functioning and progress of the program. Working group of PvPI is comprised of Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ghaziabad (U.P.), Chairman, *ex-officio*; Head of Department, Department of Pharmacology, AIIMS, New Delhi, Member; Three nominees of Drugs Controller General (India), Member; A nominee from a medical institution run by the Central Government (to be nominated by the Chairperson, Steering Committee), Member; Two nominees from medical institutions run by the State Government (to be nominated by the Chairperson, Steering Committee), Member; A nominee from a pharmacy institution (to be nominated by the Chairperson, Steering Committee), Member; A nominee from a nursing institution (to be nominated by the Chairperson, Steering Committee), Member; Officer-in-charge (Pharmacovigilance Cell), Indian Pharmacopoeia Commission (to be nominated by the Chairperson, Working Group), Member Secretary.

In PVPI there is provision of effective communication channels among the key stakeholders which ensures the continuous bidirectional nature of the transfer of data, information, and knowledge.

The roadmap for the PvPI has stated its implementation in five years from June 2010 onwards. Program was designed in five phases which included initiation phase (2010-2011), expansion and consolidation phase (2011-2012), expansion and maintenance phase (2012-2013), expansion and optimization phase (2013-2014) and Excellence phase (2014-15).

The targets for each of these five phases are listed below:

Phase I (Initiation phase), 2010 -2011

- Enroll 40 medical colleges.
- Start data collection for Adverse event following immunization.
- Development and establishment of training centre.
- Training of pharmacovigilance human resource.
- Linkage with uppsal monitoring centre, sweden.
- Initiate software development for national drug safety data base.
- Training of pharmacovigilance human resource.
- Publication of drug safety news letter.

Phase II (Expansion and consolidation phase), 2011-2012

- Enroll additional 60 medical colleges.
- Training of pharmacovigilance human resource.
- Training in pharmacovigilance software provided by UMC.
- Identify gaps and address through appropriate training
- Software development and validation.

- Zonal workshop for public awareness of drug safety.

- Publication of drug safety news letter.

Phase III (Expansion and maintenance phase), 2012- 2013

- Enroll additional 100 medical college.
- Training of pharmacovigilance human resource.
- Zonal workshop for public awareness of drug safety.
- Publication of drug safety news letter.

Phase IV (Expansion and optimization phase), 2013- 2014

- Enroll additional 100 medical college.
- Training of pharmacovigilance human resource.
- Interaction with international pharmacovigilance bodies.
- Publication of drug safety news letter.

Phase V (Excellence phase) 2014-2015

- Create centre of excellence for pharmacovigilance in Asia pacific.

To ensure that the PvPI is functioning effectively and achieving its objectives, there is a provision to monitor and evaluate the program using indicators viz (i) **process** (i.e. number of AMCs participating in the PvPI,

