



# REVIEW ON PHARMACOVIGILANCE IN INDIA

<sup>1</sup>Muskan R. Shaikh, <sup>2</sup>Nisha K. Bhakare, <sup>3</sup>Kalyani B. Kokane, <sup>4</sup>Parag B. Funde, <sup>5</sup>Ganesh R. Phadtare, <sup>6</sup>Dr. Sanjay Arote.

<sup>1</sup>Student, <sup>2</sup>Student, <sup>3</sup>Student, <sup>4</sup>Student, <sup>5</sup>Associate Professor, <sup>6</sup>Principal,

Department of Pharmacology,

<sup>1</sup>Indrayani Institute of Pharmaceutical Education And Research, Talegaon Dabhade, Pune.

**Abstract:** Pharmacovigilance (PV) plays a key role in the healthcare system by assessing, monitoring and detecting drug interactions and adverse drug reactions in humans. Medicines are intended to cure, prevent or treat disease. However, there are also risks, especially adverse drug reactions (ADRs) that can cause serious harm to patients. Therefore, for safe drugs, adverse reactions should be monitored throughout the life cycle of each drug, during drug development (e.g. pre-market, including early stages of drug design, clinical trial phase and post-marketing surveillance). Pharmacovigilance is the science and activities concerned with the detection, assessment, understanding and prevention of adverse effects or any other drug/vaccine related issues.

In addition, PV has traditionally been involved in recording spontaneous reports and submitting them to national surveillance systems. An emerging trend in PV is to link pre-market data to human safety information observed in the post-market phase. The PV Systems team captures valuable additional information, building on the scientific data contained in the original report, making it even more informative. This calls for extreme demands for effective regulation of the drug approval process and conscious vigilance against adverse effects before and after approval, especially in India.

Adverse events reported through the PV system can benefit the community due to their linguistic and intellectual proximity to the public and public health practitioners, and the reporter can be easily contacted electronically. Thus, PV can help patients stay healthy and manage optimally or ideally, avoiding disease. This review summarizes the objectives and approaches used in PV and provide a critical review of existing PV in India, challenges to overcome and future prospects in the Indian context.

**Keywords:** pharmacovigilance, adverse drug reactions, clinical trials, pharmacogenomics, Indian Pharmacopoeia Commission.

## I. INTRODUCTION

PV is the science of collecting, monitoring, researching, evaluating and evaluating information from health care providers and patients about the adverse effects of drugs, products biologics, blood products, herbal remedies, vaccines, medical devices, traditional and complementary medicine. intended to identify new hazard information associated with the product and to prevent harm to patients. The challenges of maximizing drug safety and maintaining public confidence are becoming increasingly complex. Pharmaceutical and biotechnology companies must not only monitor drug risk, but also proactively estimate and manage it throughout the product lifecycle, from development to post-marketing.

PV specifically relates to adverse reactions, which are adverse and unexpected drug reactions occurring at doses normally used to prevent, diagnose, or treat disease or to alter physiological function. Ongoing monitoring of a drug's effects, side effects, contraindications, and outright harms is critical to maximizing benefits and minimizing risks. No amount of care or caution in the pre-clinical and clinical testing phases can guarantee that a drug will be absolutely safe when it is marketed and prescribed to large numbers of people across the country and beyond. Because clinical trials can involve thousands of patients at most, less common side effects and adverse reactions are often unknown when a drug hits the market.

Post-marketing PV uses tools such as data collection and review of case reports to identify relationships between drugs and adverse reactions. Drug monitoring and management services are responsible for establishing wells.

## II. BACKGROUND

Many developed countries instituted drug monitoring programs following the thalidomide scandal in the 1960s. India developed its own program in the 1980s. Medicines has taken many forms, but the Central Drug Standards Control Organization developed India's current pharmacovigilance program in 2010. Now, the program is well integrated with government legislation, regulatory agencies as leaders and research centers that are part of Indian Pharmacopoeia Commission. Board of Pharmacists of India: Pharmacovigilance as one of the subjects of undergraduate courses in pharmacy.

- Medicines and Cosmetics Act and its rules 1945: The establishment of pharmacovigilance rooms in the pharmaceutical industry is mandatory.

- National Health Policy: Drug Monitoring, including prescription audits, including antibiotic use, Ministry of Health and Ministry of Health; Family Welfare, Government of India.

Table 1.1 : History and Development Of pharmacovigilance in India:

YEAR	HISTORY
1747	Very known clinical trials by James Lind, providing the usefulness of lemon juice in preventing scurvy.
1937	Death of more than 100 children due to toxicity of sulfanilamide
1950	Aplastic anemia reported due to chloramphenicol toxicity
1961	Worldwide tragedy due to thalidomide toxicity
1963	16 <sup>th</sup> World Health Congregation recognize significant to rapid action on Adverse Drug Reaction(ADRs)
1968	WHO research project for International Drug monitoring on pilot scale
1996	Global standard level clinical trials initiated in India
1997	India attach with WHO Adverse Drug Reaction Monitoring Program
1998	Initiation of Pharmacovigilance in India
2002	67 <sup>th</sup> National Pharmacovigilance centre established in India
2004-05	India launched National Pharmacovigilance Program.
2005	Accomplishment of Structured Clinical trials in India
2009-10	Pharmacovigilance Program PvPI Started

### III.PHARMACOVIGILANCE IN INDIA

In India consideration of adverse reaction monitoring developed relatively late in India, as the concept of drug monitoring traditionally did not exist in the country. Although still in its infancy, photovoltaic is not new to India. It was not until 1986 that some physicians, mostly from academic institutions, called for greater attention to potential adverse effects and rational prescribing of prescription drugs. Due to this, the formation of the first ADR monitoring program consisting of 12 regional centers, each covering a population of 50 million, without success. Little changed until a decade later, when India joined the WHO adverse drug reaction monitoring program in Uppsala, Sweden in 1997.

Three adverse drug reaction monitoring centers have been identified, mainly in teaching hospitals: the National Pharmacovigilance Center of the Department of Pharmacology, All India Institute of Medical Hospital, Aligarh). These centers are required to report adverse reactions to the Indian Medicines Regulatory Agency. The main role of these centers is to monitor the adverse effects of drugs sold in India. However, they do not work because information about the need to report adverse reactions and the functionality of these monitoring centers never reaches prescribers, and the government lacks funding. This attempt failed and hence, from 1 January 2005, a National Pharmacovigilance Program (NPVP), sponsored by WHO and funded by the World Bank, was again instituted for India.

The NPVP was established in January 2005 and is overseen by the National Pharmacovigilance Advisory Committee of the Central Drugs Standards Control Organization (CDSCO). Two regional centers, South West (SW) Regional Center (located at Seth GS Medical College, Mumbai and Department of Clinical Pharmacology, KEM Hospital) and North East (NE) Regional Center, (located at Department of Pharmacology AIIMS, New Delhi) will gather information from across the country and is transmitted to the Commission as well as to the Uppsala Monitoring Center (UMC) in Sweden. Three regional hubs will report to central Mumbai and two to central New Delhi. Each regional center will in turn have a number of peripheral centers (24 in total) attached to it. The plan has three main objectives.

The short-term goal is to promote a culture of reporting, the medium-term goal is to involve a large number of healthcare professionals in the system in the dissemination of information, and the long-term goal is to make the program a global benchmark for drug monitoring. However, this plan also failed.

### IV.INDIA'S CURRENT PV PROGRAM

India's current PV program recognizes the need to revive NPVP and the framework for the new current program was developed in a brainstorming workshop jointly organized by the Department of Pharmacology, AIIMS and CDSCO at the end of 2009. The program, now renamed Pharmacovigilance Initiative of India (PVPI), was launched by the Government of India on July 14, 2010, with AIIMS New Delhi acting as the National Coordinating Center (NCC) for monitoring adverse reactions in the

country to protect public health. In 2010, 22 ADR monitoring centres, including AIIMS in New Delhi, were created under this project.

To ensure more efficient implementation of the program, the NCC was transferred from AIIMS, New Delhi to Indian Pharmacopoeia Commission (IPC), Ghaziabad, Uttar Pradesh on 15 April 2011. Generate independent drug safety data that meets global drug safety monitoring standards.

The latest PVPI AMC report was prepared by VigiFlow's ADR service. In May 2014, the CNC received a total of 3,537 individual case safety reports (ICSRs) and 1,948 post-vaccination adverse events (AESIs) from AMCs. Seven centers received access to VigiFlow from UMC in Sweden. Of the 97 AMCs that operate Vigiflow, 82 have filed traffic complaints via VigiFlow.

PGIMER in Chandigarh recorded the highest number of adverse reaction reports (311 in May 2014), followed by MMC in Chennai with 225. JSS, Mysore 216 reports; 184 reports from UCMS-GTBH, Delhi; 167 LHMC Reports, New Delhi. The report has been assessed by the NCC (qualitative and medical).

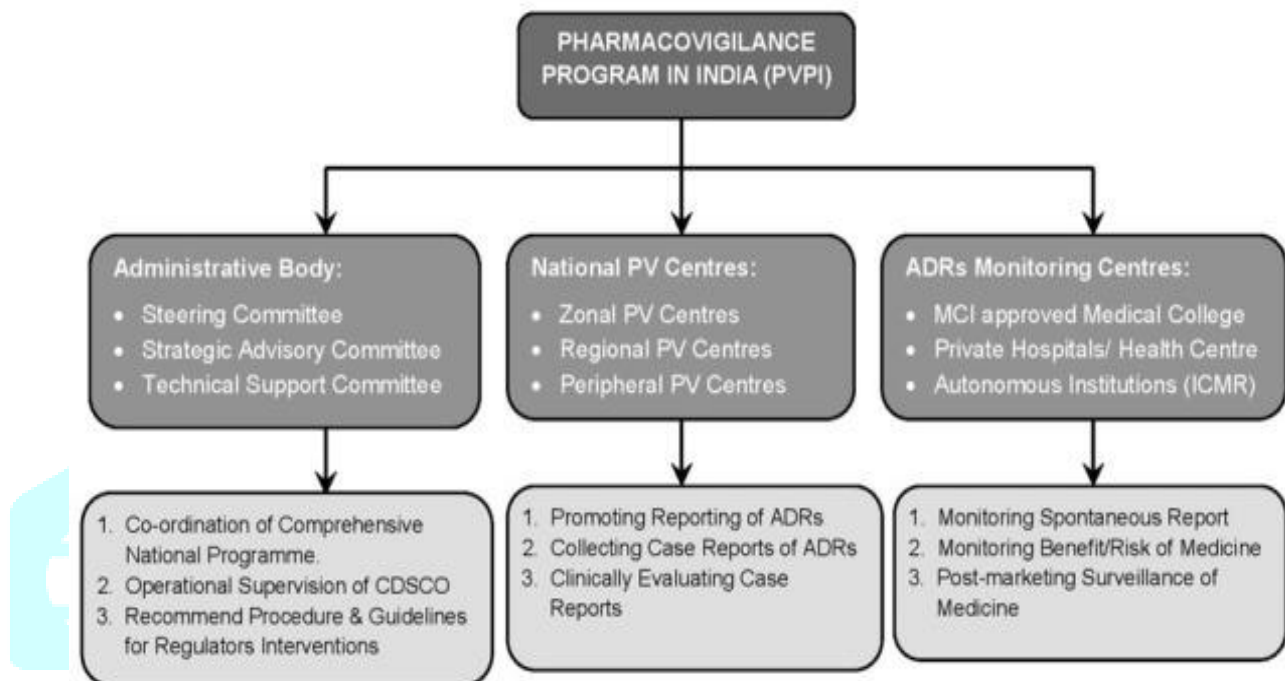


Fig. 1.1: Pharmacovigilance Program In India

The program will be implemented in three phases. The first phase includes 40 ADR monitoring centers (AMC), which will be deployed in 2010 and then, the program will expand in Phase 2 to include up to 140 MCI-accredited medical schools by 2011.

At the end of 2011, only 60 asset managers were included. By 2013, the third phase will cover the entire health system. AMC receives operational and logistical support from their respective CDSCO Regional Centers which are located in Ghaziabad, Kolkata, Mumbai and Chennai. CDSCO Regional Centers will be administratively controlled from CDSCO Headquarters in New Delhi. The organizational structure and related responsibilities of PVPI are shown in Fig.

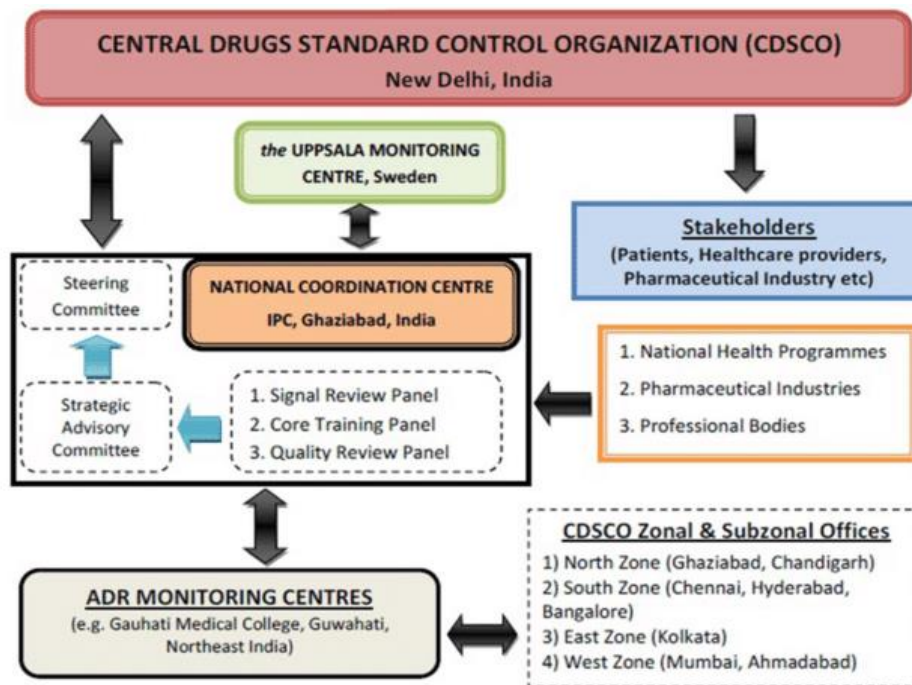


Fig.1.2 : Organisational Structure of PvPI

## V.COMPLICATIONS IN PV PROGRAM

Insufficient PV skills and their challenges include a still conservative infrastructure, large time gaps between guidelines and legislation, orthodox attitudes towards research into new drugs, and virtually non-existent PV and regulatory controls. As India has a highly developed IT sector, the system needed to be perfected in conjunction with Information Technology (IT) with the help of photovoltaic experts. Since PV handles a large number of ADRs, it is wise for PV experts to work with software professionals to develop and build a robust system. Software programs have been developed to collect and analyze data sets to identify trends in drug use, compliance, medication errors, and drug interactions leading to adverse effects in various areas pathological. Additionally, with increasing clinical studies and outsourcing of PV to India, it is worth investing in a robust PV system for DCGI that enables evaluators and decision makers to analyze safety data and inform regulatory decisions without relying on other countries/regions.

However, adverse effects are sometimes not recognized by physicians on admission, and adverse effects can result in the death of many patients. In addition, the financial cost of ADRs to the healthcare system is substantial. In the market, when new drugs are introduced without long-term safety studies by regulators, patients self-medicate more widely and shift from prescription (POM) to over-the-counter (OTC) drugs, which is a major reason for exposure to ADRs.

## VI.CONCLUSION

PV in India has become an important public health issue as regulators, drug manufacturers, consumers and healthcare professionals face many challenges. PV in India is constantly growing, developing and improving. India, the largest drug producer, is now a major center for global clinical trials. It looks like you need a specialization that combines PGx with clinical requirements. This makes it possible to identify the drug and the factors that increase the risk of side effects before starting treatment, and to tailor the drug to each patient. PV also uses data mining techniques for voluntary reporting to national surveillance systems. The PVPI is coordinated to the IPC by the NCC, which is under the control of the Government of India, to generate independent drug safety data that will be aligned with global standards for drug safety monitoring.

Moreover, in India, he is responsible for a whole campaign to improve knowledge about PV and to increase the number of reports of adverse effects up to the reference level set by WHO. Adverse events reported by the PV system can benefit the community due to their proximity to the public and public health practitioners in terms of language and knowledge of patient lifestyles and habits, which facilitates the contact with journalists.

However, improved PV systems are needed to more effectively monitor and act on drug-related safety issues to increase their contribution to public health. Therefore, ensuring that the PV of drug safety enables patients to recover and manage optimally or ideally to avoid disease is a shared responsibility of industry, drug regulators and clinicians, as well as other health professionals. Financial support and future projects will help enable a more inclusive photovoltaic business in India.

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