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PHARMACOVIGILANCE IN INDIA: PERSPECTIVES AND PROSPECTS

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ABSTRACT

Pharmacovigilance (PV) is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. With the growing complexity of drug therapy, PV has become an essential component of public health to ensure the safe and rational use of medicines. This review highlights the history, objectives, processes, methods, challenges, and future perspectives of pharmacovigilance, with special reference to its global and Indian context. In the scenario of ever-increasing range and potency of medicines, safety of medicines is one of the key parameters along with therapeutic efficacy for success of any drug. India is now a preferred clinical trials destination for to be launched drug entities. By keeping in view the increasing incidences, dug related mortality, proper identification, reporting, evaluation and understanding of adverse drug reaction lead to development of pharmacovigilance. It is a branch of pharmacological science critical to effective clinical practices and public health with immense capability for growth. These necessities the utmost need of effective regulations for drug approval and conscious pre and post approval vigilance of undesired effect especially in India. This article summarized aims objectives and methodologies used in pharmacovigilance with a critical overview of existing pharmacovigilance system in India, challenges to overcome and future prospects with respect to Indian context.

KEYWORDS: Adverse drug reaction, Clinical trial, Drug safety, Pharmacovigilance, Post

marketing surveillance.

1. INTRODUCTION

Pharmacovigilance plays a crucial role in monitoring the safety of pharmaceutical products throughout their lifecycle. Despite rigorous preclinical and clinical trials, some adverse drug reactions (ADRs) only become apparent after widespread use in the general population. Therefore, post-marketing surveillance through pharmacovigilance is necessary to identify, assess, and minimize drug-related risks. The term *pharmacovigilance* is derived from the Greek word *"pharmakon"* (drug) and the Latin word *"vigilare"* (to keep watch). The ultimate goal is to promote safe and effective use of medicines and improve patient care and public health. Clinical research industry has grown around the world at an unbelievable rate in the past few years. The main survival point of the pharmaceutical industry is innovation and for introducing new drugs in the market, the companies have to conduct clinical trials as per ICH GCP guidelines as well as guidelines of the country where trial is planned. Pharmacovigilance is an important and integral part of clinical research. Both clinical trials safety and post marketing pharmacovigilance are critical throughout the product lifecycle especially in ensuring the safety.[1] According to the World Health Organization, pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problem, particularly long term and short term adverse effects of medicines.[2] Systematic pharmacovigilance is essential to build up reliable information on the safety of all category medicines for the development of appropriate guidelines for safe effective use. It basically involves identification and evaluation of safety signals. Pharmacovigilance is the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers, pharmaceutical companies and patients on the adverse effects of medications, biologicals, herbal and traditional medicines. Pharmacovigilance is used in different sectors as shown in Fig. 1.

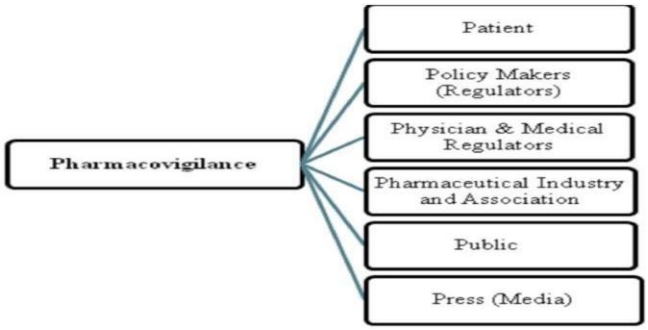

Figure 1: Pharmacovigilance in different sectors.

Pharmacovigilance involves monitoring and assessing the quality of drugs along with detection and prevention of any adverse effect of drugs with following objectives:

- To identify new information about hazards associated with medicines.
- To prevent harm to the patients.
- To improve patient care and safety in relation to the use of medicines, and all medical and paramedical interventions.
- To improve public health and safety in relation to the use of medicines.
- To contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost-effective).
- To promote understanding, education and clinical training in pharmacovigilance and its effective communication to health professionals and the public.[3]
- To identify risk factors and possible mechanisms underlying adverse reactions.
- To estimate quantitative aspects of benefit/risk analysis and dissemination of information needed to improve drug prescribing and regulation.

2. History of Pharmacovigilance

The need for drug safety monitoring emerged after several drug-related tragedies:

- **1937:** Sulfanilamide disaster in the U.S. caused over 100 deaths, leading to the Federal Food, Drug, and Cosmetic Act (1938).
- **1961:** The *thalidomide tragedy*, resulting in birth defects, led to the establishment of formal ADR monitoring systems globally.
- **1968:** The **WHO Programme for International Drug Monitoring (PIDM)** was initiated.
- **1998:** The **Uppsala Monitoring Centre (UMC)** in Sweden was designated as the WHO Collaborating Centre for International Drug Monitoring.[4]

❖ **Early Concerns (Before 1900)**

- **1848 – First documented drug-related death: Hannah Greener**
- A 15-year-old girl, **Hannah Greener**, died after receiving **chloroform** anesthesia for a minor surgery.
- Her sudden death raised questions about **drug safety**, but at that time there was **no system** to collect or analyze such events.
- This incident is considered the **first milestone** in the history of pharmacovigilance.

Late 1800s – Unregulated drug markets

- Medicines were sold with **false claims**, no scientific testing, and no safety checks.
- Many deaths occurred due to contaminated or toxic preparations, but no international mechanism existed to track them.

❖ **Early Regulatory Foundations (1900–1930) 1906 – Pure Food and Drug Act (USA)**

- The first major attempt to regulate drug manufacturing.
- Prohibited **misbranded and adulterated** drugs.
- But still **did not mandate pre-market safety testing**.

- **1911 – US Supreme Court decision**
- Focused only on labeling, not drug efficacy or safety → still insufficient.
- No global movement yet—only country-specific controls existed.

❖ **1937 Sulfanilamide Disaster – The Turning Point Before Modern PV The disaster**

- A company used **diethylene glycol (DEG)** (a toxic solvent used in antifreeze) to
- formulate liquid sulfanilamide.
- Caused **107 deaths**, including many children.

- **Impact**
- Shocked the medical world and public.

- Resulted in the **1938 Federal Food, Drug and Cosmetic Act**
- Mandatory **preclinical safety testing**
- Manufacturers must prove a drug is **safe before marketing**
- This was the beginning of scientific drug regulation, but structured PV still didn't exist.

❖ **The Most Important Event: 1961 Thalidomide Tragedy What happened?**

- Thalidomide was marketed to pregnant women for nausea.
- Caused **severe birth defects** (phocomelia — short or missing limbs).
- Over **10,000 babies** affected in Europe, Australia, and other regions.

- **Significance**
- Exposed the **global lack of ADR monitoring**.
- Showed that even drugs considered "safe" can cause hidden serious effects.
- This tragedy is considered the **birth of modern pharmacovigilance**.

- **Regulatory impact**

Drug approval processes became stricter.

- Required:
- Preclinical testing in pregnancy
- Stricter clinical trial rules
- Ongoing safety monitoring after approval

❖ **1963 – WHO Establishes the International Drug Monitoring Programme**

- After the thalidomide disaster, WHO initiated:
- A program for **international ADR reporting**
- Collaboration between countries to detect **rare adverse reactions**

- **Uppsala Monitoring Centre (UMC), Sweden**
- Established as the **central global PV database**.
- Collects ADR reports from member countries.

- **Birth of spontaneous ADR reporting**
- Doctors, nurses, pharmacists could now report ADRs.
- Led to "yellow card" reporting systems (UK) and similar programs globally.

❖ **Expansion of National PV Systems (1970s–1990s)**

- During these decades:
- Many countries established **national PV centers**.
- ADR forms and cards were standardized.
- WHO expanded its monitoring network to 130+ countries.

- **Important developments**
- **1970s:** UK "Yellow Card Scheme"
- **1980s:** Computerization of ADR data
- **1990s:** International harmonization begins (ICH)

❖ **Global Harmonization (1990–2005)**

- **1990 – Formation of ICH (International Council for Harmonisation)**
- Brought together regulatory authorities and pharmaceutical industry.
- Important guidelines affecting PV:

- **ICH E2A:** Clinical safety data management
- **ICH E2B:** Electronic transmission of ICSRs
- **ICH E2C:** Periodic Safety Update Reports (PSURs)
- **ICH E2E:** Pharmacovigilance planning

- This made PV **structured, uniform, and internationally accepted**.
  - **2005 – Launch of VigiBase**
  - World's **largest ADR database**, maintained by UMC.
  - Stores millions of ADR reports.
  - Supports **signal detection** using statistical tools.

❖ **Strengthening of PV Laws (2005 – Present)**

- **2010–2012 – European Union PV Legislation**
- Among the most advanced globally:
- Mandatory **Risk Management Plans (RMP)**
- Mandatory **Periodic benefit–risk evaluation reports**
- Direct patient reporting of ADRs
- Black triangle symbol for newly monitored drugs

- **US FDA Advances**
- REMS (Risk Evaluation and Mitigation Strategies)
- Sentinel Initiative → real-world data monitoring (claims, EHRs)

- **India's Pharmacovigilance Programme of India (PvPI) – 2010**
- National coordinating centre at IPC Ghaziabad.
- Uses **VigiFlow** for ADR reporting.

❖ **Recent Advances (2015–2025)**

- Pharmacovigilance now expands into:
- **Biologics and biosimilars**
- **Vaccines safety monitoring**
- **AI/ML tools for signal detection**
- **Big data analytics**
- Integration with real-world evidence (RWE)
- COVID-19 vaccine monitoring accelerated global PV

- Near real-time safety monitoring
- Global collaboration and rapid reporting

3. Objectives and role of Pharmacovigilance

1. Detect previously unknown adverse drug reactions.
2. Assess the risk-benefit ratio of marketed drugs.
3. Disseminate information to healthcare professionals and the public.
4. Prevent and minimize harm to patients.
5. Promote rational and safe use of medicines.[5]

Role: The role of pharmacovigilance is to check the safety monitoring in clinical trials involves collecting adverse events, laboratory investigations and details of the clinical examination of patients. Pharmacovigilance staff may be involved to varying degrees in all phases of clinical trials, including the planning, execution, data analysis and reporting of safety.[6] Pharmacovigilance approve the drug regulatory authorities needs to go further than the approval of new medicines, to encompass a wider range of issues relating to the safety of medicines, namely.

- Clinical trials;
- The safety of complementary and traditional medicines, vaccines and biological medicines
- The receipt, processing and reporting of adverse event reports.
- Following-up with reporters to obtain further details about a case report.
- providing an information service to healthcare professionals and patients on product safety; and providing safety expertise to internal cross-functional.[7]

4. Key Components of Pharmacovigilance

4.1 Adverse Drug Reaction (ADR)

An ADR is defined by WHO as a "response to a drug which is noxious and unintended and occurs at doses normally used in humans."

4.2 Signal Detection

Signal detection refers to identifying new or rare ADRs that may indicate a new causal association or a new aspect of a known association.

4.3 Risk Management

Risk management involves strategies to minimize or prevent adverse outcomes, such as patient education, labeling changes, or drug withdrawal.[8]

5. Methods of Pharmacovigilance

5.1 Spontaneous Reporting System (SRS)

Healthcare professionals and consumers voluntarily report suspected ADRs to national centers (e.g., PvPI in India).

5.2 Cohort and Case-Control Studies

Used to establish statistical associations between drug exposure and adverse events.

5.3 Prescription Event Monitoring (PEM)

Observes real-world outcomes of drug usage through prescription tracking.

5.4 Electronic Health Records (EHR) Analysis

Data mining of hospital databases to identify potential ADR patterns.[9]

5.5 Pharmacovigilance of Herbal Medicines

Now a day's herbal medicine are very popular in general public but the safety of these remedies are major issue for public health. The use of herbs in traditional medicines continues to expand rapidly across the world.[9] In various national health-care settings for the health of the patients, herbal products have a very large share almost prescribed medicines.[10] However, mass media reports of adverse events tend to be sensational and give a negative impression regarding the use of herbal medicines in general rather than identifying the causes of these events, which may relate to a variety of issues.[10] Monitoring of herbal safety but require modification to address specific challenges such as botanical nomenclature, quality, adulteration, labeling issues, prescriber/reporter differences and under-reporting.[11]

5.6 Pharmacovigilance Methods

As per International Conference on Harmonization Efficacy Guidelines 2 (ICHE2E) guidelines, the pharmacovigilance methods can be categorized as:

Passive surveillance

(a) Spontaneous reporting system (SRS)

(b) Case series

6. Global Pharmacovigilance Network

- **WHO–UMC**: Collects and analyzes global ADR data through the *VigiBase* database.
- **FDA (USA)**: Maintains *FAERS* (FDA Adverse Event Reporting System).
- **EMA (Europe)**: Uses *EudraVigilance* for ADR monitoring.
- **India**: Operates under the *Pharmacovigilance Programme of India (PvPI)* since 2010, coordinated by the Indian Pharmacopoeia Commission (IPC), Ghaziabad.

7. Pharmacovigilance in India

1. The **PvPI** was launched in 2010 under the Ministry of Health and Family Welfare.
2. **National Coordinating Centre (NCC):** Indian Pharmacopoeia Commission.
3. **Functions:** Collection of ADR reports from hospitals and medical colleges.

- Causality assessment. oSubmission of data to WHO–UMC.
- Training healthcare professionals.

4. ADR Reporting Tools

a. *Suspected ADR Reporting Form*.

b. *ADR mobile app* for consumers and healthcare professionals.

8. Challenges in Pharmacovigilance

1. Underreporting of ADRs.
2. Lack of awareness among healthcare professionals.
3. Limited infrastructure and trained personnel.
4. Difficulty in establishing causality.
5. Variation in regulatory frameworks across countries.

9. Future Perspectives

- Integration of **artificial intelligence** and **machine learning** for signal detection.
- Use of **big data analytics** from electronic health records.
- Encouraging **patient-centric** reporting systems.
- Strengthening **international collaboration** and regulatory harmonization.

10. CONCLUSION

Pharmacovigilance is vital for ensuring drug safety and protecting public health. Continuous monitoring, timely reporting, and regulatory actions are essential to prevent adverse drug outcomes. With the growth of digital health and global communication, pharmacovigilance is

evolving into a proactive and data-driven discipline that will shape the future of drug safety worldwide.

REFERENCES

1. World Health Organization. *The Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products.* WHO, Geneva, 2002.
2. Indian Pharmacopoeia Commission. *Pharmacovigilance Programme of India (PvPI) Annual Report*, 2023.
3. Edwards IR, Aronson JK. *Adverse drug reactions: definitions, diagnosis, and management.* Lancet, 2000; 356(9237): 1255–1259.
4. FDA. *FDA Adverse Event Reporting System (FAERS)*, 2023.
5. EMA. *EudraVigilance Public Access Database (European Medicines Agency)*, 2023.
6. Prakash S, Pharmacovigilance in India, Indian J Pharmacol, 2007; 1: 125-128.
7. Phillips KA, Veenstra DL, Oren E, Potential role of pharmacogenomics in reducing adverse drug reactions: A systematic review, JAMA, 2001; 4: 2270-2279.
8. Goldstein DB, Pharmacogenetics in the laboratory and the clinic, N Engl J Med., 2003; 6: 553-556.
9. Weinshilboum R, Inheritance and drug response, N Engl J Med., 2003; 6: 529-537.
10. Evans WE, McLeod HL, Pharmacogenomics: Drug disposition, drug targets, and side effects, N Engl J Med., 2003; 6: 538-549.
11. De Vane CL, Clinical significance of drug binding, protein binding, and binding displacement drug interactions, Psychopharmacol Bull, 2002; 2: 5-21.