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THE ROLE OF PHARMACOVIGILACE IN ENHANCING DRUG SAFETY: A REVIEW WITH INDIAN PERSPECTIVE

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Pharmacovigilance

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Abstract:

Pharmacovigilance involves monitoring how medicines perform once they are administered to actual patients. Its main aim is to identify unforeseen effects, comprehend their causes, and prevent damage. Although the idea has been informally recognized for many years, it became significantly important after several tragedies related to medications underscored the need for enhanced safety systems. Today, it is a crucial aspect of healthcare that guarantees the advantages of a drug surpass its risks. The goal of pharmacovigilance is to safeguard individuals from adverse drug effects, promote safe prescribing, and inform decisions taken by health authorities. Since clinical trials are conducted with a limited number of participants under controlled circumstances, many side effects only emerge when larger populations start utilizing the medication. Continuous monitoring of safety is crucial. Beyond its scientific significance, pharmacovigilance inherently comes with an ethical obligation—patients have the right to receive treatments that are effective and safe. Adverse drug reactions (ADRs) are undesired effects that may arise after medication usage. These can vary from minor irritations to serious health issues. By monitoring these reactions, healthcare systems can recognize trends, uncover new dangers, and modify treatment guidelines as needed. Each report adds to a broader database, assisting specialists in comprehending how medications function in real-world conditions. In India, a network of monitoring centres facilitates ADR reporting, allowing healthcare professionals and the public to provide information on suspected reactions. These submissions undergo review and validation before being included in both national and international safety databases. This collective data aids global organizations in pinpointing signals and advising on safety protocols.

Keywords: Pharmacovigilance, Adverse Drug Reaction.

Introduction: The phrase "Pharmacovigilance" originated in French during the late 1960s, when it contrasted "Pharmacovigilance intensive" and "Pharmacovigilance spontaneé." Drug safety and Pharmacovigilance continue to be a vibrant area of clinical and scientific inquiry. Pharmacovigilance plays a crucial role throughout clinical trials, including drug development and post-marketing monitoring. (Rathod & Barhate, 2023)The World Health Organization defines pharmacovigilance as the study and activities focused on identifying, evaluating, understanding, and preventing adverse reactions or other potential issues related to medications. It is subject to strict regulations in key regions globally where pharmaceuticals are developed. (Karan et al., 2024)Significant progress in the field of pharmacovigilance has primarily occurred in Western countries, while India has made less advancement. There is a substantial necessity to recognize the significance of pharmacovigilance and its influence on the product lifecycle. Doing so will facilitate the incorporation of effective pharmacovigilance practices into processes and procedures to ensure regulatory adherence and improve safety during clinical trials and post-marketing monitoring. (Singh et al., n.d.)Pharmacovigilance encompasses the science and activities related to locating, evaluating, understanding, and predicting adverse effects or any other possible drug-related concerns. Spontaneous reporting of adverse events and harmful drug reactions is the most common method employed for generating safety data. Pharmacovigilance is responsible for gathering information about upcoming treatments to assess their benefits and risks and to develop strategies to minimize identified risks, ensuring that the anticipated benefits surpass the risks. (Dhingra et al., 2022)

Objectives:

Pharmacovigilance's primary goals are to demonstrate the effectiveness of medications by tracking their adverse effect profile over a long period of time, from the lab to the pharmacy; to improve public health and safety in relation to medication use; to encourage the safe, sensible, and economical use of medications; to advance knowledge, education, and clinical training in pharmacovigilance; and to effectively communicate with the general public.

1. To establish a national reporting system for patient safety.
2. To determine and examine the new signal (ADR) from the cases that have been reported.
3. To produce data on the safety of medications based on evidence.
4. To evaluate the benefit-risk ratio of drugs that are sold.
5. To assist regulatory bodies in making drug-related decisions.
6. To tell different stakeholders about medication safety information in order to reduce the risk.
7. To become a nationally recognized centre for pharmacovigilance initiatives.
8. To assist other national pharmacovigilance programs with training and consulting.
9. To work together for data management and information exchange with other national centres. (Rathod & Barhate, 2023)

Need For Pharmacovigilance:

1. Social concern: Inadequate clinical trial evidence of safety Phase 1-3 research on animal tests before marketing authorization.
2. Drugs are meant to save lives. While it is unacceptable to die from a medication, it is occasionally unavoidable to die from a condition.
3. The cost of ADRs to the nation is more than the cost of the drugs.
4. Encouraging adherence and sensible medication use.
5. Maintaining public trust.
6. Ethics: It is unethical to know anything that could hurt someone who doesn't know and to keep it a secret. (Singh et al., n.d.)

History of Pharmacovigilance:

In India, pharmacovigilance started in 1986. With 12 regional centres, each serving a population of 50 million, a formal Adverse Drug Reactions (ADR) monitoring system was established. But no significant progress was made. India then joined the World Health Organization's (WHO) Adverse Drug Reaction (ADR) scrutiny program in Uppsala, Sweden, in 1997, but it was unsuccessful. Thus, the National Pharmacovigilance Programme (NPPV) of India was launched in 2005 with funding from the World Bank and WHO. (Rathod & Barhate, 2023)

Sr. No.	Duration	Event	Description
1	1950s–1960s	Thalidomide Tragedy	Thalidomide, prescribed as a sedative and antiemetic, caused severe birth defects in thousands of infants. This disaster highlighted

			the need for systematic drug safety monitoring and increased awareness of drug risks during pregnancy.
2	1968	Formation of WHO Programme	WHO established the International Drug Monitoring Programme after the thalidomide incident, creating a global network of pharmacovigilance centres for collecting and analysing ADR data.
3	1970s	FDA and AERS	The FDA launched the Adverse Event Reporting System (AERS) to collect, manage, and analyse drug-related adverse events in the U.S., strengthening drug safety monitoring.
4	1990s	ICH Guidelines	The International Conference on Harmonisation (ICH) standardized global pharmacovigilance practices. Guidelines like ICH E2B enabled harmonized safety data collection and exchange.
5	2005	EU Pharmacovigilance System	The European Union developed a comprehensive pharmacovigilance system coordinated by the EMA to improve safety assessments, monitoring, and risk-management strategies.
6	2000s onward	Periodic Safety Update Reports (PSURs)	PSURs became mandatory for marketing authorization holders, allowing regulators to continuously evaluate the ongoing safety profile of medicines.
7	21st Century	Digital Age & Signal Detection	Advancements in technology enabled the use of big data, digital platforms, algorithms, and data mining for automated signal detection and improved identification of potential safety concerns.
8	Current era	Global Collaboration	Modern pharmacovigilance emphasizes worldwide cooperation. WHO's system enables standardized exchange of ICSRs across countries, involving regulators, industry, healthcare professionals, and patients in ensuring safe medicine use.

Table No. 1 (Vishwakarma et al., 2024)

Goals of PV:

- Short Term goals:
  1. To create and execute an Indian pharmacovigilance system.
  2. To motivate medical personnel to report adverse medication, vaccination, medical device, and biological product reactions.
  3. To gather data and case reports.
- Long term goals:
  1. The pharmacovigilance program would be extended to all Indian hospitals and public health program centres.
  2. Making it essential to inform medical professionals of any negative effects.
  3. The creation of an electronic reporting system. (Karan et al., 2024)

Challenges:

1. Adverse Drug Reaction Underreporting: The underreporting of adverse drug reactions (ADRs) is one of the biggest issues in pharmacovigilance. Research indicates that only a small portion of adverse drug reactions (ADRs) are reported to regulatory bodies, creating gaps in the safety profiles of pharmaceuticals.

2. Time restrictions, the belief that adverse drug reactions (ADRs) are not severe enough to require reporting, and healthcare personnel' ignorance of reporting standards are two factors that lead to underreporting. Additionally, patients might not understand how important it is to record their pharmaceutical experiences. This underreporting may make it more difficult to identify warning signs and postpone important regulatory responses.
3. Data Quality and Integrity
   Another challenge is ensuring the quality and integrity of data collected through pharmacovigilance systems. Variability in the quality of data submitted by different sources, inconsistent reporting formats, and a lack of standardized definitions for adverse drug reactions (ADRs) can make it difficult to analyse and interpret data. [10] Also, electronic reporting systems may have technical problems that compromise data accuracy. Ensuring high data quality is essential for effective signal detection and risk assessment, as poor-quality data can lead to misleading conclusions regarding drug safety.
4. Integration of Real-World Evidence
   Real-world evidence (RWE) integration into safety monitoring procedures offers both opportunities and challenges as pharmacovigilance develops. RWE can improve knowledge of medication safety in a variety of populations and long-term usage scenarios since it is based on real-world data, such as electronic health records and patient databases. However, real-world data can be difficult to understand and analyse due to its heterogeneity, and worries about data security and privacy are still quite important. (Chauhan et al., 2024)

Future Aspects:

It is essential to create systems that can efficiently identify novel adverse drug reactions (ADRs) and carry out regulatory measures to protect public health as pharmacovigilance (PV) develops. Information that helps patients and healthcare providers make decisions has not received enough attention. One of PV's main goals is to gather and distribute safety information, especially using active surveillance techniques. It is essential to collect comprehensive and accurate data on each significant reported occurrence while developing new active post-marketing surveillance approaches. PV should prioritize patients as important information sources in the future, in addition to more conventional sources like medical experts. By incorporating Good Pharmacovigilance standards (GPP) into procedures that guarantee regulatory compliance and promote clinical trial safety and post-marketing surveillance, the Drug Controller General of India (DCGI) should move quickly to improve PV standards. Healthcare providers, regulatory bodies, pharmaceutical businesses, and consumers all gain from the responsible use of medications, which requires an efficient PV system. For both the industry and regulatory bodies, post-marketing PV is currently a difficult and time-consuming procedure. PV prioritizes new and important safety issues while effectively receiving and documenting information online. Even though they are regularly screened, non-serious events are not as important as severe ones. For example, GlaxoSmithKline has developed a novel PV strategy that blends imbalance and data visualization tools with conventional case-based techniques. This approach improves knowledge management by enabling real-time examination and tracking of safety issues. (R. Waghmare, 2024)

Adverse Drug Reactions: Adverse drug reactions (ADRs) are unintended and harmful effects of medications that pose a significant threat to patient safety. Monitoring and reporting these reactions are a critical component of pharmacovigilance, aiming to ensure safe and effective drug use. (A. kumar, 2025)

Individual differences in drug metabolism, interactions with other drugs or substances, allergies, dosage mistakes, or underlying medical disorders are some of the causes of adverse drug reactions (ADRs). Nausea, dizziness, skin rashes, gastrointestinal issues, and allergic responses are a few typical ADRs. ADRs can cause organ damage, anaphylaxis, or even death in more serious situations. Because ADRs can affect patient safety and treatment outcomes, it is essential to track and understand them in the healthcare industry. The technique of tracking and assessing medication safety, or pharmacovigilance, is crucial for identifying and controlling adverse drug responses. In order to evaluate drug safety profiles, update drug labels, and make well-informed decisions regarding the continued use of drugs, pharmacovigilance allows regulatory bodies and medical experts to gather and analyse data on adverse drug reactions (ADRs) (Tadge et al., 2023). PvPI's primary duty in India is to play a significant role and encourage the optimal use of medications in order to prevent adverse drug reactions. PvPI is in charge of educating the public about adverse medication reactions brought on by active pharmaceutical ingredients. 8 Individuals are being motivated to come forward and report unwanted drug reactions. Every Indian citizen can report an adverse medication reaction to the NCC by filling out a

specific form that is available in multiple languages for healthcare professionals. 9. Adverse Drug Monitoring Centres (AMCs) are currently operational throughout India. (Sahu & Das, 2024)

Benefits of ADR monitoring:

1. It caters data around quality and security of pharmaceutical items.
2. It starts risk-management plans.
3. It anticipates the unsurprising unfavourable impacts and makes a difference in measuring ADR adherence.
4. It instrument wellbeing care group i.e., patients, drug specialists and medical caretakers approximately antagonistic medicate Impacts and makes mindfulness with respect to ADRs.(Hailu & Mohammed, 2020)

Analysis of ADR:

Information To determine the likelihood and seriousness of reported or suspected ADRs, the data must be analysed once it has been gathered. For efficient monitoring and reaction, techniques for classifying each ADR according to these criteria must be developed [33]. Additionally, the incorporation of AI/ML into systems such as ARIS G and ARGUS has enhanced the quality of causality evaluations in individual case safety reports (ICSRs), making it easier to detect any safety issues early on and improving the precision of regulatory reporting. (A. kumar, 2025)

ADR Monitoring Process:

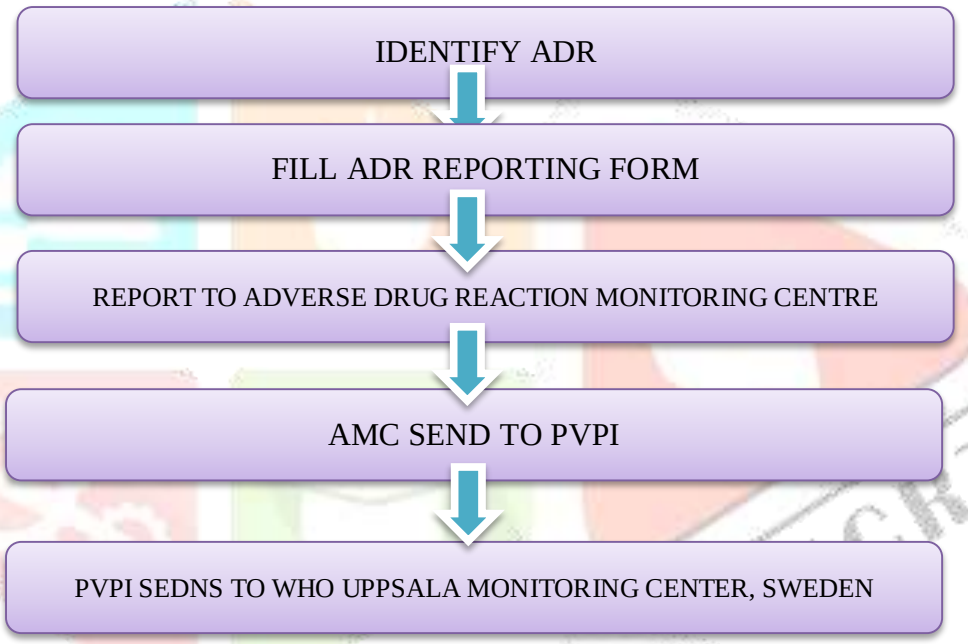

Figure No.1

Types of ADR:

Type	Name	Key Features	Example
Type A	**Augmented**	Dose-dependent, predictable from known pharmacology	Hypoglycaemia from insulin; bleeding from warfarin
Type B	**Bizarre**	Not dose-dependent, unpredictable, often immunologic or idiosyncratic	Anaphylaxis to penicillin; Stevens-Johnson syndrome
Type C	**Chronic**	Occurs after long-term therapy	Adrenal suppression from prolonged corticosteroid use
Type D	**Delayed**	Occurs after some time, even after stopping drug	Carcinogenic effect of alkylating agents; teratogenicity
Type E	**End-of-Use (Withdrawal)**	Effects after sudden discontinuation	Withdrawal seizures after stopping benzodiazepines

Type F	**Failure of Therapy**	Unexpected failure of drug efficacy	Antibiotic resistance leading to treatment failure
Type G	**Genotoxic**	DNA-damaging, mutation-related effects	Chemotherapy-induced secondary malignancies
Type H	**Hypersensitivity**	Immune-mediated, immediate or delayed	Type I–IV hypersensitivity reactions
Type I	**Drug–Drug Interaction (DDI)**	Reaction due to interaction with another drug	Warfarin + NSAID → increased bleeding
Type J	**Drug–Drug–Disease Interaction**	Reaction due to drug plus underlying disease	Beta-blockers worsening asthma
Type K	**Kinetic (Pharmacokinetic issues)**	Issues with absorption, metabolism, excretion	Toxicity due to CYP450 inhibition

Table no. 02

Adverse Drug Reaction Monitoring in India:

In order to improve safety and public health, it is the primary duty of healthcare professionals to report adverse drug reactions produced by marketed drugs. All Indian citizens should be aware of adverse drug reactions and how to report them. 11 PvPI encourages people to report any suspected adverse drug response related to pharmaceutical products, despite whether the reaction is known or unknown, severe or moderate, frequent or uncommon. If someone experiences an adverse drug reaction, they should report it right away. The healthcare provider can complete the suspected adverse drug reaction form and submit it to AMC if any incidents involving a certain medication occur while they are caring for the patients. In addition, patients can visit the nearest AMC under PvPI to report an adverse drug reaction. The IPC's official website has information about AMCs. A form known as "Suspected Adverse Drug Reaction" is available for medical personnel to report ADRs.

Adverse Drug Monitoring Centres (AMCs)

The AMCs are established under NCC to gather patient ADRs. The goal is to identify any adverse medication reactions that were missed in previous clinical trial programs. NCC gives AMCs the personnel and logistical support they need to manage adverse medication reactions. Many AMCs are currently in operation throughout the nation and are connected to CDSCO in India. CDSCO complies with AMCs' technical support and administration standards in order to report adverse medication reactions. 16. With time the numbers of AMCs are expanding to coping with the importance in monitoring and reporting of adverse medication reaction. AMCs actively use the software provided by WHO UMC to report Individual Case Safety Reports and adverse medication reactions. The WHO Drug Dictionary and WHO-Adverse Reaction Terminologies are supported by the most recent version of this software, which enables manual data entry. 17th AMC is made up of PvPI employees because it functions as a committee. The first is the Co-ordinator (Department of Pharmacology), who is responsible for monitoring the general operations of AMC. (Sahu & Das, 2024)

Conclusion:

Pharmacovigilance plays an essential role in ensuring that medicines remain safe for everyone who uses them. Even though drugs undergo many tests before they reach the market, some reactions only become visible when large numbers of people start taking them. This makes continuous monitoring extremely important. By paying attention to unexpected effects and sharing this information, healthcare systems can protect patients, improve treatment decisions, and prevent avoidable harm. Adverse drug reaction monitoring helps identify new risks early, supports regulatory action, and builds public trust in medicines. India’s growing network of ADR Monitoring Centres and the efforts of healthcare workers, pharmacists, and citizens have strengthened the national safety system. When people report their experiences, it creates a clearer picture of how medicines behave in real-life settings, helping experts make better decisions about their use. Although challenges like underreporting and inconsistent data still exist, improving awareness, simplifying reporting, and using modern

technology can make the system more efficient. A strong pharmacovigilance program benefits everyone—patients, healthcare professionals, pharmaceutical companies, and regulators. Ultimately, the goal is simple: to ensure that every medicine used in the country offers maximum benefit with minimal risk, supporting safer healthcare for all.

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