Review Article

Pharmacovigilance and Adverse Drug Reaction Monitoring: A Review

Chaitali.S.Dalavi,* Omkar.A.Devade, Dr.Prakash.D.Jadhav, Sonali.T.Kolekar, Nikita.C.Mohite, Rahim.M.Shaikh, Vaishnavi.V.Bhosale
Yashoda Technical Campus, College of Pharmacy, Satara, Dist- Satara Maharashtra, India.
***Corresponding author's E-mail:** dalavichaitali36@gmail.com

Received: 06-03-2026; **Revised:** 18-05-2026; **Accepted:** 25-05-2026; **Published online:** 20-06-2026.

ABSTRACT

Pharmacovigilance supports safe and appropriate use of drugs. Spontaneous reporting of adverse drug reactions (ADRs) is an essential component of pharmacovigilance. However, there is significant underreporting of ADRs. Adverse drug reactions have become a major problem in developing countries. Knowledge of pharmacovigilance could form the basis for interventions aimed at improving reporting rates and decreasing ADRs. Pharmacovigilance, the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems, is intrinsically linked to effective information management. The pivotal role of information in pharmacovigilance encompasses data collection, analysis, and dissemination for optimal patient safety. The foundation of pharmacovigilance lies in robust information system that facilitates the collection of adverse event reports from healthcare professionals, patients, and other stakeholders. The evolution of data sources, emphasizing the integration of electronic health records, wearable devices and real-world evidence to enhance the depth and breadth of information available for analysis. Innovative technologies, including artificial intelligence and machine learning, are transforming pharmacovigilance by automating signal detection and predictive modeling. How those tools are utilized to sift through vast datasets, identifying potential safety concerns and aiding regulatory decision-making. Furthermore, the abstract delves into the importance of structured information sharing between regulatory agencies, pharmaceutical companies, and healthcare providers. Timely transparent communications of safety information ensure a proactive response to emerging risk and enable the development of effective risk management strategies.

Keywords: Adverse drug reaction, Pharmacovigilance, Reporting, healthcare professionals, patients.

INTRODUCTION

The word pharmacovigilance comes from two older words: the Greek word pharmakon, meaning drug or medicine, and the Latin word vigilare, meaning to keep watch. Pharmacovigilance is a very important part of the drug development process. It means carefully watching and studying the side effects or any problems that may happen when people use medicines.

This helps protect patients by checking the risks and benefits of each drug. Thanks to modern technology, pharmacovigilance has become better and faster. It helps make sure that medicines are safe, work well, and are cost-effective—not just when they are first developed, but also after they are released for public use.[1]

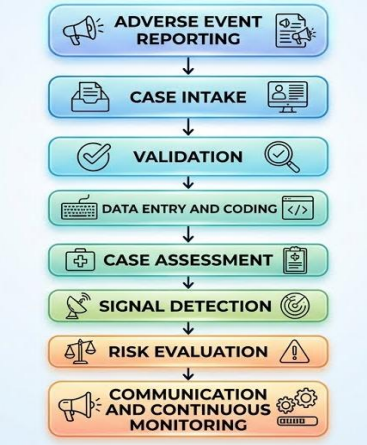

Figure 1: Pharmacovigilance Process

History:

Certainly, let's delve into more detail on the key points in the history of pharmacovigilance

Thalidomide Tragedy (1950s-1960s): Thalidomide was a medicine given to help people sleep and to treat morning sickness during pregnancy. But it caused serious birth defects in thousands of babies. This disaster showed how important it is to carefully check the safety of medicines, especially for pregnant women. After this, people became more aware of the dangers some drugs can cause.

Formation of WHO Program (1968): After the thalidomide disaster, the World Health Organization (WHO) started the International Drug Monitoring Program in 1968. This program helped create a worldwide system where countries work together to collect and study information about harmful side effects from medicines.

FDA and AERS (1970s): In the 1970s, the FDA started the Adverse Event Reporting System (AERS). This system became an important way to collect and study reports of harmful side effects from medicines. It helps the FDA keep track of drug safety and protect people's health in the United States.

ICH Guidelines (1990s): The International Conference on Harmonization (ICH) helped make drug safety rules more consistent around the world. Its guidelines, like E2B, created a common way to collect and share safety information about medicines. This made it easier for countries to work together to keep drugs safe.

EU Pharmacovigilance system (2005): The European Union set up a strong system to watch and check the safety of medicines. The European Medicines Agency (EMA) led this effort by helping to review safety information and manage any risks related to medicines.

Periodic safety update reports (PSURs): PSURs (Periodic Safety Update Reports) became a regular requirement for companies that sell medicines. These reports are sent to drug safety authorities and include updated information about the medicine's safety. This helps make sure the medicine stays safe for use throughout its time on the market.

Digital Era and Signal Detection (21st century): In the 21st century, new technology made it easier to use big data and digital tools in drug safety. Automated systems, using computer programs and data analysis, helped find possible safety problems faster and more accurately by looking through large amounts of information.

Global collaboration (present): Modern drug safety focuses on working together globally. Programs like the WHO's Individual Case Safety Reports (ICSRs) platform help countries share safety information in a standard way. This teamwork includes drug companies, health agencies, doctors, and patients all working together to keep medicines safe.[2]

Objective:

Monitoring Adverse Effects: Continues surveillance to detect and evaluate adverse drug reactions (ADRs) that arise during the use of medications.

Assessment Of Risk and Benefits: Analyzing the risk-to-benefit ratio of drugs to ensure that the therapeutic benefits outweigh potential risks or adverse effects.

Data Collection and Analysis: Systematically gathering and analyzing information on medication safety, including reports from healthcare providers, patients, and clinical trials.

Risk Management and Mitigation: Developing strategies to manage and minimize risks associated with medications, such as updating labeling ,implementing risk minimization plans, or even withdrawing drugs from the market if necessary.

Promoting Safe Use of Medications: Educating healthcare professionals and patients about the safe and effective use of medications, including appropriate dosing, administration ,and monitoring.

Communication and Information Dissemination: Facilitating the dissemination of safety information to healthcare providers regulatory agencies, and the public to ensure informed decisions-making about medication use.

Regulatory Compliance: Ensuring compliance with regulatory requirements related to drug safety monitoring and reporting.

Post Marketing surveillance: - monitoring the safety of medications after they are approved and made available in the market to identify rare or long- term adverse effects that might not have been evident during clinical trials. It's about promoting, learning, training and clear communication about drug safety to healthcare professionals and the public. It involves recognizing medication-related issues and effectively sharing that information in a way that's easy to understand.

Pharmacovigilance Program of India:

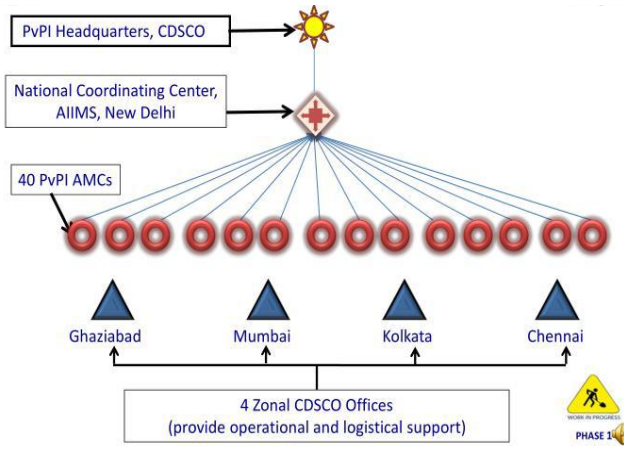

Figure 2: Pharmacovigilance Program of India (PVPI)

Pharmacovigilance Program of India (PVPI):

- PvPI is based on India's drug laws called the Drugs and Cosmetics Act (1940) and Rules

(1945).

- The program is run by the Central Drugs Standard Control Organization (CDSCO), which is the top authority in India for drug and medical device safety.
- The main goal of PvPI is to watch for harmful side effects from medicines (called adverse drug reactions or ADRs) to keep patients safe.

How PVPI Works:

- The National Coordinating Centre (NCC) manages the program and collects reports about side effects from doctors, patients, and drug companies.
- Across India, there are Regional Adverse Drug Reaction Monitoring Centres (AMCs) that collect and check these reports before sending them to the NCC.
- Reporting is made easy with an online platform by CDSCO, so healthcare workers and the public can send reports easily.

What PVPI Does:

- PVPI carefully studies the data using statistics and medical reviews to find any new safety problems with medicines.
- It shares important safety information through newsletters, alerts, and training to keep doctors and the public informed.

- PVPI also works with international drug safety groups to share information and learn from others.
- Training programs help doctors and healthcare workers understand how to report side effects and improve drug safety in India.

History Of Pharmacovigilance In India:

- India started focusing on medicine safety relatively late because there was no system for monitoring medicine side effects before.
- In 1986, some doctors asked for better attention to medicine side effects and proper prescribing. This led to the first ADR monitoring program with 12 regional centers, but it didn't work well.
- In 1997, India joined the WHO's global drug safety program and set up three centers in big hospitals to report side effects. But these centers didn't work properly because doctors didn't know about them, and there was no government funding.
- Finally, on January 1, 2005, India started the National Pharmacovigilance Program (NPVP), supported by WHO and the World Bank, which became the foundation for today's PVPI. [4,5,6]

INTRODUCTION TO ADVERSE DRUG REACTION

Definition Of ADR:

The International Conference on Harmonization, which includes groups like the WHO and the FDA, defines an adverse drug reaction (ADR) as: A harmful and unintended reaction that happens when a medicine is taken at the normal dose to prevent, diagnose, or treat a disease or to change how the body works. [7]

Classification of ADR:

Table 1: Classification of ADR

Type	Name	Simple Meaning	Example
A	Augmented	Expected side effect, gets worse with higher dose	Too much bleeding with blood thinners (e.g., warfarin)
B	Bizarre	Strange, unpredictable reaction (not related to normal effect of the drug)	Allergic rash, asthma from aspirin
C	Chronic / Chemical	Happens because of long-term use or how the body handles the drug	Liver damage from paracetamol overdose
D	Delayed	Shows up months or years later	Cancer years after taking some drugs (e.g., cyclophosphamide → bladder cancer)
E	End-of-treatment	Happens when you suddenly stop the medicine	Seizures after stopping phenytoin suddenly

Adverse Drug Reaction Detection in India

Reporting Adverse Drug Reactions (ADRs) in India:

- It is very important for healthcare professionals (like doctors and nurses) to report any harmful side effects caused by medicines. This helps protect public health and makes medicines safer.
- But not only healthcare workers—everyone in India should know about adverse drug reactions and how to report them.
- The Pharmacovigilance Program of India (PvPI) encourages people to report any suspected side effects from medicines, whether they are well-known or new, mild or serious, common or rare. If someone experiences a side effect, they should report it right away.How to Report ADRs:
- If a healthcare professional notices a side effect while treating a patient, they can fill out a "Suspected Adverse Drug Reaction Reporting Form" and send it to the nearest Adverse Drug Reaction Monitoring Centre (AMC).
- Patients, family members, or any citizen can also report side effects by visiting the nearest AMC under PvPI.
- Details about all the AMCs are available on the official website of the Indian Pharmacopoeia Commission (IPC).
- There are special forms for reporting: one for healthcare professionals and another for patients and the public. These forms can be found online (links are usually provided on official sites).
- Reports can also be sent by email to the official PvPI email address.
- To make reporting easier, there is a toll-free helpline number where people can call and report side effects.
- Additionally, there is a mobile app available on the Google Play Store that allows easy digital reporting of adverse drug reactions.[9,10]

Committees Responsible for Adverse Drug Monitoring:

In India, different committees have been created to watch for medicine side effects and make sure drug safety programs run smoothly. These groups help manage and control any problems with medicines and play an important role in making sure drug safety efforts work well. These committees include the Adverse Drug Reaction Monitoring Centres (AMCs) and the Uppsala Monitoring Centre (UMC), working together to keep medicine safety organized and effective.[11,12]

Table 2: ADR Monitoring Center

ADR Monitoring Centre	State
Department of pharmacology, All India Institute of Medical Science	New Delhi
Department of pharmacology, PGIMER	Chandigarh
Department of pharmacology, R.G.Kar Medical College	Kolkata
Department of Clinical Pharmacology, Lady Hardinge Medical College	Kolkata
Department of Clinical Pharmacy, JSS Medical College Hospital	Karnataka
Institute of pharmacology, Madras Medical College	Chennai
Department of pharmacology, SAIMS Medical College	Indore -Ujjain

Reporting ADR Approaches:What to report

These are considered as the adverse drug events which should be reported to the nearer hospital or reporting centres.[13]

Death and deadly events.

If patients get hospitalized due to drug's adverse reaction. Fetal abnormality due to certain drug.

If physician, consider any particular health event as a harmful event. If the drugs lacking efficacy.

Any drug action which is suspect

When to report

Any spontaneous events needed to be reported within 10 days.

Any adverse drug event which is suspected needs to be reported as soon as possible. Unfortunate death due to adverse reaction should be reported immediately.

Other adverse drug reactions should be reported within one week.

Any adverse drug reactions which are non-serious should be reported within 30 days.

Reporting delay leads to create more problems. So, as far as possible immediate reporting considered as ideal decision. [14]

How to report

There is a form called "Suspected Adverse Drug Reaction Reporting Form" available for healthcare professionals. (Given in "adverse drug reaction monitoring in India)

The for which is available for consumers is "Medicines Side Effect Reporting Form" (given in "adverse drug reaction monitoring in India").[13]

Causality assessment:

Causality evaluation of Adverse Drug Reactions (ADRs) includes deciding the probability of a causal connection between a medication and an unfavorable drug effect. In an early study, it was seen that there are 34 exceptional procedures for the causality assessment of ADRs.[15] ADRs are accidental and unsafe impacts that happen when a patient is taking medication, these scales and algorithms are used to assess the ADRs, and drug safety:

- The Wilholm et al. Method 1984.
- Dangaumou's french method.
- Kramer et al. 1974 method.
- Lagier et al. method / Balanced assessment method (Lagier et al. 1983).
- STP: Summary time plot/Castle et al method (Castle et al. 1984).
- Cibageigy method (Venulet et al.1980).
- Loupi et al. 1986 method.
- M and V Scale: The Maria and Victorino scale.
- Australian method.
- The WHO-UMC: WHO-Uppsala Monitoring Centre causality assessment system.
- Drug Interaction Probability Scale (DIPS).
- Bayesian Adverse Reactions Diagnostic Instrument (BARDI).
- MacBARDI spreadsheet.
- Causality assessment of vaccine-related adverse events.
- Karch and lasagna scale.
- Begaud algorithm.
- Hallas scale.
- PRISCUS list.
- RUCAM scale.
- CIOMS scale.
- Liverpool ADR scale.
- VAS: Visual Analogue Scale (Miremont et al. 1994).
- Blanc et al.
- Emanueli and sacchetti.
- Stephen's algorithm.

Severity and seriousness assessment:

Severity describes the extent to which the ADRs influence the everyday life of the patients. J Seigel and PJ Schneider categorized ADRs into seven levels of severity. Levels 1 and 2 are less severe, Levels 3 and 4 are moderate, and Levels 5, 6 and 7 are classified as severe. Karch and Lasanga classify severity into minor, moderate, severe and lethal. In minor severity, there is no need of antidote, therapy or prolongation of hospitalization. Moderate severity requires a change in the drug therapy, specific treatment or an increase in hospitalization by at least 1 day. Severe class includes all potentially life threatening reactions causing permanent damage or requiring intensive medical care. Lethal reactions are the ones that directly or indirectly contribute to death of the patient. [16,17,18]

Table 3: Severity and seriousness assessment

Level	What It Means (Simple Words)	Example
1	Side effect happened, but we didn't need to stop or change the medicine	Mild itching, no action needed
2	Had to stop or change the medicine, but no extra treatment or longer hospital stay	Rash → stopped the drug, that's all
3	Had to stop/change the drug AND gave some treatment (like antidote), but hospital stay same	Severe allergy → gave steroid injection
4	Same as Level 3, but patient had to stay in hospital longer (at least 1 extra day) OR the side effect was the reason for admission	Drug caused serious problem → admitted or stayed longer
5	Patient needed ICU / intensive care because of the reaction	Went into shock, needed ventilator
6	Side effect caused permanent damage (e.g., lost kidney function, blindness, etc.)	Permanent disability
7	Patient died because of the reaction (directly or indirectly)	Death

Predictability And Preventability Assessment:

Preventability of ADRs was analysed by Modified Schumock and Thornton scale by using nine point scale based on history of allergy, appropriateness of drug for clinical

condition, dose, frequency, route of administration as per patient's age, weight and disease state, laboratory levels for toxic serum concentration and based known treatment of ADR, Drug interactions, poor compliance and preventive measure for ADR prevention was also taken into account.[19]

Severity of ADRs was assessed by Modified Hartwig and Siegel Scale which contain seven levels and classify the ADR as Mild/Moderate/Severe.[20] Mild ADR is an ADR which requires no change in treatment with the suspected drug and/or requires treatment with the suspected drug be held, discontinued, or otherwise changed and in addition no antidote or other treatment was required, without increase in length of stay. Moderate ADR is that requires treatment with the suspected drug be held, discontinued or otherwise changed and antidote or other treatment was required without increase in length of stay/ADR which increases length of stay by at least a day/ADR was the reason for hospitalization. Severe ADR is the ADR which requires intensive medical care/cause permanent harm to the patient/directly or indirectly led to death of the patient.[20]

Predictability of ADRs was assessed as per types of ADR i.e., Type A/Type B/Type C/Type D.[20]

Prevention of Adverse Drug Reaction:

Anticipation by patient monitoring Ex- anemia- due to deficiency of G6PD, check the condition. Anticipation of dosage reeducation Ex- impaired renal / liver function – dosage should reduce. Monitoring the serum levels(drug) Ex- theophylline, aminoglycosides.

Monitoring of pharmacological activity (extensive Pharmacology activity) Ex- diuretics- to promote salt & water loss, but causes electrolyte depletion & dehydration.[21]

Minimizing non-preventable-Idiosyncratic / hypersensitivity not preventable.

Can be done by carful observation / monitoring of patient Ex- patient with meningitis

- Should be with penicillin. Chemotherapy – nausea.[22]

Management of Adverse Drug Reaction:

Confirmation of the ADRs: indicate what assisted in confirming the suspected adverse reactions.

For example:

Drug reactions confirmed by disappearance of the reaction after stopping administration of the drug or reducing the doses.

Recovery on withdrawal of suspected drug(s) if no other drug is withdrawn and no therapy given. Recovery follows treatment of the reaction in addition to withdrawal of drug.

Mention the criteria for regarding the reaction as serious

Mention any treatment given to the patient after experiencing the ADRs.

Outcome: indicate the outcome of the adverse reaction by marking X in the appropriate box with dates.[23]

Aim and Objectives

To disclose the quality and frequency of ADRs and to identify the risk factors that can cause the adverse reactions.

To improve patient care and safety in relation to the use of medicines. To improve public health and safety in relation to the use of medicines.

To identify new reactions, record the frequency with which they are reported. To evaluate factors that may increase risk of ADR.

To provide information to prescribers with a view to preventing future ADRs. To prevent predictable adverse effects and helps in measuring ADR incidence. To get information about quality and safety of Pharmaceutical products.

To detect, collect, assess, and monitor the adverse effect.

Table 4: Nine examples of serious & unexpected ADR cause to drugs [24]

Sr. No.	Drug	Year	Serious & unexpected adverse event
1	Chloroform (Anaesthetic)	1848	Episode of ventricular fibrillation & death
2	Sulphanilamide (Elixir)	1937	Death
3	Thalidomide	1961	Amelia, phocomelia & dysmelia
4	Clioquinol	1970	Subacute nephropathy
5	Practolol	1975	Sclerosing peritonitis
6	Benoxaprofen	1982	Nephrotoxicity & cholestatic jaundice
7	Terfenadine	1997	Torsade de pointes
8	Rofecoxib	2004	Cardiovascular effects
9	Veralipride	2007	Anxiety, depression & movement disorders

Basic Terminologies Used in Pharmacovigilance

Terminologies Of Adverse Medication Related Events:

Absolute risk: Risk in a population of exposed persons; the probability of an event affecting members of a particular population (e.g. 1 in 1,000). Absolute risk can be measured over time (incidence) or at a given time (prevalence).

Adverse event: Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship

with this treatment.

Allopathy: Non-traditional, western scientific therapy, usually using synthesized ingredients, but may also contain a purified active ingredient extracted from a plant or other natural source; usually in opposition to the disease.

Association: Events associated in time but not necessarily linked as cause and effect.

Attributable risk: Difference between the risk in an exposed population (absolute risk) and the risk in an unexposed population (reference risk), also referred to as excess risk. Attributable risk is the result of an absolute comparison between outcome frequency measurements, such as incidence. Examples: If the exposed persons with a particular outcome are A, the exposed persons without the outcome are B, the unexposed persons with the outcome are C and the unexposed persons with the outcome are D, then the attributable risk is calculated as: (A+B)] - [C / (C+D)]. If, during the same time period, the incidence of rash in a population treated with medicine X is 35/1,500=0.023, and the incidence of rash in a population not treated with X is 5/2,000=0.0025, the attributable risk is (35/1,500) - (5/2,000) = 0.0205.

Causal relationship: A relationship between one phenomenon or event (A) and another (B) in which A precedes and causes B. In pharmacovigilance; a medicine causing an adverse reaction.

Causality assessment: The evaluation of the likelihood that a medicine was the causative agent of an observed adverse reaction. Causality assessment is usually made according established algorithms.

Drug Abuse: It is a patterned use of a drug in which the user consumes the substance in amounts or with methods neither approved nor supervised by medical professionals.

Effectiveness/risk: The balance between the rates of effectiveness of a medicine versus the risk of harm is a quantitative assessment of the merit of a medicine used in routine clinical practice. Comparative information between therapies is most useful. This is more useful than the efficacy and hazard predictions from pre-marketing information that is limited and based on selected subjects.

Efficacy: The ability of a drug to produce the intended effect as determined by scientific methods, for example in pre-clinical research conditions (opposite of hazard).

Epidemiology: The science concerned with the study of the factors determining and influencing the frequency and distribution of disease, injury and other health-related events and their causes in a defined human population for the purpose of establishing programs to prevent and control their development and spread.

Overdose: Administration of a quantity of a medicinal product given per administration or cumulatively, which is above the maximum recommended dose according to the authorized product information.

Side effect: Any unintended effect of a pharmaceutical product occurring at normal dosage which is related to the pharmacological properties of the drug.

Vigi-Base: The name of the WHO Global ICSR Database.

Vigi-Flow: Vigi-Flow is a complete ICSR management system created and maintained by the UMC. It is web-based and built to adhere to the ICH-E2B standard. It can be used as the national database for countries in the WHO Programme as it incorporates tools for report analysis, and facilitates sending reports to Vigi-Base.

Vigi-med: Share point based conferencing facility, exclusive to member countries of the WHO Programme for International Drug Monitoring for fast communication of topical Pharmacovigilance issues.

Vigi-Mine: A statistical tool within Vigi-Search with vast statistical material calculated for all DrugADR pairs (combinations) available in Vigi-Base. The main features include the disproportionality measure (IC value) stratified in different ways and useful filter capabilities.

Vigi-Search: A search service for accessing ICSRs stored in the Vigi-Base database offered by the UMC to national Pharmacovigilance centres and other third-party inquirers.

WHO Drug Dictionary (WHO DD): The WHO Drug Dictionary is an international classification of drugs providing proprietary and non-proprietary names of medicinal products used in different countries, together with all active ingredients.

CONCLUSION

The pharmacovigilance review emphasizes that continuous monitoring of drug safety is essential for protecting patients. Timely detection and reporting of adverse drug reactions help minimize risks and improve therapeutic outcomes. Proper documentation and evaluation of safety data enhance the accuracy of the system, while active involvement of healthcare professionals further strengthens reporting practices. The review also highlights the importance of patient awareness and participation in identifying drug-related problems. Regulatory oversight ensures that appropriate safety measures are implemented without delay. Additionally, ongoing training and awareness programs are necessary to maintain an effective pharmacovigilance framework. Overall, the findings indicate that improvements in reporting, surveillance, and communication contribute significantly to drug safety. A robust pharmacovigilance system supports safe and rational use of medicines and ultimately safeguards public health.

Source of Support: The author(s) received no financial support for the research, authorship, and/or publication of this article

Conflict of Interest: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

REFERENCES

1. Tripathi DK, Shiv S. Pharmacovigilance. Pune: Nirali Prakashan; 2017. p. 262.

2. R. Dr. History and development of pharmacovigilance. [Internet]. [cited 2025].

3. Tripathi D, Shiv S. Pharmacovigilance. Pune: Nirali Prakashan; 2017.

4. Nimesh S. Pharmacovigilance program of review article. Acta Scientific Pharmaceutical Sciences. 2022.

5. Kulkarni RD. Reporting systems for rare side effects of non-narcotic analgesics in India: Problems and opportunities. Med Toxicol. 1986;1:110-3.

6. Moride Y, Haramburu F, Requejo AA, Begaud B. Under-reporting of adverse drug reactions in general practice. Br J Clin Pharmacol. 1997;43(2):177-81.

7. World Health Organization. International drug monitoring: the role of national centres. Report of a WHO meeting. Geneva: WHO; 1972. (World Health Organ Tech Rep Ser; No. 498).

8. Jose J, Rao PG. Pattern of adverse drug reactions notified by spontaneous reporting in an Indian tertiary care teaching hospital. Pharmacol Res. 2006;54(3):226-33.

9. Pharmacovigilance Programme of India (PvPI). Frequently asked questions. [Internet]. Available from: https://www.ipc.gov.in/PvPI/faq.html

10. Prakash J, Joshi K, Malik D, et al. "ADR PvPI" Android mobile app: Report adverse drug reaction at any time anywhere in India. Indian J Pharmacol. 2019;51(4):236-42.

11. Chopra D, Desai C. Adverse drug reaction (ADR) reporting in India: A long way to go. Int J Basic Clin Pharmacol. 2013;2(6):846.

12. Kalaiselvan V, Thota P, Singh GN. Pharmacovigilance Programme of India: Recent developments and future perspectives. Indian J Pharmacol. 2016;48(6):624-8.

13. Bahmani K, Gupta N. Adverse drug reactions reporting for health perspectives in India. Business Management and Social Innovations. p. 75.

14. Amale PN, Deshpande S, Nakhate Y, et al. Pharmacovigilance process in India: An overview. J Pharmacovigil. 2018;6(2):259.

15. Puvvada RK, Undela K, PBS P, Kuruvilla AV, Gupta BS. Knowledge and perception of pharmacy practice students on causality assessment of adverse drug reactions. Adv Pharmacol Pharm. 2021;9(4):94-9.

16. Jones JK. Adverse drug reactions in the community health setting: approach to recognizing, counseling and reporting. Fam Community Health. 1982;5(2):58-67.

17. Hartwig SC, Siegel J, Schneider PJ. Preventability and severity assessment in reporting adverse drug reactions. Am J Hosp Pharm. 1992;49:2229-31.

18. Begaud B, Evreux JC, Jouglard J, et al. Imputation of the unexpected or toxic effects of drugs: Actualization of the methods used in France. Therapie. 1985;40:115-8.

19. Raut AL, Patel P, Patel C, Pawar A. Preventability, predictability and seriousness of adverse drug reactions amongst medicine inpatients in a teaching hospital: A prospective observational study. Int J Pharm Chem Sci. 2012;1:1293-9.

20. Srinivasan R, Ramya G. Adverse drug reaction-causality assessment. Int J Res Pharm Chem. 2011;1:606-12.

21. Coleman J, Ferner R, Evans S. Monitoring for adverse drug reactions. Br J Clin Pharmacol. 2006;61:371-9.

22. Ferner R, Aronson J. Preventability of drug-related harms—Part I: a systematic review. Drug Saf. 2010;33:985-94.

23. Joshi S, Sapatnekar S. The importance of pharmacovigilance. Geneva: World Health Organization. Pharmacovigilance in India: How safe are the new drugs? J Assoc Physicians India. 2008;56(8):933-4.

24. Khan M A, Ali SI, Alam S. Assessment of prescribing trend of drugs at out patient's chest ward of government tertiary care hospital situated in karachi. Journal of Bioequivalence & Bioavailability. 2018; 10(1): 1-4.