CODEN [USA]: IAJPBB ISSN : 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES

SJIF Impact Factor: 7.187

https://doi.org/10.5281/zenodo.18154732

Available online at: http://www.iajps.com *Review Article*

PHARMACOVIGILANCE AND DRUG SAFETY

[1]Dr.Padige Sri Varsha*,[2] Padakanti Naga Harshitha, [3]Banda Jashwanth, [4]Vaddera Prashanthi

[1]Assistant Professor, Department of Pharmacy practice, Maisammaguda, Dhulapally, Secundrabad, 500100

[2]Pharm-D 4th year, Malla Reddy College of Pharmacy, Maisammaguda, Dhulapally, Secundrabad, 500100

[3]Pharm-D 4th year, Malla Reddy College of Pharmacy, Maisammaguda, Dhulapally, Secundrabad, 500100

[4]Pharm-D 4th year, Malla Reddy College of Pharmacy, Maisammaguda, Dhulapally, Secundrabad, 500100

Abstract:

Through the identification, evaluation, comprehension, and prevention of adverse drug reactions (ADRs) throughout a medication's lifecycle, pharmacovigilance plays a crucial role in guaranteeing drug safety. Strong pharmacovigilance systems are essential because, despite thorough pre-marketing clinical trials, uncommon, long-term, and population-specific side effects frequently only manifest during post-marketing use. The purpose of this study is to assess how pharmacovigilance can enhance drug safety outcomes, with a focus on risk minimization techniques, signal detection, and reporting adverse drug reactions. A thorough analysis of active surveillance databases, pharmaco-epidemiological studies, and spontaneous reporting systems was carried out. To evaluate patterns of ADR reporting, causality assessment, and regulatory actions taken in response to identified safety signals, data from national and international pharmacovigilance programs were analysed. The results show that early signal detection and prompt regulatory interventions, such as label modifications, risk communication, and, in certain situations, drug withdrawal, are greatly aided by efficient pharmacovigilance systems. ADR underreporting is still a significant issue, especially in low- and middle-income nations. Signal detection capabilities have been improved through the integration of real-world evidence, electronic health records, and sophisticated analytical techniques. In order to protect public health and maximize the benefit-risk profile of pharmaceuticals, pharmacovigilance is crucial. To advance drug safety surveillance worldwide, it is imperative

to adopt innovative technologies, improve data quality, and strengthen the culture of ADR reporting.

Keywords: *Pharmacovigilance, Drug Safety, Adverse Drug Reactions, Signal Detection, Post-Marketing Surveillance.*

Phytochemical studies; Herbal face serum.

Corresponding author:

Dr.Padige Sri Varsha,

Assistant Professor,

Department of Pharmacy practice, Maisammaguda, Dhulapally, Secundrabad, 500100

QR CODE

Please cite this article in ***press*** *Padige Sri Varsha* ***et al., Pharmacovigilance And Drug Safety,*** *Indo Am. J. P. Sci, 2026; 13(01).*

INTRODUCTION:

Pharmacovigilance, according to the World Health Organization, is the science and activities centre-ed on identifying, evaluating, comprehending, and preventing side effects or any other medication-related issue with the goal of enhancing patient safety and care by guaranteeing a favourable medicine benefit-risk balance throughout a drug's lifecycle. PV is the primary method for tracking and responding to possible risks, from minor headaches to serious reactions, in order to support public health. Drug safety encompasses all patient protection measures. Pharmacovigilance is the study and practice of identifying, evaluating, comprehending, and preventing side effects or any other drug-related issue. Drug Safety: The overarching objective of guaranteeing the safe use of medications, accomplished through PV's primary functions of risk identification and mitigation, benefit-risk profile management, and rational medication use.[1] "Adverse drug reaction" or "adverse reaction" refers to a reaction to medication in humans or animals that is unpleasant and unexpected, including ineffectiveness, and that happens at any dosage. It can also be the consequence of overdosing, misusing, or abusing medication.[2]. Pharmacovigilance began 169 years ago on January 29, 1848, when Hannah Greener, a young girl from the north of England, died after being given chloroform anaesthetic prior to the removal of an a toenail infection[3]. Pharmacovigilance's primary goals include demonstrating the efficacy of medications by tracking their adverse impact profile over a number of years from the research lab to the pharmacy; tracking any significant effects of medications on public health and safety regarding their use; promoting the safe, sensible, and effective use of medications; advancing knowledge, education, and clinical teaching in pharmacovigilance; and effectively communicating with the general public. Pharmacovigilance is required to keep an eye on the effects of medications both during and after they are put on the market. Keep an eye on the quality of medications, recognize the health risks associated with administering specific medications, etc. Pharmacovigilance might not depend on one approach, but a plan of complementary actions is required. There isn't a single, widely recognized method for determining causality. As a result, there is currently a need for a single, effective, and widely recognized approach.[4]

OBJECTIVES OF PHARMACOVIGILANCE:

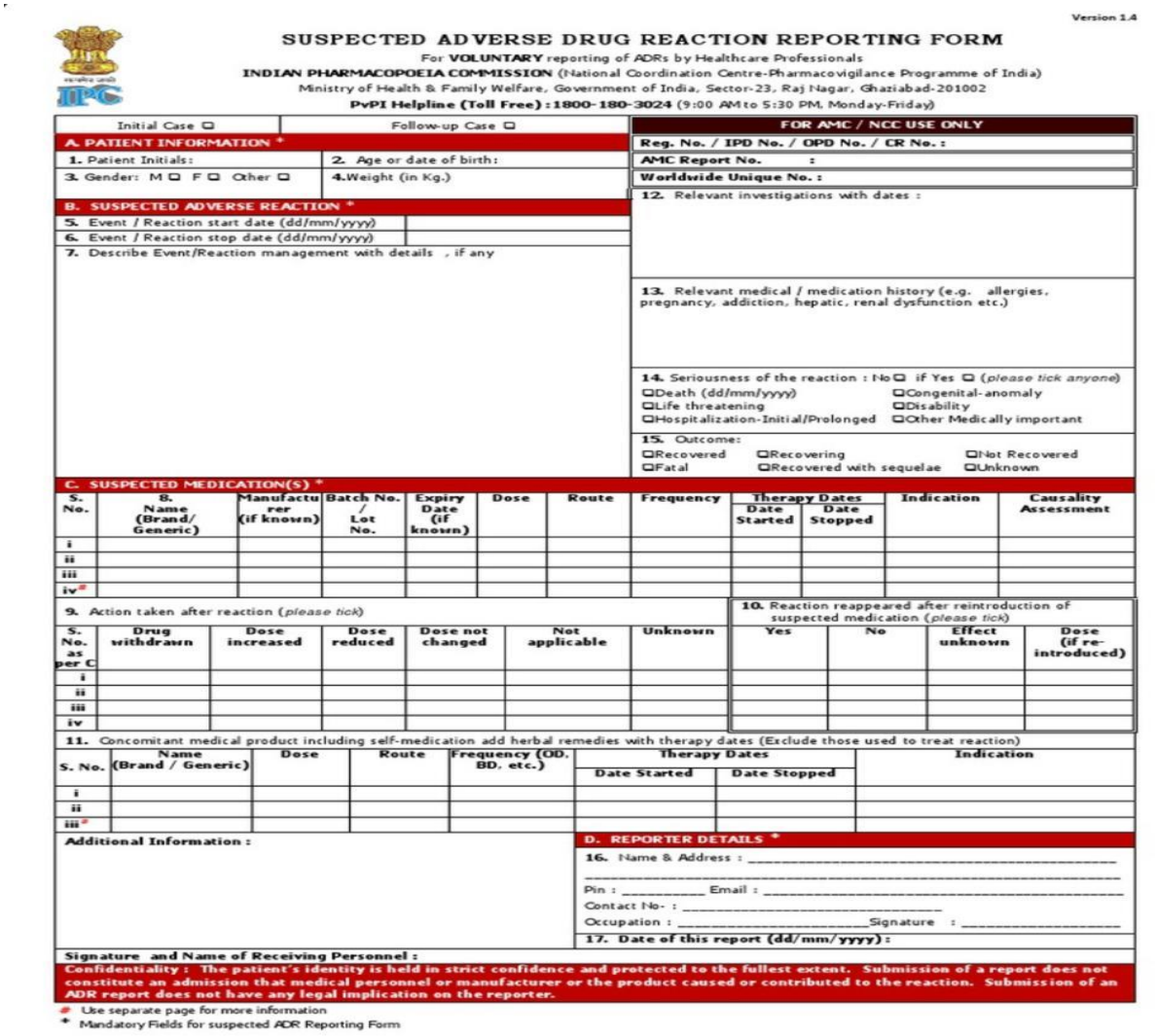
Pharmacovigilance seeks to ensure that medications are continuously assessed throughout their lifecycle in addition to identifying adverse drug reactions. Early detection of unknown adverse drug reactions (ADRs), quantification of known adverse drug reactions (ADRs), evaluation of the benefit-risk stability, prevention of medication-related harm, and encouragement of sensible drug use are the main goals. By endorsing measures like label modifications, usage restrictions, or the removal of dangerous medications, it also plays a significant part in regulatory decision-making. Furthermore, by guaranteeing openness and safety monitoring, pharmacovigilance increases patient confidence and public trust in healthcare systems.

IMPORTANCE OF PHARMACOVIGILENCE:

Finding and measuring adverse drug reactions that were previously unknown. identifying patient subgroups, such as those based on species, breed, age, gender, physiological status, and underlying disease, that are particularly vulnerable to negative drug reactions. ongoing evaluation of a product's safety in each species for which it has been approved in order to make sure that the risks and advantages are still manageable. Extending monitoring to new species and indications should be part of this. contrasting the adverse reaction profile both within and between species with that of products in the same therapeutic class. It may be necessary to keep an eye out for instances of improper prescription and administration, particularly when it comes to certain groups, such as the public or farmers. To better understand the mechanisms behind adverse drug reactions, more research should be done on the toxicological, pharmacological, or microbiological properties of a drug or product identifying drug interactions. This is especially crucial for novel medications that are subsequently administered alongside well-known goods or even other novel medications. Giving veterinarians and other people who treat animals—such as farmers, other animal owners, and veterinarians—appropriate information on drug-drug interactions and adverse drug reaction data. [5]

ADR REPORTING:

In pharmacovigilance, adverse drug reaction (ADR) reporting is the methodical process of recording, gathering, analysing, and disseminating information about suspected adverse drug reactions connected to the use of pharmaceutical products with the goal of identifying, evaluating, comprehending, and averting drug-related harm. ADR reporting is the process by which medical professionals, patients, or manufacturers report suspected adverse drug reactions to a pharmacovigilance system in order to find new safety information and guarantee the safe use of medications. When a suspected adverse reaction happens during routine clinical use of a medication, Individual Case Safety Reports (ICSRs) are required or voluntarily submitted to national or international pharmacovigilance centres.[6]



Version 1.4

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For **VOLUNTARY** reporting of ADRs by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India)

Ministry of Health & Family Welfare, Government of India, Sector-23, Raj Nagar, Ghaziabad-201002

PvPI Helpline (Toll Free) : 1800-180-3024 (9:00 AM to 5:30 PM, Monday-Friday)

Initial Case ☐ Follow-up Case ☐

FOR AMC / NCC USE ONLY

Reg. No. / IPD No. / OPD No. / CR No. :

AMC Report No. :

Worldwide Unique No. :

A. PATIENT INFORMATION *

1. Patient Initials:
2. Age or date of birth:
3. Gender: M ☐ F ☐ Other ☐
4. Weight (in Kg.)

B. SUSPECTED ADVERSE REACTION *

5. Event / Reaction start date (dd/mm/yyyy)
6. Event / Reaction stop date (dd/mm/yyyy)
7. Describe Event/Reaction management with details , if any

12. Relevant investigations with dates :

13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)

14. Seriousness of the reaction : No ☐ if Yes ☐ (*please tick anyone*)
☐Death (dd/mm/yyyy) ☐Congenital-anomaly
☐Life threatening ☐Disability
☐Hospitalization-Initial/Prolonged ☐Other Medically important

15. Outcome:
☐Recovered ☐Recovering ☐Not Recovered
☐Fatal ☐Recovered with sequelae ☐Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	8. Name (Brand/ Generic)	Manufacturer (if known)	Batch No. / Lot No.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication	Causality Assessment
i											
ii											
iii											
iv*											

9. Action taken after reaction (*please tick*)

10. Reaction reappeared after reintroduction of suspected medication (*please tick*)

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if re-introduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication add herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication
i							
ii							
iii*							

Additional Information :

D. REPORTER DETAILS *

16. Name & Address : _____

_____

Pin : _____ Email : _____

Contact No- : _____

Occupation : _____ Signature : _____

17. Date of this report (dd/mm/yyyy) :

Signature and Name of Receiving Personnel :

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

* Use separate page for more information

* Mandatory Fields for suspected ADR Reporting Form

FIGURE-1

ROLE OF PHARMACIST IN ADR REPORTING:

Over the past ten years, pharmacists' roles in reporting adverse drug reactions have changed, although they still differ by region.14 to 16 Pharmacists in Scandinavian nations were more than ten years ago.

ADRs cannot be reported on their own. Pharmacists in the UK were only permitted to independently report adverse drug reactions (ADRs) following a ten-year legal battle. In contrast, the Malaysian National Pharmacovigilance Centre received over half of all ADR reports in 2010 from pharmacists.[7] Significant differences in the role of pharmacists in reporting ADRs were also discovered in a 2004 international survey of 41 member states taking part in the WHO Drug Monitoring program.

The differences in pharmacists' roles within the healthcare system can account for the variation in pharmacists' roles in PV activities[8] .From a simple "dispenser" to a protector of medication safety and patient outcomes worldwide. Pharmacists' role in reporting adverse drug reactions (ADRs) is becoming more acknowledged as their role in health care systems continues to change[9]. Empirical data indicates that hiring pharmacists in public hospitals can not only identify and report adverse drug reactions (ADRs), but also prevent them and lower related financial and humanistic expenses[10]. Additionally, compared to community pharmacists, hospital pharmacists are more likely to report ADRs. This may be explained by the fact that clinically trained pharmacists are more knowledgeable about the ADR reporting system[11]. and often interact with prescribers. Moreover, regular communication with the patients in addition to having access to Clinical pharmacists can access patient medical records at the hospitals to gain more insight into the suspected ADRs. However, being the most readily available medical care Community and professional

pharmacists play a critical role in Additionally, by identifying and reporting adverse drug reactions (ADRs), particularly in places where general practitioners' accessibility
There are few primary care doctors.[12,13,14]

CLASSIFICATION OF ADR'S:

TYPE-A(augmented reactions): The pharmacological effects of drugs that are qualitatively normal but quantitatively abnormal are known as type A reactions. They might result from more than just the primary (or intended) pharmacological characteristic of a substance as well as its additional effects, such as the anticholinergic effects of tricyclic antidepressants, which result in tachycardia, dry mouth, and blurred vision. These reactions are typically predictable, dose-dependent, and, despite their prevalence, rarely fatal. People who are at the extremes of the dose-response curves for pharmacological effects experience type A reactions. People at one end of the spectrum will exhibit overt toxicity, while those at the other end will experience therapeutic failures (a type of adverse reaction). This kind of reaction has three causes.[15]

TYPE-B(bizarre reactions): Strange, qualitatively abnormal side effects that seem to have nothing to do with a drug's typical pharmacology are known as type B reactions. Once more, there are three fundamental reasons.[16]

TABLE 1: CLASSIFICATION OF ADVERSE DRUG REACTIONS

Type	Description	Characteristics	Examples
Type A (Augmented)	Dose-related and predictable	Common, preventable	Hypoglycaemia with insulin
Type B (Bizarre)	Non-dose related	Rare, unpredictable	Anaphylaxis with penicillin
Type C (Chronic)	Related to long-term use	Dose & time related	Adrenal suppression by steroids
Type D (Delayed)	Occurs after use	Time-related	Carcinogenesis
Type E (End-of-use)	Due to withdrawal	Withdrawal reactions	Opioid withdrawal
Type F (Failure)	Therapeutic failure	Drug interactions	Oral contraceptive failure

SEVERITY OF ADR'S:

Strange, qualitatively abnormal side effects that seem to have nothing to do with a drug's typical pharmacology are known as type B reactions. The Hartwig and Siegel severity scale was used to evaluate the severity of adverse drug reactions (ADRs), classifying them as mild (levels 1 and 2), moderate (levels 3, 4a, and 4b), and severe (levels 5–7). Level 2 required that the suspected medication be withheld, stopped, or modified without lengthening hospital stays, whereas Level 1 indicated no change in treatment. Level 3 required stopping the medication and using an antidote or other treatment without affecting the length of hospital stay. Levels 4a and 4b were either the cause of admission or prolonged hospital stay. Level 5 severe adverse drug reactions (ADRs) necessitated critical care, level 6 permanent damage, and level 7 patient death. Once more, there are three fundamental reasons.[17]

TABLE 2: SEVERITY ASSESSMENT OF ADRS (HARTWIG AND SIEGEL SCALE)

Severity Level	Description
Mild (Level 1–2)	No change or minimal change in therapy
Moderate (Level 3–4b)	Drug discontinued; hospitalization required
Severe (Level 5–7)	ICU care, permanent damage, or death

CHALLENGES IN PHARMACOVIGILANCE:

Despite significant advancements, pharmacovigilance systems face several challenges. Under-reporting of ADRs remains the most critical limitation worldwide, particularly in developing countries. Lack of awareness, fear of legal consequences, time constraints, and inadequate training among healthcare professionals contribute to poor reporting rates. Data quality issues such as incomplete reports, duplication, and reporting bias further limit signal detection accuracy. Additionally, integrating real-world data from electronic health records, social media, and insurance databases poses challenges related to standardization, privacy, and validation. Addressing these challenges requires continuous education, technological innovation, and strong regulatory support.[18]

IMPACT OF ADR'S :

Premarketing drug safety assessments' limitations:

Preclinical and clinical research must include assessments of drug efficacy as well as the identification and measurement of risks related to drug therapy. Stages (phases 1-3) of the drug development process prior to a medication's commercial release. Although they are the gold standard for assessing drug efficacy, randomized controlled trials (RCTs), which make up the majority of the premarketing clinical phases of drug development, are far less successful at identifying adverse drug reactions (ADRs). [18]

ADRs caused by improper medication use:

The fact that improper medication use is one of the main causes of adverse drug reactions (ADRs) highlights the importance of pharmacovigilance in ADR detection. Nonetheless, drug use. In contrast to the use of drugs seen in the more dynamic clinical settings, where the mode and consequences of drug use can be more complex, RCTs follow strict protocols, frequently in patients who are not frail, and in a highly controlled environment. As a result, RCTs are unable to identify ADRs brought on by improper drug use. Drug interactions, off-label use, inappropriate dosage or duration of treatment, and use in contraindicated circumstances are all potential causes of adverse drug reactions (ADRs) that can happen in both the general population and hospital settings. [19]

Adverse drug reaction epidemiology in clinical practice: The frequency of adverse drug reactions (ADRs) and the associated medical expenses in clinical practice have been shown by a number of epidemiological studies. These outcomes consist of hospital admissions, extended hospital stays, and ER visits associated with drug use. According to estimates from France, up to 123,000 patients visit their general practitioner each year with an adverse drug reaction (ADR). Hospital admissions are frequently due to drug-related reasons. [20]

Adverse drug reaction costs:

ADRs have complicated effects and can cost up to $30.1 billion a year in the United States. ADRs may result in longer hospital stays and higher costs of hospitalization and, in more severe situations, further clinical testing. Additionally, when new medications are prescribed for conditions that result from another medication—which is frequently an unidentified adverse drug reaction—ADRs may cause prescription cascades. Examples include the use of anticholinergic medications for urinary retention in Alzheimer's patients receiving cholinesterase inhibitors, or the use of antipsychotics in Parkinson's disease patients receiving dopaminergic medications. This raises the risk of additional adverse drug reactions (ADRs) and raises the cost of medication. [21]

Techniques for lowering healthcare costs and raising the quality of care:

It is evident that adverse drug reactions (ADRs) increase the financial burden on patients, their caregivers, and the healthcare systems that handle them. Moreover, it is evident that RCTs on their are insufficient for identifying and determining the frequency of ADRs. A more accurate and continuous assessment of the risk-benefit ratio for medical interventions requires more clinically relevant data with longer follow-up periods and larger population sizes, which are provided by post-marketing pharmacovigilance activities like spontaneous reporting, cohort event monitoring, and retrospective database studies that supplement RCT data. Drug safety is more likely to improve when regulatory bodies, the pharmaceutical industry, and prescribers work together, regardless of the kind of post-marketing study.[22]

PHARMACOVIGILANCE SYSTEMS:

Pharmacovigilance systems are organized frameworks that make it possible to gather, compile, analyse, interpret, and share information on adverse events related to pharmaceuticals in a methodical manner. These systems function both nationally and internationally to guarantee ongoing drug safety monitoring following market approval, identify early safety indicators, support regulatory choices, and safeguard public health.[23]

GLOBAL PHARMACOVIGILANCE SYSTEMS:

WHO PROGRAMME FOR INTERNATIONAL DRUG MONITORING (PIDM):

The science and activities pertaining to the identification, evaluation, comprehension, and avoidance of side effects or any other drug-related issue are known as pharmacovigilance, or PV. In addition to supporting public health initiatives by offering trustworthy, impartial data to evaluate the risk-benefit profile of medications, PV seeks to improve patient care and safety with regard to the use of pharmaceuticals. "A systematic collection of information on serious adverse drug reactions during the development and particularly after medicines have been made available for public use" was demanded in resolution 16.36 of the 16th World Health Assembly in 1963. The WHO Programme for International Drug Monitoring (PIDM) was established as a result in 1968. Individual Case Safety Reports (ICSRs), which are reports of adverse reactions linked to pharmaceutical products, are submitted by WHO PIDM members to the WHO global database, Vigi-Base. The Uppsala Monitoring Centre, a WHO Collaborating Centre for

International Drug Monitoring, oversees and maintains Vigi-Base. Vigi-Base had more than 35 million adverse reaction reports as of July 2023. Vigi-Base records data in an organized and thorough manner to enable the identification of possible risks to medicinal safety.
WHO introduced Vigi-Access in April of 2015. A new online tool called Vigi-Access will make it possible for anyone to obtain information and promote the reporting of side effects from pharmaceuticals.[23]

UPPSALA MONITORING CENTRE (UMC):
When Sweden took over the scientific and technical responsibilities of the WHO Programme for International Drug Monitoring in 1978, the Uppsala Monitoring Centre (UMC) became the first WHO Collaborating Centre for pharmacovigilance. The Centre is a self-sufficient, independent, non-profit organization. On behalf of WHO and its Member States, the UMC maintains Vigi-Base TM, the world's largest database of Individual Case Safety Reports (ICSRs). National centres in pharmacovigilance practice receive technical assistance and direction from the UMC. Vigi Flow, a web-based system that incorporates international standards to record and manage ICSRs at numerous national centres, is one of the reporting and data management tools that the UMC creates and provides to nations. In addition to holding training sessions, the UMC publishes books, periodicals, newsletters, and scientific articles about risk communication and pharmacovigilance.[24]

VIGI-BASE – WHO GLOBAL DATABASE:
The biggest worldwide database of suspected adverse drug reaction reports is called Vigi-Base. Tens of millions of Individual Case Safety Reports (ICSRs) from PIDM member nations are included in it. Enables early warning of safety issues. Helps pharmaceutical companies, research institutions, and regulatory bodies make evidence-based decisions. Encourages uniform methods of pharmacovigilance across the globe.[25]

NATIONAL PHARMACOVIGILANCE SYSTEMS:
National pharmacovigilance systems contribute to global data via WHO's PIDM while operating within the regulatory frameworks of individual nations. They are essential for both locally pertinent regulatory action and post-marketing safety monitoring.

UNITED STATES: US FDA (FAERS & MEDWATCH):
One of the most well-known pharmacovigilance systems in the world is run by the Food and Drug Administration (FDA) in the United States.

FDA Adverse Event Reporting System (FAERS):
The FDA's post-marketing safety surveillance for approved medications and therapeutic biologics is supported by FAERS, an electronic database. American Food and Drug Administration. It includes reports of adverse events and medication errors filed by manufacturers, consumers, and medical professionals. American Food and Drug Administration. Adverse events are coded using MedDRA terminology, and the data structure conforms to international reporting standards (ICH E2B). In addition to helping the FDA identify new safety signals and assess manufacturer compliance, FAERS data may result in regulatory actions like label modifications, risk communications, or market withdrawals.[26]

MedWatch System:
The FDA's MedWatch program facilitates voluntary reports from consumers and healthcare providers regarding safety information and adverse events. It distributes safety alerts and product recalls by integrating with FAERS to deliver safety data.[27]

European Union: EMA (Eudra Vigilance):
Pharmacovigilance throughout the European Union (EU) is coordinated by the European Medicines Agency (EMA).

System of Eudra-Vigilance:
The EU's centralized system for tracking possible adverse reactions to medications approved or under study within the European Economic Area (EEA) is called Eudra-Vigilance. It has modules for both post-authorization and clinical trial reporting, and it facilitates the electronic exchange of Individual Case Safety Reports (ICSRs). Early identification of possible safety concerns and ongoing assessment of pharmaceuticals over their whole life cycle are made possible by the system.[28]

India: Pharmacovigilance Programme of India (PvPI):
The Indian Pharmacopoeia Commission (IPC) is the National Coordination Center for the Pharmacovigilance Programme of India (PvPI), which was created in 2010 under the Central Drugs Standard Control Organization (CDSCO).[41]

TABLE 3: MAJOR GLOBAL PHARMACOVIGILANCE SYSTEMS

Region	System	Key Function
Global	WHO PIDM	International ADR monitoring
USA	FAERS	Post-marketing surveillance
EU	Eudra-Vigilance	Centralized EU ADR reporting
India	PvPI	National ADR monitoring

Objectives And Scope :
To enhance medication safety and safeguard public health, establish a national ADR reporting system. To find safety signals and produce evidence-based safety information, gather, compile, and examine ADR reports. Assist CDSCO in making regulatory decisions and share safety information with the public and medical professionals. Encourage healthcare providers to use medications sensibly and to report adverse drug reactions (ADRs).[42]

Framework for Operations:
A network of Adverse Drug Reaction Monitoring Centres (AMCs) dispersed throughout India is used to report ADRs. For global signal detection, national ICSR data are shared with Vigi-Base and input into programs like Vigi-Flow. PvPI works with international pharmacovigilance organizations to conform practices to global norms and regulations.[29]

METHODS OF PHARMACOVIGILANCE:
Throughout a medication's life cycle, pharmacovigilance uses a variety of methodological techniques to detect, evaluate, comprehend, and prevent side effects or other drug-related issues. These techniques fall into three general categories: analytical/advanced approaches, active surveillance, and passive surveillance. [30]

TABLE 4: COMPARISON OF PHARMACOVIGILANCE METHODS

Method	Type	Strengths	Limitations
Spontaneous Reporting	Passive	Cost-effective, early signals	Under-reporting
Cohort Event Monitoring	Active	Incidence estimation	Expensive
Case–Control Studies	Observational	Rare ADR detection	Bias
Data Mining	Analytical	Large datasets	False signals
PASS	Regulatory	Real-world safety	Time-consuming

PASSIVE SURVEILLANCE (SPONTANEOUS REPORTING SYSTEMS):
The most popular approach to pharmacovigilance. It involves patients, healthcare providers, and pharmaceutical companies reporting suspected adverse drug reactions (ADRs) either voluntarily or legally. Individual Case Safety Reports (ICSRs) are used to submit reports.[31]

ACTIVE SURVEILLANCE:
Instead of depending solely on voluntary reporting, active surveillance entails proactive and methodical data collection.[32]

Cohort Event Monitoring (CEM):
Patients who are exposed to a particular drug are monitored over time. Regardless of causality, every adverse event is documented.[32]

Targeted Spontaneous Reporting (TSR):
Focuses on particular adverse events, populations, or medications. It combines elements of both active and passive surveillance.[32]

Sentinel Sites and Registries:
Safety information is actively gathered by certain medical facilities or disease registries. It is common in rare diseases, pregnancy exposure registries, and oncology.[32]

COMPARATIVE OBSERVATIONAL STUDIES:
These techniques evaluate relationships between drug exposure and negative consequences.[33]

Case–Control Studies:

Compare patients who have a particular ADR (cases) with those who do not (controls). It is retrospective.[33]

Cohort Studies:
Compare the results of populations that were exposed and those that weren't. Both prospective and retrospective are possible[33].

MINING STATISTICAL DATA:
It finds patterns of disproportionate reporting using quantitative techniques.

CLINICAL TRIALS AND POST-AUTHORIZATION SAFETY STUDIES (PASS):
Phase IV clinical trials (post-marketing). It mandated by regulatory bodies to assess safety in actual environments.[34]

MONITORING LITERATURE:
Methodical review of case reports and scientific journals. Finds new or previously unreported safety issues.[35]

PHARMACOGENOMIC AND PHARMACOGENETIC METHODS:
Determine the genetic variables that affect ADR susceptibility. It promotes risk reduction and personalized medicine.[36]

SYSTEMS FOR MEDICATION ERROR AND RISK MANAGEMENT:
Identifying medication mistakes that might or might not be harmful. Incorporated into initiatives for pharmacovigilance.[37]

BIG DATA AND REAL-WORLD EVIDENCE (RWE):
Utilization of patient registries, insurance claims databases, and electronic health records (EHRs). It is more and more encouraged by regulatory bodies.[38]

DIGITAL PHARMACOVIGILANCE AND SOCIAL MEDIA:
Keeping an eye out for safety information reported by patients on the internet. Complementary but needs to be validated because of problems with data quality.[39]

FUTURE PERSPECTIVES OF PHARMACOVIGILANCE:
The future of pharmacovigilance is increasingly driven by digital innovation and artificial intelligence. Machine learning algorithms are being used to improve signal detection and predict ADRs before they become widespread. Integration of pharmacogenomics enables personalized medicine by identifying genetically susceptible populations. Mobile health applications and patient-reported outcome platforms are improving ADR reporting rates. Regulatory agencies are also promoting real-world evidence (RWE) to complement clinical trial data, ensuring more comprehensive drug safety evaluation.[40]

REFERENCES:

1)World Health Organization. The importance of pharmacovigilance – safety monitoring of medicinal products. World Health Organization, Geneva, 2002.
2)WHO, Pharmacovigilance: ensuring the safe use of medicines, Geneva: WHO, 2004.
3)Commission on Anaesthetics. Lancet, 1893; i: 629–38
4)Shuka SS, Gidwani B, Pandey R, Rao SP, Singh V, Vyas A, Importance pharmacovigilance in Indian Pharmaceutical Industry, Asian Journal of Research in
Pharmaceutical Science, 2012; (2): 04-08.
5)Stephens K. Pharmacovigilance future prospective. Journal of Pharmacovigilance, 2000; 2: 23-29.
6)Edwards IR, Aronson JK, Adverse drug reactions: definitions, diagnosis, and management.
Lancet. 2000;356(9237):1255–1259.
7)van Grootheest K, Olsson S, Couper M, de Jong-van den Berg L-,Pharmacists' role in reporting adverse drug reactions in an international perspective. Pharmaco- epidemol Drug Safe, 2004;13(7):457–464.
8)Osemene KP, Ayeni MI, Afolabi MO. The role of community pharmacists in monitoring adverse drug reactions in Nigeria. J Pharm Health, Serv Res. 2012;3(4):197–204.
9)Olsson S. National Pharmacovigilance Systems-Country profiles and Overview. 2nd ed. Uppsala: Uppsala Monitoring Centre; 1999.
10)Roberts PI, Wolfson DJ, Booth TG. The role of pharmacists in adverse drug reaction reporting. Drug Safe. 1994:11:7–11.
11)Hadi MA, Ming LC. Impact of pharmacist recruitment on ADR reporting: Malaysian experience. South Med Rev. 2011;4(2):102–103.
12)Glassman P. Clinical pharmacist's role in preventing adverse drug events:brief update review. In: Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices. Rockville, MD, agency for Healthcare Research and Quality (US); 2013 Mar. Evidence Reports/Technology Assessments, No. 211.) Chapter 4.
13) Calvert RT. Clinical pharmacy—a hospital perspective. Br J Clin Pharmacol,. 1999;47(3):231–238.
14) Schlienger RG, Lüscher TF, Haefeli WE, Schoenenberger RA. Academic detailing improves identification and reporting of ad-verse drug events,Pharm World Sci. 1999;21(3):110–5

15)Parsons RL, David JA. Gastrointestinal disease and drug absorption. In Amsterdam: EMA; 2023, Prescott LF, Nimmo WS, eds. Drug absorption. Sydney: Adis Press,1979:262-77.
16)Smith SE, Rawlins MD. Variability in human drug response, London.
17)Hartwig SC, Siegel J, Schneider PJ. Preventability and severity assessment in reporting adverse drug reactions, Am J Hosp Pharm 1992; 49: 2222–31.
18)Black D. The limitations of evidence. J R Coll Physicians Lond 1998;32:23-6.
19)Lindley CM, Tully MP, Paramsothy V, Tallis RC. Inappropriate medication is a major cause of adverse drug reactions in elderly patients. Age Ageing 1992;21:294-300
20)Atkin PA, Veitch PC, Veitch EM, Ogle SJ. The epidemiology of serious adverse drug reactions among the elderly. Drugs Aging 1999;14:141-52.
21)Kalisch LM, Caughey GE, Roughead RE, Gilbert AL. The prescribing cascade, Aust Prescr 2011;34:162-6.
22)European Medicines Agency. Guideline on good pharmacovigilance practices (GVP) EMA/813938/2011 Rev 1. 2012.
23)The importance of pharmacovigilance: safety monitoring of medicinal products, Geneva: World Health Organization; 2002.
24)The WHO Programme for International Drug Monitoring: celebrating 40 years, Uppsala: UMC; 2018.
25)VigiBase: WHO Global Database of Individual Case Safety Reports, Uppsala: UMC; 2022.
26)FDA Adverse Event Reporting System (FAERS),Silver Spring (MD): FDA; 2023.
27)MedWatch: The FDA Safety Information and Adverse Event Reporting Program,Silver Spring (MD): FDA; 2023.
28)EudraVigilance – European database of suspected adverse drug reaction reports.
29)Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India: overview and operational guidelines, Ghaziabad: IPC; 2022.
30)The importance of pharmacovigilance: safety monitoring of medicinal products, Geneva: World Health Organization; 2002.
31)WHO pharmacovigilance indicators: a practical manual for the assessment of pharmacovigilance systems, Geneva: World Health Organization; 2015.
32)Edwards IR, Aronson JK, Adverse drug reactions: definitions, diagnosis, and management, Lancet. 2000;356(9237):1255–1259.
33)International Council for Harmonisation (ICH),ICH Harmonised Guideline E2A: Clinical safety data management – definitions and standards for expedited reporting, Geneva: ICH; 1994.
34)International Council for Harmonisation (ICH), ICH Harmonised Guideline E2B(R3): Electronic transmission of individual case safety reports (ICSRs), Geneva: ICH; 2013.
35)Bate A, Evans SJW, Quantitative signal detection using spontaneous adverse event reporting systems, Pharmaco-epidemiol Drug Safe. 2009;18(6):427–436.
36)Lindquist M, VigiBase, the WHO Global ICSR database system: basic facts, Drug Inf J. 2008;42(5):409–419.
37)Waller PC, Evans SJ,A model for the future conduct of pharmacovigilance, Pharmaco-epidemiol Drug Safe. 2003;12(1):17–29.
38)Mann RD, Andrews EB, editors, Pharmacovigilance. 2nd ed,Chichester: John Wiley & Sons; 2007.
39)Strom BL, Kimmel SE, Hennessy S, Pharmacoepidemiology. 5th ed,Oxford: Wiley-Blackwell; 2012.
40)Kalaiselvan V, Thota P, Singh GN,Pharmacovigilance Programme of India: recent developments and future perspectives, Indian J Pharmacol. 2016;48(6):624–628.
41)Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India: overview and operational guidelines, Ghaziabad: IPC; 2022.
42)The importance of pharmacovigilance: safety monitoring of medicinal products.
Geneva: World Health Organization; 2002.