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Original Article

Importance in Ensuring Patient Safety

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ABSTRACT

Pharmacovigilance (PV), or drug safety, is the science and activities related to the detection, assessment, understanding, and prevention of adverse drug reactions (ADRs) and other drug-related problems. It plays an essential role in protecting patient safety, improving public health, and ensuring the safe and effective use of medicines. PV involves systematic reporting, evaluation, and monitoring of ADRs through national and international programs such as the Pharmacovigilance Programme of India (PvPI). Hospital pharmacists significantly contribute to pharmacovigilance by identifying, documenting, and reporting ADRs, providing patient counseling, and ensuring rational drug use. Despite its importance, challenges such as underreporting, lack of awareness, and limited resources remain. Strengthening training, using digital tools, increasing patient involvement, and promoting global collaboration are key to improving pharmacovigilance systems in the future.

Keywords: Pharmacovigilance (pv), Adverse Drug Reaction (ADRs), Drug Safety, Hospital Pharmacist, PvPI, ADR Reporting, Patient Safety, VigiBase, Risk Benefit Assessment, Drug Regulation

INTRODUCTION

Pharmacovigilance, often known as Drug Safety, can be abbreviated as PV or PhV. The term “pharmacovigilance” comes from the Greek word “pharmakon” meaning “drug” and the Latin word “vigilare,” which means “to keep watch.” [1]. PV is a significant and necessary component of clinical research [2]. The research and practices around the identification, evaluation, comprehension, and avoidance of side effects or other drug-related issues are known as pharmacovigilance. “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,” states the World Health Organization. [3]. Pharmacovigilance plays a crucial role in drug regulation, public health programs, and clinical practice. It promotes safe and appropriate drug use by detecting previously unknown adverse drug reactions (ADRs), identifying risk factors for ADR development, and estimating quantitative benefits/risks to improve prescribing. [4]. Pharmacovigilance focuses on adverse drug reactions (ADRs), which are undesirable and unanticipated reactions to drugs used for prevention, diagnosis, treatment, or alteration of physiological functions. [5]. Pharmacovigilance refers to the science and activities involved in detecting, assessing, understanding, and preventing adverse effects or any other drug-related issues [6]. With the increasing use of medicines in various health conditions, ensuring patient safety has become more critical than ever [7]. Pharmacovigilance plays a vital role in identifying previously unknown adverse drug reactions (ADRs), reducing harm to patients, and improving the overall healthcare system [8]. ADR is described as "an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which warrants prevention or regimen, or withdrawal of the product, and which predicts hazard from future administration” [9].

OBJECTIVES OF PHARMACOVIGILANCE

- Improve patient care and safety when using medications. [10]
- Enhance public health and safety of medications. [11]
- Identify and communicate drug-related issues effectively. [12]
- Assessing the benefits and risks of medicines, while supporting safe and effective use. [13]

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- Promote education, clinical training, and effective communication about pharmacovigilance among healthcare workers and the public. [14]
- To enhance patient safety by minimizing risks associated with drug use [15].
- To detect and assess ADRs and take necessary actions [16].
- To improve public health by monitoring drug efficacy and safety [17].
- To educate healthcare professionals and patients on drugrelated risks [18].

Types of Adverse Drug Reactions (ADRs)

Type A (Augmented): Dose-related and predictable.
Type B (Bizarre): Not dose-related and unpredictable.
Type C (Chronic): Occurs during long-term treatment.
Type D (Delayed): Appears after prolonged use or exposure.
Type E (End of use): Occurs after stopping the drug.
Type F (Failure): Lack of therapeutic effect [19], [20].

Table: - 1

Type of reaction	Description
A: Dose related	Exaggerated expected effects from medicines at usual doses e.g.) bleeding with warfarin, bradycardia with beta-blockers
B: Idiosyncratic	Unrelated to pharmacological properties e.g.) Steven's Johnsons syndrome with allopurinol
C: Dose & time related	Related to cumulative drug use over time e.g.) adrenal insufficiency with corticosteroids
D: Delayed	Apparent only use of medicines after time e.g.) skin cancers with topical tacrolimus
E: Withdrawal	Associated with withdrawal or medication cessation e.g.) rebound tachycardia with stopping beta-blockers
F: Failure of therapy	Associated with unexpected failure of therapy, possibly due to drug interaction e.g.) St. John's Wort reducing efficacy of combined oral contraceptives
G: Genetic	Associated with irreversible genetic damage e.g.) phocomelia after thalidomide
H: Hypersensitivity	Associated with an immune-mediated response to medicines in a sensitized patient e.g.) amoxicillin and interstitial nephritis (immune complex)

ADR Reporting Process:

The pharmacovigilance process involves:

Adverse event reporting is the most prevalent activity related with pharmacovigilance (PV), and it consumes a large amount of resources for drug regulatory bodies (or equivalent government organizations) and drug safety departments in pharmaceutical corporations. [21]. Identifying suspected ADRs by healthcare professionals or patients [22]. Recording the details using ADR reporting forms [23]. Sending the report to regional or national pharmacovigilance centers [24]. Analyzing data and implementing regulatory actions [25]. Adverse event (AE) reporting entails receiving, triaging, data entering, assessing, distributing, reporting (if applicable), and archiving AE data and documentation. [26].AE reporting also gives data to these firms and drug regulatory bodies, which are critical in determining the riskbenefit profile of a medicine. [27].

Reporting Procedure

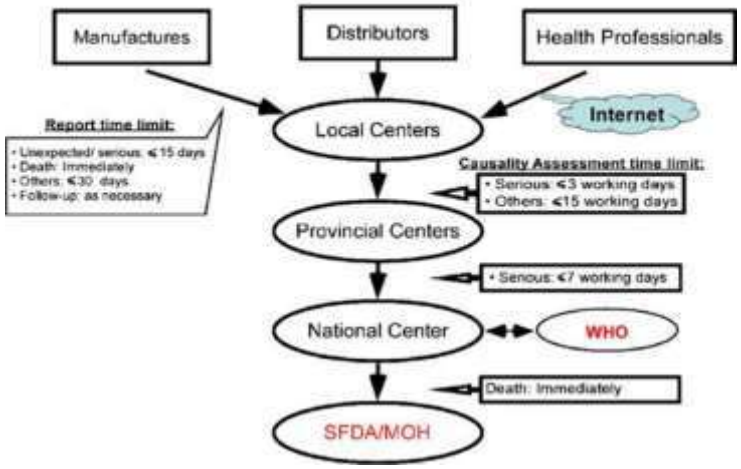
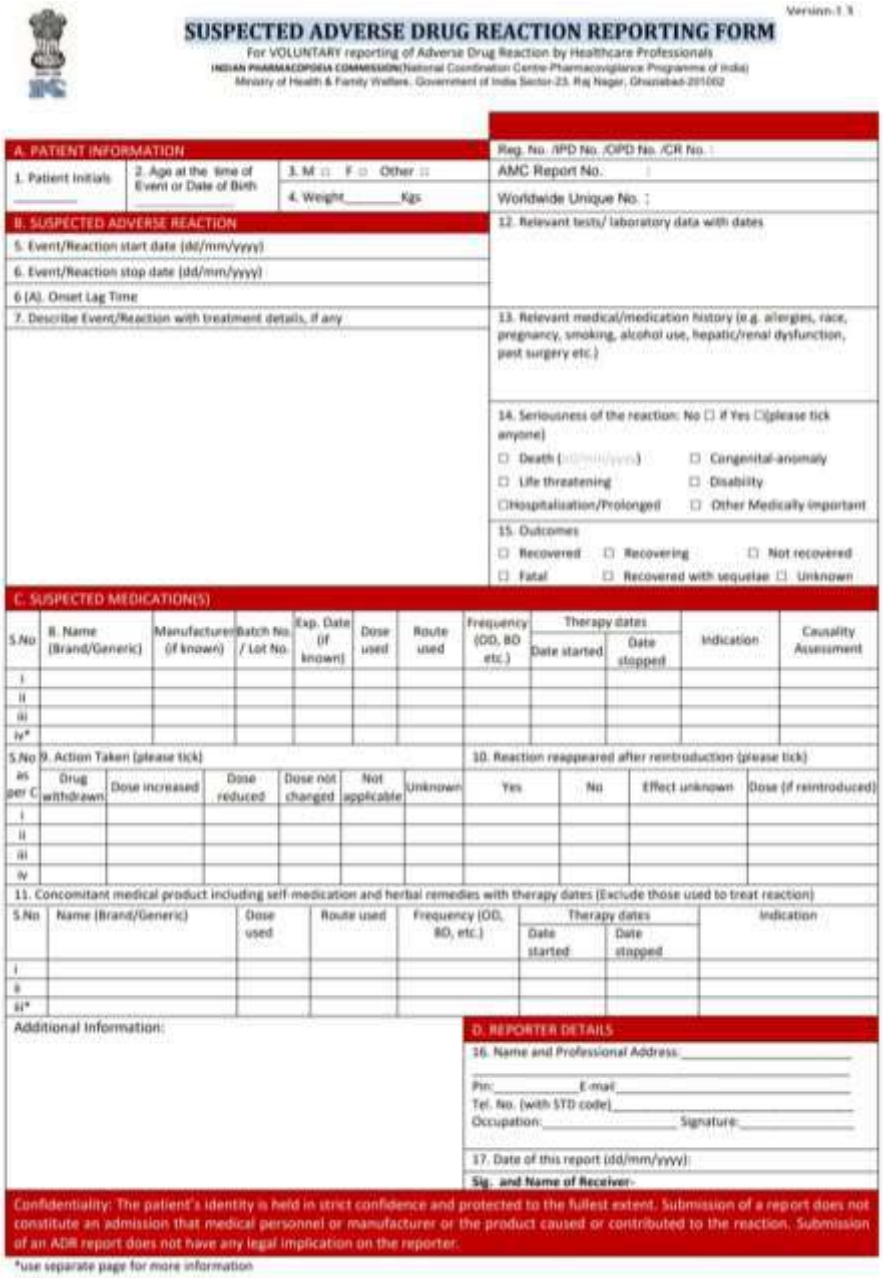


Fig: 1



Version 1.3

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reaction 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

A. PATIENT INFORMATION

1. Patient Initials	2. Age at the time of Event or Date of Birth	3. M ☐ F ☐ Other ☐
		4. Weight_____Kgs

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

AMC Report No. :

Worldwide Unique No. :

B. SUSPECTED ADVERSE REACTION

5. Event/Reaction start date (dd/mm/yyyy)

6. Event/Reaction stop date (dd/mm/yyyy)

6 (A). Onset Lag Time

7. Describe Event/Reaction with treatment details, if any

12. Relevant tests/ laboratory data with dates

13. Relevant medical/medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction, past surgery etc.)

14. Seriousness of the reaction: No ☐ if Yes ☐(please tick anyone)

☐ Death (dd/mm/yyyy) ☐ Congenital anomaly
☐ Life threatening ☐ Disability
☐Hospitalization/Prolonged ☐ Other Medically important

15. Outcomes

☐ Recovered ☐ Recovering ☐ Not recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	B. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
i											
ii											
iii											
iv*											

S.No as per C	9. Action Taken (please tick): Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Reaction reappeared after reintroduction (please tick): Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										

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

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication
i							
ii							
iii*							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address: _____

Pin:_____E-mail:_____

Tel. No. (with STD code)_____

Occupation:_____ Signature:_____

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

Sig. and Name of Receiver-

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

☑ **The following are several facets of AE reporting:**

- **Individual Case Safety Report**

One of the core concepts of adverse event reporting is determining what constitutes a single case safety report. During the triage phase of a prospective adverse event report, it is critical to determine whether the "four elements" of a valid individual case safety report exist: (1) an identifiable patient, (2) an identifiable reporter, (3) a suspect drug, and (4) an adverse event. [28].

- **Activities involved in pharmacovigilance:**

Case-control study (retrospective study) 2- Prospective research (a cohort study). 3. Population statistics. and (4) Intensive event report. 5- The spontaneous report in the case represents the population of the single case report. [29].

- **Coding of adverse events:**

Adverse event coding is the process of coding "verbatim" information from an AE reporter using standardized vocabulary from a medical coding dictionary, such as MedDRA (the most often used medical coding dictionary). The goal of medical coding is to translate adverse event data into terminology that is easy to identify and evaluate. [30].

- **Seriousness determination:**

Although it may seem apparent, pharmacovigilance has a set of criteria for distinguishing between a significant adverse event and a non-serious one. An unfavorable incident is considered serious if it fits one or more of the following conditions: The following criteria are considered serious: death or life-threatening, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity, congenital anomaly (birth defect), or "medically significant" (i.e., not meeting the preceding criteria but requiring treatment to prevent one of the preceding criteria). [31].

- **Expedited reporting:**

This refers to individual case safety reports involving a serious and unlisted occurrence (one not stated in the drug's labeling) that is thought to be related to the drug's use (US FDA). (Spontaneous reports are often assumed to have positive causation, whereas clinical trial cases are typically evaluated for causality by the clinical trial investigator and/or license holder.) In most countries, the deadline for reporting accelerated instances is 7/15 calendar days after a drug firm receives notification (referred to as "Day 0") of the case.

- **Clinical trial reporting:**

Safety information from clinical trials, also known as AE (adverse event) or SAE (serious adverse event) reporting, is used to establish a drug's safety profile in humans and is a key component that drug regulatory authorities consider when deciding whether to grant or deny market authorization (market approval) for a drug. AE reporting occurs when study patients (subjects, participants) encounter any "untoward" occurrence while clinical trials are being conducted. Non-serious adverse events are often recorded separately, at a lower level than pharmacovigilance.

- **Spontaneous reporting:**

Spontaneous reports are so named because they occur during the physician's usual diagnostic evaluation of a patient, when the clinician concludes that the drug may be involved in the event's etiology. The spontaneous reporting system (SRS) relies on watchful physicians and other healthcare professionals to not only detect but also report adverse medication reactions. It is a key source of regulatory measures, such as removing a medicine from the market or changing the label due to safety concerns. [32].

- **Aggregate reporting:**

Aggregate reporting, also known as periodic reporting, is an important component of medication safety evaluation. Aggregate reporting is the collection of safety data for a drug over a lengthy period of time (months or years), as opposed to single-case reporting, which only includes individual AE reports. The advantage of aggregate reporting is that it provides a more complete picture of a drug's safety

profile. The Periodic Safety Update Report (PSUR) and the Development Safety Update Report (DSUR) are the two most important aggregate reports globally. This is a document that is sent to drug regulatory bodies in Europe, the United States, and Japan (ICH nations), as well as other countries worldwide.

- **Other reporting methods:**

In several countries, physicians are required by law to report spontaneously. Most nations require manufacturers to report any reports received from healthcare practitioners to the national authority via their Qualified Person for Pharmacovigilance (QPPV). Others have extensive, specialized programmes that focus on new pharmaceuticals, problematic drugs, doctor prescription patterns, or pharmacists' reporting. [33]

Role of Hospital Pharmacist:

Pharmacists are ideally situated to play a key

Role in the identification and reporting of Suspected drug-related adverse effects due to Our accessibility and knowledge of drug therapy. As stated, the reporting of suspected Adverse drug reactions does not mandate That a direct cause-and-effect relationship be Established. All that is required is to document the reaction itself and the circumstances Around how it occurred (relevant history, Investigations, concurrent medications, etc.). In 2012, pharmacists submitted only 10% of Health Canada adverse drug reaction reports, which is Unacceptably low. As a profession, we need to Accept responsibility to ensure this activity is Performed systematically and consistently for All suspected adverse drug reactions. [34], [35], [36]. A hospital pharmacist provides expert advise to patients and collaborates with medical and nursing staff to provide optimal treatment. Hospital pharmacists play an essential role in ensuring patient safety [37]. Monitoring drug therapy and identifying potential ADRs [38]. Educating patients about safe drug use [39]. Reporting ADRs to appropriate pharmacovigilance bodies [40]. Collaborating with doctors and nurses in clinical settings [41]. Hospital pharmacists can suggest whether tablet, injections, Ointment or inhaler may be the best form of medication and Frequently liaise with medical staff concerning their patients. [42].

Hospital pharmacists can provide information on potential adverse effects and ensure drugs are compatible with existing medications. [43]. A hospital pharmacist plays a vital role in ensuring the safe, effective, and rational use of medicines within healthcare settings. They are responsible for dispensing medications, providing information about drug interactions and side effects, and ensuring that prescribed drugs are appropriate for each patient's clinical condition. Hospital pharmacists work closely with doctors, nurses, and other healthcare professionals to optimize patient care by offering expert advice on the selection, dosage, and administration of medicines. They also monitor therapeutic outcomes, participate in adverse drug reaction (ADR) reporting, and contribute to patient education regarding correct medicine use. Additionally, hospital pharmacists are involved in procurement, quality assurance, and inventory control to ensure the availability of essential and cost-effective medicines in hospitals. [44], [45], [46], [47].

Patient Admission

Review of Prescriptions

Check for Drug Interactions,
Allergies, and Dosage Errors

Dispensing of Medicines

Provide Drug Information and
Counseling to Patients

Monitor Therapeutic Response and
Adverse Drug Reactions (ADRs)

Collaborate with Doctors and
Nursing Staff on Wards

Ensure Rational Use of Medicines and
Maintain Medicine Inventory

Documentation & Reporting
(e.g., ADR, Medication Errors)

Pharmacovigilance Programme of India (**PvPI**):

The PvPI was initiated by CDSCO and is coordinated by the Indian Pharmacopoeia Commission (IPC) [48]. It aims to collect, analyze, and monitor ADR data from across the country and issue safety alerts. PvPI has Adverse Drug Reaction Monitoring Centres (AMCs) in hospitals that report data to IPC [49].

Digital Tools in Pharmacovigilance

✔PvPI App: Mobile application for quick ADR reporting [50].

✔VigiBase: WHO global database of ADRs [51].

✔AI tools: Used for detecting safety signals and analyzing trends [52].

✔Electronic Health Records (EHRs): Integrated for real-time monitoring [53].

Challenges in Pharmacovigilance

Underreporting of ADRs by healthcare professionals. Legal concerns and time constraints [54]. Limited access to reporting tools, especially in rural areas. Lack of awareness and training [55].

Solutions and Future Scope

Conduct training sessions and awareness campaigns [56].
Encourage patient participation in ADR reporting [57].
Use AI and digital platforms for better data handling [58].
Strengthen national policies and international collaboration [59].

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