# The effectiveness of herbal medicines using Artificial Intelligence in Pharmacovigilance

Devyani Patil[1], Ainul Shafeeque[2], Siddhi Pashte[3]
[1,3]*B. Pharmacy Student, M.S. College of Pharmacy, Devghar*
[2]*Assistant Professor, M.S. College of Pharmacy Devghar*
*doi.org/10.64643/IJIRTV12I11-195577-459*

***Abstract*—Herbal Medicines perceived safety, accessibility, and cultural acceptance have led to a significant surge in its use worldwide. Accurately determining their efficacy and safety is still severely hampered by a lack of clinical data, in consistent quality, and under reporting of adverse events. The large and diverse amounts of data produced by herbal goods, such as unplanned reports, books, social media, and electronic medical records, are frequently too much for traditional Pharmacovigilance (PV) systems to handle. Artificial Intelligence (AI) supported PV may effectively detect adverse event signals, identify patterns, and enhance causality evaluation for herbal products with sophisticated algorithms including Natural Language Processing (NLP), Machine Learning (ML), and deep learning. This method facilitates the creation of evidence about therapeutic effects while simultaneously improving the precision and promptness of safety monitoring. An innovative approach to assessing the practical efficacy of Herbal Medicines (HM), enhancing patient safety, and fortifying international health monitoring systems is the integration of AI into PV systems. In order to guarantee the ethical, fair, and dependable application of AI technologies in HM monitoring, future advancements should concentrate on creating extensive herbal databases, enhancing algorithm transparency, and encouraging global co-operation.**

## I. INTRODUCTION

Pharmacovigilance (PV) is a process of Detecting, evaluating, comprehending, and preventing adverse drug events (ADEs) and other drug-related issues is the science and practice known as pharmacovigilance (PV). Its main objective is to monitor and control the dangers connected to pharmaceutical products in order to guarantee patient safety. Although they are essential, traditional pharmacovigilance techniques like manual reporting systems and spontaneous reporting databases are frequently constrained by human error, data delay, and underreporting. These restrictions may prolong the time that patients are exposed to dangerous drugs by delaying the discovery of drug safety signals [1].

Artificial Intelligence (AI) in Pharmacovigilance- Large diverse datasets may be processed by AI, which can also identify new or subtle safety warnings that human systems would overlook. However, using AI powered PV for Herbal Medicines (HM) necessitates managing specific problems such as complicated multi-ingredient products, batch-level quality variance, nonstandard nomenclature, and a variety of data sources such as manufacturing records, social media, and traditional healer notes [2]. Healthcare is seeing a growing number of applications of artificial intelligence (AI), which is transforming procedures by automating operations, analysing large information, and spotting patterns that are impossible for humans to see. AI-based pharmacovigilance technologies, such as machine learning, natural language processing, and predictive analytics, present encouraging ways to enhance medication safety. These technologies have the potential to improve adverse medication event detection speed and accuracy, expedite data processing, and offer real-time patient outcome insights [3,4].

## II. STUDY OBJECTIVE

This study's main goal is to investigate how artificial intelligence (AI) might improve pharmacovigilance by improving adverse medication event detection, monitoring, and analysis. In addition to offering insights into the future of AI-driven drug safety monitoring, it will go over how AI might help

overcome the present shortcomings of conventional PV systems [5]

Why specific pharmacovigilance is necessary for herbal medicines - Variability in preparations and products Different species, plant parts, geographical origins, harvest times, processing methods, and formulations result in different herbal products. The toxicity risk and constituent profiles are changed by this fluctuation. The attribution of adverse events is complicated by the fact that many Herbal Medicine products have formulae with many ingredients [6]. Underreporting and deficiencies in the data the lack of product IDs on reports, patient and provider ignorance, restricted reporting routes, and safety perceptions all contribute to the lower rate of spontaneous reporting for Herbal Medicines compared to conventional medications. National PV systems frequently overlook important product information like batch or manufacturer [7]

## III. ADVERSE DRUG REACTION (ADR) IN HERBAL MEDICINES

Many societies around the world are now using herbal remedies. As hepatoprotectives, antidiabetics, and cough treatments, herbal formulations have gained universal acceptance as medicinal agents. Since herbal medicines come from natural sources, they are usually regarded as safe. This is untrue, though, as several case reports of negative reactions to herbal medications have been documented in the literature [8].

Herb–drug interactions and polypharmacy-Many Herbal Medicine users take concomitant prescription medicines; interactions (e.g., CYP enzyme modulation) can cause significant harm.

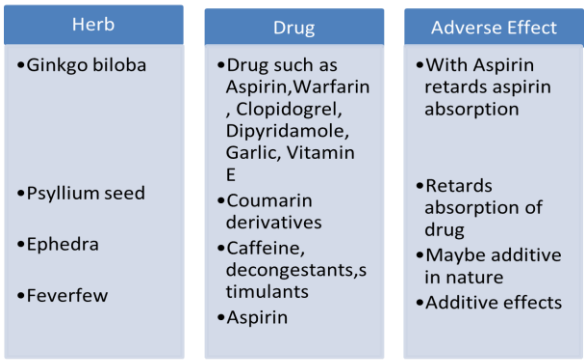



Fig.1 Herb-Drug Interactions [8]

Pharmacokinetic Interactions (ADME): The herbal supplement alters the way the body processes a prescription drug.

Absorption: Herbs can increase or decrease absorption (e.g., fiber-containing herbs). Distribution: Herbs might alter how drugs are transported in the blood. Metabolism: Herbs often affect the Cytochrome P450 (CYP450) enzyme system in the liver induces enzymes (speeds up breakdown, reduces efficacy), while others can inhibit them. Excretion: Herbs can change how quickly a drug is eliminated via the kidneys.

Pharmacodynamic Interactions: The effects of the herb and medication on the body might be combined, intensified, or counteracted. Additive/Synergistic: Effects are increased, such as combining sedative herbs (e.g., Valerian) with benzodiazepines, or blood-thinning herbs (e.g., Ginkgo) with anticoagulants. Herbs that are antagonistic neutralize the effects of drugs, such as immunosuppressants and immunological stimulants [9].

Herbs ADRs could be classified as per WHO System Organ Class (SOC). Following list is an example of SOC -Cardiovascular System with Severe ARs or Notable Drug Interaction.

| Herbal Medicines | Adverse Reaction/Drug Interaction | Treatment |
|---|---|---|
| Natural cardiac Glycosides (>20 plant sources | Ventricular tachyarrhythmia, bradycardia and heart block | Digoxin-specific Fab antibody |
| Veratrum (hellebore) | Bradycardia, AV dissociation, hypotension, and (rarely) seizures | ECG changes responsive to atropine |
| Crataegus hawthorn | Potentiates digitalis activity | NA |
| Salvia militarizes (Dan-Shen) | Potentiates warfarin activity | NA |
| Aesculus hippocastanum (Horse chestnut) | Renal and hepatic toxic effects | Dialysis to reduce toxic levels |

Table.1 Herbal Adverse drug reaction [10].

## IV. AI TECHNIQUES AND PV ASSIGNMENTS RELATED TO HERBAL REMEDIES

1. Natural Language Processing (NLP) - NLP makes it possible to extract herb names, dosages, routes, and results from free-text in social media posts, Electronic Health Record (EHRs), and case reports. Herbal Medicine names contain misspellings and colloquial words; therefore, entity normalization (linking to botanical IDs) is crucial.
2. Detecting signals with machine learning ML techniques - (supervised, unsupervised, anomaly detection) enhance the recognition of anomalous Adverse event (AE) patterns and give priority to signals that pose a high risk [11].
3. Models that support causality Through the integration of known mechanisms, co-exposures, and temporal data, AI can assist with causality judgments. For regulatory trust, explainable models are necessary.
4. By eliminating duplicates, classifying cases automatically, and sending them to experts for review, AI-powered automated case processing lessens the workload for human reviewers [12].

AI in the Recognition and Verification of Herbal Components:

Many plant species have similar morphologies and complex chemical makeups, artificial intelligence (AI) has become a potent tool for the identification and verification of herbal compounds. Conventional techniques, such microscopic inspection and chemical analysis, can be laborious and prone to human mistake. Artificial intelligence (AI) algorithms, especially those built on machine learning, can accurately differentiate between genuine and tampered herbal materials by analyzing spectral data, chemical fingerprints, and pictures. For instance, real and fake Panax ginseng roots can be distinguished using machine vision and artificial intelligence. Digital photos, surface texture, shape, and color can be analyzed by AI algorithms to find minute variations that are frequently indistinguishable to the human eye [13].

Evidence of AI used to improve the safety of herbal medicines:

Herbal Medicines produce quantifiable AE loads that differ by region and reporting practice, according to a 2024 comprehensive investigation that gathered AE data for herbal products from national AE databases. Underreporting and incorrect product identification were brought to light by this study. Social media and natural language processing (NLP) studies have demonstrated the viability of identifying patient-reported unpleasant medication experiences; these techniques are being modified to identify colloquialisms and herbal words [14]. Signals that were later confirmed in conventional surveillance have been successfully recognized by social-listening algorithms. Reviews of AI in pharmacovigilance identify reproducibility, bias, and regulatory integration as unresolved concerns, but they also affirm that AI increases processing speed and can increase signal detection sensitivity when paired with domain expertise [15].

## V. IMPLEMENTATION OBSTACLES

1. lack of standardized data on Herbal Medicines Inadequate - Data Standardization for Herbal Products Standardized naming schemes, dosing guidelines, and a uniform chemical makeup are frequently absent from herbal medicines. AI models find it challenging to evaluate safety data and identify adverse drug reactions (ADRs) because to variations in plant species, growth conditions, and extraction techniques [16].

2. Under-reporting of Adverse Events- Because many customers think herbal products are intrinsically safe, adverse reactions to herbal treatments are often underreported. For AI systems employed in pharmacovigilance signal detection, this results in insufficient data [17].

3. Poor Integration with Existing Pharmacovigilance Databases- The efficacy of AI-based monitoring systems is limited because the majority of pharmacovigilance databases are made for traditional pharmaceuticals and might not sufficiently record information on herbal medicines [18].

4. Complexity of Multi-Component Herbal Formulations- It might be challenging to identify which of the many active phytochemicals found in herbal medications is causing negative side effects.

This intricacy makes evaluating causality using AI more difficult [19].

5. Limited Digitized and Structured Data- AI-based analysis and machine learning model creation is hampered by the fact that a large number of herbal medicine records are located in printed books and traditional knowledge systems rather than digital databases.

6. Regulatory and Quality Control Issues - Regulations governing herbal medications differ between nations. Pharmacovigilance monitoring and AI data analysis are complicated by problems like adulteration, contamination, and inconsistent production procedures [20].

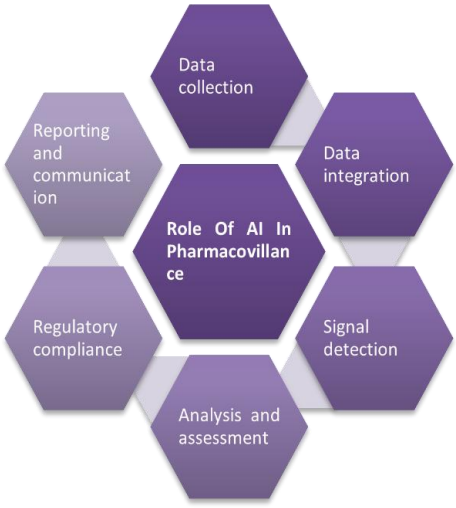



Fig.2 Overview of Pharmacovigilance Process

## VI. DETECTING SIGNALS WITH MACHINE LEARNING:

Pharmacovigilance is being revolutionized by machine learning (ML) techniques, which make it possible to find patterns and signals in massive datasets that could point to adverse drug reactions (ADRs). Important advantages and uses include: Signal Detection: More quickly than with conventional techniques, ML models can sort through enormous amounts of patient data, electronic health records (EHRs), and clinical reports to find uncommon and rare ADRs. Unsupervised learning helps detect previously unknown or uncommon ADRs by identifying hidden patterns in the data, whereas supervised learning models are trained on labelled datasets to predict known ADRs.

NLP, or natural language processing, in text mining Clinical notes, social media, and medical literature are just a few of the unstructured text data sources that can be analysed using the potent AI approach known as natural language processing, or NLP. This enables pharmacovigilance experts to: Key Insights Can Be Extracted: Natural language processing (NLP) can automatically extract pertinent information regarding ADRs from free-text inputs, saving time and effort compared to manually reviewing big files NLP algorithms can keep an eye on public platforms, like social media, for early indications of adverse drug reactions (ADRs) by analysing patient-reported outcomes and casual conversations about pharmaceuticals [21,22].

Using Predictive Analytics in Risk Evaluation To evaluate possible adverse drug events (ADEs) and identify patients who are at risk, AI-driven predictive analytics algorithms are being utilized: ADE forecasting: AI systems are able to examine patient histories, medication consumption patterns, and profiles to estimate the risk of adverse drug reactions (ADRs) before they happen. Healthcare providers can customize treatment strategies and reduce drug safety concerns by using AI technologies to stratify patients into various risk groups based on patient-specific criteria including age, genetics, and co-morbidities. Systems for Automatic Reporting AI-enabled solutions can automate the creation and submission of medication safety reports to regulatory bodies, thus streamlining the pharmacovigilance reporting process. These systems have a number of benefits: Decreased Human Workload: Automated systems reduce the need for manual report writing and data entry, which lowers the possibility of human error and frees up medical staff to make more complex decisions. Real-Time Reporting: AI technologies can produce real-time reports and continuously monitor medication safety data, which speeds up reactions to possible problems [23].

A practical approach for AI-enabled Herbal Medicine pharmacovigilance that keeps humans in the loop A suggested staged framework for national PV centres, regulators, and industry is provided below:
Phase 1: Establishment Simplify Herbal Medicine product identifiers and use botanical normalization dictionaries. Include structured reporting fields in

spontaneous reporting forms for the HM brand, manufacturer, batch, and administration route.

Phase 2: NLP and data ingestion Create NLP pipelines to extract Herbal Medicines mentions from public posts, spontaneous reports, and EHRs; utilize ontology linking to pharmacopoeia references and plant IDs. Utilize active learning and pretrained language models that have been refined using local Herbal Medicine corpora to enhance performance on local vernacular.

Phase 3: Identification and Prioritization of Signals Use ML prioritizing in conjunction with conventional disproportionality techniques to uncover unique or high-impact Herbal Medicine signals. Incorporate time-series anomaly detectors to identify cluster outbreaks (such as contamination incidents) early.

Phase 4: Causality support & triage - Provide explainable AI outputs (e.g., salient text spans, feature importance) to support expert causality assessment. Human experts should always review flagged cases

Phase 5: The feedback loop and regulatory response Initiate supply-chain audits, lab testing, and targeted messaging based on verified signals. Models are retrained using result data (closed feedback loop). To ensure regulatory transparency, keep audit trails up to date. Make sure that interdisciplinary teams consist of doctors, toxicologists, botanists, data scientists, and regulators throughout every stage, and make investments in workforce governance and training [24].

## VII. INFORMATION SOURCES FOR AI-POWERED HERBAL MEDICINE IN PHARMACOVIGILANCE (AI-PV)

1. VigiBase: The WHO Global Individual Case Safety Report (ICSR) Database - The Uppsala Monitoring Center is responsible for maintaining VigiBase the largest library of Individual Case Safety Reports (ICSRs) in the world. More than 150 countries have spontaneous reports in it. Despite being frequently referred to as "unspecified herbal and traditional medicine," herbal medicines are nevertheless included. AI can search this database for warning signs about the use of herbs, such as hepatobiliary illnesses connected to conventional treatments [25].
2. KAERS: Korea Adverse Event Reporting System - Well-categorized information about herbal medicines can be found in the Korean national pharmacovigilance system. Frequent adverse events, especially gastrointestinal and nervous system reactions, have been found in studies employing KAERS. These organized statistics can be processed by AI to reveal AE patterns unique to a given herb [26].
3. Taiwan ADR Reporting System for Herbal Medicines (TADRRS) - Reports of adverse responses to herbal medications, both single-herb and multi-ingredient, are available in Taiwan's dedicated database. This dataset is particularly useful because it allows AI to stratify hazards by include information on severity and system organ class [27].
4. Pharmacovigilance Programmed of India (PVPI) - Both allopathic and Ayurvedic/herbal medication adverse event reports have been gathered by India's PVPI. Reports contain information about patient demographics, medication details, and results. This material is particularly pertinent to the herbal and Ayurvedic formulas that are commonly utilized in India [28].
5. Ethnobotanical and Phytochemical Databases- Databases that offer chemical and ethnomedical profiles of medicinal plants include Dr. Duke's Phytochemical and Ethnobotanical Databases. These are helpful in connecting a reported herb to its active ingredients and possible toxicity pathways for AI systems [29].
6. Published Literature & Systematic Reviews- Systematic reviews, clinical research, and case reports are crucial secondary sources. Herb names, side effects, dosage, and interactions can all be extracted by AI using natural language processing (NLP). Systematic evaluations of PV databases, for instance, point to methodological flaws and trends in ADRs associated with herbs [30].

## VIII. CHALLENGES IN PHARMACOVIGILANCE AND HERBAL MEDICINES

1. Insufficient Knowledge Among Medical Professionals -A lot of medical professionals, including doctors, nurses, and pharmacists, don't know enough about herbal remedies and how they

interact with prescription medications. This may have an impact on appropriate diagnosis and treatment choices.

2. Misconception about Safety: "Natural = Safe" - Patients have a common perception that natural products are safe. However, side effects or drug interactions are possible with herbal remedies.
3. Inadequate Patient-Doctor Communication - Patients frequently utilize herbal remedies in addition to prescription medications, but many don't tell medical professionals. In a similar vein, conversations regarding concurrent medication use are frequently neglected.

Key Challenges

1. Taxonomy and Ambiguity of Ingredients- Unlabeled or mixed substances may be included in herbal products. A common name may be shared by several plant species. International guidelines underline that accurate identification is crucial yet challenging.
2. Pharmacovigilance Systems' Underreporting-A lot of people who take herbal remedies don't notice any negative side effects. Crucial information like brand name, dosage, or preparation method is frequently missing from reports. As a result, the data is inconsistent and of poor quality.
3. Low Signal Detection and Heterogeneous Data- Herbal safety cues are frequently uncommon and challenging to identify. Analysis is impacted by class imbalance and data variability, particularly in AI-based systems.
4. Issues with Regulation and Ethics-Herbal medicines are not subject to uniform regulatory regimes. Algorithmic bias in AI systems raises concerns. (e.g., social media, electronic health records).
5. Inadequate Characterization of Safety-National pharmacovigilance systems do not adequately document the safety profiles of many herbal medicines, despite their widespread usage. There is still little integration with official monitoring systems [31].

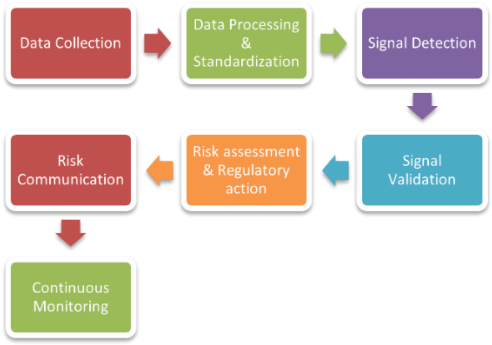



Fig.3 Cycle of Herbal Medicines Supported by AI in Pharmacovigilance [32,33].

## IX. REPORTING OF HERBAL MEDICINES

1. Who Can Report-Healthcare professionals (doctors, pharmacists, nurses, AYUSH practitioners)

- Patients and consumers
- Pharmaceutical/herbal product manufacturers
- Researchers and clinical investigators
- Pharmacovigilance centers and hospitals

2. Information Required for Reporting-Patient details: age, gender, medical history

Herbal product details:

- Botanical name and common name
- Brand/manufacturer
- Dosage form (tablet, extract, oil, etc.)
- Dosage details: dose, frequency, duration

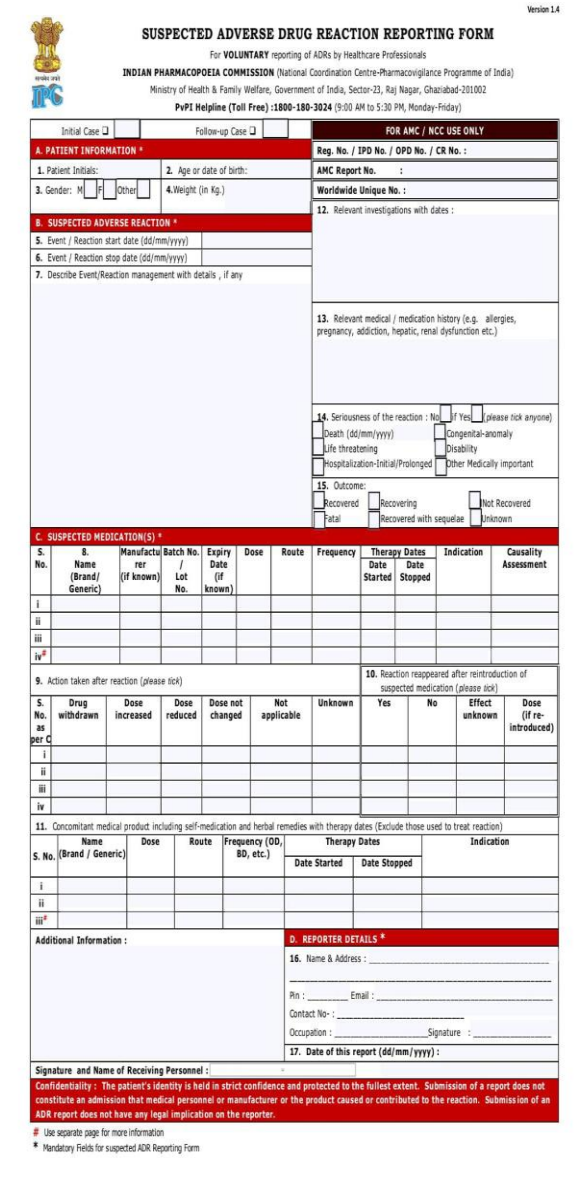
Adverse reaction details:

- Description of reaction
- Onset and duration
- Severity
- Concomitant drugs (other medicines taken)
- Outcome: recovered, ongoing, serious, fatal
- Reporter details: name and contact (optional in some systems)

3. Steps in Reporting

- Identify the adverse reaction related to herbal medicine
- Collect complete information (patient, product, reaction)

- Fill ADR reporting form (pharmacovigilance/AYUSH form)
- Submit report to: National Pharmacovigilance Centre, AYUSH Pharmacovigilance Program, Hospital ADR monitoring center
- Assessment and causality evaluation by experts
- Data entry and analysis in pharmacovigilance database
- Signal detection and regulatory action
- Feedback and awareness to healthcare professionals/public [34].



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**

**A. PATIENT INFORMATION ***

1. Patient Initials: 2. Age or date of birth: 4.Weight (in Kg.)

3. Gender: M F Other

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)

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 and 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 : _____

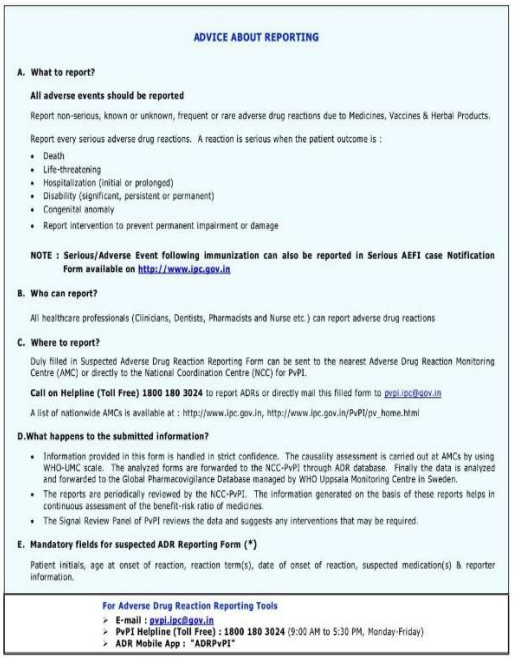
17. Date of this report (dd/mm/yyyy) :

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



**ADVICE ABOUT REPORTING**

**A. What to report?**

**All adverse events should be reported**

Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines & Herbal Products.

Report every serious adverse drug reactions. A reaction is serious when the patient outcome is :

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability (significant, persistent or permanent)
- Congenital anomaly
- Report intervention to prevent permanent impairment or damage

**NOTE : Serious/Adverse Event following immunization can also be reported in Serious AEFI case Notification Form available on http://www.ipc.gov.in**

**B. Who can report?**

All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurse etc.) can report adverse drug reactions

**C. Where to report?**

Duly filled in Suspected Adverse Drug Reaction Reporting Form can be sent to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC) for PvPI.

**Call on Helpline (Toll Free) 1800 180 3024** to report ADRs or directly mail this filled form to pvpi.ipc@gov.in

A list of nationwide AMCs is available at : http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

**D.What happens to the submitted information?**

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC-PvPI through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The Signal Review Panel of PvPI reviews the data and suggests any interventions that may be required.

**E. Mandatory fields for suspected ADR Reporting Form (*)**

Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) & reporter information.

**For Adverse Drug Reaction Reporting Tools**

- **E-mail : pvpi.ipc@gov.in**
- **PvPI Helpline (Toll Free) : 1800 180 3024** (9:00 AM to 5:30 PM, Monday-Friday)
- **ADR Mobile App : "ADRPvPI"**

ADR Reporting Form [35].

Preventing ADRs and AEs -

Get thorough history of your medications: To prevent exposing a patient to dangerous drugs again, find out about their past drug experiences, particularly any past adverse drug reactions. Sstreamline Drug Schedules: Stop using drugs that aren't essential to cut down on complexity and possible interactions. Determine High-Risk Patients and Drugs: Keep an eye out for medications that carry a high risk of adverse drug reactions (ADRs) and closely monitor patients who are more susceptible [36]. Change the dosages: To lessen the chance of negative effects, adjust medication dosages according to variables like age and renal function Deal with Interactions Between Drugs: Don't give medications that have a history of adverse interactions. Think About Non-Pharmaceutical Choices: Always consider conservative or non-pharmacological therapy methods as potential substitutes for prescription drugs [37]. Identification of adverse events is difficult Because herbal medicines are not widely known or understood, adverse events related to them are frequently underreported or not identified. Determining the source of adverse effects might be particularly difficult in groups that may utilize herbal medicines in addition

to conventional medicine. Language and cultural barriers: Herbal remedies are frequently employed in traditional medical systems that are unique to particular cultures, and the terms used to refer to these remedies might not be readily understood or translated by people from other cultures. Data collection and interpretation regarding the safety and effectiveness of herbal medicines may become challenging as a result. Restricted regulation: Herbal remedies are frequently categorized as dietary supplements as opposed to pharmaceuticals [38].

Future Directions

1. AI Advancements in the Safety of Herbal Medicines -Future analyses of AI advancements in the safety of herbal medicines center on the ongoing creation and application of increasingly sophisticated AI algorithms that can manage datasets that becoming more complicated. New technologies like deep learning and big data analytics are anticipated to improve the precision of safety evaluations, forecast infrequent negative reactions, and fine-tune the customization of herbal remedies according to metabolic and genetic profiles. Furthermore, AI-driven solutions are anticipated to enhance worldwide pharmacovigilance networks, allowing for real-time safety monitoring of herbal medicines across various populations. As these technologies develop, they will play a major role in building stronger legal frameworks and increasing public confidence in the security of herbal remedies
2. The integration of artificial intelligence (AI) into pharmacovigilance for herbal medicines offers considerable potential but also highlights key areas for future advancement. A critical priority is the standardization of herbal medicine data, since inconsistent naming and classification across databases limit accurate safety signal detection. Tools that harmonize botanical, vernacular, and commercial names can strengthen global monitoring systems [39].
3. Another direction involves the integration of multi-source real-world evidence, where AI and natural language processing (NLP) can analyze electronic health records, claims databases, and even social media to capture under-reported adverse events related to herbal products.
4. AI systems should also focus on herb–drug interaction prediction, as herbal medicines are frequently co-administered with conventional drugs. Machine learning can identify high-risk combinations and prioritize them for regulatory assessment [40].
5. To build trust and improve clinical adoption, explainable AI approaches are needed so that safety predictions highlight specific herbal ingredients, patient characteristics, or interaction factors driving the risk [41].
6. Looking globally, the development of cross-cultural pharmacovigilance frameworks is vital. By integrating traditional medicine systems such as Ayurveda, Traditional Chinese Medicine, and Kampo, AI-supported databases could provide more comprehensive safety insights.
7. Finally, advances in personalized pharmacovigilance that combine herbal use with genetic, lifestyle, and comorbidity data may lead to individualized risk prediction and safer clinical decision-making in the future [42].

## X. CONCLUSION

The integration of artificial intelligence (AI) into pharmacovigilance (PV) represents a significant advancement in improving the safety and effectiveness monitoring of herbal medicines. Conventional PV systems face challenges such as underreporting, inconsistent nomenclature, heterogeneous data, and difficulties in identifying herb–drug interactions. AI-based approaches, including machine learning and natural language processing, provide efficient tools for analyzing large and diverse datasets, enabling early detection of adverse events, improved causality assessments, and enhanced regulatory decision-making. By applying AI technologies to PV, it is possible to strengthen evidence generation, improve patient safety, and support global health monitoring systems. The successful implementation of AI in herbal medicine PV requires addressing issues related to data quality, algorithm transparency, regulatory acceptance, and ethical considerations. Future efforts should focus on the development of standardized herbal medicine databases, integration of real-world data sources, adoption of explainable AI models, and promotion of international collaboration. Overall, AI-supported PV

offers a promising approach to overcoming existing limitations and ensuring more reliable and timely evaluation of herbal medicines.

REFERENCES


[1] Enoch O, et al. AI and Pharmacovigilance: Enhancing Drug Safety Monitoring [Internet]. ResearchGate. 2024 Oct 8 [cited Date]. Available from:https://www.researchgate.net/publication/...

[2] Harpaz R, DuMouchel W, Shah NH, Madigan D, Ryan P, Friedman C. Novel data-mining methodologies for adverse drug event discovery and analysis. Clin Pharmocol Ther. 2012;91(6):1010–1021

[3] Kompa B, Hakim JB, Palepu A, Kompa KG, Smith M, Bain PA, et al. Artificial Intelligence Based on Machine Learning in Pharmacovigilance: A Scoping Review. Drug Saf. 2022;45(4):477-491. doi: 10.1007/s40264-022-01176-1.

[4] CIOMS Working Group. Artificial intelligence in pharmacovigilance. CIOMS Working Group report. Draft, 1 May 2025

[5] Rashmi, Kaur V, Kumar A, Srivastava H, Kumar S, Babu A. AI-Powered Pharmacovigilance: Revolutionizing Drug Safety for Tomorrow

[6] M.A. Shamim et al. Artificial intelligence and big data for pharmacovigilance and patient safety. Journal of Medicine, Surgery, and Public Health. 2024;3(0):00139. doi:https://doi.org/10.1016/j.jmsph.2024.00139

[7] World Health Organization. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems. Geneva: World Health Organization; 2004.

[8] Kubde S. Adverse drug reactions and pharmacovigilance of herbal medicines in India. International Journal of Green Pharmacy. 2016 Jan-Mar;10(1):S29

[9] Bisht P, Pathak A, Mishra A. Herb-drug interaction: A review. e-planet. 2021 Dec; 19(2): 196-200.

[10] Rahman SZ, Al Rashid S. Safety of medicinal tropical natural products – concerns and issues. *J Pharmacovigilant Drug Saf.* 2020;17(1). doi:10.21276/jpds.2019.17.01.03.

[11] Bailey C, Peddie D, Wickham ME, Badke K, Small SS, Doyle-Waters MM, Balka E, Hohl CM. Adverse drug event reporting systems: a systematic review. Br J Clin Pharmocol. 2016;82(1):17-29.

[12] Liang L, Hu J, Sun G, Hong N, Wu G, He Y, Li Y, Hao T, Liu L, Gong M. Artificial intelligence-based pharmacovigilance in the setting of limited resources. Drug Saf.2022;45(11):511-519. doi: 10.1007/s40264-022-01170-7

[13] Robertson S. Role of artificial intelligence in enhancing the safety of herbal medicines. Int J Sci Res. 2021;14(2):36-37.

[14] Main CL, de Souza MB, Johan V, Tistaert MB, Bredol A, de Geyter A, et al. Quality Control of Herbal Medicines: From Traditional Techniques to State-of-the-art Approaches. Planta Med. 2021 Aug;87(10-11):964-8.

[15] Jeetu G, Anusha G. Pharmacovigilance: A Worldwide Master Key for Drug Safety Monitoring. J Young Pharm. 2010;2(3):315-320. doi:10.4103/0975-1483.66802

[16] Barnes J. Pharmacovigilance of herbal medicines: a UK perspective. Drug Saf. 2003;26(12):829-51.

[17] Ekor M. The growing use of herbal medicines: issues relating to adverse reactions and challenges in monitoring safety. Front Pharmocol. 2014; 4:177.

[18] Shaw D, Ladds G, Duez P, Williamson E, Chan K. Pharmacovigilance of herbal medicine. J Ethnopharmacology. 2012;140(3):513-18.

[19] Izzo AA, Ernst E. Interactions between herbal medicines and prescribed drugs. Drugs. 2009;69(13):1777-98.

[20] Bent S. Herbal medicine in the United States: review of efficacy, safety, and regulation. J Gen Intern Med. 2008;23(6):854-59.

[21] Sartori D, Aronson JK, Brand JS, Gauffin O, Hedfors Vidlin S, Norén GN, et al. Signals of Adverse Reactions to Herbal Medicines: Evidence and Document Analysis Based on a Scoping Review. Drug Saf. 2025. doi: 10.1007/s40264-025-01506-3.

[22] Warner J, Prada Jardim AC, Albera C. Artificial Intelligence: Applications in Pharmacovigilance Signal Management. Pharmocol Med. 2025;39(3):183-190. doi:10.1007/s40290-025-00961-2.

[23] Rochefort CM, Buckeridge DL, Forster AJ. Accuracy of using automated methods for detecting adverse events from electronic health

record data: a research protocol. Implement Sci. 2015; 10:5.1-9

[24] Choi Y, Shin H-K. Adverse events associated with herbal medicine products reported in the Korea Adverse Event Reporting System from 2012 to 2021. Front Pharmocol. 2024; 15:1379268. doi: 10.3389/fphar.2024.1379268.

[25] Van Hunsel F, van de Koppel S, Skalli S, Kuemmerle A, Teng L, Wang J, et al. Analysis of Hepatobiliary Disorder Reports Associated With the Use of Herbal Medicines in the Global Suspected ADR Database Vigibase. Front Pharmacol. 2019 Nov 26;10:1326.

[26] Choi Y, Shin H-K. Adverse events associated with herbal medicine products reported in the Korea Adverse Event Reporting System from 2012 to 2021. Front Pharmacol. 2024;15:1379208. doi: 10.3389/fphar.2024.1379208

[27] Hung H-C, Chang S-Y, Chen P-C, et al. A system for reporting and evaluating adverse drug reactions of herbal medicine in Taiwan from 1998 to 2016. Sci Rep. 2021;11(1):20461. doi:10.1038/s41598-021-99950-0

[28] Kalaiselvan V, Saurabh A, Kumar R, Singh GN. Adverse reactions to herbal products: An analysis of spontaneous reports in the database of the Pharmacovigilance Programme of India. J Herb Med. 2015;5(1):48-54. doi:10.1016/j.hermed.2015.01.006.

[29] Williamson EM, et al. Using taxonomic name resolution to identify herbal adverse events. Ther Innov Regul Sci. 2020. DOI: 10.1177/1177932220921350

[30] Kongkaew C, Dang THA, Phueanpho N, Mungkorn P. Estimating Adverse Events Associated With Herbal Medicines Using Pharmacovigilance Databases: Systematic Review and Meta-Analysis. JMIR Public Health Surveill. 2024;10:1-3. doi: 10.2196/63008

[31] Ministry of AYUSH. National Pharmacovigilance Programme for ASU&H Drugs. New Delhi: Govt of India; 2018.

[32] Wang Y, Fan X, Qu H, Gao X, Cheng Y. Strategies and challenges for the quality control of traditional Chinese medicines. *J Pharm Biomed Anal.* 2013; 87:210–219.

[33] Bate A, Evans SJW. Quantitative signal detection using spontaneous ADR reporting. *Pharmacoepidemiology Drug Saf.* 2009;18(6):427–436.

[34] Barnes J, Anderson LA, Phillipson JD. Herbal Medicines. 3rd ed. London: Pharmaceutical Press; 2007.

[35] Indian Pharmacopoeia Commission. Suspected Adverse Drug Reaction Reporting Form (Version 1.4). Ghaziabad: National Coordination Centre–Pharmacovigilance Programme of India (PvPI); Ministry of Health & Family Welfare, Government of India; [cited 2026 Mar 26]. Available from: http://www.ipc.gov.in

[36] Zhang H, Liu X, Wang Y. AI and NLP in Extracting Adverse Event Information from Online Reviews of Herbal Products. Journal of Biomedical Informatics, 2019, 94: 103190.

[37] Chen Z, Huang Y, Wu X. Standardization of Herbal Medicine Production Using AI Technologies: A Comprehensive Review. Phytomedicine, 2021, 81: 153408

[38] Kim H, Cho W, Lee S. Artificial Intelligence in Personalized Herbal Medicine: Applications in Cognitive Health. Journal of Herbal Medicine, 2020, 25: 100401.

[39] Li X, Feng Y, Zhang W. The Role of Artificial Intelligence in the Authentication of Herbal Medicines: Current Advances and Future Directions. Journal of Ethnopharmacology, 2021, 272: 113907.

[40] Wu XW, Zhang Y, Liu L, Sun J, Wang Y. Development of an adverse drug reaction prediction system for Chinese herbal medicines using machine learning. Front Pharmacol. 2022;13:876543. doi:10.3389/fphar.2022.876543.

[41] Spanakis M, Kapetanakis S, Kallergis G, Tzouramanis T. Artificial intelligence models and tools for the assessment of drug safety: applications in pharmacovigilance of conventional and herbal medicines. Pharmaceutics. 2025;17(2):456. doi:10.3390/pharmaceutics17020456

[42] Liang L, Wang J, Chen M, Zhou H. Artificial intelligence–based pharmacovigilance in the safety assessment of traditional Chinese medicine: opportunities and challenges. Front Pharmacol. 2022;13:912345. doi:10.3389/fphar.2022.912345