Review Article

Role of Pharmacovigilance in Drug Safety Monitoring

Abstract

With the introduction of more and more drugs, modern medicine has succeeded in saving mankind from many fatal infections and other diseases. As newer drugs are brought into the market, the reported adverse drug events also increase. Drug safety measures include meticulous premarketing trials, post-marketing surveillance, avoidance of errors from drug prescription to administration, and ensuring the availability of quality medicines at healthcare facilities. Early diagnosis and prompt treatment of pharmacological side effects and idiosyncratic drug reactions are of utmost importance. Pharmacovigilance program helps to compile data on preventable and non-preventable adverse drug events through vigilant monitoring, utilizes the data to recommend regulations, and conveys information on potential risks associated with specific medicines to all stakeholders. The advances in technology, including artificial intelligence, offer unlimited scope to expand pharmacovigilance services. In this review, we have attempted to discuss the functioning and prospects of the pharmacovigilance program with a special focus on cutaneous adverse drug reactions.

Keywords: *Adverse drug event, drug safety, idiosyncratic drug reaction, pharmacovigilance*

Anju E. Paul, Sarita Sasidharanpillai

Department of Dermatology and Venereology, Government Medical College, Kozhikode, Kerala, India

Introduction

All newly introduced drugs must undergo clinical trials before they are registered and marketed. These clinical trials give valuable information regarding the physiological and idiosyncratic adverse effects as well as the efficacy of the medicines. Only drugs whose benefits outweigh the anticipated adverse effects receive marketing approval. However, the adverse effects that appear after prolonged use, the rare (1 in 1000) and the very rare (1 in 10,000) adverse effects, and adverse effects that manifest in specific subgroups may not be detected in premarketing trials; hence, a continuous post-marketing surveillance is needed to ensure drug safety.[1,2] This paved the way for the institution of a pharmacovigilance program (PvP) which facilitates the timely exchange of information on adverse drug events (both pre- and post-marketing phases) from healthcare professionals, pharmaceutical industries and consumers to regulatory authorities, and vice versa.[2] Pharmacovigilance is defined as the science and activities related to the detection, assessment, understanding, and prevention of adverse drug reactions or any other drug-related problems.[3] Drug safety is dependent on a three-stage, inter-related risk management process that includes a) characterization of the safety profile of a particular drug with information on what is known and what is unknown, b) pharmacovigilance activities to identify new risks and improve knowledge, and c) planning and executing risk-reduction strategies and assessing the efficacy of the same.[2]

In 1968, the WHO (World Health Organisation) established the WHO Programme for International Drug Monitoring (WHO PIDM), placing drug and vaccine safety as an important and integral component of global health care.[4] In 1978, WHO, in association with the Government of Sweden, instituted the Uppsala Monitoring Centre, a self-funded, nonprofit organization to engage stakeholders of the global pharmacovigilance community.[5,6] PvP compiles data on adverse drug events, safety, and efficacy of drugs worldwide, analyzes the data, formulates inferences to recommend regulations, and communicates risks to healthcare professionals and the public as and when needed.[2] The COVID-19 (coronavirus disease-2019) pandemic has brought to the fore the relevance of PvP when the vaccine and antiviral drug safety had to be assessed on a war footing.[7,8]

How to cite this article: Paul AE, Sasidharanpillai S. Role of pharmacovigilance in drug safety monitoring. Indian Dermatol Online J 2025;16:545-50.

Received: 05-Aug-2024. **Revised:** 15-Dec-2024. **Accepted:** 18-Dec-2024. **Published:** 17-Jun-2025.

Address for correspondence:
Dr. Sarita Sasidharanpillai, Rohini, Girish Nagar, Nallalom PO, Kozhikode - 673027, Kerala, India.
E-mail: saritasclt@gmail.com

Access this article online

Website: https://journals.lww.com/idoj

DOI: 10.4103/idoj.idoj_771_24

Quick Response Code:

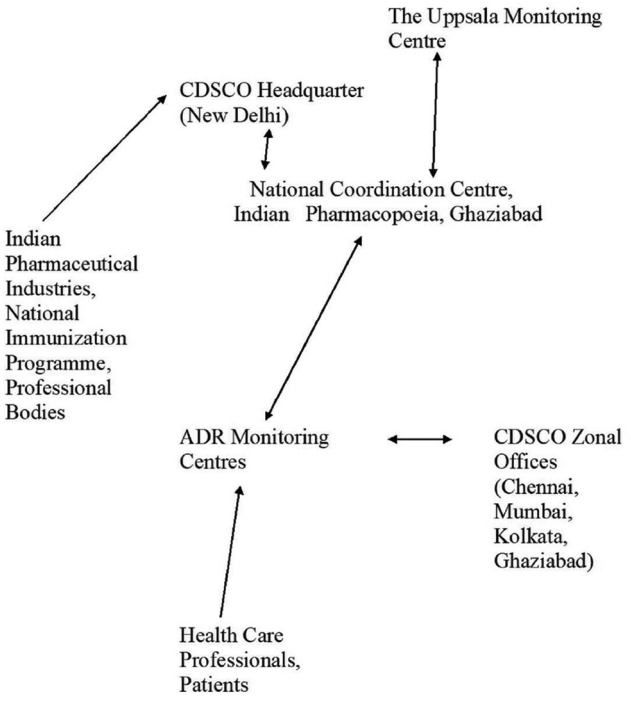
In this review, in addition to delineating the functioning of PvP (including detecting hitherto unreported reaction patterns through signal generation), we have tried to give information on identifying the offending agent in a suspected adverse drug reaction, especially in a setting of polypharmacy.

Adverse event, Side Effect, and Adverse Drug Reaction

The WHO has defined an adverse event as "any untoward medical occurrence that may present during treatment with a medicine but which does not necessarily have a causal relationship with this treatment."[9] "Any unintended effect of a pharmaceutical product occurring at doses normally used by a patient which is related to the pharmacological properties of the drug" is designated as a side effect.[9] The WHO has recommended the term adverse drug reaction to denote "a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man."[9] The above definitions place side effects, adverse drug reactions, medication errors, and even events with no causal relation with medicine intake (but the event happens during treatment) under the category of adverse drug event.

Pharmacovigilance Program of India (PvPI)

The Government of India initiated PvPI in July 2010 [Flowchart 1].[2] The program focused on continuous monitoring for adverse drug reactions observed in the country by compiling data on all adverse events during treatment. By doing a causality assessment and identifying offending drugs in relevant cases, the program is expected to ensure the safety of medicinal products. The program center was shifted on April 15th, 2011, from the National coordination center, All India Institute of Medical Sciences, New Delhi to the Indian Pharmacopoeia Commission, Ghaziabad.[2] Indian Pharmacopoeia Commission is an autonomous institution under the Ministry of Health and Family Welfare, Government of India.[2]



Flowchart 1: Indian pharmacovigilance program—flow of information. ADR: Adverse Drug Reaction, CDSCO: Central Drugs Standard Control Organization

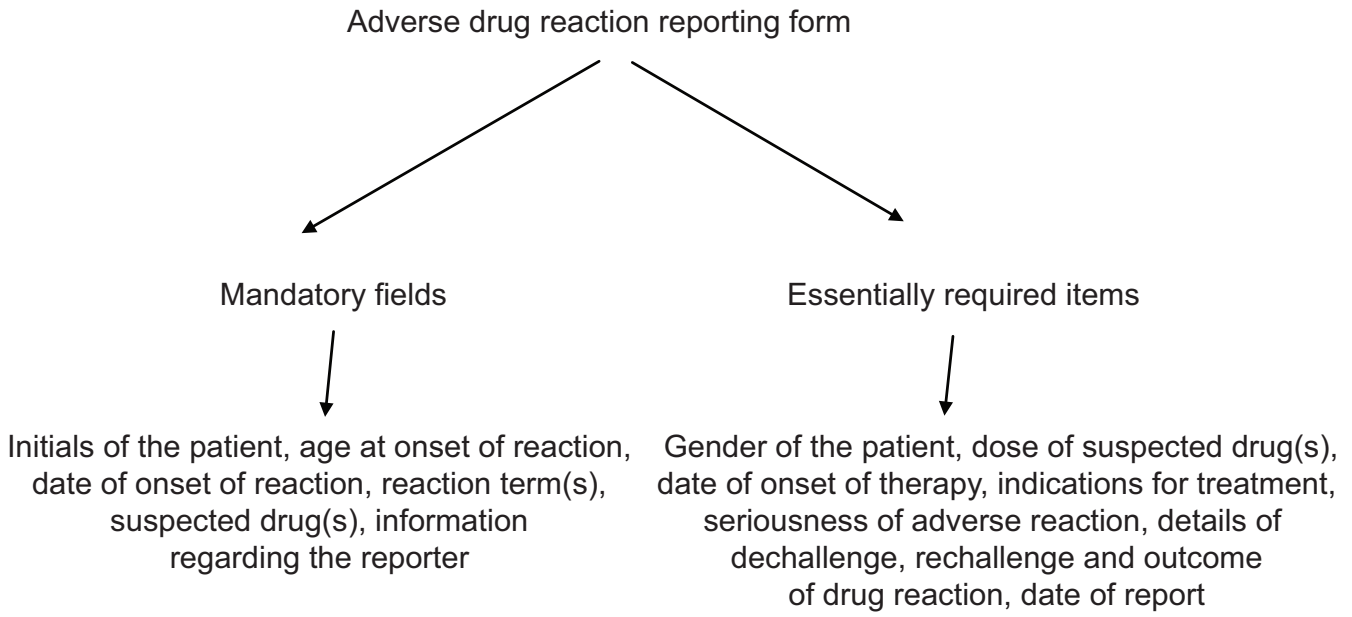
PvPI mainly depends on medical colleges and hospitals to collect individual case safety reports.[10] They serve as adverse drug reaction monitoring centers by collecting data on drug safety and performing follow-up to collect supplementary information (if needed) for further assessment.[2,10]

The monitoring for adverse drug reactions is carried out through a passive or active surveillance system. A passive surveillance system does not carry out any measures other than encouraging healthcare professionals to report the adverse drug events encountered in clinical practice. Active surveillance is carried out through a continuous and pre-organized process such as ensuring strict follow-up of patients initiated on specific medications or vaccines. PvPI now focuses primarily on data collection through passive surveillance, i.e., spontaneous reporting of adverse events by healthcare professionals, pharmaceutical companies, or patients. Preset adverse drug reaction reporting forms are available [Supplementary File 1], with specific forms designed for adverse events following vaccines/transfusion of blood and blood products. The adverse drug reaction reporting forms can be downloaded at www.ipc.nic.in or www.cdsco.nic.in.[2]

Adverse drug reaction reporting forms require data classified into mandatory fields and essential items. A valid reporting form needs at least information on mandatory fields [Flowchart 2].[2]

Pharmacovigilance encourages reporting of lack of efficacy, medication error, pharmacological side effects, and idiosyncratic reactions associated with modern medicine, as well as drugs used in traditional medicine. Undesirable outcomes following the use of medical devices or administration of radiocontrast media are also expected to be reported. Though PvPI does not currently recommend reporting adverse drug reactions following abuse/misuse/off-label use/occupational exposure of medications, the final judgement on whether to report an adverse event or not lies with the clinician. If the reporting individual is a healthcare professional, he/she is encouraged to mention the causality assessment while reporting the adverse event. (However, this is not mandatory as the responsibility for causality assessment rests with the adverse drug reaction monitoring centers which in turn are reviewed by

the National Coordination Centres). The filled form can be submitted to the nearby adverse drug reaction monitoring center or National Coordination Centre, or can be mailed directly to PvPI at pvpi.ipcindia@gmail.com. PvPI has set up a helpline number 1800-180-3024 at which adverse reactions can be reported from 9.00 am to 5.30 pm on weekdays. The National Coordination Centre passes the collected data to the World Health Organisation–Uppsala Monitoring Centre (WHO-UMC). The software "Vigiflow" is used to build an Indian patient safety database and for submission of Indian data to the WHO global database, "Vigibase."[2]



Flowchart 2: Data collected through pre- set adverse drug reaction reporting form of PvPI. PvPI: Pharmacovigilance program of India

Table 1: World Health Organisation–Uppsala Monitoring Centre (WHO-UMC) causality assessment scale[11]

*Causality assessment	Characteristic assessed			
	Time relationship of event or laboratory abnormality to drug intake	Whether event or laboratory abnormality can be explained by disease or other drugs	Response to withdrawal of drug	Information on drug rechallenge
Certain	Plausible	No	Plausible	Rechallenge satisfactory (if necessary)
Probable/likely	Reasonable	Unlikely	Clinically reasonable	Rechallenge not required
Possible	Reasonable	Could be explained by disease or other drugs as well	Information on response to drug withdrawal lacking or unclear	-
Unlikely	Improbable (but not impossible)	Plausible explanation by disease or other drugs	-	-

*Conditional/unclassified: More data needed for proper assessment/additional data under examination; Unassessable/unclassifiable: Available information insufficient/contradictory data, which cannot be verified or supplemented

Table 2: Usual time interval between onset of drug intake and manifestation of cutaneous adverse drug reaction

Adverse drug reaction	Time interval between onset of drug intake and cutaneous adverse drug reaction
Urticaria	Less than one day
Fixed drug eruption	30 minutes to a few hours (may be delayed up to two weeks)
Symmetric drug-related intertriginous and flexural exanthem	Hours to a few days
Acute generalized exanthematous pustulosis	2–5 days
Maculopapular drug rash	5–21 days
Stevens–Johnson syndrome—Toxic epidermal necrolysis	5–28 days
Drug reaction with eosinophilia and systemic symptoms	2–6 weeks (range: 1–6 months)
Drug-induced vasculitis	Extremely variable (hours to years)

How to Assess Causality in Adverse Drug Reaction

Causality assessment is defined as "the evaluation of the likelihood that a medicine was the causative agent of an observed adverse event."[11] The common tools used to assess the causality include WHO-UMC causality scale, the Naranjo adverse drug reaction probability scale, and the algorithm of drug causality for epidermal necrolysis (ALDEN).[11-13] In addition, different tools are devised to assess the preventability (Schumock and Thornton scale) and severity (Hartwig and Siegel's scale) of adverse drug reactions.[14,15]

For causality assessment, PvPI utilizes the WHO-UMC causality scale [Table 1].[11]

Temporal relation between a particular drug and the observed adverse reaction is assessed (whether plausible, reasonable, or improbable) based on the information on the latent period between the onset of drug intake and the specific reaction pattern. From the viewpoint of a dermatologist, the time interval between the onset of drug intake and drug reaction can vary from minutes to hours in urticaria and angioedema to weeks to months in drug reaction with eosinophilia and systemic symptoms and at times to years in drug-induced vasculitis [Table 2].[16-19] The time interval shown in Table 2 is valid only for initial exposure to the medicine; on reexposure, an immediate reaction (within 24 hours) is noted, irrespective of the reaction pattern.[16-18]

In patients on polypharmacy, the most likely offending drug can be identified based on the latent period between drug intake and the reaction pattern. A drug, the patient has been taking for weeks, could be an unlikely agent for a recent urticaria; however, it can be the offender in drug reaction with eosinophilia and systemic symptoms.[16,17]

The dilemma deepens when a patient who is initiated on multiple new drugs simultaneously presents with an adverse drug reaction. The gold standard test to determine the offending drug in such scenarios is a drug rechallenge test; however, this may not be an ethical option unless the medicine is life-saving for the patient with no equally effective alternative. A clue to the most likely offending agent (when multiple drugs are initiated simultaneously and show a plausible time relation with the adverse reaction) can be obtained from the known frequency of a specific drug reaction in patients using a particular medicine [Table 3].[16,17] There are websites that can provide this information (*https://www.epocrates.com*, Micromedex® -https://www.merative.com).[2] The drug (among the drugs taken by the patient which show a plausible time relation to the adverse reaction) with the highest frequency of producing the specific drug reaction may be assigned the causality assessment "probable" and the others as "possible."[11]

Occasionally, drug interactions precipitate adverse drug reactions, even when the individual drugs are well-tolerated by the patient. For example, febuxostat when coadministered with azathioprine can increase the blood levels of the latter to toxic levels by inhibiting xanthine oxidase.[20] Information on drug interactions is also available at *https://www.epocrates.com* or at Micromedex® -https://www.merative.com.[2]

PvP encourages reporting of all suspicious adverse events after intake of medication, which is essential to identify new reaction patterns and recognize rare manifestations.[2]

Identifying New Drug Reaction Patterns or a Known Reaction Pattern Previously not Reported with a Specific Medicine

Council for International Organizations of Medical Sciences (CIOMS) Working Group VIII defines a signal as "information that arises from one or multiple sources (including observations and experiments), which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action".[21] In other words, a signal is generated when

Table 3: Common drugs associated with cutaneous adverse drug reactions

Cutaneous adverse drug reaction	Common Drugs
Urticaria	Antibiotics (mainly beta lactam antibiotics), NSAIDs
Maculopapular drug rash	Penicillins, sulfonamides, NSAIDs, aromatic anticonvulsants, allopurinol
Fixed drug eruption	Trimethoprim, tetracycline, barbiturates, NSAIDs, phenolphthalein, azithromycin, quinolones
Symmetric drug-related intertriginous and flexural exanthem	Penicillins, cephalosporins, clindamycin, erythromycin, NSAID, terbinafine
Stevens–Johnson syndrome—Toxic epidermal necrolysis	Aromatic anticonvulsants, allopurinol, lamotrigine, sulfasalazine, antibiotics, NSAIDs
Acute generalized exanthematous pustulosis	Aminopenicillins, macrolides, quinolones, hydroxychloroquine, sulfonamides, terbinafine, diltiazem
Drug reaction with eosinophilia and systemic symptoms	Aromatic anticonvulsants, allopurinol, minocycline, dapsone, isoniazid, lamotrigine, sulfasalazine, vancomycin, abacavir
Drug-induced vasculitis	Isoniazid, hydralazine, minocycline

NSAID: Nonsteroidal anti-inflammatory drug

available data suggest that a drug may be associated with an adverse event "previously not attributed to the particular drug" or "a known adverse event occurs in a population group in whom it was not reported before" or "a known adverse event to a drug shows quantitative (more frequent/less frequent) or qualitative (more severe or less severe manifestation) variations from existing knowledge."[2] Multiple sources can provide data for signal generation [Table 4].[2]

In the setting of spontaneous adverse drug reaction reporting, a signal refers to a series of similar cases of suspected adverse drug reaction with a temporal relation to a specific drug. Generally, a minimum of three cases of similar adverse reactions to a specific drug generates a signal.[2]

To detect signals from spontaneous reporting data, different statistical methods are used, which measure disproportionality (determining the difference between the number of observed cases and the number of expected cases). The large adverse drug reaction database compiled over a period of time is taken as the baseline to estimate the expected cases for a particular reaction pattern in the absence of a signal. The statistical methodology used by WHO-UMC is the Bayesian Confidence Propagation Neural Network.[2]

In PvP including PvPI, a signal review panel monitors the database to identify signals, which are then carefully reviewed. Signal validation (ruling out a random occurrence or effect of confounding factors) is followed by signal confirmation (establishing a causal relation between the drug and the event). A conclusion is made only after the analysis of the reviewed signals by clinicians and drug safety experts. Before attributing a particular adverse event to a single drug, a thorough analysis of relevant data is performed to rule out medication errors and drug interactions. As mentioned before, a drug well-tolerated when given alone may result in an adverse event in polypharmacy due to drug interactions with certain other medicines, and identification of a drug-drug interaction is important in PvP for the judicious and safe use of medicines.[2,21]

Table 4: Sources for signal generation in pharmacovigilance

Individual case safety reports
Active surveillance programs
Clinical trials
Published literature
Large adverse drug reaction databases (such as the FDA AE reporting system)

FDA: Food and Drug Administration, AE: adverse event

Table 5: Factors considered for prioritization and risk assessment of signals in pharmacovigilance

1.	Severity, outcome, reversibility of adverse reaction, potential for prevention
2.	Patient exposure, estimated frequency of reaction
3.	Patient exposure in vulnerable population
4.	Consequence of withdrawal of treatment, available therapeutic options
5.	Expected regulations—addition of adverse reactions, warnings, contraindications, suspension, revocation
6.	Is the signal applicable to other medicines of the same class?

Signal analysis follows confirmation, which assesses the impact of the signal on public health. This is followed by prioritization [Table 5] and assessment, where critical signals are acted upon on a priority basis.[2,21]

The actions recommended after prioritization and assessment are directed at risk minimization and communication. This can vary from changing the prescribing information/pack insert to the withdrawal of drug and exchange of information with stakeholders through newsletters, media briefings, press releases, dedicated websites (e.g., https://www.ipc. gov.in), publications such as national pharmacopeia, and specific knowledge updates aimed at healthcare professionals. The actions are recommended by the WHO or the National Coordination Centres based on compiled information. Signal management also includes tracking of follow-up activities and assessing their efficacy in minimization of risk.[2,21]

COVID-19 and Challenges

Digitalization of medical information and data in the last decades has improved the efficiency of the PvP. However, the COVID-19 pandemic posed unforeseen challenges within the realms of pharmacovigilance. The clinicians had to rely on repurposed (hydroxychloroquine and lopinavir/ritonavir) as well as new drugs (remdesivir).[22] Many drugs received emergency use authorization during the pandemic, and post-marketing pharmacovigilance was important in ensuring long-term patient safety.[22] In the absence of data from well-conducted randomized controlled trials, decisions had to be taken based on observational data. A similar approach had to be adopted for vaccines against COVID-19.[7,8] The pandemic has highlighted the significance of a faster and smoother analysis of real-world data to formulate real-world evidence which can guide regulatory interventions.

Future Prospects

With the revolutionary introduction of artificial intelligence, the way forward for PvP appears exciting. The United States Food and Drug Administration (US FDA) has rightly highlighted that drug safety expert's services should be used wisely on complicated aspects of pharmacovigilance that have an impact on public health.[23] The expert's time spent on collecting and organizing information from individual case safety reports and detection, validation, analysis, and

prioritization of signals may be saved by effective machine learning programs.[23] It can start from the identification and exclusion of duplicate data. In addition, artificial intelligence can help in disproportionality analysis to categorize drug–event combinations, which can be extrapolated to drug-drug interactions and identification of risk factors. Machine learning programs can formulate statistical predictive models for signal detection and further help in language processing of regulatory information.[24] Though the current algorithms designed for PvP have not reached the reliability standards mandatory for full automation, the progress in the field has been tremendous.[25]

Conclusion

Lifestyle diseases and geriatric diseases are the newer challenges which are the price we have to pay for the modern lifestyle and the longevity we enjoy. Emerging and re-emerging infections have become a global concern as the pathogens native to specific geographic areas can find ways to households in distant continents (in this era of global trade and travel). The pharmaceutical industry is bringing out newer medicines daily in the fight against neoplasms, lifestyle diseases, and infections. Here, the challenge is to ensure drug safety, which requires the pharmacovigilance program to efficiently and rapidly compile and analyze the real-world data, translate the same to real-world evidence, and bring out regulatory interventions as and when needed. Attempts to incorporate machine learning in pharmacovigilance have shown promising results, though there is room for further improvement.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

References

1. Spelsberg A, Prugger C, Doshi P, Ostrowski K, Witte T, Husgen D, *et al*. Contribution of industry funded post-marketing studies to drug safety: survey of notifications submitted to regulatory agencies. BMJ 2017;356:2.
2. Indian Pharmacopoeia Commission. Guidance document for adverse drug reaction reporting. Available from: www.ipc.gov.in [Last accessed on 2025 Jan 08].
3. Sienkiewicz K, Burzyńska M, Rydlewska-Liszkowska I, Sienkiewicz J, Gaszyńska E. The importance of direct patient reporting of adverse drug reactions in the safety monitoring process. Int J Environ Res Public Health 2021;19:413. doi: 10.3390/ijerph19010413.
4. Available from: www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance. [Last accessed on 2024 Jun 19].
5. Available from: www.who-umc.org. [Last accessed on 2024 Jun 19].
6. Available from: https://who-umc.org/about-uppsala-monitoring-centre/ [Last accessed on 2024 Jun 19]
7. Available from: https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines. [Last accessed 2024 Jun 19].
8. Available from: https://www.lshtm.ac.uk/research/centres/vaccine-centre/covid-19 [Last accessed on 2025 Jan 08].
9. Available from: www.who.int/medicines/. [Last accessed on 2024 Jun 19].
10. Prakash B, Singh G. Pharmacovigilance: Scope for a dermatologist. Indian J Dermatol 2011;56:490-3.
11. World Health Organization (WHO)-Uppsala Monitoring Centre. The use of the WHO-UMC system for standardized case causality assessment. Available from: http://www.who-umc.org/Graphics/24734.pdf.
12. Naranjo CA, Busto U, Sellers EM, Sandor P, Ruiz I, Roberts EA, *et al*. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther 1981;30:239-45.
13. Sassolas B, Haddad C, Mockenhaupt M, Dunant A, Liss Y, Bork K, *et al*. ALDEN, an algorithm for assessment of drug causality in Stevens-Johnson Syndrome and toxic epidermal necrolysis: Comparison with case-control analysis. Clin Pharmacol Ther 2010;88:60-8.
14. Schumock GT, Thornton JP. Focusing on the preventability of adverse drug reactions. Hosp Pharm 1992;27:538.
15. Hartwig SC, Siegel J, Schneider PJ. Preventability and severity assessment in reporting adverse drug reactions. Am J Hosp Pharm 1992;49:2229-32.
16. Ardern-Jones MR, Lee HY. Benign cutaneous adverse reaction to drugs. In: Chalmers R, Barker J, Griffiths C, Bleiker T, Creamer D. editors. Rook's Text Book of Dermatology. 9th ed. Hoboken: Wiley Blackwell; 2016. p. 118.1-17.
17. Walsh S, Lee HY, Creamer D. Severe cutaneous adverse reaction to drugs. In: Chalmers R, Barker J, Griffiths C, Bleiker T, Creamer D. editors. Rook's Text Book of Dermatology. 9th ed. Hoboken: Wiley Blackwell 2016. p. 119.1-21.
18. Holder SM, Joy MS, Falk RJ. Cutaneous and systemic manifestations of drug-induced vasculitis. Ann Pharmacother 2002;36:130-47.
19. Sharma S, Jayakumar D, Palappallil DS. Pharmacovigilance of cutaneous adverse drug reactions among patients attending dermatology department at a tertiary care hospital. Indian Dermatol Online J 2019;10:547-54.
20. Logan JK, Senarath Yapa SW, Harinstein L, Saluja B, Munoz M, Sahajwalla C, *et al*. Drug interaction between febuxostat and thiopurine antimetabolites: A review of the FDA adverse event reporting system and medical literature. Pharmacotherapy 2020;40:125-32.
21. CIOMS. Practical aspects of signal detection in pharmacovigilance. Report of CIOMS Working Group Viii. 2008. Available from: https://cioms.ch/working_groups/working-group-viii/ [Last accessed 2025 Jan 08].
22. Chandler RE, McCarthy D, Delumeau JC, Harrison-Woolrych M. The role of pharmacovigilance and ISoP during the global COVID-19 pandemic. Drug Saf 2020;43:511-2.
23. Ball, R, Dal Pan G. "Artificial Intelligence" for Pharmacovigilance: Ready for Prime Time? Drug Saf 2022;45:429-38.
24. uppsalareports.org. Artificial intelligence in pharmacovigilance: Harnessing potential, navigating risks. [Last accessed on 2024 Oct 28].
25. Lavertu A, Vora B, Giacomini KM, Altman R, Rensi S. A new era in pharmacovigilance: Toward real-world data and digital Monitoring. Clin Pharmacol Ther 2021;105:1197-202.

Supplementary File 1

Adapted from suspected adverse drug reaction reporting form version 1.4

Initial case ☐	Follow-up case ☐	For AMC/NCC use only
A. PATIENT INFORMATION*		Reg. No./IPD No./OPD No./CR No.:
1.Patient initials:	2. Age or date of birth:	AMC Report No.:
3.Gender M/F/other	4. Weight (in kg):	Worldwide unique No.:
B. SUSPECTED ADVERSE REACTION*		12. Relevant investigations with dates:
5. Event/reaction start date dd/mm/yy		13. Relevant medical/medication history (e.g., allergies, pregnancy, addiction, hepatic, renal dysfunction, etc,)
6. Event/reaction stop date dd/mm/yy		14. Seriousness of the reaction: No ☐ if yes ☐ (please tick anyone) ☐ Death (dd/mm/yy) ☐ Congenital anomaly ☐ Life threatening ☐ Disability ☐ Hospitalization—Initial/prolonged ☐ Other medically important
7. Describe event/reaction management with details (if any)		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 date		Indication	Causality assessment
								Date started	Date stopped		

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 products including self-medication and herbal remedies with therapy dates (exclude those used to treat reaction)

S.No.	Name (Brand/Generic)	Dose.	Route	Frequency (O.D., B.D., etc.)	Therapy dates		Indication
					Date started	Date stopped	
I							
II							
III#							

Additional information:	D. REPORTER DETAILS*
	16. Name and address:
	PIN: Email:
	Contact No.:
	Occupation: Signature:
	Date of this report (dd/mm/yy):
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 adverse drug reaction report does not have any legal implication on the reporter. # Use separate page for more information *Mandatory fields for suspected adverse drug reaction reporting form-under patient information only patient initials and age at onset of reaction are mandatory.