System of adverse drug reactions reporting: What, where, how, and whom to report?

Sir,

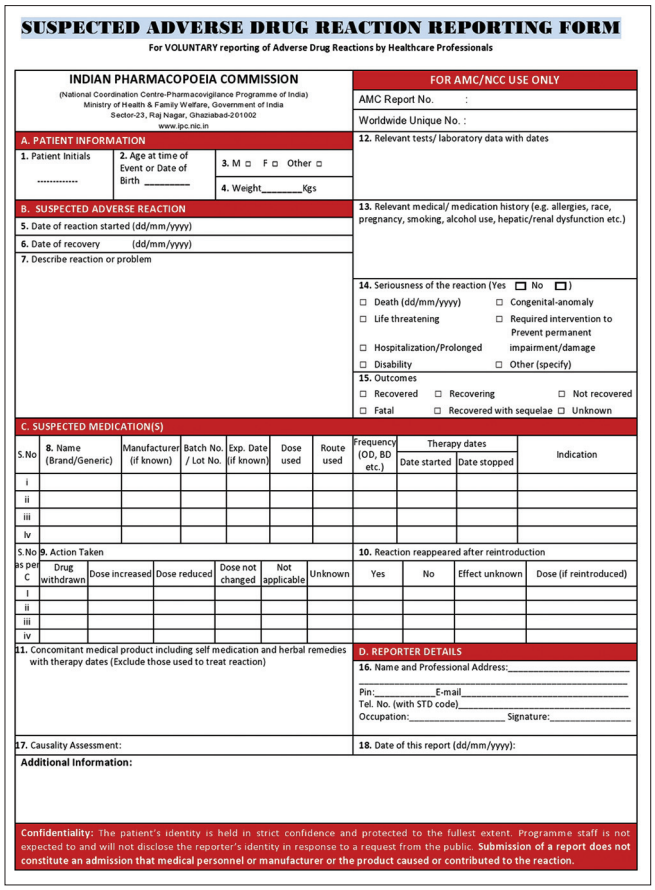
The continuous progress in medical and pharmaceutical sciences has made the availability of pharmaceutical products in the Indian market to prevent and control of several disease conditions. Irrespective of the benefits associated with the use of medicines adverse effects associated with them has emerged the challenges of monitoring Adverse Drug Reactions (ADRs) over large population base. World Health Organization (WHO) defined ADR as "A response which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function."[1]

To improve public health, the safe use of medicine must be monitored through an effective pharmacovigilance (PV) system. PV is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects, or any other possible drug-related problems.[2]

Indian Pharmacopoeia Commission (IPC), Ghaziabad is functioning as a National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI). One Hundred and fifty ADR monitoring centres (AMCs) were established in various medical institutions/hospitals across India to monitor and collect ADR reports under NCC-PvPI.[3]

What to Report

PvPI encourages all types of suspected ADRs reporting whether they are known, unknown, serious, or nonserious, frequent, or rare regardless of an established causal relationship between a drug and the reaction. ADRs related with the use of allopathic medicines, vaccines, traditional medicines, medical devices, contrast media, etc., can be reported.



SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions 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
www.ipc.nic.in

FOR AMC/NCC USE ONLY

AMC Report No. :

Worldwide Unique No. :

A. PATIENT INFORMATION

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

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)

6. Date of recovery (dd/mm/yyyy)

7. Describe reaction or problem

12. Relevant tests/ laboratory data with dates

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

14. Seriousness of the reaction (Yes ☐ No ☐)
☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Required intervention to Prevent permanent impairment/damage
☐ Hospitalization/Prolonged ☐ Disability ☐ Other (specify)

15. Outcomes
☐ 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.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication
i										
ii										
iii										
iv										

S.No as per C	9. Action Taken: Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Reaction reappeared after reintroduction: 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)

D. REPORTER DETAILS

16. Name and Professional Address:_____
Pin:_____E-mail_____
Tel. No. (with STD code)_____
Occupation:_____ Signature:_____

17. Causality Assessment:

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

Additional Information:

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. **Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.**

Figure 1: Suspected adverse drug reaction reporting form

Where to Report

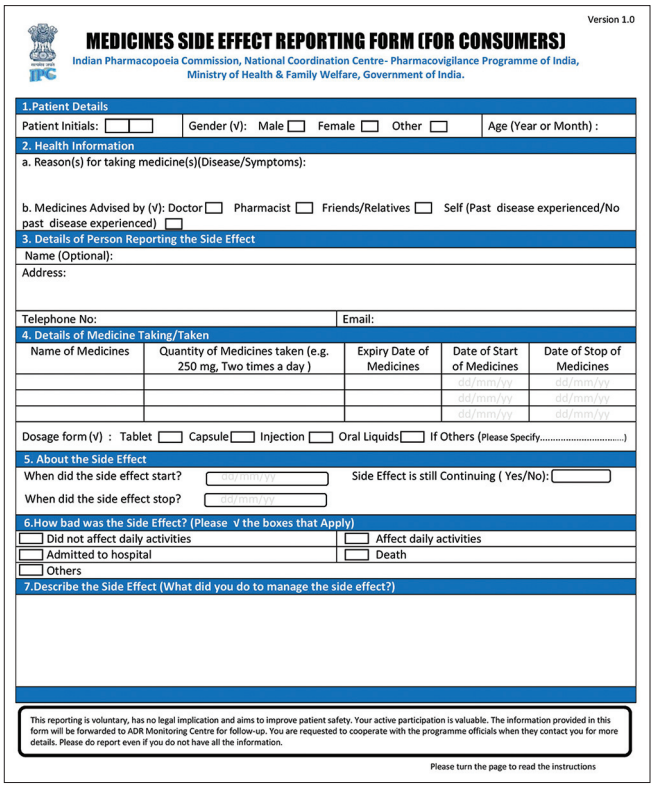
All healthcare professionals (clinicians, dentists, pharmacists, nurses) and patient/consumers can report ADRs to NCC or AMCs. The pharmaceutical companies can also send individual case safety reports for their product to NCC.

How to Report

Suspected ADR reporting forms [Figure 1] for healthcare professionals and consumers are available on the website of IPC to report ADR. To remove language barrier in ADR reporting, the consumer reporting form [Figure 2] are made available in 10 vernacular languages (Hindi, Tamil, Telugu, Kannada, Bengali, Gujarati, Assamese, Marathi, Oriya, and Malayalam). ADRs can be also reported via PvPI helpline number (18001803024) on weekdays from 9:00 am to 5:30 pm.[3] The mobile Android application for ADR reporting has also been made available to the public.

Whom to Report

A reporter can send filled ADR reporting form directly to NCC or their nearest AMC. In case of AMC, these reports are confirmed by healthcare professionals and



Version 1.0

MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

Indian Pharmacopoeia Commission, National Coordination Centre- Pharmacovigilance Programme of India,
Ministry of Health & Family Welfare, Government of India.

1.Patient Details

Patient Initials: ☐☐ Gender (√): Male ☐ Female ☐ Other ☐ Age (Year or Month) :

2. Health Information

a. Reason(s) for taking medicine(s)(Disease/Symptoms):

b. Medicines Advised by (√): Doctor ☐ Pharmacist ☐ Friends/Relatives ☐ Self (Past disease experienced/No past disease experienced) ☐

3. Details of Person Reporting the Side Effect

Name (Optional):

Address:

Telephone No: Email:

4. Details of Medicine Taking/Taken

Name of Medicines	Quantity of Medicines taken (e.g. 250 mg, Two times a day)	Expiry Date of Medicines	Date of Start of Medicines	Date of Stop of Medicines
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy

Dosage form (√) : Tablet ☐ Capsule ☐ Injection ☐ Oral Liquids ☐ If Others (Please Specify.....)

5. About the Side Effect

When did the side effect start? dd/mm/yy Side Effect is still Continuing (Yes/No): ☐

When did the side effect stop? dd/mm/yy

6.How bad was the Side Effect? (Please √ the boxes that Apply)

☐ Did not affect daily activities ☐ Affect daily activities
☐ Admitted to hospital ☐ Death
☐ Others

7.Describe the Side Effect (What did you do to manage the side effect?)

This reporting is voluntary, has no legal implication and aims to improve patient safety. Your active participation is valuable. The information provided in this form will be forwarded to ADR Monitoring Centre for follow-up. You are requested to cooperate with the programme officials when they contact you for more details. Please do report even if you do not have all the information.

Please turn the page to read the instructions

Figure 2: Medicines side effect reporting form (for consumers)

entered into Vigiflow and sent to NCC for further assessment.[4] These reports are then finally reviewed at NCC and committed to WHO-Uppsala Monitoring Centre. The obtained information is entered in the drug safety database, analyzed, and assessed by the experts to identify new signals.[5]

The submitted ADR report does not have any legal implication on the reporters. The patients' identity are held in strict confidence and protected to the fullest extent.

Therefore, healthcare providers are encouraged to report ADRs for better understanding of the risk associated with the use of medicines and to safeguard the health of Indian population.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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