Pharmacovigilance Programme of India: System put in place to Report Adverse Drug Reactions

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Dear Editor,

Adverse drug reaction (ADRs) is response to a drug which is noxious and unintended and which occurs at doses normally used in human for the prophylaxis, diagnosis or treatment of disease, or for the modification of physiological function.[1] ADRs are one of the major public health issues and found to cause of morbidity and mortality.[2] The impact of ADRs in India is significant and leads to the enormous burden to the public. Therefore, Ministry of Health & Family Welfare (MoHFW), Government of India launched a nationwide Pharmacovigilance Programme of India (PvPI) in the year 2010 to monitor the safety of drugs. Indian Pharmacopoeia Commission (IPC) under the MoHFW functions as National Coordination Centre (NCC) for PvPI. To monitor and report ADRs to NCC, teaching hospitals and corporate hospitals have been identified as ADRs Monitoring Centres (AMCs).[3-5] ADR reporters (healthcare professionals) who is not a part of AMC can also fill the suspected ADR reporting form (Figure 1) and submit to nearby AMC (available at www.ipc.gov.in). Reporter can call on 'PvPI-Helpline-1800 180 3024' for further assistance in ADRs reporting.[6] To report ADRs simply and quickly, NCC introduced android mobile application which will also enhance the participation of private practitioners. All types of suspected adverse events with all pharmaceutical products irrespective of whether they are known or unknown, serious or non-serious and frequent or rare can be reported. The obtained information is entered in the drug safety database Vigiflow™ (web-based software for International Drug Monitoring in the WHO Programme), analysed and assessed by the experts to identify new signals. This is also used as a main source for identifying and reducing the risks associated with the drugs. Submission of ADRs report does not have any legal implication on the reporter and also the confidentiality of the reporter and patients will be maintained. The provided information contributes to promote patients' safety in many ways such as generation of drug safety data on Indian population, for taking appropriate regulatory decisions, educational initiatives for healthcare professionals for promoting safety of medicines, benefit-risk assessment, updating prescribing information leaflet (ADRs, warning, contraindication etc) and promote rational use of medicines. Therefore, healthcare providers are encouraged to report ADRs for better understanding and to safeguard the health of Indian population.

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Version-1.2

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

FOR AMC/NCC USE ONLY

AMC Report No. :

Worldwide Unique No. :

Report Type ☐ Initial ☐ Follow up

A. PATIENT INFORMATION

1. Patient Initials _____

2. Age at time of Event or Date of Birth _____

3. M ☐ F ☐ Other ☐

4. Weight_____Kgs

12. Relevant tests/ laboratory data with dates

B. SUSPECTED ADVERSE REACTION

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

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

7. Describe reaction or problem

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

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

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Required intervention to Prevent permanent
☐ Hospitalization/Prolonged impairment/damage
☐ 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		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
Iv											

S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	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		Indication
					Date started	Date stopped	
i							
ii							
iii							

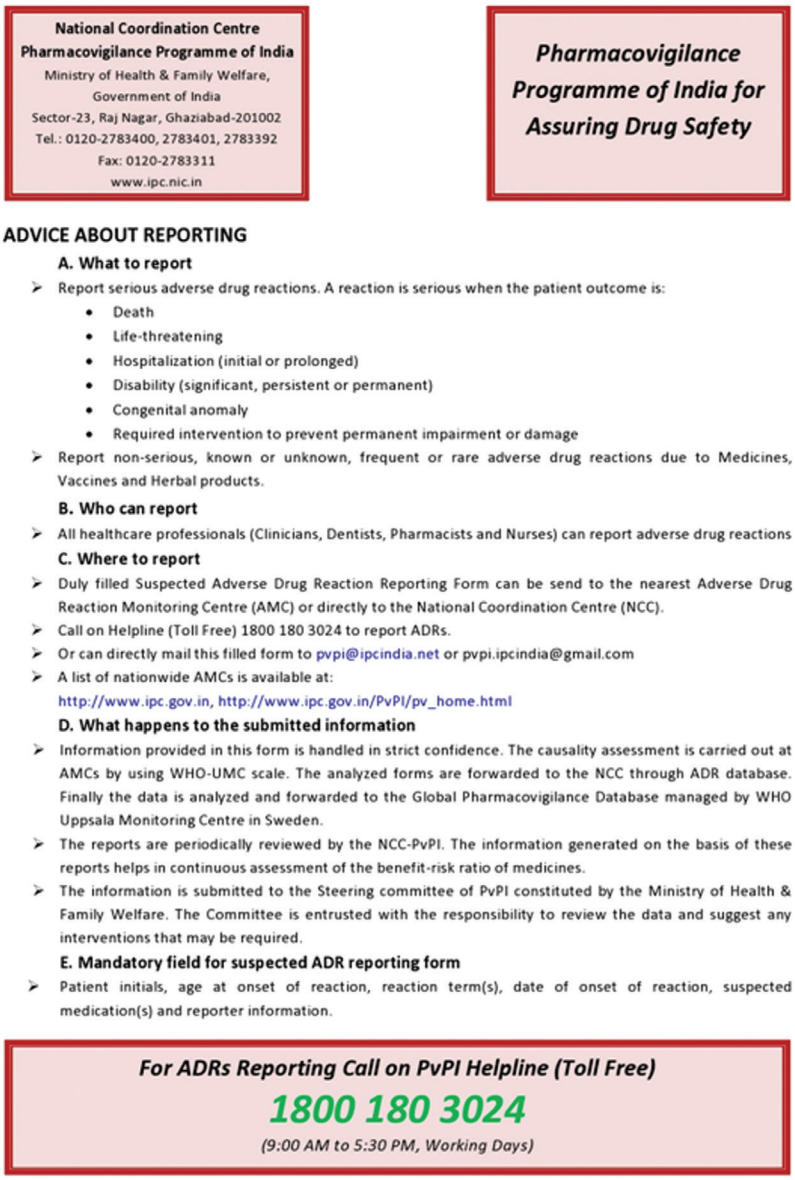
Additional Information:

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):

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.



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Pharmacovigilance Programme of India for Assuring Drug Safety

ADVICE ABOUT REPORTING

A. What to report

- Report 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
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

B. Who can report

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

C. Where to report

- Duly filled Suspected Adverse Drug Reaction Reporting Form can be send to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC).
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.
- Or can directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- 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 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 information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

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

For ADRs Reporting Call on PvPI Helpline (Toll Free)

1800 180 3024

(9:00 AM to 5:30 PM, Working Days)

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