

PHARMACY COUNCIL OF INDIA

(Constituted under the Pharmacy Act, 1948)

TELEGRAM : FARMCOUNCIL'

TELEPHONE: 011-61299900, 61299901

: 011-61299902, 61299903,

E-MAIL : pcipresident@gmail.com

WEBSITE : www.pci.nic.in

NBCC Centre, 3rd Floor,

Plot No.2, Community Centre

Maa Anandamai Marg Okhla Phase I

New Delhi – 110 020

Ref.No. 14-126/2019-PCI (A)

4499-4501

- 9 AUG 2019

To,

All Pharmacy Institutions, Hospital pharmacists and Community pharmacists in the country.

Sub: ADR reporting to the nearest AMC or to the National Coordination Centre, PvPI.

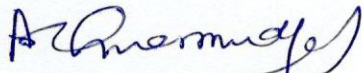
Ref. Letter No. P.12023/01/2019 dt.06/08/2019 received from Indian Pharmacopoeia Commission (IPC).

Sir/Madam,

Please find enclosed herewith a copy of letter dt. 6.8.2019 alongwith enclosures received from Indian Pharmacopoeia Commission on the subject cited above.

It is for urgent necessary action at your end.

Yours faithfully



~~(ARCHANA MUDGAL)~~
Registrar-cum-Secretary



INDIAN PHARMACOPOEIA COMMISSION

National Coordination Centre- Pharmacovigilance Programme of India (PvPI)

MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA

SECTOR-23, RAJ NAGAR, GHAZIABAD- 201 002.

Tel No: 0120- 2783392, 2783400, 2783401 Fax: 0120-2783311

e-mail: pvpi@ipcindia.net, lab.ipc@gov.in, Web: www.ipc.gov.in

File No: P.12023/01/2019

Dated: 06/08/2019

To,

The Dean/Principal of Pharm.D. institutions across the country

Subject: ADR reporting from Pharm.D. Institutions - Regarding

Sir/ Madam,

Warm Greetings from National Coordination Centre, Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission!!

As you will be aware that Pharmacovigilance Programme of India (PvPI) has been launched by the Ministry of Health and Family Welfare, Govt. of India to monitor the adverse drug reactions (ADRs) to enhance patient safety. It is a matter of great honour that NCC-PvPI has been recognized as the WHO Collaboration Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services. PvPI initiates intensive concerted effort to gather scientific information on Adverse Drug-Reaction monitoring from hospitals to evaluate the benefit and risks of medicines. At present, 270 ADR Monitoring Centers are within the ambit of PvPI. Therefore, the Pharmacovigilance actions and ADR monitoring centers need to be scaled up and is the need of the hour.

It is known that as a Part of Pharm.D. curriculum, the students collect ADRs from hospitals as their project work. The practice of collecting ADR information from hospitals can play a crucial role in contributing to patient safety and to understand the benefit and risk of medicines. Keeping this in view and to ensure the effective implementation of Pharmacovigilance system in the country, you are hereby requested to bring the content of this notice to all concerned Staff/Head of departments of your institutions to report Adverse Drug Reactions preferably to the nearest AMC or to the National Coordination Centre, PvPI directly in the larger interest of our population for continuous patient safety perspective.

Best Regards

Dr. Jai Prakash 06/08/2019
Officer-In-Charge, PvPI

Copy to:

1. Mrs. Archana Mudgal, Registrar-Cum-Secretary, Pharmacy Council of India, Combined Councils' Building, Kotla Road, Post Box No. 7020, New Delhi - 110002

"Let us join hands with PvPI to ensure patients safety"
ADR Reporting Help line (Toll Free): 1800-180-3024

Scanned by CamScanner

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 <input type="checkbox"/> F <input type="checkbox"/> Other <input type="checkbox"/>	Reg. No. /IPD No. /OPD No. /CR No. :
		4. Weight _____ Kgs	AMC Report No. _____ :
			Worldwide Unique No. :
B. SUSPECTED ADVERSE REACTION			12. Relevant tests/ laboratory data with dates
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			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 <input type="checkbox"/> if Yes <input type="checkbox"/> (please tick anyone)
			<input type="checkbox"/> Death (dd/mm/yyyy) <input type="checkbox"/> Congenital-anomaly <input type="checkbox"/> Life threatening <input type="checkbox"/> Disability <input type="checkbox"/> Hospitalization/Prolonged <input type="checkbox"/> Other Medically important
			15. Outcomes
			<input type="checkbox"/> Recovered <input type="checkbox"/> Recovering <input type="checkbox"/> Not recovered <input type="checkbox"/> Fatal <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> 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): _____

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

National Coordination Centre for Pharmacovigilance Programme of India

Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392, Fax: 0120-2783311
www.ipc.nic.in

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 etc.

Note- 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 Nurses 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@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 Signal Review Panel of PvPI to review the data and suggest 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) and reporter information.

For ADRs Reporting

- **E-mail:** pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- **PvPI Helpline (Toll Free): 1800 180 3024** (9:00 AM to 5:30 PM, Monday-Friday)
- **ADR Mobile App: "ADR PvPI"**