



INDIAN PHARMACOPOEIA COMMISSION

National Coordination Centre - Pharmacovigilance Programme of India (NCC-PvPI)

Ministry of Health & Family Welfare, Government of India

Sector-23, Raj Nagar, Ghaziabad- 201002

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Format No. IPC/PvPI/QA/021-F01-04

ENROLMENT FORM FOR NEW ADR MONITORING CENTRE UNDER PvPI

Date:

Referred for enrolment as new AMC by:

- (a) Self ()
(b) AMC/RTC/Individual.
(c) Any other (Please Specify)

I. Institutional Information:

a. Name of the Institution/Hospital with complete postal Address

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State District Pin Code

b. Type of Institution: Pharmacy/Pharm.D/Medical college/Hospital/ Others (Please Specify)

c. Central Government/State Government /Non-Government (Please Specify)

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d. Approval / Accreditation status

- National Medical Commission (NMC) (For Medical Colleges) : (Yes/No).....
- Pharmacy Council of India (PCI) (For Pharmacy/Pharm.D Colleges) : (Yes/No)
- Accreditation status from NABH (Yes/No).....
- Any other, Specify.....

i) Medical Colleges

- Distance between Hospital & Medical College (in Km)
- Is there any Pharmacovigilance Committee constituted? (Yes/No).....
- If Yes, please provide the details of PV Committee duly verified by the Head of Institution (Please enclose separate document if required)

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- Are you submitting AE/ADR reports to NMC? (Yes/No)
- Details of AE/ADRs reported to NMC during last one year, if any: (Attach List of ADRs)
- Name of the affiliated hospital with complete address.

ii) Hospitals

- Number of beds in the hospital:
- Patient statistics (Inpatient/outpatient) monthly:
- Total no. of departments:

iii) Pharm.D/Pharmacy Colleges

- Name of the Affiliated Hospital:
- Is the Affiliated Hospital already an ADR Monitoring centre under PvPI:(Yes/No)
- If Yes, Please attach Letter of Consent from the Affiliated Hospital

II. Logistic/infrastructural/manpower facilities to function as an Adverse drug reaction Monitoring Centre (AMC) under PvPI:

- Name of department to function as an AMC:
- Total number of faculties in the department
- Whether specific workplace is allocated for Pharmacovigilance Activities (Yes/No)
- Whether computer & logistic facilities is available for PvPI (Yes/No)
- Whether AMC is willing to function without getting manpower from PvPI (Yes/No)

III. Technical Information:

- Details of the Proposed Coordinator and Deputy Coordinator:

Particulars	Coordinator	Deputy Coordinator
Name		
Designation		
Qualification		
Total Experience		
Email i.d.		
Mobile Number		

- Details of ADRs reported to NCC-PvPI during last one year, if any, (Attach Annexure-I)

- Any other relevant information.

IV. Contact Details of Head of Institution:

S.No.	Designation	Name	Phone No. (Extension No. if any)	Mobile No.	Email Id
	Director/Principal / Dean / Medical Superintendent/ Incharge/other (Please tick)				

Terms of Reference (TOR):

- a) If the proposed centre is accepted as AMC, it's essential to function with its own logistic/infrastructural facilities.
- b) List of logistics required to setup an AMC under PvPI:
 - Dedicated area/Room for PvPI to carry out the Pharmacovigilance activities
 - Computer system with Internet connection, Printer with Scanner
 - Telephone
 - Table & chair, storage cabinet/almirah with lock & key facility
 - Stationary items
 - Notice board etc.
- c) The competent authority of PvPI reserves all the rights to accept/reject the proposal and suggest any other suitable measure.
- d) The HOD/Dean/Principal/Coordinator/Deputy Coordinator of the proposed centre shall be responsible to establish/implement PvPI activities in the centre.
- e) The HOD/Dean/Principal/ Coordinator/Deputy coordinator of the institute shall be responsible to identify new Coordinator & Deputy Coordinator and to intimate NCC-PvPI in case of any change (transfer/ superannuation etc) immediately.
- f) If your centre is accepted as an AMC, NCC-PvPI will provide regular training and technical support for Pharmacovigilance activities.
- g) NCC-PvPI, IPC may provide financial assistance to the centre on the basis of proven track record of being active in terms of number of ADR reporting, awareness/sensitization training programs and outreach activities of PvPI.
- h) The job responsibility of coordinator and deputy coordinator are notified in Annexure-II
We have understood the above terms of reference and are agree to undertake the responsibility of AMC under the PvPI. Our institute may be considered for the same.
- i) If your centre is approved by NCC-PvPI, a letter of confirmation will be sent by IPC, NCC-PvPI, IPC.
- j) It is not necessary that PvPI will provide the manpower to your AMC and you are willing to work without manpower.

Signature

Proposed Coordinator/ In-charge of AMC
(With Seal/Stamp)

Signature

Head of Institution
(With Seal/Stamp)

(ANNEXURE- I)
Format for the Details of ADRs reported during last 1 year

S. No.	Patient details		AE	Suspected Drug	Date of reaction	Details of Reporter	Date of Reporting	Name of the AMC/NCC- PvPI where Report submitted
	Age	Sex						

Separate sheet may be used if required.

“Let us join hands with PvPI to ensure patients safety”

Job Responsibility of Coordinator and deputy coordinator at AMC

Responsibility of Coordinator at AMC

1. Responsible for the overall performance of Pharmacovigilance activities and progress of AMC.
2. To ensure the formation of Causality Assessment Committee (CAC) and timely conductance of meetings as per SOP.
3. Ensure the availability of all the documents at AMC as per SOP.
4. Monitor and guide the Pharmacovigilance Associate (if appointed) to perform the assigned duties of PvPI.
5. Maintain the confidentiality of the VigiFlow/ADRMS login details and ensure timely electronic transmission of Individual Case Safety Reports (ICSRs) to NCC-PvPI through software.
6. Ensure the quality of Pharmacovigilance data submitted to the NCC-PvPI.
7. Establish mechanisms enabling the traceability and follow-up of ADR reports and ensure that it is handled and stored in a way to allow accurate reporting, interpretation and verification of that information whenever queried from NCC/Competent authorities.
8. Ensure the availability of the archiving arrangements for the electronic and/or hardcopies of the ADR reports (Source documents) at AMC and the retention of the documents as per the Pharmacovigilance norms.
9. Ensure availability of the summary / description of the training / CME / awareness / sensitization programmes on Pharmacovigilance etc. conducted at AMC including the records and certificates.
10. Ensure good Coordination/communication between the appointed PvA and various departments of the college/hospital.

Responsibility of Deputy Coordinator at AMC

1. Assisting and coordinating with the Coordinator of the AMC for PvPI activities and smooth functioning of the AMC.
2. Assist in ensuring the adherence to the defined core principles and quality policy of PvPI.
3. Ensure the timely and effective communication with NCC-PvPI in absence of the AMC Coordinator and vice versa.
4. Handling of overall activities of AMC in case of Superannuation/transfer of the Coordinator till further appointment of the Coordinator at the centre and intimation to NCC-PvPI immediately.
5. Coordination with the AMC coordinator for awareness among healthcare professionals and patient for ADR reporting and drug safety.
6. Assisting coordinator to provide the information for adequate compliance management.