



PHARMACY COUNCIL OF INDIA

(Constituted under the Pharmacy Act, 1948)

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Circular

**All the Pharm.D and Pharm.D (PB) Institutions approved by PCI
u/s 12 of the Pharmacy Act, 1948.**

**Subject: Enrolment of all Pharm D. Institutions as ADR Monitoring Centre (AMC) under
Pharmacovigilance Programme of India (PvPI)-reg.**

Sir/Madam,

This has a reference to the subject cited above. In this connection, it is informed that-

- a) A joint meeting of Pharmacy Council of India (PCI) and Indian Pharmacopoeia Commission (IPC) was held to discuss the enrolment of Pharm D. Institutions as ADR Monitoring Centre (AMC) under Pharmacovigilance Programme of India (PvPI) and to improve the job opportunities for pharmacists.
- b) The IPC an autonomous institution under the Ministry of Health and Family Welfare, Government of India is entrusted with the responsibility of PvPI since April 2011 with the objective to improve the patient safety and welfare of Indian population by monitoring drug safety and thereby reducing the risks associated with the use of medicines. Pharmacovigilance is based on sound scientific principles and is an integral part of effective clinical practices. The discipline needs to develop further to meet the demands of public health for which continuous monitoring of drugs is essential. Such monitoring will help in assessing, monitoring and detecting adverse effects of drugs, their interactions etc.
Hence the ADR reporting culture amongst healthcare professionals needs to be scaled up by enrolling Pharm.D institutions as ADR Monitoring Centre under PvPI in a phased manner.
- c) In view of above, in order to ensure further strengthening of PvPI, it was decided that approved Pharm.D institutions under PCI may get enrolled under PvPI as ADR monitoring Centre (AMC) as their support and participation will help data collection, analysis and drug safety monitoring to achieve the target of better reporting of adverse events under PvPI.

The following information in this regard is enclosed for ready reference -

- i) brief about PvPI and advantages of enrolment as Adverse Drug Reaction Monitoring Centre under PvPI - **Annexure-I.**

ii) application form titled "Letter of Intent" to be filled by Pharm.D institutions for submission to IPC for AMC enrolment under PvPI - Annexure-II.

iii) the duly filled in application form shall be submitted to -

**The Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
Sector 23, Raj Nagar Ghaziabad - 201002.**

The form can also be downloaded from the website of Indian Pharmacopoeia Commission (www.ipc.gov.in).

It is emphasized that reporting of adverse events shall not have any legal obligation on reporter; therefore, your active participation in ADR reporting is a need of an hour for the sake of patient safety and optimum clinical outcome. This will also create the platform for job opportunities. Since a strong base in the form of Pharm.D institutions and clinically trained workforce is already available in the country, your kind support is solicited in the matter.

Yours faithfully

Name : Dr. Archana Mudgal
Designation : Registrar-cum-Secretary
Signature : Archana Mudgal

Pharmacy Council of India (PCI)

Registrar - cum - Secretary
Pharmacy Council of India
New Delhi - 110 020

Yours faithfully

Name : Dr. Rajeev Singh Raghuram
Designation : Secretary-cum-Scientific Dir
Signature : Rajeev Singh

Indian Pharmacopoeia Commission (IPC)

Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
M/o Health & Family Welfare, Govt. of India
GHAZIABAD (U.P.)

Brief Information about**Pharmacovigilance Programme of India (PvPI) and Advantages of Enrolment as Adverse Drug Reaction Monitoring Centre (AMC) under PvPI**

Adverse drug reaction (ADR) is one of the leading causes of morbidity and mortality worldwide. The consequences of ADRs burden the healthcare system with increased cost of therapy and prolongation of hospitalization. India is a vast socio-ethnic, biodiverse country with different healthcare facilities. Due to its varied geographical expanse, disease patterns and different practising systems of medicine, Indian population encounters Adverse Drug Reactions which could be entirely different from other countries. It is, therefore, imperative to evaluate the safety of medicines in a scientific manner through a highly specialized system i.e. Pharmacovigilance.

So, in order to gain a complete safety profile of medicine in real world scenario, continuous post-marketing surveillance system is required that can be accomplished through Pharmacovigilance System. Any known or unknown adverse events can be monitored through this system. Understanding the compelling need for a stable ADR reporting system in India, Ministry of Health and Family Welfare, Government of India launched a robust techno-science-based system in the form of Pharmacovigilance Programme of India (PvPI) in July 2010, initially housed at All India Institute of Medical Sciences (AIIMS), New Delhi as the National Coordination Centre (NCC). Further, in order to safeguard the health of Indian Population and take PvPI to greater heights and implement this programme in a more effective way, the Ministry of Health and Family Welfare, Government of India recasted this programme and shifted the National Coordination Centre at Indian Pharmacopoeia Commission (IPC), Ghaziabad vide an Order dated 15th April, 2011.

The mission, vision and Objectives of PvPI are as under:

Mission

To safeguard the health of Indian population by ensuring that the benefits of use of medicine outweigh the risks associated with its use.

Vision

To improve patient safety and welfare of Indian population by monitoring safety of medicines, thereby reducing the risk associated with their use.

Objectives

The objectives of the PvPI are to:

- Create a nation-wide system for patient-safety by ensuring drug-safety
- Identify and analyse new signals from the reported cases

- Analyse the benefit-risk ratio of marketed medications
- Generate evidence-based information on safety of medicines
- Support regulatory agencies in the decision-making process on use of medications
- Communicate safety information on use of medicines to various stakeholders for preventing/minimizing the risk
- Collaborate with other national Centres for exchange of information and data management
- Provide training and consultancy support to other National Pharmacovigilance Centres across the globe
- Promote rational use of medicines
- Emerge as a National Centre of Excellence for Pharmacovigilance Activities

Pharmacovigilance Programme of India (PvPI) is Government of India's flagship drug safety monitoring programme which continuously monitors adverse drug reactions from the use of medical products across the country. Realizing the importance of Pharmacovigilance in recent years and the need for evidence based indigenous data for policy decisions, the PvPI has succeeded in establishing a nationwide network of 395 ADR Monitoring Centres (AMCs) across the country. PvPI has been initiating an intensive and concerted effort to gather scientific information on Adverse Drug-Reaction monitoring from hospitals to evaluate the benefit and risks of medicines. The gathered Adverse Event/Adverse Experience data are collected, collated and analyzed for ADRs at NCC-PvPI, IPC serves as a major source of evidence-based scientific support which is provided to the National Regulatory Authority, the Central Drug Standards Control Organization (CDSCO) for regulatory interventions. It is of worthy interest to note that NCC-PvPI has identified and issued 124 drug safety alerts, 57 Prescribing Information Leaflet (PIL) changes including 7 signals for sensitization of stakeholders. NCC is continuously communicating the findings of PvPI to Central Drugs Standards Control Organisation for regulatory actions. India-specific Individual Case Safety Reports (ICSRs) reported under the umbrella of PvPI is to a tune of about 5 lacs and currently India stands tall in becoming 9th largest contributor of ADR data to WHO database. Moreover, the quality of ICSR from India is much higher as compared to rest of the world.

Recognising the strength and progressive journey of PvPI in the area of Pharmacovigilance, it is a matter of great honour and pride for the nation that NCC-PvPI has been recognized as the "WHO Collaboration Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services". PvPI has also been working in close collaboration with other National Health Programmes being run in the country such as National Tuberculosis Elimination

Programme (NTEP), National AIDS Control Organization (NACO) and National Vector Borne Disease Control Programme (NVBDCP), Universal Immunisation Programme (UIP) etc.

Several tools and methods have been introduced by the PvPI including Suspected ADR Reporting form (For Healthcare Professionals), Medicines Side Effect Reporting form (For consumers) in Hindi, English and other vernacular languages, Mobile App (ADR PvPI), PvPI Helpline (Toll-free 1800 180 3024), etc. For further details visit www.ipc.gov.in. NCC-PvPI organizes regular training programmes including skill development programmes on Pharmacovigilance to enhance knowledge, skills and practice of stakeholder's and to promote quality and safety of medicines manufactured and marketed in India. Therefore, effective implementation of Pharmacovigilance in healthcare facilities will provide a dynamic and stable system to monitor the ADR reporting mechanism about safety of the drugs used in the country. This will reduce our dependence on western world data for taking regulatory decisions on drug safety on account of evolution of evidence based drug safety mechanism. Therefore, the Pharmacovigilance actions and ADR monitoring centres need to be scaled up and is the need of the hour. Advantages of Enrolment as an AMC

The Advantages of Enrolment as an AMC are:

1. Health partner for the Nation-wide ADR Reporting System
2. Access to WHO Global safety database, VigiFlow to evaluate benefit-risk assessment of Medicines
3. Eligible for Financial/Manpower assistance and other expenses for training/ conferences/telephone/internet etc.
4. Scientific Publications/ Case Studies/Project related to pharmacovigilance
5. Reduce India's dependence on western world data for taking regulatory decisions on drug safety.
6. Boost Public confidence in safety of medicines

For further details, please contact at: pvpi.ipc@gov.in; www.ipc.gov.in



INDIAN PHARMACOPOEIA COMMISSION

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

Ministry of Health & Family Welfare, Government of India

Sector-23, Raj Nagar, Ghaziabad- 201002

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

E-mail: pvpi.ipc@gov.in, lab.ipc@gov.in, Web: www.ipc.gov.in

Format No. IPC/PvPI/QA/021-F01-02

LETTER OF INTENT

Date :.....

I. Institutional Information:

- a. Name of the Institution/Hospital:
- b. Approval status from NMC (National Medical Commission) /PCI (Pharmacy Council of India) (Yes/No):
- c. Affiliation of the Hospital (if any):
.....
- d. Government/Non-Government/Private or any other. (Please Specify)
.....
- e. Distance between Hospital & Institution for e.g. Medical College (optional)
.....
- f. No. of beds in the hospital:
- g. Patient statistics (Inpatient / outpatient):
.....
.....
- h. Total no. of departments:

II. Logistic/infrastructural facilities to function as an adverse drug reaction monitoring centre (AMC) under PvPI:

- a. Name of department to function as an AMC:
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- b. Total no. of faculties in the department:.....
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.....
- c. Whether workplace is allocated for Pharmacovigilance Activities (Yes/No):
.....
.....
- d. Whether computer & logistic facilities available for PvPI (YES/No):.....
.....

III. Technical Information:

- a. Details of the Proposed Coordinator:

Name:.....
Designation:.....
Qualification:.....
Total Experience:.....
.....

- b. Details of the Proposed Deputy Coordinator:

Name:.....
Designation:.....
Qualification:.....
Total Experience:.....
.....

- c. Details of ADRs reported during last one year, if any, (optional), (Annexure-I)

- d. Any other relevant information.

IV. Contact Details

S.No.	Designation	Name	Phone No. (Extension No. if any)	Mobile No.	Email Id
1.	Director/Principal / Dean / Medical Superintendent/Incharge (Please tick)				
2.	Coordinator				
3.	Deputy Coordinator				
4.	Others (if any)				

:

Complete Postal Address of Proposed AMC:

.....
.....
.....

State..... **Pin code**.....

Terms of Reference (TOR):

- a) If the proposed centre is accepted as adverse drug reaction monitoring centre (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, Computer table/chair, Almirah, Stationary and Notice board etc.
- c) NCC-PvPI, IPC may provide the trained manpower provided the centre shows potential to become active participant in the programme.
- d) The competent authority of PvPI reserve all the rights to accept/reject the proposal and suggest any other suitable measure.
- e) The HOD/Dean/Principal/Coordinator/Deputy coordinator of the proposed centre shall be responsible to establish/implement PvPI activities in the centre.
- f) 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.
- g) If your centre is accepted as an AMC, NCC-PvPI will provide regular training, skill development, financial & technical support to the personnel engaged in PvPI activities.

We have understood the above terms of reference and are agree to undertake the responsibility of ADR Monitoring Centre under the Pharmacovigilance Programme of India (PvPI). Our institute may be considered for the same.

Signature
Proposed Coordinator/ In-charge of PvPI

Signature
Head of Institution

*If your centre is approved, you will be sent with the detailed terms & conditions along with roles and responsibilities.

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

S. No.	Patient details		ADR	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”
ADR Reporting Help line (Toll Free): 1800-180-3024