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INDIAN PHARMACOPOEIA COMMISSION

National Coordination Centre-Pharmacovigilance Programme of India



STANDARD OPERATING PROCEDURE

Page No.

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SOP No.

IPC/PvPI/QA/021

Division

QA Division

Revision No.

00

Effective Date

01/11/2016

Review Date

31/10/2019

Title: SOP for enrolment of new AMCs under PvPI

1.0 OBJECTIVE

To lay down the procedure for enrolment of new Adverse Drug Reaction Monitoring centres under PvPI.

2.0 SCOPE

This SOP shall be applicable to PvPI.

3.0 RESPONSIBILITY

- 3.1 The Pharmacovigilance Associate, Quality-Manager/Technical-Manager shall be responsible for the identification and enrolment of new AMCs.
- 3.2 Quality Manager/Technical Manager shall ensure overall implementation of this SOP.

4.0 ACCOUNTABILITY

Officer Incharge - Pharmacovigilance Programme of India.

5.0 PROCEDURE

- 5.1 A 'Letter of Intent' is required to be submitted by the Head of the Institution/hospital to participate in this nationwide programme to monitor drug safety. After examining the suitability by the competent authority, the proposed centre may be inducted as an AMC under PvPI.

	Name	Designation	Signature	Date
Prepared by	Ranay Kumar	PvA	[Signature]	19/10/2016
Reviewed by	Dr. Pawan K. Saini	Scientific officer	[Signature]	25/10/2016
Approved by	Dr. Kaliselman	PSO	[Signature]	26/10/2016

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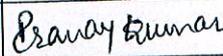
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 सत्यमेव जयते 	INDIAN PHARMACOPOEIA COMMISSION National Coordination Centre-Pharmacovigilance Programme of India		
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Title: SOP for enrolment of new AMC's under PvPI

- 5.2 The criteria for the selection of the new AMC's shall be based on the following approach:
- 5.2.1 Rational approach based on population and geographical distribution of the state.
 - 5.2.2 Assessing performance based on the quality and quantity of the ADR reports received from the proposed centre.
 - 5.2.3 States where AMC's are not recognised in the previous phases.
 - 5.2.4 Performance of the proposed centre in last one year in terms of ADR reporting and awareness on Pharmacovigilance among health care professionals of their organization.
- 5.3 The proposed centre shall accept the following Terms of Reference (TOR) to be accepted as AMC under PvPI:
- 5.3.1 If the proposed centre is accepted as adverse drug reaction monitoring centre (AMC), it is essential for the instution/hospital to function with own logistic/infrastructural facilities.
 - 5.3.2 List of logistics required to setup an AMC under PvPI:
 - 5.3.2.1 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.
 - 5.3.2.2 NCC-PvPI, IPC may provide the trained manpower if the centres performance is found satisfactory.
 - 5.3.3 The proposal may be accepted based on the significant track record on Pharmacovigilance.
 - 5.3.4 The acceptance of the centre as an AMC is based on the quality, quantity & frequency of Adverse Drug Reaction (ADR) reporting.
 - 5.3.5 The competent authority /committee of PvPI reserve all the rights to accept/reject the proposal.

	Name	Designation	Signature	Date
Prepared by	Pranay Kumar	PVA		19/10/2016
Reviewed by	Dr. Pawan K. Saini	S.O.		25/10/2016
Approved by	Dr. Kalaiselvan	PSO		26/10/2016



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- 5.3.6 The HOD/Dean/Principal of the proposed centre shall be responsible to establish/implement PvPI activities in the centre.
- 5.3.7 The HOD/Dean/Principal 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.
- 5.3.8 If the centre is accepted as an AMC, NCC-PvPI will provide regular training, skill development & technical support to the personnel engaged in PvPI activities.
- 5.4 Once the centre is approved as an AMC the centre is provided with the detailed roles and responsibilities of the Coordinator & deputy coordinator. Further, NCC communicates the AMC details to WHO-UMC to obtain vigiflow (WHO-UMC global software) login details, which is further communicated to the AMC Coordinator to upload ICSRs from their regional centres.

6.0 SAFETY AND PRECAUTIONS

- 6.1 Do not use any SOP if it is not signed and issued by QA Personnel's or the authorized signatories.
- 6.2 Do not use adhesive tape or whitener on SOP.
- 6.3 Do not share the SOP information outside the organization.

7.0 REFERENCES : In-house

8.0 ABBREVIATIONS

SOP : Standard Operating Procedure

AMCs : Adverse Drug Reaction Monitoring Centres

	Name	Designation	Signature	Date
Prepared by	Pranay Kumar	PVA	<i>[Signature]</i>	29/10/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	<i>[Signature]</i>	25/10/2016
Approved by	Dr. Kalisekaran	PS	<i>[Signature]</i>	26/10/2016

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Title: SOP for enrolment of new AMCs under PvPI

- NCC : National Coordination Centre
- PvPI : Pharmacovigilance Programme of India
- IPC : Indian Pharmacopoeia Commission
- HOD : Head of Department
- ADR : Adverse Drug Reaction
- WHO : World Health organization
- UMC : Uppsala Monitoring Centre
- ICSRs : Individual Case Safety Reports
- TOR : Terms of Reference
- QA : Quality Assurance

9.0 ANNEXURE(s):

Annexure I - Letter of Intent (Format No. IPC/PvPI/QA/021-F01-00)

	Name	Designation	Signature	Date
Prepared by	Pranay Kumar	PvA	<i>Pranay Kumar</i>	19/10/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	<i>PK</i>	25/10/2016
Approved by	Dr. Lalajee Wan	PJO	<i>W</i>	26/10/2016



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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- 201 002.

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Sign: [Signature] Dt: 26/10/2016

Tel No: 0120- 2783392, 2783400, 2783401, Fax: 0120-2783311
e-mail: pvpi@ipcindia.net, ipclab@vsnl.net, Web: www.ipc.gov.in

Format No. IPC/PvPI/QA/021-F01-00

LETTER OF INTENT

Date:.....

I. Institutional Information:

- a. Name of the Institution/Hospital:.....
.....
- b. Name of the hospital affiliated:.....
.....
- c. Govt. /Non Govt. /Private (Please Specify):
- d. Distance between hospital & institution:.....
.....
- e. No. of beds in the hospital:.....
.....
- f. Patient statistics (Inpatient / outpatient):.....
.....
.....
- g. 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:.....
.....
- b. Total no. of faculties in the department:.....
.....

26/10/2016

[Signatures]

- c. Whether workplace is allocated for PvPI (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 (Preferably Clinicians):
Name:.....
Designation:.....
Qualification:.....
Total Experience:.....
.....
- c. Experience of Proposed Coordinator/Deputy Coordinator in Pharmacovigilance:
Coordinator:.....
.....
.....
.....
Deputy Coordinator:.....
.....
.....

(Additional sheet may be used)

6/11/16 *MW* *Mo*

d. Details of training / CME on PvPI attended by Coordinator /Deputy Coordinator
 in last 2 years:.....

 (Additional sheet may be used)

e. Details of ADRs reported during last 1 year (to be furnished as per the details in
 Annexure-I).

IV. Contact Details:

S.NO	Designation	Name	Phone no. (extension no. if any)	Mobile no.	Email Id
1.	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.....

Bh
19/10/16

[Handwritten signatures]

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Sign. *Bu* Dt. 26/10/2016

Terms of Reference (TOR):

- a) All the above fields are mandatory to be filled otherwise the proposal shall be rejected.
- b) If the proposed centre is accepted as adverse drug reaction monitoring centre (AMC), it's essential to function with own logistic/infrastructural facilities.
- c) 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, Almira, Stationary and Notice board etc.
- d) NCC-PvPI, IPC may provide the trained manpower if the centres performance is found satisfactory.
- e) Your proposal may be accepted based on the significant track record on Pharmacovigilance.
- f) The acceptance of your centre as an AMC is based on the quality, quantity & frequency of Adverse Drug Reaction (ADR) reporting.
- g) The competent authority /committee of PvPI reserve all the rights to accept/reject the proposal.
- h) The HOD/Dean/Principal of the proposed centre shall be responsible to establish/implement PvPI activities in the centre.
- i) The HOD/Dean/Principal 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.
- j) If your centre is accepted as an AMC, NCC-PvPI will provide regular training, skill development & technical support to the personnel engaged in PvPI activities.

We have undergone the terms of reference and are interested 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/ Incharge 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.

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

Signature
19/11/16

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 (ANNEXURE D)

Details of ADRs reported during last 1 year

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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						
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								
15.								

Separate sheet may be used if the numbers are more.

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

ADR Reporting Help line (Toll Free): 1800-180-3024

Handwritten signatures and initials in the top left corner.