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INDIAN PHARMACOPOEIA COMMISSION  
National Coordination Centre-Pharmacovigilance Programme of India

सत्यमेव जयते



## STANDARD OPERATING PROCEDURE

Page No.

1 of 4

SOP No.

IPC/PvPI/QA/016

Section

All Section

Revision No.

01

Effective Date

01/09/2016

Review Date

31/08/2019

Title: SOP for documentation at AMCs.

## 1.0 OBJECTIVE

- 1.1 To lay down the procedure for documentation at ADR Monitoring Centres of Pharmacovigilance Programme of India.

## 2.0 SCOPE

- 2.1 This SOP shall be applicable to the AMCs working under PvPI.

## 3.0 RESPONSIBILITY

- 3.1 The Pharmacovigilance Associates working at AMCs and Coordinators/Deputy Coordinators of respective AMCs shall be responsible for adhering to this SOP.
- 3.2 The Coordinators/Deputy Coordinators of respective AMCs shall ensure that this SOP has been reflected in the Pharmacovigilance division of AMC.
- 3.3 Quality-Manager/Technical-Manager shall ensure overall implementation of this SOP.

## 4.0 ACCOUNTABILITY

- 4.1 Officer Incharge - Pharmacovigilance Programme of India.

## 5.0 PROCEDURE

- 5.1 The documents related to PvPI shall be kept separately in the Pharmacovigilance division of AMCs in such a way that it is easy to find out and can be produced when required.

	Name	Designation	Signature	Date
Prepared by	Pranay Kumar	PVA	Pranay Kumar	24/08/2016
Reviewed by	Dr. Rawan K. Saini	Scientific officer	[Signature]	25/08/2016
Approved by	Dr. V. K. Bhatnagar	PSO	[Signature]	26/8/2016



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- 5.2 A copy of letter of intent sent to NCC-PvPI at the time of enrolment and the acceptance letter issued from NCC-PvPI to function as an AMC shall be available in the Pharmacovigilance division of all the AMCs.
- 5.3 All the AMCs shall maintain a file of SOPs received from NCC-PvPI. It is the responsibility of the coordinator/deputy coordinator and the pharmacovigilance associate (if appointed) to ensure the availability of current version of all the SOPs.
- 5.4 A file of Pharmacovigilance Associate shall be maintained at AMC (if appointed) separately. The appointment order, Extension order issued time to time from NCC-PvPI shall be maintained in the file including the vigiFlow Non- disclosure Agreement form. All the attendance/assessment reports of the pharmacovigilance associates shall be maintained. In case of resignation, a copy of resignation letter of the PvA, No Dues certificate and the relieving letter issued from NCC shall be available at AMC before the relieving of the PvA from AMC.
- 5.5 All the collected ADR reports shall be kept in a separate file holding the subsequent year name and shall be separated month wise. The PvA is responsible to maintain the file and shall be able to provide the source document (ADR reporting form and the related documents; if any) whenever required by NCC or by the auditor/authorised personnel appointed for the audit purpose.
- 5.6 A copy of Monthly progress report received from NCC-PvPI shall be kept in a separate file in the name of "Monthly progress report". All the communication to NCC- PvPI made by AMCs or vice versa shall be maintained in a separate file holding the file name "NCC-Communication."
- 5.7 A file with title "Resource materials - PvPI" shall be maintained at all the AMCs. A copy of all the resource materials (newsletter/guidance document/pamphlets/posters etc.) received from NCC-PvPI shall be available at AMCs.

	Name	Designation	Signature	Date
Prepared by	Pranay Kumar	PvA	Pranay Kumar	24/08/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	[Signature]	25/08/2016
Approved by	Dr. V. Kalaiselvan	PSO	[Signature]	26/08/2016

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5.8 All the necessary documents mentioned in the SOP of Audit/Inspection of AMCs (SOP no.-IPC/PvPI/QA/018) and any other file relating to PvPI (including promotional activities at AMC or its peripheral hospitals) shall be maintained as per the requirement of AMC with the permission of the AMC coordinator.

## 6.0 SAFETY AND PRECAUTIONS

- 6.1 Do not use any SOP if it is not signed and issued by QA Personnel 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.
- 6.4 All the files related to PvPI must be kept carefully in order to avoid any damage /loss of documents.

7.0 REFERENCES : In-house

## 8.0 ABBREVIATIONS

SOP	:	Standard Operating Procedure
IPC	:	Indian Pharmacopoeia Commission
PvPI	:	Pharmacovigilance Programme of India
AMCs	:	Adverse Drug Reaction Monitoring Centres
NCC	:	National Coordination Centre
ICSRs	:	Individual Case Safety Reports
ADR	:	Adverse Drug Reaction
QA	:	Quality Assurance

	Name	Designation	Signature	Date
Prepared by	Pranay Kumar	PVA	Pranay Kumar	24/08/2016
Reviewed by	Dr. Pawan K. Saini	S.O.		25/08/2016
Approved by	Dr. K. Kalaiselvan	P.S.O.		26/08/2016

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IPC

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01

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Title: SOP for documentation at AMCs.

## 9.0 ANNEXURE(s):

Annexure I : Performa for No Dues Certificate-

(Format No. IPC/PvPI/QA/017-F01-00)

	Name	Designation	Signature	Date
Prepared by	Pranay Kumar	PVA	Pranay Kumar	24/08/2016
Reviewed by	Dr. Bawan K. Saini	S.O.		25/08/2016
Approved by	Dr. V. Kalaiselvan	Pdo		26/08/2016

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Annexure-II  
Performa for No Dues Certificate

Format No. IPC/PvPI/QA/016-F01-00

NO DUES CERTIFICATE

Date: \_\_\_\_\_

Mr. / Mrs. / Miss: \_\_\_\_\_ has  
submitted his / her resignation on dt. \_\_\_\_\_ and the same is accepted.

Kindly confirm the dues, advances, office belongings, if any in his / her possession.

Name of AMC :				
Name of Pharmacovigilance Associate :				
Dept. :		Reporting to:		
Date of Joining:		Date of Leaving:		
Dept. / Section	Please Specify Submission status		Initials	Remarks
	Dues	No Dues		
• To handover files handled by him/her (soft & hard copies) (List should be attached)				
• Status of Reverted Reports (No.)				

	Name	Designation	Signature	Date	Page
Prepared by	Pranay Kumar	PVA	Pranay Kumar	24/08/2016	1 of 2
Reviewed by	Dr. Raman K. Singh	S.O.		25/08/2016	
Approved by	Dr. V. Kalaiselvan	PSO		26/8/2016	

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Sign: [Signature] Date: 24/08/2016

Annexure-II  
Performa for No Dues Certificate

Format No. IPC/PvPI/QA/016-F01-00

• Status of Pending Reports to enter				
• Submission of documents held (Yes/ No)				
• Submission of logistics held (Yes/No)				
IT : - (PC & any other tools provided)				
Floppies & CDs used				
• Books/journals borrowed/issued from concerned dept. (if any)				
• Educational /training Declaration, if any				
• Articles communicated for Peer review /publication (if any )				
• Ensure VigiFlow Password Changed (Yes/No)				
others :-				

Signature with seal/stamp  
Co-ordinator/ Incharge of AMC (PvPI)

**Note: -**

- The relieving order of the Pharmacovigilance Associate shall be issued subject to the submission of No dues certificate.

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Prepared by	Pranay Kumar	PvA	Pranay Kumar	24/08/2016	2 of 2
Reviewed by	Dr. Pawan K. Saini	S.O.	[Signature]	25/08/2016	
Approved by	Dr. V. Kalaiselvan	PSS	[Signature]	26/8/2016	