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National Coordination Centre-Pharmacovigilance Programme of India

STANDARD OPERATING PROCEDURE		Page No.	1 of 5
Section	All section	SOP No.	IPC/PvPI/QA/010
Effective Date	01/09/2016	Revision No.	00
		Review Date	31/08/2019

Title: SOP for Preparation and submission of Progress Reports.

1.0 OBJECTIVE

- 1.1 To lay down a procedure for making progress reports under Pharmacovigilance Programme of India.

2.0 SCOPE

- 2.1 This SOP shall be applicable to PvPI.

3.0 RESPONSIBILITY

- 3.1 The personnel engaged in the PvPI activity shall be responsible for adhering to this SOP.
- 3.2 All Pharmacovigilance Associates working at NCC-PvPI shall be responsible for adhering to this SOP.
- 3.3 Quality Manager, Technical Manager, Section-In-charge & AMC Coordinator shall ensure overall implementation of this SOP.

4.0 ACCOUNTABILITY

- 4.1 Officer Incharge - Pharmacovigilance Programme of India

5.0 PROCEDURE

- 5.1 The Progress Report under PvPI shall be of following type :
 - A) Daily Progress Report
 - B) Monthly Progress Report of AMCs
 - C) Monthly Progress Report of PvPI

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	P. Associate	<i>RK</i>	16/08/2016
Reviewed by	Dr. Parveen K. Saini	Senior officer	<i>PK</i>	17/08/2016
Approved by	Dr. Kalaisekaran	PS D	<i>KS</i>	18/8/2016

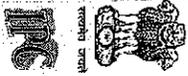
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D) DMU Report (Quarterly)
E) Annual Performance Report

5.2 Daily Progress Report

5.2.1 Monthly Summary of ICSRs and Communication Details shall be prepared by the individual PVA engaged in PvPI activities as per annexure I.

5.2.2 Daily Progress Report shall be prepared by the individual personnel engaged in PvPI activities as per annexure II.

5.2.3 The Daily Progress Report shall include the day to day activities/work performed by the personnel at NCC and shall be provided in a date wise manner for that particular month.

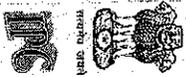
5.2.4 The Daily Progress Report shall be supported with Monthly Summary of ICSRs & Communication Details which shall be filled by individual PVA engaged in PvPI activities at NCC for their allotted centres.

5.2.5 Monthly Summary of ICSRs and Communication Details shall be prepared by providing the details like name of AMCs (arranged in alphabetical order as per AMC i.d.), name of Coordinator, name of PVA with Communication details; total no. of ICSRs received in the particular month mentioning no. of serious ICSRs in parentheses, The details on number of ICSRs committed, reverted and pending till date of submission of details. The detail of no. of ICSRs nullified (if any) shall also be provided in the feedback/remarks column.

5.2.6 The PVA shall provide the details of communication with the AMC's PVA/coordinators/concerned person for the allotted centres in the specified column as per Annexure-I.

5.2.7 The Daily Progress Report and Monthly Summary of ICSRs and Communication Details of AMCs that shall be submitted in hard copy to QA section on the first working day of every next month. The e-version format shall be used to prepare

Name	Designation	Signature	Date
Prepared by Rishu Kumar	Pv Associate		16/08/2016
Reviewed by Dr. Rausan K. Sahni	S.O.		17/08/2016
Approved by Dr. Kalishelvi	PS 6		14/01/2016



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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.

7.0 REFERENCES : In-House

8.0 ABBREVIATIONS

SOP	:	Standard Operating Procedure
AMC	:	Adverse Drug Reaction Monitoring Centre
PvPI	:	Pharmacovigilance Programme of India
NCC	:	National Coordination Centre
QA	:	Quality Assurance
ADR	:	Adverse Drug Reaction
ICSRs	:	Individual Case Safety Reports
PvA	:	Pharmacovigilance Associate
DMU	:	Delivery Monitoring Unit
MoH&FW	:	Ministry of Health and Family Welfare
No.	:	Number

9.0 ANNEXURE(S):

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	P. Associate		16/08/2016
Reviewed by	Dr. Pawan K. Saini	S.O.		17/08/2016
Approved by	Dr. Lal Bahadur Shastri	P.S.O		18/01/2016



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Annexure-I Monthly Summary of ICSRs and Communication Details of AMC

Format NO.-IPC/PvPI/QA/010-F01-00

Annexure-II- Daily Progress Report Format NO.-IPC/PvPI/QA/010-F02-00

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Associate		16/08/2016
Reviewed by	Dr. Pawan K. Saini	S.O.		17/08/2016
Approved by	Dr. Kalai Selvan	PSO		18/08/2016



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Annexure - I
Monthly Summary of ICSRs and Communication Details of AMCs

Format No. IPC/PvPI/QA/010-F01-00

Name of Pharmacovigilance Associate(NCC) :				Employee ID:				Month : June 2016				
AMCs Detail				Communication Detail				ICSRs received in index month	ICSRs Processed in index month	No. of ICSRs Reverted in index month	Total No. of ICSRs Pending till date	Feedback/Remark
S. No	Name of the AMC	Name of Coordinator	Name of Tech. Associate	By Phone (Date wise)		By Email (Date wise)						
				R	D	R	S					

R: Received, D: Dial S: Send

Submitted by:

Verified by:

Note:-

1. The above details to be furnished & submitted to QA section on the first working day of every next month.
2. In the feedback/remark column provide only important information.
3. You are required to fill the Performa in legible hand writing.

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Pv. Associate	[Signature]	16/08/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	[Signature]	17/08/2016
Approved by	Dr. Kalai Selvan	PSO	[Signature]	18/08/2016

