1.0 OBJECTIVE

To explain the responsibility and authority of all the key personnel and staff working at appropriate positions in the NCC-PvPI.

2.0 SCOPE

This SOP shall be applicable to Pharmacovigilance Programme of India.

3.0 RESPONSIBILITY

All personnel engaged in the PvPI activity shall be responsible for adhering to this SOP.

4.0 ACCOUNTABILITY

Officer-in-charge – Pharmacovigilance Programme of India.

5.0 PROCEDURE

5.1 The authorities and responsibilities are defined by the Secretary-cum-Scientific Director.

5.2 Director is fully authorized to make deviations, additions, deletions or any other changes regarding responsibilities.

5.3 The authority and responsibility of key personnel is as follows:

5.3.1 Responsibilities of Principal Scientific Officer

- ❖ Implementation of Technical & Administrative matters in PvPI and Communicating with AMCs & UMCs.

	Name	Designation	Signature	Date
Prepared by	Madhu Smita	HR Associate	Madhu Smita	26/10/2016
Reviewed by	Dr. Pawan K. Saini	Scientific Officer		27/10/2016
Approved by	Dr. Kalaiselvan	PSO		28/10/2016

- The primary responsibility to ensure functioning of PvPI effectively through its various Technical Committees.
- Coordinating/Communicating with similarly placed Organisations & stakeholders.
- Organising Technical Committees, meetings, trainings & awareness programs on PvPI at NCC and across the country.
- Reviewing the content of resource materials like PvPI Newsletter, Guidance Document, Quality Manual, Annual report, e-Media and other Communications etc.
- Responsible for overall organizational functions pertaining to the system maintenance and technical operations by implementation of policies, processes and system related to performance, checking, evaluation and release of reports.
- Regular evaluation regarding improvement in the effectiveness of managerial and technical parameters.
- Continuous review of Quality objectives.
- Responsible to run the organization in professional manner.
- Responsible for approving Quality System Procedures or SOP.
- To maintain integrity of the system by proper planning.
- Any other work assigned by the Secretary cum-Scientific Director.

5.3.2 **Responsibilities of Scientific Officer**

- Responsible to ensure the effective functioning of Quality Management System.
- Associated in implementation of Technical & Administrative matters of PvPI and Communication with the partners/stakeholders

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Approved by	Dr. Kaleiselvan	PSO		28/10/2016

- ❖ Coordinating with CDSCO for the integration of PSURs/PMS processing.
- ❖ Organising of Quality review panel meetings under PvPI.
- ❖ Coordinating /communicating with the PvPI personnel at NCC for QA related activities, Training & Education, Communication & Publication.
- ❖ Coordinating /communicating for Materiovigilance Programme of India (MvPI).
- ❖ Reviewing of the resource materials related to MvPI.
- ❖ Reviewing the PvPI monthly progress report & Delivery Monitoring Unit (DMU).
- ❖ To review the Quality Manual, SOPs and issuing.
- ❖ To supervise the maintenance, logistic, finance and administration related work.
- ❖ Any other work assigned by the Secretary cum-Scientific Director.

5.3.3 **Responsibilities Scientific Assistant**

- ❖ To assist the National Pharmacovigilance Programme.
- ❖ ICSRs Processing & Quality Review of the ADR Monitoring Centres (AMCs).
- ❖ Coordinating with allotted AMCs.
- ❖ Preparation of PvPI monthly progress report and delivering monitoring unit report of NCC-PvPI.
- ❖ Assisting in preparation of PvPI Newsletter, Guidance Document & Training Manual Content.
- ❖ Assisting in preparation and updating of SOPs.
- ❖ Assisting in conducting Working Group and Steering Committee meeting under PvPI.
- ❖ Coordination with WHO-UMC for technical support.
- ❖ Organising of Core Training Panel meetings under PvPI.
- ❖ Any other work assigned by the Secretary cum-Scientific Director.

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5.3.4 **Responsibilities of Pharmacovigilance Associate (PvA) at NCC**

The major responsibility of Pharmacovigilance Associates at NCC is processing of ICSRs. Further additional duties division wise as given below are assigned to them: -

5.3.4.1 **Training & Education (TE) Division**

- ❖ Organizing PV training and skill development at AMCs/Regional Centres/NCC.
- ❖ Preparation and updating training manual and SOPs.
- ❖ Conducting Continuous Medical Education (CME) programme on pharmacovigilance at various zones.
- ❖ Conducting periodic trainings and workshops for all stakeholders enrolled at AMCs.

5.3.4.2 **National Health Programme (NHPs) Division**

- ❖ Assisting in coordination with National Health Programmes such as RNTCP, NACO, AEFI etc and activities related to enrolment of other NHPs under PvPI.
- ❖ Compiling of AEFI ICSRs cases, identification and communication to Immunization Technical Support Unit (ITSU).

5.3.4.3 **Promotion and Communication& Publication (PCP) Division**

- ❖ Activities related to Communication & Publications (Annual Report, Guidance Document, Newsletter, Pamphlet, Display Boards, etc.).
- ❖ Maintenance & updating of photo gallery in PvPI web link and on Notice Boards.

5.3.4.4 **SUSARs/SAE Division**

- ❖ Backlog Clearance of ICSRs
- ❖ Data Analysis

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Approved by	Dr. Kalaiselvan	PSO		28/10/2016

- ❖ Identification of SUSARs/SAE
- ❖ Drug Alert
- ❖ Clinical Relevance

5.3.4.5 **International Cooperation Division**

- ❖ All the activities related to international co-operation of PvPI.

5.3.4.6 **Individual Case Safety Reports (ICSRs) Processing Division**

- ❖ The received ICSRs at NCC are subject to the quality & clinical review by respective PvA.

5.3.4.7 **Quality Assurance Division**

- ❖ Developing and strengthening the quality system through implementation of quality manual & quality system procedure.
- ❖ Preparation of PvPI monthly reporting status (quantitative) and monthly progress report of AMCs and NCC-PvPI.
- ❖ Compiling documentation scoring for individual AMCs, Quality Review Panel (QRP) meetings, audit & inspection.
- ❖ Resolve the ADRs reverted by UMC.
- ❖ Preparation of PvPI status on monthly basis and sending feedback/appreciation letters to the stakeholders.
- ❖ Preparation and updating of SOPs and PvPI documents for National Regulatory Authority (NRA) meetings.
- ❖ To Identify and address practical issues and difficulties faced by AMCs in order to improve the system and to draw policies for future use and benefit.

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Approved by	Dr. Kalaiselvan	PSO		28/10/2016

5.3.4.8 **Marketing Authorization Holders (MAHs) Affairs Division**

- Entry of SUSAR's/SAEs/ ICSRs received from industries into database and sending feedback to industries.
- Review of Periodic Safety Update Reports (PSURs).
- Preparation & updating of SOPs related to PSURs review.
- Integration of PvPI-SUSARs data with CDSCO-SAE's data & requesting pharmaceutical companies for the SUSAR's pertaining to a medicine.

5.3.4.9 **Signal Detection Division**

- Identification of SUSARs/SAE and assessment of clinical relevance of ICSRs
- Drug alert and data analysis.
- Signal detection and sharing with signal review panel/meetings (Signal detection, preliminary signal evaluation, preparation & updating of signal related SOPs) and correspondence to CDSCO for regulatory recommendations.

5.3.4.10 **Benefit-Risk Assessment Division**

- Coordination with Indian Medical Association (IMA) & Healthcare Professionals.
- To develop the capacity building of benefit-risk assessment under PvPI.
- Preparation & updating of SOPs related to benefit-risk assessment.

5.3.4.11 **Information Technology (IT) Division**

- Developing new innovative methods for ADR reporting.
- Assisting in PvPI IT Internet tools development.
- Promoting the availability of helpline/mobile application etc. and handling of ADR received through same.

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5.3.5 **Responsibilities of Pharmacovigilance Associate at AMC**

- Collection of ADR Reports.
- Follow up with the reporters/patients for Completeness as per SOPs.
- Data Entry in VigiFlow.
- Reporting to NCC-PvPI through VigiFlow with the source data (Original) attached each ADR case.
- Training/Sensitization/Feedback to physicians through news letter circulated by the NCC- PvPI.
- Other activities as assigned by the competent authority from time to time.

5.3.6 **Responsibilities of HR Associate**

- Documentation and preparing reports relating to organizational activities (PvPI) in respect of personnel (staffing, recruitment, training, grievances, performance evaluations etc)
- Assisting in compilation and organizing the performance reports of employees under PvPI.
- Assisting and monitoring the attendance of the employees of PvPI on monthly basis(including NCC & AMCs)
- Maintaining and updating the data base of the newly engaged personnel within NCC and AMCs.
- Maintaining performance appraisal system of the employees from time to time using the assessment information for the purpose of trainings, promotions, and incentives.
- Other activities as assigned by the competent authority from time to time.

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Approved by	Dr. Kalaiselvan	PSO		28/10/2016

5.3.7 **Responsibilities of IT Associate**

- ❖ Handling of the issues related to ADR e-reporting.
- ❖ Development and maintenance of IT tools related to PV such as e-reporting, Mobile Application.
- ❖ Development of innovative IT technology.
- ❖ Developing indigenous software for ADR reporting.
- ❖ Setting up new user's accounts and profiles and dealing with password issues of PV software.
- ❖ Troubleshooting Computer system and network problems.
- ❖ Other activities as assigned by the competent authority from time to time.

5.3.8 **Responsibilities of Biostatistician**

- ❖ Designing and implementing data gathering.
- ❖ Evaluating the statistical methods and procedures used to obtain data in order to ensure validity, applicability, efficiency, and accuracy.
- ❖ Developing data collection and signal detection process.
- ❖ Interpretation of results of signal detection.
- ❖ Process large amounts of data for statistical modelling including information in the form of graphs, charts, and tables and graphic analysis using statistics.
- ❖ Presentation of data to assist in coordinating and monitoring various activities of the programme.
- ❖ Other activities as assigned by competent authority from time to time.

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5.3.9 **Responsibilities of Senior Pharmacovigilance Associate**

- Review & analysis of PSURs and follow up action with stakeholders.
- Benefit-risk evaluation of Medicinal Products available in Indian Market.
- To supervise the assigned work and assist the Senior Officials.
- Assisting in quality review and signal review of ICSRs.
- To provide Vigiflow hands on training to the newly engaged personnel in PvPI.
- Assisting the NCC for document control.
- Any other activities as assigned by competent authority from time to time.

5.3.10 **Responsibilities of Data Entry Operator**

- Assisting in compiling and preparing the training module for training programmes.
- Assisting in drafting of resource materials of PvPI.
- Dispatch of printed as well as e-version of resource materials of PvPI in various regions.
- Assisting in procurement, financial and administrative works related to PvPI.
- Assisting in preparation of documents related to Quality Assurance.
- Assisting in preparation of all PvPI related documents, control, maintenance and archival.
- Follow up action with the finance& account division for all finance related matters of AMCs, RTCs, NCC and others.
- Any other activities as assigned by competent authority from time to time.

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5.3.11 **Responsibilities of Multi Tasking Staff**

- Upkeep of the section; carrying of files and other papers within the building.
- Photocopying, making sets, stapling, spiral bindings, sending of FAX etc.
- Other non-clerical work in the section, assisting in routine office work like diary, dispatch; Delivering of dak inside and outside of Institute;
- Opening & closing of rooms, windows, machineries etc.;
- Some office related work in all respects as per the needs of the section like LCD Projector, Computer, OHP, Audio-Video system as required in Seminar, Conference Hall etc.,
- Other events inside the institute and other venues where the events would be held.
- Any other work assigned by the seniors.

6.0 SAFETY AND PRECAUTIONS (IF ANY)

6.1 Do not use any SOP if it is not signed and issued by QA Personnel or the Authorised signatory.

6.2 Do not use adhesive tape or whitener on SOP

6.3 Do not share the SOP information outside the organization.

7.0 REFRENCES : In-house

8.0 ABBREVIATIONS

SOP : Standard Operating Procedure

NCC : National Coordination Centre

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PvPI	:	Pharmacovigilance Programme of India
QA	:	Quality Assurance
IPC	:	Indian Pharmacopoeia Commission
HR	:	Human Resource
IT	:	Information Technology

9.0 Annexure :

Annexure I : Job Responsibility Format No. IPC/PvPI/HR/002-F01

	Name	Designation	Signature	Date
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सत्यमेव जयते IPC	**INDIAN PHARMACOPOEIA COMMISSION** **National Coordination Centre-Pharmacovigilance Programme of India** **Annexure-I** **JOB RESPONSIBILITY**

Format No. IPC/PvPI/HR/002-F01-00

JOB RESPONSIBILITY			
Name of the employee			
Designation			
Employee ID		**Version No.**	
Department			
Division /AMC			
Date of joining			
Responsibilities: **Reporting To:**			
Employee Signature/Date			
Evaluated & Approved by (Officer -in-charge):	**Received by (HR Division):**		

	Name	**Designation**	**Signature**	**Date**
Prepared by	Madhu Smita	HR Associat	Madhu Smita	26/10/2016
Reviewed by	Dr. Pawan K. Saini	S.O.		27/10/2016
Approved by	Dr. Kalaiselvan	PSO		28/10/2016