

Indian Pharmacopoeia Commission
National Coordination Centre (NCC)-Pharmacovigilance & Materiovigilance Programme of India
(NCC-PvPI & MvPI)

A. PvPI Monthly Progress Report: January 2018

Sr. No.	Title of Activity	Description	Major Outcome/Action Taken
1.	Data collation and processing of ICSRs	During the index period, NCC-PvPI received 6239 ICSRs from AMCs/ pharmaceutical industries/consumers	The reported cases are under assessment for completeness, listed/unlisted and clinical relevance. Lack of quality/incomplete reports will be reverted to the reporter/sender for further necessary action.
2.	Yearly Assessment and Brain Storming session for Pharmacovigilance Associates	The Yearly Assessment and Brain Storming session for Pharmacovigilance Associate was held from January 2, 3 and 4 at Conference Room, IPC, Ghaziabad	<ul style="list-style-type: none"> • PvAs presented their achievements and activities at AMCs for the year 2017 • The experts of the Assessment Committee were Dr. V. Kalaiselvan, PSO, Officer In charge, NCC PvPI, Mr. P.C.P Mahapatra, Former Administrative Officer, NIB, Dr. Somnath Basu, Assistant Drug Controller, CDSCO, Dr. Kanchan Kohli, Prof. Pharmaceutics, Jamia Hamdard, assessed the performance of PvPI staff for the year 2016-17
3.	Pharmacovigilance workshop on	Second workshop on Fundamental Office Procedure (Noting & Drafting)	Employees of IPC including technical, finance, HR, administration and purchase divisions gained

	Fundamental Office Procedure (Noting & Drafting) at NCC PvPI, IPC	was conducted from January 9 to 12, 2018 at IPC, Ghaziabad. Shri P.C.P Mahapatra, former Administrative Officer of National Institute of Biologics convened 4 days workshop on office procedures and writing skills for 25 technical and supporting staffs.	knowledge and training on administrative procedures and written communication skills (Noting & Drafting).
4.	Meeting with Joint Secretary Regulation- Mr. Sudhir Kumar	A meeting was held with Joint Secretary (Regulation) – Mr. Sudhir Kumar on 12 th January, 2018 at Nirman bhawan, Ministry of Health & Family Welfare	<ul style="list-style-type: none"> • Mr. Sudhir Kumar, Joint Secretary (Regulation) suggested to prepare annual outcome of PvPI based on PV indicators for the year 2018 • Officer In-charge has initiated the task and the same was circulated among division of PvPI
5.	Skill Development Programme on Basics and Regulatory Aspects of Pharmacovigilance at NCC PvPI, IPC	PvPI organised Skill Development Programme on Basics and Regulatory aspects of Pharmacovigilance for the States/UTs of Punjab, West Bengal, Gujarat, Jharkhand, Daman & Diu, Andaman & Nicobar from 15 th January 2018 to 24 th January, 2018 at IPC, Ghaziabad.	<ul style="list-style-type: none"> • In this 10 days training, 20 participants attended the training programme • Participants acquired basic knowledge in Pharmacovigilance • Participants acquired the abilities to deliver good pharmacovigilance- practices at par with international requirements • Participants visited NDDTC and Yashoda Super Speciality Hospital which are functioning as AMCs and experienced working culture of AMC and ADR reporting • Participants were given hands-on training on different modes of ADR-reporting

6.	Training of PG students from Lady Hardinge Medical College, Delhi	The officials and PG students from Lady Hardinge Medical College, Delhi visited IPC on 29 th January, 2018 for training	<ul style="list-style-type: none"> • Students gained knowledge about the working culture and modes of reporting • ICSR processing and quality grading system was explained through presentations • Students also understood functioning of different divisions of PvPI
7.	Pharmacovigilance Partners meeting 2018	Pharmacovigilance partners meeting was organised at MoHFW, Nirman Bhawan on 30 th January, 2018.	<p>Dr. V. Kalaiselvan, Principal Scientific Officer and Officer In charge-PvPI, IPC and other officials of PvPI attended the meeting.</p> <ul style="list-style-type: none"> • Updated excel sheet of NRA recommendation shared with WHO-India and will be monthly updated with the activities done. • PV Partners has discussed about TA/DA of SIPSA to resolve the issues. • Draft SOP for generation of signals will be share by AEFI Sect. to PvPI & CDSCO for other inputs.
8.	Extending Technical support to Deworming Programme	A meeting was held among PvPI, CDSCO and Deworming programme officials aimed to ensure safe deworming programme which is scheduled on 10 th February, 2018.	<ul style="list-style-type: none"> • List of PvPI ADR monitoring centres shared with Deworming officials to ensure seamless adverse event reports. • Deworming programme officials of state or region wise will be communicated to PvPI. • PvPI ADR Reporting tools such as helpline, mobile app and customised reporting form to be utilised by the Deworming Reporting

			officials.
9.	Drug Safety Alert	<p>During the index period the following Drug Alert were revealed:</p> <p>Suspected Drug: Fluoxetine</p> <p>Indication: Fluoxetine is a SSRI antidepressant which is used in psychological disorder and also in premature ejaculation</p> <p>Adverse Reaction: Urinary Incontinence</p>	<p>These informations were communicated to the medical colleges, ADR Monitoring Centres and other healthcare professionals etc. Via SMS and updated in the website.</p>

Indian Pharmacopoeia Commission
National Coordination Centre (NCC) - Materiovigilance Programme of India (MvPI)

MvPI Monthly Progress Report- January 2018

Sr. No.	Title of Activity	Description	Major Outcomes/Action Taken
1.	Data collation and processing of MDAEs reports received at NCC-MvPI	During the index period, NCC-MvPI received 17 MDAE reports from AMCs/MDMCs/ Medical Device industries	The reported cases are under assessment for completeness, and clinical relevance. Lack of quality/incomplete reports will be reverted to the reporter/sender for further necessary action.
2.	Interactive meeting with MvPI Partners	The meeting was convened to review the progress and also review on MDAE reports on 19 th January, 2018 at IPC, NCC-MvPI, Ghaziabad	The officials from NHSRC & CDSCO interacted with NCC-MvPI officials and discussed the followings: <ul style="list-style-type: none"> • Review of MDAE Reports • Finalization of roles and responsibilities of MvPI partners • Formation of Causality Assessment Group (CAG) • Recruitment of Research Associates
3.	1 st Skill Development Programme- 2018 on Basics and regulatory Aspects of Pharmacovigilance	Dr. Pawan Saini, SO IPC presented MvPI overview and reporting of MDAEs during the Skill Development Programme on 22 nd January 2018	Participants gained knowledge on: <ul style="list-style-type: none"> • MvPI and its objectives • Process of reporting MDAEs • MDMC centres under MvPI and their

			functions
4.	One day training session on quality/ processing of ICSRs and signal detection	The session was organised on 29 th January 2018 at IPC, Ghaziabad. A MvPI presentation was given by Dr. Pawan Saini, SO IPC	Nearly 12 participants (MD Pharmacology students from Lady Hardinge Medical College, New Delhi) were aware and trained about what, where and how to report adverse event due to the use of medical devices.
5.	One awareness lecture in “ASPIRE ‘18” (Annual Sri Ramachandra University Pharmacology Insight and Review Course “18)	Program was organised on 31 st January 2018 by Department of Pharmacology, SRMC and RI at Sri Ramachandra University, Porur, Chennai – Mr. Hari Haran, RA, (MvPI) presented about the MvPI	Participants were trained about what, where and how to report adverse event due to the use of medical devices