

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

A. PvPI Monthly Progress Report: November 2017

Sr. No.	Title of Activity	Description	Major Outcome/Action Taken
1.	Data collation and processing of ICSRs	During the index period, NCC-PvPI received 6076 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 for further necessary action.
2.	6 th Skill Development Programme on Basics and Regulatory Aspects of Pharmacovigilance Striving for Excellence 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 November 6 to 15, 2017 at IPC, Ghaziabad.	<ul style="list-style-type: none"> • In this 10 days training, 55 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 were taken on Field visit to PGIMS-Rohtak to understand the working culture of AMC and ADR reporting. • Participants were given hands-on training on different modes of ADR-reporting

3.	Pharmacovigilance workshop on Fundamental Office Procedure (Noting & Drafting) at NCC PvPI, IPC	A workshop on Fundamental Office Procedure (Noting & Drafting) was conducted from November 7 to 10, 2017 at IPC, Ghaziabad.	<p>Shri P.C.P Mahapatra, former Administrative Officer of National Institute of Biologics convened 4 days workshop on office procedures and writing skills for 22 technical and supporting staffs.</p> <p>Outcome: Employees of IPC including technical, finance, HR, administration and purchase divisions gained knowledge and training on administrative procedures and written communication skills (Noting & Drafting).</p>
4.	Regional Review cum Sensitization Workshop on Kala-Azar Elimination Program under National Vector Borne Disease Control Program at Dhumka, Jharkhand	The Sensitization Workshop on Pharmacovigilance of Kala-Azar drugs & process of ADR- reporting was organized by WHO at Dhumka, Jharkhand from November 7 to 8, 2017.	<p>Mr. Arvind Kumar Sharma, Scientific Assistant, IPC and Mr. Pranay Kumar, Senior Pharmacovigilance Associate, PvPI delivered a talk on the following topics during the technical sessions:</p> <ul style="list-style-type: none"> • Importance of Pharmacovigilance in Public Health: Introduction to Pharmacovigilance Roadmap of Vector Borne Diseases in India. • Introduction to PvPI Software & Hands on training on Data Entry to PvPI Software and Suspected ADR reporting form and its various components. • Participants gained the knowledge of the process of ADR reporting for Kala-Azar drug.

5.	Workshop on Pharmacovigilance and Establishment of Pharmacovigilance System in pharmaceuticals Industries	Workshop on Pharmacovigilance and Establishment of Pharmacovigilance System in pharmaceuticals Industries held at Hotel Regenta Central Decaan, Chennai on November 10, 2017.	<p>Mr. Rishi Kumar, Senior Pharmacovigilance Associate, PvPI, IPC delivered a talk on “Pharmacovigilance Guidance Document for Marketing Authorization Holders of Pharmaceutical Products”.</p> <p>Outcome:</p> <p>The queries related to “Pharmacovigilance Guidance document for Marketing Authorization Holders of Pharmaceutical Products” were effectively resolved in the talk.</p>
6.	Pharmacovigilance Partners Meeting at MoHFW, Nirman Bhawan at MoHFW	Pharmacovigilance partners meeting was organised at MoHFW, Nirman Bhawan on November 14, 2017.	<p>Dr. V. Kalaiselvan, Principal Scientific Officer and Officer In charge-PvPI, IPC and Mr. Pankaj Bhatt, Senior Pharmacovigilance Associate, PvPI, IPC attended the meeting.</p> <p>Outcome :</p> <ul style="list-style-type: none"> • Hiring of SIPSA/DIPSA: Immunization Division may nominate an AEFI surveillance subject expert to the interview panel. • Improving SOPs for signal review: Endorsement of decisions related to vaccine signals by the DC (UIP) and Chair, National AEFI Committee will be included in the SOP. • Strengthening SOP for convergence between partners- All organizations will study each other’s SOPs on convergence and

			<p>information sharing and improve upon them in a separate meeting.</p> <ul style="list-style-type: none"> • Status of poster for AEFI reporting through the ADR helpline centre: The PvPI will share the first draft of the poster in which changes were made as well as the draft for approval to the AEFI Secretariat which will be put on file for approval.
7.	Meeting with Jan Aushadhi at CDSCO	Dr. V. Kalaiselvan, PSO, IPC A meeting was held with the Chairman of Jan Aushadhi at CDSCO on November 14, 2017.	<p>Dr. V. Kalaiselvan, Principal Scientific Officer, Officer In charge- PvPI, IPC attended a meeting with Jan Aushadhi.</p> <p>Outcome:</p> <ul style="list-style-type: none"> • Planning to establish a Pharma skill council which aims to provide training and skills to the Pharmacy professionals engaged.
8.	Advance Level Training at AIIMS, Bhopal on November 17, 2017	ALT-2017 for AMC-Coordinators & PvA from Madhya Pradesh & Chattisgarh was organised by PvPI at AIIMS, Bhopal.	<p>As many as 45 participants, including AMC-Coordinators, PvAs from the AMCs of Madhya Pradesh & Chattisgarh along with the representatives of CDSO & Mr. Tarani Prakash Shrivastava, Pharmacovigilance Associate, NCC PvPI, IPC participated in the meeting.</p> <p>Participants were trained on:</p> <ul style="list-style-type: none"> • Signal Detection & Analysis

			<ul style="list-style-type: none"> • SWOT Analysis • Materiovigilance • ADR Reporting, Mobile app
9.	Coordinator Meeting Cum Advanced Training Program organised at PGIMER	Coordinator Meeting Cum Advanced Training Program for Patient Safety Pharmacovigilance Associates (Ps-PvAs) was organised at PGIMER, Chandigarh on November 17, 2017.	<p>Dr. Prasad Thota, Scientific Assistant, PvPI, IPC and Mr. Omkar Mishra, IT Associate, PvPI delivered a talk on NCC- mobile app and demonstrated the same.</p> <p>Outcome: The training provided an opportunity to promote and demonstrate about the newly developed PvPI Android Mobile applications to Ps-PvAs and Coordinators.</p>
10.	Symposium on Pharmacovigilance for Herbal Medicines at IPC	A symposium on Pharmacovigilance for herbal Medicines was organised on November 20, 2017 at IPC, Ghaziabad.	<ul style="list-style-type: none"> • The symposium was attended by as many as 30 participants from licensing authority, CDSCO regulatory authority, policy makers, industry, practitioners and academia. • Dr. Sunita Vohra, Professor, University of Alberta, California served as Guest of Honour who delivered a talk on Study of Natural Health Product (NHP) Adverse Reactions (SONAR). <p>Outcome: It was agreed that AYUSH colleges to be inducted as Adverse Drug Reaction Monitoring Centres</p>

			(AMCs) to report ADRs so that ADRs from herbal medicines and other Indian system of medicines can be reported and analysed.
11.	Visit to MSD, Gurugram	A visit of 6 officials of PvPI was organised by NCC-PvPI in order to understand and learn the Pharmacovigilance activities performed by Multi National Companies on 22 nd November, 2017.	<p>The outcomes of this visit were:</p> <ul style="list-style-type: none"> • Participants gained knowledge and learnt about Pharmacovigilance activities at MSD. • PvPI Officials interacted with MSD Team, which provided an opportunity to get an insight into MSD's whole Pv activities. • Provided an opportunity to understand Pv tools to enhance Pharmacovigilance activities with regulatory system, MAHs in coordination with PvPI. • Detailed discussion held on PSUR & RMP submissions as per requirements in MAHs Pv guidelines.
12.	International PV Core Curriculum Expert Meeting for Undergraduate Education	International PV Core Curriculum Expert meeting was held at Hertogenbosch, Netherlands from 22 nd November to 24 th November, 2017.	<p>Dr. V. Kalaiselvan, Principal Scientific Officer, IPC attended the Experts Meeting on Pharmacovigilance in Undergraduate education.</p> <p>Meeting Objective:</p> <ul style="list-style-type: none"> • To create formats for cooperation between universities and National Pharmacovigilance (PV) centres. • To share current practices and issues in Pv education for undergraduate students across the world. • To provide concepts and materials to

			<p>implement and educate PV.</p> <p>Outcome:</p> <ul style="list-style-type: none"> • Interaction between NPV centre and universities. • Pv e-learning modules for the students and other healthcare professionals to be developed by the PvPI. • Annual Meeting between National Pv Centres and Universities to exchange the Pv developments both at National and Regional level.
13.	Monthly Partners Coordination Meeting	Monthly Partners Coordination meeting was organised by AEFI Secretariat on November 27, 2017 at MoHFW, New Delhi.	<p>Mr. Pankaj Bhatt, Senior Pharmacovigilance Associate, PvPI, IPC attended the meeting.</p> <p>Outcome:</p> <ul style="list-style-type: none"> • Excel sheet of NRA recommendation shared with PvPI, AEFI and CDSCO and shall be update with the activities on monthly basis. • A SOP for generation of signals for AEFIs has been jointly discussed. • CDSCO will conduct one day training on PV inspection for the officials of AEFI Sect., CDSCO and PvPI.

B. MvPI Monthly Progress Report- November 2017

Sr. No.	Title of Activity	Description	Major Outcomes/Action Taken
1.	Data collation and processing of MDAEs received at NCC-MvPI	During the index period, NCC-MvPI received 30 MDAE reports from AMCs/MDMCs/Medical Device Industries	The reported cases are under review/ process for completeness. Lack of quality/incomplete reports will be reverted to the reporter for further necessary action.
2.	Sensitization to MDMCs on Global recall alerts	The information on global recall alerts was shared with all MDMCs through official emails	The Research Associates and coordinators at MDMCs checked non-availability of all the listed medical devices at their centres and provided feedback
3	MvPI presentation during the Skill Development Programme on “Basics and regulatory Aspects of Pharmacovigilance”	Dr. Pawan Saini, Scientific Officer, NCC-PvPI, IPC presented on MvPI during the Skill development Programme on November 13, 2017.	Nearly 60 participants from different field like academia, doctors, pharma industry etc. were sensitized about the Materiovigilance programme of India and made aware about the process of reporting adverse event due to the use of medical devices.
4.	Training of Drugs Inspectors, CDSCO at NCC- PvPI, IPC	05 newly recruited Drug Inspectors were trained about MvPI on November 16, 2017	Newly recruited Drugs Inspectors of CDSCO were sensitized on the followings: <ul style="list-style-type: none"> • Overview of MvPI Program • How to fill MDAE reporting Form • Process of reporting AEs to NCC-MvPI
5.	Materiovigilance Workshop at PGIMER, Chandigarh	A Materiovigilance workshop was organized by PGIMER, Chandigarh, a Medical Device Adverse Event monitoring Centre (MDMC) of MvPI on	More than 70 healthcare professionals were trained of the region. Dr Pawan Saini, SO, IPC & Mr. Mohammad Ameel, Sr. Consultant HCT division (NHSRC), Technical support unit of MvPI given

		November 14, 2017.	presentations to sensitized on the followings: <ul style="list-style-type: none">• Overview of MvPI Program• How to fill MDAE reporting Form• Process of reporting AEs to NCC-MvPI
--	--	--------------------	--