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

A. PvPI Monthly Progress Report: December 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 6015 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.	Basics of Pharmacovigilance and Implementation of Pharmacovigilance System at CRI Kasauli, HP	A workshop on the Basics of Pharmacovigilance and Implementation of Pharmacovigilance System was held on December 1, 2017 at CRI Kasauli, HP.	Senior Pharmacovigilance Associates, Mr. Adusumilli Pramod Kumar and Mr. Pankaj Bhatt, attended the workshop on behalf of PvPI. • CRI officials were trained on Pharmacovigilance activities of PvPI; specifically on AEFI related activities through a presentation and a hands-on training on Vigiflow and ADR reporting • Planning to develop a Quality Manual System (QMS) for Pharmacovigilance at CRI Kasauli with the help of PvPI • The CRI official team also showed interest to visit IPC, Ghaziabad to understand the complete system of Pharmacovigilance at NCC-PvPI, IPC

			Ghaziabad.
3.	Interview of State Immunization Patient Safety Associate (SIPSA)	The interviews for State Immunization Patient Safety Associate were held at R.S. Iyer Hall, IPC between December 11 & 12, 2017	• The Selection committee was chaired by Dr. Satinder Aneja, Prof. Sharda University, Dr. Deepak Polpakara, Programme Lead, AEFI Vaccine Safety, Ms. Swati Srivastava, Deputy Drug Controller, CDSCO and Dr. V. Kalaiselvan, PSO, Officer In-charge. • Out of 100 eligible candidates, 51 participated in the interview for SIPSA.
4.	Group 3 (Vigilance for Medical Products): WebEx with Working Group (WG) Members for SEARN	WebEx with Working Group members (WG) for SEARN on December 12, 2017 at Mini Conference Hall, NCC-PvPI, IPC.	• All the participants briefed about existing PV system in their country. • It was decided in the meeting that a set of questionnaire may be prepared and share with all the WHO member countries in SEARN. • This questionnaire may provide a way/or will act as an important tool to assess the current status and the need of PV in the respective country. • The same questionnaire has been prepared by IPC, NCC-PvPI and has been shared with WHO-Country Office India, for further assessment/comments. • After finalization of the questionnaire, it will be shared to all WHO member countries in SEARN, for their feedback. • A follow-up meeting (WebEx/telecon) has been scheduled in the first week of Jan 2018, to review the feedback/ progress on the same.

5.	Interactive meeting of PvPI, CDSCO and USFDA officials on Pharmacovigilance Workshop	An Interactive meeting of PvPI, CDSCO and USFDA Officials on Pharmacovigilance Workshop was held at Mini Conference, NCC PvPI, IPC on December 14, 2017.	• USFDA, CDSCO & PvPI agreed to conduct two workshops in the month of February 2018 • It was discussed to prepare two different agendas for both the workshops as the participants will be different in both the meetings. PvPI will share draft agenda with USFDA officials for review • Further discussions can be made by scheduling meetings
6.	Visit of Joint Secretary, Ministry of Commerce and Industry	Mr. Shyamal Misra, Joint Secretary, Ministry of Commerce and Industry visited IPC, PVPI on December 15, 2017.	• Joint Secretary assures to provide his full support for PvPI expansion • Inaugurated the ICSR processing (South zone and North Zone) Departments of PvPI
7.	2nd Periodic Progress Review Meeting	Dr V Kalaiselvan, Officer in-charge PvPI, IPC along with other officials of PvPI conducted the meeting on December 18, 2017 at R.S. Iyer Hall, IPC.	• Officials of PvPI presented department wise progress review • Dr V Kalaiselvan, provided valuable inputs to every division on new initiatives as per WHO-CC • The team prepared an action plan for 2018
8.	Visit to Pharmalex India Private Ltd, New Delhi	A visit of 3 PvPI official was organized by NCC-PvPI in order to understand and learn the Pharmacovigilance activities performed by Multi National Companies on December 19, 2017	• Visit provided an opportunity to understand PV tools to enhance Pharmacovigilance activities with regulatory system, MAHs in coordination with PvPI. • Detailed discussion on PSUR & RMP

			submissions as per requirements in PV guidelines for MAHs.
9.	10th Working Group and 5th Steering Committee Meeting	10th Working Group meeting and 5th Steering Committee Meeting on December 20, 2017 at R.S. Iyer Hall, IPC.	• Follow up action on letter dated 26.10.2016 issued by the Joint Secretary (Regulation), MoHFW, to the Principal Secretaries of the states/UT's governments for mandatory reporting of ADRs to PvPI. • Integration of Pharmacovigilance with Pharmacy colleges/institutions in India • Integration of Pharmacovigilance with Nursing colleges/institutions in India • PvPI training calendar for the year 2018 • Functioning of IPC, NCC-PvPI as WHO-Collaborating Centre • Effective implementation of Pharmacovigilance Guidelines for Marketing Authorization Holders
10.	69th Indian Pharmaceutical Congress 2017	The 69th Indian Pharmaceutical Congress 2017 was held at Chitkara University, Chandigarh from December 22 to 24, 2017	A complementary stall was provided by Indian Pharmaceutical Congress to showcase tools of ADR Reporting among the healthcare professionals and to aware participants on Pharmacovigilance activities of PvPI for ensuring Patient safety.
11.	Yearly Assessment of Pharmacovigilance Associates	The Yearly Assessment of Pharmacovgilance Associate was held on 26th December, 2017 at R.S. Iyer	The experts in the Assessment Committee were DR. V. Kalaiselvan, PSO Officer In charge NCC PvPI, MR. P.C.P Mahapatra, Former Administrative

		Hall, IPC.	Officer, NIB, Dr. Somnath Basu, Assistant Drug Controller, CDSCO, Dr. Kanchan Kohli, Prof. Pharmaceutics, Jamia Hamdard. They assessed the performance of 26 PvPI staff for the year 2016-17.

B. MvPI Monthly Progress Report- December 2017

Sr. No.	Title of Activity	Description	Major Outcomes/Action Taken
1.	Number of reports (MDAEs) received at NCC-MvPI	Collection and analysis of MDAE reports	As many as 33 reports were received at NCC-MvPI, the team at NCC-MvPI analysed the reports
2.	Awareness programme regarding the Medical Device Adverse events in the MDMCs	In MDMCs there was a awareness programme in which all the departments of the centre took part	The Research Associates and coordinators at MDMCs convened awareness programmes and participants were sensitized on benefits of ADR reporting and procedure of reporting MDAEs to MDMCs
3	22nd Asian Harmonization Working Party Annual Meeting on 4th Dec-2017 and 6th Dec-2017 at New Delhi	Dr Pawan K Saini, Scientific Officer and Mr Bharat Kumar, Pharmacovigilance Associate attended the meeting	• Provided an opportunity to understand the regulation of Medical Devices in different countries • Exchanged ideas to enhance PV activities of the MvPI • Discussion on Medical Device Rules-2017

4	MvPI presentation during Yearly Assessment of Pharmacovigilance Associate on Basics and regulatory Aspects of Materiovigilance	MvPI presentation was given during the Yearly Assessment by Dr. Pawan Saini, SO IPC on 27th December 2017	Participants were trained on reporting of MDAE cases by the MDAE reporting form and were sensitized to increase reporting of adverse events due to medical devices.