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

A. PvPI Monthly Progress Report–September 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 5,918 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	5th Skill Development Programme on Basics & Regulatory Aspects of Pharmacovigilance	The programme was organized between September 4 & 13, 2017 at NCC-PvPI IPC, Ghaziabad	The programme was inaugurated by Mr A K Pradhan, DDC (I), North-zone, Ghaziabad attended as chief guest, 35 participants from Maharashtra, Kerala, Telangana, Mizoram, Sikkim & Rajasthan attended the training programme
3	Assessment of Kala-azar Elimination Programme with states and partners	The meeting was organised by NHM and NVBDCP on September 5, 2017at Vivanta Taj-Ambassdor, Sujan Singh Park, Subramaniam Bharti Marg, New Delhi	Principal Scientific Officer & Officer I/c, PvPI, Dr V Kalaiselvan, presented progress, issues, challenges and ways forward in Pharmacovigilance Programme of India.
4	3rd Regional Workshop on Basics of Pharmacovigilance and Establishment of Pv System in	3rd workshop for Pharmaceutical Industries held on September 5, 2017 at IPC, Hyderabad Brach-CDSCO Zonal Office, Hyderabad	Technical sessions during workshop covered the followings: 1. An Introduction to IPC & its mandates 2. Pharmacovigilance: Basics, Methods & Practices 3. Pharmacovigilance: A legal obligation under

	Pharmaceutical Industries - A Way Forward		D & C Rules, 1945 4. Monitoring & Reporting AEs/ADRs: (Introduction to E2B XML Reporting of ADRs/AEs to PvPI, Other Forms & Formats) 5. Engagement of MAHs in PvPI: Current Scenario & Way Forward
5	Visit to Nirman Bhawan, New Delhi	Dr V Kalaiselvan, Principal Scientific Officer & Officer I/c, visited Nirman Bhawan, New Delhi, on September 7, 2017	• Submitted minutes of agenda for launch of PvPI Mobile app for ADR reporting on September 29, 2017 to the Secretary Office, New Delhi. • Submitted a file to the PS to Health Minister, New Delhi for the formal launch of IPC, PvPI WHO Collaborative Centre for PV in PHP & Regulatory Services.
6	2nd Regional Workshop on Basic of Pharmacovigilance and Establishment of Pv System in Pharmaceutical Industries - A Way Forward	3rd workshop for Pharmaceutical Industries held on September 9, 2017 at PGIMER, Chandigarh	Technical sessions during workshop covered the followings: 1. Pharmacovigilance: Basics, Methods & Practices 2. Pharmacovigilance: A legal obligation under D & C Rules, 1945 3. Monitoring & Reporting AEs/ADRs: (Introduction to E2B XML Reporting of ADRs/AEs to PvPI, Other Forms & Formats) 4. Current status of Pharmacovigilance Programme of India

7	Meeting at WHO-Country Office, New Delhi	Principal Scientific Officer & Officer I/c, Dr V Kalaiselvan, visited WHO-Country Office, New Delhi on September 15, 2017.	Dr V Kalaiselvan, Dr Madhur Gupta had a tele-conference with Dr Shanthi Pal, Medicines Safety Programme Manager, Essential Medicines & Health Products, WHO HQ, Switzerland and proposed: • Date for inauguration of IPC, PvPI as WHO-Collaborating Centre on October 30, 2017 • Drafting Agenda & list of delegates to be invited for the inaugural session • Proposing India International Centre/India Habitat Centre, New Delhi as the venue for the launch
8	Follow-up meeting with USFDA delegates at the US Embassy	Following the visit to NCC-PvPI, IPC, Ghaziabad by the FDA delegation from the US on August 21 2017, Dr R Chandrashekar Rao, DDC (I), CDSCO, FDA Bhawan, New Delhi & Dr V Kalaiselvan, Principal Scientific Officer & Officer I/c, PvPI, Ghaziabad visited the US Embassy, New Delhi, on September 20, 2017. The topics discussed/presented by USFDA officials during the meeting included: • General Overview of USFDA's Regulatory Authority on Pharmacovigilance • USFDA's Pharmacovigilance efforts,	• Understood the pattern of Pharmacovigilance followed in the United States • Importance of Mandatory Pharmacovigilance system was found to be the core strength for higher patient safety standards in India • Strict compliance of Post-Approval Drug Evaluation was recommended

		including reporting systems and Regulatory Actions • Collaboration between USFDA and WHO • Collaboration for effective implementation of Pharmacovigilance	
9	National AEFI Committee Meeting	National AEFI Committee Meeting was held on September 25, 2017 at Hotel Park, New Delhi. Dr V Kalaiselvan, Principal Scientific Officer & Officer I/c, PvPI represented PvPI in the meeting	• AEFI surveillance update • Update on Causality Assessment of reported AEFI cases • AEFI national sub-committees' revamping, membership, constitution of terms of reference and work plans
10	25th annual 'Health Mela' by Healthcare Foundation of India	President, Health Care Foundation of India, Dr K K Aggarwal, organised 25th annual 'Health Mela' (fair) at NDMC Convention Centre, New Delhi on 27th September.	Dr V Kalaiselvan, Principal Scientific Officer & Officer I/c, PvPI, Ghaziabad, sensitized consumers and healthcare professions on ADR reporting, its channels of reporting and Pharmacovigilance Programme of India and its role in monitoring ADRs.
11	Launch of Mobile Application & Release of Pv Guidance Document	PvPI Mobile applications and Release of Pv Guidance Document for marketing authorization holders were launched at Nirman Bhawan, New Delhi on 29th September	Shri. C.K. Mishra, Secretary, Health, Ministry of Health & Family Welfare was launched PvPI-Mobile Application for reporting of ADRs and released Pv Guidance Document for marketing authorization holders.

B. MvPI Monthly Progress Report–September 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 329 reports were received at NCC-MvPI,the team at NCC-MvPI analysed the reports received at NCC-MvPI
2.	Sensitization to MDMCs for globally recall alerts	The information on recall alerts was shared with all MDMCs	The Research Associates and coordinators at MDMCs checked non-availability of all the listed medical devices at their centres and provided feedback
3.	Sharing of MvPI reports (Hip Implant reports) with CDSCO, New Delhi	Adverse events reported from J& J Pharmaceuticals were analysed for quality and completeness	As per requirement of CDSCO, NCC-MvPI shared all the cases of hip Implants (till June 2017) with CDSCO
4	MvPI Awareness Program at Hotel Pride Plaza, New-Delhi on 22nd September 2017	MvPI presentation was given in the CITD(Capacity Building Initiative for Trade Development) training program organised by European Commission and NABL(National Accreditation Board for Testing and Calibration Laboratory) on Accreditation of Testing Laboratory For Calibration /Traceability of Medical Device organised at Hotel Pride Plaza, New -Delhi	MvPI Technical support unit i.e. NHSRC, New-Delhi given an overview on Materiovigilance Programme of India

5.	Drug Inspectors Training Programme (Batch 2)	Training to Drug Inspectors on MvPI awareness during training programme on dated 26-09-2017	Newly recruited Drug Inspectors of the CDSCO were sensitized on the followings: • Overview of MvPI Program • How to fill MDAE reporting Form • Process of reporting AEs to NCC-MvPI