

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

**A. PvPI Monthly Progress Report–September 2017**

<b>Sr. No.</b>	<b>Title of Activity</b>	<b>Description</b>	<b>Major Outcome/Action Taken</b>
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	5 <sup>th</sup> 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, 2017 at 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	3 <sup>rd</sup> Regional Workshop on Basics of Pharmacovigilance and Establishment of Pv System in	3 <sup>rd</sup> 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		<p>D &amp; C Rules, 1945</p> <p>4. Monitoring &amp; Reporting AEs/ADRs: (Introduction to E2B XML Reporting of ADRs/AEs to PvPI, Other Forms &amp; Formats)</p> <p>5. Engagement of MAHs in PvPI: Current Scenario &amp; Way Forward</p>
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	<ul style="list-style-type: none"> <li>Submitted minutes of agenda for launch of PvPI Mobile app for ADR reporting on September 29, 2017 to the Secretary Office, New Delhi.</li> <li>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 &amp; Regulatory Services.</li> </ul>
6	2 <sup>nd</sup> Regional Workshop on Basic of Pharmacovigilance and Establishment of Pv System in Pharmaceutical Industries - A Way Forward	3 <sup>rd</sup> workshop for Pharmaceutical Industries held on September 9, 2017 at PGIMER, Chandigarh	<p>Technical sessions during workshop covered the followings:</p> <ol style="list-style-type: none"> <li>1. Pharmacovigilance: Basics, Methods &amp; Practices</li> <li>2. Pharmacovigilance: A legal obligation under D &amp; C Rules, 1945</li> <li>3. Monitoring &amp; Reporting AEs/ADRs: (Introduction to E2B XML Reporting of ADRs/AEs to PvPI, Other Forms &amp; Formats)</li> <li>4. Current status of Pharmacovigilance Programme of India</li> </ol>

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.	<p>Dr V Kalaiselvan, Dr Madhur Gupta had a tele-conference with Dr Shanthi Pal, Medicines Safety Programme Manager, Essential Medicines &amp; Health Products, WHO HQ, Switzerland and proposed:</p> <ul style="list-style-type: none"> <li>• Date for inauguration of IPC, PvPI as WHO-Collaborating Centre on October 30, 2017</li> <li>• Drafting Agenda &amp; list of delegates to be invited for the inaugural session</li> <li>• Proposing India International Centre/India Habitat Centre, New Delhi as the venue for the launch</li> </ul>
8	Follow-up meeting with USFDA delegates at the US Embassy	<p>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 &amp; Dr V Kalaiselvan, Principal Scientific Officer &amp; Officer I/c, PvPI, Ghaziabad visited the US Embassy, New Delhi, on September 20, 2017.</p> <p>The topics discussed/presented by USFDA officials during the meeting included:</p> <ul style="list-style-type: none"> <li>• General Overview of USFDA's Regulatory Authority on Pharmacovigilance</li> <li>• USFDA's Pharmacovigilance efforts,</li> </ul>	<ul style="list-style-type: none"> <li>• Understood the pattern of Pharmacovigilance followed in the United States</li> <li>• Importance of Mandatory Pharmacovigilance system was found to be the core strength for higher patient safety standards in India</li> <li>• Strict compliance of Post-Approval Drug Evaluation was recommended</li> </ul>

		<p>including reporting systems and Regulatory Actions</p> <ul style="list-style-type: none"> <li>• Collaboration between USFDA and WHO</li> <li>• Collaboration for effective implementation of Pharmacovigilance</li> </ul>	
9	National AEFI Committee Meeting	<p>National AEFI Committee Meeting was held on September 25, 2017 at Hotel Park, New Delhi.</p> <p>Dr V Kalaiselvan, Principal Scientific Officer &amp; Officer I/c, PvPI represented PvPI in the meeting</p>	<ul style="list-style-type: none"> <li>• AEFI surveillance update</li> <li>• Update on Causality Assessment of reported AEFI cases</li> <li>• AEFI national sub-committees' revamping, membership, constitution of terms of reference and work plans</li> </ul>
10	25 <sup>th</sup> annual 'Health Mela' by Healthcare Foundation of India	<p>President, Health Care Foundation of India, Dr K K Aggarwal, organised 25<sup>th</sup> annual 'Health Mela' (fair) at NDMC Convention Centre, New Delhi on 27<sup>th</sup> September.</p>	<p>Dr V Kalaiselvan, Principal Scientific Officer &amp; 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.</p>
11	Launch of Mobile Application & Release of Pv Guidance Document	<p>PvPI Mobile applications and Release of Pv Guidance Document for marketing authorization holders were launched at Nirman Bhawan, New Delhi on 29<sup>th</sup> September</p>	<p>Shri. C.K. Mishra, Secretary, Health, Ministry of Health &amp; Family Welfare was launched PvPI-Mobile Application for reporting of ADRs and released Pv Guidance Document for marketing authorization holders.</p>

### **B. MvPI Monthly Progress Report–September 2017**

<b>Sr. No.</b>	<b>Title of Activity</b>	<b>Description</b>	<b>Major Outcomes/Action Taken</b>
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 22 <sup>nd</sup> 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	<p>Newly recruited Drug Inspectors of the CDSCO were sensitized on the followings:</p> <ul style="list-style-type: none"> <li>• Overview of MvPI Program</li> <li>• How to fill MDAE reporting Form</li> <li>• Process of reporting AEs to NCC-MvPI</li> </ul>
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