

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

A) PvPI Monthly Progress Report -- August 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 6,418 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	Meeting with CIMS, Asia	As Directed by Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Dr G N Singh, Principal Scientific Officer NCC-PvPI Dr V Kalaiselvan and Scientific Assistant Dr Prasad Thota attended the 6 th edition of Indian Pharma Expo organised by CIMS, Asia, at Pragati Maidan in New Delhi on August 4, 2017 and met Managing Director, CIMS, Asia, Dr Monica Bhatia for devising means to strengthen through CIMS the	<ul style="list-style-type: none"> • NCC-PvPI, IPC & CIMS, Asia in principle join hands for promotion of patient safety in India. • CIMS, Asia agreed to publish PvPI's Pharmacovigilance-related information and ADR reports and their significance in its quarterly publication. • Dr Kalaiselvan suggested that NCC-PvPI data be utilised in updating quarterly the ADR information for all drugs available at CIMS on commercial basis. • CIMS, Asia suggested that PvPI ensure the

		pharmacovigilance activities by private practitioners in India.	<p>unique code/harmonization of the drug information/data available at National Formulary of India & CIMS</p> <ul style="list-style-type: none"> • Mr Biplab Chatterjee requested PvPI to share Suspected ADR reporting form for ensuring its availability at 2,000 Jan Aushadi Kendras across India.
3	Meeting with officials of CDSCO at FDA Bhawan in New Delhi.	<p>Dr Kalaiselvan, Principal Scientific Officer & Officer (I/C) PvPI, met CDSCO officials at FDA Bhawan in New Delhi on August 17, 2017.</p> <p>Coordinated with Ms Rubina Bose, Deputy Drugs Controller, CDSCO.</p> <p>Discussion with Mr ACS Rao, Deputy Drugs Controller, CDSCO.</p> <p>Briefed DCGI on updating developments at PvPI.</p>	<ul style="list-style-type: none"> • Reviewed Pharmacovigilance Guidelines for MAHs. • Finalized agenda for the upcoming Pharmacovigilance workshop at Chandigarh. • Proposed formal inclusion of Pharmacovigilance system for marketing authorization holders (MAHs) as an agenda for upcoming Drug Consultative meeting.
4	FDA delegation from the US visits NCC-PvPI, IPC	The USFDA delegation included its Country Director Dr Letitia Robinson, Assistant Country Director Dr Soloman Yimam, International Program Drug	<ul style="list-style-type: none"> • Dr V Kalaiselvan gave a brief presentation to the delegates on overall functioning of PvPI and its achievements during the last six years.

		Analyst Mr Kristan Callahan and International Relations Drugs Specialist Ms Ademola Daramola. The delegation visited NCC-PvPI, IPC, Ghaziabad on August 21, 2017	<ul style="list-style-type: none"> • Dr S P Shani briefed the delegates about the functioning of Indian Drugs Regulatory Authority and fielded their queries related to drugs regulation in India. • Dr Robinson, Dr Soloman and other delegates were impressed by the work culture at NCC-PvPI and unanimously appreciated PvPI for its remarkable expansion across the country. They felicitated NCC-PvPI for earning the distinction of becoming a WHO-Collaborating Centre in southeast Asia. • Dr Robinson proposed a meeting for demonstration of Pharmacovigilance activities in the US and detailed discussion on scope of collaboration between PvPI and USFDA at US Embassy in New Delhi on September 20, (Wednesday) 2017 from 11 AM to 1.30 PM.
5	National Technical Advisory Group on Immunization (NTAGI) Standing Technical Sub-Committee meeting	National Institute of Health & Family Welfare, New Delhi, organised an NTAGI Standing Technical Sub-Committee meeting at Nirman Bhawan in New Delhi on August 23, 2017. Dr Pradeep Halder, Deputy Commissioner chaired the meeting and	Dr V Kalaiselvan, Principal Scientific Officer & Officer (I/C)-PvPI, who also attended the meeting, presented the current status & achievements of PvPI.

		Dr Sowmya Swaminathan, Secretary, DHR, ICME & Dr K Vijay Raghavan, Secretary, DBT, co-chaired the meet.	
6	Induction-cum-Training Programme	NCC-PvPI organised an Induction-cum-Training Programme for Coordinators and Patient Safety Pharmacovigilance Associates of 45 newly-enrolled AMCs in two batches from 21 st to 25 th August & 28 th August to 1 st September 2017.	<p>Presentation and elaboration of PvPI's overview & updates, basic concepts of Pv, understanding of ADRs & related terminologies in Pv, QMS in PvPI, role of AMCs and their Coordinators in developing an effective Pv system & GVP, Introduction to ADR-Reporting form: What, Where, How & Whom to report.</p> <p>An elaborate exercise on 'VigiFlow -- An introduction & data entry' and hands-on training, Documentation grading-Report Completeness, Integration of PvPI-AEFI in vaccine safety monitoring, 'Causality assessment: The logic & Methods', including workshop, Signal detection-PvPI: Logic & Methods, Role of CDSCO in PvPI including field visit to All India Institute of Medical Sciences (AIIMS) & University College of Medical Sciences, New Delhi.</p>
7	Video shoot by Doordarshan News	Mr Nitendra Singh, Senior Correspondent, Doordarshan News, visited IPC on August 28, 2017 to take a news byte of NCC-PvPI	Mr Nitendra Singh with his team made a video-shoot of current scientific activities of PvPI & IPC for telecast on Doordarshan News.

B) MvPI Monthly Progress Report- August 2017

Sr. No.	Title of Activity	Description	Major Outcomes/Action Taken
1.	MvPI Awareness Programme at Narayana Hrudayalaya, Bangalore	MvPI awareness programme was conducted at Narayana Hospital, Bengaluru on August 2, 2017	MvPI Staff made a presentation to healthcare professionals on the following topics: <ul style="list-style-type: none"> • Basic overview of MvPI Programme • How to fill MDAE Reporting Form
2.	Constitution of Core Technical Committee (CTC)	CTC for advising MvPI on training, signal monitoring and other technical issues, reviewing overall progress of programme.	The process of CTC constitution completed and order issued on August 8, 2017
3.	Induction-cum-training programme for coordinators and Pv Associates (Batch 1)	Training to PvPI Coordinators & Pv Associates on MvPI awareness during Induction-cum-training programme on 25-08-2017	Newly-recruited PvAs and coordinators of the newly-identified AMCs were sensitized on: <ul style="list-style-type: none"> • Basic overview of MvPI Programme • How to fill MDAE reporting Form
4.	Induction-cum-training programme for coordinators and Pv Associates (Batch 2)	Training to PvPI Coordinators & Pv Associates on MvPI awareness during Induction-cum-training programme on 29-08-2017	Newly-recruited PvAs and coordinators of the newly-identified AMCs were sensitized on: <ul style="list-style-type: none"> • Basic overview of MvPI Programme • How to fill MDAE reporting Form
5.	MvPI presentation during workshop on 'Regulatory	An MvPI presentation was made during the workshop organised at National	MvPI Technical support unit i.e. NHSRC, New-Delhi presents an overview on Materiovigilance Programme

	Requirements for Assessment of In-vitro Diagnostic Medical Devices and Planning' by WHO and CDSCO'	Institute of Biologicals, Noida, on August 10, 2017	of India & its overall progress
6.	Sensitization of MAHs to use of MDAE reporting form	All MAHs who report ADRs to PvPI have been intimated to use MDAE form for reporting of Adverse Events due to Medical Devices vide email on 18.08.2017	MAHs have started using MDAE form for reporting of adverse events due to the use of medical device
7.	Sensitization of MDMCs on Medical device recall alerts issued by US FDA, CDSCO, TGA, EU, etc	NCC-MvPI regularly shares medical device recall alerts issued by US FDA, CDSCO, TGA, EU with Research Associates on regular basis with MDMCs	Research Associates posted at MDMCs ensure that such recall alerts are adhered to