

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

PvPI Monthly Progress Report -June 2017

Sr. No.	Title of Activity	Description	Major Outcome/Action Taken
1	Data collation and processing of ICSRs	During the index period, NCC received 5,892 ICSRs from AMCs/ Pharmaceutical industries/consumers. The reported cases are under assessment for completeness, listed/unlisted and clinical relevance.	The reported ICSRs are being assessed for completeness and quality for medical/clinical review. Lack of quality/incomplete reports will be reverted to the reporter for further necessary action.
2	Meeting with Dr Roop Narayan Gupta	Dr Roop Narayan Gupta, Professor, Department of Pharmaceutical Sciences & Technology, Birla Institute of Technology, Mesra, Ranchi, visited IPC on 01/06/2017	<ol style="list-style-type: none"> 1. PvPI needs to promote patient safety by placing ads in national and regional newspapers. It was recommended that IPC place an advertisement in newspapers, inviting Pharmacies/Drug Stores to become the focal centre under PvPI for collecting ADR reports which ensure <ul style="list-style-type: none"> • Availability of a registered pharmacist at Pharmacy/Drug Store • Chain Pharmacies to be kept in loop 2. It has been noted that Pharmacy Council of India issued a notice to all Pharmacy colleges to open one generic drug store & it was suggested to accept those drug stores as AMCs.

			<p>3. Pharmacy colleges in a town/area will be nominated for contacting Clinical Pharmacies for ADR reporting.</p> <p>4. Awareness posters on Pharmacovigilance & ADR reporting to Clinical Pharmacists shall be prepared jointly by Dr Roop Narayan Gupta & NCC-PvPI.</p>
3	Industry consultation meeting	<p>During 35th Scientific Body Meeting of IPC it was recommended that PvPI schedules a consultation meeting with MAH associations. In this context, a consultation meeting with Indian Drugs Manufacturing Association (IDMA), Organization of Pharmaceutical Producers of India (OPPI) and Indian Pharmaceutical Association (IPA) was held at Central Drugs Standard Control Organization (CDSCO) Headquarters in New Delhi on June 5, 2017</p>	<p>1) MAH associations appreciated the idea of, and committed their support to, making PvPI a self-sustainable programme. They assured of having a detailed discussion with their members for effective implementation of Pv practices.</p> <p>2) PvPI will prepare a brief note/justification for levying charges on, and providing services to, MAH vis-a-vis Pharmacovigilance activities carried out by PvPI.</p> <p>3) MAH associations will review the draft of “Pharmacovigilance Guidelines of Pharmaceutical Products for MAHs in India” and provide comments/suggestions within 15 working days.</p>
4	16 th Governing Body meeting of IPC	<p>16th Governing Body meeting of IPC was held at Nirman Bhawan in New Delhi on June 13, 2017</p>	<p>Dr G N Singh, Member Secretary, Governing Body, gave a presentation on achievements of PvPI:</p> <p>1. Members agreed for integration of all vigilance activities under one umbrella i.e. PvPI.</p>

			<ol style="list-style-type: none"> 2. Members in principle approved of the proposal to design and develop an indigenous software for PvPI & commercialization of Pv data for revenue generation. 3. Members agreed in principle to the proposal for an annual Pharmacovigilance fee/levy charges on MAHs & decided that a separate proposal be moved in this context
5	Workshop-cum-Training programme on Pharmacovigilance for NABH-accredited hospitals of Tamil Nadu	NCC-PvPI, IPC, in collaboration with Vadamalyan Hospitals, Madurai, organised a Workshop-cum-Training programme on Pharmacovigilance for NABH-accredited hospitals of Tamil Nadu, at Vadamalyan Hospitals, Madurai, on June 13, 2017.	<p>As many as 30 members from NABH-accredited hospitals of Tamil Nadu attended the workshop-cum-training programme.</p> <ol style="list-style-type: none"> 1. Dr Guhapriya Mohanraj, NABH Accreditation Coordinator, Vadamalayan Hospital, chaired the session. 2. Dr V Kalaiselvan, Officer I/c-PvPI & Principal Scientific Officer, gave an overview of PvPI's current activities. 3. Mr Thirumalai Nambi, Sr Pv Associate, outlined the methodologies & filling up of ADR reporting Forms along with hands-on training in filling up of ADR reporting forms. 4. Dr M Malathi delivered a presentation on setting up of a Pharmacovigilance system in hospitals.
6	Second Intensive Drug Monitoring Meeting	NCC-PvPI, IPC, in coordination with Coimbatore Medical College organised the second Intensive Drug-Monitoring Meeting, at Coimbatore Medical College,	<ol style="list-style-type: none"> 1. Dr N Shanthi, PvPI Coordinator, explained threadbare the activities performed by the CMCH AMC. 2. Dr V Kalaiselvan, Principal Scientific Officer,

		Coimbatore, on June 15, 2017.	<p>PvPI, IPC, stressed upon the need for intensive drug monitoring and the purpose for conducting these studies at AMCs under PvPI.</p> <p>3. As many as 11 hospitals & pharmacy institutes in Tamil Nadu were identified for conducting these studies.</p>
7	Regional Workshop on “Basics of Pharmacovigilance & Establishment of Pharmacovigilance System in Pharmaceutical Industries - A Way Forward”	IPC organised a Regional Workshop on “Basics of Pharmacovigilance & Establishment of Pharmacovigilance System in Pharmaceutical Industries -- A Way Forward”, at AIIMS, Rishikesh, on 23/06/2017.	<p>Following sessions were covered during the technical session:</p> <ol style="list-style-type: none"> 1. Pharmacovigilance: Basics, Methods & Practices 2. Pharmacovigilance: A legal obligation under D & C Rule, 1945 3. Monitoring & Reporting AEs/ADRs: (Introduction to E2B XML Reporting of ADRs/AEs to PvPI, Other Forms & Formats) 4. Webinar on setting up of Pv System at Pharmaceutical companies <p>Outcome:</p> <ul style="list-style-type: none"> • Prof Ravi Kant urged PvPI to adopt BIS model for certifying the quality of generic medicines. • Creating awareness among participants to report ADRs to PvPI through various channels of reporting like helpline, email ids, suspected ADR form, mobile application, etc. • Participants agreed to develop a system for submission of ADRs to NCC-PvPI in XML format. • Participants suggested to conduct such workshops in future for sensitizing

			pharmaceutical industries on reporting ADRs and to resolve their Pv-related issues.
8	Advance-level training on Pharmacovigilance	KEM Medical College & Hospital, a Regional Training Centre under PvPI, organised its Advance-level training on Pharmacovigilance at KEM Hospital, Mumbai, on 24/06/2017.	Dr V Kalaiselvan, Principal Scientific Officer, PvPI, IPC, gave a talk on “Status of PvPI at International level”.
9	Filling of Pharmacovigilance Associates posts (Contract basis) for various AMCs & NCC under PvPI	IPC advertised for filling the posts of Pharmacovigilance Associates (Contract basis) for various AMCs & NCC under PvPI. The interview for the same was held at IPC, Ghaziabad, from 27/06/2017 to 29/06/2017.	Dr V Kalaiselvan, Principal Scientific Officer, PvPI, IPC, as a Member conducted the interview.