

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

PvPI Monthly Progress Report- September 2016

Sr. No.	Title of Activity	Description	Major Outcomes/Action Taken
1	Data collation and processing of ICSRs	During the index period, NCC received 4764 ICSRs from AMCs/ Pharmaceutical industries/ consumers. The reported cases are under assessment for completeness, listed/ unlisted and clinical relevance.	The reported ICSRs yet to be assessed for the completeness & quality for further process (listed and unlisted) & under medical/clinical review. Lack of quality/incomplete reports will be reverted back to the reporter.
2	IPC-WHO-RNTCP National Collaborative Workshop on Causality Assessment for Bedaquiline Pharmacovigilance in India	IPC in collaboration with WHO Country Office and RNTCP organised an IPC-WHO-RNTCP National Collaborative Workshop on “Causality Assessment for Bedaquiline Pharmacovigilance in India” from 06 th -09 th September 2016, at Hotel Lalit, New Delhi.	The workshop was attended by key functionaries for Bedaquiline from six identified Drug Resistant TB Centres including Local Causality Assessment Committee members, State TB officers, Medical Officers and Statistical Assistants of RNTCP; and Pharmacovigilance Associates from PvPI. The key principles of cohort event monitoring for Bedaquiline, causality assessment for monitoring ADR reporting were discussed along with deliberations on data flow from peripheries using

			the suspected ADR monitoring form of PvPI, for likely adverse events from facilities to the DR TB centres.
3	WHO Assessment of the National Vaccine Regulatory Authority and Relevant Institutions in India	Secretary-HFW convened a meeting with relevant institutions for WHO Assessment of the National Vaccine Regulatory Authority on 07/09/2016 at Nirman Bhawan, New Delhi.	The major direction given by Secretary as follows: Effective communication channels for coordinated approach between the PvPI, AEFI and CDSCO may be established with a view to showcase the robustness of the surveillance and vigilance activities.
4	External Audit of PvPI	As constituted & directed by Secretary-cum-Scientific Director. The following Officials from various organisations audited & reviewed the NCC-PvPI activities at IPC, Ghaziabad on 16/09/2016. 1. Dr B. K. Rana-Director NABH, New Delhi 2. Ms. Sudha V. Gopinath, Scientist Grade-III, NIB, Noida 3. Mohammed Ameel, Consultant, HCT Division, NHSRC, New Delhi - (Member) 4. Mr. Ajay Basil, Consultant, HCT Division, NHSRC, New Delhi.	The major observations of this audit as follows: ➤ NCC-PvPI has introduced a QMS in 2014, however, It has introduced a formal QMS w.e.f. 1 st September, 2016. ➤ NCC-PvPI has developed a QMS based on ISO/IEC 17025, ICH-E2B guidelines and Good Pharmacovigilance Practices (GPvP). Management is committed to realise its objectives. Staff is qualified, trained and competent. ➤ Audit Team reviewed its documents, records and interacted with staff to check compliance to documented policies and procedures. ➤ Checklist being used for audit is just

			<p>introduced. It needs modification at various places for its contents as already explained to concerned personnel.</p> <ul style="list-style-type: none"> ➤ Quality manual is in draft stage and yet to be approved by the Competent Authority ➤ Quality Manual needs amendments at certain places as explained to QA Team. ➤ QMS needs to be percolated down the line to all staff. ➤ Induction programme to include information on QMS including Quality Policy and Core Principles. ➤ Personal files of all staff to be streamline and all information to be filed at one place. ➤ Personal files to be kept secured. ➤ IT System to strengthen to avoid any unauthorised access. ➤ There is a need for effective communication between <u>NCC-PvPI</u>, CDSCO and <u>UIP-ITSU</u> under Ministry of Health & Family Welfare through a document describing roles and responsibility of each organization and approved. ➤ Many information and data is stored in personal computers. It is suggested to have
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			<p>a central server for data storage and dissemination of information.</p> <ul style="list-style-type: none"> ➤ Currently ADR reports from stakeholders is done through helpline, mobile applications and paper based. Helpline is in English and Hindi only. It is advisable to have an IVRS with multiple languages for better reporting. ➤ Document control needs strengthening. ➤ Standard Operating Procedure (SOPs) may be reviewed for their completeness to align with work practices. ➤ Organogram to be elaborated and date of issue to be incorporated. ➤ ADR reporting centres are using single ID for multiple programmes reporting leading to reporting of only one program and zero reporting for rest of the programs. ➤ Lack of coordination between focal person of various national health programmes, Pharmacovigilance Associates and NCC-PvPI. ➤ Staff are using personal e.mail ID for official communication which may be discouraged. Each division may have official e.mail IDs for effective and secure communication.
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5	3 rd Quality Review Panel Meeting of PvPI	IPC, NCC-PvPI organised its 3 rd QRP meeting at IPC, Ghaziabad on 19/09/2016.	<p>The outcome of this meeting as follows:</p> <ol style="list-style-type: none"> 1. SOPs of PvPI were reviewed by the panel and the house approved all SOPs. 2. Quality Manual of PvPI was reviewed & approved by the members. 3. The panel reviewed the findings of the internal and external audit and suggested to take preventive and corrective actions as early as possible. 4. PvPI stakeholders feedback form was critically reviewed by the panel members. 5. The members appreciated the Quality Management System (QMS) developed by NCC-PvPI and recommended to implement the same to all AMCs under PvPI.
6	Discussion with Millennium Telecom	A preliminary meeting with the Chief Operating Officer and other officials of	As per letter no MTL/COO/Min_Health_FW/2016-17 of dated 08.08.2016 sent to Secretary Health,

	Ltd. (MTL) to develop IT tool/mobile app for PvPI	Millennium Telecom Ltd. (a subsidiary of Mahanagar Telephone Nigam Limited) was held on 22 nd September 2016 at IPC, Ghaziabad	MOHFW, Nirman Bhawan, New Delhi. The same was received at IPC through CDSCO, HQ vide email dated 22.08.2016. In this regard, a preliminary meeting was held to develop IT tool/ Mobile App for PvPI
7	Discussion with IT firm for development of software for PvPI	A meeting with the Officials of one IT firm was held on 21 st September 2016 at FDA Bhawan, New Delhi	Various leading IT firms were contacted/ invited to give a brief demo on development of indianised software for PvPI. One IT firm expressed/presented their views to develop software for PvPI. The meeting was summarised with DCG (I) and he suggested having further meeting with Additional Secretary along with the NIC and C-DAC Officials to know their views and comments to take further steps.
8	WHO Assessment of the National Vaccine Regulatory Authority and Relevant Institutions in India.	Joint Secretary (Regulation)-HFW convened a meeting with relevant institutions for WHO Assessment of the National Vaccine Regulatory Authority on 23/09/2016 at Nirman Bhawan, New Delhi.	Officer In-charge PvPI briefed about the progress made with respect the NRA assessment on the following: AEFI Individual Case Safety Reports (ICSRs) Exchange of Information Data analysis and signal detection on vaccine Documented Scientific Evidence Quality Management System (QMS) NRA Assessment tool PvPI and state AEFI coordination

9	Visit of Secretary Department of Pharmaceuticals to IPC	The Secretary, Department of Pharmaceuticals Shri Jai Priya Prakash visited IPC on 23.09.2016	He visited NCC-PvPI and appreciated the steps taken by the PvPI to develop a robust system of pharmacovigilance in India.
10	Meeting of Indian Society of Clinical Research	A meeting of Indian Society for Clinical Research was held on 24.09.2016 at New Delhi	DCG (I) inaugurated the meeting, In this meeting, the achievements of PvPI and about the role of professional bodies in the programme was also discussed.
11	WHO- Country Office and PvPI meeting on collaboration	A meeting was held between WHO- Country Office and PvPI on 28.09.2016 at Nirman Bhawan, New Delhi	WHO- Country Office and PvPI started dialogue to deliberate Terms of Reference (TOR) for declaring the IPC, a WHO collaborating center.