

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

PvPI Monthly Progress Report- August 2016

S. No.	Title of Activity	Description	Major Outcomes/Action Taken
1	Data collation and processing of ICSRs	During the index period, NCC received 5167 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	Memorandum of understanding between IPC & National Vector Borne Disease Control Programme (NVBDCP)	IPC, NCC-PvPI had MOU with NVBDCP, Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India on 03/08/2016 at Nirman Bhawan, New Delhi.	The main objectives of setting up of Pharmacovigilance systems in NVBDCP are 1. Earliest possible recognition of new adverse reactions, including interactions. 2. Measure risk (incidence), including comparative risk of different dose regimens or individual medicines. 3. Identify risk factors for important reactions so that appropriate risk management can be applied and the risk of harm minimized. 4. Assess safety in pregnancy and lactation. 5. Provide evidence for:

			<ul style="list-style-type: none"> <input type="checkbox"/> Effective risk prevention and management; <input type="checkbox"/> Safer use of drugs used in treatment of Vector Borne Diseases; <input type="checkbox"/> Benefit or harm assessment of different regimens or products; <input type="checkbox"/> Evidence-based regulatory action.
3	Monthly Pharmacovigilance meeting AEFI partners	Monthly AEFI pharmacovigilance partners Meeting was held on 05/08/2016 at Nirman Bhawan, New Delhi.	<p>The important outcomes of this meeting are as follows.</p> <ol style="list-style-type: none"> 1. Work frame for NRA assessment-2016-17 to be prepared & shared with all AEFI Pharmacovigilance partners by WHO-Country Office (India) 2. ITSU-AEFI will share the patient information form to PvPI for further review & follow up for identified AEFI-cases at AMCs. 3. NRA Assessment 2016-17 indicators needs to be reviewed & submitted to WHO-Country Office (India) on or before September 2016.
4	Meeting with NVBDCP & WHO-Country Office Officials	PvPI officials attended the Meeting with NVBDCP & WHO-Country Office Officials on 10/08/2016 at Nirman Bhawan New Delhi to finalise the format, design, capture Adverse Events for all the possible drugs used in vector borne disease control programme.	<p>The outcomes of this meeting are as follows.</p> <ol style="list-style-type: none"> 1. House reviewed AE reporting form of medicines for kala-azar treatment & also suggested to get the feedback from the Health care professionals in the endemic areas of kala-azar (Bihar) 2. Discussed on the mechanism of AE data flow from NVBDCP to VigiFlow & recommended to design the SOP, follow up form to collect adverse events.
5	Induction-cum-Training programme to the newly recruited Pharmacovigilance Associates (45) under PvPI	IPC, NCC-PvPI organised Induction-cum-Training programme for the newly recruited Pharmacovigilance Associates (45) from 22/08/2016 to 27/08/2016 at IPC, Ghaziabad.	<p>NCC-PvPI team covered the following</p> <ol style="list-style-type: none"> 1. Basic concept & essentials of Pharmacovigilance & ADR Reporting 2. Reporting of ADRs (What, How & Where to Report) 3. Coding of drugs & ADRs 4. Overview on Pharmacovigilance Programme of India.

			<ol style="list-style-type: none"> 5. Demonstration of VigiFlow Software 6. Importance of report completeness & System for documentation grading at NCC-PvPI. 7. Causality Assessment: The Logic & Methods including case studies. 8. Overview on Signal Detection 9. Orientation among the AMCs/AEFI/RNTCP/ ART Centres & Drug Addiction Centres for effective data management. 10. Role of ADR Monitoring Centre (AMCs) & its Coordinators in developing effective Pharmacovigilance. 11. Hands on training on how to fill ADR Reporting form 12. Hands on training on VigiFlow Software to the Participants. 13. Case Narrative exercises. 14. Problems and Challenges faced by Pharmacovigilance Associates while reporting of Adverse Drug Reaction-A practical scenario. 15. An insight into Regulatory Pharmacovigilance. <p>PvPI also provided field training for the participants at UCMS & GTB Hospital, Delhi.</p>
6	Interactive session with Pharma Marketing Authorization Holders of Abbott, Novartis & Baxter	IPC, NCC-PvPI had meeting with Marketing Authorization Holders of Abbott, Novartis & Baxter on 9/08/2016, 11/08/2016 & 29/08/2016 to discuss the issues related to ICSRs reporting & VigiGrade Completeness score of their ICSRs reported to PvPI.	<p>NCC-PvPI officials has reviewed the ICSRs received from Abbott, Novartis & Baxter marketing authorization holders and emphasised on the Indian ICSRs VigiGrade Completeness in comparison to their individual MAH's VigiGrade score.</p> <p>Officials also informed to MAH's that there is an urgent need to improve on the following fields</p> <ol style="list-style-type: none"> 1. Indication of drugs.

			<ol style="list-style-type: none"> 2. Dosage of the drugs. 3. Start date of the drug in take. 4. Start date of the reaction. 5. Outcome of the reaction. <p>While processing of ICSRs and submission to NCC-PvPI & its impact on the overall Indian ICSRs VigiGrade score.</p>
7	8 th Working Group meeting of PvPI	IPC, NCC-PvPI was organised its 8 th working group meeting on 26/08/2016 at CDSCO, FDA Bhawan, New Delhi	<p>The Working Group members discussed & suggested on the following matters.</p> <ol style="list-style-type: none"> A. Reviewed the performance of ADR Monitoring Centres- 14 AMCs under PvPI B. Development of Indigenous Software for PvPI C. Identification of state wise experts/spokespersons for PvPI D. Disclosing of ICSR's information through RTI E. Motivation/carrier progression of the Pharmacovigilance staff F. Casual/Sick Leave to contractual staff working in PvPI G. Transfer of PvA from one AMC to another AMC H. Providing of Pharmacovigilance Associates to Corporate Hospitals I. Introduction of Biometric attendance system for AMC staff