

Indian Pharmacopoeia Commission

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

Monthly Progress Report- June 2016

S. No	Title of Activity	Description	Major Outcomes/Action Taken
1.	Data collation and processing of ICSRs	During the index period NCC received 5654 ICSRs from AMCs/ Pharmaceutical industries/ consumers. The reported cases are under the 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 reports will be reverted back to the reporter.
2.	Expert committee for assessing safety and tolerability of Transcutol in Diclofenac Injection 75 mg/ml	As desired by DCG(I), NCC-PvPI, IPC officials attended expert committee meeting for assessing safety and tolerability of Transcutol in Diclofenac Injection 75 mg/ml on 21.06.2016 at Dte. DHS, Committee room, Nirman Bhavan, New Delhi.	PvPI Officials presented the current status on the ADRs reported to PvPI on Diclofenac Injection 75 mg/ml
3.	Vaccine-PSUR expert committee meeting.	PSUR expert committee meeting was held on 21 st June 2016 at CDSCO, New Delhi.	Committee reviewed the AEFI cases of the Japanese Encephalitis
4.	Workshop on discussing initiatives towards strengthening nursing cadre	Workshop on discussing initiatives towards strengthening nursing cadre held on 27-29 th June 2016 at Hotel Crowne Plaza, Okhla Phase 1, New Delhi.	Officials from PvPI attended this workshop & represented the Current status on PvPI with special emphasis on the role of nursing professionals in PvPI & importance of Pharmacovigilance in nursing educational curriculum.

<p>5.</p>	<p>Second Meeting of National AEFI Committee 2016</p>	<p>Second Meeting of National AEFI Committee 2016 held on 28th June 2016 at Hotel Ashoka Lakeview, Bhopal.</p>	<p>Major Outcomes of this meeting as follows:</p> <ol style="list-style-type: none"> 1. Action taken report of last meeting and updates on National AEFI surveillance, zone-wise updates on state level AEFI surveillance were presented by the 4 Zonal Consultants. 2. Updated on involvement of WHO–NPSP in AEFI surveillance by Dr. Sujit Kumar Jain. Dr. Arti Kapil presented a proposal on Lab profiling of all vaccine preparations to serve as a standard comparator for testing of open vaccine vials. 3. A review of cases with congenital heart diseases under AEFI was carried out followed by feedback to State AEFI Committee. 4. It has been decided by National AEFI Committee that ASHAs will be provided with injection adrenaline to be used in cases of anaphylaxis following a vaccine. Keeping in view the adverse effects of adrenaline, special pharmacovigilance measures would be recommended to report adverse effects to Adrenaline itself. <p>Major Recommendations:</p> <ol style="list-style-type: none"> 1. Zonal Consultants need to follow up State AEFI committees if possible by visits and/or phone calls to the centers, as communications by mails was not proving to be enough. Meetings of State AEFI committees also need to be more frequent and regular. 2. The National AEFI Committee has decided to hold 2 out of 3 meetings outside Delhi. This can be adopted by
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			PvPI also. Some of the meetings can be held in state capitals instead of New Delhi.
6.	Interactive meeting to review(Clinical) ICSRs/PSURs	NCC-PvPI, Clinical review team had meeting with Dr. Mita Nandy, Consultant- CDSCO on - 28/06/2015at IPC, Ghaziabad.	<p>Clinical relevance between following Drug-ADR Combinations were reviewed:</p> <ul style="list-style-type: none"> a) Piperacillin/Tazobactam : DRESS Syndrome b) Artemether/Lumefantrine: SJS/TEN c) Cefixime: AGEP d) Itraconazole: Photosensitivity Reaction e) Peg Interferon alpha-2a: Kidney Failure f) Albendazole: Dyspnoea g) Ibuprofen: SJS/TEN h) Methoxy Polyethylene glycol-epoetin beta-Myocardial infarction & kidney disorder