

Indian Pharmacopoeia Commission

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

Monthly Progress Report- May 2016

S. No	Title of Activity	Description	Major Outcomes/Action Taken
1.	Data collation and processing of ICSRs	During the index period NCC received 5164 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.	JS(R) Visit to IPC	JS (R) visited IPC on 2 nd May 2016& emphasised to strengthen Pharmacovigilance.	JS was briefed about the extensive efforts towards PvPI. The progress made in the engagement of pharmaceutical industries was also overviewed and concurred that PSUR guidance document for MAHs to be made available. JS was overwhelmed to see the progress and emphasized over the value additions in PvPI and improve its standing at par with the international arena.
3.	Visit of Mr. Azadeh, World Health Organization Geneva, Switzerland to IPC	Dr Azadeh visited NCC-PvPI, IPC on 2 nd May 2016.	Outcomes of this meeting as follows: WHO & NCC-PvPI, IPC to put the heads together about deworming medicine monitoring. PvPI will work with WHO to ensure the safety of Albendazole was pronounced on national deworming day.

4.	Vaccine-PSUR expert committee meeting.	PSUR expert committee meeting was held on 05 th May 2016 at CDSCO, New Delhi.	Experts of CDSCO, ITSU & PvPI were reviewed (Oral Polio) vaccines PSUR and recommended MAHs to provide vigorous quality information in the reports & also to improve frequency of the reporting.
5.	Government Analyst's training on Pharmacovigilance & ADR reporting	IPC organised one month training to government analysts from 05/04/2016 to 05/05/2016, PvPI Officials presented its updates on 03/05/2016 during this training.	During this training program PvPI Officials emphasised on the current status, net working of PvPI & role of government analysts in reporting of ADRs related to spurious drugs & also lack of therapeutic effect due to drugs.
6.	1 st National level meeting on participation of Nursing Professionals in PvPI	PvPI organised 1 st National level meeting on participation of Nursing Professionals in PvPI at IPC, Ghaziabad on 6 th May 2016	<p>The outcomes of this meeting as follows</p> <ol style="list-style-type: none"> 1. Suggested to include nursing professionals as one of the experts in various committees of PvPI 2. Secretary-cum-Scientific Director, IPC recommended to constitute a panel of minimum 21 Nursing Experts across the country to strengthen the PvPI activities & also to prevent the ADRs occurring at AMCs under PvPI. 3. Proposed to send a notification through D.G.H.S. to all State Health Secretaries & Indian Nursing Council, where two credit hours on Pharmacovigilance & ADR reporting as mandatory for renewal of practising nurses by State, UT's Nursing Councils & also Pharmacovigilance as one of the chapter in the course curriculum of Nursing professionals. 4. Recommended to organise zone wise training for Nursing Professionals at AMCs under PvPI by coordinating with State Nursing Councils. 5. Proposed to include Pharmacovigilance as one of the e Module in Continuous Nursing Education (CNE) of State Nursing Council being organised by Tamilnadu. 6. Suggested to include Pharmacovigilance in Nursing

			Curriculum & also to Develop Training Module for Nurses
7.	Meeting with Bedaquiline CAP sites/Centres	Central TB division organized a one day meeting with Bedaquiline CAP sites on 09 th May 2016 at Indian Council of Medical Research (ICMR) Head Quarter, AIIMS Campus New Delhi.	Objective of the meeting was to review implementation of Bedaquiline CAP and status update of Bedaquiline sites. It is also aimed to gain a better understanding of ongoing programme, preparation and challenges to roll out Bedaquiline CAP under PMDT RNTCP.
8.	32 nd Scientific Body Meeting of IPC	<p>IPC organised 32nd Scientific Body meeting at Malviya Smriti Bhawan, New Delhi on 29th May 2016 & for the same meeting PvPI proposed the following Agenda items.</p> <ol style="list-style-type: none"> 1. Need to development of indigenous IT tool for ADRs reporting, analysis and signal detection. 2. To set up a separate Institute/Centre of excellence in Pharmacovigilance has been emerged 3. ICMR institutions will be recognised as “PvPI collaborating Centres”. The scope of activities of 06 ICMR institutions has been identified. 4. To authorise NCC-PvPI have to request Secretary, Health to write a letter to the state and UT Health Secretaries, where ADRs reporting to be mandatory for the clinicians. 5. PvPI reach out to district & PHCs. 	<p>The outcomes of this meeting as follows</p> <ol style="list-style-type: none"> 1. The members reviewed the updates of PvPI & suggested to hire one IT-Consultant for the PvPI & IPC as well. 2. Scientific Body recommended NCC to hire one Senior Pharmacovigilance Associate (SPA) in addition to Pharmacovigilance Associate working at ADR Monitoring Centres under PvPI & proposed to keep PharmD/ M. Pharmacy with 3 years of experience in Pharmacovigilance as the essential qualification for the SPA.