

Indian Pharmacopoeia Commission

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

Monthly Progress Report- January 2016

S. No	Title of Activity	Description	Major Outcomes/Action Taken
1.	Data collation and processing of ICSRs	During the index period NCC received 4606 ICSRs from AMCs/ Pharmaceutical industries/ consumers. The reported cases are under the assessment for completeness, listed/ unlisted and clinical relevance.	<p>The reported ICSRs yet to be assessed for the completeness & quality for further process (listed and unlisted) & under medical/clinical review.</p> <p>Lack of quality reports will be reverted back to the reporter.</p>
2.	Memorandum of understanding between NCC-PvPI, IPC & IMA	A Letter of Intent for cooperation was signed between IPC, NCC-PvPI and IMA on 6 th January 2016. Dr. G. N. Singh, DCG(I) & Secretary-cum-Scientific Director, IPC and Dr. S. S. Agarwal, President, IMA signed the Letter of Intent for cooperation on behalf of IPC and IMA respectively and exchanged the same.	<p>NCC-PvPI and IMA agreed to cooperate for the following areas:</p> <ol style="list-style-type: none"> 1. PvPI-IMA patient safety monitoring cell should be started at IMA Head Quarter in the designated space provided by IMA. 2. Organising Continuing Medical Educations (CMEs), disseminating PvPI information/concept of Pharmacovigilance (PV) in IMA in News, Journals etc. 3. IMA to identify the nodal centres for education/

			<p>advocacy and ADR monitoring and recommend to NCC-PvPI for recognition.</p> <ol style="list-style-type: none"> 4. Training to the nodal coordinators/medical officers. 5. Development/up-gradation of Mobile app. for ADR monitoring. 6. A “National Day on Patient Safety” is to be celebrated by NCC-PvPI and IMA in collaboration. 7. Other areas to promote patient safety.
<p>3.</p>	<p>Involvement and Responsibilities of Corporate and District level Hospitals in PvPI- Ghaziabad & Noida Region</p>	<p>The participation of corporate hospitals in PvPI is paramount because the newly introduced drugs are only used in the corporate hospitals not in the government setup. Also the range & drugs used in private sector is higher than public sector. Therefore there is a need for PvPI to collaborate with the corporate hospitals to monitor the safety of new drugs available in the market. IPC organised one day workshop on 11th January 2016 “Involvement and Responsibilities of Corporate and District level Hospitals in PvPI- Ghaziabad & Noida Region”.</p>	<p>Total 25 participants from various corporate hospitals in Ghaziabad, & Noida region participated in workshop. Officials from NABH, CDSCO, PvPI emphasized on Why ADR reporting is important to PvPI to promote patient safety in the country. The important outcome of this workshop as follows:</p> <ol style="list-style-type: none"> 1. The certificate of award may be issued by NCC-PvPI to the corporate hospitals based on the contribution to PvPI. 2. The participants suggested that the ADR reporting posters to be made available in Hindi and other regional languages. 3. The participants appreciated the developments and efforts taken to promote PvPI and suggested it needs to be advertized in newspapers, TV and radio. 4. There is an urgent need to reach out the message to the community pharmacists. This will create a scope for ensuring the safety of OTC products. 5. More number of corporate hospitals may be

			<p>recognized as an AMC under PvPI.</p> <ol style="list-style-type: none"> 6. The participants were convinced regarding the need for Pharmacovigilance system in their respective hospitals and agreed to contribute to PvPI. 7. The house suggested to NCC-PvPI to develop ADR e-reporting system. 8. Corporate Hospital collected ADR reports should be assessed during NABH accreditation/renewal by adopting PvPI's VigiGrade scoring system to generate meaningful outcome subsequently. 9. The Technical Associate from NCC-PvPI will be visiting to the corporate/district hospitals of Delhi NCR region periodically to facilitate/initiate the ADR monitoring & reporting.
4.	Visit of AEFI appraisal committee to IPC, NCC-PvPI	Dr. Suneeta Singh, CEO from Amaltas visited IPC on 20th January 2016 to understand Present coordination between PvPI and ITSU plan for further better coordination and understanding.	<p>The major outcome of this meeting as follows:</p> <ol style="list-style-type: none"> 1. The process to identification of new signals on vaccines in PvPI and AEFI such to be integrated. 2. Suggested to build an effective communication, between state AEFI and AMC level.
5.	Mandatory credit hours on PvPI for nursing registration & renewal by state nursing councils	As per the recommendation of 7 th Working Group meeting under PvPI, IPC circulated letters to 27 state nursing council registrars to include 2 mandatory credit hours on ADR reporting, Pharmacovigilance & PvPI during the renewal of nursing registration by state nursing councils	As state Nursing Councils are playing a crucial role in Nursing Education & Practice, PvPI approached state nursing councils to implement the ADR reporting by Nurses during their professional services. This can be implemented as two mandatory credit hours out of 30 hours for Pharmacovigilance activities & PvPI while renewal of nursing registration in the state nursing council.

6.	Meeting with Dr. Manisha Verma & Mr. Raman Prasad	IPC received a letter from DFQC section & stated that Ministry of Health & Family Welfare & Doordarshan, Prasar Bharathi had MOU. In this regard Officials of PvPI have conducted a meeting with Mr. Raman Prasad, PO (AV) on 22/01/2016 at Nirman Bhawan.	<p>The Outcome of this meeting.</p> <ol style="list-style-type: none">1. Doordarshan shall provide 60 seconds of spot to advertise on PvPI activities to promote patient safety in the country.2. In this regards, IEC suggested to prepare a spot for the same. <p>PvPI started working for the same by coordinating with the experts in making the film as per the suggestion of Secretary-cum-Scientific Director, IPC.</p>
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