

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

**PvPI Monthly Progress Report- October 2016**

<b>Sr. No.</b>	<b>Title of Activity</b>	<b>Description</b>	<b>Major Outcomes/Action Taken</b>
1	Data collation and processing of ICSRs	During the index period, NCC received 5360 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	15 <sup>th</sup> Meeting of Governing Body of the IPC	IPC organised its 15 <sup>th</sup> Meeting of Governing Body on 4 <sup>th</sup> October at Nirman Bhawan, New Delhi	The members reviewed the progress of PvPI and appreciated the performance of NCC. The points related to PvPI was referred to put up in next SFC meeting for financial approval.
3	3 <sup>rd</sup> Interactive Session on Participating of Marketing Authorization Holders (MAHs) in PvPI: A way forward	PvPI organised “3 <sup>rd</sup> Interactive Session on Participation of Marketing Authorization Holders (MAHs) in PvPI: A way forward” on 7 <sup>th</sup> October at IPC, Ghaziabad.	During interactive session PvPI officials discussed on 1. Quantitative & Qualitative analysis of Pharmaceuticals Industries ICSRs received at NCC-PvPI. 2. Demo on import of E2B XML ADRs report in to VigiFlow database. 3. Comparison of Indian Package Insert leaflets (PILs) with others & it’s importance in India.

4	Visit of Shri K. B. Agarwal, Additional Secretary to IPC	Shri K. B. Agarwal, Additional Secretary, MoHFW visited IPC on 8 <sup>th</sup> October 2016	Additional Secretary instructed PvPI to develop e-system at CDSCO/PvPI for PSURs and ADR reporting. He also instructed, evaluation of PSURs is a pharmacovigilance activity and should be evaluated by NCC-PvPI
5	Meeting with Millennium Telecom Ltd. (since PvPI received an e-Mail from CDSCO, HQ along with the letter sent by MTL to Secretary health vide letter No. MTL/COO/Health/Device-Montrng/2016-17, dated 08/09/2016)	As instructed by additional secretary to develop e-system at CDSCO/PvPI of PSURs and ADR reporting during his visit to IPC, on 8 <sup>th</sup> October 2016 also further directed by Secretary-cum-Scientific Director IPC, a preliminary meeting to explore the option for the same was held on 17/10/2016 with millennium telecom Ltd.	<p>It was suggested by NCC that the following areas may be worked out:</p> <ul style="list-style-type: none"> <li>a. Telecom Sector Application                             <ul style="list-style-type: none"> <li>i. Upgradation of Toll Free Number (1800-180- 3024) of NCC-PVPI – This has limitations since it’s on a single line and works only when the computer is on.</li> <li>ii. Replacement of Existing Mobile App.</li> </ul> </li> <li>b. Cloud Based E-Reporting Compatible With Mobile Phones / Desktop And Laptops                             <ul style="list-style-type: none"> <li>i. For submission of PSURs (Periodic Safety Update Reports) from MAH to CDSCO/ PvPI.</li> <li>ii. Spontaneous ADR Reporting to PvPI.</li> </ul> </li> </ul> <p style="text-align: center;">MTL agreed to review the whole system and will submit a detailed proposal in this regard then a subsequent meeting shall be arranged with Secretary-cum- Scientific Director for further direction.</p>
6	Visit of experts from Netherlands National Pharmacovigilance Centre	Prof. (Dr.) Eugene van Puijenbroek (Head Science and Research at the Netherlands and Pharmacovigilance Centre) and Dr. Wil Hilgersom (Vaccine	Experts overviewed the culture of reporting ADR’s of vaccines under PvPI and were highly impressed by the way of working and reporting on Pharmacovigilance.

		<p>Safety Expert, Lareb, Netherlands) visited to the Indian Pharmacopoeia Commission on 20<sup>th</sup> October 2016 to exchange ideas on AEFI Pharmacovigilance.</p>	<p>Prof Eugene shared his insights on recent Pharmacovigilance experience in the Netherlands and Dr. Wil Hilgersom highlighted on AEFI signals. Prof Eugene on behalf of Netherlands Pharmacovigilance Centre, Lareb is ready to provide support to PvPI on the following areas:</p> <ol style="list-style-type: none"> <li>1. Modules and training resource materials to educate the personnel's on Pharmacovigilance.</li> <li>2. Methodology to identify new signals.</li> <li>3. PvPI and Netherlands Pharmacovigilance Centre, Lareb agreed on mutual collaboration for exchange of information.</li> </ol>
7	<p>Visit of Experts from WHO UMC</p>	<p>Dr. Marie Lindquist (Director-UMC) and Prof Edward (Senior Advisor, UMC) visited the Indian Pharmacopoeia Commission (IPC) on 21<sup>st</sup> October 2016 to overview the progress and initiatives taken by the PvPI.</p>	<p>Dr. Marie on behalf of WHO UMC expressed that all support will be extended to PvPI and also suggested that IPC, NCC -PvPI can collaborate in the following areas.</p> <ol style="list-style-type: none"> <li>1. WHO-UMC training on Pharmacovigilance in India under PvPI umbrella.</li> <li>2. Advance level training on signal detection on the drugs used in neglected diseases in which PvPI may be identified as hub for Asian countries where disease incidence rate is high.</li> <li>3. Broader developments in the area of Medication errors and reporting of lack of efficacy of drugs.</li> <li>4. UMC will facilitate to establish a link between PvPI and international medical services.</li> </ol>

			Dr. Marie requested that Secretary-cum-Scientific Director, IPC, should submit a proposal on the above mentioned areas to initiate necessary action.
8	Interactive session between International Society of Pharmacovigilance (ISOP) and National Coordination centre, Pharmacovigilance Programme of India (NCC-PvPI), IPC	Dr. J. Christophe Delumeau, Executive Committee Member, ISOP visited Indian Pharmacopoeia Commission to understand the functioning and future action plan of PvPI to extend the possible support from ISOP on 21 <sup>st</sup> October 2016.	<p>He mentioned that PvPI has expanded over the years and its efforts are well recognized by global Community. He also briefed about the scope and objectives of ISOP, as PvPI and ISOP share the same objectives of promoting patients safety. He proposed to work with PvPI and further discussed on the following areas for future collaborations.</p> <ol style="list-style-type: none"> <li>1. Training programmes for NCC-PvPI professionals on various topics like signal detection, lack of efficacy studies, benefit-risk assessment, and medication errors.</li> <li>2. Invited the PvPI staff to contribute research articles on Drug Safety, an international journal.</li> <li>3. ISOP membership of PvPI professionals.</li> <li>4. Extended support from ISOP to develop IT tools for Pharmacovigilance.</li> <li>5. Development of advanced version of Mobile ADR App.</li> </ol>