

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

**PvPI Monthly Progress Report- November 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 4885 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	Third Core Training Panel meeting (CTP) cum second Regional Training Centres (RTCs) Coordinators meeting	NCC-PvPI organised its Third Core Training Panel meeting (CTP) cum second Regional Training Centres (RTCs) Coordinators meeting on 7 <sup>th</sup> November at CDSCO, FDA Bhwan, New Delhi.	The Major Recommendations of this meeting as follows: <ul style="list-style-type: none"> <li>• The panel recommended to include sensitization/awareness activities of each AMCs in Monthly Progress Report circulated to all AMC from NCC. This will motivate other under reporting AMCs for increasing sensitization activities in their region.</li> <li>• The panel member also recommended for conducting sensitization programme for consumers</li> <li>• Panel member recommended for issuing guidelines for bill submission and bill should</li> </ul>

			<p>get reimbursed within 15 working days.</p> <ul style="list-style-type: none"> <li>• Panel member recommended for issuing guidelines for bill submission and bill should get reimbursed within 15 working days.</li> <li>• Panel recommended that RTCs will be identifying the trainers for CME/Advance Level Training.</li> <li>• Panel members agreed to keep AIIMS Rishikesh as RTC under the guidance of PGIMER, Chandigarh and IMS BHU, Varanasi as new RTC after getting proposal from them</li> <li>• Panel recommended that a training manual on Pharmacovigilance to be prepared and the chapters for the same will be prepared by RTCs coordinators</li> </ul>
3	<p>Representation from IPC to Thirty-ninth Annual Meeting of Representatives of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring</p>	<p>Officer I/c-PvPI, IPC on behalf of India represented to Thirty-ninth Annual Meeting of Representatives of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring from 14-17 November at Muscat, Oman</p>	<p>The outcome of this meeting as follows</p> <ul style="list-style-type: none"> <li>• Officer I/c-PvPI participated as one of a panellist in the topic "regional challenges on Pharmacovigilance"</li> <li>• The following topics has been given as oral presentation during Problems of Current Interest (PoCI) sessions             <ol style="list-style-type: none"> <li>1. Active surveillance on Bedaquiline: India Initiatives</li> <li>2. An outlook of ADR reporting by consumers</li> <li>3. Quality of Individual case safety reports</li> </ol> </li> <li>• The following topic has been given as poster</li> </ul>

			<p>presentation during Problems of Current Interest (PoCI) sessions</p> <ol style="list-style-type: none"> <li>1. Adverse drug reactions related to herbal products: status in India (Analysis of PvPI data)</li> </ol>
4	Meeting with Techno-commercial Officer MTNL	<p>MTL submitted a proposal to upgrade PvPI facilities such as Helpline and mobile app. The Secretary-cum-Scientific Director, IPC instructed to examine the suitability of the proposal. PvPI had a meeting with Techno-commercial Officer MTNL on 21<sup>st</sup> November at IPC Ghaziabad.</p>	<p>The major Recommendations and Outcomes of this meeting as follows: It was suggested by NCC that the following areas may be worked out:</p> <ol style="list-style-type: none"> <li>a. Telecom Sector Application             <ol 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. It was decided that initially a small call center operational manned one shift and for balance hours enabled by voice call recording facility shall be made available.</li> <li>ii. Mobile App For ADR Reporting                 <ol style="list-style-type: none"> <li>1. This would replace the existing mobile app and cover all the stakeholders (at present its limited to Healthcare Professionals) be it Healthcare Professionals, Patient themselves or their LAR (Legally Accepted Representatives). The existing mobile app for</li> </ol> </li> </ol> </li> </ol>

			<p>ADRs reporting in PvPI is available in android platform. Therefore the proposed facility to be made available in android, apple, i-phone etc. The facility shall have KYC capture along with audio recording and update of snapshots of relevant data which the stakeholder may have to update related to the problem. MTL shall also provide API for its export to its existing ICSRs Data Management system.</p> <p>iii. Mobile App For Lack Of Efficacy (LOE) Reporting</p> <ol style="list-style-type: none"> <li>1. This would be a new application cover all the stakeholders be it Healthcare Professionals, Patient themselves or their LAR (Legally Accepted Representatives). The facility shall have KYC capture along with recording and update of snapshots of the medicine details along with its Batch and Lot Number etc. The output shall be in a simple MIS whose format shall be provided by PvPI.</li> <li>2. PvPI will designate a control room for this purpose to enable MTL personnel to do a technical study of the site visit and visit the infra structure required including fiber connectivity at site. PvPI mentioned</li> </ol>
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			<p>that there is already a BSNL fiber dropout at the site.</p> <p>3. MTL agreed to review the whole system and will submit a techno commercial offer.</p>
5	9 <sup>th</sup> SRP meeting under PvPI	PvPI organised its 9 <sup>th</sup> SRP meeting at CDSCO, West Zone Office, Mumbai on 29 <sup>th</sup> November.	<p>The Outcome of this meeting as follows</p> <p>I) The panel Reviewed the ICSRs of potential signals for the following Drug-ADR combinations</p> <ul style="list-style-type: none"> <li>a) Tinidazole : Skin Hyperpigmentation</li> <li>b) Ranitidine : Burning Sensation</li> <li>c) Meropenem : Hypokalaemia</li> <li>d) Itraconazole : AGEP</li> <li>e) Lamivudine : Hearing decreased</li> <li>f) Leflunomide : DRESS syndrome</li> <li>g) Propranolol : Torsade de Pointes</li> <li>h) Furosemide : Dermatitis Lichenoid</li> <li>i) Montelukast : Tinnitus</li> <li>j) Phenytoin : AGEP</li> <li>k) Lithium Carbonate : DRESS Syndrome</li> <li>l) BCG Vaccine: Lymphadenopathy</li> <li>m) Docetaxel : Candidiasis</li> </ul> <p>II. The Chairman &amp; Member Secretary-SRP discussed on the reconstitution of the PvPI-SRP Panel.</p>