

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

**PvPI Monthly Progress Report- December 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 6585 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	2 <sup>nd</sup> Bedaquiline drug safety monitoring committee meeting	PvPI officials attended to 2 <sup>nd</sup> Bedaquiline drug safety monitoring committee meeting on 5 <sup>th</sup> December at New Delhi	Committee reviewed drug safety data which was presented by PvPI and RNTCP, the committee opined that, the information available till date on BDQ is considered to be safe; suggested for further safety data needs to be received/generated to establish its safety.
3	Official meeting with President & Vice Chancellor of Alberta University	IPC, PvPI Officials attended a meeting with Dr. David Turpin, President & Vice Chancellor of Alberta University at Canadian Networking reception on 5 <sup>th</sup> December at Canada House, New Delhi.	PvPI Officials updated to president on current status & functioning of PvPI.

4	Knowledge sharing session between Quintiles IMS (QI) and PVPI	IPC-PvPI had conducted Knowledge sharing session between Quintiles IMS (QI) and PVPI on 14 <sup>th</sup> December at IPC, Ghaziabad.	<p>During this knowledge sharing session, the following are discussed.</p> <ul style="list-style-type: none"> <li>• Quintiles IMS SARA-practical aspects of literature safety surveillance in pharmacovigilance</li> <li>• PVPI presented a session on signal management process at PVPI.</li> </ul>
5	Meeting with Secretary-Medical Council of India	PvPI-Officials had a meeting with Secretary-Medical Council of India on 14 <sup>th</sup> December-2016 at New Delhi.	<p>The outcome of this meeting as follows:</p> <ul style="list-style-type: none"> <li>• PvPI proposed for integration of MCI with PvPI in regularly to monitor the ADR reporting by various AMCs under PvPI</li> <li>• To Sensitize/update MCI auditors about ADR monitoring and reporting &amp; functioning of ADR Monitoring Centres at various medical colleges under PvPI.</li> <li>• 3. Secretary informed to resend a letter to MCI Secretary with attachment of all previous letter issued by Director, IPC. For inclusion of Pharmacovigilance practice in medical MBBS course curriculum and training during internship of MBBS students at department of pharmacology (ADR Monitoring Centre).</li> <li>• 4. PvPI suggested MCI for mandatory inclusion of ADR reporting form in IPD and OPD form of hospitals in medical colleges.</li> </ul>

6	WHO-NRA debriefing meeting	PvPI Officials attended to WHO- NRA debriefing meeting on 15 <sup>th</sup> December-2016 at CDSCO, New Delhi.	Joint Secretary (Regulation) suggested to appoint 50 Pharmacovigilance Associates to work with district immunization officers to promote vaccine safety in the country.
7	4 <sup>th</sup> Steering Committee meeting of PvPI	IPC had conducted its 4 <sup>th</sup> steering committee meeting of PvPI at CDSCO, FDA Bhawan on 28 <sup>th</sup> December 2016 at New Delhi.	<p>The committee discussed on the following</p> <ul style="list-style-type: none"> <li>• Approval of Pharmacovigilance Officer posts in every state</li> <li>• Creation of Drug Safety Research Fellowship (DSRF) under PvPI</li> <li>• Allotting a project to MTNL for developing Mobile Apps for ADR &amp; Lack of efficacy reporting for PvPI</li> <li>• Identification of Medical Superintendent as Chief-Coordinator of ADR Monitoring Centres under PvPI</li> <li>• Approval for the Identification of Pharmacy Institutions (Pharm. D, which are having MoU with Corporate Hospitals as PvPI)</li> </ul>
8	1 <sup>st</sup> National level advisory committee Meeting for engagement of Community Pharmacists	IPC-NCC, PvPI organised 1 <sup>st</sup> National level advisory committee Meeting for engagement of Community Pharmacists in PvPI on 28 <sup>th</sup> December 2016 at New	<p>The outcome of this meeting as follows:</p> <ul style="list-style-type: none"> <li>• Committee Identified zonal wise focal persons to educate/advocacy to community pharmacists on PvPI.</li> </ul>

	in PvPI	Delhi.	<ul style="list-style-type: none"> <li>• Committee reviewed &amp; approved JSS, College of Pharmacy-Training Modules for community pharmacists in reporting ADRs as standard modules.</li> <li>• Pharmacy Council of India, All India Organization of Chemists &amp; Druggists was in principle agreed to work together with PvPI, IPC.</li> </ul>
9	PvPI progress review meeting	PvPI officials conducted a meeting with national scientific coordinator of PvPI at AIIMS, New Delhi on 29 <sup>th</sup> December 2016.	<p>The outcome of this meeting as follows:</p> <ul style="list-style-type: none"> <li>• Made amendments in suspected ADR reporting form of PvPI.</li> <li>• Discussed on the C DSCO-PvPI collaborated PSUR-review draft expenditure plan.</li> </ul>