

## Indian Pharmacopoeia Commission

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

Monthly Progress Report- November 2015

S. No	Title of Activity	Description	Major Outcomes/Action Taken
1.	Data collation and processing of ICSRs	During the index period NCC received 5129 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) &amp; under medical/clinical review.</p> <p>Lack of quality reports will be reverted back to the reporter.</p>
2.	Workshop on WHO ATC/DDD Methodology & Drug Utilization Research	NCC-PvPI, IPC in collaboration with WHO Collaborating Centres for Drug Statistics Methodology, Oslo organised on 2-3/11/2015 at New Delhi.	<p>Total-80 participants were attended this workshop from different countries &amp; trained on WHO ATC coding &amp; Defined Daily Dose methodology, the following were discussed during workshop:</p> <ul style="list-style-type: none"> <li>• Description on WHO ATC/DDD system and procedure used to assign ATC code and DDD</li> <li>• Information on sources of data, methods, their use and limitations for drug utilization studies</li> <li>• Identity need for drug utilization studies in their own country and environment</li> </ul>
3.	A pre meeting Let's talk PV	A pre meeting was organised by WHO-UMC & NCC-PvPI, IPC on 3/11/2015 at The Grand Hotel,	Total 120 participants attended this meeting from the national centres for Pharmacovigilance from 40

		<p>New Delhi Let's talk PV! Speakers from national pharmacovigilance centres, regulators, academia and UMC were delivered a talk on problems of current interest.</p>	<p>countries &amp; the following are discussed during the meeting:</p> <ul style="list-style-type: none"> <li>• Latest scientific developments in the field of signal detection</li> <li>• Impact communication: how do we tell the Pharmacovigilance story?</li> <li>• Pharmacovigilance in focus – how do we develop it in challenging scenarios?</li> <li>• Sustainability of Pharmacovigilance data management</li> </ul>
<p>4.</p>	<p>38<sup>th</sup> Annual Meeting of Representatives National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring</p>	<p>NCC-PvPI, IPC in collaboration with WHO-Country Office, India organised 38<sup>th</sup> Annual Meeting of Representatives National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring from 4/11/2015 to 6/11/2015 at New Delhi.</p>	<ul style="list-style-type: none"> <li>• More than 150 delegates from 58 countries attended this meeting. This meeting provided confidential platform to member states, to share medicines safety information and problems of mutual concern.</li> <li>• Scientific sessions during the meeting involved national &amp; international experts from hospitals, pharmaceutical industries, academics and regulatory authority for updates and trust areas of Pharmacovigilance.</li> <li>• Working Groups during the meeting provided opportunity for the countries participating in the WHO Programme for International Drug Monitoring to showcase their innovative approaches and shared the best practices that have helped to address the bottlenecks in Pharmacovigilance.</li> </ul>

5.	Foundation Stone Laying Ceremony of “Advanced Level Research Centre” at Indian Pharmacopoeia Commission	Hon’ble Union Minister of Health & Family Welfare, Government of India, Shri. J.P. Nadda laid the Foundation Stone of “Advanced Level Research Centre” at Indian Pharmacopoeia Commission on 14/11/2015 during this occasion Health Minister also inaugurated the “Medicines Benefit-Risk Assessment Cell” at NCC-PvPI division of IPC.	<ol style="list-style-type: none"> <li>1. NCC-PvPI Officials briefed the importance of importance of signal detection.</li> <li>2. Hon’ble Health Minister reviewed the status of ADR reporting via Helpline number.</li> <li>3. Hon’ble Health Minister also suggested to further strengthen the PvPI with respect to manpower and infrastructure.</li> </ol>
6.	Review meeting of Materiovigilance Programme of India (MvPI)	A review meeting of MvPI was held at NHSRC, New Delhi on 19/11/2015 with the official from SCTIMST, NHSRC and NCC-PvPI	<ol style="list-style-type: none"> <li>1. Status of 10 Medical Device Monitoring Centres were reviewed</li> <li>2. MD adverse event reporting form reviewed</li> <li>3. Progress of recruitment of Research Associates</li> <li>4. MvPI tool kit draft reviewed</li> </ol>
7.	Induction Programme For Assistant Drugs Inspectors	CDSCO is organising Induction Programme For Assistant Drugs Inspectors from 05/10/2015 to 31/12/2015 at National Institute of Biologicals. There was a scientific session on PvPI scheduled on 24/11/2015	<p>During this PvPI session NCC-PvPI Officials delivered the following talks on</p> <ol style="list-style-type: none"> <li>1. Pharmacovigilance: The basic introduction</li> <li>2. How, Where, What to Report on ADRs to PvPI</li> <li>3. Regulatory interventions on PvPI</li> <li>4. Practical hands on training in filling of Suspected ADR Reporting form.</li> </ol>
8.	Second CTP & First RTC(Regional Training Centre) Coordinators Meeting under PvPI	PvPI organised its second CTP & First RTC Coordinators Meeting on 30/11/2015 at IPC, Ghaziabad	<p>The suggestions made by CTP &amp; Coordinators of RTC</p> <ol style="list-style-type: none"> <li>1. NCC may appoint Technical Associate for every RTC, which doesn’t have T.A at present.</li> <li>2. RRCTTS renamed as RTC.</li> <li>3. One of newly identified RTC i.e. IMS-BHU, Varanasi is de-recognised as RTC under PvPI due to their non-acceptance. Instead of this the panel members suggested to identify AIIMS, Rishikesh</li> </ol>

			<p>as RTC.</p> <ol style="list-style-type: none"><li>4. The Chairperson had instructed RTC's to organise one advanced level workshop at each RTC at their AMC per year &amp; also to organise one CME at any other AMC under their region.</li><li>5. Panel recommended to make training content/Power point presentations for organising CMEs &amp; Advance level training at RTCs.</li><li>6. Panel also instructed RTCs to monitor &amp; review the functioning status of AMCs under their region, corrective measures in case of non-reporting AMCs/under reporting.</li></ol>
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