

Indian Pharmacopoeia Commission

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

Monthly Progress Report- October 2015

S. No	Title of Activity	Description	Major Outcomes/Action Taken
1.	Data collation and processing of ICSRs	During the index period NCC received 8326 ICSRs from AMCs/Pharmaceutical industries/consumers. The reported cases are under the assessment for the 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 reports will be reverted back to the reporter.
2.	Joint Secretary (Regulation) visit to IPC	Shri. K.L. Sharma visited the IPC on 01.10.2015& reviewed the progress of PvPI, given the directions for expansion of PvPI as follows. <ol style="list-style-type: none"> 1. Initiation of research approach in Pv (Pharmacogenomics). 2. Expansion of PvPI outreach up to the district hospitals. 3. To make PvPI as self sustainable revenue generating models may be proposed. 	As directed by the JS (R), IPC invited Dr. Lalji Singh, Director-Centre for Cellular & Molecular Biology to initiate research on pharmacogenomics.
3.	Strengthening National Regulatory Authority	A previsit to WHO NRA reassessment in 2016, WHO NRA team follow up visit-meeting was held	During this meeting IPC officials presented the Status on vaccines ICSRs & steps taken by PvPI (from last

	<p>WHO NRA follow up visit – India</p>	<p>at CDSO, New Delhi on 5 & 6.10.2015. This visit is a joint mission involving the Coordinators and Group Leads of the Regulatory Systems Strengthening (RSS) team of the Essential Medicines and Health Products Department in close collaboration with the WHO Country office (WCO) and WHO Regional office (SEARO).</p>	<p>four years) to promote vaccine safety in India.</p>
<p>4.</p>	<p>UMC/IPC Joint signal detection workshop</p>	<p>IPC in collaboration with WHO-UMC organised joint signal detection workshop from 5-8.10.2015 at IPC, Ghaziabad. The following experts from WHO-UMC trained the various participants in the workshop.</p> <ol style="list-style-type: none"> 1. Dr. Ruth Lesley Savage, Senior Medical Advisor UMC, Sweden 2. Dr. Ola Caster, Senior Researcher UMC, Sweden 3. Ms. Lovisa Sandberg, Analysis Specialist UMC, Sweden 	<p>The experts from WHO-UMC trained PvPI-IPC personnel, CDSCO-SAE division personnel, PvPI-Signal Review Panel members on signal identification from Indian ICSRs by using VigiRank (India). During this workshop 168 drug-ADR combinations of Indian ICSRs reviewed by participants as an exercise, but from these 7 drug-ADR combinations were proposed as potential signal & recommended to Dr. Ruth Savage to validate the following drug-ADR combinations as signals from Indian origin</p> <ol style="list-style-type: none"> 1. Citicoline – Hallucination 2. Azithromycin - Acute Generalized Exanthematous Pustulosis (AGEP) 3. Amikacin - Drug Hypersensitivity Syndrome 4. Cloxacillin - Acute Generalized Exanthematous Pustulosis (AGEP) 5. Artemisinin derivatives – Steven Johnson Syndrome 6. Phenytoin : Vestibular Disorder 7. Betamethasone – Photosensitivity

5.	6 th SRP meeting of PvPI	6 th SRP meeting of PvPI was held on 06.10.2015 at IPC, Ghaziabad.	<p>The panel members reviewed the potential signals for the following drug-ADR combinations</p> <ol style="list-style-type: none"> Ranitidine : Cardiac Arrest Iron Sucrose: Anaphylactic Shock Zoledronic Acid: Myocardial Infarction Methyldopa: Death intrauterine/Miscarriage (Foetal Death) Anti Rabies Vaccine: Erythema Multiforme Paracetamol: DRESS Syndrome Surfactant: Pulmonary Hemorrhage
6.	Fifth meeting of the various committees to support “38th WHO Programme for International Drug Monitoring (WHO, PIDM 2015)”	The stock taking meeting with IPC & WHO-Country Office to host the mentioned event was held on 14.10.2015 at IPC, Ghaziabad.	<ol style="list-style-type: none"> Invitation card was finalised. Dress code for volunteers finalised. Mementoes for speakers & delegates were finalised. List of members for local tour & Agra tour was finalised.
7.	Pharmacovigilance Training in the district Etawah, U.P	Under the aegis of NCC-PvPI UP Rural Institute of Medical Sciences, Etawah organised Pharmacovigilance training cum sensitization programme to the district & primary health centres	<p>During this training program, Health care professionals of primary health centres were trained on</p> <ol style="list-style-type: none"> Pharmacovigilance programme of India (History, aims, objective and role on patient safety) How to approach ADR cases and how to fill the ADR forms
8.	Vaccine PSUR Review meeting	Meeting was held at CDSCO on 23.10.2015 to review the vaccine’s PSURs	NCC-IPC officials shared the Rota vaccine ICSRs data reported to PvPI

<p>9.</p>	<p>Sixth meeting of the various committees to support “38th WHO Programme for International drug Monitoring (WHO, PIDM 2015)”</p>	<p>The stock taking meeting with IPC & WHO-Country Office to host the mentioned event was held on 28.10.2015 at IPC, Ghaziabad.</p>	<ol style="list-style-type: none"> 1. Rehearsal of cultural events was reviewed. 2. Content for position paper was finalised. 3. PvPI resource materials to be provided in kits was finalised. 4. Printing materials of WHO for kits was finalised.
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