Indian Pharmacopoeia Commission

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

Monthly Progress Report- February 2016

S. No	Title of Activity	Description	Major Outcomes/Action Taken
1.	Data collation and processing of ICSRs	During the index period NCC received 5428 ICSRs from AMCs/ Pharmaceutical industries/ consumers. The reported cases are under the 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 reports will be reverted back to the reporter.
2.	Training on Pharmacovigilance to Nursing Professionals of Jaypee Hospitals, Noida	Training cum interactive session was conducted by NCC- PvPI for the nursing staff at Jaypee Hospital, Noida on 5/02/2016.	NCC- PvPI conducted training cum interactive session for nursing staff at Jaypee Hospital, Noida on 5th February 2016. In this training, NCC-PvPI officials presented about how to identify an ADR, what to report and whom to report & team of NCC-PvPI explained about how to fill the ADR reporting form, how to reports ADRs through PvPI Helpline toll free number and use of ADR reporting android mobile application respectively.
3.	Visit of Food and Drugs Authority, Ghana to IPC	Mr. Nana Ansah Adjei, Medicines Quality & Safety Specialist, Food and Drugs Authority, Ghana visited to IPC on 09/02/2016	PvPI updated Mr. Nana in the areas of PvPI understanding, leadership and communications, insight into operations with the use of data collection, analytical and executive pharmacovigilance tools. He appreciated the skill knowledge, competence and collaborative mindset of NCC and also he

			overwhelmed about the PvPI helpline number, which is a unique facility in India for reporting ADRs among the Asian countries and also expressed that he would like to introduce in Ghana also.
4.	"Induction-cum-Training Programme for newly recruited Technical Associates" under PvPI	NCC-PvPI organized the 'Induction – cum-Training' for the newly appointed Technical Associates (TAs) in various AMCs of PvPI from 15-19th February 2016 at IPC, Ghaziabad.	In the 'Induction-cum- training, various newly appointed TAs have been trained on the concept and good Pharmacovigilance practices. They are also provided to learn, perform and enhance their potential by inculcating multi skill with to accomplish the objectives of PvPI. In the batch of 15 TAs are trained not only technical and non-technical but ethics, morality and human values were also taught.
5.	Monthly AEFI pharmacovigilance partners meeting	PvPI officials attended to Monthly AEFI pharmacovigilance partners meeting at Nirman Bhawan on 22/02/2016	The outcome of this meeting: • Updated on new vaccines to be introduced under UIP. • Updated on AEFI trainings to be conducted at state and district level • PvPI officials updated & shared the signal on vaccines 1. Rota Vaccine-Intussception 2. Anti-Rabies Vaccine-Erythema Multiforme
6.	Interactive meeting to review(Clinical) ICSRs/PSURs	NCC-PvPI, Clinical Review team had meeting with Dr. Mita Nandy, Consultant- CDSCO on - 18/02/2016 at IPC, Ghaziabad	reviewed the Clinical relevance of the SUSARs identified by NCC-PvPI under the supervision of Dr. Mita Nandy. The following drug-ADR combinations are reviewed a) Lamotrigine : Stevens Johnson Syndrome b) Lamotrigine : Toxic Epidermal Necrolysis c) Ceftriaxone : Stevens Johnson Syndrome d) Thyroxine : Urticaria e) Sodium Valproate : Diplopia f) Sodium Valproate : Slurred speech

			g) Phenytoin : Diplopia
7.	Participation of PvPI Officials in National Symposium on "Quality Safety and Rational use of Medicines"	IPC conducted National Symposium on "Quality Safety and Rational use of Medicines" at IPC, Ghaziabad on 26/02/2016	During this symposium PvPI Officials updated on the recent developments & future action plan of PvPI to the participants
8.	Review meeting of Materiovigilance Programme of India (MvPI)	The progress of Materiovigilance Programme of India (MvPI), the coordination meeting among IPC, CDSCO, NHSRC, SCTIMST Thiruvananthapuram and others conducted on 29/02/2016 at NHSRC, New Delhi.	• Experts reviewed the draft Medical Devices Adverse Events reporting form & incorporated the appropriate comments & suggested to further review by medical devices industries representatives in the meeting to be held on 09/03/2016. • Experts reviewed MvPI Tool Kit & suggested to use the same for six months as pilot tool kit & suggested to further review after six months with the help of medical devices industries representatives • Experts reviewed & suggested that M.S (Pharma) in Medical Devices is not relevant qualification for the post of research associate • Committee suggested to schedule working group meeting and training programme for newly inducted coordinators and Research Associates prior to steering committee meeting.