Indian Pharmacopoeia Commission

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

PvPI Monthly Progress Report- July 2016

S. No.	Title of Activity	Description	Major Outcomes/Action Taken
1	Data collation and processing of ICSRs	During the index period NCC received 5741 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/incomplete reports will be reverted back to the reporter.
2	8th SRP meeting of PvPI	IPC organised its 8th SRP meeting of PvPI at CDSCO, FDA Bhawan, New Delhi on 08.07.2016.	The outcomes of the meeting is as follows: • SRP suggested PvPI to keep a watch on Piperacillin/Tazobactum induced DRESS Syndrome combination if reported in future. • Suggested PvPI to issue drug alert for Artemether/ Lumefantrine induced SJS/TEN and also suggested to integrate with the National Vector Borne Disease Control Programme (NVDBCP) for the monitoring of Anti-Malarial drugs. • SRP considered Cefixime induced Acute Generalized Exanthematous Pustulosis (AGEP) combination to be a potential signal as it was supported by histopathological reports with positive IC_{025} value (0.26) and suggested CDSCO to incorporate into the package inserts of this suspected drug being marketed in India. • Suggested CDSCO to incorporate Itraconazole induced

			Photosensitivity reaction into the package inserts of this suspected drug being marketed in India. • Suggested PvPI to issue Peg Interferon alpha-2a and ribavirin induced Kidney failure as drug alert and also to write letter to the concerned MAH to obtain additional information to ensure the quality/completeness of the reports. • Suggested no further action should be taken on Albendazole induced Dyspnoea. • Suggested CDSCO to incorporate Ibuprofen induced SJS/TEN into the package inserts of this suspected drug being marketed in India. • Suggested to incorporate Amoxicillin/Clavulanate Potassium: Stevens - Johnson Syndrome (SJS)/Toxic Epidermal Necrolysis (TEN) in package inserts as Adverse Drug Reaction of suspected drug marketed domestically & recommended PvPI to communicate the same to CDSCO. • Suggested to incorporate Ciprofloxacin: Stevens-Johnson Syndrome (SJS)/Toxic Epidermal Necrolysis (TEN) in package inserts as Adverse Drug Reaction of suspected drug marketed domestically & recommended PvPI to communicate the same to CDSCO. • Suggested to incorporate Sodium Valproate: Gum Hyperplasia in package inserts as Adverse Drug Reaction of suspected drug marketed domestically & recommended PvPI to communicate the same to CDSCO.

3	WHO National Regulatory System Follow up and Pre-Benchmarking Visit on 19 July 2016 ahead of the - Re-benchmarking (re-assessment) of NRA in India for vaccines in December 2016	WHO National Regulatory System Follow up and Pre-Benchmarking Visit ahead of the - Re-benchmarking (re-assessment) of NRA in India for vaccines in December 2016was organised on 19th July 2016 at CDSCO, FDA Bhawan, New Delhi	The officials of WHO (CO), CDSCO and NCC-PvPI participated and outcome of the meeting was briefed to JS (R) • WHO updated NRA about the latest version of the WHO global benchmarking tool. • Queries regarding the use of the WHO NRA benchmarking tool were resolved. • Discussed preparations for the forthcoming NRA assessment. • Suggested to develop the reassessment roadmap and all actions need to be performed prior to benchmarking including: self-assessment, validation of self-assessment, observed audit, field visits, etc • Joint strategic cooperation plan was prepared for forthcoming NRA assessment
4	WHO - CDSCO International Workshop on Good Regulatory Practices for National Regulatory Authorities: Using Good Regulatory Practices (GRP) Principles for Strengthening State Drug Regulatory Authorities in India	WHO - CDSCO International Workshop on Good Regulatory Practices for National Regulatory Authorities: Using Good Regulatory Practices (GRP) Principles for Strengthening State Drug Regulatory Authorities in India was organised on 20-21 July 2016 at Hotel Lalit, New Delhi	The outcome of the workshop is as follows: • Suggested to strengthen the regulation of medical products and Good Regulatory Practices in India and implementation of Certification of Pharmaceutical Products • WHO NRA Global Benchmarking Tool demonstrated to the participants including CDSCO/ state drug regulators • Pharmacovigilance is one of the very important components in benchmarking tool and need to be further strengthen • Feedback was taken by WHO from the selected states in India on the state adapted tool for NRA Strengthening. Both CDSCO and WHO agreed to

			consider the issues of states like manufacturing states, consuming states, porous border states etc as WHO NRA Global Benchmarking Tool may not be implemented as such to the states. Modification will be done as per the requirement • It was proposed by the states to conduct regular training for the regulators
5	WHO – CDSCO International Dissemination and Training Workshop on Drug Safety- Introduction to the WHO Surveillance and Monitoring System for Substandard, Spurious, Falsely labelled, Falsified and Counterfeit Medical Products	WHO – CDSCO International Dissemination and Training Workshop on Drug Safety organised on 22nd July 2016, at Hotel Lalit, New Delhi	The outcomes of the training workshop are as follows: • For globalization of drug safety, increased vigilance is the need of the hour • Anti-Microbial Drug Resistance is linked with the Quality of Medicines • Suggested to develop surveillance and monitoring system for Anti-Microbial Drug Resistance • The role of the National Focal Point was discussed
6	1st Meeting on strengthening of Pharmacovigilance system and patient safety in eastern Uttar Pradesh	NCC-PvPI organised a meeting to strengthen the pharmacovigilance system and patient safety in eastern Uttar Pradesh on 25th July 2016 at IPC, Ghaziabad	The outcome of the meeting is as follows: • Recommended to send an Order from MoHFW, GoI to the state secretary/authority to sensitize the HCP's for ADRs reporting. • Mapping of the registered medical practitioners/hospitals and to make them aware about the need to report ADRs: This activity to be initiated in Mirzapur district as a pilot study. • Rural advertisement to promote patients safety: Displaying the importance of ADRs reporting through banners, hoardings etc in vernacular languages • Broadcasting of PvPI via All India Radio of Banaras Station • Coordinating with eastern UP IMA branch for strengthening PvPI

			• Identified 'PvPI Eastern UP Collaborating Centre' for effective functioning of the system • Declaring SHEAT College of Pharmacy, Varanasi & ITM GIDA Gorakhpur, SHIATS College of Pharmacy, Allahabad as a 'PvPI supporting centre in Eastern UP for education, advocacy and enhancing the PV practice among Pharmacists and other health workers. • In major hospitals education/awareness to be created through a seminar by inviting learned speakers to convince about the benefits of reporting and allay doctor's fear. • Train the trainer so that local AMC coordinator can conduct the training program • Identified new AMCs in eastern UP: Azamgarh Medical College (Azamgarh) and Mata Anandamayee Hospital (Varanasi) are proposed • National Pharmacovigilance Day to be declared by the MoHFW, GoI • Suggested to made available Mobile App for general public in reporting ADRs • Coordinating meeting of the PvPI stakeholders of eastern UP to be held at least twice in a year
7	Induction cum Training Programme on Pharmacovigilance for Coordinators of Newly recognised AMCs under PvPI	Induction-cum-training Programme on Pharmacovigilance for Coordinators of newly recognized AMCs under PvPI was organised by IPC on 26 & 27th July at IPC, Ghaziabad	The coordinators suggested the following during the inauguration of training programme to DCG(I) 1. Since clinicians participation in PvPI is very essential and therefore their active participation is the need of the hour. In light of this, it was suggested that Secretary Health may be requested to send a circular/order to the state/UT health

			secretaries stating that ADRs reporting by the clinicians and other healthcare professionals be adopted. 2. To conduct national level (annual) meetings of the co-ordinators of AMCs of PvPI to discuss the current challenges and action plan. 3. PvPI to coordinate with clinicians of professional bodies such as dermatology etc. for effective functioning and monitoring the drug safety. 4. In the current system of PvPI, for the functioning of AMCs the annual contingency amount of Rs. 60,000/ year (maximum) is reimbursed at the end of every financial year. However, the co-ordinators suggested that at least Rs. 30,000/ may be given as an advance so that they can kick start the activities at their respective centres. This shall be adjusted against the total amount sanctioned for the year. 5. More number of experts need to be identified from every zone/state who will be acting as ambassador for the success of the PvPI program. 6. Every AMC should have one Pharm D. professional besides a Pharmacovigilance Associate, once the workload and ADR reporting has geared up.
8	" To optimize the safety of medicines through research based Pharmacovigilance- ICMR Institutions as PvPI Colloborating Centres"	A meeting on Optimization the safety of medicines through research based pharmacovigilance ICMR Institutions as PvPI collaborating centres held on 28th July 2016 at ICMR, HQ, AIIMS Campus, New Delhi	The outcome of the meeting is as follows: DG, ICMR in principally agreed to depute following seven ICMR institutions as PvPI collaborating centres for research based pharmacovigilance in the field appended below: 1. National Institute of Epidemiology (NIE), Chennai-

			for Pharmacoepidemiology and data management platforms 2. National Institute of Nutrition (NIN), Hyderabad- for Nutraceuticals safety monitoring 3. National Institute of Malaria Research (NIMR), Delhi- for safety of anti-Malarial drugs 4. National AIDS Research Institute (NARI), Pune- for monitoring the safety of anti-HIV/AIDS drugs 5. National Institute for Research in Reproductive Health (NIRRH), Mumbai- for safety monitoring of reproductive drugs and devices 6. National Institute of Cholera & Enteric Diseases (NICED), Kolkata- for safety monitoring of vaccines and drugs used in Communicable Diseases 7. National Institute for Research in Tuberculosis (NIRT), Chennai- for Research in Tuberculosis
9	Interactive Meeting with Scientists of NDDTC, Ghaziabad	As directed by Secretary-cum-Scientific Director-IPC, NCC-PvPI organised meeting with Dr. Atul Ambekar, Professor-NDDTC, Ghaziabad 29th July 2016 at IPC, Ghaziabad.	The outcome of this meeting. • NCC-PvPI & NDDTC centre agreed to bridge the gap between AMCs under PvPI & Drug Addiction Treatment Centres under NDDTC. • NDDTC recommended PvPI to organise orientation programme for 05 Drug Addiction treatment centres of PGIMER, Chandigarh, NIMHANS, Bengaluru, KEM, Mumbai, RIMS, Imphal & KGM, Imphal at NCR, New Delhi on 13th September 2016. • PvPI recommended NDDTC to monitor the drugs causing the dependence as ADRs indentified from PvPI database & to make prevention plans for the same.