Indian Pharmacopoeia Commission

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

Monthly Progress Report- April 2016

S. No	Title of Activity	Description	Major Outcomes/Action Taken
1.	Data collation and processing of ICSRs	During the index period NCC received 5177 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.	Five years of Indian Pharmacopoeia Commission's commitment as National Coordination Centre for Pharmacovigilance Programme of India	In order to mark the event as "PvPI appraisal and way forward" a meeting was organized on 14th April 2016 at India Habitat Centre, New Delhi.	Officials from Ministry of Health & Family Welfare and Chemicals & Fertilizers appraised work done by PvPI, IPC & agenda for the next five years was discussed. During the event 23 new AMCs were launched in which 2 specialised hospitals for focused Pharmacovigilance were identified, those are 1. National Drugs Dependence Treatment Centre (NDDTC), Ghaziabad. 2. Institute of Liver & Billiary Diseases, New Delhi During the event Medical Device Adverse Event (MDAE) reporting Form for Materiovigilance Programme of India and Pamphlet on "Achievements and Road map for PvPI"

			were also released.
3.	Meeting to Reconstitute the Quality Review Panel under PvPI	IPC organized a meeting with Quality Review Panel (QRP) members of the PvPI to reconstitute the existing QRP on 21st April at IPC, Ghaziabad	Dr. S.K. Gupta, Chaiman-QRP, Dr. C. Aditan, Sr. Member-QRP suggested to reconstitute the QRP & proposed QRP need to composed of at least 30% experts from industry (from Pharmacovigilance domain), 30% of Clinical experts and 40% Pharmacologists from AMCs, accordingly the proposed new QRP consist of 11 members in total & needs to be submitted for DCG(I), CDSCO for approval.
4.	Orientation program on Pharmacovigilance & PvPI at NDDTC, Ghaziabad	Officials from PvPI, IPC was conducted orientation program on Pharmacovigilance & PvPI to the medical fraternity of the NDDTC, Ghaziabad on 22nd April,2016	During this orientation program, medical fraternity were briefed on basic concepts of Pharmacovigilance & current status of PvPI, hands on training in filling the suspected ADR reporting form, mode of communication in reporting of ADRs to PvPI.
5.	Visit of FDA, Ghana delegation to IPC	Officials from FDA, Ghana visited IPC on 25th April 2016.	Officials were briefed on the Current status of PvPI & its (Qualitative, Quantitative, Scientific) contribution to WHO-UMC were explained along with its recommendations to CDSCO, India.
6.	Preliminary meeting with Director-Institute of Liver & Billiary Diseases, New Delhi	As directed by Secretary-cum-Scientific Director, Officials of PvPI had a meeting with Director-ILBS, New Delhi on 26th April 2016	Officials from PvPI briefed on the scope to the staff of clinical research department for the drugs being used in liver & Billiary diseases as focused Pharmacovigilance as an ADR monitoring centre
7.	2nd Interactive session on Challenges and issues in ADRs reporting by Pharmaceutical Industries to PvPI	IPC organised 2nd Interactive session on Challenges and issues in ADRs reporting by Pharmaceutical Industries to PvPI meeting on 29th April 2016 at IPC, Ghaziabad	During this meeting total 60 participants attended from various industries & Officials from CDSCO chaired the session. The major outcome of this meeting as follows. • MAHs instructed to provide their Package Insert leaflet

			to be made available on company website. • Industries need to implement/develop a system for alignment of databases for PSUR reporting in XML ICH E2B Format with in 15days. • Accessibility of information available on website of MAHs (HCPs/Consumers) for PIL. • Marketing authorization holder's responsibility to report ADR reporting in case of Contract manufacturing of Pharmaceutical Products. • MAHs are instructed to focus on new AE of new products. • Industries are requested to improve the quality of Reports and focus on causality assessment. • Reporting from Medical representatives of MAHs. • Focusing on unlabelled ADRs of the drugs. • Inclusion of follow up cases in ADR reporting App. • Signal monitoring system at the level of MAHs. • Helpline no. to be promotable by MAHs by medical representatives of the Ph. Companies. The received reports will be validated from the companies. • Development of a system of signal monitoring system at the level of MAHs. • Committee to be constituted for Good Pharmacovigilance practices.