Indian Pharmacopoeia Commission

National Coordination Centre (NCC) – Pharmacovigilance & Materiovigilance Programme of India (NCC-PvPI& MvPI)

A) PvPI Monthly Progress Report- May 2017

Sr. No.	Title of Activity	Description	Major Outcomes/Action Taken
1	Data collation and processing of ICSRs	During the index period, NCC received 6200 ICSRs from AMCs/ Pharmaceutical industries/ consumers. The reported cases are under assessment for completeness, listed/ unlisted and clinical relevance.	The reported ICSRs are being assessed for the completeness and quality for further process under medical/clinical review. Lack of quality/incomplete reports will be reverted back to the reporter for further necessary action.
2	3rd Skill Development Programme on Basics & Regulatory Aspects of Pharmacovigilance	3rd Skill development Programme on Basics & Regulatory Aspects of Pharmacovigilance was conducted by NCC-PvPI from 1st to 10th May 2017 at IPC, Ghaziabad	The programme was inaugurated by Professor Ramesh K Goyal, Vice Chancellor, Delhi Institute of Pharmaceutical Sciences & Research University, New Delhi and Lt Dr Praful Mohan, Assistant Professor-Department of Pharmacology, Armed Forces Medical College, Pune, attended as chief guest. 45 participants from Tamil nadu, Madhya Pradesh, Haryana, Meghalaya, Nagaland & Puducherry attended this skill development programme.
3	Visit of Mr. Nana Ansah Adjei to IPC, Ghaziabad	Mr. Nana Ansah Adjei, Senior Regulatory Officer & Regional Pharmacovigilance Officer, Food and	During his visit to IPC, Mr. Nana familiarised with the new achievements & updates of NCC-PvPI and also delivered a lecture on “Pharmacovigilance experience

		Drugs Authority, Ghana, West Africa visited IPC, Ghaziabad, on May 3, 2017.	in Ghana" to the participants of 3rd Skill Development Programme on Basics & Regulatory Aspects of Pharmacovigilance and interacted with staff of NCC-PvPI & participants.
4	Induction Programme for Assistant Drug Inspectors (ADIs) to upgrade technical, professional & other functional skills	Central Drugs Standard Control Organisation (CDSCO), New Delhi started Induction Programme for Assistant Drug Inspectors (ADIs) to upgrade technical, professional & other functional skills from March 8, 2017 to June 7, 2017 at National Institute of Biologicals, Noida.	During this Induction Programme, Dr. V. Kalaiselvan, Principal Scientific Officer, Officer I/c-PvPI gave a presentation on "Overview of Pharmacovigilance Programme of India" on dated 04th May 2017.
5	Guest Lecture on Pharmacovigilance	Officials from NCC-PvPI delivered a lecture on Pharmacovigilance at PDM College of Pharmacy, Bahadurgarh, Haryana on May 5, 2017	Dr. V. Kalaiselvan, Principal Scientific Officer, Officer I/c-PvPI gave an "Overview of Pharmacovigilance Programme of India".
6	Meeting with National President, Indian Medical Association (IMA), New Delhi.	Officials from NCC-PvPI had a meeting with Dr K K Agarwal, National President, Indian Medical Association (IMA), New Delhi, to discuss the issues related to PvPI & MvPI, at IMA House, New Delhi, on May 5, 2017.	Dr Prasad Thota, Scientific Assistant, NCC-PvPI, met Dr K K Agarwal & requested him to nominate one Cardiologist & one Orthopaedician) from IMA, New Delhi, to work as expert in Core Technical Committee (CTC) of MvPI.
7	Meeting with AS & DG CGHS, New Delhi	Officials of NCC-PvPI had a meeting with AS & DG (CGHS) at Nirman Bhawan,	Dr. V. Kalaiselvan, Principal Scientific Officer, Officer I/c-PvPI invited AS & DG-CGHS, New Delhi for

		New Delhi on 09/05/2017	"Setting up a Pharmacovigilance system in Govt. Drug supply Chain".
8	7th Standard Finance Committee (SFC) meeting of IPC	Dr. V. Kalaiselvan, Principal Scientific Officer, Officer I/c-PvPI attended to 7th Standard Finance Committee meeting of IPC held at Nirman Bhawan, New Delhi on 09/05/2017	The major outcomes of this meeting as follows: • Committee recommended to appoint senior technical personnel (Consultant @ Rs.50, 000/Month & Senior Consultant Rs.80, 000 to 1,00,000/Month) to ensure smooth functioning of MvPI. • SFC in principle approved for the expenditure incurred for executing PvPI being reimbursed by CDSCO under provisional services. • Committee noted & reviewed expenditure for the financial year 2016-17 & Appraisal budgetary expenditure 2017-18 in respect of PvPI.
9	USP Chief Scientific Officer with USP-India team visits IPC	USP Chief Scientific Officer, Dr Jaap Venema, with USP-India officials Dr Sameer Navalgund and Ms Sireesha Yadlapalli visited IPC on 15/05/2017	The visiting team has first-hand experience of various scientific activities/mandates undertaken at the IPC. Principal Scientific Officer & Officer I/c-PvPI, Dr V Kalaiselvan, briefs the experts on the achievements of NCC-PvPI & its contribution to WHO-UMC
10	9th Working Group Meeting of PvPI	9th Working Group meeting of PvPI held at CDSCO, FDA Bhawan, New Delhi, on 16/05/2017	Major outcome of the meeting: 1. Members reviewed the performance of 20 AMCs & decided to delist 05 AMCs & suggested that a showcause notice be sent to 15 AMCs. 2. Members reviewed the proposals received from

			45 Medical Colleges & District Hospitals to enrol them as AMCs under PvPI. Of the 45 proposals, members recommended to enrol 41 as new AMCs under PvPI. 3. Members recommended to share with them the draft copy of the PvPI Guidance Document, Version 1.2, for further suggestions & approval. 4. Members appreciated and approved of the suggestion by NCC-PvPI to draft a standard text book on Pharmacovigilance with the recommendation to include two below-mentioned chapters in addition to the proposed chapters in the proposed book. - Role of Clinician in ADR reporting - Role of Pharmaceutical industries in ADR reporting.
11	10th SRP meeting of PvPI	10th SRP meeting of PvPI held at CDSCO, FDA Bhawan, New Delhi, on 16/05/2017	Major outcome of the meeting: 1. Members reviewed 15 ICSRs of Sulfasalazine-related Stevens Johnson Syndrome & 7 ICSRs for Sulfasalazine-associated toxic epidermal Necrolysis. They recommended that the PvPI suggests to the CDSCO to incorporate Sulfasalazine- associated Stevens Johnson Syndrome & toxic epidermal necrolysis into the package inserts of the drug being marketed in

			India. 2. Members reviewed 13 ICSRs of Meropenem-associated hypokalaemia received by NCC-PvPI & suggested PvPI to keep a watch on Meropenem-associated hypokalaemia and collect more such reports for data strengthening. 3. Members reviewed 15 ICSRs of Phenytoin-associated angioedema & 5 ICSRs of Phenytoin-associated Osteoporosis received by NCC-PvPI & suggested PvPI to keep a watch on Phenytoin-associated angioedema & Osteoporosis and collect more such reports for data strengthening. 4. Members recommended to PvPI that no action was required on Amoxicillin + Clavulanate-associated Anaphylactic Shock.
12	Workshop-cum-training programme on Pharmacovigilance for the NABH-accredited hospitals of Delhi-NCR	NCC-PvPI, IPC & NABH-Quality Council of India, New Delhi, organised a Workshop-cum-training programme on Pharmacovigilance for the NABH-accredited hospitals of Delhi-NCR on 18/05/2017	Dr B K Rana, Director, NABH, shared his experiences and emphasized the need for Pharmacovigilance in NABH-accredited hospitals. Dr V Kalaiselvan, Principal Scientific Officer & Officer I/c-PvPI, gave an overview of the basics and the PvPI activities at NCC-PvPI, IPC. Dr Pooja Gupta, Assistant Professor, AIIMS, New Delhi, delivered a presentation on "Issues and Challenges for setting up of a Pharmacovigilance System in hospitals". The technical staff of NCC-PvPI submitted a presentation, outlining the methodologies and filling-up of ADR reporting forms.

			The following additional Points were also discussed during the workshop-cum-training programme: 1. Dr Harish Nadkarni, CEO, NABH, agreed to the use of suspected ADR reporting form of PvPI for all NABH-accredited hospitals for reporting of Adverse Event/Adverse Drug Reaction to ensure Pharmacovigilance practices in NABH-accredited hospitals are carried out satisfactorily. 2. NABH staff will be made aware that ADR reporting to PvPI will be considered as one of the requirements for accreditation of hospitals. 3. It was decided that the next workshop-cum-training programme for NABH-accredited hospitals of Tamil Nadu may be conducted at Vadamalyan Hospitals, No. 9 A, Vallabhai Road, Chikkikulum, Maduraion 13th June 2017.
13	Meeting with officials of WHO-Country Office (India)	NCC-PvPI Officials had a meeting with officials of WHO-Country Office (India) at WHO-Country office, New Delhi, on 18/05/2017	NCC-PvPI and WHO-India officials discussed with WHO-Netherlands Supply Chain Management consultant Dr Frans Stobbelaar, the essence of "Pharmacovigilance and the Emerging Issues".
14	Hands-on training to Assistant Drug Inspectors	NCC-PvPI organised a training session for Batch-A of Assistant Drug Inspectors of CDSCO, New Delhi, at IPC,	During this session Assistant Drug Inspectors were imparted training on various technical aspects like VigiFlow-Hands-on experience on ICSR processing,

		Ghaziabad, on 18/05/2017	causality assessment; duplicate checking of ICSRs, and quantitative signal detection from VigiLyze tool of WHO-UMC.
15	Meeting with Officials of IMA, HQ, New Delhi	Dr V Kalaiselvan, Principal Scientific Officer & Officer I/c-PvPI, had a meeting with National President & Honorary Secretary General, IMA, HQ, New Delhi, on 19/05/2017	Dr V Kalaiselvan, Principal Scientific Officer & Officer I/c-PvPI, gave to National President & Honorary Secretary General, IMA, HQ, New Delhi, an update on recent activities undertaken at NCC-PvPI.
16	"Setting up a Pharmacovigilance system in Govt. Drug supply Chain"	NCC-PvPI organised a meeting on "Setting up a Pharmacovigilance system in Govt. Drug supply Chain" at IPC, Ghaziabad on 22/05/2017	Dr. Y. K. Gupta, National Scientific-Coordinator PvPI chaired this meeting Dr. R.K. Agarwal, Dir. (Proc & QC), Pradhan Mantri Bharatiya Jan Aushadhi Pariyojna (PMBJP), New Delhi, Dr. Deepak Saxena from Employees' State Insurance Corporation , New Delhi, Mr. Suresh Singh from Central Medical Services Society, New Delhi were attended in this meeting & the major recommendations of this meeting as follows: a. Clarity on this subject: Roles and responsibilities/accountabilities of the stakeholders to be defined without duplicating the efforts, modalities to be worked out. b. Sensitization of the staff of supply chain on Pharmacovigilance. c. In an initial phase, cohort areas such as malaria, tuberculosis, HIV, vaccination, and antibiotics to be covered.

			d. A proposal to be submitted to the MoHFW for enforcement of ADR monitoring by the CGHS, hence the need for upgradation of the CGHS tool by incorporating the facility of ADR reporting, also to link CGHS and Jan Aushadhi with PvPI. e. Community Pharmacists engaged with the Jan Aushadhi require to be trained by the AMCs of their region. f. NCC-PvPI will send an ADR notification form (draft) for necessary action at the level of Jan Aushadhi. They are suggested to enclose this notification form with the prescription to facilitate the ADR reporting. g. The chairman appreciated the need for pharma waste management to avert any environmental degradation fraught with health hazards to human and animal life.
17	1st meeting on Intensive Drug Monitoring Programme under PvPI	NCC-PvPI organised 1st meeting on Intensive Drug Monitoring Programme under PvPI at IPC, Ghaziabad on 24/05/2017	This meeting was chaired by Professor Ramesh Kumar Goyal, Vice-chancellor, Delhi Institute of Pharmaceutical Sciences & Research University, New Delhi (DIPSARU). The important outcomes of this meeting as follows: 1. Institute of Liver & Billiary Sciences was identified for intensive drug monitoring on sofosbuvir drug. 2. Madras Medical College (Chennai), Maharshi

			Markendeya University (Mullana), KIET school of Pharmacy (Ghaziabad) & DIPSARU (Delhi) were identified for intensive drug monitoring for SGLT2 Inhibitors (Canagliflozin, Emphagliflozin & Dapagliflozin) & Pioglitazone drugs.
18	Hands on training to Assistant Drug Inspectors	NCC-PvPI organised a training session to Batch-B of Assistant Drug Inspectors of CDSCO, New Delhi at IPC, Ghaziabad on 25/05/2017	During this training session Assistant drug inspectors trained on various technical aspects like VigiFlow-Hands on experience on ICSR processing, causality assessment; duplicate checking of ICSRs, and quantitative signal detection from VigiLyze tool of WHO-UMC.
19	Teleconference with Ms. Noha Iessa, Safety and Vigilance Medicines Safety, WHO-HQ, Geneva	Dr. V. Kalaiselvan, Principal Scientific Officer & Officer I/C had a teleconference meeting with Ms. Noha Iessa, Safety and Vigilance Medicines Safety, WHO-HQ, Geneva at IPC, Ghaziabad on 25/05/2017	During this teleconference Dr. V. Kalaiselvan, Principal Scientific Officer & Officer I/C had emphasised on recent activities undertaken at NCC-PvPI in the following divisions Training & Education, National Health Programmes-special emphasis on Bedaquiline-Cohort Event Monitoring Reporting under PvPI, Marketing Authorization Holders.
20	First executive committee meeting for engagement of research staff in PvPI	NCC-PvPI, IPC conducted First executive committee meeting for engagement of research staff in PvPI at IPC, Ghaziabad on 26/05/2017.	The committee members reviewed the draft proposals of the NCC-PvPI for engagement of research staff in PvPI & recommended the following: • Recommended to advertise & recruit 15 research trainee posts up to July 2017 • Approved to provide partial scholarship (drug safety research fellowship) to 15 research trainees

			@ Rs.20,000/9 months (1st term after joining of 4 months & 2nd term at 9th Month of joining) • Suggested this proposal help Pharmacovigilance research at minimum cost & should greatly benefit to NCC-PvPI in terms of providing research.
21	35th Scientific Body Meeting of IPC	35th Scientific Body Meeting of IPC was held at IPC, Ghaziabad on 27/05/2017	Members of Scientific Body approved the following PvPI related matters: • All the vigilance activities related to the following medicinal products should work under the umbrella of PvPI. 1) Medicinal drugs 2) Vaccines 3) rDNA products 4) Phytopharmaceuticals 5) Radio pharmaceuticals 6) Blood and Blood Related Products 7) Medical Devices (Notified) • Revenue generation models for self sustainability of PvPI 1. Annual Pharmacovigilance fee/levy charges from MAHs 2. Certification for Pv System at MAHs

B) MvPI Monthly Progress Report- May 2017

Sr. No.	Title of Activity	Description	Major Outcomes/Action Taken
1.	Data collation and processing of MDAE reports	During the index period, NCC received 20 MDAE reports from AMCs/MDMCs/ Pharmaceutical industries/ consumers. The reported cases are under assessment for completeness.	The reported MDAE reports are being assessed for the completeness and quality for further process under medical/clinical review. Lack of quality/incomplete reports will be reverted back to the reporter for further necessary action.
2.	Progress review meeting with MvPI Partners	A progress review meeting with MvPI Partners was held on May 3, 2017	The progress review meeting was attended by the representative from SCTIMST, NHSRC, CDSCO & IPC. The outcome of the meeting is as follows: • The members suggested IPC to take up the responsibilities of root cause analysis. • Member suggested to IPC to get reports through vigiFlow and to provide software training to Research Associates posted at MDMCs. • Partners suggested IPC to organise interactive session with Medical Device Manufacturers/Associations • Partners emphasised to upload the MvPI Guidance document (Version 1.0) on website • The recruitment rules for the post of Medical Device Safety and Wellness Analyst was prepared

			in consultation with NHSRC, SCTIMST & CDSCO officials.
3.	Incorporation of MvPI activates in PvPI News Letter	A write up has been incorporated in PvPI Newsletter for MvPI activities performed during the period.	Published in Volume 7, issue 18 of PvPI news letter
4.	Circular from Secretary-cum-Scientific Director, IPC to all AMCs to start reporting Medical Device Adverse Events	A circular was issued by Secretary-cum-Scientific Director, IPC, to all AMCs to start reporting through VigiFlow.	It was instructed to all AMCs/Pharmacovigilance Associates are hereby directed to coordinate with biomedical engineering/cardiac/orthopaedic departments etc. of their respective AMCs and report Medical Device Adverse Events on day to day basis with immediate effect.