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

PvPI Monthly Progress Report- March 2017

Sr. No.	Title of Activity	Description	Major Outcomes/Action Taken
1	Data collation and processing of ICSRs	During the index period, NCC received 6134 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	2nd Skill Development Programme on Basics & Regulatory Aspects of Pharmacovigilance	2nd Skill development Programme on Basics & Regulatory Aspects of Pharmacovigilance was held by NCC-PvPI on 1st March 2017 at IPC, Ghaziabad	The programme was inaugurated by Shri. Anshul saxena, Director- NOS Development & Curriculum Advisory Life Sciences Sector Skill Development Council (NSSSDC) and welcomed NCC to have Memorandum of understanding with NSD for the following areas. 1. To organise a joint training programme by NCC & NSSSDC for Medical Representatives to enhance their knowledge. 2. To organise Zone Wise Pharmacovigilance Training for Medical Representatives as a pilot study in the NCR, New Delhi region. 3. ADR reporting to PvPI shall be considered in National Standards for Pharmacovigilance to be finalised in September 2017 by NSSSDC

			4. To invite officials from Confederation of Indian Pharmaceutical Industry, New Delhi to start Pharmacovigilance training at various zones to initiate ADR reporting to PvPI from Medium, Small & Micro Pharmaceutical Industries.
3	International forum on Patient Safety and Access to Safe Online Pharmacies	International Forum on Patient Safety And Access to Safe Online Pharmacies organised on 1-2nd March 2017 at India Habitat Centre, New Delhi	Officials from NCC-PvPI have attended this meeting and Dr. V. Kalaiselvan, Principl Scientific Officer, Officer I/c-PvPI received "Effective Drug Regulatory Official of the year 2016" a award from Ms. Madhulika Sukul, Additional Secretary, Ministry of Consumer Affairs, Govt of India & Mr. Bejon Mishra-Founder Director, Partnership for Safe Medicine
4	Interactive meeting with M/s. Roche Pharma	Interactive meeting on improving the quality and upload error issue of ICSRs received from M/s Roche Pharma was held by NCC on 3rd March 2017 at IPC, Ghaziabad	Ms. Seema Shimpi, Associate Director-Regulatory Affairs & Ms. Nidhi Vaish Das, Drug Safety Manager were nominated by Roche, Pharma to attend this meeting. The following items were discussed in the meeting. 1. Discussion on upload error issue in reporting of ICSRs (E2B-xml format) & quality of the ICSRs. 2. VigiGrade Completeness Score of ICSRs at WHO-UMC and its status in India during the last 6 years.
5	5th National Conference of Pharmacoeconomics and Outcomes Research	Delhi Pharmaceutical Sciences & Research University (DPSRU) organised 5th National Conference of Pharmacoeconomics and Outcomes Research on 03 & 4th March 2017 at DPSRU, New Delhi	The outcome of this conference is as under:- 1. Officials of NCC delivered a talk on "Pharmacovigilance & ADR reporting to PvPI" on 4th March 2017 at DPSRU. 2. Discussed with Dean, Vice Chancellor-DPSRU, for inclusion of Pv & PvPI in Memorandum of

			Understanding between IPC and DPSRU.
6	Internal meeting with Finance & Accounts Officer and Administrative Officer of Indian Pharmacopoeia Commission	Officer I/c had a meeting with Finance & Accounts Officer & Administrative officer of IPC, Ghaziabad on 6th March 2017 at IPC, Ghaziabad.	During this meeting the following agenda items were discussed and those outcomes are as follows : • Posting of permanent staff in PvPI division of IPC. Presently 3 permanent staff of IPC are deputed in PvPI. As the activities of PvPI have increased considerably, PvPI demanded posting of 6 more permanent staff to cope up with the increased work load- FAO & AO (i/c) assured to take up this matter with the Competent Authority to post permanent staff in PvPI at the earliest. • Salary Revision of Pharmacovigilance Associates and Senior Pharmacovigilance Associates. Presently Pharmacovigilance Associates are paid a consolidated amount of Rs. 25.000/-pm and Senior Pharmacovigilance Associates are getting Rs.30,000/-pm which is very less when compared to the technical staff working in CDSCO. • Vacancies of Pharmacovigilance Officers, PvAs, State Immunization Patient Safety Associates & District Immunization Patient Safety Associates has been advertised in Employment News- The Committee reviewed the RR for the post of PVO and suggested to revise the RR as under;

			Age limit: 40 years, Experience: 5 years in which 2 years experience in Managerial capacity. • Further it was decided to advertise 4 vacancies of PvOs and 90 post of PvAs, 10 post of State Immunization Patient Safety Associate & 40 post of District Immunization Patient Safety Associates in the Employment News immediately. • To ensure punctuality and accountability of employees working in AMCs by introducing Biometric attendance system. To install the Biometric attendance system in all AMCs the Coordinators are designated to identify a dedicated PC for the attendance purpose only. • Contractual staff working in PvPI to attend National and International conference/workshop/training- The contractual staff who are interested to apply to attend any conference/workshop/ training they should inform Admin at least 15 days in advance for approval of the Competent Authority.
7	AEFI-Monthly Coordination PV Partners meeting	AEFI-Monthly Coordination PV Partners meeting was held on 7th March 2017 at Nirman Bhawan, New Delhi	During this meeting the following agenda items were discussed. • Use of PvPI toll free helpline for AEFI reporting • Inclusion of reporting of AEFIs in NABH • Sharing of vaccine cases (inline listing format) between AEFI and PvPI on monthly basis. • Status of SISPA and DISPA hiring

			• Weekly assistance from AEFI Secretariat for short-listing of candidates for the posts of SPSPvAs & DPSPvAs • Sharing of contact information (mobile number) of all staff of AEFI Secretariat and CDSCO for regular message alert. The outcome of this meeting as follows: • PvPI officials requested AEFI-Secretariat to nominate officials from AEFI-Division to review and shortlist the applications received for the posts of SPSPvAs & DPSPvAs and AEFI-Secretariat agreed for the same. • AEFI-Secretariat agreed in promoting PvPI-Helpline facility for reporting of vaccine AEFI
8	23rd Quality Improvement Programme on "Update on trends in Pharmaceutical Sciences" by Delhi Pharmaceutical Sciences & Research University (DPSRU)	Delhi Pharmaceutical Sciences & Research University (DPSRU) organised its 23rd Quality Improvement Programme on "Update on trends in Pharmaceutical Sciences" on 7th March 2017 at DPSRU, New Delhi.	Dr. V. Kalaiselvan, Principal Scientific Officer, Officer I/c-PvPI, IPC had attended this programme as a resource person and interacted with Faculty and staff of DPSRU & emphasised on "Initiatives of PvPI". To engage research staff in PvPI, Officer I/c also discussed with staff of department of Regulatory Affairs, DPSRU.
9	Meeting with Dr. P. Das Gupta, Former-DCG (I)	As directed by Secretary-cum-Scientific Director, Dr. V. Kalaiselvan, Principal Scientific Officer, Officer I/c-PvPI, IPC had a meeting with Dr. Das Gupta, Former-DCG (I) on 8th March 2017 at IPC, Ghaziabad.	The Drugs Controller General (India) desired that Pharmacovigilance activities must be strengthened in India so as to improve patient safety. In this reference, Dr. P. Das Gupta, Former-DCG (I) visited National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC), Ghaziabad on 8th March for experiencing overall activities undertaken

			by PvPI. He shared his insight on strengthening the Pharmacovigilance in India with officials of PvPI. Suggested that there must exist a stable Pharmacovigilance programme so that its recommendations may be used in bolstering the regulatory decisions. Also commented on gaps in existing rules and addressed on the areas through which the Pharmacovigilance may be strengthened in India. Recommendations as under:- 1. Representation of Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India in the Drug Technical Advisory Board (DTAB)- Members of DTAB comprising of various disciplines, institutes or laboratories and DTAB have a mandate to advise the Central Government and the State Governments on technical matters arising out of the administration of Drugs & Cosmetics Act (hereinafter the Act) and to carry out the other functions assigned to it by the Act. The work done by NCC-PvPI, IPC has a direct regulatory bearing on decisions made by DTAB. Hence, IPC-PvPI may be made a member in the DTAB by necessary Notification. 2. Strengthening of Benefit-Risk Assessment-The Indian Safety data is recorded through a guided system of Pharmacovigilance by IPC, audited by World Health Organization (WHO) from time to

			time. Benefit-Risk Assessment constitute an important balance for consideration by Regulatory Authority, particularly, in the field of New Drugs as data on safety and efficacy continue to emerge right from animal experimentation to human studies. Therefore, there is a need for strong Benefit-Risk Assessment system. 3. Assisting Central Drugs Standard Control Organization (CDSCO) in Pharmacovigilance inspection. 4. Revisiting guidance document for Marketing Authorization Holders (MAH).
10	Meeting with Pharma-Marketing Authorization Holders	As directed by Drugs Controller General (India), Dr. V. Kalaiselvan, Principal Scientific Officer, Officer I/c-PvPI, IPC had attended to a meeting on 8th March 2017at CDSCO, New Delhi with Pharma-Marketing Authorization Holders	Dr. V. Kalaiselvan, Principal Scientific Officer, Officer I/c-PvPI, IPC emphasised on the current status & significance of ADRs being reported by MAH's to PvPI.
11	Interactive Meeting with M/s. Astrazeneca Pharma India, Bengaluru	Dr. V. Kalaiselvan, Principal Scientific Officer, Officer I/c-PvPI, IPC had an interactive meeting with representatives from M/s. Astrazeneca Pharma, Bengaluru on 9th March 2017 at IPC, Ghaziabad	Dr. Nagaraju-Head, Regulatory Affairs & Patient Safety, Astrazeneca-India and Mr. Zulfikar attended this meeting & discussed on the possibilities to train the medical representatives of Astrazeneca on ADR reporting, Pharmacovigilance & PvPI.
12	Concluding Meeting of Skill development programme on Basics & Regulatory Aspects of Pharmacovigilance	Closing Meeting of Skill development programme on Basics & Regulatory Aspects of Pharmacovigilance on 10th March 2017 at IPC, Ghaziabad.	a. Participants were made to ensure the effectiveness of Training Programme b. Feedback from Participants was obtained to understand discrepancies and scope for further improvement of training programme.

			c. Ms. Robina Bose, DDC (I), CDSCO attend the concluding meeting
13	Meeting with Officials of CDAC	PvPI initiated the process to develop an India specific Pharmacovigilance IT tool in collaboration with Centre for Development of Advanced Computing (CDAC) & Meeting was held under the chairmanship of Mr. Chandrashekhar R, DDC(I), CDSCO on 14th March 2017 at IPC, Ghaziabad.	The CDAC team also attended the meeting to understand functioning of PvPI and data flow of WHO IT tools available at WHO UMC for Pharmacovigilance. During the meeting the following points have been suggested: 1. Decided to develop India specific IT tool for Pharmacovigilance activities which must be featured with reporting, collation, analysis, comparison, data mining and pharmacogenomics classifications. 2. It was decided to include the following features in IT tools for pharmacovigilance a. Ethnicity facility b. Integration with software used in National Health Program c. Integration with Electronic Health Record CDAC officials requested PvPI permission for visiting IPC for two days to get hands on experience on functioning of PvPI, in order to send the workable proposal.
14	Pv India Network Meeting	Pv India Net work Meeting was held at Mumbai on 16th March 2017	Dr. V. Kalaiselvan, Principal Scientific Officer, Officer–I/c participated in this meeting through teleconference. The outcome of this meeting as follows: 1. Pharmacovigilance Guidelines for Marketing Authorization Holders in India was emphasised

			and discussed. 2. Pv India Network committed to continue their support to PvPI
15	IPC-USP Convention partnership/MoU and Vision-2030 of IPC	IPC organised IPC-USP Convention partnership/MoU and Vision-2030 meeting of IPC on 17th March 2017 at IPC, Ghaziabad.	During Think Tank Meeting "PvPI way forward 2030" was discussed & members visited PvPI division of IPC, overviewed various activities of PvPI and appreciated the efforts of PvPI and to make the presence of PvPI program all over the country.
16	Visit of Dr. V. J. Somani, JDC (I), CDSCO	Dr. V. J. Somani-JDC (I), CDSCO, HQ visited IPC on 17th March 2017	Dr. V. J. Somani, JDC (I), CDSCO overviewed the functioning of various division of NCC-PvPI and experienced on the signals being detected at NCC-PvPI and he expressed satisfaction and appreciated the progress made by PvPI with in short span of time.
17	Meeting with President, Medical Council of India	A meeting with Dr. Jayshree Mehta, President-Medical Council of India was held on 20th March 2017 at MCI, New Delhi.	• MCI agreed to explore the possibilities of collection of adverse drug reactions & its reporting to PvPI by Medical Colleges to be kept as proposal in MCI Academic Committee and the decision of Academic Committee may be further put forth to Executive Committee and General Body of the Council. • Dr. Jayshree Mehta expressed her concern that PvPI may focus on research based Pharmacovigilance to ensure better patients safety outcomes. In this regard, she agreed to provide experts from across the country. • MCI suggested state-wise categorising non-reporting AMCs of PvPI for intimating to the respective Deans/Medical Superintendents of AMCs under PvPI as well as respective State Medical Councils for information & further

			necessary action.
18	Interactive session with Technical Team of CDAC	Interactive session with Technical Team of Centre for Development of Advanced Computing (CDAC) was held on 20th March 2017 at IPC, Ghaziabad	Ms. Payal & Mr. Anshu Jain from CDAC were experienced on the flow chart, data flow of ADRs from AMCs to NCC subsequently to WHO-UMC in India & also had experienced on the PvPI-VigiFlow-Individual Case Safety Management Tool & requested PvPI to send a request to WHO-UMC to get an access to WHO-Drug Dictionary Interface.
19	2nd Steering Committee & Working Group Meeting of MvPI	IPC organised 2nd Steering Committee & Working Group Meeting of MvPI on 21st Match 2017 at IPC, Ghaziabad	During the meeting the following agenda items were discussed. • MvPI partners roles and responsibilities • Guidance Document-Materiovigilance Programme of India • Medical Devices Adverse Event (MDAE) Monitoring Centres and identification of new MDMCs • Technical Resource Centre for centralised procurement of technical resource material (Journals, standards, books etc). • Scope for Constitution of Technical Panel for overall progress of the programme including quality, training & signal related issues, developing online MDAE reporting form; software tools to analyse report over a period of time- Data trend analytics at IPC • Creating awareness team for hosting MvPI awareness program across India & Collaborating with Hospital Association • Involvement of MAHs in voluntary reporting of

			Adverse Events • Strategies for data management system such as reporting, techniques to avoid duplication in report & analysis at each level, dedicated emails at the level of SCTIMST for Medical Devices Adverse Event (MDAE) monitoring & reporting. • Annual Financial Assistance to NHSRC, SCTIMST and MDMCs as per PvPI financial Guideline for AMCs • Progress for recruitment of 10 vacant posts of Research Associates • Future plan and challenges of the MvPI • HR/Administration related issues
20	Visit of Ms. Leena Menghaney, Regional Head-South Asia, Medicines Sans Frontieres to IPC, Ghaziabad on 21st March.	As directed by Secretary cum Scientific Director, IPC, Officials of PvPI held a meeting with Ms. Leena Menghaney, Regional Head-South Asia, Medicines Sans Frontieres on 21st March 2017	In order to reach the activities of PvPI to District, rural & urban level Dr. G. N. Singh, Secretary-cum-Scientific Director, IPC suggested to coordinate with NGO's. Ms. Leena Menghaney from MSF came forward and agreed to her full support to expand the activities of PvPI to district level
21	Interactive session with Technical Team of CDAC	Interactive session with Technical Team of CDAC was held on 23rd March 2017 at IPC, Ghaziabad.	Ms. Payal & Mr. Anshu Jain from CDAC were experienced on WHO-UMC tool i.e. VigiLyze, hands on experience on signal detection process of PvPI by using quantitative techniques i.e. Information Component in VigiLyze.
22	Meeting with Officials of CDSCO, New Delhi	Officials of PvPI held a meeting with Officials of CDSCO on 23rd March 2017 at CDSCO, New Delhi.	• Dr. V. Kalaselvan-Principal Scientific Officer Officer In charge, PvPI held a meeting with Mr. A. K. Pradhan, DDC (I), CDSCO, on 23rd March to discuss on allocation of fund to PvPI. • PvPI Management Review Meeting as per quality

			management system of PvPI is scheduled on 30/03/2017 at CDSCO, FDA Bhawan as recommended by Secretary-cum-Scientific Director. • Draft Memorandum of Understanding between PvPI, IPC & National Skill Development Corporation (NSDC) submitted to Mr. Rishikant-Legal Advisor, CDSCO
23	Meeting with Joint Secretary (Regulation), MoHFW	Officials of PvPI held a Meeting with Shri. K.L. Sharma, JS (R) on 23rd March 2017 at Nirman Bhawan, New Delhi	Shri. K. L. Sharma had reviewed the draft MoU between PvPI & NSDC and suggested the following: • Revenue generation model of PvPI should be initiated & implemented by incorporating the same in MoU. • Roles & Responsibilities of IPC & LSSSDC should be elaborated with regard to financial aspects in draft MoU.
24	Meeting with Officials of National Accreditation Board of Hospitals (NABH)	NABH-IPC-MoU follow up meeting was held on 23rd March 2017 at Nirman Bhawan, New Delhi	During this meeting the following items were discussed:- • Issue of circular to NABH accredited Hospitals for ADR reporting to PvPI • Appointment of Pharmacovigilance personnel at NABH Hospitals • Knowledge enhancement of NABH assessors on Pharmacovigilance • PvPI and NABH joint awareness programme on Pharmacovigilance for NABH accredited hospitals
25	Meeting with Mr. Sunil Malik, Print & Design studio	Meeting was held with Mr. Sunil Malik to discuss about designing and development of various resource materials of PvPI on 24th March 2017 at	• Decided to design and print a PvPI plan to expand its outreach to district level • Preparation of booklet to document the glimpses of IPC's 'Think Tank' Meeting held on 17th March

		IPC, Ghazibad	2017.
26	Stock taking of ADRs reported due to Bedaquiline (BDQ) at site	Dr. V. Kalaiselvan, Principal Scientific Officer Officer In charge, PvPI visited, Tambaram TB centre on 25th March 2017 one of a BDQ CAP initiated site to review the progress and stock taking of ADRs reported. He also visited to SRM Hospital on 26th March 2017 – one of an ADRs Monitoring Centres of PvPI	• Tambaram centre enrolled 65 MDR TB patients – administered with BDQ • Centre has kept all records and SOP related to PvPI • ADRs reports have been regularly communicated to PvPI • SRM Medical College reporting ADRs to PvPI, Since reporting is less, it was suggested to have a effective coordination with Clinical Departments, Dean and Medical Superintendent
27	First annual meeting of National AEFI Committee – 2017	First annual meeting of National AEFI Committee – 2017 was held at Hotel Holiday In, Panchkula, Haryana on 29th March 2017	Officials from Postgraduate Institute of Medical Education & Research, Chandigarh, AMC under PvPI attended to this meeting, during this meeting the following agenda items were discussed: • Update on National AEFI surveillance programm, training and AEFI reporting software, Causality Assessment of reported AEFI Cases, reported AEFI cases (2012-14)with inadequate information for causality assessment, Guidelines for ineligible cases for CA, Guidelines to accelerate cluster case investigations • Reviewed reports of AEFI death cases with Post mortem reports

28	Preliminary meeting for organising First Annual Meeting of South-East Asia Regulatory Network (SEARN)	Preliminary meeting held with Shri. Brijesh Kumar Sharma, Consultant-WHO, SEARO on 29th March 2017 at IPC, Ghaziabad.	During this meeting the documents (Specific activities in SEARN in Information Sharing platform & Specific activities in SEARN in Vigilance for medicinal products) needs to be submitted for organising First Annual Meeting of South-East Asia Regulatory Network (SEARN) was reviewed by Shri. Brijesh Kumar Sharma, Consultant-WHO, SEARO
29	1st Management review Meeting of IPC, NCC-PvPI	1st Management review Meeting of IPC, NCC-PvPI held to review a progress made in the financial year 2016-17 and an action plan for 2017-18 held at IPC, Ghaziabad on 30th March 2017.	The agenda items discussed and their outcomes of this meeting as follows:- • Promotional and Career Avenue for PvPI • PvPI may submit a proposal to CDSCO for the financial assistance to meet the expenditure incurred in running of PvPI • In order to strengthening PvPI activities, Secretary-cum- Scientific Director instructed Administrative Officer, IPC to recruit 50 Scientific staff (Salary 30000-80000) immediately. The recruitment process needs to be expedited. • The Financial queries of PvPI experts were discussed and Timely disbursement of TA, DA to experts of PvPI was instructed to Finance officer, IPC. • A meeting of PvPI officials to be arrange with Dr. K.K. Singh, Library and Publication officer, IPC, Sh. Chander Shekar, DDC, CDSCO, New

			Delhi, to discuss the matter of separate PvPI website launch, which is developed in-house by IT-team of PvPI. • Three Drugs Inspectors may be in-housed in IPC for two days in a week, in order to bridge the gap between IPC and CDSCO.
30	Surveillance Audit Visit of IPC by Quality Austria Central Asia Private Limited	Mr. Kaushik Laha & Mr. Sundeep Handa visited & audited IPC, Ghaziabad from Quality Austria, Central Asia Private Limited on 30th March 2017	During this audit the team auditors overviewed and experienced the overall functioning & various activities of NCC-PvPI.