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

A. PvPI Monthly Progress Report: March 2018

Sr. No.	Title of Activity	Description	Major Outcome/Action Taken
1.	Data collation and processing of ICSRs	During the index period, NCC-PvPI received 5792 ICSRs from AMCs/ pharmaceutical industries/consumers	The reported cases are under assessment for completeness, listed/unlisted and clinical relevance. Lack of quality/incomplete reports will be reverted to the reporter/sender for further necessary action.
2.	8th Skill Development Programme on Basics and Regulatory Aspects of Pharmacovigilance at NCC PvPI, IPC	PvPI organised Skill Development Programme on Basics and Regulatory aspects of Pharmacovigilance for the States/UTs of Punjab, West Bengal, Gujarat, Jharkhand, Daman & Diu, Andaman & Nicobar from 5th March, 2018 to14th March, 2018 at IPC, Ghaziabad.	• In this 10 days training, 17 participants attended the training programme • Participants acquired basic knowledge in Pharmacovigilance • Participants acquired the abilities to deliver good Pharmacovigilance- practices at par with international requirements • Participants visited AIIMS, Rishikesh which is functioning as AMCs and experienced working culture of AMC and ADR reporting were showcased.

			• Participants were given hands-on training on different modes of ADR-reporting.
3.	PV India Forum Meeting	Pharmacovigilance India Forum Meeting was conducted on 7th March, 2018 at ITC Maratha, Mumbai.	A meeting of Pharmacovigilance-India Forum was conducted on 7th March, 2018 at ITC Maratha, Mumbai. Mr. Pranay Kumar (Sr. Pharmacovigilance Associate) attended the said meeting and participated in the debate on "Continuing the PV change journey".
4.	Meeting on "Policy, Capacity building, Strengthening & Implementation of Pharmacovigilance" amongst officials of PvPI, CDSCO & USFDA	Meeting on "Policy, Capacity building, Strengthening & Implementation of Pharmacovigilance" amongst officials of PvPI, CDSCO & USFDA was held on 12th March, 2018 at Indian Pharmacopeia Commission	• Participants gained knowledge on both regulatory aspects of USFDA and CDSCO. • Compulsory evaluation of drugs after 18 months of approval can be adopted by the CDSCO. • An indigenous software may be develop for ADR reporting & data control • Enforcement for Gazette Notification compliance & to enhance ADR reporting from MAHs
5.	USFDA delegates visit to ADR Monitoring Centres (AMCs)	USFDA Delegates visited ADR Monitoring Centre-AIIMS-National Drugs Dependence Treatment Centre (NDDTC), Ghaziabad and Yashoda Hospital, Kaushambi, to understand Pharmacovigilance Activities in AMCs	• Mutual exchange of information between USFDA, CDSCO & PvPI on ADR reporting, Pharmacovigilance regulation current scenario and future prospects. • USFDA officials interacted with ADR

		on 13th March 2018.	monitoring team, which provided an opportunity to get an insight into whole PV activities that's occurring at AMC level. • USFDA officials gained knowledge about various ADR reporting tools available in India. • Prescription event monitoring is also one of the functions of AMC. • Detailed discussion on serious ICSR collected & reported at AMC.
6.	National AEFI Committee Meeting	National AEFI Committee Meeting was held on 13th March 2018 at Vivanta Hotel Ambassador, New Delhi. Mr. Pankaj Bhatt, Sr. Pharmacovigilance Associate attended the meeting.	• Causality assessment of all serious AEFI cases were discussed and evaluated with the team members of National AEFI committee members. • Draft SOP for generation of signals will be share by AEFI Sect. to PvPI & CDSCO for further inputs. • For PSUR, it was recommended to have benchmarks for PSUR meetings (4 to 6 meetings per year). There is need for developing SOPs for drug inspectors in the states regarding their role in AEFI surveillance.
7.	National Seminar on 'Pharmacovigilance Addressing the safety of patient in Madhya Pradesh through National	Mr. Tarani Prakash (Pharmacovigilance Associate) attended the National Seminar on 'Pharmacovigilance Addressing the safety of patient in Madhya Pradesh	• Spread awareness regarding activities of PvPI-IPC. • Participants gained knowledge and were trained on basic aspect of Pharmacovigilance • Participants interacted with and asked

	Pharmacovigilance Programme'	through National Pharmacovigilance Programme' on 16th March, 2018 at VNS Institute of Pharmacy, VNS Group, Ratibad, Bhopal.	about the procedure of joining PvPI trainings • Provided an opportunity to identify and improve the gap areas to enhance the ADR reporting. • Understand tools to integrate Pharmacovigilance activities involving pharmacy students.
8.	National workshop on "Good Pharmacovigilance Practices" by the PvPI, CDSCO & USFDA.	National workshop on "Good Pharmacovigilance Practices" by the PvPI, CDSCO & USFDA was held on 15th & 16th March 2018 at Scitech Centre, Mumbai.	• Participants gained knowledge on both regulatory aspects of USFDA and CDSCO. • USFDA officials interacted with the participants and answered the questions raised by the participants on regulatory system in US, causality assessment, challenges & issues they faced during aggregate reporting and signal generation. • Participants were keen to know about how to set up a good PV system in their organization and how to collect & report ADRs to PvPI. • Training for marketing professionals is essential to collect adverse events direct from physicians at hospital. • Detailed discussion on case studies held between participants and speakers. • Workshops on regular basis are demanded by the participants to perform good Pharmacovigilance practices in India.
9.	The Second Annual Meeting of South-East	The Second Annual Meeting of South-East Asia Regulatory Network (SEARN)	The Working Group 3- vigilance for medical products meeting was chaired by Dr. V. Kalaiselvan. The other Members of the Group

	Asia Regulatory Network (SEARN)	was held at Movenpick Hotel, Colombo, Sri Lanka on 21st -23rd March, 2018. Dr. V. Kalaiselvan, Principal Scientific Officer & Officer-In-charge, PvPI, IPC attended the said meeting.	were Mr. Imran from Indonesia; Ms. Aurus Kondphanich from Thailand; Mr. Gopi Krishantha from Sri Lanka and Mr. Pelden Chejor from Bhutan. This meeting was focused to review the progress made since 2017 and discussed the work plan for next two years. • SEARN provides a platform for India to play a lead role in Vigilance for medical products, • Mutual exchange of information – for better outcomes and good decision making process; • Mapping of resources – scope for ensuring cost effectiveness. **Action plan for the next two years was discussed as follows**: a. Information sharing – India to play a lead role, b. PV workshop/training – India to play a lead role, c. IPC-PvPI as a WHO CC to support SEARN countries in PV capacity building.

10.	One-day Workshop-cum-Training Programme	One-day Workshop-cum-Training Programme was scheduled at Vivekananda Polyclinic and Institute of Medical Sciences, Vivekananda Puram, Nirala Nagar, Lucknow on March 24th, 2018.	• This Training Programme provided a platform for the NABH-Accredited Hospitals of that region to understand the systems and procedures involved in ADR-reporting and relevant practices in Pharmacovigilance; • The faculties from ADR Monitoring Centres and NCC-PvPI provided hands-on training on the subject to the participants.
12.	12th Signal Review Panel Meeting	12th Signal Review Panel Meeting was held at IPC on 27th March, 2018.	A total of 15 Drug ADR combinations were reviewed by the Panel members out of which 8 Drug combinations were approved for the recommendations to CDSCO.
13.	Drug Safety Alert	During the index period the following Drug Alert were revealed: Suspected Drug: Cefixime Indication: For treatment of Otitis media, respiratory tract infections, uncomplicated UTIs, effective against infections caused by enterobacteriaceae, H. Influenza species Adverse Reaction: Skin Hyperpigmentation	These informations were communicated to the medical colleges, ADR Monitoring Centres and other healthcare professionals etc. Via SMS and updated in the website

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B. MvPI Monthly Progress Report- March 2018

Sr. No.	Title of Activity	Description	Major Outcomes/Action Taken
1.	Data collation and processing of MDAEs reports received at NCC-MvPI	During the index period, NCC-MvPI received 26 MDAE reports from AMCs/MDMCs/ Medical Device industries	The reported cases are under assessment for completeness, and clinical relevance. Lack of quality/incomplete reports will be reverted to the reporter/sender for further necessary action.
2.	Review/ Analysis of MDAE reports received at NCC-MvPI	MDAE reports received at NCC-MvPI were thoroughly reviewed and following cases were identified for further deliberation • DePuy ASR Hip Implants (J&J) – 127 Reports • Ultimaster- Sirolimus Eluting Coronary Stent System (Terumo India Pvt Ltd.) – 9 Reports • IUD Mirena (Bayer) – 18 Reports	To deliberate/ discuss the cases, first Core Technical Committee meeting is proposed to be held on 6th April 2018 to discuss the followings agenda: • Review of MDAE cases • Review of comments received from Medical device associations on Guidance Document-Materiovigilance Programme of India (Version 1.0) • Review of comments received from Medical device associations on Medical Devices Adverse Event Reporting Form (Version 1.0) • Review of various draft SOPs of MvPI

			• Discussion on expansion plan of MvPI • Discussion for strengthening of AMCs/MDMCs for AE/SAE reporting
3.	2nd Skill Development Programme- 2018 on Basics and regulatory Aspects of Pharmacovigilance	The programme was organised from 5-14th March 2018 at IPC, Ghaziabad. MvPI presentation was given by Ms. Ritu Jain, Research Associate, MvPI, IPC on 13.01.2018	More than 17 participants were aware and trained about what, where and how to report adverse event due to the use of medical devices and also had hands on training session for reporting MDAE form.
4.	Two days National Workshop on "Good Pharmacovigilance Practices' organized by IPC, NCC-PvPI in collaboration with CDSCO and USFDA.	Two days National Workshop on "Good Pharmacovigilance Practices' was held at Mumbai on 15-16 March 2018.	More than 135 participants were aware about the programme during panel discussion. Feedback received from the participants that a separate session on Materiovigilance may be provided in future workshops.

(Dr. V. Kalaiselvan)
Principal Scientific Officer

Secretary-cum-Scientific Director