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

A) PvPI Monthly Progress Report -- July 2017

Sr. No.	Title of Activity	Description	Major Outcome/Action Taken
1	Data collation and processing of ICSRs	During the index period, NCC received 5,388 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 completeness and quality under medical/clinical review. Lack of quality/incomplete reports will be reverted to the reporter for further necessary action.
2	Indo-European Summit	As instructed by Secretary-cum-Scientific Director, Dr. V. Kalaiselvan, Principal Scientific Officer, PvPI, attended a dinner-cum-interactive session with European delegates at India International Centre on 14/07/2017	During the dinner-cum-interactive session with the European delegates, Dr. V. Kalaiselvan, Principal Scientific Officer, PvPI, laid emphasis on the safety issues of sodium valproate used by pregnant women in India, raising awareness about the same through PvPI newsletter.
3	Brainstorming session among PvPI, CDSCO and subject experts on finalizing	NCC-PvPI organised a brainstorming session among PvPI, CDSCO and subject experts on finalizing Pharmacovigilance guidelines for MAHs'	Dr V. G. Somani, JDC (I), chaired the meeting & appreciated the stakeholders for their contribution in giving the document a final shape. The final draft was discussed threadbare by members and they

	Pharmacovigilance guidelines for MAHs	pharmaceutical products in India, at CDSCO, HQ, New Delhi, on July 18, 2017.	agreed upon all the modules contained in the document/s with minor modification/suggestions. The following points were suggested to be incorporated before release. 1. Causality assessment mentioned in the document should be made mandatory for the new drugs' manufacturers only and the generic manufacturers can submit their ICSRs without the causality assessment that will be taken care of by the PvPI. 2. A flow chart needs to be inserted at the end of the document. 3. The frequency of audit and inspection of MAHs may be minimized for those which have established an effective Pharmacovigilance system. 4. Preface needs to be rewritten.
4	Workshop-cum-training programme on Pharmacovigilance for NABH-accredited hospitals	NCC-PvPI, IPC, Ghaziabad, in coordination with NABH, Quality Council of India, New Delhi, organised a workshop-cum-training programme on Pharmacovigilance for NABH-accredited hospitals at CHL Group of Hospitals, Indore, on July 22, 2017	Twenty-six participants attended the training programme. The training was imparted on the following topics: • Basics of Pharmacovigilance and mandates and activities of NCC-PvPI • Monitoring and reporting of ADR (Methodology, forms and formats) • Setting up of a Pharmacovigilance system in NABH-accredited hospitals • Reporting of ICSRs through vigiflow • ADR reporting mobile app

5	Bedaquiline CAP review meeting	The BDQ CAP review meeting was held in New Delhi on 24-07-2017 & 25-07-2017 with the objectives of reviewing the status of implementation of BDQ CAP in five states, including Delhi, Gujarat, Assam, Maharashtra and Tamil Nadu, the conversion from sputum culture +ve to sputum culture –ve of BDQ, the AE/SAE identification and mechanism of management and the status of recording and reporting of CEM forms.	The session was inaugurated by Dr. V. S. Salhotra, ADDG TB. • All 6 BDQ CAP sites' coordinators/treating physicians had explained the actual situation under BDQ CAP programme records. They expressed the difficulties faced by them during the patient enrolment and data entry. • Dr. Padmapriya, NITRD, Chennai, expressed the deficiencies in data entry by Nikshay software of CTD. Data contained by PvPI vigiflow software has more ADR entries than those in the Nikshay, she added. Dr. Salhotra concluded the meeting with the following observations: • Bedaquiline is relatively safer for MDR and XDR TB patients with minimal ADR profile • Around 70 % of patients had turned from sputum culture +ve to sputum culture –ve which shows the efficacy of this drug. • The BDQ expanded programme is in the pipeline and should be rolled out which should target 8,800 MDR and XDR TB patients so that the Indian patients can be benefited. • Nikshay pending entries should be completed by August 15, 2017. • A pre-DSMC meeting is planned by the DSMC chair which should take place during 15th-22nd

			August 2017. All 6 BDQ CAP sites have been instructed to follow accordingly.
6	Publishing a standard textbook on Pharmacovigilance	Officials of NCC-PvPI, IPC, Ghaziabad, on 26/07/2017 had a meeting with Dr. S. K. Gupta, Professor Emeritus (Clinical Research), Delhi Pharmaceutical Sciences and Research University, New Delhi, to define the title and contents of the textbook on Pharmacovigilance.	Dr. S. K. Gupta chaired the meeting and proposed the following three titles for the book: "Essentials of Pharmacovigilance", "Basic Concepts of Pharmacovigilance" and "Pharmacovigilance for Safety Monitoring of Medicines". The other suggestions at the meetings were as follows: • Editor of the book will be Dr. G N Singh. • The book should focus on the basics of Pharmacovigilance. • It should contain the list of drugs banned worldwide and the reason for the ban be clearly explained. • In-house contribution in writing the chapters for the book should be maximized. • The book should be simple and comprehensive.
7	National AEFI Committee meeting	National AEFI Committee meeting was held at Hotel Park, Connaught Place, New Delhi, on 27/07/2017. Dr. V. Kalaiselvan, Principal Scientific Officer, PvPI, attended the meeting.	The committee members discussed the following items: 1. Update on Causality Assessment of reported serious AEFI cases 2. Update on Pharmacovigilance Programme of India 3. AEFI Reporting through PvPI Mobile App 4. Circulation of tollfree Helpline # for AEFI reporting at AMCs.

			Outcome of the meeting: 1. PvPI will support AEFI Secretariat for notification of all serious AEFI cases received through mobile app and Helpline. 2. Hands-on training for Mobile App was suggested for AEFI team 3. Draft pamphlet for AEFI reporting through tollfree Helpline discussed with AEFI Secretariat
8	Association of Radio Operators for India (AROI) on public awareness campaign of Pharmacovigilance Programme of India	Officials of NCC-PvPI, IPC, had a meeting with Association of Radio Operators for India (AROI) at Central Drugs Standard Control Organisation, FDA Bhawan, New Delhi, on 28/07/2017	Mr Uday Chawla, Secretary General, AROI, said that AROI with 300 operators in India has the potential to raise awareness about the essence and outreach of pharmacovigilance pan-India by infotainment programmes conducted by professional radio jockeys. Dr. G. N. Singh, DCG (I), concurred that it was a unique opportunity for NCC-PvPI to disseminate the information to masses about reporting of ADRs to PvPI. Outcome of the meeting: • AROI & NCC-PvPI, IPC, in principle agreed upon coordination for promoting pharmacovigilance as a national/social cause • Secretary-cum-Scientific Director suggested that MoHFW be informed for proposed inclusion of AROI as social media for promotion of PvPI • Recommended NCC-PvPI provide training to Radio Jockeys for promotion of Helpline and

			Mobile App at IPC, Ghaziabad • Suggested to send a letter to Ministry of Information and Broadcasting regarding availability and promotion of Helpline and Mobile App • Press release for Helpline and Mobile App be circulated • A pilot study be conducted for promotion of PvPI Helpline and Mobile App in Delhi-NCR region through AROI.

B) MvPI Monthly Progress Report – July 2017

Sr. No.	Title of Activity	Description	Major Outcome/Action Taken
1.	MvPI Partners' Meeting for Assessment of Medical Device Adverse Event (MDAE) reports & other MvPI-related issues.	A meeting was convened with MvPI partners for assessment of MDAE reports & other MvPI-related issues at NHSRC, New Delhi, on July 13, 2017.	The following issues were discussed: • Review of comments received from various stakeholders, medical device associations and medical device manufacturing industries on Guidance Document (Version 1.0). • Review of MDAE reports received from MDMCs, AMCs and industries. MDAE reports related to quality, maintenance and breakdown of medical devices were proposed to be considered as "Near-Miss Incidence". • Work on identifying causality assessment parameter & grading scale for MDAE reports was

			discussed. • NHSRC proposed Goggle MDAE reporting form for maintaining online database of MDAE reports. The designed form was reviewed and suggested to be put forth to Working Group for their views.
2.	Constitution of Core Technical Committee (CTC) under MvPI	Suggested by the Working Group & Steering Committee members of MvPI	Constitution of Core Technical Committee (CTC) under MvPI in process. Invitation letters sent to the proposed members and consent letters have been received
3.	Meeting of Screening Committee	A meeting for shortlisting applications for the posts of Research Associate, held at IPC, Ghaziabad on July 27, 2017.	The screening Committee shortlisted 38 candidates out of 81 applications received by IPC for 10 posts of Research Associate under MvPI.
4.	Teleconference with Medical Device Adverse Event Monitoring Centres (MDMCs)	NCC-MvPI on July 27, 2017 had a teleconference with MDMCs having Research Associates.	Issues related to performance of MDMCs, including awareness drive for HCPs, MDAE reporting, challenges in reporting, etc, were discussed with RAs posted at MDMCs