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 Outcomes/Action Taken
1	Data collation and processing of ICSRs	During the index period, NCC received 5388 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 processing under medical/clinical review. Reports not satisfying quality standards of PvPI shall be reverted back to the reporters for further necessary action.
2	Indo-European Summit	As instructed by Secretary-cum-Scientific Director, Dr. V. Kalaiselvan, Principal Scientific Officer, PvPI attended to interactive dinner with European delegates at India International Centre on 14/07/2017	During this session, the delegation including, Dr. V. Kalaiselvan, Principal Scientific Officer, PvPI and European representatives, emphasised on the safety issues of sodium valproate in pregnant women in India & its awareness to pregnant women through PvPI news letter.
3	Brainstorming session among PvPI, CDSCO and subject experts on finalizing Pharmacovigilance guidelines for MAHs	NC-PvPI organised Brainstorming session among PvPI, CDSCO and subject experts on finalizing Pharmacovigilance guidelines for MAHs Pharmaceutical products in India, at CDSCO, HQ, New Delhi, on July 18,	Dr V. G. Somani-JDC (I), Chaired this meeting & appreciated all the stakeholders who contributed to bring this document in final shape. The final draft was thoroughly discussed by the members and agreed on all the modules of the documents with minor modification/suggestions. The following points

		2017.	were suggested to incorporate before release. 1. Causality assessment mentioned in the document should be mandatory for the new drugs manufacturers only and the generic manufacturers can submit their ICSRs without the causality assessment that will be taken care by the PvPI. 2. A flow chart need to be inserted at the end of the document 3. The frequency of audit and inspection of MAHs may be minimized those have established effective Pharmacovigilance system. 4. Preface needs to be re-written.
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 Workshop-cum-training programme on Pharmacovigilance for NABH-accredited hospitals at CHL Group of hospitals, Indore, on July 22, 2017	Total 26 participants were participated in this training programme Following topics were taught during workshop to participants: • 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 held in New Delhi from 24-07- 2017 & 25-07-2017 with the	The session was inaugurated by Dr. V. S. Salhotra ADDG TB. • All 6 BDQ CAP Site's coordinators/treating

		objectives to review the status of implementation of BDQ CAP in all 5 states, 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.	physicians had explained the actual situation under BDQ CAP programme records. They also explained about the difficulties faced by them during the patient enrolment and data entry. • Dr. Padmapriya, NITRD, Chennai had explained about many deficiencies in data entry in Nikshay software of CTD. PvPI vigiflow ADR entries are more than the Nikshay, she added. Dr. Salhotra, concluded the meeting as under: • 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 8800 MDR and XDR TB patients, so that the Indian patients can be benifited. • Nikshay pending entries should be completed by the end of 15 Aug 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 had a meeting with Dr. S. K. Gupta Professor Emeritus (Clinical Research),	Dr. S. K. Gupta chaired the meeting and proposed three book titles as “Essentials of Pharmacovigilance”, “Basic concepts of

		Delhi Pharmaceutical Sciences and Research University, New Delhi to define the title and content of the book for Publishing a standard textbook on Pharmacovigilance on 26/07/2017.	Pharmacovigilance" and "Pharmacovigilance for safety monitoring of medicines". The other suggestions of this meeting are as follow: • Editor of the book will be Dr. G N Singh. • It was decided that the book should be more emphasized on basics of Pharmacovigilance. • It should contain the list of drugs banned worldwide and the reason behind to ban these drugs should also be clearly explained. • In-house contribution in writing the chapters for book should be maximized. • The book should be simple and should not be very exhaustive.
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 to this meeting.	The committee members discussed on the following agenda 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. Circulate Toll-free helpline no. for AEFI reporting at AMCs. Outcomes of this meeting are as follow: 1. PvPI will support AEFI Secretariat in notification of all serious AEFI Cases which will be receiving through mobile app and helpline number. 2. Hands-on trainings on Mobile App will be

			provided to AEFI team 3. Draft pamphlet for AEFI reporting through Toll-free number has been discussed with AEFI Secretariat
8	Association of Radio Operators for India (AROI) on awareness campaign of Pharmacovigilance Programme of India	Officials of NCC-PvPI, IPC had a meeting with Association of Radio Operators for India at Central Drugs Standard Control Organisation, FDA Bhawan, New Delhi on 28/07/2017	The outcome of the meeting are as follow: • Secretary-cum-Scientific Director suggested to get approval from Ministry to including AROI for promotion of PvPI • Training of Radio Jockeys to promote Helpline and Mobile APP at IPC, Ghaziabad • Write a letter to Ministry of Information regarding availability and promotion of Helpline and Mobile APP • Press release for Helpline and Mobile APP • Conduct a pilot study for promotion of PvPI-Helpline and Mobile APP in Delhi-NCR region through AROI

B) <u>MvPI Monthly Progress Report-July 2017</u>

Sr. No.	**Title of Activity**	**Description**	**Major Outcomes/Action Taken**
1.	MvPI Partner's 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 points discussed during the meeting is as follows: • Review the comments received from various stakeholders, medical device associations and medical device industries on guidance document

			(Version 1.0). • Reviewed MDAE reports received from MDMCs, AMCs and industries. The MDAE reports related to quality, maintance and breakdown of medical devices were proposed to be considered as "Near-Miss Incidence". • Discussed to work on identifying causality assessment parameter & grading scale for MDAE reports. • NHSRC proposed goggle MDAE reporting form for maintaining online database of MDAE reports. The designed form was reviewed and considered to put 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 is in process. Invitation letters sent to the proposed members and Consent letters has been received
3.	Meeting of Screening Committee	A meeting for short listing the applications for the posts of Research Associate, held at IPC, Ghaziabad on July 27, 2017.	The screening Committee shortlisted 38 candidates out of the total 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 had a teleconference with MDMCs having Research Associates on July 27, 2017.	Various points related to the performance of MDMCs including awareness for HCPs, MDAE reporting, challenges in reporting etc were discussed with RAs posted at MDMCs