

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

A. PvPI Monthly Progress Report–October 2017

Sr. No.	Title of Activity	Description	Major Outcome/Action Taken
1.	Data collation and processing of ICSRs	During the index period, NCC-PvPI received 5,471 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 for further necessary action.
2.	4 th Core Training Panel (CTP) meeting and 3 rd RTC meeting	Dr V Kalaiselvan, Officer in-charge PvPI, IPC along with other officials of PvPI conducted the meeting on October 5, 2017 at CDSCO, FDA Bhawan, New Delhi for reviewing the progress and future planning of trainings.	Discussions during the meeting included: <ul style="list-style-type: none"> • Reviewed the functioning of existing RTCs • Recommended the Action plan on Non-performing/non-Functioning RTC's under PvPI • Suggested to Harmonize the training modules to conduct CME's/advance level trainings at RTC's • Revision of Financial Guidelines for RTC's to conduct CME's and ALT's • Finalized training calendar for the year-2018
3.	8 th Meeting of Standing Finance Committee of the Indian Pharmacopoeia	Dr V Kalaiselvan, Officer in-charge PvPI, IPC attended, 8 th Meeting of Standing Finance Committee of the Indian Pharmacopoeia Commission	<ul style="list-style-type: none"> • Chairperson asked to submit a detailed financial proposal for MvPI in the next meeting • Committee discussed on financial arrangements with IPC for developing an

	Commission	on October 9, 2017 in the Chamber of AS&DG (CGHS), Room No. 252 'A' Wing, Nirman Bhawan, New Delhi.	indigenous software of PvPI for ADR reporting <ul style="list-style-type: none"> • Committee also discussed review of expenditure of PvPI for financial year 2016-17
4.	4 th Quality Review Panel Meeting of PvPI	IPC, NCC PvPI organised its 4 th Quality Review Panel Meeting at IPC, Ghaziabad on October 10, 2017	The outcome of this meetings is as under: <ul style="list-style-type: none"> • ADR form was reviewed and amendments were made. • On the basis of external audit it was found that PvPI Personnel should be trained on the QMS Standards i.e. ISO 9001:2015 • SOPs for Benefit-Risk Assessment were reviewed by the panel. Chairman felt great need of Benefit- Risk assessment training/workshop for AMC Coordinators and all the technical staff of PvPI • QMS developed by NCC-PvPI is recommended to be implemented by AMCs under PvPI • Constitution of Causality Assessment Committee (CAC) and review of its functioning
5.	4 th Regional Workshop on Basics of Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries- for MAHs	Dr. Pawan Kumar Saini, Scientific Officer PvPI along with other PvPI officials attended the Workshop, organized on October 12, 2017 at SciTech, Mumbai.	Technical sessions during workshop covered the followings: <ul style="list-style-type: none"> • Pharmacovigilance: Basics, Methods, Practices & A brief overview of PvPI • Importance of ADR Monitoring in Generic Pharmaceutical Products • Importance of PIL/SmPCs in Safety Monitoring • Monitoring & Reporting AEs/ADRs (Suspected Adverse Drug Reaction Reporting Form, CIOMS

			& E2B XML Reporting) <ul style="list-style-type: none"> Pharmacovigilance: A legal obligation under Drugs & Cosmetics Rule and Set-up of Pharmacovigilance System in Pharmaceutical Industries.
6.	One day Workshop on Media Event on Immunization at UNICEF.	Mr. Abhinav Paliwal, Pharmacopoeial Editor, IPC attended one day workshop on Media Event Immunization on October 12, 2017 at UNICEF India, New Delhi.	A detailed discussion held with the Radio jockeys and National Programming Heads of private FM radio stations was done on following points: <ul style="list-style-type: none"> Developing radio bites of PvPI officials and messages for common masses Highlight the IPC-PvPI activities ensuring safety of medicines to protect the health of all citizens of our country
7.	2 nd Pharmacovigilance - Skill Enhancement Seminar (Pv-SKES)	The Seminar was organized on October 13, 2017 at NCC-PvPI, IPC, Ghaziabad.	The Seminar was chaired by Dr. Manu Saxena, Director- CSIR- Human Development Centre. The topic discussed was "Creativity at work and Problem Solving". 32 employees of PvPI participated in the Seminar.
8.	Meeting with officials at All India Radio	Mr. Abhinav Paliwal, Pharmacopoeial Editor, IPC attended the meeting on October 18, 2017 at All India Radio.	Discussed recording/telecast of interview of Secretary-cum-Scientific Director, IPC on FM Rainbow.
9.	Pharmacovigilance India Meeting at ITC Maratha Hotel, Mumbai	Mr. Naveen Chandu Gorantala, Senior Pharmacovigilance Associate, PvPI delivered a presentation in Pv India Meeting at ITC Maratha Hotel, Mumbai on October 25, 2017	Presentation on MAHs Pharmacovigilance Guidance Document was delivered by Mr. Naveen Chandu. Gorantla Senior Pharmacovigilance Associate, PvPI was appreciated. He replied to various queries raised by the delegates.

11.	Interactive Session with Dr. Soumya Swaminathan Director General, ICMR	The Interactive Session on Skype was organized at R.S. Iyer Hall, IPC on October 27, 2017	An Interactive Session on Skype was organised at R.S Iyer Hall on 27 th October, 2017 with Dr. Soumya Swaminathan, Director General, ICMR which was attended by all PvPI staff.
12.	The Launch of Indian Pharmacopoeia Commission, NCC PvPI as WHO Collaborative Centre (CC)- Pharmacovigilance for Public Health Programmes and Regulatory Services	The Launch of IPC, NCC-PvPI as WHO Collaborative Centre was organised at IPC premises on October 30, 2017.	<p>A formal inauguration event was organised at IPC for the Launch of IPC, NCC PvPI as WHO Collaborative Centre on October 30, 2017.</p> <ul style="list-style-type: none"> • The launch was inaugurated by Honourable Dr. R.K. Vats, IAS, Additional Secretary, MoHFW, Dr. Clive Ondari, Coordinator, Safety & vigilance, WHO HQ, Geneva and Dr. Shanthy Pal, Group Lead, Medicines Safety, WHO (HQ). • Technical sessions during workshop covered the followings: <ul style="list-style-type: none"> ➤ The WHO Programme for International Drug Monitoring: Current Developments ➤ Regulatory Challenges in the safety of Medicinal Products ➤ Integration of Pharmacovigilance Programme with Public Health Programmes in India. ➤ Pharmacovigilance: India Perspectives. • National Strategic Plan for Scale up of Pharmacovigilance in India was launched. • PvPI Guidelines for Stakeholders was also launched. • Padma Shree Dr. Nitya Anand was felicitated.

B. MvPI Monthly Progress Report- October 2017

Sr. No.	Title of Activity	Description	Major Outcomes/Action Taken
1.	Number of reports (MDAEs) received at NCC-MvPI	Collection and analysis of MDAE reports	As many as 357 reports were received at NCC-MvPI, the team at NCC-MvPI analyzed the reports received at NCC-MvPI
2.	Sensitization to MDMCs for globally recall alerts	The information on global recall alerts was shared with all MDMCs	The Research Associates and coordinators at MDMCs checked non-availability of all the listed medical devices at their centres and provided feedback
3	MvPI presentation in Awareness workshop on “Radiation Safety” at NHSRC, New-Delhi	MvPI presentation was given in the workshop organised at NHSRC, New Delhi on Oct 13,2017	MvPI Technical support unit i.e. NHSRC, New-Delhi given an overview on Materiovigilance Programme of India & reporting of adverse event those are associated with medical devices to approximately 40 participants of the workshop..
4.	MvPI Awareness Program at Narayana Hrudayalaya, Bangalore	MvPI awareness program was conducted at Narayana Hospital, Bengaluru on October 23, 2017	MvPI Staff given presentation to approximately 40 healthcare Professionals of NH Hospitals on the following topics:

			<ul style="list-style-type: none"><input type="checkbox"/> Basic overview of MvPI Program<input type="checkbox"/> How to fill MDAE Reporting Form
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