

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

**A. PvPI Monthly Progress Report: February 2018**

<b>Sr. No.</b>	<b>Title of Activity</b>	<b>Description</b>	<b>Major Outcome/Action Taken</b>
1.	Data collation and processing of ICSRs	During the index period, NCC-PvPI received 6717 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.	Brain-Storming Session on “Role of State & UT Regulators for Effective Implementation of Indian Pharmacopoeia Commission’s (IPC) Services	A Brain-Storming Session was held on 2 <sup>nd</sup> February 2018 in R.S. Iyer Hall, Indian Pharmacopoeia Commission	<ul style="list-style-type: none"> <li>• State Drugs Regulators are required to ensure effective monitoring &amp; reporting of serious adverse events by the manufacturers through implementation of Schedule M para 28(2) during inspection of the manufacturing facilities/MAH’s organization</li> <li>• Regular visits of Drug Inspectors to AMCs for effective coordination between State Drugs Controllers and AMCs</li> <li>• CDSCO zonal offices may conduct quarterly meeting with respective state regulators for better monitoring of the ADR reporting by the manufacturers, healthcare professionals, patients etc.</li> </ul>

			<ul style="list-style-type: none"> <li>• Separate schedule may be framed for Pharmacovigilance under Drugs &amp; Cosmetics Act &amp; Rules, 1940 and Rules 1945.</li> </ul>
3.	04 <sup>th</sup> Asia Pacific Training on Pharmacovigilance, JSS University, Mysore, Karnataka	Mr. Arvind Kumar, Scientific Assistant and Mr. Akhilesh Kumar Sachan and other Sr. Pharmacovigilance Associates from AMCs attended the training from 29 <sup>th</sup> January to 9 <sup>th</sup> February 2018 at JSS University, Mysore	<ul style="list-style-type: none"> <li>• Interacted with officials of 12 countries national Pharmacovigilance centers regarding the legislation for Pharmacovigilance, Organizational structure, Adverse Drug Reaction(ADR)-Reporting route, report sources, No. of reports/year, reported by, dictionary for coding of ADRs</li> <li>• Identified and improved the gap areas in PvPI and CDSCO</li> <li>• Detailed practical knowledge about causality assessment of ICSRs</li> <li>• Hands-on training on Signal Detection</li> <li>• Interaction with industry professionals and understand about industry reporting system</li> <li>• Provided an opportunity to deliberate and interact about various ADR reporting forms across world</li> </ul>
4.	Visit of Shri Manikandhan, IAS Officer	Shri Manikandhan, IAS Officer visited IPC on 2 <sup>nd</sup> February 2018	<ul style="list-style-type: none"> <li>• An interactive session was held with Shri Manikandhan, IAS Officer at Conference Hall, IPC, who motivated all the staff of NCC-PvPI towards public services</li> </ul>

5.	PMDA-ATC Pharmacovigilance Seminar, Tokyo, Japan	Dr. Prasad Thota, Scientific Assistant, IPC attended the PMDA-ATC Pharmacovigilance Seminar, Tokyo, Japan from 5 <sup>th</sup> – 8 <sup>th</sup> February 2018	<ul style="list-style-type: none"> <li>• PvPI and CDSCO initiatives were projected among the international participants</li> <li>• All delegates were informed about the performance and achievements of PvPI</li> <li>• Gained specific knowledge and skill development on Pharmacovigilance-risk management system for new drugs from industry perspective</li> <li>• Gained specific knowledge on relief services for adverse effects by PMDA in Japan.</li> </ul>
6.	Meeting to review the progress on SEAR nations training for PV at NCC-PvPI, IPC	A meeting was held to review the progress on SEAR nations training for PV at NCC-PvPI on 6 <sup>th</sup> February 2018 at R.K. Khanna Tennis Stadium, New Delhi.	<p>A meeting was held to review the progress on SEAR nations training for PV and other issues pertaining to the reporting of ADRs through various stakeholders:</p> <ul style="list-style-type: none"> <li>• Work plan was prepared so that the entire stakeholders can maintain good ADR reporting practices</li> <li>• Meeting dates for “Workshop on Compliance of Good Pharmacovigilance practice for Low Middle Income Countries” have been finalized</li> </ul>
7.	National Deworming Day – 2018 programme	National Deworming Day was conducted on 12 <sup>th</sup> February 2018 at different Government Schools.	Sensitization & Awareness program regarding 'Pharmacovigilance on National Deworming Day' was conducted successfully in various Govt. Schools across the country by Pv Associates. Participants were made aware of the Adverse Drug Reaction of Albendazole & to report if any

			adverse event that may occur due to Albendazole
8.	A meeting on “Pharmacovigilance in Undergraduate Pharmacy Curriculum - An effective Implementation”	A meeting on “Pharmacovigilance in Undergraduate Pharmacy Curriculum - An effective Implementation” was held at RS Iyer Hall, Indian Pharmacopoeia Commission, Ghaziabad on 16 <sup>th</sup> February 2018 under the Chairpersonship of Prof. (Dr.) Geeta Lakshmi, Vice-Chancellor, Dr. M.G.R University, Chennai to give direction to the Programme.	<p>Recommendations by the Committee:</p> <ul style="list-style-type: none"> <li>• The faculty of Pharmacy colleges/institutions have to encourage students to choose Pharmacovigilance (BP805ET) as elective subject in the 8<sup>th</sup> Semester of the Graduation in Pharmacy as per the syllabus of Pharmacy Council of India</li> <li>• Member’s suggested that NCC-PvPI should prepare a course/training module exclusively for the teachers/faculties of the Pharmacy institutions.</li> </ul>
9.	3 days Training Programme for Participants from Yashoda Hospital, Kaushambi	The training programme was conducted from 19 <sup>th</sup> to 21 <sup>st</sup> February 2018 at Mini Conference Room, IPC.	<p>3 days training programme for participants from Yashoda hospital, Kaushambi included:</p> <ul style="list-style-type: none"> <li>• Basic concept of Pharmacovigilance</li> <li>• ADR-reporting forms and modes of reporting in PvPI</li> <li>• Hands-on training on VigiFlow</li> </ul>
10.	Meeting with Director, Health Services (DHS), Bhopal, Madhya Pradesh	Mr. Arvind Kumar Sharma, Scientific Assistant attended a meeting with Shri Dhanaraju S. (IAS), Director, Health Services, Madhya Pradesh on 23 <sup>rd</sup> February 2018 at Office of DHS, Bhopal, Madhya Pradesh.	<ul style="list-style-type: none"> <li>• Shri Dhanaraju S. (IAS), Director, HS, Bhopal, agreed to take initiatives towards strengthening of PvPI in Madhya Pradesh</li> <li>• He agreed to have Adverse Drug Reaction reporting system in all the District Hospitals of Madhya Pradesh, and also assured that an official letter will be issued soon to all the</li> </ul>

			<p>Chief Medical Officers mentioning the same</p> <ul style="list-style-type: none"> <li>• He also agreed to include Pharmacovigilance as a part of training module of newly joined Healthcare Professionals/Doctors</li> </ul>
11.	Drug Safety Alert	<p>During the index period the following Drug Alert were revealed:</p> <p>Suspected Drug: Dapsone</p> <p>Indication: For treatment of leprosy; acne vulgaris, dermatitis, pneumocystic pneumonia</p> <p>Adverse Reaction: Erythema nodosum</p>	<p>These informations were communicated to the medical colleges, ADR Monitoring Centres and other healthcare professionals etc. Via SMS and updated in the website</p>

**Indian Pharmacopoeia Commission**  
**National Coordination Centre (NCC) - Materiovigilance Programme of India (MvPI)**

**MvPI Monthly Progress Report - February 2018**

<b>Sr. No.</b>	<b>Title of Activity</b>	<b>Description</b>	<b>Major Outcomes/Action Taken</b>
1.	Data collation and processing of MDAEs reports received at NCC-MvPI	During the index period, NCC-MvPI received 66 MDAE reports from AMCs/MDMCs/ Medical Device industries	<p>The reported cases are under assessment for completeness, and clinical relevance</p> <p>Lack of quality/incomplete reports will be reverted to the reporter/sender for further</p>

			necessary action
2.	Placing of MvPI posters at vital places/Notice boards of Narayana Hrudalaya Hospital, Bengaluru	MvPI poster placed at Narayana Hrudalaya Hospital, Bengaluru a Medical Device Adverse Event Monitoring Centre (MDMC) between 15 <sup>th</sup> -20 <sup>th</sup> February 2018	<ul style="list-style-type: none"> <li>• About 100 MvPI posters were printed &amp; placed in following wards/places</li> <li>• Operation theatres (OT), Cath lab, Wards, Canteen, Consultation rooms of Narayana Institute of Cardiac Science (NICS) etc</li> <li>• Staff members in these departments were also sensitized for reporting of MDAEs</li> </ul>
3.	Presentation on Materiovigilance during one day symposium on "Pharmacovigilance and Drug Safety"	Presentation on Materiovigilance in One day symposium on "Pharmacovigilance and Drug Safety" was delivered at NDMC Medical college & Hindu Rao Hospital , New Delhi on 21 <sup>st</sup> February 2018	<ul style="list-style-type: none"> <li>• Doctors, interns, junior residents of NDMC Medical college &amp; Hindu Rao Hospital were sensitize about ADR reporting and drug safety</li> <li>• Participants were trained on what, where and how to report adverse event due to the use of medical devices</li> </ul>
4.	e-poster presentation on Adverse Event Reporting in Materiovigilance Programme of India"	An e-poster was presented in "2 <sup>nd</sup> National Conference on Health Technology Management" held at School of Public Health, PGI Chandigarh on 24 <sup>th</sup> & 25 <sup>th</sup> Feb 2018	Participants were trained on what, where and how to report adverse event due to the use of medical devices