

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

PvPI Monthly Progress Report- February 2017

Sr. No.	Title of Activity	Description	Major Outcomes/Action Taken
1	Data collation and processing of ICSRs	During the index period, NCC received 5523 ICSRs from AMCs/ Pharmaceutical industries/ consumers. The reported cases are under assessment for completeness, listed/unlisted and clinical relevance.	The reported ICSRs yet to be assessed for the completeness & quality for further process (listed and unlisted) & under medical/clinical review. Lack of quality/incomplete reports will be reverted back to the reporter.
2	National Meeting on Accelerated Roadmap Plan for Kala-azar Elimination-2017 and National Workshop on Pharmacovigilance for Vector Borne Diseases	WHO-Country office in coordination with NCC-PvPI, IPC organised National Meeting on Accelerated Roadmap Plan for Kala-azar Elimination-2017 And National Workshop on Pharmacovigilance for Vector Borne Diseases from 2-4 th February 2017 at Hotel Grand, New Delhi	The workshop inaugurated by Shri. Faggan Singh Kulsate, Hon'ble Minister of State, Health & Family Welfare, Government of India and Director-NVBDCP. The following technical sessions were conducted for state VBD officers:- <ul style="list-style-type: none"> • Plenary-Kala-azar Elimination: Regional and India Perspective • Highlights of National Roadmap Accelerated Plan for kala-azar elimination • Thematic areas for Kala-azar elimination: diagnosis, case detection, treatment & vector control in Kala-azar • Thematic areas for kala-azar elimination: HIV-VL co-infection management, capacity building and

			<p>health management information system new initiatives and health management information system</p> <ul style="list-style-type: none"> • Thematic areas for kala-azar elimination: Basic Concepts and Essentials of Pharmacovigilance • Kala Azar Adverse Drug Reaction Reporting
3	PMDA-Asia Training Center Pharmacovigilance Seminar 2017	PMDA-Asia Training Center Pharmacovigilance Seminar 2017- organized by Pharmaceuticals and Medical Devices Agency (PMDA) from 6-9 th February at PMDA, ShinKasumigaseki Bldg, 3-3-2, Kasumigaseki, Chiyoda-Ku, Tokyo, Japan.	<p>Dr. V. Kalaiselvan, Principal Scientific Officer, IPC and Officer I/c NCC-PvPI attended to this seminar & the outcomes of this seminar are under:-</p> <ol style="list-style-type: none"> 1. Gained specific knowledge and skill development on Pharmacovigilance-risk management system 2. Competency in processing, managing and assessing risk management plan 3. PvPI and CDSCO initiatives were projected among the international participants 4. Provided an opportunity to identify and improve the gap areas in PvPI and CDSCO 5. As directed by Dr. G. N Singh, Secretary-cum-Scientific Director, the delegation also met Ms. Nasiga Shin, Rewa Pharmaceuticals, Tokyo to explore the possibilities of appointing an IPC Commissioner at Japan 6. Understood tools to integrate Pharmacovigilance activities with regulatory system for better patient's safety outcomes

4	WHO-NRA Assessment 2017	WHO-National Regulatory Authority (NRA) Assessment of India was carried out from 13 th to 17 th February 2017 at Central Drugs Standard Control Organisation, New Delhi.	<p>A team of WHO led international experts covered the assessment of National Regulatory Authority Assessment of India comprising of CDSCO, State Drug Regulatory Authorities, PvPI & Adverse Events Following Immunization structures at Central & State levels.</p> <p>The outcome of this assessment as follows:</p> <p>Indian NRA has been declared as functional in respect of 09 different functionalities with the maturity level of 04, i.e. the highest level as per WHO currently evolved definitions in respect to 05 functions (PvPI was one of it) & maturity level 03 in respect of 04 functions & team reported a 100% compliance. This is one of the major achievements of IPC.</p>
5	Visit of WHO-NRA Assessor Dr. Brigitte to IPC on 14 th February 2017	Dr. Brigitte, WHO-NRA Assessor, Germany assessed (Pharmacovigilance Indicators) the functioning of PvPI on 14 th February 2017 at IPC, Ghaziabad.	<p>The remarks & suggestions of Dr. Brigitte as follows:-</p> <p>Remarks:</p> <ul style="list-style-type: none"> • NCC had an Excellent & advanced Pharmacovigilance System in India. • PvPI had an Excellent ADR reporting tool i.e. ADR Mobile Apps. • PvPI have Excellent Quality Management System. • PvPI have Excellent training system on Pharmacovigilance

			<p>Suggestions:</p> <ul style="list-style-type: none"> PvPI had a good data mining system; it should be integrated with AEFI system. <p>Conclusion: Pharmacovigilance & PvPI Functionality in India declared with maturity level 04 i.e. the highest level as per WHO currently evolved definitions, NRA Assessment team reported a 100% compliance in PvPI system of IPC.</p>
6	NRA assessment debriefing meeting	Dr. V. Kalaiselvan, Officer I/c of PvPI had convened a meeting on 20 th February with NCC & IPC staff to brief about the outcomes of the NRA assessment debriefing meeting at IPC, Ghaziabad.	<p>Brief outcome of this meeting:</p> <p>The NRA assessment was done in respect of 09 different functionalities and Indian NRA has been declared “functional “ with a maturity level of 4, i.e. is the highest level as per currently evolved definitions in respect of 05 functions (PvPI is one of it), and maturity level 3 in respect of 04 functions.</p>
7	Interactive session at Army College of Medical Sciences, New Delhi	NCC-PvPI had an interactive session cum sensitization program on PvPI on at Army College of Medical Sciences, New Delhi on 20 th February.	Officials from NCC-PvPI briefed on the current status & achievements of PvPI to the medical fraternity of the Army College of Medical Sciences, New Delhi.
8	Internal meeting with MAH Division of NCC-PvPI	Officer I/c of PvPI had convened a meeting with MAH Division of NCC-PvPI at IPC, Ghaziabad on 21 st February.	<p>The outcomes of this meeting are as follows:</p> <ol style="list-style-type: none"> MAH’s Division to coordinate with CDSCO, HQ for issuing a circular to MAHs in India directing mandatory reporting of PSUR’s (PDF format) with a copy to NCC-PvPI and CDSCO.

			<ol style="list-style-type: none"> 2. To invite 3 MAH's namely M/s Sun Pharma, M/s Eisai Pharmaceuticals and M/s Boehringer for reviewing the PSUR's submitted by MAH's in coordination with officials from New Drugs Division of CDSCO. 3. MAHs Division to follow up with CDSCO for issuing a circular to MAH's for updating their marketed products PIL's in their websites. 4. To organise 4th meeting on current challenges in reporting of ADRs by Indian MAH's to PvPI on 29th April 2017 at IPC, Ghaziabad for the maximum of 50 participants.
9	Interactive meeting with M/s. Sun Pharma ltd to improve the quality of ICSRs	Interactive meeting on improving the quality and upload error issue of ICSRs received from M/s. Sun Pharma was held by NCC at IPC, Ghaziabad on 22 nd February.	<p>Mr. Devesh Mishra nominee of M/s. Sun, Pharma to attend this meeting.</p> <p>The following issues were discussed in meeting:-</p> <ol style="list-style-type: none"> 1. Upload error issue in reporting of ICSRs (E2B-xml format) & quality of the ICSRs. 2. VigiGrade Completeness Score of ICSRs at WHO-UMC and it's status in India during the last 6 years.
10	Regional workshop on Pharmacovigilance for Vector Borne Diseases held on 21-22 nd February 2017.	Ministry of Health & Family Welfare, Government of India organised its Regional workshop on Pharmacovigilance for Vector Borne Diseases on 21 & 22 February 2017 at Hotel AVN Grand, Ranchi	<p>This workshop was inaugurated by Dr Nupur Roy, Addl. Director NVBDCP.</p> <p>The following technical sessions were conducted to benefit programme officers.</p> <ul style="list-style-type: none"> • Progress in kala-azar elimination in Jharkhand and Uttar Pradesh • Basic Concepts and Essentials of

			<p>Pharmacovigilance</p> <ul style="list-style-type: none"> • Tools of Pharmacovigilance • Causality Assessment • Modalities of ADR reporting
11	Induction-cum-training program was held on 22-23 rd February 2017.	NCC organised Induction-cum-training programme to the newly indentified AMC's (10), Medical Device Monitoring Centre's (10) Coordinators & Research Associates at IPC, Ghaziabad on 22-23 rd February 2017.	<p>The training programme was inaugurated by Dr. Manisha Shridhar, Regional Advisor-SEARO-WHO.</p> <p>During training program the following topics were considered :-</p> <p>PvPI: An overview & Updates, Basic concepts of Pv, Understanding of ADRs & Terminologies in Pv, QMS in PvPI, Roles of AMCs & their Coordinators in developing effective Pv System & GVP, Introduction to ADR Reporting form: What, where, how & whom to report including exercise, VigiFlow-An introduction & data entry & hands on training, Documentation grading-Report Completeness, Integration of PvPI-AEFI in vaccine safety monitoring, Causality assessment: The logic & Methods including workshop, Signal detection-PvPI: Logic & Methods, Role of CDSCO in PvPI.</p>
12	Induction-cum-training program was held on 22-23 rd February 2017.	NCC organised Induction-cum-training program to the Medical Device Monitoring Centre's (MDMCs) (10) Coordinators & Research Associates at IPC, Ghaziabad on 22-23 rd February 2017..	<p>The training programme was inaugurated by Dr. Manisha Shridhar, Regional Advisor-SEARO-WHO.</p> <p>During training program the following topics were considered :-</p> <p>MvPI: An overview, Understanding of MDAEs and</p>

			<p>terminologies in Mv, Concept of Mv & Its implementation for Good materiovigilance practice, Role of MDMCs & their coordinators in developing effective Mv, Establishment of reporting culture in MvPI, MDAEs reporting and guidelines: Industry Perspective, Introduction to MDAE Reporting form: What, where, how & whom to report including exercise, Signal detection & group exercise, Causlaity Assessment: failure mode & effect analysis and root cause analysis, Group exercise on causality assessment, roles & responsibilities of Coordinators & Research Associates, Role of CDSCO in MvPI.</p>
13	<p>1st National Level Advisory Committee (Community Pharmacist) of NCC-PvPI Action Plan meeting held on 23rd February 2017</p>	<p>NCC convened a meeting with Ms. Archana Mrudgal, Registrar-cum-Secretary, Pharmacy Council of India on 1st National Level Advisory Committee (Community Pharmacist) of NCC-PvPI Action Plan on 23rd February 2017 at PCI, Office, New Delhi.</p>	<p>The following issues were discussed.</p> <ol style="list-style-type: none"> 1. In order to leverage the PvPI, Pharmacy Council of India agreed to include Pv & PvPI in course contents of the refresh courses being organised by Pharmacy Institutions to Community Pharmacists in various states for which the budget being provided by PCI. 2. Suggested to send a letter to the President- PCI mentioning that concept note of Pv, PvPI & modes of ADR reporting to PvPI for approval & further circulating to State/UT pharmacy council registrars in order to hand over the same to every registered pharmacist during registration & renewal of Pharmacist Licence

			by their councils
14	Meeting held with Officials of National Skill development Corporation (NSDC) on 23 rd February	PvPI started Skill development programme on “Basic & Regulatory Aspects of Pharmacovigilance”. In this regard NCC had convened a meeting with Officials of NSDC on 23 rd February.	NCC emphasised on the skill development programme being organised by NCC-PvPI to Officials of NSDC and also invited Mr. Manish Kumar, CEO & MD, Mr. Rajiv Mathur, Head-Standards & QA, NSDC to inaugurate 2 nd batch of this training, from 1 st March to 10 th March 2017 on 1 st March 2017 at IPC, Ghaziabad.