**Indian Pharmacopoeia Commission**

**National Coordination Centre (NCC) - Pharmacovigilance Programme of India (PvPI)**

**Monthly Progress Report- March 2016**

| S. No | Title of Activity | Description | Major Outcomes/Action Taken |
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| **1.** | Data collation and processing of ICSRs | During the index period NCC received 5242 ICSRs from AMCs/ Pharmaceutical industries/ consumers. The reported cases are under the 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.<br><br>Lack of quality reports will be reverted back to the reporter. |
| **2.** | 7th SRP meeting under PvPI | PvPI organised its 7th SRP meeting on 1st March 2016 at CDSCO, FDA Bhawan, New Delhi | Outcome of this meeting:<br>SRP recommended the following to CDSCO to incorporate<br>1. SJS as Adverse Drug Reaction in Indian package insert of marketed Ceftriaxone.<br>2. TEN& SJS as Adverse Drug Reaction in Indian package insert of marketed Lamotrigine.<br>3. Photosensitivity to be incorporated in package inserts as Adverse Drug Reaction of Betamethasone, marketed domestically.<br>4. Acute Generalised Exanthematous Pustulosis (AGEP) to be incorporated in package inserts as Adverse Drug Reaction of Azithromycin marketed domestically. |

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| | | | 5. Acute Generalised Exanthematous Pustulosis (AGEP) to be incorporated in package inserts as Adverse Drug Reaction of Cloxacillin marketed domestically.<br>6. Instructed PvPI the following Drug alerts may be issued to sensitize the Health Care Professionals and follow precautions while prescribing the following drugs.<br>• Phenytoin:Angioedema<br>• Phenytoin:Osteoporosis<br>• Bleomycin:Hyperkinesia<br>• Olanzapine:Hyponatraemia |
| **3.** | Interactive session with Swedish counterpart to promote Patient Safety | CDSCO organized a meeting to discuss the Memorandum of Intent between India & Sweden to understand and to update the various issues related to regulatory and Pharmacovigilance on 2nd March 2016 at CDSCO headquarters, New Delhi. | On behalf of Swedish Medical Product Agency Mr. Backman Christer and Mrs.Karin Grondal participated and provided rich updated information and development in their National Regulatory Authority (NRA). The developments in various areas of CDSCO were also presented by respective officials of various departments. In this meeting mutual information was exchanged among both the NRAs. PvPI updated information was shared with the Visiting delegates. |
| **4.** | Two days workshop on Pharmacovigilance and Pharmacoepidemiology in RNTCP | Two days workshop on pharmacovigilance and pharmacoepidemiology in RNTCP was held on 4-5th March 2016, at National Research Institute in Tuberculosis (NRIT), Chennai. | Dr. Soumya Swaminathan, DG-ICMR emphasized that PvPI & ICMR Institutions has to work together for improving the pharmacovigilance standards, basic knowledge & skills of Health Care Professional (HCPs) and ensuring the safety of the vulnerable population while exposed with different drug regimen. She concluded the workshop by stating that ICMR Institutions may be declared as PvPI collaborating centres. |

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| | | | She suggested PvPI to identify the scope of the activities for collaboration and mutual avenues. |
| **5.** | Medical Representatives of Alkem Laboratories Limited trained on Pharmacovigilance- | M/s Alkem Laboratories limited invited PvPI Officials to teach on basic pharmacovigilance, on how, where, what, whom & why to report ADRs to PvPI. As one of recommendation during " A round table meeting on " Challenges and Issues for the Pharmaceutical Industries in Reporting ADRs to PvPI" held at Indian Pharmacopoeia Commission, Ghaziabad on 29th April 2015 to train the Medical Representatives of the pharmaceutical industries on the concept of pharmacovigilance. | PvPI officials of IPC attended & trained 25 medical representatives (all over India) of, M/s Alkem Laboratories Pvt Ltd at Lonavala, Mumbai on 07/03/2016 & Officials emphasized on key responsibilities of the MRs to enhance the quantity of ADR reporting further to promote drugs safety in India especially which are being prescribed by private practitioners. |
| **6.** | MvPI Industry Consultation meeting | PvPI organised one day MvPI Industry Consultation meeting on 9$^{th}$ March 2016 at IPC to Review the draft Medical Device Adverse Event (MDAE) Reporting Form and MvPI Toolkit. | Total 20 experts from 15 different pharmaceutical industries attended this meeting & The comments received from three different associations/organisations in this meeting are as follows:<br>1. Confederation of Indian Industry (CII) representative suggested to redesign MDAE form capturing the details considering the following: Applicability of AE reporting, definition of AE & SAE, timelines for reporting, scope of reporting, who shall be reporting along with clarification,<br>2. Federation of Indian Chambers of Commerce &Industry (FICCI), American Chamber of Commerce |

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| | | | (AMCHAM): representative from both organisations expressed their views that a clear Guidance document must be published on adverse event reporting before this MDAE form gets implemented for Industry. The guidance should include a decision tree or flow chart to help manufacturers to make their Vigilance assessment.<br>• Under Section F of draft MDAE form – Causality assessment is very important to know whether the adverse event was related to device or not. Current language needs a change because it is not a matter of choice whether the causality assessment is done or not rather a clear expectation to present the Causality assessment report should be mentioned on the form. Criteria for assessment are clearly defined in enclosed GHTF document Pg. 7 point#3.2<br>• This form should be only applicable for notified medical devices & IVDs |
| **7.** | Govt. of India Launched Bedaquilline- New Anti TB drug for drug resistant TB | World TB day was held on 21st March 2016, at the event the honourable health Minister Shri J P Nadda, launched Bedaquiline – new anti-TB drug for Drug Resistant TB as part of the Revised National Tuberculosis Control Program (RNTCP). | The Officials from PvPI attended this meeting& Major Outcomes of this meeting:<br>• Shri. J. P. Nadda, launched Bedaquiline – new anti-TB drug for Drug Resistant TB & also released Guidelines for Prevention and Management of Adverse reactions associated with anti-TB drugs.<br>• Shri. B. P. Sharma urged the need for collective commitment of all stakeholders said that stakeholders need new tools for diagnostics and new research and |

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| | | | further said that delivery mechanism should be in conformity with goals we have set for ourselves. |
| **8.** | Visit of Students and faculty members of Devaki Amma Memorial College of Pharmacy, Kerala | Students and faculty members of Devaki Amma Memorial College of Pharmacy visited IPC on 30th March 2016. | PvPI Officials given introduction about ADR, Where, How, What to & Whom to report ADRs, & its importance, Pharmacovigilance & PvPI to the 60 students |
| **9.** | Coordination Meeting with National Vector Borne Disease Control Programme(NVBDCP) Officials | Dr. Dhariwal, Director-NVBDCP had a meeting with PvPI & WHO-Country Office (India) Officials on 31st March 2016 at Nirman Bhawan, New Delhi. | Since PvPI already monitoring the ADRs of drugs used in NVBDCP through its AMCs, further it was discussed the monitoring can be done at district/Primary Health Centres of seven highly endemic districts in the Bihar (Kala-Azar) |