

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

PvPI Monthly Progress Report- April 2017

Sr. No.	Title of Activity	Description	Major Outcomes/Action Taken
1	Data collation and processing of ICSRs	During the index period, NCC received 6320 ICSRs from AMCs/ Pharmaceutical industries/ consumers. The reported cases are under assessment for completeness, listed/unlisted and clinical relevance.	<p>The reported ICSRs are being assessed for the completeness and quality for further process under medical/clinical review.</p> <p>Lack of quality/incomplete reports will be reverted back to the reporter for further necessary action.</p>
2	Template for review of autonomous bodies	As directed by Secretary-cum-Scientific Director, IPC, Dr. V. Kalaiselvan, Principal Scientific Officer, Officer I/c-PvPI prepared the IPC template form of the PvPI on 5 th April 2017	<p>In this template Revenue is also proposed to be generated through PvPI related publications, products and data sharing etc. as per the proposals below:</p> <ul style="list-style-type: none"> (i) Imparting education -short term certificate course on Pharmacovigilance; (ii) Publishing an official book of standards for Pharmacovigilance; (iii) Pharmacovigilance audit to the marketing authorization holders; (iv) Periodic Safety Update Reports (PSURs) evaluation; and (v) Commercialization of Pharmacovigilance data. <p>The template review document has been submitted to MoHFW for further review & approval.</p>

3	Visit of Shri. P. Das Gupta to PvPI.	Dr. P. Das Gupta, Former-DCG (I) visited National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC), Ghaziabad on 5 th April 2017	The outcome of this meeting as follows: 1. Reviewed guidance document for Marketing Authorization Holders (MAH). 2. Reviewed proposal for Representation of Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India in the Drug Technical Advisory Board (DTAB) of CDSCO. Delivered a lecture on Therapeutic Drug Monitoring (TDM) is important for certain drugs to prevent toxicity and for optimal therapeutic effect-TDM is very important for Pharmacovigilance.
4	A meeting to discuss on Expenditure Finance Committee (EFC)/ SFC Memorandum for appraisal of Schemes of PvPI with Shri. K. L. Sharma, JS (R) at Nirman Bhawan, New Delhi.	As directed by Secretary-cum-Scientific Director, IPC, Dr. V. Kalaiselvan, Principal Scientific Officer, Officer I/c-PvPI prepared the Format for Expenditure Finance Committee (EFC)/ SFC Memorandum for appraisal of Schemes of NCC-PvPI FY 2017-2020 on 6 th April 2017.	The draft format for Expenditure Finance Committee (EFC)/ SFC Memorandum for appraisal of Schemes of NCC-PvPI FY 2017-2020 has been submitted to JS (R) at Nirman Bhawan.
5	A meeting to discuss on Expenditure Finance Committee (EFC)/ SFC Memorandum for appraisal of Schemes of PvPI with Shri. K. L. Sharma, JS (R)-MoHFW at Nirman Bhawan, New	As directed by Secretary-cum-Scientific Director, IPC, Dr. V. Kalaiselvan, Principal Scientific Officer, Officer I/c-PvPI prepared the Format for Expenditure Finance Committee (EFC)/ SFC Memorandum for appraisal of Schemes of NCC-PvPI FY 2017-2020 on 7 th April 2017.	The draft format for Expenditure Finance Committee (EFC)/ SFC Memorandum for appraisal of Schemes of NCC-PvPI FY 2017-2020 has been reviewed by JS (R), MoHFW at Nirman Bhawan and suggested to compile it with IPC's EFC and submission as single EFC Scheme.

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6	First Annual Meeting of South-East Asia Regulatory Network	WHO-regional office for south east asia organised its First Annual Meeting of South-East Asia Regulatory Network at Hotel Viceroy, New Delhi on 11 th April 2017	Dr. V. Kalaiselvan, Principal Scientific Officer, Officer I/c-PvPI had participated in working group on Pharmacovigilance
7	Meeting with National President Indian Medical Association	As directed by Dr. V. Kalaiselvan, Principal Scientific Officer, Officer I/c-PvPI, Officilas from PvPI met Dr. K. K. Aggarwal, National President-IMA at IMA Office on 11 th April 2017	Dr. Prasad Thota, Scientific Assistant-PvPI met Dr. K. K. Aggarwal, as per his direction prepared & communicated a letter to all State/UT President/Honorary Secretaries of IMA branches for further coordination between all IMA zonal branches & AMCs under PvPI for effective implementation of Pharmacovigilance activities at district level.
8	One day training to NCC-PvPI staff on Medical writing	Dr. Girijaa Kadam, Senior Manager, Drug Safety & Risk Management, Lupin Limited, Mumbai given one day training to staff of NCC-PvPI at IPC, Ghaziabad on 11 th April 2017.	During this training session the following were taught to staff of NCC-PvPI. <ul style="list-style-type: none"> • How to write narrative writing for ICSRs (Clinical trials, follow-up cases, literature cases, medication error cases, spontaneous cases received from consumers)
9	First Annual Meeting of South-East Asia Regulatory Network	WHO-regional office for south east asia organised its First Annual Meeting of South-East Asia Regulatory Network at Hotel Viceroy, New Delhi on 12 th April 2017	Dr. V. Kalaiselvan, Principal Scientific Officer, Officer I/c-PvPI had participated in working group on Pharmacovigilance
10	Meeting with Dr. Mita Nanday, Consultant-CDSCO, New Delhi	Dr. Mita Nandy, Consultant, CDSCO, New Delhi visited IPC, Ghaziabad on 13 th April 2017	Dr. Mita Nandy reviewed the clinical relevance of the ICSRs for the unlisted drug-ADR combinations reported to NCC-PvPI & also discussed on the PvPI revenue generation module with respect to

			marketing authorization
11	Review of documents for the Expenditure Finance Committee (EFC)-2017-18 to 2019-2020	As IPC received proposal from Ministry of Health & Family Welfare (MoHFW) for sending the EFC of the IPC from 2017 to 2020 at IPC, Ghaziabad on April 15 th 2017	Officials of NCC reviewed & submitted the estimated budget & manpower requirement for PvPI, MvPI & HvPI as per EFC format of MoHFW to Officials of IPC for compilation & making as single document.
12	Monthly Coordination AEFI-Pv partners Meeting	Monthly Coordination AEFI-Pv partners Meeting held at Nirman Bhawan, New Delhi on 19 th April 2017.	During this meeting the following agenda items were discussed. <ul style="list-style-type: none"> • Discussion on notification of AEFI cases through ADR helpline centre • Update on VAEIMS and AEFI trainings at regional, states and district levels • Status of SISPA and DISPA hiring • Discussion on support required for AEFI Secretariat from PvPI • Update on Analysis of minor AEFIs at PHC and district levels
13	National ToT for expansion of Bedaquiline & Shorter MDR-TB Regimen with updated Guidelines for PMDT in India	National ToT for expansion of Bedaquiline & Shorter MDR-TB Regimen with updated Guidelines for PMDT in India held at New Delhi on 19 th April 2017.	Dr. V. Kalaiselvan, Principal Scientific Officer delivered a talk on causality assessment & it's importance in Pharmacovigilance.
14	Interactive meeting with M/s. Eli Lilly Pharma	Interactive meeting on improving the quality and upload error issue of ICSRs received from M/s Eli Lilly Pharma was held by NCC on 21 st April 2017 at IPC, Ghaziabad.	Ms. Mamatha Associate Director-Regulatory Affairs & Mr. Ashish Yadav were nominated by Eli Lilly, Pharma to attend this meeting. The following items were discussed in the meeting.

			<ol style="list-style-type: none"> 1. Discussion on upload error issue in reporting of ICSRs (E2B-xml format) & quality of the ICSRs. 2. VigiGrade Completeness Score of ICSRs at WHO-UMC and its status in India during the last 6 years. 3. Guidance document for reporting of Individual Case Safety Reports by Marketing Authorization Holders.
15	Representation of PvPI in 1 st National conference on Pharmacy Practice.	SGT College of Pharmacy Gurgaon organised 1 st National conference on Pharmacy Practice at SGT University, Gurgaon 22 nd April 2017.	During this conference technical personnel from NCC-PvPI participated as resource person & delivered a lecture on What, where, how & to whom to report ADRs & how to fill the suspected ADR reporting form.
16	Pharmacovigilance Knowledge-Sharing Programme -India & Ethiopia	IPC, NCC-PvPI organised Pharmacovigilance Knowledge-Sharing Programme -India & Ethiopia to 07 experts of Ethiopia Food, Medicine Health care Administration & Control Authority at IPC, Ghaziabad from 24.04.2017 to 28.04.2017	<p>During the this knowledge sharing programme the experts were taught on</p> <ul style="list-style-type: none"> • Overview of Pharmacovigilance System in India (PvPI) • Administrative Structure of PvPI (Programme Governance & organogram) • Introduction to Suspected ADR Reporting Form • Systems & Procedures to monitor Reports collation of ADR reports • Integration of PvPI with National Health Programs(NHPs) • Quality Management System (QMS) of PvPI, Audit & Inspection • Communication System in PvPI • Data Mining & Identifying Country Specific Signal.

			<p>Apart from above activities the other activities of this programme as follows:</p> <ul style="list-style-type: none"> • Interaction session held with Indian National Regulatory Authority (NRA) –CDSCO, Ministry of Health & Family Welfare, Govt. of India • Field visit to ADR monitoring centre - Yashoda Super Speciality Hospital, Kaushambi, Ghaziabad
17	4th Interactive Session on "Participation of Marketing Authorization Holders in PvPI"	NCC-PvPI organised 4th Interactive Session on "Participation of Marketing Authorization Holders in PvPI" at IPC, Ghaziabad on 28 th April 2017.	<p>The major outcomes of this interactive session as follows:</p> <ul style="list-style-type: none"> • Quality grading of the ICSRs reported by MAHs <p>Presented by NCC-PvPI. Panel discussion held on</p> <ul style="list-style-type: none"> • Pharmacovigilance System set up at MAHs • Effective Implementation of PvPI - Comments & suggestions from MAHs