



Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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PvPI~AMCs Kashmir to Kanyakumari

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Secretary-cum-Scientific Director's Message



Dear Readers,

It gives me an immense pleasure to note that Pharmacovigilance Programme of India (PvPI) under Indian Pharmacopoeia Commission (IPC), initiated in 2011 has achieved considerable success and accomplished several milestones in terms of having an infrastructure of the pharmacovigilance system after addressing many hurdles and barriers. On this occasion, let's acknowledge the efforts of all the PvPI stakeholders and develop the insights of pharmacovigilance, drug safety and risk management by analysing its latest developments, to ensure availability of safer drugs to the society.

On the auspicious occasion of 5th anniversary of commencement of NCC-PvPI, I on behalf of IPC, NCC-PvPI extend warm greetings and felicitations to all those who have contributed to make the PvPI a success. The hard work, sheer determination, dedication and sincerity of the professionals has brought this programme at par with global standards. The role of healthcare professionals in PvPI is gradually making a paradigm shift-from accepting the transformation to adopting the practice. I would say, this is a significant move in the interest of patient welfare.

The process of drug safety monitoring and its outcomes will not only improve patient's quality of life, but will also help in bringing changes in policies related to healthcare economics and other issues of national importance. I am sure the next 5 years are going to be a challenging period for all of us in terms of pharmacovigilance and its concerned areas because knowledge, attitude and practice of pharmacovigilance needs to be ensured by the healthcare providers in districts and primary health centres.

I congratulate PvPI team and stakeholders for their efforts and cooperation to establish and develop a robust pharmacovigilance system in place. I am sure with all your commitment and devotion the programme will attain a new height and achieve PvPI goals successfully.

Dr. G. N. SINGH

Secretary-cum-Scientific Director,
Indian Pharmacopoeia Commission,
Ministry of Health & Family Welfare,
Government of India.

5th Anniversary Celebrations of NCC-PvPI

“Five years of Indian Pharmacopoeia Commission’s commitment as National Coordination Centre for Pharmacovigilance”

To mark five years of Indian Pharmacopoeia Commission’s (IPC) commitment to establish as National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI), an event was organized on 14th April 2016, at India Habitat Centre, New Delhi. The event was celebrated with the theme of “Performance appraisal and way

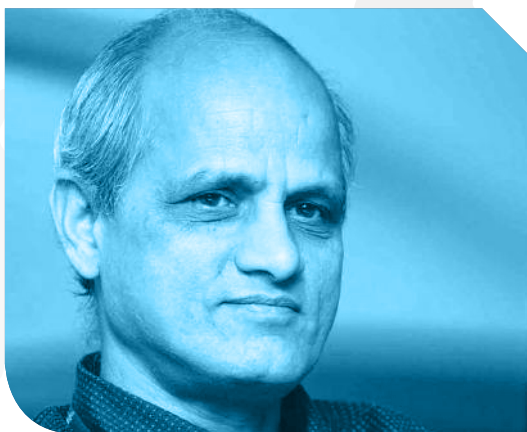
ahead”. The meeting was well attended by more than 150 participants from industry, academia, hospitals and various government organizations. During inauguration, 23 new ADR Monitoring Centres (AMCs) were launched across the country. Further, a panel discussion on various topics was conducted. The consequences of deliberations/debates are as follows :-

23 new AMCs have launched across the country

AMCs of PvPI are located from Kashmir to Kanyakumari

Total AMCs reached to 202

AMCs are established in 29 states and 4 Union Territories



Shri K. L. Sharma, Joint Secretary (Regulation), Ministry of Health and Family Welfare (MoHFW), Government of India (GoI) suggested that PvPI should focus on self-sustainability, multidimensional focus, stringent legal action against the individuals/organizations for non-compliance of pharmacovigilance practices. He endorsed Dr. G.N. Singh’s suggestion to setup separate institution to carry out pharmacovigilance activities.



Shri Sudhansh Pant, Joint Secretary (Policy), Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, GoI mentioned that PvPI has survived the danger of infant mortality as it has completed 5 years and it would now grow as a healthy child to benefit the nation.



Dr. G.N. Singh, Drug Controller General (India) (DCG(I)) and Secretary-cum-Scientific Director, IPC opined that Pharmacovigilance in India aims to enhance the global outreach and to play a leading role in pharmacovigilance at a global level. To achieve this objective he proposed that a new institution by the name “Indian Institute of Pharmacovigilance (IIP)” to be set up under the aegis of MoHFW, GoI through an act of Parliament.



Dr. K.K. Aggarwal, Honorary Secretary General, Indian Medical Association (IMA), assured to support the PvPI proposal regarding mandatory ADR reporting of doctors and non-reporting should be made punitive.

Eminent personalities such as Dr. S.K. Gupta, National Advisor, PvPI, Dr. Y.K. Gupta, National Scientific Coordinator, PvPI, Mr. Bejon Misra, Founder, Consumer Forum of PvPI, were also present in the said meeting and shared the dais.

The Medical Device Adverse Event (MDAE) reporting form for Materiovigilance Programme of India (MvPI) and pamphlet on “Achievements and Roadmap for PvPI” were also released during the inaugural event.

The Pharmaceutical Industries are undoubtedly significant to provide technical support and strengthening of the Adverse Drug Reactions (ADRs) monitoring centres along with the encouragement of PvPI activities.



Distinguished personalities released PvPI achievements/prospects and Medical Device Adverse Event Reporting Form on 14th April 2016 at India Habitat Centre, New Delhi while celebrating 5th anniversary of NCC-PvPI

IMPORTANT EVENTS



Dignitaries launched new ADRs Monitoring Centres



Dynamic team of PvPI on the occasion of IPC commitment as NCC for PvPI based on the theme of "Performance appraisal and way ahead"

This event has been valuable in respect of all spheres of pharmacovigilance and has defined the future goals to set new standards of patient safety. Pharmacovigilance can definitely move to the next level of glory and excellence by following the proposed recommendations.

Major Recommendations

- Development of Indigenous system or Information Technology (IT) tool to report, collate, analyse and identify new signals in pharmacovigilance is the need of hour to ensure that a robust pharmacovigilance system is in place.
- NCC-PvPI along with Central Drugs Standards and Control Organization (CDSCO) may begin auditing of Marketing Authorization Holders (MAHs) to ensure that the pharmacovigilance systems are in place.

Marketing Authorization Holders are Pivotal in PvPI

Challenges and Issues for the Pharmaceutical Industries in Reporting ADRs to PvPI

Contribution of pharmaceutical industry has increased considerably after the first interactive session “Challenges and Issues for the Pharmaceutical Industries in Reporting ADRs to PvPI” held on 29th April, 2015. However, still there is a need for improvement in the following areas-:

- ◆ Quality of reports and focus on causality assessment.
- ◆ ADR reporting from medical representatives of MAHs.
- ◆ Focusing on unlabelled ADRs of drugs.

- ◆ Inclusion of follow up cases in ADR reporting via mobile application.
- ◆ The MAHs shall establish the Pharmacovigilance system in their respective organizations.
- ◆ To develop an E2B XML format system for submission of Individual Case Safety Reports (ICSRs) to PvPI within one month.

In order to discuss and resolve above issues “2nd interactive session on Challenges and Issues in ADRs reporting by pharmaceuticals industries to PvPI” was organized by NCC-PvPI, IPC on 29th April 2016 at IPC, Ghaziabad.



Senior officials of CDSCO and IPC during the 2nd interactive session with industry representatives on 29th April 2016 at IPC, Ghaziabad.



Exchange of views among the industry delegates

Recommendations

- Updation of Patient Information Leaflets (PILs) regularly and submission of updated PILs to CDSCO/NCC-PvPI.
- Availability of updated package insert-leaflet information of the respective products on their website by MAHs.
- Industries need to implement/develop a system to report Indian ICSRs/ Periodic Safety Update Reports (PSUR) in XML ICH E2B format within 30 days.

Nurses Participation in PvPI-Need of the Hour

NCC-PvPI Organized 1st National level meeting on participation of Nursing Professionals in PvPI

To enlighten the importance and to create the awareness of pharmacovigilance among nursing professionals, NCC-PvPI organized “1st national level meeting on participation of Nursing Professionals in PvPI” on 6th May 2016 at IPC, Ghaziabad, as the nurses are one of the main stakeholders in pharmacovigilance

programme, Hence NCC decided to play a proactive role in motivating nursing professionals to understand their role and responsibility in the detection, management, reporting and prevention of suspected ADRs and all essential activities for optimizing patient safety.



Dr. G. N. Singh, Secretary-cum-Scientific Director, IPC briefed about responsibilities of nursing professionals during the meeting at IPC, Ghaziabad on 6th May 2016

Dr. G. N. Singh, Secretary-cum-Scientific Director, IPC briefed the participants about the present scenario of pharmacovigilance and explained the importance of nursing professionals involvement in PvPI. He said that they can act as a backbone for the pharmacovigilance programme and their active involvement in ADR reporting is also important from the regulatory point of view as the safety information is incorporated from the ADR reporting.

Dr. Chetna Desai, Prof. B.J. Medical College (BJMC), Ahmedabad in her key note address emphasized on the role of nursing professionals in preventing the ADRs and improve patient safety. She also deliberated on various topics like how to induct nurses in pharmacovigilance, why should nurses report ADRs & other important regulatory aspects. She introduced the notification form for ADR reporting by nurses & answered the queries of participants regarding legal liability for ADR reporting.



Recommendations

- To form a panel of 21 members including nursing experts, to advise the PvPI about the safety, efficacy of the drugs and for making drugs safe.
- One nursing expert should be recommended as a member of reconstituted Steering Committee of PvPI.
- Chief Nursing Staff should act as a member of PvPI panel in ADR Monitoring Centre.

PvPI in International Arena

Dr. Azadeh, World Health Organization (WHO), Geneva, Switzerland visited NCC-PvPI

Dr. Azadeh, Representative of WHO visited NCC-PvPI, IPC on 2nd May 2016 to discuss about Deworming Medicine Monitoring. PvPI will work with WHO to ensure the safety of Albendazole is pronounced on National Deworming day.



Dr. G. N. Singh, DCG(I) (left), Shri K. L. Sharma JS(R), MoHFW, GoI (Middle), Dr. Azadeh, WHO (Right) on 2nd May 2016 at IPC during discussion session.

Joint Secretary Reviews PvPI Progress

The progress made in the engagement of Pharmaceutical Industries was overviewed and concurred, i.e., draft of PSUR guidance document for MAHs is in discussion with Stakeholders and will be finalized by end of this year

Shri K. L. Sharma, JS (R), MoHFW, GoI and Dr. G. N. Singh, DCG (I) and officials of PvPI met at IPC, Ghaziabad on 2nd May 2016 to review the progress of PvPI and take situational updates of the programme. JS (R) briefed about the extensive efforts MoHFW made towards PvPI. The progress made in the engagement of pharmaceutical industries

in pharmacovigilance was also overviewed and concurred, so that PSURs Guidance Document for MAHs draft is in discussion with stakeholders and will be finalized by end of this year. JS (R) was overwhelmed to see the progress and emphasized the value additions in PvPI to improve its standing in the international arena.



Dr. Azadeh, WHO (Left), Shri K. L. Sharma, JS (R) (Second left) Dr. G. N. Singh, DCG (I) (Third left) and Mr. A. K. Pradhan, Deputy Drug Controller (India) CDSCO during the meeting on 2nd May 2016.

PvPI Drug Safety Alerts (April-June 2016)

The preliminary analysis of Suspected Unexpected Serious Adverse Reactions (SUSARs) from PvPI ICSRs database reveals that following drugs are associated with the risks

ROFLUMILAST

Indication: Reduce the risk of Chronic Obstructive Pulmonary Disease Exacerbation

Alert: Gynaecomastia

CLOZAPINE

Indication: Management of Schizophrenic Patients.

Alert: Neutropenia

DISULFIRAM

Indication: Alcohol-abuse deterrent.

Alert: Erythroderma

PIPERACILLIN & TAZOBACTAM

Indication: In the treatment of lower Respiratory tract infection/Urinary tract infection intra abdominal infections, Skin and skin structure infections, Bacterial septicaemia involving polymicrobial infection.

Alert: Blurred Vision

MOMETASONE FUROATE, TOPICAL

Indication: Steroid responsive dermatitis, Eczema/Atopic dermatitis

Alert: Hypertrichosis/Hirsutism, Skin Depigmentation

RANIBIZUMAB

Indication: Neovascular Age-Related Macular Degeneration (AMD), Visual impairment due to Diabetic Macular Edema (DME), Visual impairment due to Choroidal Neovascularization (CNV) secondary to Pathologic Myopia (PM).

Alert: Myocardial Infarction

PEGINTERFERON ALPHA-2A

Indication: Chronic active hepatitis B & C

Alert: Vasculitis

AMPHOTERICIN B (Conventional)

Indication: Life threatening fungal infections including Histoplasmosis, Coccidioidomycosis, Paracoccidioidomycosis, Blastomycosis, Aspergillosis, Cryptococcosis, Mucormycosis, Sporotrichosis and Candidiasis; Visceral and mucocutaneous leishmaniasis unresponsive to pentavalent antimony compounds; Severe meningitis. Perioral candidiasis.

Alert: Bone Marrow Depression

DOXORUBICIN

Indication: Soft tissue and Bone sarcomas, Acute leukemia, Malignant lymphoma, Hodgkin's disease, Breast carcinoma, Small cell carcinoma of lungs, AIDS-related Kaposi's sarcoma, Multiple myeloma, Gastrointestinal tract carcinoma, Bladder cancer, Ovarian carcinoma, Acute myeloblastic leukemia, Thyroid carcinoma, Neuroblastoma.

Alert: Photosensitivity Reaction

CRIZOTINIB

Indication: Locally advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC) that is Anaplastic Lymphoma Kinase (ALK) – Positive.

Alert: Pneumonitis, Hepatic Encephalopathy

Healthcare professionals, patients/consumers are advised to closely monitor the possibility of the above adverse events while prescribing/consuming above suspected drugs and report to the NCC-PvPI either by filling of Suspected Adverse Drug Reactions Reporting Form for Healthcare Professionals/ Medicines Side Effect Reporting Form for Consumer (<http://www.ipc.gov.in>) or by PvPI Helpline No. 1800-180-3024.

Comparative Status of Global Drug Alerts with PvPI Database

NAME OF DRUG	RISK	INTERNATIONAL STATUS	INDIA STATUS
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CISPLATIN



Risk of blood clots in the veins (venous thromboembolism)



Health Canada recommended to update the warning about the increased risk of venous thromboembolism in the prescribing information of cisplatin products



PvPI received three ICSRs of cisplatin-induced thromboembolism. One ICSR of cisplatin revealed about deep thrombophlebitis, venous thrombosis, and deep vein thrombosis.

IMATINIB MESYLATE



Decline in kidney function during long-term treatment



Health Canada recommended to include in the product label, the long-term treatment with imatinib may result in decline in renal function. Patients treated with imatinib in clinical studies had a decrease over time in estimated glomerular filtration rate (eGFR). Monitoring for renal function should be undertaken before initiating therapy and periodically thereafter.



A total of seven ICSRs received by PvPI for the decline in kidney function after the treatment of Imatinib mesylate. Out of seven ICSRs, One ICSR of renal impairment, Two ICSRs of abnormal renal function, One ICSR of renal disorder Not specified (NOS), One ICSR of renal function test NOS abnormal and two ICSRs of kidney dysfunction.

OPIOID PAIN MEDICINES



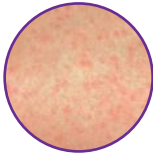

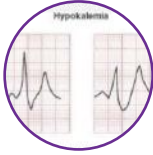
Several safety issues require label changes



The US Food and Drug Administration (FDA) issued safety warnings against an entire class of opioid medicines. FDA recommended that labels of all opioid drugs should contain warnings about the risks of potentially harmful interactions with other medications, problems with adrenal glands and decreased sex hormone levels. An opioid can interact with antidepressant, migraine medicines to cause serotonin syndrome and opioid administration can lead to adrenal insufficiency. FDA has decided to include serotonin syndrome as a drug interaction and adverse reaction, adrenal insufficiency as a warnings in all opioid medications. Also, FDA is now adding decreased sex hormone levels as an adverse reaction to all opioid product labels.



One ICSR of serotonin syndrome induced by Fentanyl citrate treatment was documented by PvPI.

NAME OF DRUG	RISK	INTERNATIONAL STATUS	INDIA STATUS
PIPERACILLIN CONTAINING PRODUCTS (ALONE OR IN COMBINATION WITH TAZOBACTAM)	 <p>Risk of Drug Reaction/ Rash with Eosinophilia and Systemic Symptoms (DRESS)</p>	<p>Health Canada has updated the prescribing information of Piperacillin alone as well as Piperacillin + Tazobactam combination products with DRESS as a potential adverse effect.</p>	<p>Six ICSRs of DRESS/ Hypersensitivity Syndrome were received by PvPI.</p>
BCR-ABL TYROSINE KINASE INHIBITORS	 <p>Potential harm to the foetus</p>	<p>The potential of Bcr-Abl tyrosine kinase Inhibitor to cause harm to the foetus was included in the Canadian product label. Recently, Health Canada (HC) reviewed imatinib clinical studies and states that overall healthy babies were the most reported outcomes (50.2%), elective abortions (30.7%), miscarriages (10.6%) and birth defects (8.4%). After the HC review, manufacturers has updated the prescribing information for Imatinib, to tell doctors to confirm by pregnancy test that female patients are not pregnant before starting treatment.</p>	<p>Two ICSRs of foetal death/miscarriage and four ICSRs of abortion were documented by PvPI.</p>
SPIRONOLACTONE AND RENIN-ANGIO-TENSIN SYSTEM DRUGS	 <p>Risk of potentially fatal hyperkalaemia</p>	<p>The Medicines and Healthcare products Regulatory Agency (MHRA) has reminded health-care professionals that the concomitant use of spironolactone with angiotensin converting enzyme inhibitors (ACEi) or angiotensin receptor blocker (ARB) is not recommended as routine treatment because of the risks of severe hyperkalaemia, particularly in patients with marked renal impairment.</p>	<p>PvPI received Sixty Two ICSRs of Spironolactone induced hyperkalaemia. Out of this, five serious ICSRs of severe hyperkalaemia were noticed due to concomitant use of Spironolactone and ACEi or ARB.</p>

Healthcare professionals are sensitized to carefully monitor the above mentioned alerts. If any event related to these drugs are to be reported to NCC-PvPI.

Strengthening of Pharmacovigilance in Eastern Uttar Pradesh-Moti Lal Nehru Medical College, Allahabad

Moti Lal Nehru Medical College was formally inaugurated on 5th May 1961 by the first President of India Dr. Rajendra Prasad, which was situated at amalgamation of three holy rivers Ganga, Yamuna & Saraswati.

Eastern Uttar Pradesh (UP) is a geographic region of northern India comprises of approximately 4.2 crores population which is 3.5% population of India. Drug safety monitoring is one of the emergence areas for health benefits and patient's quality life. Based on this, PvPI has set up AMCs across eastern UP. Moti Lal Nehru (MLN) Medical College, Allahabad has taken initiatives in reporting ADRs being recognized as AMC to safeguard the health of people in eastern UP.

MLN Medical College was formally inaugurated on 5th May 1961 by the first President of India Dr. Rajendra Prasad which was situated at amalgamation of three holy rivers Ganga, Yamuna & Saraswati.

MLN Medical College recognized as AMC under PvPI in 2012. Dr. R. C. Chaurasia, Head, Associate Professor, Dept. of Pharmacology held



Enthusiastic participants of CME at MLN Medical College, Allahabad

the responsibility of Coordinator, positively supported under chairmanship of Prof. S. P. Singh, Principal, MLN Medical College. This centre caters more than six lakhs population of Eastern UP having 1000 bed facility.

This AMC effectively translates the concept of pharmacovigilance into a medical and paramedical fraternity. It is driving to bring the positive changes in ADR reporting and anticipate to adopt pharmacovigilance practices by stakeholders.

Coimbatore Medical College-AMC on Precedent Success of Pharmacovigilance

Coimbatore Medical College (CMC) is celebrating 50 years, golden jubilee in June 2016 by focusing



ADRs Reporting Form Drop Box released in Coimbatore Medical College to facilitate consumer reporting on 21st March 2016

pharmacovigilance as one of the major theme. NCC-PvPI congratulates CMC on this occasion for the dedicated service to the patient for the last 50 years. Coimbatore Medical College and Hospital (CMCH) experienced a significant increase in ADR reporting in the past 6 months.

Dr. Edwin Joe, M.D, Dean (CMCH), Coordinator Dr. N. Santhi, M.D, Professor & Head, Dept. of Pharmacology, CMC has created a comprehensive transformation of PvPI among the corporate and district hospitals, TB, HIV treatment centre in Coimbatore.

Guntur Medical College (GMC)-Springboard for Pharmacovigilance Practice

Guntur is one of the big cities of newly carved state of Andhra Pradesh. Lots of development is enduring in every aspects of the state. NCC-PvPI also expects many transformation in drug safety monitoring from this region through promoting PvPI by association with Pharmacy Institutes and Public-Private Partnership (PPP) model. Dr. D.S. Raju Naidu, Medical Superintendent and Dr. A. Meena Kumari, Coordinator, GMC, Guntur are adequately boosting the programme to ensure patient safety.



Dr. D.S. Raju Naidu Medical Superintendent and Dr. A. Meena Kumari, Coordinator, GMC, discussed the progress of PvPI with Dr. V. Kalaiselvan, PSO, IPC after conducting CME at Chalapathi Institute of Pharmaceutical Sciences, Guntur on 23rd April 2016

Armed Forces Medical College, Pune-Paradigm of Pharmacovigilance

Armed Forces Medical College (AFMC) Pune is one of the three AFMC in India actively functions as AMC of PvPI since 2 years to ensure patient safety by developing an ADR reporting culture. The high level premier and prestigious engagement has built a network among the health care providers in the



Lt Col (Dr) A. K. Gupta Coordinator, Dept. of Pharmacology, AFMC, Pune elaborated the need of Pharmacovigilance to defence healthcare professionals



hospital. Lt Col (Dr) A K Gupta, Coordinator, Department of Pharmacology, AFMC is playing a major role and instrumental in creating awareness of pharmacovigilance among defence healthcare professionals.

Approved New Drugs in India

The following drugs were approved during the period of April to June 2016 by the CDSCO

S.No	DRUG	INDICATION
1	Tofacitinib Tablets 5 mg	To treat adult patient with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to Methotrexate. It may be used as monotherapy or in combination with methotrexate or other non-biologic Disease-modifying antirheumatic drugs (DMARDs).
2	Ceftaroline Fosamil Injection 600 mg/Vial	For the treatment of adult (>18 years of age) patients with community-acquired pneumonia.
3	Panobinostat Hard Gelatin Capsules 10 mg/15 mg/20 mg (Panobinostat lactate)	In combination with bortezomib and dexamethasone, is indicated for the treatment of multiple myeloma, who have received at least 1 prior therapy.
4	Bepotastine Besilate Bulk & Bepotastine Besilate 1.5 %w/v Ophthalmic solution	For the treatment of itching associated with allergic conjunctivitis.
5	Ibutilide Bulk & Amp; Ibutilide Fumarate Injection 0.1 mg/ml	For the rapid conversion of atrial fibrillation or atrial flutter of recent onset to sinus rhythm. Patient with atrial arrhythmias of longer duration are less likely to respond to Ibutilide Fumarate Injection. The effectiveness of Ibutilide has not been determined in patients with arrhythmias of more than 90 days in duration.

- Healthcare professionals are urged to closely monitor the safety of these drugs.
- ADRs if any to be reported to PvPI.

Adverse Event Following Immunization Updates

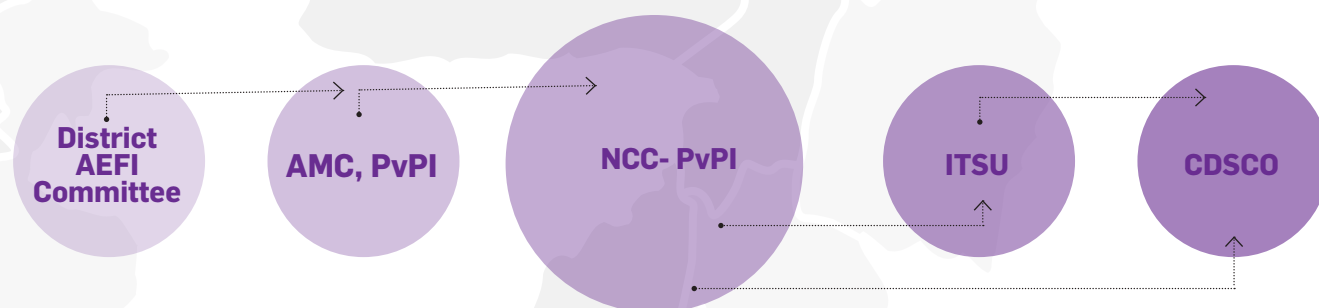
PvPI AMC team at Indira Gandhi Institute of Child Health Sciences, Bengaluru jointly working with Brihat Bengaluru Mahanagar Palike.

Periodic Safety Update Report Expert Committee Meeting was held on 5th May 2016 at CDSCO, FDA Bhawan, New Delhi. Experts of CDSCO, Immunization Technical Support Unit (ITSU), PvPI reviewed vaccines PSUR and recommended MAHs to provide vigorous quality information.

PvPI AMC team at Indira Gandhi Institute of Child

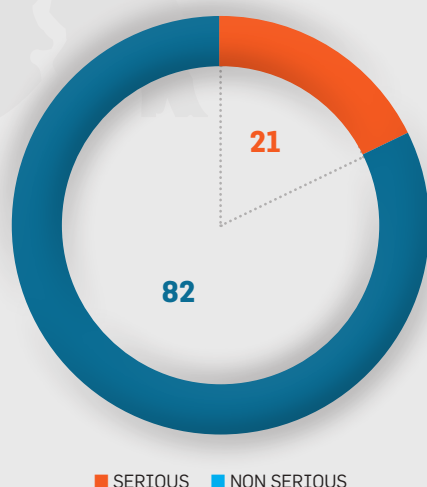
Health Sciences (IGICH), Bengaluru jointly working with Brihat Bengaluru Mahanagar Palike (BBMP) to ensure monitoring of Adverse Event Following Immunization (AEFI) and in this context a joint visit was carried out. Dr. B. Y. Sudarshana Paediatrician, Programme officer, Immunization Programme, BBMP is actively coordinating with PvPI team.

Collection of ADRs jointly by AMC and District AEFI from the respective district hospitals.

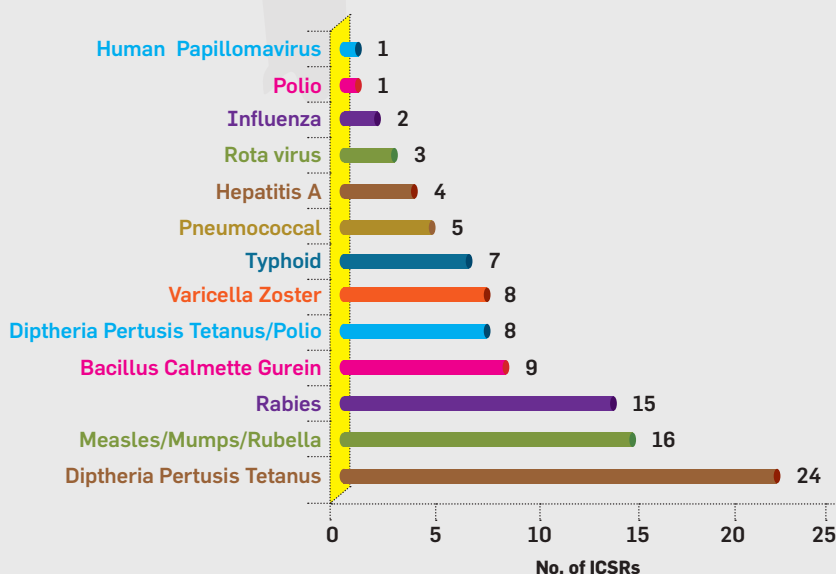


NCC-PvPI has reported 103 AEFI-ICSRs, received from AMCs and Pharmaceutical Industries during the period of Apr-June 2016. Out of which, 21 ICSRs were serious and 82 ICSRs were non-serious. All the ICSRs were communicated to ITSU and CDSCO for the further follow-up actions. The particular vaccines name are given below.

NUMBER OF SERIOUS AND NON-SERIOUS ICSRs



NUMBER OF VACCINES RECEIVED BY NCC-PvPI



Nizam Institute of Medical Sciences, Telangana-Patronize to promote PvPI

An ascertainable CME on pharmacovigilance was organized by Nizam Institute of Medical Sciences, Hyderabad on 2nd April 2016 at Visakhapatnam. Dr. P. Usha Rani, Coordinator, PvPI, in the introductory speech said that there is an under reporting of ADRs in India. Hence, an urgent need to increase the number of reported ADRs becomes vital. This data will be useful in detection of new signals. Accordingly, drug labelling can be changed and new drug safety information in product package inserts shall be suggested. This workshop was conducted with an aim to create awareness among the healthcare professionals.



Eminent speakers on the dais during the CME interactive session

Different aspects of Pharmacovigilance as under were discussed

Dr. S. V. Adinarayana (Member of Andhra Pradesh Medical Council)	There is a need to check the safety of drugs specially ADRs with herbal preparations. He also said that pharmacologists are the pillars of clinical research.
Mr. P. B. N. Prasad (Deputy Drugs Controller (India), CDSCO Zonal Office, Hyderabad)	The vision of PvPI with respect to safety aspects of drugs, promotion of public health in India and also role of PvPI in stipulating rules. He has pointed out that post marketing vigilance is poor in India and it needs to be improved. PvPI programme helps the MoHFW in laying down the rules and safe use of drugs in the society.
Mr. Somnath Basu (Asst. Drug Controller (India), CDSCO Zonal Office, Hyderabad)	Narrated the adverse events followed by Immunization. He explained the current status of Immunization programme of various groups such as children, pregnant women and vaccination injection ADRs in India.
Dr. Ch. R. Venkatachalam (Prof & HOD, Department of Cardiology, Kakinada)	He enumerated ADRs are 4-6 th most common causes of death in the hospital. He said that clinical research is conducted in restricted conditions, but the real life situations are much different. He explained the benefits of pharmacovigilance with examples. He also emphasized that 1/3rd of ADRs are preventable.

Silchar Medical College & Hospital (SMCH), Assam-CME on Pharmacovigilance



Participants of Pharmacovigilance CME at SMCH, Silchar on 24th April 2016

SMCH Silchar, one of the nine Regional Training Centres (RTCs), organized a CME on pharmacovigilance awareness and issues on 24th April 2016. More than 100 participants attended the CME. Dr. Pinaki Chakraborty, Coordinator of SMCH and his pharmacovigilance team shared PvPI goals to ensure drug safety in Silchar.

New AMCs Launched in PvPI



ANDHRA PRADESH

Centre Name

Rangaraya Medical
College, Kakinada, Andhra
Pradesh-533001

Coordinator Name & Designation

Dr. K.V. Siva Prasad
(Prof. Pharmacology)

General Hospitals, Chaitanya
Health City, Amalapuram,
East Godavari District-533201,
Andhra Pradesh

Coordinator Name & Designation

Dr. Anand Acharya
(Prof. & HOD Pharmacology)

KARNATAKA

Centre Name

Shri B.M. Patil Medical
College, BLDE University,

Vijayapur-586103, Karnataka

Coordinator Name & Designation

Dr. Anant Khot
(Asst. Prof. Pharmacology)

Centre Name

Shivamogga Institute of
Medical Sciences, Sagar
Road, Shivamogga-577201,
Karnataka

Coordinator Name & Designation

Dr. S. Nagaraja Prasad
(Asst. Prof. pharmacology)

Centre Name

M.R. Medical College,
Kalaburagi-585105, Karnataka

Coordinator Name & Designation

Dr. Santosh Kumar Jeevangi
(Prof. Pharmacology)

KERALA

Centre Name

Sree Gokulam Medical
College & Research
Foundation (S.G.M.C.
& R.F.) Venjaramoodu,

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Zero Defect and Zero Effect Output

To err is human and to forgive is Divine' is an idiom, no doubt but there is too a correction message beyond words and an alert to be skilled and accountable to give errorless output to the satisfaction of defined and qualified rules and norms. It should never be mistaken for becoming careless and callous in discharging the assigned stint with repeated errors in any specified area of organization that ruins its image and tarnishes the credibility of a system. It is often experienced that attitude unbecoming of the individual not to accept the mistakes and defects to be rectified in wrong doing things creates hurdles in smooth functioning and such type of power stupor of chair imperils the matter that reflects the incompetency and circumvent approach of concerned equation. Power stupor is an evil, not to be welcomed since it destabilizes the harmonious human relations of staff and gives negative impact to mutual trust that creates hard ship in leading ahead the projects of organization by properly utilizing

the time, manpower and money.

Zero defect output invites a very high professional excellence, expertization and accuracy that to keep oneself in regular updation by requiring education and knowledge in relevant area of theme to meet errorless output in terms of quality and quantity both. Need not to be hesitant in sharing knowledge with each other to meet the defined purposes and also to extend thanks to right thing producers.

Zero defect output propounds the theory of 'competent plus less competent is more than competent' that is to say a team spirit and good human behaviour have top place to gear up the multi dimensional progress in any stream.

Zero effect output asserts straightway that we should treat others as we want to be treated. It in no way allows us to inflict pain and negative impact to the life on other side may be human beings, animals or plant kingdom in surroundings. All types of pollution, harmful to ecological balance and ecofriendly

equilibria, be controlled and avoided.

The interaction with each other and the project to be done should be so designed not to bring any harassment of humanity and disruption of peace in ecosystem. 'Zero defect and zero effect output' relates us to skill development programmes.

Since zero defect and zero effect output is the demand of time globally so for high I. Q. profile and clairvoyance also it is essential and enthusiastic to adopt the principle of zero defect and zero effect output and to boost the morale of each component to bring honour peace and progress at every level of organization/Nation which may be held outstanding as compared with highest standards of human life in developed countries of the planet.

I rejoice to share this flavour of my thought with IPC-PvPI staff my respected countrymen and global family also in the interest of fame, creativity and prosperity forever everywhere

A thought framed up by Satya Prakash Tyagi, S.O., IPC, Ghaziabad, Ministry of Health and Family Welfare, Government of India



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