

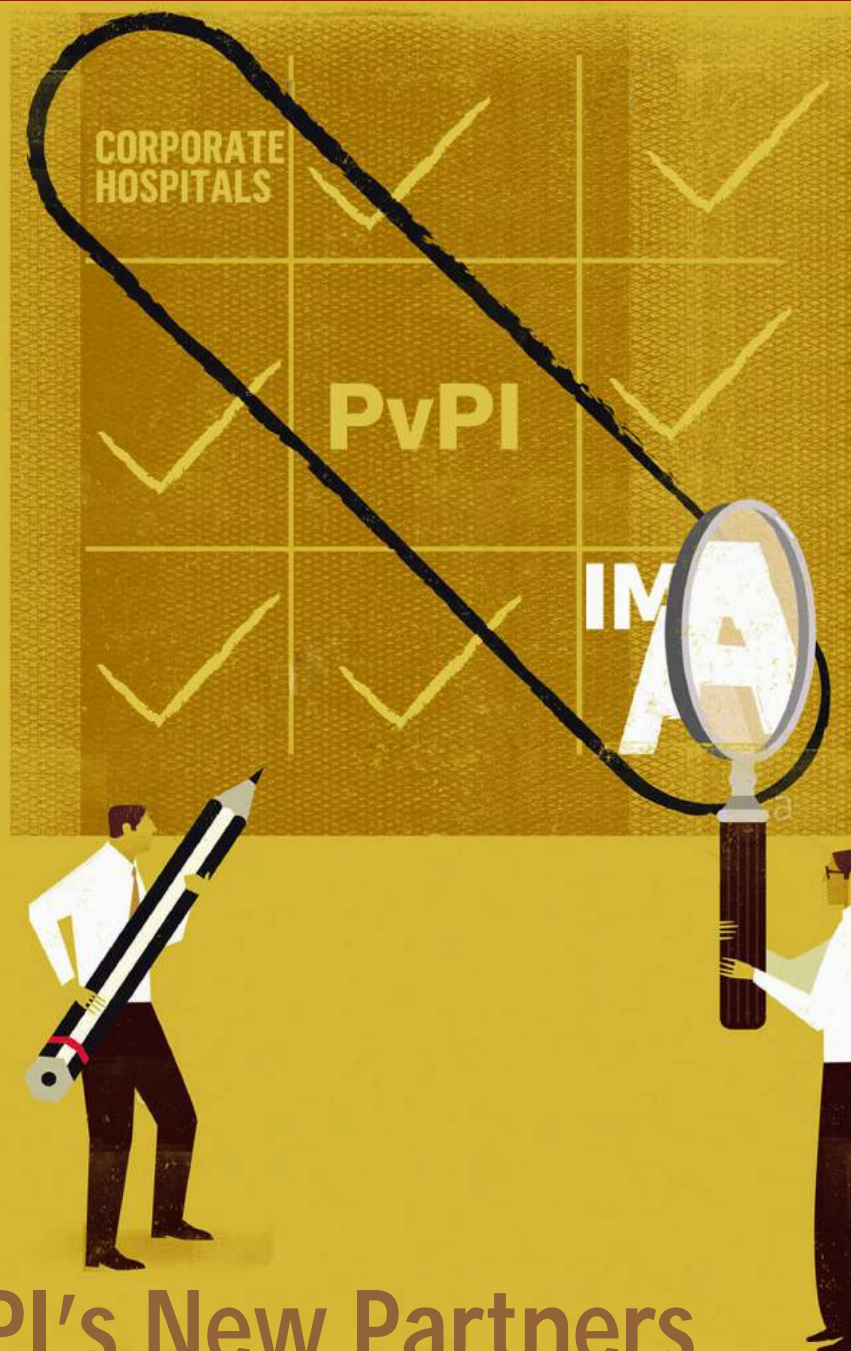


Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

VOL 6 | ISSUE 14 | 2016

Pharmacovigilance
in Drugs & Cosmetics
Act 1940 & Rules 1945



Govt of India
Launched
Bedaquiline-
New Anti TB
drug for Drug
Resistant TB

PvPI's New Partners for Common Interest

04 IMPORTANT EVENTS

04 | Govt. of India Launched Bedaquiline-
New Anti TB drug for drug resistant TB

06 | National Formulary of India (NFI) an
effective tool to promote patient safety:
JS (R), AS & DG, MoHFW

08 | ICMR Institutions to join hands with PvPI:
Secretary, DHR

09 | CDSCO interacts with Swedish
counterpart to promote Patient Safety

05 | IMA accelerates clinician
services to PvPI

07 | Holistic Approach
of PvPI

09 | PvPI in International
Arena

10 TRAINING & EDUCATION

10 | Newly Recruited Technical Associates
"Induction cum Training Programme"

11 | New Drugs Approval Status in India

12 RECOMMENDATIONS AND REGULATORY ACTION

12 | PvPI Recommendations and
Regulatory Action

13 | SGLT 2 Inhibitors induced Urinary
Tract Infection (UTI) – Status in
PvPI Database with USFDA

14 FIELD ACTIVITIES

16 IMPORTANT EVENTS

16 | Update on AEFI
Surveillance Programme

18 NEWS DIGEST

18 | Pharmacovigilance System
Mandate for Drug
Manufacturers

18 | Now PvPI reaches Private
Practitioners by Empowering MR
Training on Pharmacovigilance

19 | Second Asia Pacific Pharmacovigilance
Training Course

19 UPCOMING EVENTS

20 APPRECIATION COLUMN

Dr. Jagdish Prasad

M.S. M.Ch., FIACS
Director General of Health Services



सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
स्वास्थ्य सेवा महानिदेशालय
निर्माण भवन, नई दिल्ली-110 108

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF HEALTH SERVICES
NIRMAN BHAWAN, NEW DELHI-110 108
Tel : 23061063, 23061438 (O), 23061924 (F)
E-mail : dghs@nic.in

Dated: 06/04/2016

दिनांक/Dated.....

MESSAGE

Dear Readers,

At the outset I am delighted to express my warm greetings to you all! I am extremely happy to reach you all through this newsletter! I am also proud of your valued contributions to PvPI. Please accept my heartiest congratulations.

I am happy to learn that Indian Pharmacopoeia Commission (IPC) is celebrating its 5th anniversary as a National Coordination Centre for Pharmacovigilance Programme of India on 15th April 2016. The IPC, notified as NCC for PvPI by Ministry of Health & Family Welfare, Govt. of India in the year 2011 is serving to ensure the safety of medicines.

I take this opportunity to appeal all the health care professionals to involve and adopt the system and culture of reporting adverse events so that the analysis and learning from the reported events will try to prevent the recurrence of such an event. The dissemination of learning throughout the established system is crucial in minimising the error and protecting the patients in future endeavour. Focusing on the changes and advancement there is a need of connecting all health care professionals, patients and the partners/stakeholders of PvPI in an effective manner – regardless of the hindrances and breaking the barriers through skill development, competence and utilisation of the available resources. Increasing patient engagement and awareness through greater collaboration and exchange of information will become a key source in achieving better clinical and regulatory outcomes.

I am glad to note that good amount of work has been done in the first three months of 2016 in the areas of skill development, identifying the new partners for PvPI and regulatory pharmacovigilance. I am sure the amount of work and outcome is expected to be increased many folds in the future. Hence, I am expecting the same commitment and enthusiasm from the stakeholders.

I am proud to state that today our drug regulators are in a comfortable position to take appropriate regulatory decisions based on our own patient's data rather than referring data of other countries. I am sure that IPC will continue to pursue excellence in pharmacovigilance and discharge its duties with dedication, commitment and professionalism.

I invite you to glance this newsletter's updates to get a sense of the pharmacovigilance in making health benefits, capacity building in patient safety and research activities in India. I wish you all the best.

(Dr. Jagdish Prasad)



Honourable Health Minister Shri J P Nadda with Officials of MoHFW and WHO released Guidelines for Prevention and Management of Adverse drug reactions on World TB day .

Govt. of India Launched Bedaquiline Released Guidelines for Prevention and Management of ADRs Associated with New Anti TB Drug for Drug Resistant TB

A MAJOR BREAKTHROUGH FOR PATIENTS SUFFERING FROM MULTI-DRUG RESISTANT TUBERCULOSIS; DRUG LAUNCHED ON WORLD TB DAY TO BE MADE AVAILABLE AT SIX TERTIARY CENTERS FIRST

World TB Day was held on 21st March 2016, and on the occasion 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 approved Bedaquiline is being introduced at six identified tertiary care centres across India and having advanced facilities for laboratory testing and intensive care for patients. Bedaquiline will be given to multi-drug resistant TB patients with resistance to either all fluoroquinolone and/or all second line injectables and extensive drug resistant TB. On this occasion,

Health Minister also released Guidelines for Prevention and Management of Adverse Drug Reactions (ADRs) associated with anti-TB drugs.

Shri B P Sharma, Secretary, Health & Family Welfare (HFW) urged the need for collective commitment of all stakeholders on the occasion of World TB Day. He stated that the RNTCP is one of the most successful programmes and also laid emphasis on surveillance and monitoring. He said that we need new tools for diagnostics and new research and further added that delivery mechanism should be in conformity with goals we have set for ourselves.

Speaking on the occasion, Dr Soumya Swaminathan, Secretary (DHR) and DG (ICMR), highlighted the challenges of the frontline health workers. She said that there is a need for new and innovative tools for conducting tests and investment in research. She further

added that we need to use drugs optimally.

Dr. (Prof) Jagdish Prasad, DG, DGHS, Shri C K Mishra, AS & MD, and other senior officers of the Health Ministry, representatives of WHO, World Bank and other development partners were present on this occasion.

IMA accelerates clinician services to PvPI

The Indian Medical Association (IMA) and IPC agreed to strive together to enhance the ADRs reporting. Since clinicians, are having wider spectrum in patient care, both the organizations have taken this conventional step. While signing formal MoU, Dr. S. S. Agarwal, President, IMA and Dr. G. N Singh, Secretary-cum-Scientific Director, IPC expressed their mutual commitment for the noble cause. While speaking on the occasion Dr. K. K. Aggarwal said that IMA shall accelerate the process of clinicians, ADRs reporting to PvPI. He further mentioned that PvPI resource materials and general information shall be communicated

to more than 2.5 lakhs registered physicians of the organization. The following step will be taken to accelerate the clinicians' participation in PvPI:-

- 1) *To provide regular training and advocacy on pharmacovigilance.*
- 2) *To identify IMA- nodal centres as patient safety monitoring centres.*
- 3) *To declare "National Patient Safety Day".*
- 4) *To familiarize the channels of ADR reporting*



Dr. G. N. Singh, DCG(I), CDSCO & Secretary-cum-Scientific Director, IPC (Right) and Dr. S. S. Agarwal, President, IMA (Left) signing and exchanging the Letter of Intent.

IMA-PvPI patient safety monitoring cell is being set at IMA-HQ, New Delhi.

This cell aims to mobilize physicians about ADRs reporting.

Received ADRs will be forwarded to NCC-PvPI for assessment.

The cell is equipped with skilled manpower, dedicated helpline number for ADR reporting and other logistics.

National Formulary of India (NFI)

an effective tool to promote patient safety: JS (R), AS & DG, MoHFW



Shri K B Aggarwal, AS, MoHFW felicitated by Dr. Y. K Gupta with bamboo sampling as symbolic to promote Green India

With a view to enhance the popularity of National Formulary of India (NFI) amongst the professional community and disseminate comprehensive knowledge about the latest edition NFI 2016, IPC organized a National Symposium on "Role of National Formulary of India for Improving Use of Generic Medicines" at India International Centre, New Delhi on 14th



Shri. K. L. Sharma (centre) JS(R), MoHFW and other dignitaries during the symposium on 14th January 2016

January 2016. The symposium was inaugurated by Prof. Y. K. Gupta, Head, Department of Pharmacology, AIIMS, New Delhi in the presence of other eminent dignitaries. Shri K. L. Sharma, Joint Secretary, MoHFW while addressing the gathering emphasized that NFI should reach all primary health centres for rational prescribing of drugs. Prof. Y. K. Gupta, Chairman Core Group of NFI 2016, cited an example from his college days stating that they were asked to bring five essential study objects while coming to hospital and emphasized that the need of the hour is to bring the sixth object also i.e. NFI which could only be added with willingness of doctors. He said that in order to create the demand for NFI there is a need to make an USP (Unique Selling Proposition) for the same. He also acknowledged the constructive inputs received from experts while developing NFI. Prof. Gupta has been instrumental for successfully leading the team in bringing out two consecutive editions of NFI i.e. NFI-2011 fourth edition and NFI-2016 fifth edition.

Themed on creating awareness among stakeholders, the event featured visionary talks from renowned academicians and regulators, technical presentations from researchers and two plenary sessions on importance of NFI.

While speaking on the occasion Shri K. L. Sharma, JS (R) pointed out that NFI & PvPI should closely work together to promote patient safety.

He also emphasized that NFI should reach primary health centres for rational prescribing of drugs.

Speaking on the occasion, Shri K.B. Aggarwal, Addl. Secretary, MoHFW, GoI, Chief Guest of the symposium appreciated the untiring efforts of expert committee members and IPC officials in bring out NFI 2016 and also expressed the need to make NFI interactive. In the plenary session on stakeholder's perspective on NFI, he encouraged stakeholders to adopt NFI in their routine clinical practice to promote rational use of medicines and promote patient safety.

The event was successfully managed with overall support of Secretary-cum-Scientific Director, IPC and associated staff. With participants from various hospitals, academia and pharmaceutical companies, the symposium

showcased the concept in bringing out the 5th edition of NFI, emphasizing its process of development and salient features. An overall excellent feedback was received from majority of participants.

Holistic Approach of PvPI

“INVOLVEMENT AND RESPONSIBILITIES OF CORPORATE AND DISTRICT LEVEL HOSPITALS IN PVPI- GHAZIABAD & NOIDA REGION”

The current Adverse Drug Reaction Monitoring Centres (AMCs) under PvPI are government teaching hospitals as well as corporate medical colleges for reporting of ADRs. The participation of corporate hospitals in PvPI is paramount because the newly introduced drugs are mostly used in the corporate hospitals. Also the range of drugs used in private sector is higher than public sector. Therefore, there is a need for PvPI to collaborate with the corporate hospitals to monitor the safety of new drugs available in the market. To enhance the participation of district/corporate level hospitals in PvPI, IPC invited corporate hospitals and district hospitals of Ghaziabad and Noida region for the same.

The meeting held on 11th January 2016 at IPC, was chaired by Dr. K.K. Kalra, CEO NABH,

who urged the corporate hospitals to come forward to support PvPI. As 80% of the patient care is provided by corporate hospitals, there is a huge responsibility in their hands to promote patient safety. He also informed that the ADR reporting by the corporate hospitals is mandatory for the NABH accreditation of hospitals or its subsequent renewal. Ms. Rubina Bose, Deputy Drugs Controller, CDSCO also emphasized the same proposal.

Dr. Sanjeev Sharma, Clinical Pharmacologist, Apollo hospital, New Delhi delivered a talk on “How to setup a pharmacovigilance system/unit in corporate hospitals” and he clarified that no investment is required by corporate hospitals in setting up the system as the same can be established with the help of existing logistics and manpower in the hospital.



Dr. K. K. Kalra, CEO, NABH with CDSCO and IPC officials during the meeting with corporate hospitals and district hospitals participants organized by PvPI at IPC on 11th January 2016

The following suggestions and recommendations have emerged during the interactive session:

1. The certificates of award may be issued by NCC-PvPI to the corporate hospitals based on their contribution to PvPI.
2. The participants appreciated the developments and efforts taken to promote PvPI and suggested to advertize the achievements in newspapers, TV and radio. The participants suggested that the ADR reporting posters be made available in Hindi and other regional languages. The house also suggested NCC-PvPI to develop ADR e-reporting system.
3. The participants were convinced regarding the need of Pharmacovigilance system in their respective hospitals and agreed to contribute to PvPI. For this purpose, more number of corporate hospitals may be recognized as AMCs under PvPI. There is an urgent need to reach out the message to the community pharmacists. This will create a scope for ensuring the safety of OTC products.
4. The Technical Associates from NCC-PvPI will be visiting the corporate/district hospitals of Delhi NCR region periodically to facilitate/initiate the ADR monitoring and reporting.

ICMR Institutions to join hands with PvPI: Secretary, DHR

The two days workshop on Pharmacovigilance and Pharmacoepidemiology in RNTCP was held on 4-5th March 2016 at National Research Institute in Tuberculosis (NRIT), Chennai.

The objective of this workshop was to gain a better understanding of the ongoing Programme and the challenges in reporting of ADRs to anti-TB treatment.

It was also aimed to develop an operational research protocol related to daily anti-TB treatment.

The meeting was attended by more than 70 experts of PvPI, AMC coordinators, TB treatment centres, RNTCP, Scientists/Director's of various Indian Council of Medical Research (ICMR) Institutes and WHO experts. While addressing the gathering Dr. Soumya Swaminathan, Director General (DG), ICMR, Department of Health Research (DHR) emphasized that PvPI & ICMR Institutions must work together for improving the pharmacovigilance standards, basic knowledge & skills of Healthcare Professional (HCPs) to ensure the safety of the vulnerable population while exposed to different drug regimen. The ICMR institutions such as National AIDS Research Institution (NARI), Pune, Institute of Research in Reproductive Health (IRRH), Mumbai, National Institute of Cholera & Enteric Diseases (NICED), Kolkata, National Institute of Nutrition (NIN), Hyderabad, National Institute of Epidemiology (NIE), Chennai, National Institute of Malaria Research (NIMR), Delhi have expressed their deep interest to collaborate with PvPI. Dr Soumya Swaminathan concluded the workshop by stating that ICMR Institutions may be declared as PvPI collaborating centres. She also suggested PvPI to identify the scope of the activities for collaboration and mutual avenues.



Dr. Soumya Swaminathan, Director General (DG), ICMR, Department of Health Research (DHR) along with Participants of Pharmacovigilance and Pharmacoepidemiology in RNTCP workshop held on 4-5th March 2016 at Chennai

PvPI in International Arena

Mr. Nana Ansah Adjei, Ghana- Visited IPC

GHANIAN GOVERNMENT OFFICIAL HAILS STEPS TAKEN BY PvPI AS IMPORTANT AND EXPRESSES INTENT TO WORK TOGETHER WITH INDIA FOR BETTER PHARMACOVIGILANCE



Mr. Nana Ansah Adjei, interact with PvPI helpline section on 9th Feb 2016



Mr. Nana Ansah Adjei, Medicines Quality & Safety Specialist, Food and Drugs Authority (FDA), Ghana visited IPC, NCC-PvPI on 9th Feb 2016. Mr. Nana discussed the importance of PvPI and showed interest of Ghana FDA to work together for pharmacovigilance. He also updated the areas of PvPI understanding, leadership and communications, insight into operations with the use of data collection, analytical and executive pharmacovigilance tools. He appreciated the skill, knowledge, competence and collaborative mindset of NCC officials. He was overwhelmed about the PvPI helpline number, which is a unique facility in India for reporting ADRs. He also expressed his desire to introduce this facility in Ghana also.

CDSCO interacts with Swedish counterpart to promote Patient Safety


The CDSCO organized a meeting to discuss the Memorandum of Intent between India & Sweden to understand and to update the various issues related to regulation and pharmacovigilance on 2nd March 2016 at CDSCO headquarters, New Delhi. On behalf of Swedish Medical Product Agency Mr. Backman Christer and Mrs. Karin Grondahl 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. This meeting was fruitful and mutual information was exchanged among both the NRAs. As far as PvPI is concerned it was a second deliberation with Swedish NRA as first meeting was held on 25th Nov 2014. As compared to Swedish Signal Detection in Pharmacovigilance, India is still in the process of integration of PSUR and Clinical Trial data.



Mr. Backman Christer and Mrs. Karin Grondahl, Medical Product Agency Sweden participated in the meeting held on 2nd March 2016 at CDSCO Headquarter

“Induction cum Training Programme” **Newly Recruited Technical Associates’**

FULFILLING NCC’S OBJECTIVE OF PROVIDING AVENUES FOR SKILL DEVELOPMENT, A PROGRAMME WAS ORGANIZED WHERE NEW RECRUITS WERE TRAINED IN BEST PRACTICES AND EDUCATED ABOUT THE NEED TO UPHOLD MEDICAL ETHICS AND MORALITY

 Since the Government of India’s flagship scheme of Pradhan Mantri Kaushal Vikas Yojana (PMKVY) is geared up for imparting skill development training to youth, NCC is pledged to implement the same to cater the training and skill development of the young Pharmacovigilante’s. In the last couple of years, NCC organized several skill development programs for the healthcare providers to empower them in pharmacovigilance.

Further, NCC-PvPI organized the ‘Induction – cum-Training’ for the newly appointed Technical Associates (TAs) in PvPI from 15-19th February 2016 at IPC, Ghaziabad. Dr. Ajay Sachan, Asst. Drugs Controller (India), CDSCO (North Zone) inaugurated the training and congratulated the participants for choosing pharmacovigilance as a career. He motivated

the participants to become good healthcare providers. He also emphasised the hard work and commitment of PvPI in the direction.

On the occasion, Dr. Jyotsna Sharma, Asst. Professor, Santosh Medical College, Dr. Ruchi Choudhary, Asst. Professor, Subharti Medical College, coordinators of various ADRs monitoring centres, Dr. Greeshma Upendra, Dr. Maria Barretto, post graduate students of GMC Bambolim and staff of NCC-PvPI, were present. In the ‘Induction-cum-Training’, the newly appointed TAs were trained on the concept and Good Pharmacovigilance Practices. They were also trained to learn, perform and enhance their potential by inculcating multi skills to accomplish the objectives of PvPI. They were taught not only technical and non-technical aspects but also ethics, morality and human values.

Nursing Professionals “Indispensable role”

Patient safety is an essential and vital component of quality nursing care. This profession is pivotal in helping patients manage their medications and prevent polypharmacy which may lead to nonadherence with the medication regimen and several drug-drug interaction/medication errors further leading to ADRs. Nurses have a unique opportunity to help identify patients at risk for inappropriate polypharmacy and to educate patients and families about risk reduction.

Spontaneous Reporting of ADRs has existed

as the cornerstone of pharmacovigilance and is important in maintaining patient safety. Nurses working in hospitals could play an important role in ADRs reporting, as they are in direct contact with the patients and have good knowledge of health criteria, symptoms, drugs and ADRs. Given their unique position in drug administration and recording side effects, nurses are well-placed to monitor the patients’ response to drugs. They are often the source in alerting the responsible physician about possible ADRs. There is thus an



Nursing Staff, Jaypee Hospital Noida participating in training-cum interacting session conducted on 5th February 2016

obvious reason to involve nurses and encourage them to contribute in ADR reporting system.

This training of Nursing Professionals was conducted to assess the nurses' knowledge towards Pharmacovigilance, reasons for not reporting ADRs, and their Pharmacovigilance practice. The main cause of under-reporting of the suspected ADRs was lack of awareness about the existence of nationwide programme. For the awareness of Pharmacovigilance Programme of India, training cum interactive session was conducted by NCC- PvPI for the nursing staff at Jaypee Hospital, Noida on 5th February 2016. In this training, official team of NCC-PvPI presented, how to identify an ADR, what to report and whom to report.

Team of NCC-PvPI also described how to fill up the ADR reporting form and how to report ADRs through PvPI toll free helpline number and use of ADR reporting Android Mobile Application respectively. An interactive session was conducted between the nursing staff and official team of NCC-PvPI to discuss various aspects related to pharmacovigilance clarifying the reporting criteria. Some effective

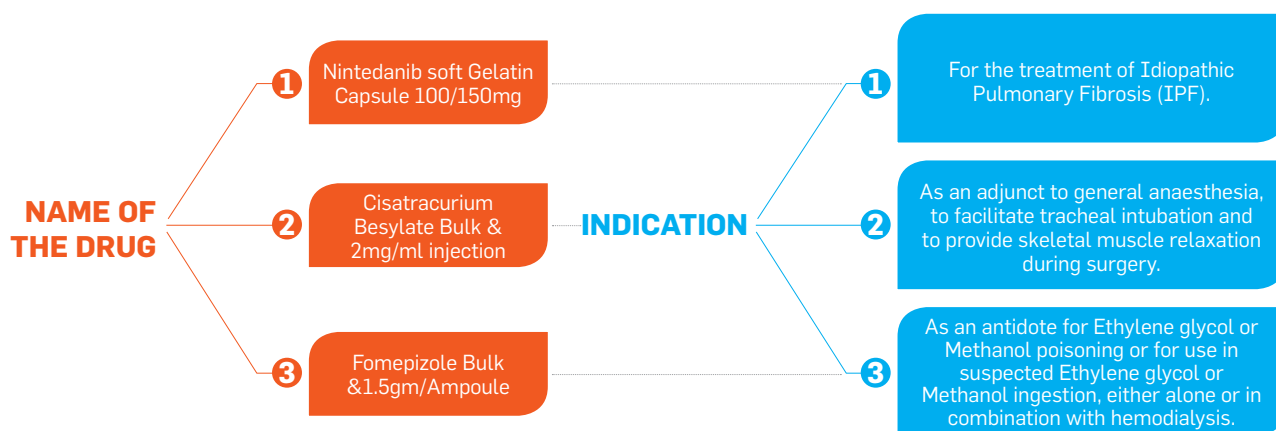
measures were discussed to improve the situation such as inclusion of pharmacovigilance into pre and post-graduate continuing education programs, provision of guidelines for ADR spontaneous reporting and giving feed-back information to the Reporters, establishment of Regional Pharmacovigilance units which could efficiently stimulate ADR reporting.

Every State Nursing Councils will play a crucial role in nursing education & practice to implement the ADR reporting by nurses during their professional services. This can be executed as two mandatory credit hours out of thirty hours for pharmacovigilance activities & PvPI while renewal of nursing registration in the State Nursing Council.

Hence, nurses can enhance patient safety being competent team leaders by identifying potential risks and learning the proper terminology to identify and describe health care errors. These activities will most likely to occur in a non-punitive environment where nurses feel safe and secure while reporting ADRs/Medication Errors/Drug-Drug Interactions.

New Drugs Approval Status in India

THE FOLLOWING DRUGS WERE APPROVED DURING THE PERIOD OF JANUARY TO MARCH 2016 BY CENTRAL DRUGS STANDARDS CONTROL ORGANIZATION (CDSCO)



PvPI Recommendations and Regulatory Action

PERTINENT RECOMMENDATIONS MADE BY PvPI TO CONCERNED BODIES AFTER COLLECTING AND REVIEWING REPORTS OF VARIOUS DRUGS, HAVE BEEN TAKEN INTO CONSIDERATION AND WAS IMPLEMENTED



PvPI collected several reports across the country. The unlisted reports of piperacilline & tazobactam induced hypokalemia and bronchospasm are segregated which are based on the strong underlying association and published literature, Piperacillin & Tazobactam induced hypokalemia and bronchospasm were identified and was confirmed by Signal Review Panel (SRP) of PvPI and recommended CDSCO to change the label on package of Fixed Drug Combination (FDC) of piperacilline & tazobactam. Subsequently, CDSCO

recently issued instruction to manufacturers to ensure label change on package FDC of piperacilline & tazobactam.

PvPI RECOMMENDATIONS

The 6th and 7th meetings of PvPI held on 6th October 2015 and 1st March 2016 recommended to Indian regulatory Authority i.e CDSCO for the Label change and warning in package inserts of certain pharmaceutical products which are marketed in India as follows:

S.NO	DRUGS	ADVERSE DRUGS REACTIONS	RECOMMENDATIONS
1	Ranitidine	Cardiac Arrest	For Label Change
2	Anti Rabies Vaccine	Erythema Multiforme	For Label Change
3	Pulmonary Surfactant	Pulmonary Haemorrhage	For Label Change
4	Ceftriaxone	Stevens Johnson Syndrome	For Label Change
5	Lamotrigine	Stevens Johnson Syndrome and Toxic Epidermal Necrolysis	For Label Change

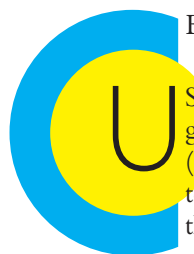
REGULATORY ACTIONS

As per the recommendations of PvPI, the Indian National Regulatory Authority, CDSCO has taken further action as detailed below:

S.NO	DRUGS	ADVERSE DRUGS REACTIONS	CDSCO ACTIONS
1	Carbamazepine	Stevens Johnson Syndrome and Toxic Epidermal Necrolysis	CDSCO instructed to Marketing Authorization Holder (MAH) to comply with the same
2	Mannitol	Hypokalaemia	Approved in the Subject expert committee (SEC) of CDSCO
3	Rotavirus Vaccine	Intussusception	Approved in the SEC of CDSCO
4	Piperacilline & Tazobactam	Hypokalaemia and Bronchospasm	CDSCO instructed to MAH to comply with the same

SGLT 2 inhibitors induced Urinary Tract Infection (UTI) – Status in PvPI database with USFDA

PRODUCT LABELS OF DRUGS UPDATED AFTER STUDY BY PvPI REVEALS DISEASES INDUCED BY THEIR COMBINATION; 13 CASES RECORDED TILL MARCH 2016



USFDA has updated the product labels of sodium glucose cotransporter-2 (SGLT 2) inhibitors (canagliflozin, dapagliflozin and empagliflozin) to include Urinary Tract Infection (UTI) after the review of 73 ICSRs of ketoacidosis in patient with type-1 and type-2 diabetes treated with SGLT-2 inhibitors and 19 cases of life-threatening

blood infection (urosepsis) and kidney infections (pyelonephritis). After a brief study in extracted cases of PvPI database there were 13 case reports with similar drug-ADR combination upto March 2016. All SGLT 2 induced UTI are already listed in Indian package insert. Therefore healthcare professionals are requested to monitor and follow precautions:-

NAME OF DRUG	RISK	STATUS IN USFDA	PvPI STATUS
Sodium glucose co-transporter 2 (SGLT2) inhibitors canagliflozin, dapagliflozin and empagliflozin	Risk of acid in blood and serious urinary tract infections	The USFDA has updated the product labels of Sodium glucose co-transporter 2 (SGLT2) inhibitors to include warnings about risk of too much acid in blood and serious urinary tract infections.	PvPI have received total 13 reports of ketoacidosis and UTI. Urinary tract infection including genito-UTI and 8 cases were of ketoacidosis which also included cases of urosepsis, encephalopathy and diarrhoea. Therefore healthcare professionals are advised to assess for ketoacidosis and UTI in patient taking SGLT2 inhibitors who present with suggestive symptoms.

PvPI DRUG ALERTS

The preliminary analysis of SUSARs from the PvPI database reveals that the following drugs are associated with the risks as given below.

OLANZEPINE HYPONATRAEMIA

Indication: Schizophrenia, acute mania episodes in bipolar disorder

Alert: Hyponatremia is found among patients, who have been taking the olanzepine for 1-6 months.

NICORANDIL RISK OF ULCER COMPLICATION

Indication: Angina Pectoris, Vasodilator

Alert: Nicorandil can cause serious skin, mucosal, and eye ulceration, including gastrointestinal ulcers which may progress to perforation, haemorrhage, fistula or abscess.

PHENYTOIN ANGIOEDEMA, OSTEOPOROSIS

Indication: Generalized tonic-clonic seizures, partial seizures, status epilepticus

Alert: Angioedema is found people who have been taking the phenytoin for <1 month. Osteoporosis data suggests that long term use of phenytoin is associated with decreased bone mineral density that may lead to osteopenia, osteoporosis and increased fracture.

CRIZOTINIB RISK OF CARDIAC FAILURE

Indication: Locally advanced or metastatic non-small cell lung cancer (NSCLC) that is Anaplastic Lymphoma Kinase (ALK)

Alert: Monitor all patients for signs and symptoms of heart failure (including dyspnoea, oedema or rapid weight gain from fluid retention).

Healthcare professionals and patients are advised to closely monitor the possibility of the above adverse events while prescribing/consuming above suspected drugs and report to the NCC-PvPI.

Pharmacovigilance in Government Rajaji Hospital, Madurai

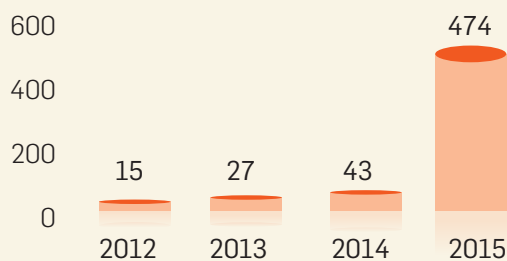
THE AMC TEAM HAS EFFECTIVELY SENSITIZED ALL DEPARTMENTS OF THE 2200-BED HOSPITAL ABOUT ADVERSE DRUG REACTIONS AND MADE CRITICAL INTERVENTION BY REPLACING 3000 DEFECTIVE IV SETS

The Government Rajaji Hospital (GRH), Madurai is situated at the heart of temple city. This magnificent hospital stands as a living testimony for the relentless efforts of the pioneers behind the establishment of the institution. To commemorate this, a spacious area with various departments having in-patient capacity of around 2200 beds is established. The Pharmacovigilance (Pv) cell in the Institute of Pharmacology, commenced in the year 2012 by the Dean, Madurai Medical College, was approved as an AMC by the year 2014. Dr. M. Sheik Davooth, is an enthusiastic, intelligent and active Coordinator. His involvement in day to day activities of AMC, his efforts and active participation took the AMC to these levels of success. The Coordinator conducted different sensitization and awareness programmes on pharmacovigilance and ADR reporting in all the departments of GRH Madurai. The centre continues to concentrate on both excellence and magnitude of reporting and is helpful to the stakeholders of PvPI. As part of the programme, the AMC found defective IV sets and replaced 3000 IV sets, which might have caused ADRs (Chills, Rigors) in 3000 patients. The AMC is grateful to all the clinicians of GRH for their participation in PvPI and reporting adverse drug reactions being the back bone of the Pharmacovigilance system and working for the national cause and patient safety.

- Drug eruption induced by Ciprofloxacin
- Drug eruption induced by Amoxycilin & Clavulanic acid
- Erythroderma induced by Leflunomide
- Acute Generalized Exanthematous Pustulosis (AGEP) induced Amikacin/Meropenum

The possibility of the above mentioned SAE have been communicated to all HCPs in order to take appropriate preventive measures for the patients who were prescribed above mentioned drugs. Also the Rajaji hospital has send out a clear message across the country to closely monitor the above possible listed/unlisted ADRs.

Year wise number of ICSRs report



CAC Committee & Department of Pharmacology faculty members of MMC in Presence of Director Dr. R. Parameswari in a meeting at GRH Madurai

THE FOLLOWING SERIOUS ADRS HAVE BEEN NOTICED IN THE HOSPITAL AND REPORTED TO PvPI.

- Stevens Johnson Syndrome(SJS) induced by Carbamazepine

Goa Medical College: AMC on the ascendancy

The GMC Bambolim, Goa is recognized by PvPI as an AMC in the year 2010. It is the only AMC in the union territory of India to cater the PV. In order to gear up the activities several matters have been exchanged between NCC-PvPI and GMC. As one of the moves, NCC requested officials of the CDSCO, Goa office to visit the GMC to take stock of the situation. CDSCO Officials visited and while lauding of work progress in the department, pointed out, the challenges too. They suggested for the appointment of Technical Associate, and pharmacovigilance training and skill development must be provided on top priority. Based on the suggestions, NCC-PvPI took a prompt action on the mentioned issues.

Jabalpur Medical College: Incredible growth story of pharmacovigilance

NSCB Medical College, Jabalpur recognized as AMC under PvPI in the year 2014. Dr. K. K. Daryani, Prof (HOD) of Dept. of Pharmacology and Dr. Sachin Kuchya Associate Professor in Dept. of Pharmacology held the responsibilities of Coordinator and Deputy Coordinator respectively.

Several meetings were held with the Heads of various clinical and preclinical departments to appraise them about ADR reporting and the role they need to play. In regular activities, they started daily visits to wards, OPD and various departments to appraise the staff about reporting ADR and to collect, correct and follow up ADR reports. They sent monthly reports to the Dean and various departments of AMC. They have also motivated and encouraged health care professionals through PvPI newsletters.

From time to time they have conducted meeting with HOD and Staff of one department at a time. The Coordinator, Deputy Coordinator and TA met departmental staff personally about ADR reporting including consultant, PG students, paramedical and nursing staff of that department.

Eight seminars on ADR reporting have been conducted in various departments at NSCB Medical College. On 31st October 2015 they organized a regional workshop which includes 25 medical colleges of MP, Chhattisgarh, Maharashtra and UP. The workshop aimed to sensitize practitioners and give hands on training for ADR reporting to students (UGs and PGs) through ADR reporting form and mobile app as well. The Speakers, Prof (Dr) S P Dhaneria, DM DNB (Clinical Pharmacology), Dean (Academics), AIIMS, Raipur and Prof. (Dr) Prem Nyati, MD (Pharmacology), Vice Dean, Index Medical College & Research Centre, Indore (MP) were facilitators for the workshop.

ACHIEVEMENTS OF AMC

The most innovative tool among various aspects of ADR reporting android based application for India which has been developed by Dr. Sachin Kuchya with the collaboration of IPC was launched

nationally by IPC on 22nd May 2015. The ADR reporting application has been widely appreciated as an innovative idea. It has many features like fill in defaults, auto-entry etc and has positive impact on quality of reporting and for expanding our horizon for ADR reporting.

The Centre also tied up with BMC, Sagar on 21st December 2015 for ADR reporting through their AMC. They have been visiting private hospitals to sensitize them about importance of ADR reporting and ADR reporting Application.

The Centre is planning to introduce toll free number for ADR reporting on their OPD slip with a message for ADR reporting by consumers in local languages. They have also made a “seal” to print on OPD slip which includes PvPI toll free number and AMC number. They have also displayed posters in wards and OPD along with Hindi pamphlets.

The efforts regarding sensitization of public health officials had been noticed by various news papers. They have also broadcasted a programme by Dr. Sachin Kuchya on local FM channel to sensitize public on ADR reporting.

The Coordinator of the centre Dr. K K Daryani has also sensitized the faculty of Vehicle Factory Jabalpur Hospital about rational use of drugs and importance of ADR reporting and pharmacovigilance. He has also made them install ADR app and demonstrated how to use.

The Centre also contacted State Health Department and requested them to arrange workshop for ADR reporting for staff working at Dist. Hospitals, CHPs, PHCs.

The Centre reported total number of 250 ADRs ever since the establishment of AMC at NSCB Medical College. The departments of ART and RNTCP are performing as the best AMCs.



PvPI staff of NSCB Medical College during the sensitization programme held on 31st October 2015

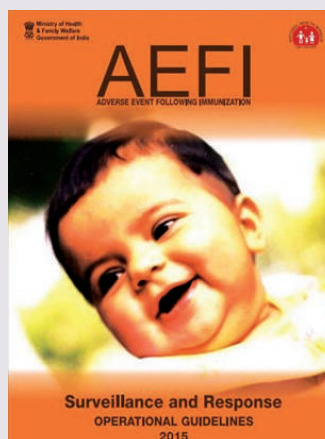
Update on AEFI surveillance program

GOVERNMENT PUBLISHES NEW GUIDELINES TO STREAMLINE EFFORTS TOWARDS TACKLING ADVERSE EFFECTS DURING IMMUNIZATION; PLANS TO LEVERAGE SURVEILLANCE WITH HELP OF WHO NATIONAL POLIO SURVEILLANCE PROJECT NETWORK

The revised Adverse Event Following Immunization (AEFI) guidelines published by Ministry of Health & Family Welfare (MoHFW), Government of India (GoI) ensure more effective implementation and surveillance on vaccine safety. These guidelines also aim to strengthen vaccine risk communication including program communications and media AEFI report handling including crisis management. AMC Coordinators are encouraged to review the new AEFI Guidelines in the link <https://www.itsu.org.in/repository-resources/AEFI-Surveillance-and-Response-Operational-Guidelines-2015.pdf>

SALIENT FEATURES OF AEFI GUIDELINES (2015)

- ➔ Reporting Serious/ severe AEFI reports.
- ➔ New reporting formats: Case Investigation Form (CIF) Preliminary Case Investigation Form (PCIF) and Final Case Investigation Form (FCIF).
- ➔ Reporting of all AEFI cases following all prophylactic vaccines including Universal Immunization Programme (UIP) as well as Non UIP vaccine
- ➔ Reporting Timelines are reduced: (CIF-within 48 hours of notification; PCIF- within 10 days of notification; FCIF- within 70 days of notification; state causality assessment- within 100



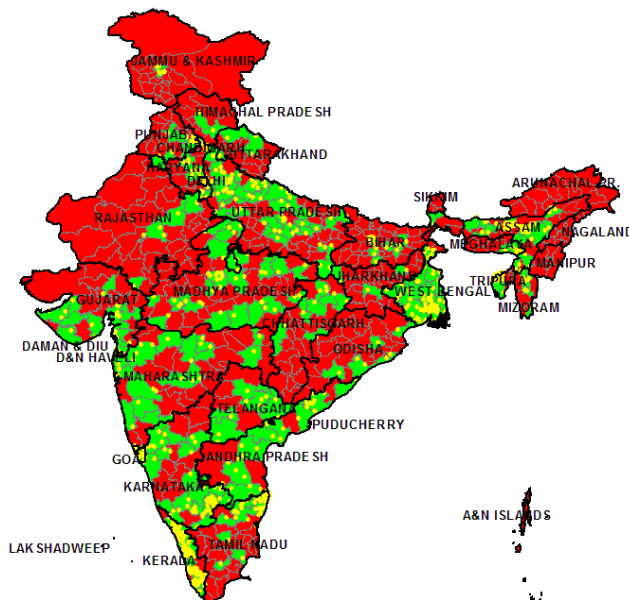
- days of notification)
- ➔ Emphasis is placed on clinical diagnosis of reported cases
- ➔ Verbal Autopsy format for death cases (For brought dead/home death/ insufficient medical records/not hospitalized/ incase clinical diagnosis not possible)
- ➔ Guidance document for autopsy of reported AEFI deaths
- ➔ Nil reporting: Vaccine Preventable Disease (VPD) forms of H002 and D001.

The last couple of years have witnessed progressive strengthening of the National AEFI Surveillance System in the country. The Ministry of Health & Family Welfare, Government of India has taken number of initiatives including to strengthen the Operational aspects of AEFI surveillance by establishment of the National AEFI Secretariat at Immunization Technical Support Unit (ITSU) since 2012 and the National AEFI technical collaborating centre at Lady Hardinge Medical College (LHMC) for technical oversight and support. Regular Causality Assessment meetings

have been conducted by the Secretariat together with the National AEFI Technical Collaborating Centre as per the new WHO causality assessment protocol to ensure all reported cases are causally assessed. Causality assessment classification of approx. 1000 AEFI reports has been completed by the National AEFI Committee and shared on the MoHFW website. State AEFI Committees are in place in all 36 states/UTs and in 95% of all districts. The District AEFI Committees, which play an active role in AEFI case investigations, are in place.

Moreover, to strengthen AEFI surveillance the support of WHO National Polio Surveillance Project network is being leveraged further at state and district level. ANM and ASHA training on a special immunization curriculum including a module on detecting, reporting and managing AEFIs in the field. A film on AEFI has been developed to sensitize the health workers on reporting and management of AEFIs and is being disseminated across the country. Communication guidelines for AEFI for health workers for maintaining vaccine confidence in UIP together with Spokespersons training to advocate and build confidence have been undertaken in 8 states.

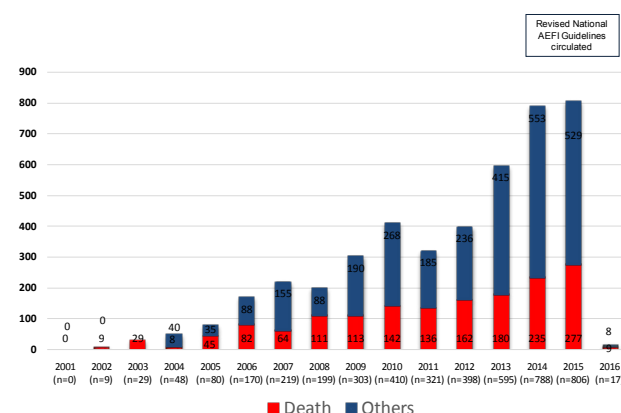
Due to these initiatives reporting of AEFI cases has improved over the years considerably but there is still scope for further improvement in terms of reporting of AEFIs in India, when compared to number of doses administered to children in the country. There is close coordination with vaccine pharmacovigilance stakeholders for collating all vaccine safety reports from all sources i.e. Indian Pharmacopoeia Commission (IPC), CDSCO and AEFI surveillance program to strengthen the National Regulatory Authority in India. There is already a data sharing arrangement for immediate sharing of serious AEFI reports and monthly sharing of non-serious AEFI reports received by PvPI with the National AEFI Secretariat, Govt. of India.



Reporting districts in India (Year 2015)

Yellow dot- Reported cases Green - Reporting district
Red - Non Reporting districts

AEFI Death cases trend out of serious AEFI cases reported, 2001-2016*



*Data as on 16-Jan-2016

Increasing trend of reporting National AEFI Surveillance Programme

COORDINATION BETWEEN IPC (PVPI) FOR IMMEDIATE REPORTING OF AEFI CASES

- Technical Associates/ Nodal Coordinator are encouraged to become members of District AEFI committee
- Technical Associates/ Nodal Coordinator (ADR monitoring center) identify serious and severe AEFI, complete patient identifiers and vaccine details (i.e. First page of CRF and current status) and encouraged to share the copy by Email to local District Immunization Officer (DIO)
- District Immunization Officer (DIO) to verify the details, complete the CRF and send to aefiindia@gmail.com within 24 hours of case notification by Technical associates/ Nodal Coordinator (ADR monitoring centre)
- District AEFI Committee to investigate the reported AEFI as per National AEFI guidelines and share the remaining reporting formats (PCIF, FCIF, relevant records) to state and National Level as per timelines.
- Inclusion of PvPI Staff in State AEFI Committees. IPC National representatives are already members of the National AEFI Committee.

Pharmacovigilance System Mandate for Drug Manufacturers

Periodic Safety Update Report (PSUR) and Post Marketing Surveillance (4th phase of clinical trial) is described in schedule Y of Drugs & Cosmetic Act 1940 and its rules 1945. Now Government of India, Ministry of Health & Family Welfare on 8th March 2016 published a Gazette Notification under Drugs & Cosmetics Act 1940 and rules 1945 there under included Pharmacovigilance system as a mandate for drugs approved by drug regulatory authorities. The details included in the Gazette Notification G.S.R. 287 (E) are as under:-

Post Marketing Surveillance.-

I) The applicant shall have a pharmacovigilance system in place for collecting, processing and forwarding the report to the licensing authority for information on adverse drug reactions emerging from the use of the drugs manufactured or marketed by the applicant in the country.

Ia) The system shall be managed by qualified and trained personnel and the officer in-charge of

collection and processing of data shall be a medical officer or a pharmacist trained in collection and analysis of adverse drug reaction reports.

Ib) Subsequent to approval of the product, new drug shall be closely monitored for its clinical safety once it is marketed.

Ic) The applicant shall furnish Periodic Safety Update Reports (PSURs) in order to-

- (a) Report all relevant new information from appropriate sources;
- (b) Relate the data to patient exposure;
- (c) Summarise the market authorisation status in different countries and any significant variations related to safety; and
- (d) Indicate whether changes shall be made to product information in order to optimise the use of product."

PvPI reaches private practitioners by empowering MR training on pharmacovigilance

Medical Representatives (MR) play an essential role as they directly interact with the HCP's to introduce them about the novel drugs & their associated adverse effects. As one of recommendation during "A round table meeting on "Challenges and Issues for the Pharmaceutical Industries in Reporting ADRs to PvPI" was held at Indian Pharmacopoeia Commission, Ghaziabad on 29th April 2015 to train the Medical Representatives of the pharmaceutical industries on the concept of

pharmacovigilance. M/s Alkem Laboratories limited invited PvPI officials to discuss basic pharmacovigilance, on how, where, what, whom & why to report ADRs to PvPI. PvPI officials trained 25 medical representatives (all over India) of, M/s Alkem Laboratories Pvt Ltd at Lonavala, Mumbai on 7th March 2016 & officials emphasized on key responsibilities of the MRs to enhance the quantity of ADR reporting and further to promote drugs safety in india especially which are being prescribed by private practitioners.

Second Asia Pacific Pharmacovigilance Training Course

JSS College of Pharmacy, Mysuru is an AMC and also acts as regional Training Centre (RTC) under PvPI. JSS University in collaboration with UMC conducted “Second Asia Pacific Pharmacovigilance Training Course” from 18-29th January 2016 at Mysuru. Experts from UMC, course drew 14 attendees from national regulatory authorities, pharmaceutical companies, academia, contract research organizations, and the health care sector in eight Asian and two African countries.



Mentors, Participants in Second Asia Pacific Pharmacovigilance Training Course” held on 18-29th January 2016 at Mysuru

Upcoming Events

S.No	Date	Title	Organised by	Organised at	Participants/ Target Audiences
1	29 th April	Round Table Meeting on Challenges and Issues for the Indian Pharmaceuticals Industries in Reporting ADR to PvPI	IPC, NCC-PvPI	IPC, Ghaziabad	NCC-PvPI, CDSCO & Pharmaceutical Manufacturers
2	6 th May	1st National level meeting on participation of Nursing Professionals in PvPI	IPC, NCC-PvPI	IPC, Ghaziabad	Nursing Stakeholders

Appreciation column

PvPI is extremely happy with the personnel working as Technical Associates in various AMCs. PvPI acknowledges the contribution of those committed people whose efforts in protecting lives of patients are commendable. The professional and tactful way in which they interact with the patients to protect them is praise worthy. We are proud of our team who are extremely efficient and alert. We provide a secure and comfortable platform for patients. We acknowledge their efficiency and capability to save lives of patients. These following personalities make patient safety paramount and we acknowledge their immense contribution to PvPI:-

MR. THIRUMALI NAMBI. T

Technical Associate, Madurai Medical College,
Madurai, Tamil Nadu

Contributions

- Prevention of the mishap which might be caused ADRs in 3000 patients.
- Informing the same to state drug regulatory authorities for appropriate action.



MR. KUNAL

Technical Associate, AIIMS, Patna, Bihar

Contributions

- Implementation in Registration Consent Form of OPD.



MR. VIKAS SAINI

Technical Associate,
PGIMER, Chandigarh

Contributions

- Incorporation of the suspected ADR documentation form in In-patient file.



MS. SWATI THAPLIYAL

Technical Associate,
Veer Chandra Singh Garhwali Medical
Science and Research Institute. Srinagar,
Pauri Garhwal, Uttarakhand

Contributions

- Incorporation of the suspected ADR documentation form in the In-patient file.



Indian Pharmacopoeia Commission

National Coordination Centre,
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare, Govt. of India,
Sector-23, Raj Nagar, Ghaziabad- 201002
Tel.: 0120-2783400, 2783401, 2783392
Fax: 0120-2783311

For any other Information/Suggestions/ Query contact:

Officer Incharge

Pharmacovigilance Programme of India

Email: ipclab@vsnl.net, pvpi@ipcindia.net

Website: www.ipc.gov.in

let us join hands with PvPI to ensure patient safety

ADR reporting Helpline (Toll Free): 1800-180-3024