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# Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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# PvPI Milestones @ 2018

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# *Message from National Scientific Coordinator*

I take this opportunity to reach out to the readers, who may be stakeholders or general public, and convey my appreciation to the Pharmacovigilance Programme of India (PvPI), IPC. PvPI has done remarkably well during its infancy and has progressed significantly in detection and reporting of adverse drug reactions, analyzing the data and taking it forward. Since its inception, the PvPI today stands at a pedestal with the World Health Organization granting it the status of a WHO-CC for Asia in sustainable pharmacovigilance practices.

I personally believe that PvPI is a mission and the personnel involved in the programme have the requisite knowledge and expertise to take up the future challenges and make it a grand success. Let us repose trust in them as they lead the international arena by their untiring efforts and transparency in work process.

With Best Wishes!

**Prof Y K GUPTA**
National Scientific Advisor,
Pharmacovigilance Programme of India

# *Secretary-cum-Scientific Director's Message*


Dear Readers,

It is a great pleasure to release the Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission (IPC) October-December 2018 issue of Newsletter. I am pleasantly surprised with the momentum and advancement in research and development in areas of Pharmacovigilance.

Last quarter brought proud recognition and special honour to PvPI as our team took a step forward in vaccine safety and development of WHO-BMGF 3S Project. IPC put it best foot forward in providing DRA-Bhutan and North Korean delegations training in Pharmacovigilance.

To safeguard the health of Indian population, PvPI joined hands with WHO to develop an advanced set-up of six monitoring centres for Delamanid/Bedaquiline in India. We successfully organized 6th WHO Bi-annual Inter-regional Seminar for Quality Control Laboratories (QCLs) and 4th WHO Global Forum on Medical Devices aimed at increasing public access to Medical Devices. As per the MoU we consistently provide support to NABH in strengthening patient safety with adherence to GvPs.

I trust the institution will make new inroads into advanced research and attain dizzying heights in the near future.

**Dr G N SINGH**
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare
Government of India

# Annual Progress of PvPI @2018

***In year 2018, PvPI resonated with all healthcare stakeholders for drug safety***

In 2018, NCC-PvPI extended its outreach to various public health programmes in India, encouraging them to participate and contribute in nation-wide drug-safety monitoring programme. PvPI, has embarked on a journey across south-east Asia with a mission to establish and strengthen PV system in low-and-middle income countries in Asia.

Year 2018 brought serendipity to the Pharmacovigilance Programme of India (PvPI). IPC participated in PMDA-Asia Training Centre at Tokyo to understand the regulatory changes and compliances with new pharmacovigilance-risk management and adverse event reporting initiatives from International regulatory agencies. A three-phase USFDA-PvPI venture on PV policy and capacity-building meetings were held with the aim of discussing challenges and issues in effective implementation of PV system, PV audits and inspections. Second annual meeting of SEARN was successfully conducted in Sri Lanka with a detailed work plan for mutual exchange of information and mapping of resources for ensuring cost-effectiveness. IPC organized 6th WHO Bi-annual Inter-regional Seminar for Quality Control Laboratories (QCLs). It also participated in 4th WHO Global Forum on Medical Devices -- Increasing Access to Medical Devices held at Visakhapatnam. We shared our training platform with DRA Bhutan and Korean delegations for healthcare safety and management systems in PV.

PvPI joined hands with academic institutions and universities, exhorting Pharma students to opt for pharmacovigilance as an elective subject. PvPI conducted various seminars and lectures with medical professionals on safety of medicines and medical devices. In conjunction with DPSRU, New Delhi, IPC conducted a pre-conference on "Present Status & Future Challenges of Pharmacovigilance: Safety of Medicines & Medical Devices." With the aim of encouraging aspiring entrepreneurs for adopting technologies across the country in the Pharma sector, IPC organized an Entrepreneur Development Programme on Pharmacopoeial and Pharmacovigilance Services.

IPC metastasized wings in MvPI, introducing first national workshop on "Ensuring Quality and Safety of Medical Devices". MvPI drafted a guidance document for medical device safety in cooperation with the NHSRC& BIS, New Delhi. It also conducted regional workshop in Benguluru to raise awareness and understanding of MvPI.

NCC-PvPI collects suspected ADRs from all stakeholders, including MAHs, and reviews the safety information on a regular basis, enabling the regulatory authority – CDSCO to make appropriate regulatory decisions. More than 75 MAHs are enrolled with the PvPI. The feedback by MAHs following the establishment of an effective PV system at their site/ sector has been quite encouraging as it helps ensure patient safety.

Empowering northeast India, a regional workshop was conducted on "Basics of Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries — A Way Forward" for pharmaceutical industries at Royal Plaza hotel in Gangtok, Sikkim and a second workshop was conducted in Kilpauk Medical College, Chennai. IPC conducted first national workshop on "Best Practices and Compliance of Indian Pharmacopoeia standards for herbal drugs and phyto-pharmaceuticals.

Three SDPs with the objective of enhancing PV skills of healthcare professionals were conducted during the year which included technical and practical sessions with field visits to AMCs.

PvPI in 2018 traversed the path to Pharmacovigilance with a speed which resonated with all healthcare stakeholders and, we believe, made remarkable progress in ensuring drug safety.

## LANDMARK EVENTS 2018

- Pharmacovigilance seminar by PMDA-ATC in Tokyo
- Six drug alerts and 14 package insert updates issued from the PvPI database
- WHO-BMGF 3S Project unveiled
- Second annual meeting of South-East Asia Regulatory Network (SEARN) hosted by Sri Lanka
- PvPI all set to address Delamanid/Bedaquiline safety in India
- PvPI as a counterpart in National Deworming Programme of Health mission


- DRA-Bhutan visits IPC for PV and MvPI training
- 1st national workshop on Medical devices' quality/safety and sensitization programme on MDAE reporting
- Regular training on PV for NABH hospitals
- Workshop on 'PSUR evaluation, PV Audits/Inspections'
- Regular Skill Development Programme (SDP) on Basics & Regulatory aspects of Pharmacovigilance
- Workshop on IP standards for phytopharmaceuticals

# 6th WHO Biannual Inter-regional Seminar for QCLs

For the first time in India, IPC in collaboration with World Health Organization (WHO), Geneva organized "06th WHO Bi-annual Inter-regional Seminar for Quality Control Laboratories (QCLs) involved in WHO Pre-Qualification." Held between October 23-25, 2018, at Hotel The LaLit, New Delhi, the seminar was inaugurated by Ms. Preeti Sudan, Hon'ble Secretary, Ministry of Health and Family Welfare, Government of India. This seminar also witnessed august presence of eminent persons like Dr R K Vats, Additional Health Secretary, Dr S Venkatesh, Director General Health Services, Dr Henk Bekedam, WHO Representative India, and Mr Rutendo Kuwana, Technical Officer, WHO Geneva.

The seminar focused on components of Good Laboratory Practices (GLP) to be adopted by the QCLs to achieve the WHO norms and standards. It also stressed need of networking amongst various laboratories in India.

During the inaugural speech, Ms. Preeti Sudan, highlighted that IPC is the only WHO pre-qualified laboratory in the public sector and stressed a need for more number of laboratories to be certified by WHO. She also suggested that state and central drugs testing laboratories should utilize the resources and services available at IPC. Many technical sessions by the experts of WHO and IPC were delivered during the seminar.

A total of 48 participants from 32 countries (Armenia, Belgium, Brazil, Burkina Faso, China, Colombia, Cote d-Ivoire, Cuba, Egypt, Ethiopia, France, Ghana, Indonesia, Kazakhstan, Kenya, Madagascar, Morocco, Niger, Nigeria, Russia, Senegal, South Africa, Tanzania, Thailand, Tunisia, Uganda, Ukraine, Uruguay, USA, Viet Nam, Zambia and Zimbabwe) were invited to attend the seminar and 40 delegates from government and private pharmaceutical companies were also present.

## KEY POINTS

- Proficiency Testing Programme (PTP) by IPC available in the Quality Control Laboratories (QCLs) Network.
- Strengthening Quality assurance and control in SEARN countries.
- Focus on laboratory strengthening including quality control, validation, Quality Management Systems, EQAAS etc
- IPC to hold national level joint workshops with WHO for capacity building
- Impart training to public and private sector laboratories on various analytical technique in drug testing

# 4th WHO Global Forum on Medical Devices

With an objective of sensitizing healthcare professionals and consumers in Andhra Pradesh about ADR-reporting in MvPI, the officials from IPC, attended the 4th WHO Global Forum on Medical Devices-Increasing access to Medical Devices which was held December 12-15, 2018 at Andhra Med Tech Zone (AMTZ), Pragathi Maidan, Visakhapatnam. Meeting was inaugurated by Shri Chandrababu Naidu, honourable Chief Minister, Andhra Pradesh and witnessed the auspicious presence of Shri Ashwini Kumar Chaube, Minister of State for Health and Family Welfare, Govt. of India and other senior officials of Govt. of India. More than one thousands participants from different parts of world attended the meeting. Apart from attending the sessions, IPC as a WHO Collaborating Centre conducted the workshop on "Leveraging regulatory network-South East Asia Regulatory Network (SEARN)" for access to quality, safer and affordable medical devices. In addition, Dr. Kalaiselvan, PSO, IPC also presented his views on Materiovigilance Programme of India (MvPI)-an Overview.

## BENEFITS AND OUTCOME:

- Sensitized the gathering on functioning of MvPI
- Spread awareness regarding activities of MvPI-IPC Ghaziabad
- Provided an opportunity to identify and improve the gap areas to enhance the adverse events reporting
- Understand tools to integrate vigilance activities with regulatory system, in coordination with AMTZ

# North Korean Delegation at IPC

As a WHO-CC, the collaborative efforts between WHO and NCC-PvPI, IPC in promotion of PV activities in Asia, continues by providing regular technical support in terms of training and consultation to the member countries in South East Asia Regional Network (SEARN). In this series, a delegation of three members namely Mr Pak Sung-il, Mr Kim Yong-liam and Mr Sol Yong Hyok from North Korea visited NCC-PvPI between November 12-14, 2018. During the visit, the delegation was acquainted with PvPI activities including Quality Management System (QMS), signal detection, benefit-risk assessment, training and education and also attended the ongoing 11th Skill Development Programme for 3 days. The delegation was also provided with the scientific resource materials published by PvPI for awareness and promotion.

Mr Pak Sung-il, appreciated the different kind of training programmes undertaken by PvPI, the delegation recognized the contribution of PvPI in ensuring patient safety in India.

# *Vaccine safety and development under 3S Project-WHO-IPC*

A two day meeting was conducted from December 19-20, 2018 at AEFI secretariat, New Delhi and CDSCO, New Delhi. The objective of the meeting was to improve the interaction between the MAHs and CDSCO on:

- Exchange of AEFI data between IPC and AEFI secretariat
- ADR/AEFI reporting – real cases – reporting system – reports from MAHs
- Causality assessment and signal reporting- real AEFI cases for the rota virus vaccines from the MAHs
- Existing and planned reporting tools for MAHs
- Enhance interaction between CDSCO and PvPI on vaccine safety

## OUTCOME

- Vigilance of Rota-virus vaccine being used in India
- Focused training on signal detection, Benefit-Risk Assessment, risk management and mitigation for all the stakeholders
- Explore PvPI Mobile App on utilization of data submitted by the HCPs and consumers
- Case Reporting Form data should flow into the PvPI database

The Smart safety surveillance (3S) project is an initiative by WHO-Bill and Melinda Gates Foundation (BMGF) to identify, access and manage the risk associated with new medicines and vaccines.

## NOTABLE EVENTS

# *ISPOR & SOPI Pre-Conference Workshop at IPC*

IPC in collaboration with DPSRU, New Delhi has organized a Pre-Conference workshop on "Present Status & Future Challenges of Pharmacovigilance: Safety of Medicines & Medical Devices" in connection with National conference on Pharmacovigilance, Pharmacoeconomics & Outcomes Research, incorporating17th Annual Conference of the Society of Pharmacovigilance India (SOPI) & 7th International Conference of ISPOR India chapter on October 8, 2018 at IPC, Ghaziabad.


Workshop was inaugurated in presence of Dr G.N.Singh, Secretary-cum-Scientific Director, IPC, Dr R.K. Goyal, Vice Chancellor DPSRU, Dr K.C. Singhal Founder President SOPI, Dr Govind Mohan, President SOPI,Dr Rajani Mathur, Organising Secretary, Dr Jai Prakash, Senior Principle scientific officer & Dr V. Kalaiselvan, Principle scientific officer.

The Programme was attended by as many as 60 delegates covering 30 technical sessions and 9 practical sessions. The pre-conference workshop concluded with the closing remarks by Dr. KK Sharma.

The conference continued in the DISPAR campus for two days was attended by IPC officials Dr Jai Prakash (Sr PSO) in Dr V. Kalaiselvan (PSO). They also delivered lectures on role of Indian Pharmacopoeia and Ensuring patient Safety through PvPI.

# 1st Entrepreneur Development Programme on Pharmacopoeia & PV

The Start-up cell, IPC, Ghaziabad organized the 1st Entrepreneur Development Programme on Pharmacopoeial and Pharmacovigilance Services with the aim of encouraging aspiring entrepreneurs and technologies across the country in the area of pharma sector including standards setting in Pharmacovigilance, Pharmacopoeial Standard setting, Phytopharmaceutical and Regulatory services to address the rapidly expanding pharmaceutical industry. The programme was organized on November 16, 2018 at IPC Conference Hall. The Programme was graciously inaugurated in the presence of eminent personalities - Dr. D. Roy, Former DDC(I), CDSCO; Mr. Aseem Sahu, DDC, CDSCO and Dr. G.N. Singh, Secretary-cum-Scientific Director, IPC. As many as 51 delegates participated including physicians, students and industrial professionals.

## SALIENT FEATURES

- Provide handholding support and mentorship to resources for young aspirants in pharma sector and channelize innovation for social impact
- Promote and foster entrepreneurship in the areas of Pharmacovigilance & Regulatory services
- Medical devices testing, Phytopharmaceuticals laboratory, Analytical/ Laboratory services in terms of drug analysis and Pharmacopoeial compliance
- To highlight the necessity of entrepreneurship in pharmaceutical sector, to ensure societal development and economical growth of the nation.

# PvPI at National AEFI Meet

National secretariat for Adverse Events following Immunization (AEFI) organized two successive meeting of National AEFI committee which were held at National Documentation Centre of the National Institute of Health and Family Welfare (NIHFW), Munirka, New Delhi, on October 17 and 19, 2018 respectively. Attended by members of National AEFI committee and various subject experts across the country these meetings were focused on national agendas related to AEFI surveillance in the country. The following points were discussed during the two successive meets:

- Update on Causality Assessment of reported AEFI Cases
- Viral detection from clinical specimens
- Barriers to reporting of AEFIs-Qualitative study results
- Analysis of allergic reactions reported during MR campaign
- Review of AEFIs related to JE vaccine
- Update on AEFI trainings
- Pharmacovigilance Inspection at MAHs
- Strengthening PvPI partnership in vaccine safety across all the ADR monitoring centres

# 'Pharmacology for Future' Meet in HP

A three-day International Conference of Pharmacology and Drug Discovery on Pharmacology for Future: "Towards Translational Approach for Next Generation Pharmacologists" was organized by Maharaja Agrasen University, Baddi, Himachal Pradesh from October 4-6, 2018. The conference was attended by researchers, scientists, academicians, regulatory & healthcare professionals, and students. During the conference, Dr R S Ray, Scientific Assitant, IPC, delivered a talk on "Pharmacovigilance Programme of India: Promoting Medicine Safety for Public Health" highlighting the achievements of IPC, NCC-PvPI in promoting patient safety and also sensitised the audience about the Skill Development Programme at IPC.


# PV partners' monthly meet on AEFI

Pharmacovigilance partners' monthly meeting was held at, UIP Division in MoH&FW, Nirman Bhawan, New Delhi on October 29, 2018. Dr R S Ray, Scientific Assistant, NCC-PvPI and Mr Pankaj Bhatt, Sr Pharmacovigilance Associate, NCC-PvPI represented the IPC. Other partners included Dr M K Aggarwal, DC (UIP) Division, MoH&FW, Dr Deepak Polpakara, AEFI Secretariat, New Delhi, Dr Nidhi Gupta, AEFI Secretariat, New Delhi, Mr Somnath Basu, ADC (I), CDSCO (HQ), New Delhi, Dr. Vikas Madaan, Program Manager at ITSU-MoHFW and Dr Kapil Singh, UNDP, India. Following issues were discussed:

## MEETING POINTS

- Reporting of AEFI cases through notification form by AMCs
- Sensitization regarding serious/severe AEFIs and to liaison with SEPIOs and Zonal Consultants as was done recently in AIIMS Bhopal, MP and Chhattisgarh.
- National TOT for use of adrenaline by health professionals for initial management of anaphylaxis was held at Delhi.

## RECOMMENDATIONS

- AEFI surveillance system can be boost up by regular training and meetings with the Zonal consultants to facilitate AEFI reporting.
- PV coordinators and technical associates of respective AMCs conduct training and meetings at state level.

# Academic visitors at IPC Library


To facilitate strong networking amongst educational institutes, research laboratories and healthcare stakeholders, IPC Library holds visiting programmes for students, academicians and scientists from all across the India and abroad. In this series, a delegation of as many as 140 of students along with the faculty members from KMCH College of Pharmacy, Coimbatore & Karpagam Academy of Higher Education, Coimbatore visited IPC, Ghaziabad on December 21, 2018. During the visit, the delegates got acquainted with the resources available in the library and also various products of IPC like various editions of Indian Pharmacopeia, National Formulary of India and thematic journals of international repute.

# IPC at One Day Symposium, Mullana-Ambala

A talk on "Pharmacovigilance programme of India: Current Scenario and Way forward" was delivered by Dr. Ray, Scientific Assistant, IPC at one day symposium organised by Maharishi Markendeshwar College of Pharmacy, MM University, Mullana-Ambala on November 13, 2018. The Symposium was graced by the eminent personalities like Vice chancellor, MMU, Pro-Vice chancellor, MMU, Shri. Ved Praksh, Member, Pharmacy Council of India, and Dr. Summeet Gupta, Director, MM College of Pharmacy, Ambala. The talk highlighted the achievements of IPC, NCC-PvPI in promoting patient safety and also sensitised the audience about the regular Skill Development Programme at IPC. Offering food for thought for undergraduate and postgraduate students the symposium also stressed upon careers in pharmacy especially in Pharmacovigilance.

# Training on PV Audit & Inspection

To provide an insight on audit and inspection procedures in the PV, a one day in-house training-cum-workshop with the title; "Pharmacovigilance Audit & Inspection" was held on November 16, 2018 at NCC-PvPI, IPC, Ghaziabad. Welcoming the participants to the workshop, Dr Jai Prakash, Senior Principal Scientific Officer, In-charge PvPI, IPC, highlighted the importance of such regular trainings for continuously updating over worldwide regulatory reforms. Ms Durga Mane, Sr Manger-Delivery Excellence, Cognizant, Mumbai as a resource person of the session, delivered a series of presentations on:

- Structuring of documents in PV-systems
- Format and contents of Internal/External audits
- Audit planning and preparation of check lists
- Do's and Don'ts of audits and inspections
- Corrective and Preventive Actions (CAPA) for a system update
- Quality Management Systems (QMS) and requirements
- Validation of internal tools/systems as per critical findings and outcome
- Conduct during inspections and Regulatory Compliance

Participants also raised their queries on maintenance and updating of SOPs, review procedure for CAPA and communication during the audits/inspections which were satisfied by the speaker.

# 8th Regional Workshop on PV-system Establishment in Pharma Sector


In a series of workshops to train Marketing Authorization Holders (MAHs) on "Basics of Pharmacovigilance and Establishment of PV system in Pharmaceutical Industries" the 8th workshop was held at Kilpauk Medical College, Chennai on December 7, 2018. The primary objective of these workshops is to raise awareness among MAHs on the requirements of a PV system according to the Good Pharmacovigilance Practices (GvP) guidelines.

## TOPICS ADDRESSED:

- Pharmacovigilance: Basics, Methods, Practices & a Brief Overview of PvPI
- Pharmacovigilance: A legal obligation under Drugs & Cosmetic Act, 1940 and Rules, 1945
- Modules of Pharmacovigilance Guidelines for MAHs in India
- Engagement of MAHs in PvPI: Current Scenario & Way Forward

## OUTCOME/ RECOMMENDATIONS:

- 59 Participants gained knowledge on Regulatory-Pharmacovigilance aspects
- Indigenous software may be developed by PvPI for ADR reporting & data control
- Enforcement of Gazette Notification may be made by both CDSCO & PvPI for compliance with mandatory ADR reporting by MAHs to PvPI
- Participants were keen to know as to how to set up a good PV System in their organization and how to collect & report ADRs to PvPI
- Training for marketing professionals is essential to collect adverse events direct from physicians at hospitals

# IPC at 70th Indian Pharmaceutical Congress

The Indian Pharmaceutical Association organizes the Indian Pharmaceutical Congress every year throughout the country in which professional and academic representatives participate to create the awareness about the pharmacy and pharmacy profession amongst the public. The Indian Pharmaceutical Congress was held on December 21-23, 2018 at Amity University, NOIDA, UP. Several IPC officials were present at the conference along with Dr. G. N. Singh, Secretary cum Scientific Director. A Stall was arranged at the conference to display the resource material of IPC and PvPI including Indian Pharmacopoeia, NFI, annual reports, newsletters etc. Several healthcare professionals were sensitized on functioning of PvPI and ADR-reporting.

# PvPI at 29th RAJ APICON, Ajmer

The Jawaharlal Nehru Medical College, Ajmer, Rajasthan functions as an ADR Monitoring Centre under leadership of Dr. Anil Jain, Principal & Controller. Dr. Sunil Kumar Mathur, Professor (Pharmacology) & AMC Coordinator, Department of Pharmacology has been carrying out Pharmacovigilance activities. Dr. Sanjeev Maheshwari, Professor, General Medicine and Dr. Vandana Goyal, Professor, Pharmacology are the members of the Causality Assessment Committee and actively involved in Pharmacovigilance activities. An annual conference of Physician of India (Rajasthan Chapter-RAJ APICON) was organized at Mayo College, Ajmer, Rajasthan on December 22 & 23, 2018. Patient Safety Pharmacovigilance Associate from IPC, Ghaziabad, Ms. Shivangi Tripathi & Mr. Sandeep Kumar and Mr. Saurabh Kumar Jain, AMC, JLN Medical College were nominated to attend the conference and to arrange an exhibition to spread the awareness of Pharmacovigilance Programme of India (PvPI) among the healthcare Professionals. They displayed various posters and videos for the same and distributed the resource materials to a large number of physicians attending the stall in the exhibition. IPC team was interacting with Physicians to Sensitization on Basics of Pharmacovigilance, mandates and activities of PvPI, ADR reporting tools like ADR forms, Mobile app & Helpline number.

# 2nd Induction-cum-Training Programme on MvPI

MvPI aims to promote and facilitate adverse event reporting of Medical Devices and subsequently evaluating these events. The scientific and systematic evaluation of these medical device events / reports will foster monitoring trends for improving and protecting the health and safety of patients/Users. Objective of the programme is to educate/aware Coordinators/Deputy Coordinators/ Research Associates of Medical Devices Adverse Event Monitoring Centres (MDMCs) in order to strengthen the MvPI and also to enhance their general understanding about Medical Device Adverse Event Reporting, PSUR submission and Risk analysis. The Programme was organised on December 3-4, 2018 at IPC, Ghaziabad.

## TOPICS DEBATED:

- Medical Device Rule 2017- An Overview
- Medical Devices: PSUR & risk analysis
- Materiovigilance Programme of India (MvPI) : An overview and its Concepts & Terminologies
- Role of Medical Devices Monitoring Centre (MDMC) & its Coordinator & Research Associate in Developing effective Materiovigilance
- Introduction to MDAE Reporting Form & How to fill MDAE Reporting Form
- Causality Assessment : Root cause Analysis

## OUTCOME

- Participants sensitize on how to effectively fill the MDAE reporting form.
- Participants learned the process of performing causality assessment at MDMC.
- Identification of three hospitals as a potential Medical Devices Monitoring Centre (MDMC).

# 11th Skill Development Programme

NCC-PvPI, IPC, Ghaziabad conducted its serial Skill Development Programmes (SDP) on **"Basics & Regulatory Aspects of Pharmacovigilance: Optimizing Medicine Safety is Our Goal"** to enhance pharmacovigilance skills of the healthcare professionals in order to promote patient safety. The 11th SDP was organized during November 12-20, 2018. A total of 15 participants from seven states of India attended this training programme. The nine-day training programme included Technical/ Practical sessions with field visit to ADR Monitoring Centre at North Delhi Municipal Corporation and Hindu Rao Hospital, New Delhi.

The training programme was inaugurated by Chief Guest Dr. Pramod Kumar Jain, Director of IIT BHU, Varanasi. In his inaugural address he extended his warm greetings and best wishes to all the participants. He appreciated the interest and aspiration of the participants to choose Pharmacovigilance as a career. Mr. Sanjai Agrawal, Chief Operation Officer, HLL Hites Ltd has been invited as a guest of honour. Dr. Bejon Mishra, International Consumer Policy Expert, has given his dynamic and vibrant speech concerning

the role of health care professionals in promoting better health care and on behalf of PvPI, he stressed on the importance and need of young professionals in the field of Pharmacovigilance.

## DETAIL OF PARTICIPANTS

The Participants having the medical & pharmacy background participated in this training programme.

| 11th BATCH | NO. OF PARTICIPANTS |
|---|---|
| **STATE/UNION TERRITORY** | |
| Himachal Pradesh | 03 |
| Uttar Pradesh | 02 |
| Chandigarh | 01 |
| Kerala | 06 |
| Rajasthan | 01 |
| West Bengal | 01 |
| Tamil Nadu | 01 |
| **Total no.** | **15** |
| **PARTICIPANTS PROFESSIONAL BACKGROUND** | |
| Industry Professionals | 01 |
| Students | 11 |
| Research Officials | 02 |
| Academicians | 01 |

# North zone-Coordinator Meet-cum-ALT at PGIMER- Chandigarh

PGIMR- Chandigarh, which is an enrolled as a Regional Training Center at North zone, held a day-long programme entitled "North Zone-Coordinator meeting cum-Advance Level Training (ALT)" on December 1, 2018 at lecture theatre complex, Nehru Hospital, PGIMER-Chandigarh for PS PvAs. The program was organized under the supervision of Prof. Bikash Medhi and the organizing team included Mr. Kotni Murali, PS-PvAs and Ms Neha Dhir, which was inaugurated by Dr. A.K. Gupta, Medical Superintendent, PGIMER. The programme was also privileged with the presence of Dr. S. Eswara Reddy, DCGI, Government of India, Dr. Y.K Gupta, Former Dean, AIIMS, New Delhi, Dr. B. Dinesh Kumar, IPS President, Dr. Prasad Thota, Scientific Assistant, IPC and other dignitaries in the field.

## TOPICS DISCUSSED

- Advances in pharmacovigilance and updates of PvPI programme
- Role of medical recording in pharmacovigilance
- Role of PV in Malaria, nutraceutical vigilance
- Emerging concern of antibiotic resistance, roles and responsibilities of PvPI
- Contribution of India in signal detection and targeted spontaneous reporting.
- Off-label use of drugs in Indian and ADR monitoring experiences


## OUTCOMES

- Sensitization of healthcare professionals for ADR-reporting.
- Enhancing the technical skills of coordinators for their competent contribution in PvPI
- Awareness on documentation practices at AMCs and NCC-PvPI

# PV Workshop for NABH-accredited Hospitals in Jharkhand

In continuation of a series of trainings for NABH-accredited hospitals as per the MoU between IPC and NABH, PvPI has reached to the state of Jharkhand where a day-long workshop-cum-training programme was conducted at Santevita Hospital, Ranchi, Jharkhand on October 12, 2018. This training programme was organized with an objective of providing a platform for NABH-accredited hospitals of the region to understand the PV system in the country, developed by PvPI.

As many as 52 delegates including clinicians, nurses, technicians and biomedical engineers were trained during the programme. Patient safety-Pharmacovigilance Associates, Ms Shavya Singh and Ms Kalpana Joshi, participated as resource person and delivered sessions on:

- Basics of Pharmacovigilance and Mandates and Activities of PvPI

- Importance and Significance of ADR reporting for Accredited Hospitals in India
- Monitoring and Reporting of ADRs
- Setting up of Pharmacovigilance System in Hospitals
- Causality Assessment, Logics and Methods
- Hands-on training on ADR forms

# 3rd ALT for MP & CG at AIIMS Bhopal

Being instrumental in sensitizing healthcare professionals in Madhya Pradesh and Chhattisgarh on Pharmacovigilance, the Regional Training Centre, AIIMS Bhopal organized 3rd ALT programme on November 02, 2018. As many as 45 participants including; AMC Coordinators and PV-Associates from all the AMCs of MP & Chhattisgarh as well as other healthcare professionals from AIIMS, Bhopal attended the training. ALTs are dedicated trainings for stakeholders of PvPI to update them on activities, regulatory perspectives and global scenario of PV.

## TOPICS DEBATED:

- An introduction to AEFI & role of AMCs in reporting of AEFI cases
- Good documentation practices for AMCs and data management
- Pharmacovigilance in clinical Practice - Objectives, way ahead and challenges
- Causality assessment of ADRs
- Addictovigilance
- Management of Severe cutaneous ADRs
- Open discussion & presentation of PV-activities from AMCs

## BENEFITS AND OUTCOME:

- Dr. Rohan Thakur, Senior Consultant Zonal AEFI, MP, sensitized participants on AEFI reporting
- Awareness on documentation practices at AMCs and NCC-PvPI
- Provided an opportunity to identify and improve the gap areas to enhance the ADR-reporting
- Identify tools to integrate PV activities with state regulatory authorities

# Approved New Drugs in India

## New drugs approved by CDSCO during October-December 2018

| S. No | DRUG | INDICATION |
|---|---|---|
| 1 | **Sacubitril/Valsartan (as sodium salt complex) and FDC of Sacubitril + valsartan 50 (24+26)/100 (49+51)/200 (97+103) mg film coated tablets** | To reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction |
| 2 | **Fimasartan potassium trihydrate bulk drug and Fimasartan film coated tablets 30mg/60mg/120mg** | For the treatment of mild hypertension |
| 3 | **Lorcaserin Hydrochloride Bulk and 10mg tablets** | An adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial BMI of 30 kg/m2 or greater (obese) or 27 kg/m2 or greater (overweight) in the presence of at one weight related comorbid condition (e.g. Hypertension, dyslipidaemia, type 2 diabetes) |
| 4 | **Evogliptin Tartrate Bulk and Tablets 5mg** | For treatment of type-2 diabetes mellitus as an adjunct to diet and exercise to improve glycemic control, when used as amonotherapy or in combination with Metformin |
| 5 | **Ceftazidime 2gm/Avibactam 0.5gm powder (for concentrate, solution, and infusion)** | Complicated Intra-abdominal infections, Complicated Urinary tract infections including pyelonephritis Hospital-acquired pneumonia including ventilator associated pneumonia with susceptible gram negative microorganisms |

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

[Last accessed on-21-01-2019] Source: https://cdsco.gov.in/opencms/opencms/en/Approval_new/Approved-New-Drugs/index.html

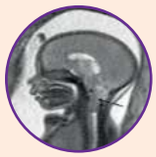
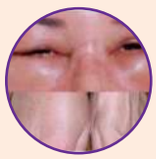
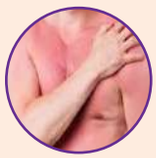
# Drug Safety Alerts for October-December 2018

**Preliminary analysis of Suspected Unexpected Serious Adverse Reactions (SUSARs) from the PvPI database reveals that the following drugs are associated with the risks as given below:**

**Suspected Drugs:** **Telmisartan**
**Indication:** **Hypertension**
**ADR:** **Lichenoid keratosis**

Healthcare professionals, patients/consumers are advised to closely monitor the possibility of above-mentioned adverse events while prescribing/consuming above-quoted suspected drugs and report to the NCC-PvPI either by filling up suspected Adverse Drug Reactions Form/Medicines Side-Effect Reporting Form for Consumer (http://www.ipc.gov.in) **Helpline # 1800-180-3024.**

# *Comparative status of Global Drug Alerts with PvPI Database*

| NAME OF DRUG | REACTIONS | INTERNATIONAL STATUS | INDIA STATUS |
|---|---|---|---|
| CLOZAPINE |  Clozapine: reminder of potentially fatal risk of intestinal obstruction, faecal impaction, and paralytic ileus | https://www.gov.uk/drug-safety-update/clozapine-reminder-of-potentially-fatal-risk-of-intestinal-obstruction-faecal-impaction-and-paralytic-ileus | Intestinal Obstruction – 01 ICSR reported in PvPI database |
| GLYCOPYRRONIUM BROMIDE |  Angioedema | https://www.ema.europa.eu/documents/minutes/minutes-prac-meeting-4-7-november-2013_en.pdf | Angioedema – 01 ICSR reported in PvPI database |
| MESALAZINE |  Risk of Photosensitivity Reaction | https://www.ema.europa.eu/documents/prac-recommendation/prac-recommendations-signals-adopted-29-august-1-september-2017-prac-meeting_en.pdf | Photosensitivity Reaction – 01 ICSR reported in PvPI database |
| MIRABEGRON |  Urinary retention | https://www.ema.europa.eu/documents/minutes/minutes-prac-meeting-13-16-may-2013_en.pdf | Urinary retention – 01 ICSR reported in PvPI database |

**Healthcare professionals are sensitized to carefully monitor the above mentioned alert. Any event related to these drugs has to be reported to NCC-PvPI.**

# JSS-Mysore in Patient Safety Services

The healthcare services were established in 1974 as a JSS Primary Health Center and later upgraded to 1,200-bed hospital at Mysore. In the year 2008 foundation stone for a 1,800 bed hospital was laid by His Holiness Jagadguru Sri Shivarathri Deshikendra Mahaswamiji. JSS Hospital is providing wide range of services and one of the biggest critical and emergency care facilities with 260 beds. In the year 2011, Department of Clinical Pharmacy located at JSS Hospital, Mysore is recognized as ADR Monitoring Center and Regional Training Center for the South Zone, PvPI. The AMC actively participated in the Pharmacovigilance activities under the leadership of Dr. G. Parthasarathi, Coordinator and Dr. M. Ramesh, Deputy Coordinator, AMC, JSS Hospital, Mysuru. Dr. P. Rahul Krishna is working as a Patient Safety Pharmacovigilance Associate in JSS Hospital, Mysuru since August 2017.


# OMC plays key role in patient safety by PV


Osmania Medical College (OMC) also known as "The Hyderabad Medical School", established at Koti, Hyderabad by Nizam Nawab Nasirudaula in 1846. Postgraduate courses in clinical and para-clinical subjects were started in 1956 and super specialty course between 1972 and 1975. Osmania General Hospital (OGH) is one of the oldest hospitals in India founded in 1910 from Darulshifa to present OGH, located at Afzalgunj, Hyderabad. It is run by the Government of Telangana, and is one of the largest in the state.

Department of Pharmacology, Osmania Medical College and Osmania General Hospital was designated as AMC in 2014 under the supervision of Professor and Head of Pharmacology, Department Dr. V Prasanna, Dr. T Chakradhar successive head & coordinator of AMC since October 2016; Deputy Coordinator Dr. Bhuvaneswari under the guidance and support of Principal Dr. P Sashikala Reddy and Hospital Superintendent Dr. B Nagendar. Ms Sravani Marpaka is the PsPvA at OMC.

# STAKEHOLDERS' FEEDBACK

**Dr. (Col) M DAYANANDA**, Director, JSS Hospital, Mysore

I am delighted to pen down my observations on the department of Clinical Pharmacy at our hospital. The department of Clinical Pharmacy actively supports the hospital in carrying out pharmacovigilance activities. They carry out clinical audit and bring medication errors on a realtime basis. This has significantly reduced the number of medication errors in our hospital. The department actively participates in various National Health Programmes. They conduct CMEs at various medical colleges across India, sensitizing healthcare personnel to the paramount need for drug safety. Their contribution to healthcare is immense. I congratulate the whole team and urge them to continue to work with the same zeal.

**Dr. M GURUSWAMY**, Medical Superintendent, JSS Hospital, Mysore

As a medical superintendent of 1,800-bed tertiary care teaching hospital I believe the need for pharmacovigilance needs no reiteration as patient safety is imperative for at all times in our workforce. The early detection of loopholes in patient care not only helps us reduce the iatrogenesis but also creates a safer environment for all those who seek state of the art services at our hospital. The Pharmacovigilance Committee and the Department of Clinical Pharmacy are indispensable assets of our hospital in realising the goal of drug safety. I appreciate the Department of Clinical Pharmacy for all its initiatives in ensuring drug safety inculcated by JSS Hospital for more than two decades. Being part of PvPI as an AMC and regional training centre gives us broader scope to reach out to our peers in upholding patient safety.

**Dr. H BASAVANAGOWDAPPA**, Professor & Principal, JSS Medical College, JSS AHER, Mysore

As medication management therapies are growing more complex day by day, ensuring patient safety has become all the more imperative. In the hectic schedule of a physician to keep abreast of latest drug safety updates and contributing to the drug safety is a rewarding challenge. Pharmacovigilance activities not only help reduce the repeated occurrence of adverse drug events but also make the patient stay in the hospital safer. Active monitoring and reporting of aberrations in drug safety in the outpatients'department is also equally important and all healthcare professionals should emphasize on dissuading patients from resorting to self-medication practices. I appreciate the PvPI for its initiatives in expanding the horizons of ADR reporting and monitoring. I also appreciate the active involvement of Department of Clinical Pharmacy and their contribution in enhancing patient safety in our daily practice.

**Dr. M D RAVI**, Professor, Department of Paediatrics, JSS Medical College, JSS AHER, Mysore

Having been part of the PvPI programme for several years, I have first-hand knowledge on the kind of exemplary work they are doing. After the initiation of this programme, we have been able to generate good data on various drug-related issues, including medication errors. This, in turn, has helped us take corrective and preventive action. As a result the number of drug-related problems including unnecessary or unjustified use of medication, medication errors has significantly reduced. This kind of programme is a must for all hospitals. The emphasis has always been on patient safety during treatment and and PV is the most effective way of ensuring this. I congratulate the team AMC & Regional Training Centre for South Zone located at Department of Clinical Pharmacy, JSS Hospital, Mysore for their active involvement in, and contribution to, patient safety.

**Dr. K. RAMESH REDDY**, Director of Medical Education, Telangana State

India consists of vast and diversified ethnic and genetic variation of population. It has also got various types of food habits and multi-modes of treatment practices giving a big challenge to monitor the patient safety involving the pharmaceutical compounds. In order to face this challenge in our country, Govt. of India has started PvPI under the umbrella of IPC. PvPI is playing a good role via AMCs in medical colleges-hospitals and public health programs across India to out-reach its final objectives for protecting the well-being of patients as patient safety. Pharmacovigilance is the best supporting tool in clinical practice to monitor the patient safety with enhancing the efficacy and quality standards of drugs, vaccines and medical devices. Monitoring and reporting ADRs/AEs is inevitable through the life cycle of a pharmaceutical compound, so that high quality of medical care and patient management is maintained. I appreciate the entire team of AMC-OMC for the excellent promotion of Pv in our state and Best wishes toPvPI for future endeavors.

**Dr. P SASHIKALA REDDY**, Principal Professor, Department of Microbiology, Osmania Medical College, Hyderabad

Osmania Medical College (OMC) formerly known as "The Hyderabad Medical School" has a long history and tradition in producing stalwart in the medical field. Most of them are reputed nation-wide. In addition to imparting medical education the college undertakes various programs in surveillance and research. In recent past dept. of Pharmacology-OMC has set up AMC in tune with IPC-PvPI for the purpose of Monitoring and reporting ADRs/AEs in the post marketing so that a robust system of safety data base is established in India contributing to global system. Along with the clinicians, para clinical stakeholders, nursing staff and pharmacist are involved to support this program at OMC. Besides the regular activities the medical students are also taught to inculcate prime objectives and roll out pharmacovigilance practicing tool for patient safety and medicine safety with PvPI support. I wish every success in achieving the goal of the program.

**Dr. B NAGENDAR**, Medical Superintendent Professor, Department of General Surgery, Osmania General Hospital, Hyderabad

Osmania General Hospital (OGH) being one among the very oldest hospitals in the country referring as the landmark of Hyderabad merits an independent chronicling of its history as Darulshifa. Presently acting as back bone to all the specializations in the medical treatment. OGH always focuses on the patient health care while prioritizing the patient-safety and lessening the economic burden of the public. Keeping this main objective OGH supports and encourages PvPI activities through AMC-Department of pharmacology so, that we can create and standardized our own country's drug safety data base contributing to globally as well. At this juncture on behalf of OGH and all HCP's we look forward from IPC-PvPI to fulfill the gaps of Indian data in near future by reporting ADRs/AEs. Wish you the best success of this program!

**Dr. BALAJI**, Prof & HOD, Department of General Medicine, Osmania General Hospital, Member of CAC, AMC-OMC, Hyderabad

Indian health care system has its own idiosyncratic methods of treating patients. Due to these methods many pros and cons arise affecting the safety of patients while treating with the pharmaceuticals. In particular, to monitor and report the cons of these pharmaceuticals as in-house set up of good Pharmacovigilance system is in need. From our department we report ADRs/AEs and encourage all the HCP's to contribute their part to OMC-AMC such that they can play their role well for Pharmacovigilance programme of India to achieve its vital goal of patient safety and give a take home message of safety alerts and signals while prescribing.

**Dr. T CHAKRADHAR**, Professor & Head (Pharmacology), AMC-Coordinator, Osmania Medical College, Hyderabad

I am happy and privileged to be part of this developing healthcare sector in India which is mainly focusing on patient safety. Though our country lacks the stringent regulations over the approval and sale of medicines, prescription audits and various modes of practicing modern medicine still the drug safety profile stands as a need of hour for monitoring the ADRs/AEs in patient's well-being. AMC at Osmania Medical College is persistently promoting PvPI activities in its unique ways to educate all the HCP's and Common public in masses of both urban and rural areas of the Telangana state through print and electronic media along with routine regular sensitization workshops to HCP's . I extend my heartiest support and hope this program to go in a long way in generating the safety data for safe-guarding the Indian population.

**Dr. JOSEPH BENJAMIN G**. Professor, Department of Radiation Oncology, MNJ Institute of Oncology Research Centre and Hospital-OMC, Hyderabad

Being clinicians our main aim lies in providing the best treatment to the patients with less harm caused due to drugs and medical devices. This happens only when a good health care management system is placed correctly. Pharmacovigilance as ADR/AE monitoring and reporting plays a pivotal indicator in focusing the efficacy and safety profile of the drugs in order to establish patient safety in our day to day clinical practices. The safety alerts generated by NCC-PvPI are circulated to all the HCP's through AMC is helping us to enrich the knowledge by acting as a triggers while prescribing and patient counselling. I acknowledge, the AMC-OMC; PvPI and extend my support in reporting ADRs/AEs in future as caption of saying play your part!

# दवाईयों से होने वाले प्रतिकूल प्रभाव/दुष्प्रभाव की निगरानी एवं मरीजों की सुरक्षा के प्रति जागरुकता

## फॉर्माकोविजीलैंस प्रोग्राम ऑफ़ इंडिया, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार द्वारा जनहित में जारी

जैसा कि हम सभी जानते हैं कि दवाईयों (टैबलेट्स, कैप्सूल्स, सीरप, इंजेक्शन, टीके इत्यादि) के उपयोग से किसी न किसी प्रकार के प्रतिकूल प्रभाव/दुष्प्रभाव की सम्भावना रहती है इसको ध्यान में रखते हुए स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार ने एक विशेष कदम उठाया एवं इस कदम के अंतर्गत फॉर्माकोविजीलैंस प्रोग्राम ऑफ़ इंडिया को नवीकृत किया, जिसका राष्ट्रीय समन्वय केंद्र भारतीय भेषज संहिता आयोग, राजनगर, गाज़ियाबाद, उत्तर प्रदेश में स्थित है। इस समन्वय केंद्र का मुख्य कार्य दवाओं से होने वाले प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी ए.डी. आर. मॉनीटरिंग सेंटर के द्वारा एकत्रित करके उसका आँकलन एवं विश्लेषण करना है जिससे किसी भी दवा के फायदे एवं नुकसान की जानकारी अग्रिम कार्यवाही हेतु केन्द्रीय औषधि मानक नियंत्रण संगठन, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार को प्रेषित की जा सके।

"फॉर्माकोविजीलैंस का अर्थ है औषधि सतर्कता", यदि किसी मरीज या व्यक्ति को दवाई लेने के बाद कोई प्रतिकूल प्रभाव/दुष्प्रभाव जैसे कि त्वचा संबंधित परेशानी, डायरिया, जी मिचलाना, उल्टी, बुख़ार, रक्तचाप (उच्च/निम्न), सिरदर्द या अन्य कोई दुष्प्रभाव प्रतीत होता है तो ऐसी स्थिति में अपने चिकित्सक से या नजदीकी अस्पताल में जाकर चिकित्सक से परामर्श लें।

राष्ट्रीय समन्वय केंद्र फॉर्माकोविजीलैंस प्रोग्राम ऑफ़ इंडिया, में दवाईयों के प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी एकत्रित करने हेतु विभिन्न सुविधाजनक माध्यम उपलब्ध हैं, जैसे कि:

- निःशुल्क हेल्पलाइन नम्बर 1800-180-3024
  (सोमवार से शुक्रवार प्रातः 9:00 बजे से सायं 5:30 बजे तक)
- मोबाइल ऐप (ADR PvPI)
- ए.डी.आर. मॉनीटरिंग सेंटर
- ए.डी.आर. रिपोर्टिंग फॉर्म

(ए.डी.आर. मॉनीटरिंग सेंटर एवं फॉर्म की जानकारी भारतीय भेषज संहिता आयोग की वेबसाइट www.ipc.gov.in पर उपलब्ध है)

अगर आपको पहले किसी दवा से किसी भी प्रकार की कोई असुविधा हुई हो तो अपने चिकित्सक को इसकी सूचना अवश्य दें, जिससे चिकित्सक को आपका उपचार बेहतर ढंग से करने में सहायता मिले।

यदि कोई चिकित्सक, फॉर्मासिस्ट, नर्स या अन्य कोई स्वास्थ्यकर्मी प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी देता है तो उनके विरुद्ध किसी प्रकार की कार्यवाही नहीं की जाती है बल्कि इससे दवाईयों के प्रभाव को बेहतर ढंग से समझने में एवं रोगी के उचित उपचार में सहायता मिलती है इसलिए अपने मन से इस प्रकार के समस्त डर व भ्रमों को दूर करके जनहित में स्वास्थ्य संबंधित इस महान कार्य में अपना सहयोग दें।

वर्तमान में भारत के अधिकतर राज्यों में ए.डी.आर. मॉनीटरिंग सेंटर कार्यरत हैं एवं राष्ट्रीय समन्वय केंद्र द्वारा फॉर्माकोविजीलैंस विषय पर वर्ष भर कौशल विकास कार्यक्रम का आयोजन किया जाता है। इस कार्यक्रम की पूर्ण जानकारी भारतीय भेषज संहिता आयोग की वेबसाइट पर उपलब्ध है।

राष्ट्रीय समन्वय केंद्र द्वारा फॉर्माकोविजीलैंस प्रोग्राम ऑफ़ इंडिया आप सभी से अनुरोध करता है कि दवाओं के सेवन से हुए सभी प्रकार के प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी अवश्य दें जिससे कि दवाओं का सुरक्षित उपयोग सभी के लिए सुनिश्चित किया जा सके।

सत्यमेव जयते
IPC

**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**