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Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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NCC-PvPI, IPC IS DESIGNATED WHO-CC

India is the world's sixth country recognised by The World Health Organization as a WHO-Collaborating Centre for Pharmacovigilance in Public Health Programme and Regulatory Services



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



Greetings to Readers,

It is a great pleasure to release the July-September 2017 issue of Indian Pharmacopoeia Commission (IPC), Pharmacovigilance Programme of India (PvPI) newsletter. I am pleasantly surprised with the great momentum in the field of Pharmacopoeial (drug) research and development, Pharmacovigilance and other related areas.

Last quarter brought proud recognition and special honour to Pharmacovigilance Division (PvPI), being recognised and designated as a WHO Collaborating Centre for Pharmacovigilance in public health programmes and regulatory services. With this responsibility the scope of activities undertaken by PvPI has amplified.

To safeguard the health of Indian population, PvPI has lately developed an advanced version of android mobile app that empowers healthcare professionals and consumers for ADR reporting. The app "ADR PvPI" was fully developed in-house. Guidelines for marketing authorization holders (MAHs) laid down by PvPI and CDSCO in its "Guidance Document for MAHs" delineates the path for Pharmacovigilance activities by the Pharma industry. Both mobile app and Guidance Document for MAHs were launched by the Union health secretary, Govt of India.

I trust the institution as a whole will progress rapidly in research and attain new heights in shortest possible time. Best of Luck and Happy New Year!

Dr G N Singh

Secretary-cum-Scientific Director
Ministry of Health & Family Welfare
Government of India

India shines as a star on WHO horizon

WHO on July 18, 2017 bestowed upon India the honour of being the sixth country in the world as a WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services

The milestone – marking the formal launch of Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission (IPC) as the World Health Organization (WHO)-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services – was laid at IPC in Ghaziabad on October 30, 2017. It was unveiled by the additional Union health secretary Mr R K Vats in presence of DCG(I) Dr G N Singh and the visiting WHO brass from Geneva and Country Office-India.

The launch ceremony was organised by PvPI, IPC in collaboration with the regulatory authority CDSCO and the Union Ministry of Health and Family Welfare (MoH&FW) as an elaborate day-long function, peppered by speeches and exhortations by the Geneva-based WHO dignitaries, and felicitations to illustrious scientists.

In a first of its kind, the World Health Organization (WHO) on July 18, 2017 bestowed upon India the honour of being the sixth country in the world as a WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services. The recognition came in the wake of a sustainable, research-oriented and data-based drug-monitoring system and regulatory intervention services by IPC and its pivotal arm the Pharmacovigilance Programme of India (PvPI). PvPI is committed to making Indian health services an affordable, worldclass infrastructure facility with access to safe medicine for the masses after duly collecting and analysing data on adverse drug reactions (ADRs) associated with use of such medicine.

PvPI as a WHO-CC will provide scientific support to countries in Asia for Pharmacovigilance in public health programmes such as tuberculosis, neglected tropical diseases, vector-borne diseases, HIV-AIDS, Adverse Event Following Immunization (AEFI) and regulatory issues.

The designation of India as a WHO-Collaborating Centre (WHO-CC) for Pharmacovigilance in Public Health Programmes and Regulatory Services for 'Asia and beyond' follows a series of landmark achievements in drug monitoring systems by WHO-recognized global bench marking tool (GBT) and National Regulatory Authority (NRA) assessment.

PvPI as a WHO-CC will provide scientific support to countries in Asia for Pharmacovigilance in public health programmes such as tuberculosis, neglected tropical diseases, vector-borne diseases, HIV-AIDS, Adverse Event Following Immunization (AEFI) and regulatory issues

► INDIA

Designation Date: 18/Jul/2017

WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services

Institution: Pharmacovigilance Division, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare

► TERMS OF REFERENCE

- Enhancing Pharmacovigilance (Pv) practices in low and middle income countries (LMIC) in Asia and beyond through relevant tools and guidelines
- Capacity building of WHO member states to establish high quality pharmacovigilance systems
- Scientific support to countries for pharmacovigilance in public health programmes (e.g. Tuberculosis, Neglected Tropical Diseases, Vector Borne Diseases, HIV-AIDS; Immunization Programme) and regulatory issues
- Work-sharing and joint activities in regulatory pharmacovigilance

OTHER WHO-CCs FOR Pv IN THE WORLD

► SWEDEN

Designation Date: 01/Nov/1982

WHO Collaborating Centre for International Drug Monitoring

Institute: The Uppsala Monitoring Centre

► NORWAY

Designation Date: 01/Nov/1982

WHO Collaborating Centre for Drug Statistics Methodology

Institution: Department of Pharmacoepidemiology Norwegian Institute of Public Health

► GHANA

Designation Date: 06/Oct/2009

WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance

Institution: Centre for Tropical Clinical Pharmacol & Therapeutics University of Ghana Medical School

► MOROCCO

Designation Date: 02/Nov/2011

WHO Collaborating Centre for Strengthening Pharmacovigilance Practices

Institution: Centre Anti Poison and Pharmacovigilance of Morocco

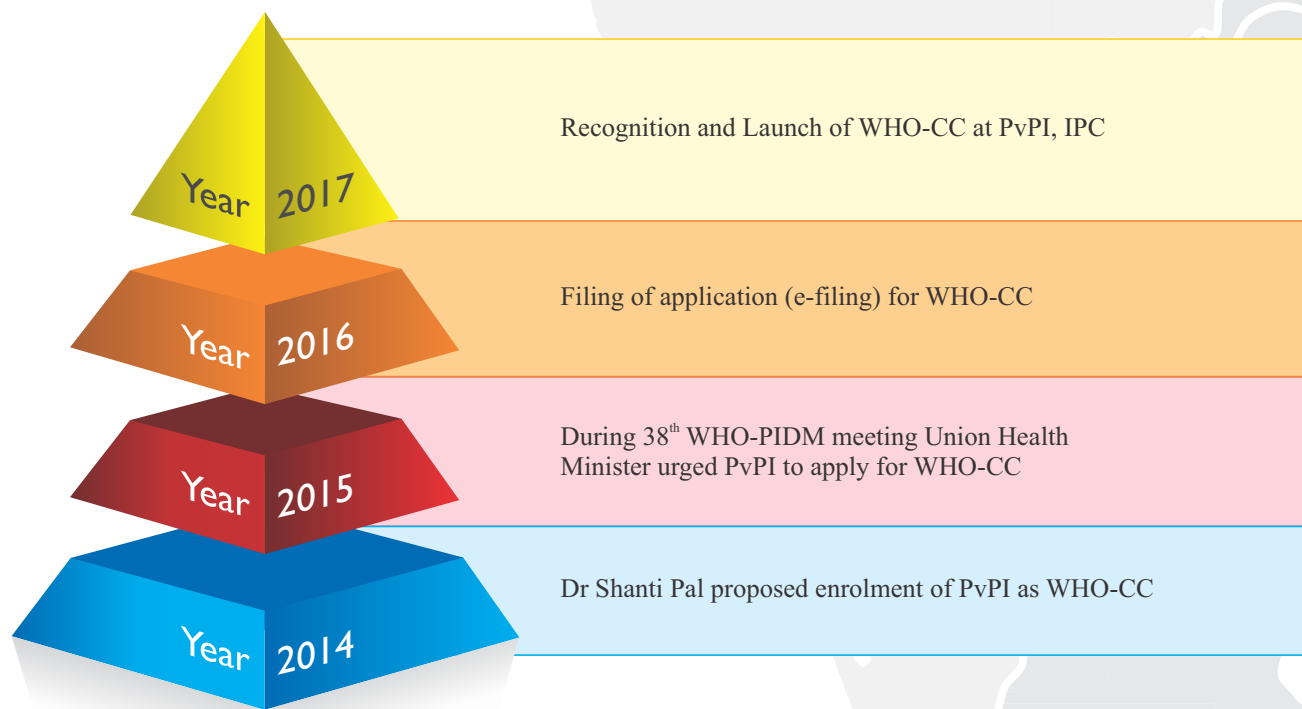
► NETHERLANDS

Designation Date: 13/May/2013

WHO Collaborating Centre for Pharmacovigilance in Education and Patient Reporting

Institution: The Netherlands Pharmacovigilance Centre Lareb

Milestones in enrolment of PvPI as WHO-Collaborating Centre



Glimpses of WHO-CC Launch



PvPI to work in unison with USFDA

An expert team from USFDA headed by Dr Letitia Robinson, Country Director, Mr Dean Rugnetta, Deputy Director, Dr Solomon Yimam, Asst Country Director, Ms Kristan Callahan, International Program Drug Analyst, and Dr Ademola Daramola, International Relations Drugs Specialist, USFDA visited Indian Pharmacopoeia Commission, Ghaziabad on August 21, 2017.

The meeting was held with an objective of understanding the functioning of US Pharmacovigilance system and identifying the scope for future collaboration between NCC-PvPI, IPC and USFDA. USFDA officials appreciated PvPI's efforts for developing and strengthening ADR reporting system in India, including IT reporting tools.

A subsequent meeting was held on September 20, 2017 at US embassy, India Office, New Delhi. USFDA officials presented an overview of US regulatory authority, Pharmacovigilance efforts and ADR reporting system in the US. Experts agreed to carry on technical discussion and dialogue for promotion of Pharmacovigilance in India.



USFDA delegation (left) during a briefing at PvPI, IPC, Ghaziabad

IPC at 8th International Meet of World Pharmacopoeias

Indian Pharmacopoeia Commission (IPC) participated at the 8th International Meeting of World Pharmacopoeias on July 11-12, 2017, and Brazilian Pharmacopoeia Meeting on July 11-14, 2017, at Brasilia, Brazil. The Meeting of World Pharmacopoeias was jointly hosted by the World Health Organisation (WHO) and Brazilian Pharmacopoeia.

The documents on Good Pharmacopoeial Practices (GPhP) for “Compounded Preparation and GPhP for Herbal medicines” were presented and deliberated upon. IPC scientists contributed significantly to the entire process of developing the documents.



Participants, including Dr P L Sahu (2nd right), at 8th International Meet of World Pharmacopoeias, in Brasilia, Brazil, on July 12, 2017

PvPI releases Guidance Document for MAHs

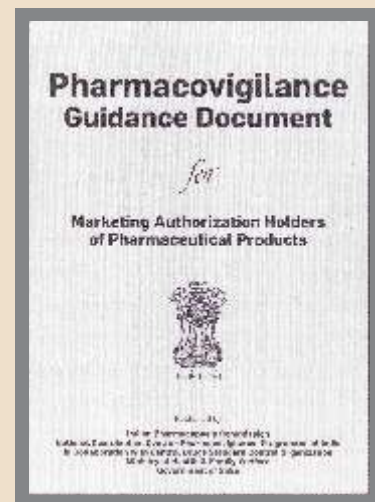
Laying down responsibilities, and monitoring the same, for marketing authorization holders (MAHs) of pharmaceutical products, including their manufacture, sale, import and distribution in India, PvPI in collaboration with CDSCO has released the Pharmacovigilance Guidance Document for MAHs. The guidance document seeks to establish an effective Pharmacovigilance system for MAHs.

The guidelines reiterate the need for having a pharmacovigilance system in place for collecting, processing and forwarding report/s on adverse drug reactions, emerging from the use of the drug manufactured or marketed by the applicant in the country, to the licensing authority. The system will be managed by qualified and trained personnel, and the officer in-charge for collection and processing of data will be a medical officer or a pharmacist trained in collection and analysis of adverse drug reaction reports.

The guidance document was released by Secretary (Health & Family Welfare) in presence of Dr Jagdish Prasad, Director General of Health Services, Dr G N Singh, Drugs Controller General (India) and Secretary-cum-Scientific Director, IPC, and Dr V Kalaiselvan, PSO, IPC, in New Delhi on September 29, 2017.

The guidance document for MAHs comprises the following modules:

- **Module 1** – Pharmacovigilance System Master File
- **Module 2** – Collection, Processing & Reporting of Individual Case Safety Reports
- **Module 3** – Preparation & Submission of Periodic Safety Update Reports
- **Module 4** – Quality Management System at Marketing Authorization Holder
- **Module 5** – Audits & Inspections of Pharmacovigilance System at MAHs
- **Module 6** – Submission of Risk Management Plan



PvPI on AIR

Pharmacovigilance Programme of India plays a vital role in ensuring healthcare by monitoring drug safety in India. The programme has been expanding at a pace, covering every single citizen of India and disseminating information at the grassroot level. For effective communication, PvPI has initiated different modes of communications such as social media, mobile app, helpline and media coverage. PvPI convened a meeting with the Association of Radio Operators in India (AROI) at DCGI office, CDSCO, FDA Bhawan in New Delhi on July 28, 2017 with an objective of broadcasting on AIR the need for, and the significance of, ADR reporting, thus raising awareness among the public on safe use of medicines.

RECOMMENDATIONS

- Organize a workshop for radio jockeys (RJs) to update them on PvPI activities
- Pilot study for raising awareness among public may be done by involving RJs from the Delhi region
- Step-wise extension of the activity by involving RJs from different Indian states



Mobile App for ADR Reporting and Pv

ICT has become a great facilitator for promoting public health

The access to healthcare is the primary right of the citizen. Indian Pharmacopoeia Commission, National Coordination Centre-Pharmacovigilance Programme of India (IPC, NCC-PvPI) through its e-governance initiatives has recently launched a mobile application ADR PvPI to empower the citizenry and healthcare professionals to report and engage in adverse drug reaction (event) reporting and Pharmacovigilance.

The app was launched on September 29, 2017 by then Union Health & Family Welfare secretary, Mr C K Mishra, in presence of Director General of Health Services, Dr Jagdish Prasad, Drugs Controller General (India) and Secretary-cum-Scientific Director, IPC, Dr G N Singh, Joint Drugs Controller (India), Dr S Eswara Reddy, PSO, IPC, Dr V Kalaiselvan, and scientific staff.

With the preponderance of smartphone technology and mobile applications (Apps), healthcare services could be extended to every part of country. The application 'ADR PvPI' is an Android-based mobile application, which can be installed on any smart phone device with Android OS version 5.0 or above. The application will be launched soon for other popular platforms.



MAIN FEATURES

- Supports source document and images' attachment
- Supports HCPs as well as consumer reporting
- XML generation
- Auto-fill option

PvPI encourages all healthcare professionals and consumers to utilize the mobile app for reporting ADRs.

Workshop-cum-training programme on Pv for NABH-accredited hospitals

Indian Pharmacopoeia Commission, National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) signed a Memorandum of Understanding (MoU) with National Accreditation Board for Hospitals and Healthcare Providers (NABH) on January 10, 2017 for effective implementation of ADR reporting. To train NABH-accredited hospitals' staff on Pharmacovigilance, a workshop-cum-training programme was organised on July 22, 2017. Healthcare professionals from CHL Group of Hospitals, Indore and other peripheral hospitals, clinicians and administrative professionals were trained on Basics of Pharmacovigilance, monitoring and reporting of ADRs.

The training provided a platform for the participants from NABH-accredited hospitals to understand the system and procedures involved in ADR-reporting.

OUTCOME

- Sensitization of participants on the need for Pharmacovigilance
- Training for establishing pharmacovigilance system in hospitals



Participants during the workshop at CHL Group of Hospitals, Indore

- Ensuring Pharmacovigilance practices are carried out with ease and caution at NABH-accredited hospitals
- Adhering to guidelines of ADR reporting for implementation by PvPI

PvPI, ICMR-NIN set up Centre for Pv on Nutraceuticals, Health Foods

The use of nutraceuticals/health supplements/foods for special dietary purposes is now widespread among the urban populace in India, so has the Indian market expanded, covering as much as 2% of global sales for these supplements.

The safety of nutraceuticals is no more an extraneous issue as such supplements are being sold without proper validation owing to the natural occurrence of the products. The recent incidence of ADRs has been as an eye-opener as they put such health supplements under a scanner. NCC-PvPI has put forth a proposal to develop a national database on safety of nutraceuticals by collecting, assessing and monitoring the adverse drug reactions (ADRs) due to indiscriminate use of nutraceuticals/health supplements/food supplements/herbal preparations and ayurvedic drugs.

On September 5, 2017, NCC-PvPI in collaboration with Indian Council of Medical Research-National Institute of Nutrition (ICMR-NIN) established the Centre for Nutraceuticals Safety Monitoring. Mr T Longvah, Director-in-charge, ICMR-NIN and Dr P B N Prasad, DDCI, CDSO Zonal Office, Hyderabad inaugurated the centre in presence of representatives of CDSO, IPC-PvPI and staff of ICMR-NIN.



IPC shares dais during Golden Jubilee Celebration of IPS

Dr Jai Prakash, Sr Principal Scientific Officer, IPC delivers the keynote lecture on Status of Herbal Drug Regulation in India

Indian Pharmacological Society (IPS) celebrated its golden jubilee during Northern Regional Conference (NRIPSCON-2017) at KIET School of Pharmacy, Ghaziabad, on September 1, 2017. The conference titled “Emerging Trends in Pharmacology & Pharmacy Practice” served as a platform for exchanging knowledge among academics, industry professionals, research scholars and students.

Dr Jai Prakash, Sr Principal Scientific Officer, IPC, chaired a session and delivered a lecture on Status of Herbal Drug Regulation in India, highlighting the role of pharmacists and pharmacologists in rational therapeutics. He stressed the need for standardization of herbal drugs in the country and effective implementation of IP regulatory standards for herbal drugs, including phytopharmaceutical drugs, which would improve the quality of herbal drugs available in the Indian market.



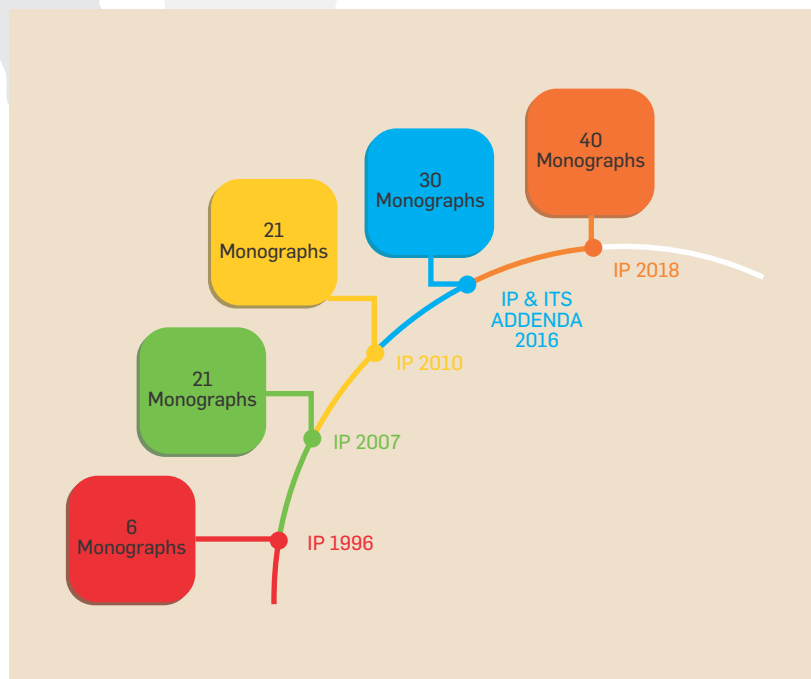
Sr Principal Scientific Officer, IPC, Dr Jai Prakash (2nd left) receives a memento during IPS golden jubilee celebration, at KIET School of Pharmacy, Ghaziabad, on September 1, 2017

IP Monographs on Blood & Its Products

Biologics section of IPC deals with blood and blood-related products' monograph development. IP started to develop and cover biologics monographs since 1996 and during its 21-year journey it now incorporates as many as 40 monographs for blood and related products.

IP 2018 covers following new monographs on blood and related products.

- Anti-D (IgM) monoclonal blood grouping reagent
- Blood Grouping Reagent Anti-Fy^a, Anti-Fy^b
- Blood Grouping Reagent Anti-Jk^a, Anti-Jk^b
- Blood Grouping Reagent Anti-K, Anti-k
- Blood Grouping Reagent Anti-M, Anti-N
- Blood Grouping Reagents Anti P₁
- Blood Grouping Reagents Anti-Le^a, Anti-Le^b
- Blood Grouping Reagents Anti-S, Anti-s
- Blood Grouping Lectins Anti-H
- Blood Grouping Lectins Anti-A₁



Regulatory Pv for Drug Safety

The process of Pharmacovigilance (Pv) ensures identifying, and responding to, benefit-risk issues arising out of marketed medicines. Pharmaceutical companies have been brought under the ambit of Pv to mandatorily report adverse drug reports (ADRs), enabling the regulatory authorities to take appropriate action. The objectives of regulatory pharmacovigilance include long-term monitoring of medicines, assessment of the benefits and risks of medicines, disseminating information among the public to optimise safe and effective use of medicines, and monitoring the impact of any action taken. Effective Pharmacovigilance is dependent on the availability of information on possible hazards associated with medicines in clinical practice. It requires a system for collecting and monitoring suspected adverse drug reactions (ADRs).

PvPI takes the necessary action to ensure maximum safety of drugs marketed, manufactured and prescribed in India. AMCs under the umbrella of PvPI play a vigilant role in ensuring the same. PvPI has received the following ADRs associated with the quality of medicinal product during the Index Period – July 2017 to September 2017:

S. No	Name of the Drug	Brand name/ Manufacturer	Suspected Adverse Drug Reaction Reported due to quality issue	Reporting AMC name	Action Taken by NCC-PvPI	Outcome
1	Inj. Ceftriaxone 1gm i.v.	Amzone/ Maxmed Life Science, Rudrapur, Uttarakhand	Analyphatic Reaction	DRPGMC, Kangra, Himachal Pradesh	Communicated to State Drug Controller For Himachal Pradesh & CDSCO North Zone office	The hospital authorities took prompt action by alerting the hospital staff and averted such adverse events in rest of the patients
2	Inj. Tranexamic acid, 100mg i.v.	T-Stat/ Mercury Laboratories Ltd., Vadodra	Chills and Rigor	GMC, Haldwani, Uttarakhand	Communicated to State Drug Controller for Uttarakhand & CDSCO North Zone office	The hospital authorities took prompt action by alerting the hospital staff and averted such adverse events in rest of the patients
3	Inj. Ampicillin 500mg	Weismanna Healthcare Pvt Ltd., Ongole, Andhra Pradesh	Analyphatic Reaction	SVIMS, Tirupati, A.P.	Communicated to state drug controller for Andhra Pradesh & DDC South Zone, The DI reported to suspend the license	The hospital authorities took prompt action by alerting the hospital staff and averted such adverse events in rest of the patients
4	Inj. Iohexol 350mg	Omnipaque/ GE healthcare, Shanghai, China Imported and marketed by Wipro GE healthcare Pvt. Ltd., New Delhi	Analyphatic Reaction	SVIMS, Tirupati, A.P.	Communicated to state drug controller for Andhra Pradesh & DDC South Zone, The DI reported to further do analysis and testing	The hospital authorities took prompt action by alerting the hospital staff and averted such adverse events in rest of the patients
5	Inj. Propofol 2mg	Kwality Pharmaceuticals Ltd., Amritsar, Punjab	Lack of efficacy and Bronchospasm	CMC, Coimbatore, Govt. Kilpauk Medical College, Chennai, Swami Mansingh Medical College, Jaipur	Communicated to DCGI & DDC South Zone	The hospital authorities took prompt action by alerting the hospital staff and averted such adverse events in rest of the patients

NOTABLE EVENTS

OUTCOME

PvPI team intervened to ensure patient safety through following steps:

- Regular reporting helped in identifying the reports related to low-quality medicines
- Data gathering also quantified the reports and alarm has been raised for intensive monitoring of ADRs due to these products
- Further spread of ADRs could be abated by suspending the supply for reported products
- As per the recommendations of PvPI, regulatory body (CDSCO) has initiated prompt action

PvPI excels in Himachal Pradesh

YS Parmar Govt Medical College, Nahan in Himachal Pradesh – an ADR Monitoring Centre (AMC) under the aegis of Pharmacovigilance Programme of India (PvPI) – organised a CME on “Basics of Pharmacovigilance and ADR Reporting” on June 2, 2017. This activity was aimed at expanding the outreach of PvPI to different districts of Himachal Pradesh.

Prof Bikash Medhi and Dr Ajay Prakash, both from PGIMER, Chandigarh, and PvPI's Dr Prasad Thota attended as resource persons and trained participants on ADR Reporting tools and modes. The prospects of expansion of PvPI in Himachal Pradesh were discussed at the forum.

At present there are four AMCs in Himachal Pradesh, which include both government and private medical colleges and hospitals.

There exists a wide network of health institutes, comprising hospitals, community health centres, primary health centres and sub-centres, which cater to the health needs of rural and urban population. Himachal Pradesh, therefore, occupies a prominent place under the expansion plan of PvPI and the target is to expand pharmacovigilance activities to all districts in the hilly state by 2018.

OPPORTUNITIES

- Induction of NABH hospitals as AMCs will widen the scope of PvPI
- Induction of district-level hospitals as AMCs
- Outreach to micro-level through **Helpline #1800-180-3024** and Mobile App (ADR PvPI)

- Dr Rajendra Prasad Govt Medical College, Tanda, Kangra-176001
- Indira Gandhi Medical College, Circular Road, Lakkar Bazar, Shimla-171001
- Maharishi Markandeshwar Medical College & Hospital, Kumarhatti, Solan, HP-173229
- Dr Yashwant Singh Parmar Government Medical College, Nahan, Sirmour District, HP-173001



5th Skill Development Programme on “Basics and Regulatory Aspects of Pv”

TRAINING PROGRAMME

NCC-PvPI conducted its 5th Skill Development Programme on “Basics and Regulatory Aspects of Pharmacovigilance” at National Coordination Centre, Pharmacovigilance Programme of India, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Sector-23, Raj Nagar, Ghaziabad, UP, from September 4, 2017 to September 13, 2017, imparting training to young healthcare professionals in the field of Pharmacovigilance. The objective of the 10-day skill development programme was to enhance Pharmacovigilance skills of healthcare professionals, thereby promoting and ensuring patient safety.

Names of STATE/UT	No. of Participants
Andhra Pradesh	02
Tamilnadu	01
Maharashtra	05
Bihar	02
Haryana	01
Himachal Pradesh	02
Telangana	13
Madhya Pradesh	01
Rajasthan	02
Uttar Pradesh	02
Uttarakhand	01
Kerala	05
Delhi	03
Total No.	40

As many as 40 selected participants from Andhra Pradesh, Tamil Nadu, Maharashtra, Bihar, Haryana, Himachal Pradesh, Telangana, Madhya Pradesh, Rajasthan, Uttar Pradesh, Uttarakhand, Kerala and Delhi participated in this training programme. The training included Technical/Practical sessions as also a field visit to Regional Training

Centre at Post-Graduate Institute of Medical Education & Research (PGIMER), Chandigarh.

The training covered four modules of Pharmacovigilance such as theory, practical, hands-on training and information technology (IT) applications.

Renowned national and international experts from various disciplines of Pharmacovigilance served as trainer/faculty in this training programme.

DETAILS OF PARTICIPANTS

Participants with medical and pharmacy background took part in this training programme. The details of the participants are as follows:

PARTICIPANTS' PROFESSIONAL BACKGROUND	
Clinicians	03
Students	23
Academia	12
Industry	02

OUTCOME

The training provided an opportunity to the participants for enrolling themselves in Pharmacovigilance units of pharmaceutical organisations with a view to following Good Pharmacovigilance Practices (GVPs) for patient safety. The training programme also opens up avenues for them to be an entrepreneur in Pharmacovigilance. During the entire course of training programme, the participants were enthusiastic to ask as many questions as they could which were fielded to their satisfaction by the speakers. All participants provided their feedback and also endorsed efforts by the PvPI team for organising this fruitful programme.



Induction-cum-training Programme on Pharmacovigilance

The National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) conducted an “Induction-cum-training Programme on Pharmacovigilance for Coordinators of newly-recognised AMCs and Pharmacovigilance Associates under PvPI” at IPC, Ghaziabad in two sessions of five days each – from August 21-25, 2017 and August 28 to September 1, 2017.

The Coordinators of newly-recognized AMCs and newly-recruited Pharmacovigilance Associates (PvAs) under PvPI participated in the training on Pharmacovigilance, formalizing themselves with the Quality Management System (QMS) of PvPI. In the first session, Coordinators & PvAs from Himachal Pradesh, Haryana, Punjab, Maharashtra, Madhya Pradesh, Rajasthan, Gujarat, Uttarakhand & Uttar Pradesh participated while Coordinators & PvAs from Andhra Pradesh, Karnataka, Kerala, Tamil Nadu, Telangana, Chhattisgarh, Odisha, Puducherry and West Bengal participated in the second session. During the five-day-each training programme, the initial three-day training session was common to both Coordinators & PvAs while the last two days were

exclusively for PvAs. The training sessions covered the basics of Pharmacovigilance, QMS, and monitoring and reporting of ADRs, collation of ADR reports, hands-on training on Vigiflow to in-depth knowledge of Causality Assessment, Signal Detection and Regulatory interventions/outcome in a systemic manner.

In the last two days, PvAs had a day-long hands-on exercise on Case Processing, Narrative Writing and Documentation at AMCs and an interactive session with each division of NCC-PvPI. A day-long field visit to Adverse drug reaction Monitoring Centre (AMC) at University College of Medical Sciences (UCMS), New Delhi was arranged for participants of the first batch and a visit to AIIMS, New Delhi for those of the second batch to understand the culture of ADR reporting and documentation at AMCs.

The training programme provided the requisite knowledge to the Coordinators & PvAs on Pharmacovigilance system of PvPI so they could implement the same at their respective AMCs.

The training sessions covered the basics of Pharmacovigilance, QMS, and monitoring and reporting of ADRs, collation of ADR reports, hands-on training on Vigiflow to in-depth knowledge of Causality Assessment, Signal Detection and Regulatory interventions/outcome in a systemic manner



Regional Workshop on “Establishment of Pv System in Pharma Industry”

PvPI has been organizing regular workshops for setting up a sustainable Pv system at Marketing Authorization Holders' (MAHs) site. In September 2017, two such workshops were held.

The second regional workshop was held at PGIMER, Chandigarh on September 9, 2017. The workshop was attended by 88 participants from MAHs, CDSCO-Punjab region, including the faculty and PG students of PGIMER, Chandigarh.

The third regional workshop was held at IPC, Regional Office-CDSCO, Zonal Office, Hyderabad on September 5, 2017. It was attended by 60 participants, comprising MAHs, CDSCO, IPC and NCC-PvPI.

TOPICS DISCUSSED

- Basics of Pharmacovigilance and mandates and activities of NCC-PvPI
- Monitoring and reporting of ADR (Methodology, forms and formats)
- Setting up of a Pharmacovigilance system at MAHs

- Reporting of ICSRs through various channels such as forms and E2B.xml
- ADR reporting through mobile app
- Importance of National Formulary of India (NFI)

OUTCOME

- Awareness among MAHs raised on activities of PvPI-IPC, Ghaziabad
- Participants gained knowledge and were trained on basic aspects of Pharmacovigilance
- Participants interacted with CDSCO officials which provided them with an opportunity to get sensitized to the regulatory perspectives of Pharmacovigilance
- Identifying and improving the gap areas to enhance ADR reporting by MAHs
- Understanding tools to integrate Pharmacovigilance activities with the regulatory system-MAHs in coordination with PvPI



Dr P B N Prasad, DDC(I), CDSCO, lights the traditional lamp at the inauguration of ICMR-NIN centre for Pv in Hyderabad



Dr Bikash Medhi, PGIMER, Chandigarh, addresses the participants during second regional workshop

Approved New Drugs in India

The following new drugs were approved by the CDSCO during July-September 2017

S.No.	Drug	Indication
1	Mirabegron Prolonged Release Tablet 25mg/50mg	Symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in patients with over-active bladder (OAB) Syndrome
2	Delamanid 50mg tablet	For use as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis (MDR-TB) in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability
3	Mirabegron Prolonged Release Tablet 25mg/50mg & Bulk	Symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in patients with over-active bladder (OAB) Syndrome
4	Efonidipine Hydrochloride Ethanolate Bulk & Tablets 10mg/20mg/40mg	Indicated for the management of <ul style="list-style-type: none"> • Hypertension • Renal parenchymal hypertension • Angina
5	Brivaracetam Film Coated Tablets 50mg/75mg/100mg	As adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy
6	Treosulfan Bulk & injection 5gm/vial	For the conditioning treatment prior to haematopoietic stem-cell transplantation
7	Ribociclib 200mg Film coated Tablets	In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of post-menopausal women with the hormone receptor (HR)-Positive, human epidermal growth factor receptor 2 (HER2)-Negative advanced or metastatic breast cancer
8	Dienogest Bulk & 2mg Tablet	For the management of Pelvic pain associated with Endometriosis




Drug Safety Alerts for July-Sept 2017

A preliminary analysis of Suspected Unexpected Serious Adverse Reactions (SUSARs) from PvPI database reveals that the following drugs are risk-prone:

S.No.	Suspected Drugs	Indication	Adverse Reactions
1	Clindamycin	Respiratory tract infections, penicillin-resistant staphylococcal infections and many anaerobes such as bacteroides, skin, soft tissue and dental infections	Acute Generalised Exanthematous Pustulosis
2	Triamcinolone	Corticosteroid	Skin Peeling
3	Polymyxin B	Antibiotic	Mottled Skin
4	Diclofenac	Acute musculo-skeletal pain, arthritis, gout, spondylitis, migraine, post-operative pain	Mottled Skin
5	Terbinafine	Treatment of fungal infections	Acute Generalised Exanthematous Pustulosis
6	Nitrofurantoin	Urinary Tract Infection (UTI), Cystitis	Vasculitis
7	Acetazolamide	Adjunct in treatment of chronic open-angle glaucoma, secondary glaucoma, as a part of preoperative treatment of acute angle-closure glaucoma	Drug Hypersensitivity Syndrome
8	Linagliptin	Type 2 Diabetes Mellitus	Acute Generalised Exanthematous Pustulosis
9	Diloxanide	Amoebiasis	Glossitis

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

Comparative Status of Global Drug Alerts with PvPI Database

Name of Drug	Risk	International Status	India Status
Loperamide	 <p>Risk of serious cardiac adverse events</p>	The National Pharmaceutical Regulatory Agency (NPRA), Malaysia, has updated the package inserts for all products containing Loperamide with warnings and safety information related to the risk of serious cardiac adverse events with high doses	Two cases of tachycardia reported
Mefloquine	 <p>Risk of long-lasting and permanent neurological and psychiatric adverse events</p>	Health Canada has recommended that the product information for Mefloquine should be updated to explain the risk of vestibular damage more clearly. A checklist to assist healthcare professionals in deciding whether to prescribe Mefloquine to individual patients will be developed to prevent mefloquine from being prescribed to patients who are contraindicated (for example past or ongoing neurological or psychiatric conditions)	The PvPI has not received any reports of severe neurological reactions with the use of Mefloquine but two cases of dizziness and one case of mania have been observed
Dipeptidylpeptidase-4 (DPP-4) inhibitors	 <p>Potential risk of heart failure</p>	Health Canada reviewed the potential risk of heart failure with the use of dipeptidylpeptidase-4 (DPP-4) inhibitors (Alogliptin, Saxagliptin, Sitagliptin and Linagliptin) following a risk communication released by the US FDA. The review included all DPP-4 inhibitors available in Canada	Two cases of cardiac failure reported

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

Stellar Role in Pv by GKMC-Chennai

Government Kilpauk Medical College (GKMC) is one of the premier government medical institutions in Chennai, Tamil Nadu. It was founded in 1960. The college has been instrumental in producing many world-renowned doctors. GKMC is a 1,500-bed tertiary hospital which provides speciality health services under the dynamic leadership of the Dean-cum-Professor, Dr P Vasanthamani. The Department of Pharmacology has been carrying out Pharmacovigilance activities following approval by the Indian Pharmacopoeia Commission in August 2011 and functions effectively under Dr C Ramachandra Bhat, Professor & HOD, Dept of Pharmacology, as the Coordinator. Mr C Stalin has been working as the Patient safety Pharmacovigilance Associate at this centre since 2014.

ACTIVITIES AT GKMC, CHENNAI

- Sensitization of healthcare professionals to ADR-reporting through regular meetings and seminars
- Organizing CMEs in association with Govt organizations such as Clinical Development Services Agency (CDSA) and CDSCO
- Sensitized nearly 10 government and private medical colleges by conducting CMEs at their institutes and thereby encouraging ADR-reporting culture
- Coordination with WHO Collaboration Centres, including

Adyar Cancer Institute, MV Diabetes Research Centre and SCARF India for ADR monitoring and reporting

- Coordination with peripheral and NABH-accredited hospitals for active ADR-reporting
- Coordination with Central government organizations such as CGHS for initiating the Intensive Drug Monitoring Programme by PvPI
- Publication of special research articles and case reports in indexed journals
- Issuing Certificate of appreciation to the reporters for their contribution to PvPI
- Circulation of newsletters, drug alerts and other information related to drug-safety among HCPs via email and WhatsApp groups
- Publication of tollfree Helpline in local newspapers to raise awareness

ACHIEVEMENT

The coordinator of the AMC received an award from IPC for Identification of Erythema Multiforme due to anti-rabies vaccine – a new safety alert drawing the attention of global community.



Pharmacovigilance Programme of India (PvPI) is very useful for both academic and Pv activities. Based on case reports, PGs are able to grasp the pharmacological profile of drugs easily. These ADR reports are of great use as learning tools for the postgraduates.

Prof (Dr) C Ramachandra Bhat
HOD-Pharmacology & Coordinator,
Govt Kilpauk Medical college, Chennai



PvPI is a great boon for our hospital. After introduction of PvPI, the agenda of pharmacovigilance committee of the hospital is more complete and technically useful. It makes all clinicians ADR-conscious. They start using drugs in more rational ways, thereby reducing the incidence of ADRs in the hospital. This makes the therapies safer.

Prof (Dr) P Vasanthamani, Dean,
Govt Kilpauk Medical College, Chennai



PvPI is useful for postgraduates of all disciplines. They are able to imbibe and consider all ADRs with great attention, thereby increasing safety of the participants in their research studies.

Prof (Dr) C Hemachandrika
Vice-Principal,
Govt Kilpauk Medical College, Chennai

AGMC-Agartala Promotes Pv

Agartala Government Medical College (AGMC), housed in a newly-constructed building, is located at GB Pant hospital campus in Agartala, Tripura. It is equipped with laboratories, dissection theatres, lecture auditoriums, a central library, cafeteria, intercom facilities, central workshop and a mechanized laundry. AGMC was enrolled as an AMC by PvPI under the leadership of Dr Debasis Ray, Associate Professor & I/C HOD, Dept of Pharmacology as coordinator for NCC-PvPI. For initiation of PvPI in the college an Institutional Pharmacovigilance Committee, including departmental heads, Matron and Medical Superintendent, has been constituted.

ACTIVITIES AT AGMC-AGARTALA

- Quarterly institutional meetings for assessment of Pharmacovigilance activities
- Distribution of drug-safety alerts issued by NCC-PvPI in printed forms
- Sensitization/feedback of HCPs through circulation of PvPI newsletter, posters and pamphlets
- Monthly Progress Report (MPR) of AGMC, generated by NCC PvPI, is circulated among HCPs
- ADR Drop Box installed in the main hospital building
- PvPI posters and charts pasted in different areas of the main hospital building and peripheral hospitals
- PvPI **Helpline #1800-180-3024** displayed at Inpatient & Outpatient departments
- Sensitization of HCPs of district and sub-divisional hospitals by Telemedicine unit of AMC-AGMC
- Annual seminar on the “Need for Pharmacovigilance and How to fill up ADR forms” for MBBS students is conducted by Dr Debasis Ray
- Workshop on sensitization to Pv organized in different schools on National Deworming Day, 2017
- Departmental CME conducted to check the completeness of filled ADR forms



Agartala Government Medical College – an AMC under PvPI

SVIMS-Tirupati – A Stepping Stone to Excellence in Pv

Sri Venkateswara Institute of Medical Sciences (SVIMS), Tirupati is a multispeciality hospital in Chittoor district of Andhra Pradesh, with 10 super-specialities, including cardiology, neurology and nephrology. SVIMS is a deemed university with a medical college which conducts special courses in physiotherapy, nursing and paramedics. SVIMS provides healthcare services to nearly four lakh patients annually. SVIMS was recognised as an AMC by PvPI in 2015. Dr K Umamaheswara Rao, Prof & HOD, Pharmacology is the coordinator, Dr K Vijaya Chandra Reddy, Assistant Prof, Pharmacology, is the deputy coordinator and is supported by PvPI representative Dr PSS Durga Devi as a Patient Safety Pharmacovigilance Associate.

ACTIVITIES AT SVIMS-TIRUPATI

- Conducting regular sensitization programmes for various clinical departments
- Display of posters on Pharmacovigilance at all IPDs & OPDs
- 34 ADR notification drop boxes (red boxes) fixed at IPDs & OPDs
- Awareness programme and training sessions on ADR reporting for nursing staff
- Trained ayurvedic physicians of SV Ayurvedic College, Tirupati report ayurvedic medicine-induced ADRs
- Pv sensitization programme for school teachers, students on Deworming day – 2017 conducted on 10-02-2017
- Two workshops on “Pharmacovigilance & ADR Reporting” for Pharm D students
- Monthly review meeting on Pharmacovigilance activities
- Field visits to peripheral hospitals such as Balaji Institute of Surgery, Research and Rehabilitation for the Disabled (BIRRD) hospital, RHC, Mangalam & UHC, Tirupati for improving ADR-reporting
- Sensitization of all departments of the institute to Materiovigilance Programme of India for reporting medical device-induced reactions



Participants during a training session at SVIMS-Tirupati

FIELD ACTIVITIES

Dr M Hanumantha Rao, MD, FICA

Principal

Senior Professor, Anaesthesiology

SVIMS, SPMC(W), Tirupati

It gives me immense pleasure in sending a congratulatory message to PvPI. SVIMS, SPMC(W), Tirupati is the second medical college exclusively for women in India. The department of pharmacology is proactively engaged in Pharmacovigilance. I appreciate the department of pharmacology, SVIMS for its outstanding contribution to Pv. I wish them all the best in their future endeavour towards patient-safety.



Dr K Umamaheswara Rao

Prof & HOD, Pharmacology

AMC Coordinator, SPMC(W), Tirupati

SVIMS, SPMC(W) put in best efforts for enriching the quality of Pv performance. The quality parameters in respect of ADR detection, quality review, and training sessions for all healthcare professionals have been meticulously met both in broad and superspeciality wings of SVIMS university. Consumer reports add value to medicine safety. The team of AMC-SVIMS, SPMC(W) puts in efforts to motivate consumer reporting. The technical support provided by PvPI-IPC as National Coordination Centre is extremely useful in fulfilling Pv needs.



PvPI assures implementation of Pv with support of DG, Uttarakhand

Addressing Uttarakhand state health authorities, chief medical officers, hospitals' staff, primary healthcare centres, director general (in-charge), Dr D S Rawat, MoHFW, Govt of Uttarakhand, directed all to report ADRs to PvPI. It was decided that all district hospitals in Uttarakhand need to submit ADRs on monthly basis.

It was decided at a meeting to recognize Government Doon Medical College, Dehradun and Sushila Tiwari Medical College, Haldwani as focal centres for collection of ADRs.

NCC-PvPI acknowledges Dr D S Rawat's efforts to support and promote PvPI activities in Uttarakhand.



Mr Prakash Pant
Cabinet Minister,
Uttarakhand



Dr Archana Shrivastava
Director General of Health,
Uttarakhand



Dr D S Rawat
Former (I/C) Director General
Health, Uttarakhand



Mr G S Bedi
General Manager, IDPL



Dr Pradeep Bharti Gupta
Principal, GDMCH, Dehradun



Dr Rangeel sing Raina
Coordinator, GDMCH, Dehradun



Dr Sushil Ojha
Deputy Coordinator, GDMCH, Dehradun

SERIOUS AEFI CASE NOTIFICATION FORM

Serious AEFI Case Notification Form shall be filled with “suspected ADR reporting form” for reporting of Serious AEFI case.

Serious AEFI Case Notification Form – ADR Monitoring Centre*																																				
ICSR No.														Reporting Format No.																						
Name & address of ADR Monitoring Centre (AMC):																																				
Patient Name																																				
Age:														Sex: Male/Female																						
Father/Husband's Name																																				
Complete Address of the Case with landmarks (<i>Street name, house number, village, block, Tehsil, PIN No., Telephone No. etc.</i>)																																				
P	I	N	-							P	H	O	N	E	-																					
Date of Vaccination: ____ / ____ / ____																																				
Address of Health facility where vaccinated (include name of village/urban area, block, DISTRICT and STATE):																																				
Name of vaccines with dose received (if known)																																				
Date of first symptom														D	D	M	M	Y	Y	Y	Y	Time of first symptom										H	H	M	M	(AM/PM)
Hospitalization: No/Yes Date-														D	D	M	M	Y	Y	Y	Y	Time of Hospitalization										H	H	M	M	(AM/PM)
Name and address of hospital (if hospitalized):																																				
CR No. /MRD No. _____																																				
Current status (encircle)														Death/ Still Hospitalized/ Recovered & Discharged with sequelae/ Recovered completely and discharged/ Left against Medical advice (LAMA)/ Not hospitalized																						
If died, date of death														D	D	M	M	Y	Y	Y	Y	Time of death										H	H	M	M	(AM/PM)
Describe AEFI (Sign and symptoms):																																				
Name & signature of AMC Coordinator/ Medical officer:																																				
Email:																																				
Contact No.:																																				
* Date of form sent to District Immunization Officer (where patient was vaccinated) __/__/____																																				
* Date of form sent to State Immunization Officer (where patient was vaccinated) __/__/____																																				
* Date of form sent to PvPI, Ghaziabad (aefi.nccpvp@gmail.com) __/__/____																																				
* Date of form sent to Immunization Division / AEFI Secretariat (aefiindia@gmail.com)- __/__/____																																				
Name & signature of Pharmacovigilance Associate:																																				
Email:																																				
Contact number:																																				

* The case is to be notified to the DIO of the district where the vaccine was administered.

* This duly filled form shall be scanned and emailed simultaneously to DIO, SEPIO, PvPI and AEFI Secretariat.

Appreciation



Mr Doreddula Sathish Kumar
PS-Pharmacovigilance Associate
GGH/KMC-Kurnool

ACHIEVEMENTS AND CONTRIBUTIONS

- PvPI tollfree number is stamped on OPD slip, RNTCP treatment card at GGH, Kurnool.
- All departments in GGH/KMC sensitized to report ADRs by distributing ADR forms and pamphlets containing contact numbers and e-mail id of the AMC
- Demonstration of ADR-reporting mobile app during workshops, sensitization programmes and seminars on Pv promotion
- A video clip on sensitization and importance of Pharmacovigilance shared with all healthcare professionals
- Raising Pv awareness on social media, including WhatsApp and Facebook, and distribution of PvPI newsletters (soft copies) to principals of pharmacy and medical colleges in and around Kurnool, Kadapa, Anathapur districts
- English and Telugu posters (displaying PvPI Helpline #1800-180-3024, AMC Pv Associate number) pasted at all OPD and IPD wards to prompt ADR-reporting by consumers and healthcare professionals



Ms Deepa Chaudhary
PS-Pharmacovigilance Associate
AIIMS-Bhopal

ACHIEVEMENTS AND CONTRIBUTIONS

- Reported unlisted AEFIs
- Actively contribute to NRA assessment process by proper maintenance of documents as per SOPs
- Actively resolve queries by WHO representatives during NRA assessment process
- An initiative to collaborate with State Immunization Programme to promote active surveillance on AEFI
- Electronic display of ADR & AEFI awareness by visual presentation at OPD registration counter and different OPD sections
- Design distribution and display of ADR awareness calendars in working cabins of all healthcare professionals, including faculty and senior Residents as well as at all wards, ICU etc
- Ensuring availability of ADR-reporting registers at all wards & ICU



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 (TollFree): 1800-180-3024