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Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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PvPI ON A ROLL

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Newsletter CONTENTS

Secretary-cum-Scientific Director's Message

Greetings to Readers,

With joy, gratitude and a sense of responsibility I look forward to NCC-PvPI, IPC discharging its scientific duty in the field of pharmacovigilance across India and Asia for the year 2018 and ahead. The year gone by has earned the Indian Pharmacopoeia Commission (IPC), Pharmacovigilance Programme of India (PvPI) many a laurel of which – last but not least – has been the designation of NCC-PvPI, IPC as a WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services for Asia and beyond.

The status accorded to India as the world's sixth country to be a WHO-CC, indeed, comes with the accreditation and recognition of NCC-PvPI, IPC's time-tested scientific approach to pharmacovigilance and regulatory services. However, it also saddles PvPI with the onus of disseminating information, imparting education and training aimed at enhancing Good PV Practices especially in low-and-middle income countries (LMIC) of Asia.

All tools, skills, guidelines and the necessary wherewithal of evidence-based ADR-data collection available with PvPI, IPC need to be put into practice for use by health stakeholders in WHO member-countries. The vulnerable sections of society across Asia need to be geared to adapt to the pharmacovigilance and regulatory science as practised in India under the aegis of PvPI, IPC.

Let us pledge to not rest on our past laurels, but surge ahead with the immense experience and knowledge of ensuring patient safety by constant drug monitoring across Asia.

I wish NCC-PvPI, IPC success in its endeavour to promote health safety

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

PvPI: 2017@Glance and Tasks Ahead

In year 2017, PvPI moved at a pace which resonated with all healthcare stakeholders

With the advent of year 2018 the NCC-PvPI, IPC has the onerous task of disseminating pharmacovigilance (PV) practices and the requisite skills to low-and-middle income countries (LMIC) in Asia and beyond with a view to establishing a healthy PV system across the spectrum. This helps enhance capacity building to forge sustainable pharmacovigilance in public health programmes, ensuring risk-optimized medication in WHO member-states. Moreover, India's well-designed and elaborate regulatory services can play a vital role in extending timely regulatory intervention to safeguard public health in countries across Asia.

Year 2017 brought several fortunes to the Pharmacovigilance Programme of India (PvPI). The year saw a successful WHO-NRA assessment with the achievement of highest maturity level – 4 out of 5 – and the initiation of a regular Skill Development Programme on "Basics & Regulatory Aspects of Pharmacovigilance: Striving for Excellence." The first quarter also saw the dawn of signing of an MoU with the National Accreditation Board for Hospitals and Healthcare Providers (NABH), promoting the monitoring and reporting of Adverse Drug Reactions (ADRs) by NABH-accredited hospitals. At the same time PvPI took a call on antimicrobial resistance (AMR) in the country by educational intervention and training aimed at curbing the menace of AMR.

During the second quarter PvPI touched another milestone – establishing seven new district-level AMCs in eastern Uttar Pradesh, all aimed at generating omnibus data on safety of medicine at the grassroot level. PvPI also initiated its 'First Intensive Drug Monitoring Programme' in collaboration with academic and research institutions like DPSRU & ILBS, New Delhi.

With a view to ensuring the effective implementation of Pharmacovigilance system at Marketing Authorization Holders (MAH)-level in accordance with the Gazette notification issued by Ministry of Health & Family Welfare, New Delhi, PvPI has formalized the participation MAHs in PV by organizing an "Interactive Session on Participation of Marketing Authorization Holders (MAHs) in PvPI". Year 2017 also charted a pathbreaking course by releasing the "PV Guidance Document for MAHs of Pharmaceutical Products". Another major task by the PvPI was the launch of an indigenous android Mobile App – "ADR PvPI". As the PV Guidance Document will serve as a reference manual for Pharma industry, the Mobile App will provide a platform for easy access to report ADRs by stakeholders.

During the calendar year 2017 PvPI has also been assigned ownership of Medical Devices Adverse Events (MDAEs)-reporting. As many as 10 government medical colleges across the country, covering various zones, were identified as MDMCs by the NCC-PvPI.

Last quarter of 2017 brought forth a coveted recognition for India with the formal launch of PvPI, IPC as the World Health Organization (WHO)-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services. A milestone to this effect was laid at IPC in Ghaziabad on October 30, 2017.

PvPI is committed to safeguarding and promoting the health of all Indians, ensuring that the benefits of use of medicine outweigh the risks associated with its use. Health safety by drug safety is the end-aim of PvPI. In year 2017, PvPI moved at a pace which resonated with all healthcare stakeholders and we believe in breaking the glass ceiling by a professional approach in drug-monitoring and ADR-reporting in the years ahead.

Year 2017 brought several fortunes to the Pharmacovigilance Programme of India (PvPI). The year saw a successful WHO-NRA assessment with the achievement of highest maturity level – 4 out of 5 – and the initiation of a regular Skill Development Programme on "Basics & Regulatory Aspects of Pharmacovigilance"

LANDMARK EVENTS 2017

- NCC-PvPI, IPC is designated WHO-CC for Public Health Programmes and Regulatory Services
- WHO-NRA assessment awards highest maturity level – 4 out of 5 – to PvPI
- Regular Skill Development Programme by PvPI on "Basics & Regulatory Aspects of Pharmacovigilance"
- PvPI takes a call on antimicrobial resistance (AMR) in the country by imparting education and training
- The release of "PV Guidance Document for MAHs of Pharmaceutical Products"
- The launch of an indigenous android Mobile App – "ADR PvPI" for ADR-reporting

Glimpses 2017

PV expert from SFDA visits PvPI

Former Director of Pharmacovigilance and Drug Safety Centre at Saudi Arabia Food and Drug Administration (SFDA), Dr Thamir Alshammary along with Dr Wasif Khan, Assistant Director-PV, PharmaLex visited NCC-PvPI on November 27, 2017. The delegation acquainted itself with the PvPI activities including Quality Management System (QMS), signal detection, benefit-risk assessment, training and education.

Dr Thamir lauded PvPI for its contribution to ensuring patient safety. He was overwhelmed with the significant number of trainings undertaken by PvPI particularly with reference to the Skill Development Programme on "Basics and Regulatory Aspects of Pharmacovigilance." He also appreciated Communications and Publications Division for publishing the scientific resource material for healthcare professionals and stakeholders.

Dr V Kalaiselvan (left) felicitates Dr Thamir Alshammary (right), ex-Director, Saudi FDA

Interactive meeting of PvPI, CDSCO and USFDA officials

The collaborative effort between the USFDA and NCC-PvPI, IPC to formulate a roadmap for streamlining pharmacovigilance in India with all healthcare stakeholders in the loop has been on for quite a while with a series of meetings conducted in 2017. To give it a further impetus, another meeting was held at IPC, NCC-PvPI, IPC, Ghaziabad on December 14, 2017. It was decided to organize regular workshops for PV stakeholders, policy-makers and regulatory authorities. The meeting was attended by Dr Ademola Daramola, International Relations Specialist, Mr Thomas Arista, Deputy Director, INO, Dr Rubina Bose, CDSCO (HQ), New Delhi, and PvPI officials.

The visiting USFDA delegation agreed to conduct two workshops with the following objectives:

Objective	Target Audience
To understand current challenges for developing effective PV system in India	Policy-makers, senior executives/scientists from CDSCO & PvPI
Good Pharmacovigilance Practices (GVPs) and Establishment of a PV system in Hospitals/ Industry/Community	MAHs, State Drug Regulators, ADR Monitoring Centre (AMC) coordinators

USFDA officials Thomas Arista and Dr Ademola Daramola (right) during a meeting with PvPI and CDSCO counterpart

IPC Symposium on PV for Herbal Medicine

Dr Sunita Vohra makes a presentation on SONAR, giving an insight into need for PV in natural health products

An informative symposium-cum-lecture session on pharmacovigilance for herbal medicines was conducted by NCC-PvPI, IPC, Ghaziabad on November 20, 2017. The programme featured Dr Sunita Vohra, Professor, Department of Pediatrics, Faculty of Medicine and Dentistry, University of Alberta, Canada, who made a presentation on "Study of Natural Health Product Adverse Reactions (SONAR)". She emphasized the need for pharmacovigilance in herbal products which are essentially natural health products, saying pharmacists must be encouraged to report adverse reactions. She also gave an overview of regulations on natural health products in Canada.

Dr Sunita Vohra makes a presentation on 'Study of natural health product adverse reactions' during the symposium

The symposium was attended by nearly 30 participants, comprising the licensing and regulatory authority, policy-makers, pharma industry, medical practitioners and academia. Dr Rubina Bose, DDC (I), CDSCO, Dr Naresh Sharma, ADC (I), CDSCO, were invited as distinguished speakers. Dr Jai Prakash, Senior PSO, IPC, made a presentation on the role of IPC in promoting quality and safety of herbal drugs.

The challenges and opportunities in causality assessment of AYUSH drugs were deliberated upon and debated threadbare. The most challenging aspect was reported to be the causality assessment vis-a-vis the Indian systems of medicine. It was unanimously agreed upon that AYUSH medical colleges be enrolled as Adverse drug reaction Monitoring Centres (AMCs) in a systemic manner so that ADRs from herbal medicines and other traditional Indian systems of medicine can be reported and analysed.

NML-Nepal delegates visit Phytopharmaceuticals at IPC

Four overseas trainees from National Medicines Laboratory (NML), Nepal visited the Department of Phytopharmaceuticals, IPC, Ghaziabad on October 6, 2017. They were briefed on Standards Development Process of Herbal Drugs Monographs in IP, Method Validation, Instrumental Analysis, and development of Botanical Reference Substances and Phytochemical Reference Substances. The cutting-edge analytical instruments such as High Performance Thin Layer Chromatography were demonstrated.

Dr Jai Prakash and his scientific staff with international trainees from Nepal at Department of Phytopharmaceuticals, IPC

WHO-CC Orientation Programme on Regulatory Services

The Indian Pharmacopoeia Commission (IPC), National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) was on July 18, 2017 recognized as a WHO-Collaborating Centre (WHO-CC) for Pharmacovigilance in Public Health Programmes and Regulatory Services.

The training session helped understand the gap areas and dwelt upon ways and means to streamline the deliverables and processes in the area of extending regulatory services to the WHO member-states following recognition of NCC-PvPI, IPC as a WHO-CC

In the aftermath of the NCC-PvPI, IPC designated as WHO-CC, the IPC in collaboration with Indian National Regulatory Authority (NRA) i.e. Central Drugs Standard Control Organization (CDSCO) conducted at CDSCO, FDA Bhawan in New Delhi on December 15, 2017 an orientation training programme for its Drug Inspectors. The training programme was aimed at appraising Indian regulators about the Pharmacovigilance audits and inspections and also developing the tools for the same. Nearly 40 regulators, comprising drug inspectors, assistant drugs controller(s), deputy drugs controller(s) and joint drugs controllers from the CDSCO headquarters in New Delhi and its various zonal offices, participated in the training programme. The important stakeholders of Pharmacovigilance (PV) such as pharmaceutical industries, WHO country office (India) and Adverse Event Following Immunization (AEFI) also attended the programme. The regulators were updated on issues such as the current system of PV, status and its guidelines for marketing authorization holders (MAHs) and draft check list for PV audit, etc.

Fourth Quality Review Panel meeting

The fourth meeting of Quality Review Panel was convened at IPC, Ghaziabad on October 10, 2017. Chaired by Prof Y K Gupta, AIIMS, New Delhi, the meeting was attended by ADC (I), CDSCO, Dr Naresh Sharma, Dr V Kalaiselvan, PSO, IPC and Dr Shashi Bhushan, SSO, IPC.

SALIENT FEATURES OF THE MEETING

- Finalization of SADR Form (Version 1.3)
- Quality Manual of PvPI be revised as per ISO 9001:2015 standards
- Discussion on strengthening of QMS in PvPI
- Constitution of CAC at all AMCs and Review their functioning

Mobile App 'ADR PvPI' – An instant enabler to promote patient safety

In emerging economies and populous countries such as India, the under-reporting of adverse drug reactions (ADRs) is an issue of serious concern. Indian IT (Information Technology) sector with its advanced technical and software knowhow has developed apps on smartphones which impact every sphere of human activity. And the same holds true in the case of public health safety. In both urban and rural areas of India, the mobile phone penetration has been on the increase. And instant communication of health hazards and medicinal safety assumes greater importance. In such a situation an easy-to-use android mobile app launched by PvPI for ADR-reporting comes handy as it facilitates public health safety by instant communication of any drug-related adverse effect. That is the rationale behind empowering PvPI stakeholders – providing them with an IT-based tool for ADR reporting. NCC-PvPI has developed an advanced version of the android mobile app "ADR PvPI" which is an enabler for all healthcare professionals and consumers to instantly report ADRs. On September 29, 2017 then Union health secretary, Shri C K Mishra, MoHFW, Government of India, dedicated to the nation the indigenously-developed mobile app "ADR PvPI" for the benefit of all healthcare stakeholders, including the common man. At the launch Shri Mishra said, "This mobile application will serve to develop a strong network of healthcare providers for promoting patient safety in the country. This application will certainly meet the expectation of stakeholders especially clinicians by saving their valuable time in reporting ADRs."

SALIENT FEATURES

The new app "ADR PvPI" has been developed to have administrative control of data at IPC, NCC-PvPI with the following features:

- Supports source document and image attachment
- Facilitates ADR-reporting by HCPs as well as consumers
- XML generation
- Option for auto-filling of reporter details to save time

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

In the series of trainings for NABH-accredited hospitals as per the MoU between IPC and NABH, a day-long workshop-cum-training programme was conducted for Telangana and Andhra Pradesh at Apollo Institute of Medical Sciences & Research, Apollo Health City Campus, Jubilee Hills, Hyderabad on October 14, 2017.

This training programme was intended to provide a platform for the NABH-accredited hospitals of the region to understand the systems and procedures involved in ADR-reporting. As many as 50 participants attended the programme.

TOPICS COVERED

- Basics of Pharmacovigilance and mandates and activities of NCC-PvPI
- Monitoring & reporting AEs/ADRs (Methodology, Forms & Formats)
- Setting up of a Pharmacovigilance System in Hospitals

Dignitaries light the traditional lamp during the workshop

PGIMER-Chandigarh holds Advanced Training programme for PvAs

The Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh is a premier medical institution and also a Regional Training Centre (RTC) for Pharmacovigilance under PvPI. As part of its continual training activities, PGIMER held a "Coordinator Meeting-cum-Advanced Training Programme for patient Safety-Pharmacovigilance Associates (PvAs)" on November 17, 2017. The training was specifically designed to update the PvAs of north zone of India on following topics:

- Benefit and Risk: Critical Assessment
- Signal Review and Regulatory Implications
- Antibiotic Resistance: Role of PvPI
- Biovigilance, Materiovigilance and Herbovigilance
- Anti-TB Drugs and Causality Assessment
- Tools of ADR reporting – Android-based mobile app of PvPI (ADR PvPI)

Dr Prasad Thota, IPC (right) is felicitated by Dr M C Gupta, PGI, Rohtak at PGIMER, Chandigarh

OUTCOME

This training has updated the PV-Associates on emerging aspects of Pharmacovigilance which include:

- Benefit-Risk Assessment
- Reporting of ADRs related to antibiotic resistance
- Monitoring ADRs of Generic Drugs
- Need for Awareness about Mobile app for ADR-reporting ADR PvPI
- Materiovigilance and Herbovigilance

AIIMS-Bhopal conducts Advance-Level Training 2017

All India Institute of Medical Sciences (AIIMS)-Bhopal is a premier medical institute for healthcare in Madhya Pradesh (MP). The institute also functions as a Regional Training Centre (RTC) under PvPI and regularly organizes trainings on various aspects of PV. Extending its training support to the coordinators and Patient Safety-Pharmacovigilance Associates (PvAs) working at various ADR Monitoring Centres (AMCs) across Madhya Pradesh and Chhattisgarh (CG), an Advance-Level Training programme (ALT-2017) was organized at AIIMS-Bhopal on November 17, 2017. As many as 50 participants, including coordinators, deputy coordinators and Pharmacovigilance Associates (PvAs), participated as delegates. PvPI and CDSCO-Indore zone (MP) officials were also present as resource persons. The training programme was designed to update participants on following Pv topics:

- Signal Detection in Pharmacovigilance
- PV in Special Populations
- Cutaneous Reactions: When to suspect a drug?
- Haemovigilance
- Materiovigilance
- SWOT Analysis in Pharmacovigilance

Dr Ratinder Jhaj (standing) Coordinator, AIIMS-Bhopal during technical session at ALT-2017

OUTCOME

- Participants updated their understanding on various technical aspects of PV
- Sensitization of participants on various ways of enhancing ADR-reporting
- Focused approaches to topical steroids-induced ADRs

Mumbai hosts 4th Regional Workshop on PV in Pharma Sector

An occasion aimed at bringing PvPI, regulatory authorities and Pharma industry/professionals together for better practice of PV in India

The fourth Regional Workshop on "Basics of Pharmacovigilance and Establishment of PV System in Pharmaceutical Industries – A Way Forward" was conducted at SciTech Centre, Jogeshwari, Mumbai on October 12, 2017.

A delegation comprising Dr V G Somani, Dr K Bangarurajan, Ms Rubina Bose from CDSCO (HQ), New Delhi, Dr Moin Don, President & CEO, PVCON Consulting, Mumbai, Dr Bikash Medhi, AMC Co-ordinator, PGIMER, Chandigarh, Dr Jaisen Lokhande, Assistant Professor, LTMMCGH-Mumbai participated in the workshop.

The objective of the workshop was to update and raise awareness among marketing authorization holders (MAHs) about the regulatory requirements of PV and establishment of a sustainable Pharmacovigilance System in Pharmaceutical Industries.

In his keynote address to the audience, Dr V G Somani, JDC (I), CDSCO (HQ), New Delhi stressed the need for an effective PV system.

Dr V G Somani (at lectern) addresses 4th Regional Workshop on PV in Pharma sector, at Mumbai

TOPICS DISCUSSED DURING THE WORKSHOP

● Pharmacovigilance: Basics, Methods, Practices & A Brief Overview of PvPI ● Importance of ADR-Monitoring in Generic Pharmaceutical Products ● Importance of PIL/SmPCs in Safety Monitoring ● Monitoring & Reporting AEs/ADRs (Suspected Adverse Drug Reaction Reporting Form, CIOMS & E2B XML Reporting) ● Setting up of a PV system in Pharma Industries

MvPI, PGIMER-Chandigarh conduct training on Materiovigilance

A day-long national training programme on Materiovigilance was conducted by PGIMER, Chandigarh in collaboration with MvPI at PGIMER in Chandigarh on November 14, 2017. The training was attended by clinicians, nurses, technicians and biomedical engineers.

Dr Pawan K Saini, Scientific Officer, IPC, participated as a resource person and delivered a lecture on "Materiovigilance Programme of India (MvPI): An Overview." Other topics discussed included:

- Materiovigilance overview from Regulatory Authorities' perspective
- Industrial aspects of Materiovigilance
- Clinicians aspects of Materiovigilance

Dignitaries light the traditional lamp during the workshop

OUTCOME

- Awareness among the stakeholders on quality and risk management of the medical devices, surgical implants and equipment used in healthcare facilities

PV-sensitization workshop for Kala-azar elimination

National Vector-Borne Disease Control Programme (NVBDCP) is a flagship programme under the aegis of MoHFW for the elimination of vector-borne diseases, including Kala-azar (KA). MoHFW organizes several state-level sensitization events to make healthcare professionals aware of treatment schedules, new developments and the much-needed pharmacovigilance in eliminating Kala-azar. PvPI as a partner with NVBDCP participates in these events to raise awareness among healthcare professionals on adverse drug reactions (ADRs) related to Kala-azar drug regimen and guides them on the various procedures for reporting ADRs to PvPI.

During the index period two such workshops were held

- Regional review-cum-sensitization workshop on Kala-azar elimination – November 7 & 8, 2017 at Dumka, Jharkhand
- Dissemination-cum-review workshop for BMOs of high endemic blocks on progress of Kala-azar elimination – December 11 & 12, 2017 at Patna, Bihar

TOPICS COVERED

- Introduction of Pharmacovigilance roadmap for Vector-borne diseases in India
- Causality assessment: Group work-exercise
- Suspected ADR-reporting form and its various components
- Hands-on training on data entry in VigiFlow

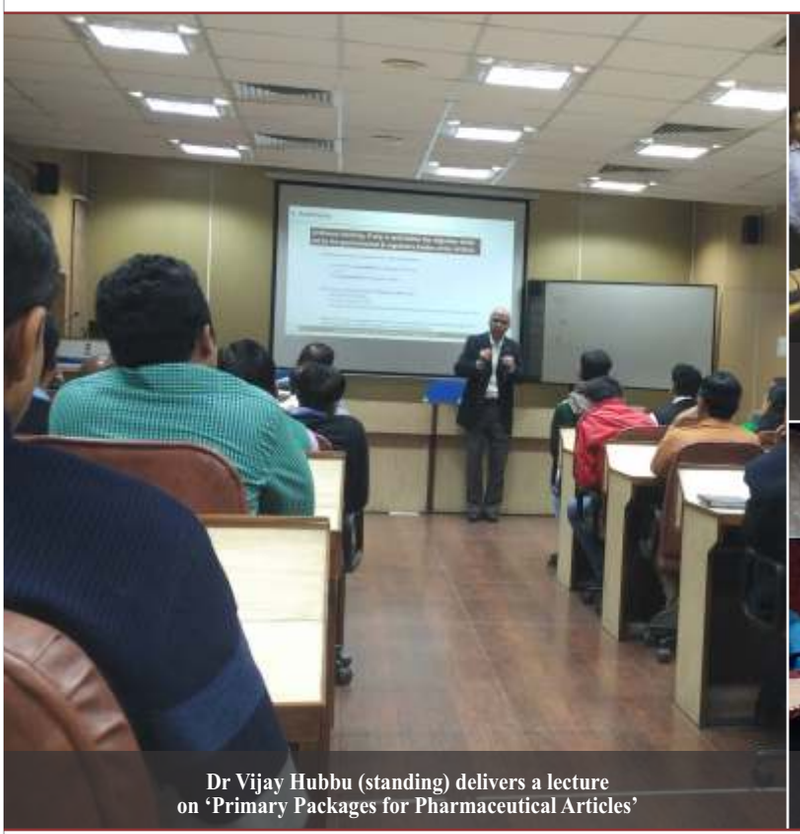
Dissemination-cum-review workshop on Kala-azar elimination, at Patna, Bihar

Guest lecture series at IPC, Ghaziabad

Indian Pharmacopoeia Commission, Ghaziabad regularly conducts a series of seminars for skill development and knowledge enhancement of its scientific staff. During the index period four such seminars were organized, providing recent updates on research and development in pharmaceuticals.

The details of activities are:

Topic	Resource Person
Development of Quality Standards of Vaccines	Dr L R Sood, former Scientist CRI, Kasauli
Good Manufacturing Practices: Recent Updates	Dr D Roy, former Dy Drugs Controller, CDSCO, North Zone, Ghaziabad
Primary Packages for Pharmaceutical Articles with Special Reference to Polymers/Plastics/PET	Dr Vijay Hubbu, Senior Vice-President, Reliance Industries Ltd, Mumbai
Counterfeit, Substandard Drugs & Ecovigilance – Applications of LCMS/MS in Pharmaceutical Analysis	Dr T Velpandian, Professor, Dr RP Centre for Ophthalmic Sciences, AIIMS, New Delhi



Dr Vijay Hubbu (standing) delivers a lecture on 'Primary Packages for Pharmaceutical Articles'

Dr L R Sood, former CRI scientist (centre) during seminar on Development of Quality Standards of Vaccines

Dr T Velpandian (centre) with participants of seminar on 'Applications of LCMS-MS in Pharmaceutical Analysis'

6th Skill Development Programme on 'Basics and Regulatory Aspects of PV'

Training Programme

In its ongoing drive by the Training and Education division of NCC-PvPI, the sixth Skill Development Programme on "Basics and Regulatory Aspects of Pharmacovigilance" was conducted at NCC-PvPI, IPC, Ghaziabad from **November 6-15, 2017.** The main objective of the 10-day training session was to enhance the basic and technical skills by imparting training to young healthcare professionals in the field of pharmacovigilance with a view to ensuring patient safety.

As many as 55 participants from Andhra Pradesh, Chandigarh, Kerala, Kolkata, Maharashtra, West Bengal, Telangana, Madhya Pradesh, Rajasthan, Uttar Pradesh and New Delhi were trained.

Names of STATE/UT	No. of Participants
Andhra Pradesh	04
Maharashtra	02
West Bengal	01
Kolkata	01
Chandigarh	02
Telangana	06
Madhya Pradesh	01
Rajasthan	11
Uttar Pradesh	07
Kerala	14
New Delhi	03
Gujrat	03
Total No.	55

Technical and practical sessions followed by a field visit to ADR Monitoring Centre at PGIMS, Rohtak were the highlights of the session. Participants were apprised of the modes of ADR collection, techniques of signal detection and an overview of VijiFlow. National and international experts from various fields served as trainer/faculty during the training programme.

LEAD FEATURES

- 290 participants trained during 2017, including students, healthcare professionals, marketing authorization holders and academicians
- Platform for students to choose PV as a career in pharmaceutical organizations
- Encourages participants to provide qualitative ADR-reporting and follow good pharmacovigilance practices (GVPs)
- Positive response by participants post-session, including their suggestions by way of presentation and feedback forms

PARTICIPANTS' PROFESSIONAL BACKGROUND	
Clinicians	03
Students	45
Academia	02
Industry	05

Participants during 6th Skill Development Programme

Tentative Training Calendar – 2018

Brainstorming session on "Role of State & UT Drug Regulators for effective utilization of Indian Pharmacopoeia Commission (IPC) services"

Date & Time	Venue	Objective
February 02, 2018 10.00 am - 04.30 pm	Indian Pharmacopoeia Commission, Ghaziabad	State/UT Drug Regulators are primarily responsible for licensing, manufacturing and sale/distribution of drugs. For effective implementation of IPC services i.e. IP, IPRS and PvPI including PV guidelines for MAHs, there is an urgent need to discuss the role and responsibilities of State/UT Drug Regulators as they have to play a crucial role in ensuring outreach of the IPC services to the public

TARGET GROUP/AUDIENCE

State/UT Drug Regulators

Regional Training on "Pharmacovigilance System Establishment & Capacity Building at Pharmaceutical Industries"

TENTATIVE TRAINING SCHEDULE FOR 2018

S. No.	State/ UT	Venue*	Date
1.	Gujarat	Ahmedabad	March 23, 2018
2.	Karnataka	Bengaluru	May 25, 2018
3.	Sikkim	Sikkim	July 13, 2018
4.	Uttar Pradesh (National Meeting)	NCC-PvPI, IPC, Ghaziabad	October 12, 2018
5.	J&K	Jammu	October 26, 2018
6.	Tamil Nadu	Chennai	December 7, 2018

TARGET GROUP/AUDIENCE

Pharmacovigilance, Quality Assurance (QA) and Regulatory Affairs (RA) professionals in Pharmaceutical Industries and Healthcare Systems

Workshop on "Challenges, Solutions and Recommendations for Integrating Pharmacovigilance with National Health Programmes in South-East Asia Region"

Date	Venue	Objective
April 05-06, 2018	Indian Pharmacopoeia Commission, Ghaziabad	To understand the modalities for integration of Pharmacovigilance with Public Health Programmes and utilization of Adverse Drug Reactions (ADRs) data for better patient-safety outcome

TARGET GROUP/AUDIENCE

National Pharmacovigilance Centres, WHO, PvPI, Maximum Participants: 30

Workshop on "Compliance of Good PV Practices for Low-Middle Income Countries (LMIC)"

TENTATIVE TRAINING CALENDAR 2018 FOR LMIC

S.No.	Tentative Dates	Venue
1	April 2-3, 2018	IPC, Ghaziabad
2	August 23-24, 2018	IPC, Ghaziabad

Workshop on "Scope for Integration of Pharmacy Institutions with National Pharmacovigilance Centres" for South-East Asia Region

Date	Venue	Objective
October 26-27, 2018	Indian Pharmacopoeia Commission, Ghaziabad	The workshop is aimed at prompting and promoting pharmacy institutions for integration with National Pharmacovigilance Centres to boost Pharmacovigilance education and its advocacy and also to enhance career avenues of the pharmacy professionals in Pharmacovigilance sector

TARGET GROUP/AUDIENCE

University Vice-chancellors, Directors/Principals/HODs/Teachers of Pharmacy Institutions, Chairmen, Managing Directors of Pvt Institutions

Workshop-cum-Training programme on PV for NABH-accredited Hospitals

S.No.	Venue	Month (Year-2018)
1	Bhubaneswar	January
2	Ludhiana	February
3	Lucknow	March
4	Bengaluru	April
5	Jodhpur	May
6	Ranchi	June
7	Gurugram	July
8	Noida	August
9	Kozhikode	September
10	North East	November

Advance-level Training by Regional Training Centres (RTCs)

S.No.	Regional Training Centres (RTCs)	Month/Date
1	BJMC, Ahmedabad	March 22-23
2	KEM, Mumbai	March 23-24
3	AIIMS, Bhopal	October 12
4	PGIMER, Chandigarh	October
5	AIIMS, Rishikesh	October
6	JSS, Mysuru	November
7	PGIMER, Kolkata	December


IPC
Skill Development Programme
2018
Basics & Regulatory Aspects of
Pharmacovigilance
"Optimising Medicine Safety is our Goal"
Jan-2018 | Mar-2018 | May-2018
July-2018 | Sep-2018 | Nov-2018
Organised by
Indian Pharmacopoeia Commission
National Coordination Centre
Pharmacovigilance Programme of India

Approved New Drugs in India

The following new drugs were approved by the CDSCO during October-December 2017

Apremilast bulk & film coated tablets 10 mg/ 20 mg/30 mg

For treatment of patients with moderate to severe plaque psoriasis who are candidate for phototherapy or systemic therapy

Arbekacin bulk & Injection 200 mg/4 ml

Treatment of following infections caused by Methicillin resistant *Staphylococcus aureus* (MRSA); sepsis pneumonia

Midostaurin 25 mg Capsules

- In combination with standard induction and consolidation chemotherapy followed by single agent in maintenance of therapy for adult patients with newly diagnosed with acute myeloid leukemia (AML) who are FLT-3 Mutation positive.
- For the treatment of adult patients with advanced systemic mastocycosis (Advanced SM)

Tenofovir Alafenamide Fumarate bulk & 25 mg capsules

For the treatment of chronic Hepatitis B virus infection in adults with compensated liver disease

Arteolane Maleate and Piperaquine phosphate Dispersible tablets (37.5 mg + 187.5 mg

Indicated in children aged 6 months to 12 years for the treatment of:

- Acute uncomplicated *Plasmodium falciparum* malaria infection
- Acute uncomplicated *Plasmodium vivax* malaria infection

Macitentan Bulk and Tablets 10 mg

Macitentan is an endothelin receptor antagonist (ERA) indicated for the treatment of Pulmonary arterial hypertension (PAH, WHO group I) to delay disease progression

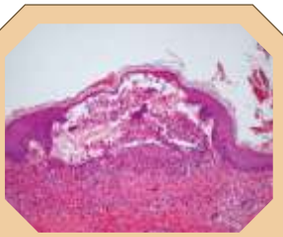
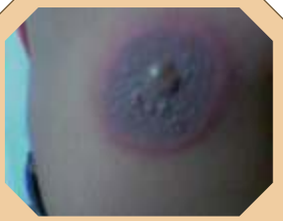
Drug Safety Alerts for Oct-Dec 2017

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

AMIKACIN	ALLOPURINOL	QUETIAPINE	CEFTRIAXONE	FLUOXETINE
Indication: Short term treatment of serious infections due to susceptible strains of Gram-negative bacteria, including *Pseudomonas* species, *Escherichia coli*, species of indole-positive and indolenegative proteus, *Providencia* species, *Klebsiella*, *Enterobacter*, *Serratia* species and *Acinetobacter* species	**Indication:** Prophylaxis of gout; prophylaxis of hyperuricaemia associated with cancer chemotherapy	**Indication:** For treatment of Schizophrenia and bipolar disorder	**Indication:** Serious infections due to sensitive bacteria, including septicaemia, pneumonia and meningitis; surgical prophylaxis; prophylaxsis of meningococcal meningitis; gonorrhoea; bone and joint infection	**Indication:** Fluoxetine is a SSRI antidepressant which is used in psychological disorders and also in premature ejaculation
ADVERSE REACTION- STEVENS-JOHNSON SYNDROME	*ADVERSE REACTION-* UVEITIS	*ADVERSE REACTION-* GYNAECOMASTIA	*ADVERSE REACTION-* PALPITATIONS	*ADVERSE REACTION-* URINARY INCONTINENCE

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 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
Azithromycin	 Acute generalized exanthematous pustulosis (AGEP)	The Ministry of Health, Labour and Welfare (MHLW), Japan and the Pharmaceuticals and Medical Devices Agency (PMDA) have announced that the package insert for Azithromycin (Zithromax®) has been updated to include the risk of AGEP as a clinically significant adverse reaction	Five cases of AGEP reported
Hyoscine butylbromide ampoule	 Caution of use in patients with pre-existing cardiac conditions	The Therapeutic Goods Administration (TGA) has updated product information for hyoscine butylbromide (Buscopan®) to include a caution regarding the use of Hyoscine ampoules in patients with pre-existing cardiac conditions (for example cardiac failure, coronary heart disease). The Australian product information for Hyoscine butylbromide already lists tachycardia, decreased blood pressure and anaphylaxis as potential adverse effects, but the product information has been updated to include a stronger warning in the precautions section because these adverse events can be more serious in patients with cardiac conditions	Five cases of palpitations and three cases of tachycardia reported
Doxycycline	 Risk of fixed drug eruptions	The Saudi Food and Drug Authority (SFDA) has updated the summary of product characteristics and patient information leaflet for Doxycycline to include the risk of fixed drug eruptions (FDE). Doxycycline is a tetracycline broad-spectrum antibiotic, used in treatment or prophylaxis against a wide range of susceptible strains of gram-negative and gram-positive bacteria and other microorganisms	62 cases of drug eruptions reported

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

RBIPMT-New Delhi excels in PV

Rajan Babu Institute of Pulmonary Medicine & Tuberculosis (RBIPMT), New Delhi was established in 1935. It is a premier institute for the treatment of respiratory diseases especially for MDR & XDR TB in Asia. The hospital serves as an ADR Monitoring Centre (AMC) under PvPI and provides special support to monitoring adverse events due to anti-tuberculosis drugs prescribed under RNTCP. Awareness and sensitization programmes are regularly conducted for healthcare professionals, pharmacists, nurses and RNTCP staff to ensure patient safety.

Recently, RBIPMT, New Delhi organized a CME on "Sensitization to PV in RNTCP". The topics discussed and presented were:

- An Update on daily regimen by Dr Anuj K Bhatnagar (HoD, TB & Chest), RBIPMT
- Sensitization to PV in RNTCP by Mr Pratik K Dixit, Patient Safety-PV Associate

Participants during a sensitization programme at RBIPMT, New Delhi

NH Group of Hospitals boosts MvPI in Bangalore

The Narayana Health (NH) Group of Hospitals functions as a Medical Device Monitoring Centre (MDMC) under the Materiovigilance Programme of India (MvPI). A team of clinicians and biomedical engineers at the NH Group of Hospitals works relentlessly to monitor adverse events due to medical devices and equipment and report these events to NCC-MvPI for ensuring patient safety.

The activities at the NH Group include sensitization and awareness of healthcare professionals in reporting Medical Device Adverse Events (MDAEs), conducting workshops on filling of MDAE reporting form, updating alerts and recall notices from regulator, and mass-media campaigns.

For imbibing the culture of reporting at the NH Group as many as 25 awareness programmes were organized at NICS, MSH NH, Bangalore. Regular follow-up and feedback from stakeholders is the norm for improving the MvPI activities by facilitating reporting of MDAEs.

JLN Medical College-Ajmer enhances PV

Established in 1965, Jawaharlal Nehru Medical College is a government medical college located in Ajmer, Rajasthan. Its conducts graduate and postgraduate courses, including MBBS, MS/MD/DM (Cardiology), as also MSc (Medicine) in certain non-clinical and paramedical subjects, GNM and BSc (Nursing) and various paramedical diplomas. The college is affiliated to Rajasthan University of Health Sciences and the Medical Council of India. The following hospitals are attached to the college:

- Jawaharlal Nehru Hospital
- Mahila Chikitsalaya
- Satellite Hospital

This institute on an average daily basis sees 3,500 OPD patients and more than 200 patients in IPD. It was designated as an AMC under PvPI in July 2017 with active support of Dr Rajendra Kumar Gokhroo, Principal and Controller, and Dr Sunil Kumar Mathur, Professor and Head (Pharmacology) & AMC Coordinator. Medical Superitendent JLN Hospital, Dr Anil Jain, who is a paediatrics professor, provides valuable guidance and support. Moreover, all heads of department are fully aware of the programme and are enthusiastic to strengthen Pv. Dr Sanjeev Maheshwari, Professor, General Medicine and additional principal, and Dr Vandana Goyal, Professor Pharmacology are members of the Causality Assessment Committee (CAC) at the AMC.

AMC ACTIVITIES

- Conducted 24 meetings with faculty and resident doctors, and other HCPs at the institute to raise awareness of the PvPI among them. They were sensitized to the need and importance of PvPI and were also trained to report an ADR in a Suspected Adverse Drug Reaction reporting form. More than 300 HCPs have been trained and 36 ADRs reported by the AMC in a short span of time
- To actively involve nursing professionals in PvPI, the AMC has also conducted an awareness-raising programme for them
- Effective coordination with Public Health Programmes like TB & Chest Hospital, ART Centre, Immunization Centre and Drug Dependence Centre adjoining JLN Hospital, a daily visit to all centres for collection of ADR reports and a regular follow-up is done
- More than 300 HCPs mobile numbers have been fed to PvPI-SMS portal so that they can receive updated drug alerts

JLN Medical College, Ajmer – an AMC under PvPI

Stakeholders' Feedback

Dr Gajendra Singh Sisodia,
Joint Director, Medical & Health,
Ajmer Division

Patient Safety is our prime objective and Pharmacovigilance is a supportive tool for patient safety. We have been working assiduously to carry forward the agenda of ADR Monitoring Centre (AMC), JLN Medical College to all government stakeholders, including CMHO/PMO/MO in Ajmer division for support to AMC under PvPI. Anti-microbial resistance is a major challenge for healthcare system, hence standardization of guidelines for monitoring antibiotic use in the hospital and community is called for. Enforcing change in existing practices can be achieved by pharmacovigilance data analysis. Hence, it is incumbent upon the hospital to monitor closely every single ADR.

Dr K K Soni,
CMHO,
Ajmer District

Generation of drug-safety data in Indian population is the prime requirement for safe use of drugs, enabling an evidence-based drug regulatory decision by CDSCO. Healthcare professionals play a vital role in reporting adverse drug reactions to PvPI. With AMC Ajmer we promote drug-monitoring awareness among HCPs in the district at both urban and rural level.

Dr Rajendra Kumar Gokhroo,
Principal & Controller,
JLN Medical College &
Associate Hospital

Usage of pharmaceutical compounds is integral part of disease management but establishment of drug safety is a global challenge and to face this challenge, pharmacovigilance programme is an essential tool in clinical practice. This programme has become a necessity now days to create database regarding ADR profile of not only a newly marketed drug, but also the drugs which are being prescribed for last many years. Since more than seven months, Our HCPs are monitoring the ADRs for effective implementation of PvPI in our institute, as evident from the number of ADR reported by them. This will certainly help to fullfill the objective of the PvPI.

Dr Sanjiv Maheshwari,
Senior Professor (Medicine),
Member of CAC,
JLN Medical College, Ajmer,

Primum non nocere is a Latin phrase that means "at least do no harm." It is one of the cardinal principles of bioethics all medical students are taught. It marks the basis for close and continuous monitoring of adverse drug reactions as this principle reminds the healthcare provider that they must consider the possible harm that any intervention might do. All our efforts must be aimed at supporting the natural defence without causing any damage or discomfort to the body system.

Dr Anil Kumar Jain,
Medical Superitendent,
JLN Medical College &
Associated Hospital

Pharmacovigilance activities are aimed at achieving safer drug therapy & patient-safety goals which include enhancing the quality of drugs & vaccines. The need for raising PV awareness among all HCPs in India to support and report ADRs to PvPI is paramount.

Dr Sunil Kumar Mathur
Professor & HoD (Pharmacology),
AMC Coordinator,
JLN Medical College & Associated Hospital

None of us can forget the "Thalidomide disaster" which reminds us of the consistent need for drug monitoring by reporting ADRs. Many ADRs are reported only during post-marketing surveillance and this may even decide the fate of the drug in quest. A number of drugs have been discontinued for reasons that the risk associated with their use outweighs the corresponding benefits. This, indeed, underlines the importance of pharmacovigilance in healthcare. PvPI has been effectively working to generate a sustainable database on drug safety which enables timely regulatory intervention. It is the utmost duty of healthcare professionals to participate in this programme by regular monitoring and reporting of ADRs.

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 *(Street name, house number, village, block, Tehsil, PIN No., Telephone No. etc.)*

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.nccpvpi@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.

PvPI Mobile App

Now you can report an ADR at any time any where in India

- Facilitate hassle free ADR reporting for healthcare professionals
- Customized consumer reporting
- Facility to report at preferred centre
- Supports attachment of images(Adverse Event) and relevant documents
- Acknowledgement to the reporter
- User-friendly User Interface (UI)

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