



# Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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## PvPI REACHES OUT TO RURAL MASSES

WITH THE PERSPECTIVE OF SAFEGUARDING THE HEALTH OF THE POOR,  
PHARMACOVIGILANCE NOW HAS REMOTE DISTRICTS IN ITS EXPANSE



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## Secretary-cum-Scientific Director's Message



Dear Readers,

The Pharmacovigilance Programme of India (PvPI) has come a long way since its inception in 2010 and has realised its potential in a guided manner, encompassing in its sphere of activity all districts across the length and breadth of the country. Adding a sustainable dimension to pharmacovigilance with every passing day has been the long-term objective of the programme which PvPI has been assiduously attempting to meet.

It is, indeed, a matter of satisfaction that seven new district-level Adverse drug-reaction Monitoring Centres (AMCs) have been set up in eastern Uttar Pradesh during the index period April-June 2017. This enhances the number of AMCs enrolled under PvPI across the country to 250, which include medical colleges, district and corporate hospitals, etc.

The more the outreach of PvPI by way of district-wise enrolment of AMCs, the more the number of people at the grassroot level are assured of the facility of health safety by constant monitoring of the drugs they use.

It is noteworthy to mention that during a meeting of the "First Intensive Drug Monitoring Programme" at NCC-PvPI, IPC, Ghaziabad, in May 2017 several academic institutions with designated hospitals attached to them were enrolled for the conduct of intensive drug monitoring. The drugs identified for monitoring included SGLT2 inhibitors, Pioglitazone and Sofosbuvir.

New Delhi also had the distinction of hosting the first annual meeting of South-East Asia Regulatory Network (SEARN) in April 2017. SEARN was launched by WHO South-East Asia Region member countries for enhancing information-sharing, collaboration and convergence of medical products' regulatory practices across the region. This guarantees access to quality medical products, helps enhance performance of the regulatory authorities, promotes effective use of resources and enables rapid exchange of information on medical products for countries in the South-East Asia region.

I felicitate the PvPI team for its consistent endeavour to raise awareness of drug safety among Indian populace.

**Dr G. N. SINGH**

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

# Outreach of PvPI at District level

Seven new District-level AMCs set up in eastern Uttar Pradesh

**I**ndian Pharmacopoeia Commission functions as National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) under the aegis of Ministry of Health and Family Welfare (MoHFW), Government of India (GoI). PvPI was established in 2010 by MoHFW, GoI, with a mission to monitor/improve patient health and safe administration of drugs, thus reducing the risk associated with use of medicine in Indian population.

PvPI's basic objectives include the creation of a nationwide system for patient-safety by ensuring adverse drug reaction (ADR) reporting, identification of new ADRs, analysis of the benefit-risk ratio of the marketed medications and generation of evidence-based information on safety of medicines. All these factors help the regulatory agencies in the decision-making process on the use of medicines.

PvPI collects and evaluates spontaneous reports of ADRs due to use of medicines, vaccines, medical devices and herbal products from all healthcare professionals and consumers/patients. To monitor ADRs and reporting the same to NCC-PvPI, ADR Monitoring Centres (AMCs) have been set up all over India. At present 250 AMCs (medical colleges, district and corporate hospitals, etc) are enrolled under PvPI across the country,

including seven new district-level AMCs set up in eastern Uttar Pradesh during the index period April-June 2017.

NCC-PvPI has been making strenuous efforts for enrolling all district hospitals across the country as AMCs so that omnibus data on safety of medicine among the Indian populace could be generated.

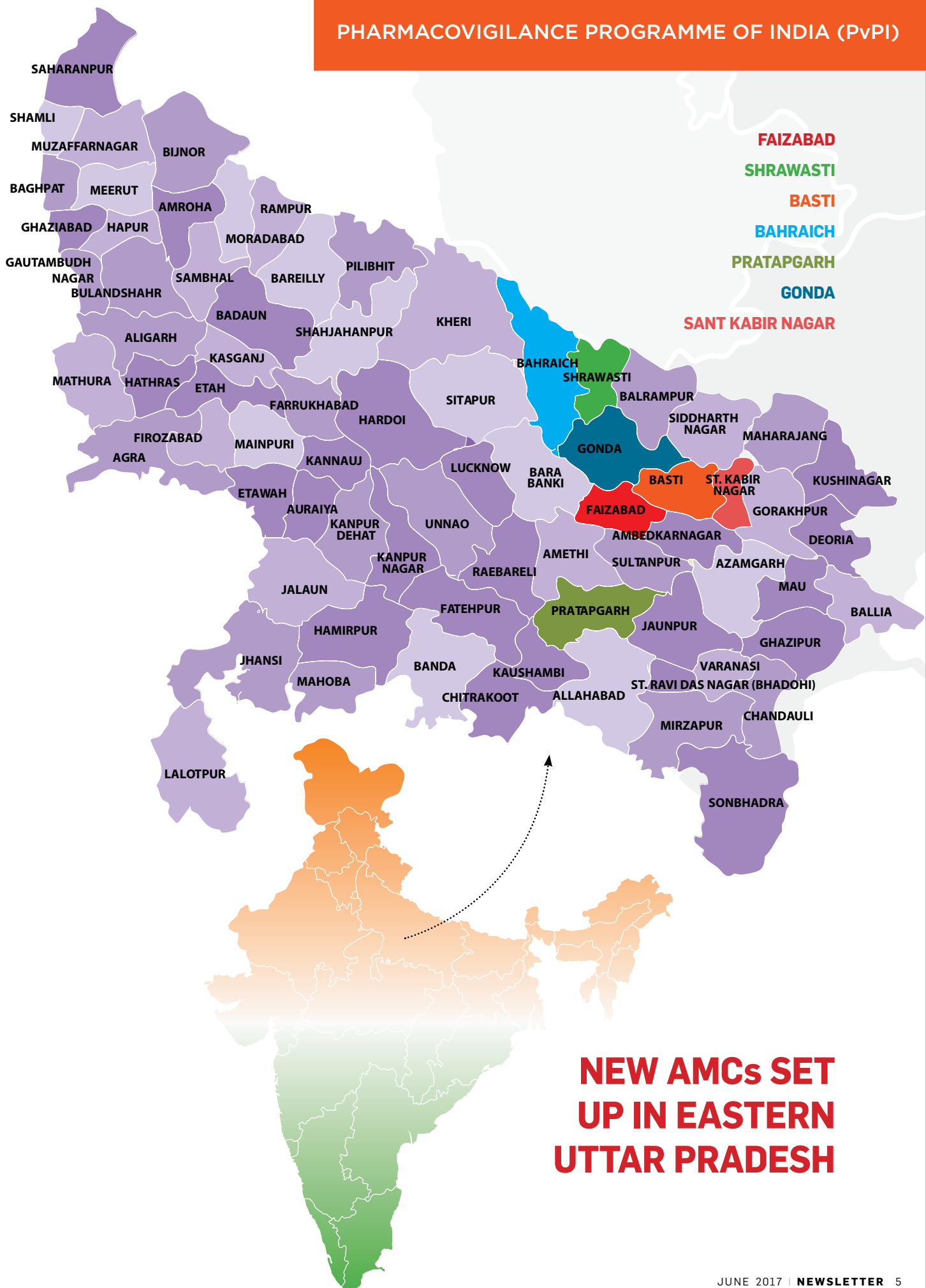
## NEW AMCs SET UP IN EASTERN UTTAR PRADESH (UP)

- Mahamaya Rajkiya Allopathic Medical College, Saddarpur, Ambedkar Nagar district, Faizabad
- Combined District Hospital, Bhinga, Shrawasti
- District Hospital, Basti
- District Hospital, Bahraich, Gurunanak Chauraha, Bahraich
- District Hospital (MALE), Pratapgarh,
- Babu Ishwar Saran District Hospital, Gonda
- Combined District Hospital, Sant Kabir Nagar

## AIMS AND OBJECTIVES OF PvPI EXPANSION

- Catering to public health safety at micro-level
- Optimization of drug safety by evidence-based research
- Public access to ADR-reporting
- Health safety by Pv network connectivity
- Prompting regulatory action by grassroot-level database
- Raising awareness level for safe drug use among rural masses
- Widening the healthcare professionals' base for Pv activity

**PvPI collects and evaluates spontaneous reports of ADRs due to use of medicines, vaccines, medical devices and herbal products from all healthcare professionals and consumers/patients**



**NEW AMCs SET  
UP IN EASTERN  
UTTAR PRADESH**



# Pharmacovigilance: India & Ethiopia on Pv knowledge-sharing spree

**N**ational Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) conducted a “Pharmacovigilance Knowledge-Sharing Programme—India & Ethiopia” for the Food, Medicine and Healthcare Administration and Control Authority (FMHACA), Ethiopia, at IPC, Ghaziabad, from April 24-28, 2017.

Seven delegates from Ethiopia, including Director-FMHACA and six Pv experts of FMHACA, participated in the five-day training programme. During the training programme the delegates were apprised of the established Pharmacovigilance system in India. The training sessions covered areas such as Quality Management System



Visiting FMHACA delegation from Ethiopia with NCC-PvPI officials at IPC, Ghaziabad



Visiting FMHACA delegation from Ethiopia (right) with DCG (I) & NCC-PvPI officials at CDSCO, New Delhi

(QMS), procedures for monitoring and collation of ADR reports, an in-depth study of signal detection process, and regulatory interventions/outcome in a methodical manner. It was followed by a day-long field visit to Adverse drug reaction Monitoring Centre (AMC) at Yashoda Superspeciality Hospital, Kaushambi, Ghaziabad, for comprehending the scientific culture of ADR reporting at AMCs. The delegates also had an interaction with officials of the Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare (MoHFW), Govt of India, to understand the nuances of Indian drug regulatory system.

### OUTCOME

The knowledge-sharing programme on pharmacovigilance between India and Ethiopia has been a success story worth emulation. All Ethiopian delegates appreciated the NCC-PvPI team for organizing the programme which enabled them to understand the Pv system in India. Such an effort, they said, would enable them to further strengthen the Pv system in their country.

As per the feedback from the delegates, the major outcome of the programme included:

- Effective implementation of Quality Management System
- Process of drafting and revising SOPs

## Ghana FDA expert appreciates PvPI's Quality Management System

Mr Nana Ansah-Adjei, Ghana Pv pioneer, during his visit to NCC-PvPI appraises himself of the functioning of QMS and SOPs followed by PvPI



Senior Regulatory and Regional Pv Officer, Food and Drugs Authority, Ghana, Mr Nana Ansah-Adjei (2<sup>nd</sup> right) at NCC-PvPI, IPC, Ghaziabad, on May 3, 2017

**M**r Nana Ansah-Adjei, Senior Regulatory and Regional Pv Officer, Food and Drugs Authority, Ghana, West Africa, visited NCC-PvPI, IPC, Ghaziabad, on May 3, 2017. He had a first-hand experience of the Quality Management System (QMS). Impressed

by innovative initiatives taken by PvPI for patient safety, he made a presentation on Pharmacovigilance system in Ghana during the 3rd Skill Development Programme on 'Basics and Regulatory Aspects of Pharmacovigilance: Striving for Excellence' at NCC-PvPI, IPC.



# PvPI to introduce Pv system in Government Drug-Supply Chain

In order to extend the reach of PvPI to government drug-supply chain, a meeting on “Setting up a Pharmacovigilance system in Government Drug Supply Chain” was convened at Indian Pharmacopoeia Commission, Ghaziabad, on May 22, 2017. The meeting

was attended by CDSCO, WHO-India, Central Medical Services Society (CMSS), Pradhan Mantri Bharatiya Jan Aushadhi Pariyojna (PMBJP), SDSTRC, and Rajiv Gandhi Institute of Chest Diseases, Bengaluru, an AMC under PvPI, and NCC-PvPI officials. The meeting was chaired by Dr Y K Gupta, Prof & Head of Pharmacology, AIIMS, New Delhi.



Head of Pharmacology, AIIMS, New Delhi, Dr Y K Gupta (3<sup>rd</sup> left) with CDSCO, WHO-India officials during a meeting on 'Setting up a Pharmacovigilance system in Government Drug Supply Chain', at Indian Pharmacopoeia Commission, Ghaziabad, on May 22, 2017

### FOCAL POINTS

- Ensuring Pharmacovigilance in Government Drug Supply Chain vital for quality assurance
- CGHS software be upgraded by providing the feature for ADR reporting
- Pharmacists in PMBJP be trained for reporting ADRs
- Roles and responsibilities/accountability for stakeholders be defined without duplication of efforts
- WHO-India to provide technical support and training on Pharmacovigilance to Government Drug Supply Chain staff
- In the initial phase, cohort areas such as malaria, tuberculosis, HIV, vaccination and antibiotics to be covered

## Industry consultation meeting for effective Pharmacovigilance system at MAHs

The Joint Secretary (Regulations), Ministry of Health and Family Welfare (MoHFW), Government of India, has directed the Pharmacovigilance Programme of India (PvPI) to upscale PvPI and explore the possibilities of developing modules aimed at making PvPI a self-sustainable programme. As a follow-up measure, the National Coordination Centre (NCC)-PvPI submitted a proposal of levying charges on MAHs for Pharmacovigilance activities. In this context, a meeting with Indian Drugs Manufacturing Association (IDMA), Organization of Pharmaceutical



CDSCO, PvPI and Pharma industry officials during a meeting for 'Effective Pharmacovigilance System for MAHs', at CDSCO, HQ, New Delhi, on June 5, 2017



Producers of India (OPPI) and Indian Pharmaceutical Association (IPA) was held at Central Drugs Standard Control Organization (CDSCO) HQ, New Delhi, on June 5, 2017.

The meeting was chaired by Prof Y K Gupta and co-chaired by Dr V G Somani, Joint Drugs Controller (India).

### MAIN FEATURES

➤ MAH associations appreciated the idea of, and committed support to, making PvPI a self-sustainable programme. They assured of effective implementation of the proposal

following a detailed discussion among members of their associations.

- PvPI to prepare a brief note/justification for levying charges on, and providing services to, MAH vis-a-vis Pharmacovigilance activities carried out by PvPI.
- MAH associations will review the draft of “Pharmacovigilance Guidelines for Pharmaceutical Products of MAHs in India” and provide their comments/suggestions within 15 working days.

## First Intensive Drug Monitoring Programme under PvPI

The “1st Intensive Drug Monitoring Programme” meeting of PvPI was held at NCC-PvPI, IPC, Ghaziabad, on May 24, 2017. The meeting was chaired by Dr R K Goyal, vice-chancellor, DPSRU, New Delhi.

The following academic institutions with designated hospitals attached with them were enrolled for the conduct of the programme. The drugs identified for monitoring included SGLT2 inhibitors and Pioglitazone.

➤ KIET College of Pharmacy, Ghaziabad with

Yashoda Hospital, Ghaziabad

- Maharishi Markandeshwar University, Mullana with Maharishi Markandeshwar Hospital, Mullana
- Madras Medical College, Chennai with Madras Medical College and Hospital, Chennai
- Delhi Institute of Pharmaceutical Sciences and Research University, New Delhi
- Monitoring of Sofosbuvir by PvPI should be performed at Institute for Liver and Biliary Sciences



DPSRU vice-chancellor, Prof Ramesh K Goyal (centre) with Dr V Kalaiselvan (2nd right) during a meeting on “First Intensive Drug Monitoring Programme under PvPI”, at NCC-PvPI, IPC, Ghaziabad, on May 24, 2017

# Pharma sector proactive role in PvPI must for patient-safety

**T**he “4<sup>th</sup> Interactive Session on Participation of Marketing Authorisation Holders (MAHs) in PvPI” was held at NCC-PvPI, IPC, Ghaziabad, on April 28, 2017. The session was planned with a view to ensuring the effective implementation of Pharmacovigilance system at MAH-level in accordance with the “Gazette notification, G.S.R. 287 (E) issued by Ministry of Health & Family Welfare, New Delhi, dated March 8, 2016”. The main objective of the interactive session was to develop draft

Pharmacovigilance Guidelines for MAHs in India as also delineating challenges for Periodic Safety Update Report (PSUR)-reporting. The interactive session also focused on the Quality and Quantity of Individual Case Safety Reports (ICSRs) received by NCC-PvPI from MAHs.

**The session emphasized that the pharmaceutical industry be actively involved with PvPI for securing comprehensive patient-safety data and building a robust Pv system at MAH-level in India.**



Experts (top) with participants (below) during ‘4<sup>th</sup> Interactive Session on Participation of Marketing Authorisation Holders (MAHs) in PvPI’ in progress, at NCC-PvPI, IPC, Ghaziabad, on April 28, 2017

S. No.	RECOMMENDATIONS
1	Weightage adopted by NCC-PvPI for quality scoring of ICSRs to be shared with MAHs
2	Awareness on system and procedure for ADR-reporting under PvPI to be included in training module for Medical Representatives
3	Participation of Medical Representatives in PvPI skill-development programme
4	Pv Guidelines for MAHs in India to be shared with all participants for their final suggestions/comments
5	Causality assessment be attempted for generic drugs by MAHs
6	PSURs' submission period be extended from 30 days to 60 days after data lock-point
7	MAHs are responsible for ADR-reporting of their products manufactured by contract manufacturer
8	Quality of ICSRs sent to PvPI needs to be improved and emphasis be on causality assessment
9	To raise awareness by Public-Private Partnership (PPP) mode
10	DCG (I) may authorize the display of PvPI tollfree Helpline number on the MAHs' websites

## MvPI puts its best foot forward for Medical Device Safety

To monitor adverse events (AEs) associated with use of medical devices in India, the Materiovigilance Programme of India (MvPI) has been established by the Drugs Controller General (India). Recently, PvPI has been assigned the ownership of Medical Devices Adverse Events (MDAE) reporting.

To gauge and oversee the progress of this nationwide programme, the partners of Materiovigilance Programme of India (MvPI) met at IPC, Ghaziabad, on May 3, 2017 and May 30, 2017 and chalked out the future action plan.

The quorum after due deliberation recommended an increase in the number of MDMCs with a view to enhancing the outreach of MvPI effectively. It was, therefore, decided that the IPC shall identify the AMCs having a biomedical engineering department to enable them function as MDMCs. Members opined that new Research Associates be recruited to ensure the smooth functioning of the programme.

### RECOMMENDATIONS

➤ Members suggested that NCC-PvPI, IPC, take up the challenge for root-cause analysis and

- causality assessment of MDAE reports
- IPC will recruit biomedical engineers with domain experience and PvPI will provide the necessary training
- Members suggested organizing interactive sessions by involving medical device manufacturers/associations
- International medical device manufacturers may submit reports in E2B format for reporting while local manufacturers may report via MDAE form
- Members emphasized the need for encouraging the participation of stakeholders/MAHs in reporting MDAEs by tollfree Helpline # 1800-180-3024
- NCC-MvPI shall design posters, pamphlets and other resource material for circulation among all MDMCs and AMCs so as to raise awareness about the programme
- Members also opined that all serious MDAE reports — owing to quality defect/malfunctioning of the device — received by NCC be conveyed to CDSCO for necessary regulatory interventions



# New Delhi hosts first Annual Meeting of South-East Asia Regulatory Network (SEARN)

**T**he first two-day meeting of South-East Asia Regulatory Network (SEARN) was convened at New Delhi on April 11–12, 2017. SEARN was launched by WHO South-East Asia Region member-countries for enhancing information-sharing, collaboration and convergence of medical products' regulatory practices across the region. This guarantees access to quality medical products, helps enhance performance of the regulatory authorities, promotes effective use of resources and enables rapid exchange of information on medical products for countries in the South-East Asia region.

SEARN has been started with a vision to enhancing the capacity of the Region's regulatory authorities that

lack sufficient technical knowhow, staff and resources to perform effectively. SEARN provides a compelling solution to today's gaps and inefficiencies – one that takes full advantage of our collective strength.

### EXPECTATIONS FROM SEARN

- Increased collaboration will enhance the ability of national regulatory authorities to ensure the safety and quality of medical products
- Establishing streamlined work-sharing arrangements
- Better and safer quality medical products
- Benefit the vulnerable sections of society which are often pushed into poverty when paying for low-quality or unsafe products

## AEFI Secretariat team visits NCC-PvPI

**A**dverse Event Following Immunization (AEFI) Secretariat representative, Dr Deepak Polpakara, with his team visited NCC-PvPI, Ghaziabad, on May 8, 2017 for discussing technical matters and means to empower the AEFI surveillance system.

### RECOMMENDATIONS/SUGGESTIONS

- Leverage PvPI tollfree Helpline 1800-180-3024 for AEFI reporting. AEFI Secretariat will also add a message with PvPI Helpline number in the job ads for auxiliary nurse midwifery (ANM) and Medical officers.
- The Suspected ADR reporting format for HCP and the Consumer will be modified to incorporate the terms “vaccines” and “AEFIs”.

- AEFI Secretariat will share official mobile numbers and CUG numbers of medical officers of states and districts with the PvPI for SMS alerts on drugs/vaccines.
- A few specific events related to vaccines eligible for signal review were discussed. It was also suggested that SMS alerts be prepared by AEFI Secretariat and shared with PvPI for circulation to HCPs so that more cases could be reported.
- Hiring of State Immunization Patient-Safety Associate (SIPSA) and District Immunization Patient-Safety Associate (DIPSA) at state and district level, respectively, was recommended.

# SRP recommends new signals

The 10<sup>th</sup> Signal Review Panel (SRP) meeting of PvPI was held at CDSCO, New Delhi, on May 16, 2017 with an objective to detect signal(s) from Indian safety database for ensuring

patient-safety. SRP recommended to CDSCO new signals, drug-safety label change and drug alerts for the following pharmaceutical products marketed in India.

S. No.	ACTION PLAN
1	<b>Sulfasalazine-associated Stevens-Johnson Syndrome</b> SRP recommended Sulfasalazine-associated Stevens-Johnson Syndrome be incorporated as a package insert
2	<b>Sulfasalazine-associated Toxic Epidermal Necrolysis</b> SRP recommended Sulfasalazine-associated Toxic Epidermal Necrolysis be incorporated into the patient information leaflet (PIL)
3	<b>Meropenem-associated Hypokalaemia</b> SRP suggested continued monitoring for Meropenem-associated hypokalaemia
4	<b>Phenytoin-associated Angioedema</b> SRP suggested continued monitoring for Phenytoin-associated angioedema
5	<b>Phenytoin associated Osteoporosis</b> SRP suggested surveillance for Phenytoin-associated Osteoporosis and collection of more reports

## Revision/upgradation of plastic container chapter of IP

PC on June 3, 2017 convened a meeting at CDSCO, West Zone, Mumbai, for revision/upgradation of plastic container chapter of IP for exploring the possibilities of inclusion of Polyethylene Terephthalate (PET).

The meeting was chaired by Prof Y K Gupta, Head, Department of Pharmacology, AIIMS, New Delhi.

The inputs of the Experts/Members/Special Invitees from different parts of the country were received on the draft chapter titled "Primary Packages for Pharmaceutical Articles".



Delegates during a PET meeting at CDSCO, West Zone, Mumbai, on June 3, 2017

# Library and Information Centre

**T**he IPC Library and Information Centre is the leading Pharmacopoeial Library in the country. It is a repository of Pharmacopoeias of different countries, reference books, scientific journals of national and international repute, national and international standards, non-book materials and e-resources to support regularly the standard of drugs used by the health professionals, patients and consumers.

IPC library provides new information on products and technical services to the users in the field of Drugs & Pharmaceuticals, Pharmacopoeial Research, Pharmacovigilance and other related areas to support scientific, pharmacopoeial and administrative work of the Commission.

### TO FULFIL THIS MISSION, THE LIBRARY IS COMMITTED TO

- Building a strong collection in the fields of Pharmacopoeia, Drugs Standardization, Pharmaceuticals, Research & Development, etc
- Promoting intellectual growth, creativity by developing a collection of documents, facilitating access to technical information resources, critical evaluation, skill development, etc
- Providing reference services, online Selective Dissemination of Information and Current Awareness Services (SDI/CAS) to IPC officials and all CDSCO-HQ, zonal offices, and Central Govt Laboratories for enhancing their knowledge and information



Visitors at IPC Library & Information Centre

**Re-assessment by NABL:** The IPC laboratory was re-assessed by NABL auditors and found to be in compliance with quality management system i.e ISO/IEC 17025:2005 in respect of Chemical testing and Biological testing.

**WHO Projects:** IPC is a participating laboratory for testing of drug samples received from WHO. This marks a step towards strengthening the testing capacity of IPC for global outreach.

**Skill development at IPC:** IPC has provided practical training in advanced chemical, microbiological and herbal drugs analytical techniques to students from different colleges of universities. IPC has also initiated a certificate course on Pharmaceutical analysis for the skill development of pharmacy and science students.

# Inclusion of Herbal Monographs in IP

**I**PC also focuses on development of herbal drugs' standards which contribute to safety of herbal medicines.

As per the provisions of the Drugs & Cosmetics Act, 1940 & Rules 1945, IP prescribes the standards for the drugs that are manufactured, imported, stocked and marketed/distributed in India. The standards of identity, purity and strength prescribed in IP ensure quality control and quality assurance of the medicines.

Herbal medicines have been used by homo sapiens for time immemorial for various healthcare needs. Nearly 80% people in the developing

countries use herbal medicines for the treatment of various diseases. India, known as the botanical garden of the world, is one of the largest producers of medicinal herbs. With the ever-increasing use of herbal medicines and their global expansion in the market, quality and safety have become a major concern for the health of the people. The quality of herbal medicines has a direct impact on their safety and efficacy. In view of this, IPC has taken the responsibility of including the herbal monographs in Indian Pharmacopoeia for providing a quality standard for herbs and herbal products. The standard operating procedures



(SOPs) have been developed by the scientists of the country to prepare the monographs of herbs, processed herbs and herbal drugs for providing them to the stakeholders. The herbal monographs of the IP have been appreciated worldwide and were included in other pharmacopoeias of the world with or without modification. A separate group of scientists is working in the specialized IPC labs under the guidance of the eminent Expert Committee for producing quality standard specifications to meet the growing demand and supply of the herbs and herbal products. A guidance document has also been published.

### INCLUSION CRITERIA SET BY THE EXPERT COMMITTEE FOR HERBAL DRUGS

- The herb should be commercially available
- Should be of public interest
- Of clear and defined botany (in case of more than one species/varieties, cultivars of the same species/variety, there could be more than one monograph in IP)
- Of known phytochemistry
- Some amount of information and/or method for analysis should be available, which can be used as a basis for development and validation. For this, knowledge of “markers”, if available, is an advantage
- Sustainable (if the herb is in any regulated list, but knowledge of its sustainability improvement is ongoing, and is of importance for use, a monograph would be considered for inclusion)
- Knowledge of its safety profiles through known history of its use
- For inclusion of an extract, either the extracts are made using traditional methods/processes on a commercial scale or standardized extracts that are available commercially using solvents are selected. For the latter cases, such extracts should have been in commercial production and use for at least 15 years, and their safety profiles known to the stakeholders
- Herbs should have therapeutic/prophylactic value
- For finished products offered for sale in the market, the products should have been approved as a phytopharmaceutical drug under Drugs & Cosmetics Act, 1940 by CDSCO or by State Regulatory Authority, as the case may be

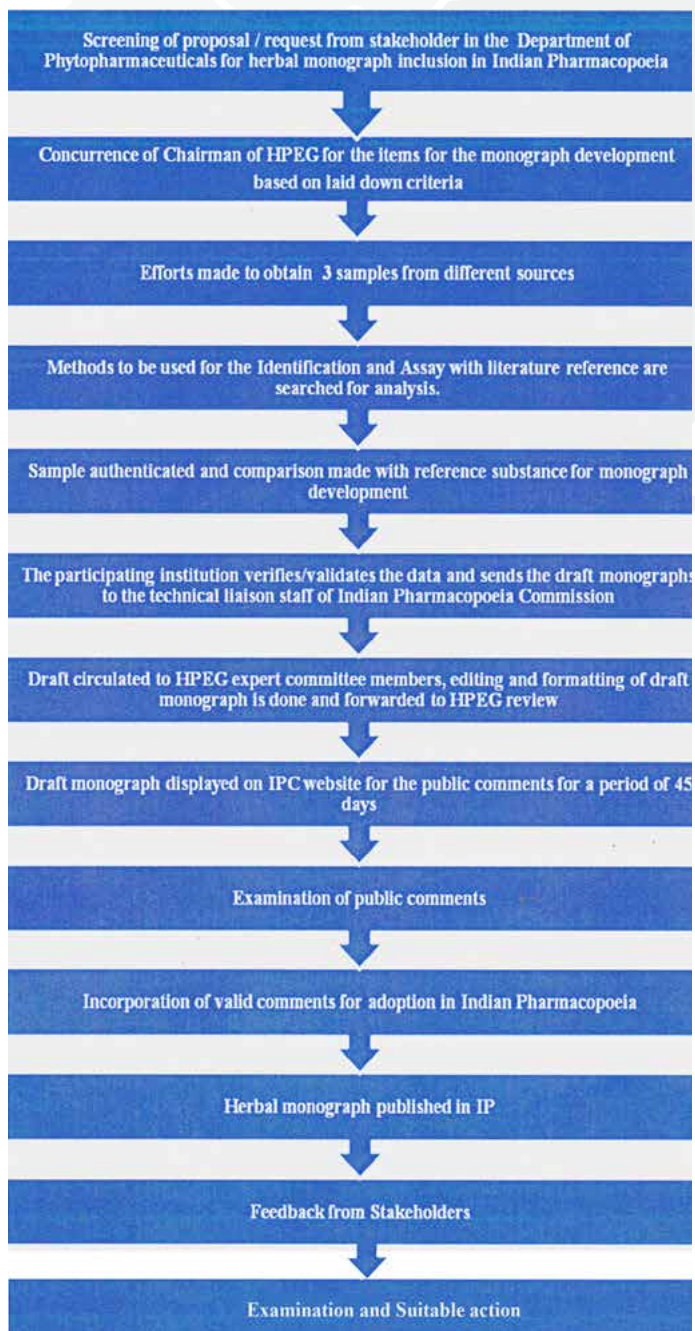
### EXCLUSION CRITERIA FOR HERBAL DRUGS

- Drugs banned in India
- Obsolete Drugs

➤ Drugs considered inappropriate by the Indian Pharmacopoeia Commission and Regulatory Authority

The flowchart gives the process of preparation of herbs and herbal products monographs

### FLOW CHART FOR DEVELOPMENT OF HERBS AND HERBAL PRODUCTS MONOGRAPHS INCLUDING THAT OF PHYTOPHARMACEUTICAL DRUGS FOR IP



# 3<sup>rd</sup> Skill Development Programme on “Basics and Regulatory Aspects of Pv: *Striving for Excellence*”

### TRAINING PROGRAMME

**N**CC-PvPI conducted its 3rd Skill Development Programme by imparting training to the young healthcare professionals in the field of Pharmacovigilance from May 01-10, 2017 at National Coordination Centre, Pharmacovigilance Programme of India, Indian Pharmacopoeia Commission. The objective of this skill development programme is to enhance Pharmacovigilance skills of the healthcare professionals in order to promote patient safety.

As many as 51 selected participants from Madhya Pradesh, Haryana, Tamil Nadu, Odisha, Meghalaya, Nagaland and Puducherry participated in this training programme. This 10-day training programme included Technical/Practical sessions along with a field visit to the 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 the programme.



### DETAILS OF PARTICIPANTS

The Participants having the medical & pharmacy background participated in this training programme. The details of the participants mentioned below in the table:

3rd Batch	No. of Participants
STATE/UNION TERRITORY	
Chhattisgarh	01
Karnataka	03
Haryana	01
Madhya Pradesh	05
Maharashtra	09
Puducherry	01
Tamil Nadu	23
Uttar Pradesh	08
Total no.	51

### PARTICIPANTS' PROFESSIONAL BACKGROUND

Clinicians	15
Students	32
Academicians	04

### END RESULT

This training provided an opportunity to the participants to enrol themselves in Pharmacovigilance units of organisations and also to follow Good Pharmacovigilance Practices (GVP) for ensuring patient safety. This training programme also encourages them to become successful entrepreneurs in Pharmacovigilance. During the entire course of the training programme, the participants were enthusiastic to ask as many questions as they could which were satisfactorily fielded by the speakers. All participants provided their feedback and endorsed the efforts by the PvPI team for organizing this fruitful programme.

# Regional Workshop on “Basics of Pv and Establishment of Pv System in the Pharmaceutical Industry – A Way Forward”

The Regional Workshop on “Basics of Pharmacovigilance and Establishment of Pharmacovigilance System in the Pharmaceutical Industry – A Way Forward” was held at AIIMS, Rishikesh, in Uttarakhand on June 23, 2017. The regional workshop on Pharmacovigilance (Pv) was organised to ensure the effective implementation of Pv system at MAH-level in accordance with the “Gazette notification (G.S.R. 287 (E), issued by Ministry of Health & Family Welfare, New Delhi, dated March 8, 2016.” The primary objective was to focus on the basics of Pv and raise awareness in the pharma industry for oversight by pharmacovigilance. The workshop discussed in detail the inculcation of a sustainable reporting culture as well as the need for setting up a comprehensive Pv system at pharmaceutical companies. It reaffirmed the involvement of MAHs in PvPI for promotion of patient-safety and building a robust Pv system at MAH-level on a par with global standards.

## OUTCOME

- Prof Ravi Kant urged PvPI to adopt the BIS model for certifying the quality of generic medicines
- Awareness raised among participants to report ADRs to PvPI through various channels of reporting such as tollfree Helpline, email ids, suspected ADR form, mobile application, etc
- Participants agreed to develop a system for submission of ADRs to NCC-PvPI in XML format
- Participants suggested that such workshops be conducted with the sole aim of sensitizing the pharma industry to report ADRs and resolve their Pv-related issues



Director, AIIMS-Rishikesh addresses participants at the one-day workshop



CDSO and NCC-PvPI officials with participants during the Regional Workshop on 'Basics of Pharmacovigilance and Establishment of Pharmacovigilance System in the Pharmaceutical Industry – A Way Forward', at AIIMS, Rishikesh, on June 23, 2017



# 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 with National Accreditation Board for Hospitals and Healthcare Providers (NABH) on January 10, 2017, for effective implementation of ADR reporting.

In order to train the NABH-accredited hospitals staff on Pharmacovigilance, a workshop-cum-training programme was organised on May 18, 2017 at New Delhi and on June 13, 2017 at Madurai, Tamil Nadu. The training was provided by subject experts/experienced faculty from ADR Monitoring Centres of NCC-PvPI.

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

The meeting was attended by clinicians, pharmacists and healthcare stakeholders.

## DURING THE MEETING PARTICIPANTS WERE TRAINED ON FOLLOWING

➤ Awareness regarding the process of reporting ADRs

## WORKSHOP ORGANISED

Agenda	Venue	Zone	Date
Workshop-cum-training programme on Pharmacovigilance for NABH-accredited hospitals	NABH Secretariat, New Delhi	North	18.05.2017
	Vadamalyan Hospitals, Madurai, Tamil Nadu	South	13.06.2017
	CHL Group of Hospitals, Indore	North	22.07.2017 (upcoming)
	Mumbai	West	13.10.2017 (upcoming)

- Setting up the Pharmacovigilance system in hospital
- Ensuring ease of Pharmacovigilance practices in NABH-accredited hospitals
- ADR-reporting to PvPI as one of the requirements for accreditation of hospitals

# Approved New Drugs in India

The following new drugs were approved by the CDSCO during April-June 2017

S.No	DRUG	INDICATION
1	Prucalopride 1mg/2mg Tablet (Prucalopride Succinate)	For the treatment of chronic idiopathic constipation in adults in whom laxatives fail to provide adequate relief
2	Pomalidomide 1mg/2mg/3mg/4mg Capsules	In combination with dexamethasone, for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression within 60 days of completion of the last therapy.
3	Sofosbuvir 400 mg +Velpatasvir 100mg Tablet & Bulk	For the treatment of adult patients with chronic Hepatitis C virus, Genotype 1,2,3,4,5 or 6 infection, without cirrhosis or with compensated cirrhosis, with decompensated with chronic for use in combination with Ribavirin.
4	Osimertinib 40 mg/80mg Film-coated tablets (Osimertinib Mesylate)	For the treatment of patient with metastatic epidermal growth factor receptor (EGFR) T790 M mutation-positive non-small cell lung cancer (NSCLC), as detected by an appropriate test, whose disease has progressed on or after EGFR TKI therapy.
5	Argatroban Hydrate Injection 250 mg/2.5 ml	1) For prophylaxis or treatment of thrombosis in adult patients with Heparin-induced thrombocytopenia (HIT). 2) As an anticoagulant in adults patients with or at risk for heparin-induced thrombocytopenia undergoing percutaneous coronary intervention (PCI)

# Drug Safety Alerts for April-June 2017

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

## DEXAMETHASONE

### Indication:

Adjunct in the emergency treatment of anaphylaxis, short-term suppression of inflammation in allergic disorders, adrenocortical insufficiency, ocular inflammation, autoimmune disorders, rheumatic disorder, cerebral oedema, unresponsive shock, bacterial meningitis along with antibiotics

**ADR: Hiccups**

## CABERGOLINE

### Indication:

For treatment of Parkinson's disease, hyperprolactinemia and inhibition of lactation

**ADR: Skin Hyperpigmentation**

## SODIUM VALPROATE

### Indication:

Generalised tonic-clonic seizures, partial seizures, atonic seizures, absence seizures, myoclonic seizures, acute mania, migraine

**ADR: Psoriasis**

## AMOXYCILLIN

### Indication:

Urinary tract infections, upper respiratory tract infections, bronchitis, pneumonia, otitis media, dental abscess, osteomyelitis, Lyme disease in children, endocarditis prophylaxis, post-splenectomy prophylaxis, gynaecological infections, gonorrhoea, Helicobacter pylori eradication

**ADR: Eye Irritation**

## TINIDAZOLE

### Indication:

Amoebiasis, trichomoniasis and giardiasis, anaerobic infections, necrotising ulcerative gingivitis, bacterial vaginosis, H pylori-associated peptic ulcers, abdominal surgery prophylaxis

**ADR: Hyperpigmentation**

## AMLODIPINE

### Indication:

Angina, Hypertension, Coronary artery disease

**ADR: Psoriasis**

## AMITRIPTYLINE

### Indication:

Moderate to severe depression, migraine prophylaxis, tension type headache, neuropathic/chronic pain, fibromyalgia

**ADR: Gingival Discolouration**

## LAMIVUDINE

### Indication:

HIV infection in combination with at least two other antiretroviral drugs

**ADR: Hearing Loss**

## HYDROXYZINE

### Indication:

For management of pruritus due to allergic conditions such as chronic urticaria and atopic contact dermatoses, and in histamine-mediated pruritus

**ADR: Bullous Pemphigoid**

## PARACETAMOL

### Indication:

Mild to moderate pain including dysmenorrhoeal pain, headache, pain relief in osteoarthritis and soft tissue lesions, pyrexia including post-immunization pyrexia, acute migraine attack

**ADR: Baboon Syndrome**

## MEBEVERINE




### Indication:

For Irritable Bowel Syndrome (IBS)

**ADR: Retrosternal Pain**

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 WARNING	INTERNATIONAL STATUS	INDIA STATUS
CASPOFUNGIN	 <p>Risk of Toxic Epidermal Necrolysis (TEN) and Stevens-Johnson Syndrome (SJS)</p>	<p>The Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA) announced that the package insert of Caspofungin (Cancidas®) updated with inclusion of the risk of TEN and oculomucocutaneous syndrome (SJS) as clinically significant adverse reactions</p>	<p>Two cases of SJS reported</p>
DENOSUMAB	 <p>Risk of multiple vertebral fractures</p>	<p>The MHLW and PMDA announced that package insert of Denosumab (Pralia®) updated with inclusion of the risk of multiple vertebral fractures as a clinically significant adverse reaction. Also, MHLW/ PMDA advised transitioning to an alternative antiresorptive medicine if treatment with denosumab is discontinued, to prevent multiple vertebral fractures that can occur due to a temporary increase in bone resorption</p>	<p>PvPI has not received any reports of fractures with the use of Denosumab but two cases of hypocalcaemia and one case of osteonecrosis were observed</p>
TICAGRELOR	 <p>Potential risk of pulmonary haemorrhage</p>	<p>The Ministry of Food and Drug Safety (MFDS), Republic of Korea announced that the label of Ticagrelor has been revised to include pulmonary haemorrhage as an adverse reaction</p>	<p>Two cases of pulmonary haemorrhage reported</p>

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



# MAMC, New Delhi, emerges PvPI torchbearer

In 2014, Department of Pharmacology, Maulana Azad Medical College (MAMC), New Delhi, was recognized as an Adverse drug reaction Monitoring Centre (AMC) under the Pharmacovigilance Programme of India (PvPI).

For initiation of Pharmacovigilance in the college, a committee, including departmental heads and the Dean, was constituted. It has been steadfast in the implementation of Pharmacovigilance programme in the college and associated hospitals.

## ACTIVITIES AT MAMC, NEW DELHI

- Awareness regarding the process of reporting ADRs
- Exclusive e-mail id dedicated for reporting of adverse drug reactions [delhiadr.mamc@gmail.com](mailto:delhiadr.mamc@gmail.com)

➤ Dedicated phone number for reporting : **9560627611**

➤ WhatsApp group made for easy reporting of ADRs

➤ One-minute ADR reporting form

To raise awareness about the Pv programme and related activities, posters were put all over the hospital, including wards and nursing stations.

Workshops to sensitize healthcare providers, including doctors, pharmacists and nurses, have been a regular affair. MBBS, BDS and postgraduate students are sensitized to pharmacovigilance activities at regular intervals.

Research-based pharmacovigilance is now an established practice at MAMC and its associated hospitals and has contributed in a large measure to ADR-reporting.



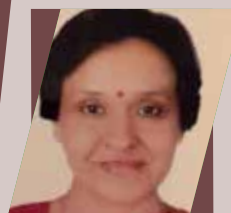
Pharmacovigilance Programme run by NCC-PvPI covers all the departments in MAMC & associated hospitals for adverse drug reactions reporting. It is covering RNTCP very well along with the newer therapeutic drug like Bedaquiline in Chest & TB Clinic, LNJP Hospital which is of utmost importance for early detection of any ADR.

DR ASHWINI KHANNA  
Chief Medical Officer, LNJP  
Hospital



In short time since its inception in 2014, the Adverse Drug Reaction Monitoring Centre at the Dept of Pharmacology at our institution, has made great deal of effort to increase awareness amongst the stakeholders in its affiliated hospitals regarding Pharmacovigilance. The centre has conducted several workshops for doctors, nurses, pharmacists and medical students. I am sure both pre-service and in-service training by the centre will gradually contribute to improved drug therapy and better monitoring of adverse drug reactions, which would ultimately translate into better and safer patient care.

Dr SIDDARTH RAMJI  
Dean, MAMC & Associated Hospitals



Ensuring patient safety through judicious use of medicines and continuous monitoring is a basic requirement of quality healthcare. Focussed Pharmacovigilance activities help in this endeavour. The implementation of the Pharmacovigilance Programme of India and the technical support provided by the National Coordination Centre is of immense help in fulfilment of this objective.

Dr VANDANA ROY  
Director Professor & Head  
Dept of Pharmacology, MAMC  
& Associated Hospitals

# AIIMS, Rishikesh, bolsters Patient Safety mandate through Pv

**A**IIMS-Rishikesh is an apex healthcare institute established by the Ministry of Health & Family Welfare (MoHFW), Government of India, in 2012 with the aim of correcting regional imbalances in quality of tertiary level healthcare services in the country and attaining self-sufficiency in graduate and postgraduate medical education. AIIMS-Rishikesh is a tertiary level medical college with a 200-bed hospital providing speciality health services to the people of Uttarakhand with an average attendance of more than 1,500 patients per day in OPD and 60 patients in IPD. AIIMS-Rishikesh was recognized as an ADR Monitoring Centre (AMC) under PvPI in the year 2014. The core team comprises Dr Puneet Dhamija as Coordinator in-charge for NCC-PvPI, Dr Manisha Bisht, Associate Professor, Department of Pharmacology and Dr Ravi Kant, Associate Professor, Department of General Medicine, as Deputy Coordinators, respectively.

## ROLE OF AMC

- Display of ADR-awareness Banners/Posters/Leaflets at all OPD counters and IPD sections
- Distribution of contact details (phone numbers and Email-Ids) of personnel concerned to all clinicians and nursing staff for reporting ADRs
- A room has been specially allotted at Medicine OPD for one-on-one interaction with patients from

various OPDs during OPD timings and routine visits to IPD for collection of complete ADR reports

- Management and Prevention of ADRs through proper patient counselling and dissemination of drug safety information to HCPs by circulating newsletters and Drug Safety Alerts issued by NCC, PvPI from time to time
- Conducting regular meetings and obtaining feedback from various departments to improve reporting of ADRs
- Sensitization of all HCPs to scale up the ADR reporting mandate of PvPI by adopting mandatory reporting of ADRs in the interest of Public Health
- Maintaining ADR database/registries of all ICSR record files for easy access and retrieval in a hassle-free manner
- Encouraging MBBS students for reporting ADR as part of observational research activities and practical exercise
- Conducting focussed Pharmacovigilance activities with practising clinicians

## ACTIVITIES OF AMC

- Pharmacovigilance awareness programme was conducted in February 2016 at Seema Dental College and Hospital for sensitization of dentists, including faculty and PG students

Pharmacovigilance and allied activities contribute towards achieving patient safety goals and improving therapeutics. An active feedback system for updating clinicians on safety aspects of drugs is required to be created to encourage reporting of ADR. I wish Pharmacovigilance Program of India great success with the efforts being put in by all of us.

Dr. RAVI KANT  
Associate Professor (General Medicine)  
Co-coordinator, AMC, AIIMS, Rishikesh



There is an urgent need to generate drug safety data from India. Many new drugs are being launched in the country along with the global launch. The recent controversy regarding pioglitazone necessitated the importance of generating the data from India. Motivating clinicians to report ADR still remains a daunting task but the program and efforts are being made in right direction. We expect to see an excellent in-house safety database in future which will contribute to patient safety.

Dr. PUNEET DHAMIJA  
Associate Professor (Pharmacology)  
Coordinator, AMC, AIIMS, Rishikesh



- AMC Coordinator held a meeting with the Programme Director, Uttarakhand, National Health Mission, for expanding coverage of PvPI in Uttarakhand.
- One-day workshop was organized in March 2017 for the participants of second batch of “Skill Development Programme on Basics and Regulatory Aspects of Pharmacovigilance 2017” for providing
  - i) Practical overview of PvPI activities carried out at AMC level.
  - ii) Hands-on training on how to collect ADRs in hospital by arranging (OPD/ IPD) visits and one-on-one interaction with the patients
  - iii) Demonstration on how to upload collected ADRs through Vigiflow software in database
- Collaborated with Govt & Private Hospitals of Rishikesh for creating awareness and implementing AEFI surveillance and reporting system to ensure vaccine safety
- Organised one-day Regional Workshop

on “Basics of Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries – A Way Forward” conducted by NCC, PvPI on June 23, 2017 with the focus on:

- (i) Sensitizing industry personnel on the need for and implementation of Pharmacovigilance system in the pharma industry
  - (ii) Development of business strategy to improve quality as well as turnover of Pharmaceutical Industry
  - (iii) Importance of Regulatory interventions in improving standards of healthcare
  - (iv) Measures to be adopted by the pharma industry for their active participation in reporting and management of ADRs
- Organised a guest lecture on “Pharmacovigilance Programme of India” addressed by Dr Sanjay Khattri, Professor, Department of Pharmacology, KGMU, Lucknow as part of ongoing sensitization activities in the Institute



Pharmacovigilance being an important pillar of modern pharmacology, department of pharmacology, GMC, Srinagar working as ADR Monitoring Centre under Pharmacovigilance programme of India has reported more than 500 ADRs with average completeness score of 0.97 to global data base. Contributing to the national programme department of pharmacology has carried out meetings of Pharmacovigilance committee from time to time thereby strengthening the Pharmacovigilance environment in our medical college and its associated hospitals.

Dr. SAMINA FARHAT  
Professor and HoD  
Department of Pharmacology, GMC,  
Srinagar



Establishment of ADR Monitoring centre under Pharmacovigilance programme of India in the Department of Pharmacology is an honour to GMC and its associated hospitals. It makes a new beginning in improving patient care in general and drug safety in particular. It would be a great achievement if all GMC associated hospitals are covered by the said programme in the near future.

Prof. (Dr.) SAMIA RASHID  
Principal/Dean  
Government Medical College,  
Srinagar



The department of pharmacology, Government Medical College, Srinagar is acting as ADR monitoring centre in Jammu and Kashmir State since August 2014. The centre is performing the Pharmacovigilance activities and has successfully incorporated ADR Reporting form in In-Patient Department (IPD) case files. We have also pasted the posters containing PvPI toll free number and Pharmacovigilance Associate's contact number in every ward of adjoining SMHS Hospital, Srinagar. The Department is looking forward to sensitize healthcare professionals and carry out Pharmacovigilance activities in all five associated hospitals of Government Medical College, Srinagar.

Dr. ZUBAIR ASHAI  
Lecturer & Coordinator AMC  
Department of Pharmacology, GMC, Srinagar



The utilization of drugs is not always beneficial but can be associated with a number of ADRs that need to be monitored and reported at the earliest. Thus the establishment of the Pharmacovigilance centre is important for any institution and we are proud to have one such centre with us.

Dr. ZORAWAR SINGH  
Consultant Pharmacology &  
Deputy Coordinator AMC  
Department of Pharmacology,  
GMC, Srinagar



## ACKNOWLEDGEMENT TO DR NITYA ANAND



### **PADMASHREE DR NITYA ANAND**

**Founder Chairman, Scientific  
Body, IPC**

Dr Nitya Anand, former Director of CDRI, Lucknow, Chairman of IPC & Scientific Body and the Chair of Think Tank Conclave 2017, is recognized for his leadership turning CDRI into a world-class centre for drug research, envisioning the creation of IPC as an autonomous institution, establishing various Pharma institutions and formulating government policy for development of pharmaceutical industry in India.

NCC-PvPI acknowledges the appreciation by Padma Shree Dr Nitya Anand who expresses his "best wishes for the trajectory of PvPI to rise higher and higher", providing many more avenues for safeguarding the health of Indian masses. He aptly points out that "adverse effects of existing drugs when reported could provide useful leads for repositioning of these drugs". Emphasizing the need for Pharmacovigilance, he exhorts all concerned with the use and manufacture of drugs to report ADRs instantaneously.

PvPI assures Dr Nitya Anand of its consistent efforts to reach out to IP pioneers like him for all time ahead.



**Indian Pharmacopoeia Commission**  
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Pharmacovigilance Programme of India  
Ministry of Health & Family Welfare, Govt. of India,  
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**Website:** [www.ipc.gov.in](http://www.ipc.gov.in)

*let us join hands with PvPI to ensure patient safety*  
**ADR reporting Helpline (Toll Free): 1800-180-3024**