PHARMACOVIGILANCE
PROGRAMME OF INDIA (PvPI)
Performance Report 2017-18

INDIAN PHARMACOPOEIA COMMISSION
MINISTRY OF HEALTH & FAMILY WELFARE, GOVT OF INDIA
SECTOR-23, RAJ NAGAR, GHAZIABAD-201002
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Ministry Of Health & Family Welfare, Govt Of India
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<th>Full Form</th>
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<tbody>
<tr>
<td>ADR</td>
<td>Adverse Drug Reaction</td>
</tr>
<tr>
<td>AE</td>
<td>Adverse Event</td>
</tr>
<tr>
<td>AEFI</td>
<td>Adverse Event Following Immunization</td>
</tr>
<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
</tr>
<tr>
<td>AIIMS</td>
<td>All India Institute of Medical Sciences</td>
</tr>
<tr>
<td>AMC</td>
<td>Adverse Drug Reaction Monitoring Centre</td>
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<tr>
<td>ART</td>
<td>Anti-retroviral Therapy</td>
</tr>
<tr>
<td>CDSCO</td>
<td>Central Drugs Standard Control Organization</td>
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<tr>
<td>CIOMS</td>
<td>Council for International Organization for Medical Sciences</td>
</tr>
<tr>
<td>CMC</td>
<td>Christian Medical College</td>
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<tr>
<td>CME</td>
<td>Continuous Medical Education</td>
</tr>
<tr>
<td>CTP</td>
<td>Core Training Panel</td>
</tr>
<tr>
<td>DCG(I)</td>
<td>Drugs Controller General (India)</td>
</tr>
<tr>
<td>DOTS</td>
<td>Directly Observed Treatment-Short course</td>
</tr>
<tr>
<td>FDC</td>
<td>Fixed Dose Combination</td>
</tr>
<tr>
<td>FIR</td>
<td>First Information Report</td>
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<tr>
<td>GVP</td>
<td>Good Pharmacovigilance Practice</td>
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<tr>
<td>HCP</td>
<td>Healthcare Professional</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>ICH</td>
<td>International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use</td>
</tr>
<tr>
<td>ICSR</td>
<td>Individual Case Safety Report</td>
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<tr>
<td>IC</td>
<td>Information Component</td>
</tr>
<tr>
<td>ICT</td>
<td>Information &amp; Communications Technology</td>
</tr>
<tr>
<td>IMA</td>
<td>Indian Medical Association</td>
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<tr>
<td>IPC</td>
<td>Indian Pharmacopoeia Commission</td>
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<td>ISOP</td>
<td>International Society of Pharmacovigilance</td>
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<tr>
<td>KAP</td>
<td>Knowledge, Attitude and Practice</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>--------------</td>
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</tr>
<tr>
<td>LOI</td>
<td>Letter of Intent</td>
</tr>
<tr>
<td>MAH</td>
<td>Marketing Authorization Holder</td>
</tr>
<tr>
<td>MCI</td>
<td>Medical Council of India</td>
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<tr>
<td>MedDRA</td>
<td>Medical Dictionary for Regulatory Activities</td>
</tr>
<tr>
<td>MoHFW</td>
<td>Ministry of Health &amp; Family Welfare</td>
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<tr>
<td>MoU</td>
<td>Memorandum of Understanding</td>
</tr>
<tr>
<td>MvP</td>
<td>Materiovigilance Programme of India</td>
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<tr>
<td>NABH</td>
<td>National Accreditation Board for Hospitals &amp; Healthcare Providers</td>
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<tr>
<td>NACO</td>
<td>National AIDS Control Organization</td>
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<tr>
<td>NCC</td>
<td>National Coordination Centre</td>
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<td>NHP</td>
<td>National Health Programme</td>
</tr>
<tr>
<td>NRA</td>
<td>National Regulatory Authority</td>
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<tr>
<td>PGIMER</td>
<td>Post Graduate Institute of Medical, Education and Research</td>
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<td>PV</td>
<td>Pharmacovigilance</td>
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<tr>
<td>Pva</td>
<td>Pharmacovigilance Associate</td>
</tr>
<tr>
<td>PvPi</td>
<td>Pharmacovigilance Programme of India</td>
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<tr>
<td>QA-QC</td>
<td>Quality Assurance—Quality Control</td>
</tr>
<tr>
<td>RNTCP</td>
<td>Revised National Tuberculosis Control Programme</td>
</tr>
<tr>
<td>SAE</td>
<td>Serious Adverse Reaction</td>
</tr>
<tr>
<td>SDP</td>
<td>Skill Development Programme</td>
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<tr>
<td>SRP</td>
<td>Signal Review Panel</td>
</tr>
<tr>
<td>SUSAR</td>
<td>Suspected Unexpected Serious Adverse Reaction</td>
</tr>
<tr>
<td>UIP</td>
<td>Universal Immunization Programme</td>
</tr>
<tr>
<td>WHO-ART</td>
<td>World Health Organisation-Adverse Reactions Terminology</td>
</tr>
<tr>
<td>WHO-DD</td>
<td>World Health Organisation-Drug Dictionary</td>
</tr>
<tr>
<td>WHO-UMC</td>
<td>World Health Organisation-Uppsala Monitoring Centre</td>
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The Index Period 2017-18 for the Pharmacovigilance Programme of India (PvPI) under the aegis of the Indian Pharmacopoeia Commission (IPC) has seen a global value-addition to its scientific functionality with NCC-PvPI, IPC designated as a WHO-Collaborating Centre for “Asia and beyond” last year. It is as much an honour as also a formidable challenge to successfully cross the health-safety hurdles facing the humonos mass of poor population across Asia. Health safety is as much an important therapeutic issue as it is about meticulous monitoring of drugs prescribed. A sustainable network of collating and analysing adverse drug reactions (ADRs) has been established by PvPI, IPC across the length and breadth of India. It is all aimed at safeguarding public health by ensuring drug safety for mass consumption.

The 250-strong nationwide Adverse drug reaction Monitoring Centre (AMC) base serves a pedestal to Pharmacovigilance (PV), ensuring healthcare by patient safety. During the Index Period i.e. April 2017-March 2018, the NCC-PvPI has received more than 71,000 Individual Case Safety Reports (ICSRs), contributing them to the global drug-safety database of WHO’s International Drug Monitoring Programme.

Raising public awareness to the very concept of risk-optimized drug-safety has been the core objective of Pharmacovigilance. To this end the Pharmacovigilance Programme of India by its pan-India publicity blitzkrieg has to reach the poorest of the poor citizen of the country as safety of their health is the prime and collective responsibility of all stakeholders.

PvPI’s ‘Skill Development Programme’, which provides hands-on and tools-equipped training for all health stakeholders, including doctors, clinicians, nurses and the pharmaceutical industry, has been gaining momentum at a rapid pace. Its outreach to the stakeholders has been instrumental in creating public awareness for monitoring of drugs at the clinical sites such as hospitals, pharmacies and other health Centres. Public health campaigns aimed at health-safety by drug-safety have gathered a critical mass following their launch at the grassroot level with the involvement of public at large as well as the stakeholders concerned.

One of the consistent endeavours by PvPI, IPC has been to foster the culture of Pharmacovigilance by dissemination of information among the public in a green and clean way. The quarterly Newsletter, the Annual Performance Report and other educational and publicity material published by PvPI, IPC has set an eco-friendly, green trend with all publications using an online paper-free module up to the final stage of printing.

Medical Devices Adverse Events Monitoring under the purview of Materiovigilance Programme of India (MvPI) has been progressively showing signs of maturity and applicability by the industry.

I sincerely thank all healthcare stakeholders and the staff of NCC-PvPI, IPC for their collective will and efforts to reach out to the masses with the cutting-edge technology and expertise to monitor and advance the scientific process of Pharmacovigilance.

Dr G N Singh
Secretary-cum-Scientific Director
Pharmacovigilance Programme of India (PvPI)

GENESIS

Adverse drug reaction (ADR) is one of the leading causes of morbidity and mortality worldwide. The consequences of ADRs burden on the healthcare system are increased cost of therapy and prolongation of hospitalization. It is, therefore, imperative to monitor the safety of medicines.

Pharmacovigilance Programme of India (PvPI) is Government of India’s flagship health-monitoring programme which collates and analyses drug-related adverse events. The Ministry of Health and Family Welfare, Government of India recasted this programme on April 15, 2011 resulting in shifting PvPI from All India Institute of Medical Sciences (AIIMS), New Delhi to Indian Pharmacopoeia Commission (IPC), Ghaziabad. Since then, IPC has been entrusted with the responsibility as the National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI).
Highlights 2017-18

Release of Guidance Document for MAHs
A comprehensive guiding tool for MAHs to establish PV system

WHO-CC Orientation Programme on Regulatory Services
Appraising Indian regulators on PV audits and inspections

Regional Workshops on Establishment of PV system in Pharma Industry
To train MAHs to follow good PV practices

ICMR-NIN Centre for PV on Nutraceuticals
National Institute of Nutrition, Hyderabad to work as Nutraceutical Safety Monitoring Centre

Enrolment of hospitals as AMCs at grassroot level
To put in place comprehensive PV system country-wide

Enrolment of PvPI as a WHO-Collaborating Centre
For providing scientific support to LMICs in Asia on PV in PHPs & regulatory services

Mobile App 'ADR PvPI' – An instant enabler to promote patient safety
Seamless alternative for healthcare professionals with ease of reporting

Workshop-cum-training programme on PV for NABH - accredited hospitals
Training healthcare professionals for setting up PV System in hospitals

Introduction of PV system in Government Drug Supply Chain
Ensuring PV in Government drug supply chain vital for Quality Assurance

First Intensive Drug Monitoring Programme under PvPI
Drugs identified include SGLT2 inhibitors and Pioglitazone
**PvPI voyage as a WHO-Collaborating Centre**

- **2nd Annual Meet of SEARN countries at Colombo, Sri Lanka**
  - Gap analysis: mapping of resources & extending services

- **USFDA, PvPI & CDSCO Joint Workshop for MAH at Ghaziabad & Mumbai**
  - PV system implementation, PV Audits, Inspections, RMP, Benefit Risk Assessment

- **National Meet with State and UT drug regulators at Ghaziabad**
  - Role of regulators in effective implementation of PV

- **Mapping of PV system set-up in SEARN**
  - Questionnaire prepared and circulated to SEARCI members

- **Orientation Programme on Regulatory Services at CDSCO New Delhi**
  - Appraising CDSCO, AEFI, PvPI & MAHs on developing tools for PV audit/inspections

- **Working Group-3 (Vigilance of Medical Products) of SEARN Countries**
  - PvPI Chaired a meeting: Questionnaire for PV system Capacity building & strengthening

- **Launch of WHO-CC at NCC-PvPI, IPC**

The milestone – marking the formal launch of Pharmacovigilance Programme of India (PvPI), Indian Pharmacopeia Commission (IPC) as the World Health Organization (WHO)-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services – was laid at IPC in Ghaziabad on October 30, 2017.

It was unveiled by the Additional Union Health Secretary Mr R K Vats in presence of DCG(I), Dr G N Singh and the visiting WHO brass from Geneva and Country Office-India. PvPI as a WHO-CC will provide scientific support to countries in Asia for Pharmacovigilance in public health programmes such as tuberculosis, neglected tropical diseases, vector-borne diseases, HIV/AIDS, Adverse Event Following Immunization (AEFI) and regulatory issues.
**PvPI: An Overview**

**Vision**

To improve patient safety and welfare of Indian population by monitoring safety of medicines, thereby reducing the risk associated with their use.

**Mission**

To safeguard the health of Indian population by ensuring that the benefits of use of medicine outweigh the risks associated with its use.
Scope and Objectives

- Create a nation-wide system for medicines safety reporting and monitoring
- Identify and analyse new signals from the reported cases
- Communicate to various stakeholders the safety information on use of medicine so as to prevent/minimise the risk
- Support the National drug regulators in the decision-making process on use of medicine
- Evidence-based decision making on safe use of medicines
- Analyse the benefit-risk ratio of marketed medicine
- Emerge as a Centre of Excellence for Pharmacovigilance
- Collaborate with other National centres for exchange of information and data management
- Provide training and consultancy support to other National Pharmacovigilance Centres
- Promote quality and safe use of medicines
- Provide scientific support to countries in Asia for PV in public health programmes and regulatory being PvPI as Collaborating centre for WHO

Partners

- WHO, Country Office-India
- UIP
- RNTCP
- NACO
- NVBDCP
- ICMR
- IMA
- NABH
PvPI: An Overview

Committees under NCC-PvPI
Following committees at NCC-PvPI ensure smooth and effective functioning of the programme:

Steering Committee
This is the chief administrative and monitoring body of NCC-PvPI which guides and supervises the programme.

Working Group
All technical issues related to the establishment and implementation of the programme, including providing technical inputs, are handled by the Working Group which reports to the CDSCO for regulatory interventions.

Quality Review Panel
Quality Review Panel is responsible for quality, causality assessment and completeness of ICSRs. The panel also makes recommendations to PvPI Working Group after data analysis and devises formats and guidance documents for follow-up action.

Signal Review Panel
The Signal Review Panel (SRP) of PvPI comprises scientists and clinical experts affiliated to government and non-government academic institutions and hospitals. As and when required experts from the pharmaceutical industry are also invited for expert inputs, to collate and analyse information from ICSRs. SRP assesses the results of identified computerized Signals from ICSRs to validate and confirm. It defines biostatistical methods for analysis and creates standardized post-analytical reports that help in understanding the information derived from ADRs. It also decides upon actionable indicators.

Core Training Panel
The Core Training Panel (CTP) of PvPI identifies training needs, organizes national and international training programmes, designs training modules and conducts the training for healthcare professionals and other stakeholders throughout the year. It also identifies trainers for zone-wise training centers. The CTP interacts with national and international agencies for participation and implementation of training programmes in Pharmacovigilance. Core Training Panel is assisted by the internal training team of PvPI.
Effective communication channels are a key to successful functioning of an organization. The use of information/communication technology at NCC-PvPI and across the AMCs under its umbrella is a role model for government bodies in India and abroad. PvPI by various modes of communication channelizes data flow as depicted in the figure below:
ADR-REPORTING AT PvPI

WHO CAN REPORT?

ADR MONITORING CENTRES (AMCs)

ALL HEALTHCARE PROFESSIONALS

PHARMACEUTICAL COMPANIES

CONSUMERS/PATIENTS

For health safety

Optimization of drug safety by evidence-based research

Prompting regulatory action by omnibus database

Raising awareness level to report ADRs

Data helps to make safe use of medicines
**WHAT TO REPORT?**

**All types of suspected ADRs:**
- Known or unknown
- Serious or non-serious
- Frequent or rare

**Special focus on drug use in:**
- Pregnancy
- Lactation
- Paediatric population
- Geriatric population

**ADRs by:**
- Medicines
- Medical Devices
- Biologicals including Vaccines
- Herbal Drugs/Nutraceuticals, etc

- Nearby ADR Monitoring Centres (AMCs)
- National Coordination Centre (NCC)
- PvPI Helpline #1800-180-3024
- PvPI Mobile App: ADR PvPI
- Clinicians
- Pharmacists
- Nurses

Pharmaceutical companies can use the Form to send their Individual Case Safety Reports (ICSRs) specific for their product directly to the NCC. Form is available on the official website of IPC (www.ipc.gov.in) or the CDSCO (www.cdsco.gov.in).
Channels of ADR reporting

Suspected ADR Form for Healthcare Professionals
Available on the website of IPC (www.ipc.gov.in) or the CDSCO (www.cdsco.gov.in) and in National Formulary of India 2016

Medicines Side-Effect Reporting Form (For Consumers)
Available in 10 local languages: Hindi, Bengali, Gujarati, Kannada, Malayalam, Marathi, Assamese, Oriya, Tamil and Telugu
Mobile App
On September 29, 2017, the then Union Health Secretary, Shri C K Mishra, Government of India, dedicated to the nation the indigenously-developed mobile app “ADR PvPI” for the benefit of all healthcare stakeholders, including common man.

PvPI Helpline
Patients/Consumers/Healthcare Professionals may report Suspected ADRs associated with the use of medicinal products to NCC-PvPI via toll free Helpline # 1800-180-3024.
Establishment of AMCs under PvPI

To monitor ADRs, ADR Monitoring Centers (AMCs) have been set up all over India which send reports to headquarters located at NCC-PvPI, IPC, Ghaziabad. NCC-PvPI started with 22 AMCs in the initial phase and currently has 250 ADR monitoring centers (Medical colleges, district and corporate hospitals etc.) under PvPI across the country. Of these centers, 21 receive information from the Revised National Tuberculosis Control Programme (RNTCP), 20 from the HIV control programme on Anti-retroviral therapy (ART) and 6 are designated Bedaquiline Cohort event monitoring centers.

WHO CAN ENROLL AS AMC?
• Government hospitals/ Medical colleges
• Private hospitals
• Corporate hospitals
• District/ Primary Health Centres

CRITERIA FOR ENROLMENT OF AMCs
• Availability of logistic and infrastructural facilities for PV at the Centre
• Significant track-record of the Centre in Pharmacovigilance - on quality, quantity and frequency of Adverse Drug Reaction (ADR)-reporting
• Preference for states where no/few AMCs exist
• HoD/Dean/ Principal of the institute to identify new AMC coordinator
• HoD/Dean/ Principal of the proposed Centre to establish/implement PvPI activities at the Centre
• Significant track-record/expertise of the proposed AMC coordinator/deputy coordinator in Pharmacovigilance

Upon recognition, NCC-PvPI provides regular training, skill development and technical support to the personnel engaged in PvPI activities.
The Pharmacovigilance Programme of India (PvPI) is responsible for collection, assessment and detection of risks associated with the use of medicines by Indians. Annual database accounts for more than 50,000 ICSRs each year. Reporting patterns are on the increase year-wise and have increased drastically in recent years.

**Year-wise ICSR reporting status 2011-2018**
ADR Monitoring Centres (AMCs) across the country are located in four different zones. Data represents percentage of ICSRs received during 2017-18 from all four zones of India.

**Zone-wise AMCs’ Contribution**

- **East Zone**: 36% (83 AMCs)
- **West Zone**: 37% (93 AMCs)
- **North Zone**: 17% (38 AMCs)
- **South Zone**: 10% (36 AMCs)

**Reporter-wise distribution of ICSRs**

NCC-PvPI receives ICSRs from various stakeholders such as physicians, pharmacists, other HCPs, consumers (non-HCPs), etc. Spontaneous ADR reports from physicians (60%) continue to be the major source of reports received, followed by other healthcare professionals (17%), pharmacists (12%) and consumers (11%) in the fiscal year 2017-18.
Gender-wise ICSRs:
Analysis of the ADRs received during the index period shows that 51% ADRs occurred in male patients and 48% in female patients. No information about the gender of the patient was provided in 1% of ADR reports.

Gender-wise Distribution of ICRs

- Female: 51%
- Male: 48%
- Unknown: 1%
Following the initiation of toll free Helpline on October 11, 2013, a steady increase in reporting through this method has been observed. The increase follows efforts by Pharmacovigilance associates posted at AMCs. The Helpline number has also been embossed on IPD and OPD prescription slips/cards. Calls are primarily responded to in English and Hindi on all working days between 09:00 AM and 05.30 PM.
PvPI contribution to National Health Programmes

Partners
- **RNTCP**: Revised National Tuberculosis Control Programme
- **UIP-AEFI**: Universal Immunization Programme (Adverse Event Following Immunization)
- **NACO**: National AIDS Control Organization
- **NVBDCP**: National Vector-Borne Disease Control Programme

Reports by

<table>
<thead>
<tr>
<th>Reports</th>
<th>2016-17</th>
<th>2017-18</th>
</tr>
</thead>
<tbody>
<tr>
<td>RNTCP</td>
<td>1294</td>
<td>1230</td>
</tr>
<tr>
<td>ART</td>
<td>723</td>
<td>476</td>
</tr>
<tr>
<td>AEFI</td>
<td>610</td>
<td>795</td>
</tr>
<tr>
<td>NVBDCP</td>
<td>0</td>
<td>58</td>
</tr>
</tbody>
</table>

Utilization of ICSR data - Drug Alerts

<table>
<thead>
<tr>
<th>Suspected Drug</th>
<th>Adverse Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lamivudine</td>
<td>Hearing Loss</td>
</tr>
<tr>
<td>Inactivated Haemoplylus Influenzae Vaccine</td>
<td>Papulovesicular exanthem</td>
</tr>
<tr>
<td>Measles Rubella Vaccine</td>
<td>Arthritis/Joint Pain, Guillain-Barre Syndrome</td>
</tr>
<tr>
<td>Dapsone</td>
<td>Erythema nodosum</td>
</tr>
</tbody>
</table>
PvPI contribution to National Health Programmes

ADR-causing prominent drugs

**RNTCP Drugs**
- Pyrazinamide
- Rifampicin
- Isoniazid
- Ethambutol
- Rifampicin/Isoniazid/
  Pyrazinamide/
  Ethambutol-FDC

**ART Drugs**
- Lamivudine/Nevirapine/
- Zidovudine-FDC
- Atazanavir/Ritonavir-FDC
- Lamivudine/Tenofovir-FDC
- Lamivudine/Zidovudine-FDC
- Efavirenz/Lamivudine/Tenofovir-FDC

**NVBDCP Drugs**
- Amphotericin B
- Miltefosine

**Vaccines**
- Bacterial and Viral vaccines
  (combined)
- Measles vaccine
- Pertussis vaccine
- Rabies vaccine
- Tetanus vaccine
## Technical Trainings

PvPI organized and participated in nation-wide trainings round the year, updating healthcare stakeholders on PV activities in PHPs:

<table>
<thead>
<tr>
<th>Training Programme</th>
<th>Topic Covered</th>
<th>Target Group</th>
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<tbody>
<tr>
<td><strong>National meet on Bedaquiline expansion and updating of PMDT Guidelines</strong></td>
<td>Bedaquiline safety status in India, hands-on VigiFlow training</td>
<td>Physicians, TB Programme Officers</td>
</tr>
<tr>
<td><strong>Pre-Drug Safety Monitoring Meeting</strong></td>
<td>Analysis of VigiFlow/VigiLyze data on Bedaquiline</td>
<td>Physicians, DEOs, PV-Associates of all Bedaquiline sites</td>
</tr>
<tr>
<td><strong>Assessment of Kala-azar elimination with states and partners</strong></td>
<td>Progress, issues, challenges &amp; way forward in Pharmacovigilance</td>
<td>Officials and physicians concerned from Kala-azar endemic states</td>
</tr>
<tr>
<td><strong>Regional Review-cum-Sensitization workshop on Kala-azar elimination</strong></td>
<td>PV roadmap for Vector-borne diseases in India, hands-on VigiFlow training for data entry</td>
<td>Officials and physicians concerned from Kala-azar endemic states, DEOs, etc</td>
</tr>
<tr>
<td><strong>Delamanid introduction under PMDT India, Capacity-Building Workshop</strong></td>
<td>ADR-Monitoring Centres (AMCs) under PvPI</td>
<td>Delhi Govt officials, physicians, WHO &amp; PvPI officials</td>
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<tr>
<td><strong>Pharmacovigilance Workshop at Central Research Institute, Kasauli</strong></td>
<td>Hands-on VigiFlow training, filling of suspected ADR reporting form for AEFI cases</td>
<td>Officials of CRI, Kasauli</td>
</tr>
<tr>
<td><strong>Strengthening of AEFI reporting system in Himachal Pradesh</strong></td>
<td>Hands-on VigiFlow training, filling of suspected ADR reporting form for AEFI cases</td>
<td>Clinicians, nurses and other healthcare professionals of ADR Monitoring Centre-DRPGMC-Tanda, Himachal Pradesh</td>
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Quality Management System in PvPI

To ensure patient safety through a transparent approach and high quality services, PvPI has been found to conform with ISO 9001:2008 quality management system (QMS) and also adopts Good Pharmacovigilance Practices (GVPs) as per WHO Pharmacovigilance Indicators with a focused approach on scientific innovation and rationality.

Major Contributions by Quality Assurance Division

Audits:
- External Audit: 01
- Internal Audit: 01

Standard Operating Procedures (SOPs):
- Updated: 05 (Change Control)
- Draft SOPs: 01

Vigi Grade Completeness Score of ICSRs

Quality of ICSR reporting
The vigiGrade™-Completeness score is a system to measure the amount of information provided on Individual Case Safety Reports (ICSRs).

The following figure depicts the average quality scores of ICSRs submitted by PvPI to UMC database.
**Workshop-cum-training on PV for NABH hospitals**

During the index period, a series of training-cum-workshops were organized by PvPI for NABH-accredited hospitals. These trainings provided a platform for the NABH-accredited hospitals to broadly comprehend the system and procedures involved in ADR-reporting and also helped sensitize the healthcare professionals to monitoring and reporting AEs/ADRs.

<table>
<thead>
<tr>
<th>Date</th>
<th>Venue</th>
<th>No. of Participants</th>
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<tbody>
<tr>
<td>May 18, 2017</td>
<td>NABH Secretariat, Quality Council of India, ITPI Building, New Delhi</td>
<td>27</td>
</tr>
<tr>
<td>June 13, 2017</td>
<td>Vadamalyan Hospitals, Madurai, Tamil Nadu</td>
<td>36</td>
</tr>
<tr>
<td>July 22, 2017</td>
<td>CHL Group of Hospitals, AB Road, Indore, Madhya Pradesh</td>
<td>26</td>
</tr>
<tr>
<td>October 14, 2017</td>
<td>Apollo Institute of Medical Sciences and Research (AIMSR), Apollo Health City Campus, Hyderabad, Telangana</td>
<td>69</td>
</tr>
<tr>
<td>January 30, 2018</td>
<td>Apollo Hospital, Bhubaneswar, Odisha</td>
<td>36</td>
</tr>
<tr>
<td>February 28, 2018</td>
<td>Dayanand Medical College and Hospital, Ludhiana, Punjab</td>
<td>38</td>
</tr>
<tr>
<td>March 24, 2018</td>
<td>Vivekananda Polyclinic and Institute of Medical Sciences, Lucknow, Uttar Pradesh</td>
<td>47</td>
</tr>
</tbody>
</table>

**Topics Covered:**
- Basics of Pharmacovigilance and mandates and activities of NCC-PvPI
- Monitoring & reporting AEs/ADRs (Methodology, Forms & Formats)
- Setting up of a PV system in Hospitals
Signal Detection

WHO defines a Signal as “Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously.

Signal detection and clinical assessment of Individual Case Safety Reports (ICSRs) form a vital domain of Pharmacovigilance. NCC-PvPI is engaged in identifying potential signals from India-specific ICSRs with technical assistance by experts in the signal review panel (SRP).

**Methods used by PvPI for Signal Detection**

Various methods are used for signal detection. The four parameters for identifying a new signal from Indian ICSRs include:

- Information Component (IC)
- Proportional Relative Risk/Proportional Reporting Ratio (PRR)
- Chi-square ($X^2$) statistics (with 1 degree of freedom)
- Total number of reports on the specific Drug-ADR combination available in the Indian database ($N_{comb}$)

**Threshold values used by PvPI for the aforementioned parameters to identify a potential signal are:**

- $|C_{0.25}| > 0$
- PRR $\geq 2$ with the lower bound of its 95% CI $> 1$
- $X^2$ statistics (with 1 degree of freedom) $\geq 4$
- $N_{comb} \geq 3$, to highlight potential signals

**Fulfilment of at least two of these four parameters is required for considering a specific drug-ADR combination as a potential signal.**
PvPI Recommendations to CDSCO

Signals/Alerts

- Sulfasalazine and Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis
- Terbinafine and Acute Generalised Exanthematous Pustulosis
- DPP-4 Inhibitors and Arthralgia
- Cefixime & Tinidazole-induced Hyperpigmentation
- Carbamazepine & Nitrofurantoin-induced DRESS

Drug Alerts

<table>
<thead>
<tr>
<th>DRUG</th>
<th>ADVERSE REACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amisulpride</td>
<td>Tinnitus</td>
</tr>
<tr>
<td>Lorazepate</td>
<td>Thrombocytopenia</td>
</tr>
<tr>
<td>Deferasirox</td>
<td>Osteoporosis</td>
</tr>
<tr>
<td>Levamisole</td>
<td>Skin Exfoliation</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>Melaena</td>
</tr>
<tr>
<td>Amitriptyline</td>
<td>Lacrimation</td>
</tr>
<tr>
<td>Metoprolol</td>
<td>Lichenoid Drug Eruption</td>
</tr>
<tr>
<td>Etoricoxib</td>
<td>Skin Hyperpigmentation</td>
</tr>
<tr>
<td>Glibenclamide</td>
<td>Lichenoid Drug Eruption</td>
</tr>
<tr>
<td>Cefepime</td>
<td>Dermatitis Lichenoid</td>
</tr>
<tr>
<td>Losartan</td>
<td>Burning Micturition</td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>Bruising</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>Nystagmus</td>
</tr>
<tr>
<td>Captopril</td>
<td>Skin Hyperpigmentation</td>
</tr>
<tr>
<td>Sodium Valproate</td>
<td>Purpura</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>Eye irritation</td>
</tr>
<tr>
<td>Thalidomide</td>
<td>Hyperpigmentation</td>
</tr>
<tr>
<td>Amitriptyline</td>
<td>Purpura</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>Gingival Discolouration</td>
</tr>
<tr>
<td>Lamivudine</td>
<td>Hearing Loss</td>
</tr>
<tr>
<td>Hydroxychloride</td>
<td>Bullous Pemphigoid</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>Behcet Syndrome</td>
</tr>
<tr>
<td>Mesalazine</td>
<td>Retrosternal Pain</td>
</tr>
<tr>
<td>Clindamycin</td>
<td>Acute Generalised Exanthematous Pustulosis</td>
</tr>
<tr>
<td>Triamcinolone</td>
<td>Skin Peeling</td>
</tr>
<tr>
<td>Polymyxin B</td>
<td>Mottled Skin</td>
</tr>
<tr>
<td>Diclofenac</td>
<td>Nicolau Syndrome</td>
</tr>
<tr>
<td>Terbinafine</td>
<td>Acute Generalised Exanthematous Pustulosis</td>
</tr>
<tr>
<td>Nitrofurantoin</td>
<td>Vasculitis</td>
</tr>
<tr>
<td>Acetazolamide</td>
<td>Drug Hypersensitivity Syndrome</td>
</tr>
<tr>
<td>Linagliptin</td>
<td>Acute Generalised Exanthematous Pustulosis</td>
</tr>
<tr>
<td>Diltiazem</td>
<td>Glossitis</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>Stevens-Johnson Syndrome</td>
</tr>
<tr>
<td>Allopurinol</td>
<td>Uveitis</td>
</tr>
<tr>
<td>Capecitabine</td>
<td>Gynecomastia</td>
</tr>
<tr>
<td>Clofazimine</td>
<td>Polycythemia</td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>Urinary Incontinence</td>
</tr>
<tr>
<td>Leviteracetam</td>
<td>Hypokalaemia</td>
</tr>
<tr>
<td>Dapsone</td>
<td>Erythema</td>
</tr>
</tbody>
</table>

Signal

Fluconazole induced Hyperpigmentation
Regulatory Pharmacovigilance

Regulatory Pharmacovigilance is the scientific process of long-term monitoring of medicines and assessment of the risks and benefits associated with their use. To optimize safe and effective use of medicines and monitoring the occurrence of any adverse effect, PvPI takes all necessary action to ensure maximum safety of drugs marketed, manufactured and prescribed in India. AMCs under the umbrella of PvPI play a vigilant role in ensuring the same. PvPI has received following ADRs which could be associated with the quality of medicinal product during the index Period 2017-18:

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Generic name</th>
<th>Reaction</th>
<th>AMC name</th>
<th>Action Taken by NCC-PvPI</th>
<th>Recommendation (CDSCO)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ultrasound Jelly</td>
<td>Blood stream infection</td>
<td>CMCH, Coimbatore</td>
<td>Communicated to State Drug Controller for Tamil Nadu &amp; CDSCO North Zone office</td>
<td>In Process</td>
</tr>
<tr>
<td>2</td>
<td>Metronidazole</td>
<td>Chills and Rigors</td>
<td>Madurai Medical College, Madurai</td>
<td>Communicated to State Drug Controller for Tamil Nadu &amp; CDSCO North Zone office</td>
<td>In Process</td>
</tr>
<tr>
<td>3</td>
<td>Inj. Magnesium Sulphate</td>
<td>Lack of efficacy</td>
<td>SVMC, Tirupati</td>
<td>Communicated to State Drug Controller for Andhra Pradesh &amp; CDSCO North Zone office</td>
<td>Request to withdraw the sample</td>
</tr>
<tr>
<td>4</td>
<td>Thiopentone, Glycopyrrolate, Atracurium besylate and Ketamine</td>
<td>Lack of efficacy</td>
<td>SMS Medical College, Jaipur</td>
<td>Communicated to State Drug Controller for Rajasthan &amp; CDSCO North Zone office</td>
<td>In Process</td>
</tr>
<tr>
<td>5</td>
<td>Inj. Ceftriaxone &amp; Cefotaxime</td>
<td>Vomiting, Chills and Rigors</td>
<td>SVMC, Tirupati</td>
<td>Communicated to State Drug Controller for Andhra Pradesh &amp; CDSCO North Zone office</td>
<td>Request to withdraw the sample</td>
</tr>
<tr>
<td>6</td>
<td>Inj. Cefotaxime</td>
<td>Rash, Seizures, Ophisthotonus</td>
<td>GMC, Thiruvananthapuram</td>
<td>Communicated to State Drug Controller for Kerala &amp; CDSCO North Zone office</td>
<td>In Process</td>
</tr>
</tbody>
</table>
Marketing Authorization Holders (MAHs) have a crucial role in reporting ADRs to PvPI. The recent amendment to the Drugs and Cosmetics Rules, 1945, has made Pharmacovigilance a legal obligation for MAHs. This has paved the way for collecting product-specific safety data, aimed at optimizing drug-safety and ensuring healthcare for Indian populace.

**ICSR Reporting Status 2017-18**

- Apr/17: 1165
- May/17: 1158
- Jun/17: 541
- Jul/17: 1577
- Aug/17: 1244
- Sep/17: 1100
- Oct/17: 1410
- Nov/17: 1018
- Dec/17: 2326
- Jan/18: 1738
- Feb/18: 1438
- Mar/18: 2151
## Training & Workshops for MAHs

<table>
<thead>
<tr>
<th>Training/Workshop</th>
<th>Date</th>
<th>Topic</th>
<th>Target Audience</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Training on Medical Writing</strong></td>
<td>April 11, 2017</td>
<td>Writing of Case Narrative in ICSRs, Writing of Literature Report</td>
<td>IPC, NCC-PvPI staff</td>
</tr>
<tr>
<td><strong>4th Interactive Session on Participation of MAHs in PvPI</strong></td>
<td>April 28, 2017</td>
<td>Drafting of PV Guidelines for MAHs, Challenges for ICSR-reporting by MAHs, Current status &amp; challenges in PSUR submission</td>
<td>MAHs and CDSCO</td>
</tr>
</tbody>
</table>

**Regional Workshop on Basics of Pharmacovigilance & Establishment of Pharmacovigilance System in Pharmaceutical Industries**

<table>
<thead>
<tr>
<th>Location</th>
<th>Date</th>
<th>Topic</th>
<th>Target Audience</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIIMS, Rishikesh Hyderabad</td>
<td>June 23, 2017</td>
<td>Challenges for ICSR-reporting by MAHs, Discussion on minimum requirements to set up PV Systems by MAHs at their site, Reporting of ICSRs in E2B-xml format by MAHs</td>
<td>MAHs, HCPs and CDSCO</td>
</tr>
<tr>
<td>PGIMER, Chandigarh Mumbai</td>
<td>September 9, 2017</td>
<td>Suggestions/comments by MAHs for incorporation in PV Guidelines for MAHs of Pharmaceutical Products</td>
<td>ISCR PV Council members and PvPI</td>
</tr>
<tr>
<td>Meeting on Policy, Capacity-building, Strengthening &amp; Implementation of Pharmacovigilance</td>
<td>March 12-13, 2018</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Two-day National Workshop on Good Pharmacovigilance Practices in collaboration with CDSCO and USFDA at Mumbai

March 15-16, 2018

Role of Spontaneous Reports in post-marketing Safety, Assessing the Impact of Regulatory programmes and actions, Causality Assessment, Good PV Practices: India perspective Group exercises on:
- Felbamate
- Dabigatran
- Combined Hormonal Contraceptives

MAHs, State Drugs Regulators, CDSCO, USFDA & HCPs

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Release of PV Guidance Document for MAHs

PvPI in collaboration with CDSCO on September 29, 2017 released the “Pharmacovigilance Guidance Document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products”. Aimed at drug monitoring and laying down responsibilities for MAHs involved in the manufacture, sale, import and distribution of pharmaceutical products, the guidance document seeks to establish an effective Pharmacovigilance system at MAHs.

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Pharmacovigilance Guidance Document for Marketing Authorization Holders of Pharmaceutical Products

Published by

[Image of the guidance document]
Education and training outreach

PvPI plays a pivotal role in imparting education and training on safe use of medicines, ensuring patient-safety. The programme through its research-based training and education has developed practical tools which serve as a scientific model to disseminate information and solutions to probable drug-related problems. The national Pharmacovigilance operations thus acquire a prominent platform for sustainable PV practices among all healthcare stakeholders.

Training: Objectives and Perspectives

- Methods for collecting Individual Case Safety Reports (ICSRs)
- Developing a positive reporting culture and effective communications
- Data management and analysis
- Fulfilling the stakeholders expectations
- Building partnerships with pharma industry to expand the PV resource base
- Honing the skills of healthcare professionals
- Specialized PV modules followed during training sessions
Tailored to cater to the needs of PV trainees and adapting to good pharmacovigilance practices, NCC-PvPI has recognized nine Regional Training Centres (RTC). These are:

<table>
<thead>
<tr>
<th>Regional Training Centre</th>
<th>State/UT under purview</th>
</tr>
</thead>
<tbody>
<tr>
<td>PGIMER, Chandigarh</td>
<td>Jammu &amp; Kashmir, Himachal Pradesh, Punjab, Haryana, Chandigarh and Delhi</td>
</tr>
<tr>
<td></td>
<td>Maharashtra, Goa, Dadra &amp; Nagar Haveli</td>
</tr>
<tr>
<td>Seth GS Medical College &amp; KEM Hospital, Mumbai</td>
<td>Maharashtra, Goa, Dadra &amp; Nagar Haveli</td>
</tr>
<tr>
<td>JSS Medical College Hospital, Mysore</td>
<td>Karnataka, Kerala, Tamil Nadu, Puducherry and Lakshadweep</td>
</tr>
<tr>
<td>Institute of Postgraduate Medical Education &amp; Research, Kolkata</td>
<td>Andaman Nicobar, West Bengal, Jharkhand, Bihar &amp; Odisha</td>
</tr>
<tr>
<td>All India Institute of Medical Sciences, Bhopal</td>
<td>Madhya Pradesh and Chhattisgarh</td>
</tr>
<tr>
<td>B.J Medical College, Ahmedabad</td>
<td>Gujarat, Rajasthan, Daman &amp; Diu</td>
</tr>
<tr>
<td>All India Institute of Medical Sciences, Rishikesh</td>
<td>Uttarakhand and Uttar Pradesh</td>
</tr>
<tr>
<td>Nizam’s Institute of Medical Sciences, Hyderabad</td>
<td>Andhra Pradesh and Telangana</td>
</tr>
<tr>
<td>Silchar Medical College &amp; Hospital, Silchar</td>
<td>Assam, Arunachal Pradesh, Nagaland, Manipur, Meghalaya, Mizoram, Tripura and Sikkim</td>
</tr>
</tbody>
</table>

During the Index Period April 2017-March 2018, 41 training programmes were conducted -- 14 by NCC-PvPI, 21 by AMCs and 6 by MAHs:

Training Programmes at NCC
- Induction-cum-Training (ICT) for PvAs and AMC Coordinators
- Skill Development Programmes (SDP)
- National and International Workshops on PV
SDP-Participants from State/Union Territory

- Uttarakhand: 13
- Uttar Pradesh: 40
- Telangana: 20
- Tamil Nadu: 26
- Rajasthan: 14
- Puducherry: 2
- Maharashtra: 23
- Madhya Pradesh: 29
- West Bengal: 7

SDP-Participants' Professional background

- Student: 166
- Clinician: 33
- Academia: 26
- Industry Professional: 10
- Pharmacist: 28
- Regulator: 9
Feedback and suggestions by trainees

Suggestions by participants during the training programmes were evaluated. Those found relevant were implemented.

Title of X Axis:
1. Objective of training at beginning
2. Objective of the training achieved
3. Facilitator Enthusiasm
4. Quality of Presentation
5. Duration of Training
6. Utilization of time
7. Participation & interaction of participants
8. Study Material
9. Training Facilities
10. Level of confidence after training
Training Programmes at AMCs

Regional & National Workshops
Advance-level Training (ALT)
Continued Medical Education (CME)
Sensitization and Awareness drive for stakeholders

Participants trained by AMCs

As many as 18,773 persons were trained by AMCs during the Index Period 2017-18.

Participants' Professional Background

Pharmacist 3,171
Nurses 3,875
Clinician 10,131
Others 1,596
MvPI ensures Medical Devices’ safety

Materiovigilance Programme of India (MvPI) was launched on July 6, 2015 at IPC, Ghaziabad. Two committees – a Steering Committee and a Working Group Committee -- were constituted for the successful operation of the programme. Ten medical colleges and hospitals across the country, covering various zones, were identified as Medical Devices Monitoring Centres (MDMCs) by the NCC-MvPI. Sree Chitra Tirunal Institute of Medical Sciences and Technology (SCTIMST), Thiruvananthapuram acts as the National Collaboration Centre (NCC) and National Health System Resource Centre (NHSRC) for technical support.

To ensure effective AE reporting culture among MDMCs, clinicians, biomedical engineers, hospital technology managers, and other healthcare professionals, the MvPI has been imparting training and holding symposia to raise public awareness. Review meetings with CDSCO are regularly held to assess the progress of MvPI.

As many as 169 AEs were reported by MDMCs during Index Period 2017-18.
Sensitization Programme on MDAE reporting conducted at PGIMER, Chandigarh and Dental Department, Punjab University

Lecture on MvPl at Hindu Rao Hospital, New Delhi on February 21, 2018

Presentation on MvPl during Annual Sri Ramachandra University Pharmacology Insight and Review Course 'ASPIRE-2018'
Promotion by Publications

NCC-PvPI plays an important role in Indian drug regulatory system as it provides scientific support and vital stats to the regulatory agency for appropriate intervention on use of medications following an adverse event. Without effective, dynamic communication with patients, health professionals and among all partners in Pharmacovigilance, the system cannot work and the vision of safer use of medicines cannot be realised. Communicating safety information to patients and healthcare professionals is a public health responsibility borne by PvPI. Till date several India-specific drug-safety alerts/signals have been identified and communicated to the regulatory authority -- the Central Drugs Standard Control Organization (CDSCO).

Need for Communication
- Improve patient care and health safety
- Promote transparency and accountability
- Understand PV to reduce adverse events
- Provide accurate evidence-based, clinical information to healthcare professionals/patients/public

Modes of Communication
- Website
- Newsletter
- Press Release
- Toll free Helpline
- Android Mobile App
- Radio Programmes
- TV Shows

Publications for Stakeholders & Partners
- Quarterly Newsletter
- Annual Report
- Guidance Document
- Handouts
- Leaflets
- Banners
The Newsletter published quarterly by PvPI serves as a platform for raising awareness among the public at large to make Pharmacovigilance a part of daily healthcare regimen. To ensure health safety by patient safety, ADR updates and drug alerts are reported in the Newsletter. It helps all healthcare stakeholders, including patients/consumers, doctors, clinicians, pharmacists, hospital staff, to guard against the use of medicines which are likely to cause adverse events. The circulation of the Newsletter among the stakeholders has registered an appreciable increase and the feedback by them has been quite encouraging.
### Public Outreach

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training/Sensitization Events</td>
<td>699</td>
</tr>
<tr>
<td>Healthcare Practitioners Trained</td>
<td>25,735</td>
</tr>
<tr>
<td>TV/Radio Broadcasts</td>
<td>04</td>
</tr>
<tr>
<td>Drug Alerts — SMS</td>
<td>10,560</td>
</tr>
</tbody>
</table>

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**NCC PvPI**

- **LinkedIn:** Users 1,900, Posts 85, Views 45,000
- **YouTube:** Shares 1,500
- **Twitter:** Tweets 96, Followers 132

Pharmacovigilance Programme of India PvPI
# Scientific Publications

<table>
<thead>
<tr>
<th>Year</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>22</td>
</tr>
<tr>
<td>2018 (till March 31, 2018)</td>
<td>06</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td><strong>AMC Publications-2017-18</strong></td>
</tr>
</tbody>
</table>

B

NCC Publications-2017-18


WHO-UMC publications highlight PvPI

PvPI's achievements are regularly shared globally by UMC and WHO publications

1. Sulfasalazine: Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis (TEN)
   Reference: http://apps.who.int/iris/bitstream/handle/10665/258800/WPN-2017-04-eng.pdf?sequence=1

2. DPP-4 inhibitors: Risk of Arthralgia
   Reference: http://www.who.int/medicines/publications/WHO-Pharmaceuticals_Newsletter_No6-2017.pdf?ua=1

3. Fluconazole: Risk of Hyperpigmentation
   Reference: http://www.who.int/medicines/publications/WHO-Pharmaceuticals_Newsletter_No6-2017.pdf?ua=1

4. Terbinafine: Risk of Acute Generalized Exanthematous Pustulosis (AGEP)
   Reference: http://www.who.int/medicines/publications/WHO-Pharmaceuticals_Newsletter_No6-2017.pdf?ua=1
## List of NCC-PvPI Staff

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Name</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Dr. G.N. Singh</td>
<td>Secretary-cum-Scientific Director</td>
</tr>
<tr>
<td></td>
<td><strong>Regular Staff</strong></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Dr. Jai Prakash</td>
<td>Senior Principal Scientific Officer</td>
</tr>
<tr>
<td>3</td>
<td>Dr. V. Kalaiselvan</td>
<td>Principal Scientific Officer</td>
</tr>
<tr>
<td>4</td>
<td>Dr. Shashi Bhushan</td>
<td>Senior Scientific Officer</td>
</tr>
<tr>
<td>5</td>
<td>Dr. R.S. Ray</td>
<td>Scientific Assistant</td>
</tr>
<tr>
<td></td>
<td><strong>Contractual Staff</strong></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Mr. Prabhakar Mishra</td>
<td>Senior Pharmacovigilance Associate</td>
</tr>
<tr>
<td>7</td>
<td>Ms. Archana Saurabh</td>
<td>Senior Pharmacovigilance Associate</td>
</tr>
<tr>
<td>8</td>
<td>Mr. Vipin Kumar</td>
<td>Senior Pharmacovigilance Associate</td>
</tr>
<tr>
<td>9</td>
<td>Mr. Pramod Kumar</td>
<td>Senior Pharmacovigilance Associate</td>
</tr>
<tr>
<td>10</td>
<td>Mr. Naveen Chandu. G</td>
<td>Senior Pharmacovigilance Associate</td>
</tr>
<tr>
<td>11</td>
<td>Mr. Pankaj Bhatt</td>
<td>Senior Pharmacovigilance Associate</td>
</tr>
<tr>
<td>12</td>
<td>Dr. Vijit Agrawal</td>
<td>Senior Pharmacovigilance Associate</td>
</tr>
<tr>
<td>13</td>
<td>Mr. Akhilesh Kumar</td>
<td>Pharmacovigilance Associate</td>
</tr>
<tr>
<td>14</td>
<td>Ms. Shavya Singh</td>
<td>Pharmacovigilance Associate</td>
</tr>
<tr>
<td>15</td>
<td>Ms. Shrishti Saroha</td>
<td>Pharmacovigilance Associate</td>
</tr>
<tr>
<td>16</td>
<td>Mr. Bharat Kumar</td>
<td>Pharmacovigilance Associate</td>
</tr>
<tr>
<td>17</td>
<td>Mr. Amit Kamboj</td>
<td>Pharmacovigilance Associate</td>
</tr>
<tr>
<td></td>
<td>Name</td>
<td>Position</td>
</tr>
<tr>
<td>---</td>
<td>-----------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>18</td>
<td>Mr. Tarani Prakash Shrivastava</td>
<td>Pharmacovigilance Associate</td>
</tr>
<tr>
<td>19</td>
<td>Ms. Shivangi Tripathi</td>
<td>Pharmacovigilance Associate</td>
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<td>20</td>
<td>Mr. Polisetty Ramanjaneyulu</td>
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<td>21</td>
<td>Ms. Swathi Thapliyal</td>
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<td>Dr. N. Surendra Reddy</td>
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<td>Ms. Kalpana Joshi</td>
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<td>Dr. Vobbineni Lokesh Reddy</td>
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<td>25</td>
<td>Mr. Sandeep. K.</td>
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<td>Ms. Shilpa Choudhary</td>
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<td>27</td>
<td>Dr. Senthil Prabhu. N</td>
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<td>28</td>
<td>Mr. Jayachandran C.V.</td>
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<td>29</td>
<td>Mr. Deepak Malik</td>
<td>IT Associate</td>
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<tr>
<td>30</td>
<td>Mr. Omkar Mishra</td>
<td>IT Associate</td>
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<td>31</td>
<td>Ms. Anusha. R.</td>
<td>HR Associate</td>
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<td>32</td>
<td>Ms. Madhu Smita</td>
<td>HR Associate</td>
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<tr>
<td>33</td>
<td>Ms. Anjali Babu</td>
<td>HR Associate</td>
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<tr>
<td>34</td>
<td>Mr. Girish Pal Singh</td>
<td>Multi Tasking Staff</td>
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<tr>
<td>35</td>
<td>Mr. Shiv Maurya</td>
<td>Multi Tasking Staff</td>
</tr>
</tbody>
</table>
Acknowledgement

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Dr Jai Prakash, Senior Principal Scientific Officer
Dr V. Kalaiselvan, Principal Scientific Officer
Dr Shashi Bhushan, Senior Scientific Officer
Dr R S Ray, Scientific Assistant
Mr Tarani Prakash Shrivastava, Pharmacovigilance Associate
Mr Jayachandran C.V., Pharmacovigilance Associate
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Dr Sushma Srivastava, Senior Consultant, IPC
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Shri S A Alishah, Advisor, IPC
All other Technical, Administrative and Financial staff of IPC.

Dr G N Singh
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
Ghaziabad
Current List of AMCs under PvPI

Andhra Pradesh

Centre Name: Andhra Medical College, King George Hospital (KGH), Jagadamba Area, KGH Down Road, Maharanipeta, Visakhapatnam-530002
Coordinator: Dr. J. Sudha
E-mail: prabhakar2202@gmail.com
Contact: 09849903051

Centre Name: Guntur Medical College, Kanna Vari Thota,Guntur-522004
Coordinator: Dr. A. Meena Kumari
E-mail: meenaphani@gmail.com
Contact: 09849533268

Centre Name: Peoples Education Society Institute of Medical Sciences and Research, Kuppam, Chittoor - 517425
Coordinator: Dr. A. Leena
E-mail: 
Contact: 

Centre Name: S. V. Medical College, Alipiri Road , Tirupati, Chittoor - 517507
Coordinator: Dr. Vasundhara Devi
E-mail: vasudak61@yahoo.com
Contact: 09849633262

Centre Name: Kurnool Medical College, Budhawarpet, Kurnool-518002
Coordinator: Dr. Y. Vijayabhaskar Reddy
E-mail: drvijayabhaskarreddy@gmail.com
Contact: 09989502205

Centre Name: Sri Venkateswara Institute of Medical Sciences, Sri Padmavathi Medical College For Women, Tirupati-517507
Coordinator: Dr. Umanaheswara Rao
E-mail: svimspharmacovigilance@gmail.com
Contact: 09849832292

Centre Name: Rangaraya Medical College, Kakinada-533001
Coordinator: Dr. K.V. Siva Prasad
E-mail: sivakpt@gmail.com
Contact: 09440345642

Centre Name: Konaseema Institute of Medical Sciences and Research Foundation & KIMS General Hospitals, Chaitanya Health City, Amalapuram, East Godavari-533201
Coordinator: Dr. Anand Acharya
E-mail: anand_kims@yahoo.co.in
Contact: 09963598050

Centre Name: Shantiram Medical College & General Hospital, N. H-18, Nandyal, Kurnool- 518502
Coordinator: Dr. Yakaiah
E-mail: 
Contact: 08106363463

Arunachal Pradesh

Centre Name: Tomo Riba State Hospital, Naharlagun -791110
Coordinator: Dr. Dohkum Raina
E-mail: medicalsupt@yahoo.com
Contact: 09436041290

Centre Name: Health Training & Research Centre, NH-52 High Region,East Siang Pasighat-791102
Coordinator: Dr. T Toli
E-mail: drigibi@yahoo.com
Contact: 09436043020

Assam

Centre Name: Govt. Medical College, Narakachal Hill Top, Guwahati-781032
Coordinator: Dr. Mangala Lahkar
E-mail: dr_mlahkar@rediffmail.com
Contact: 09864073346

Centre Name: Silchar Medical College & Hospital, Ghangool, Silchar-788014
Coordinator: Dr.Pinaki Chakraborty
E-mail: dr_pinaki@yahoo.com
Contact: 0995719505

Centre Name: Jorhat Medical College & Hospital, Kushal Konwar Path, Barbheta, Jorhat-785001
Coordinator: Dr. Swapnanil
E-mail: Gohainpharmacologyjmc@gmail.com
Contact: 09613860565
Bihar

Centre Name: Indira Gandhi Institute of Medical Sciences, Bailey Road, Sheikhpura, Patna-80014
Coordinator: Prof. (Dr.) Harhar Dikshit
E-mail: dikshit.harharpatna@yahoo.co.in, amcigsims2015@gmail.com
Contact: 09334106381

Centre Name: All India Institute of Medical Sciences, Pahulwar Sharif, Patna-801050
Coordinator: Prof. P.P. Gupta
E-mail: drprempugupta@gmail.com
Contact: 07763800139, 09415210579

Centre Name: Katihar Medical College, Post Box No. 23, Katihar-854105
Coordinator: Dr. C.B. Choudhary
E-mail: drcb_choudhary@yahoo.co.in
Contact: 09431025891

Centre Name: M. G. Memorial Medical College, Purabballi, Dinaipur Road, Kishanganj-855107
Coordinator: Dr. Rabindra Nath Chatterjee
E-mail: mgmkkc@gmail.com
Contact: 09434134121

Centre Name: Narayan Medical College & Hospital, Jamuwar, Sasararam-821305
Coordinator: Dr. Rahul Mohan
E-mail: braj_rahul@yahoo.co.in
Contact: 09431470647

Centre Name: Sri Krishna Medical College & Hospital, Umamgar, Muzaffarpur-842004
Coordinator: Asso.Prof. (Dr.) S.K. Pathak,
E-mail: drsatyendra.pathak7@gmail.com
Contact: 09835626756

Chhattisgarh

Centre Name: Pt. JNM Medical College, Jail Road, Raipur- 492001
Coordinator: Dr. Rajesh Hishikar
E-mail: rishikar@gmail.com
Contact: 09424205700

Centre Name: All India Institute of Medical Sciences, Tatibandh, GE Road, Raipur-492099
Coordinator: Dr. Suryaprapaksh Dhaneria, Dr. Nitin R. Galkwad (Dy. Coord.)
E-mail: deam@alimsraipur.edu.in, nitinagalkwad2707@gmail.com
Contact: 09826045357, 08518881725

Goa

Centre Name: Goa Medical College & Hospital, NH 17, Bambolim, Tiswadi-403202
Coordinator: Dr. Padmanabab V. Rataboli
E-mail: rataboli_padmanab@rediffmail.com
Contact: 09822386263

Gujarat

Centre Name: SMT NHL Municipal Medical College, Ellise Bridge, Ahmedabad-380006
Coordinator: Dr. Supriya D. Malhotra
E-mail: supriyadmalhotra@gmail.com
Contact: 09727760262

Centre Name: BJ Medical College, New Civil Hospital, Asarwa, Ahmedabad-380016
Coordinator: Dr. Mira K. Desai
E-mail: desaimira@yahoo.co.in
Contact: 09825055107

Centre Name: Government Medical College, Near State Road Transport Corporation Bus Stand, Bhavnagar-364002
Coordinator: Dr. C.B. Tripathi
E-mail: cbtripathi@yahoo.co.in
Contact: 09825995167

Centre Name: Surat Municipal Institute of Medical Education & Research, Ring Road, Near Sahara Darwaja, Opposite Bombay Market, Umarwara, Bharat Nagar, Surat-395010
Coordinator: Dr. Sachendra K. Srivastava
E-mail: sachendra5@rediffmail.com
Contact: 09898464713, 09979596006

Centre Name: M.P. Shah Medical College, Pt. Nehru Road, Jamnagar- 361008
Coordinator: Dr. Hiren R. Trivedi
E-mail: drht13@yahoo.com
Contact: 09825210878

Centre Name: PDU Medical College, Civil Hospital Campus, Jam Nagar Road, Rajkot- 360001
Coordinator: Dr. Anil Singh
E-mail: docani71@yahoo.co.in
Contact: 09426974679

Centre Name: Gujarat Medical Education & Research Society Medical College, Gotri, Vadodara-390021
Coordinator: Dr. Prakash Bhabhor
E-mail: drbhabhor@gmail.com, deannmgv@gmail.com
Contact: 09925014449
**Centre Name:** Pramukhswami Medical College & Shree Krishna Hospital, Gokal Nagar, Karamsad, Anand-388325
**Coordinator:** Prof.(Dr.) Alpa Gor, Asso.Prof.(Dr.) Nazima Mirza, (Dpy.Coord)
**E-mail:** alpagor@charutarhealth.org, nazimaym@charutarhealth.org
**Contact:** 09924115170, 09898041036

**Centre Name:** Government Medical College, Baroda, Anandpura, Vadodara-390001
**Coordinator:** Dr. Niyati A. Trivedi
**E-mail:** natrivedi@yahoo.com, deannmcbrd@gmail.com
**Contact:** 09998961097

**Centre Name:** Smt. Bhikhiben Kanjbhai Shah (SBKS) Medical Institute & Research Centre, At. & P.o. Piparia, Tal. Waghodia, Vadodara-391760
**Coordinator:** Dr. B. M. Sattigiri
**E-mail:** dr.bhagya.ms@gmail.com
**Contact:** 09426234943

**Centre Name:** GMERS Medical College, Sola, Near Gujarat High Court, S.G. Highway, Ahmedabad-380060
**Coordinator:** Dr. Mukesh Kumar B. Vora
**E-mail:** mukeshkrutin@gmail.com
**Contact:** 09228117957

**Centre Name:** Spandan Multispeciality Hospital, Besides ward no. 4, Sindhwai Mata Road, Vadodara-390011
**Coordinator:** Dr. Ankur Bhavsar, (ICU Incharge)
**E-mail:** drdradbhavsar@yahoo.com
**Contact:** 09825227437

**Haryana**

**Centre Name:** Medanta-The Medicity Sector-38, Gurgaon-122001
**Coordinator:** Dr Lalit Kanodia
**E-mail:** lalit.kanodia@medanta.org
**Contact:** 09650655660

**Centre Name:** Artemis Hospital, Sector-51, Gurgaon
**Coordinator:** Mr. Ankur Panchal
**E-mail:** clinicalpharmacologist@artemisshealtheceans.com, ankurpanchal22@gmail.com
**Contact:** 09993080826

**Centre Name:** Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences, Rohtak-124001
**Coordinator:** Dr. M.C. Gupta, Dr. Savita Verma
**E-mail:** dr.mcgupta@yahoo.co.in, dr.mcgupta57@gmail.com, savita_verma@hotmail.com
**Contact:** 09896015035, 09812283746

**Centre Name:** BPS GMC for women, Khanpur Kalan, Sonepat-131305
**Coordinator:** Dr. Seema Rani
**E-mail:** Seema17march@gmail.com
**Contact:** 09466359666

**Centre Name:** Maharishi Markandeshwar Institute of Medical Sciences and Research, Mullana, Ambala-133207
**Coordinator:** Dr. Rani Walia
**E-mail:** hod.pharmacology@mmumullana.org
**Contact:** 09815551386

**Centre Name:** Faculty of Medicine & Allied Health Sciences, Shree Guru Gobind Singh Tricentenary University, Farukh Nagar Road, Buhera, Distt. Gurgaon-122505
**Coordinator:** Dr. Poonam Salwan
**E-mail:** salwanpoonam@yahoo.co.in
**Contact:** 09910925873

**Centre Name:** Shaheed Hasan Khan Mewati Govt. Medical College, Nalhar, Nuh-122107
**Coordinator:** Asso.Prof.(Dr.) Naveen kumar
**E-mail:** nk999999@rediffmail.com
**Contact:** 09868257149

**Centre Name:** World College of Medical Sciences and Research, Gurawar, Jhajjar-124103
**Coordinator:** Asso.Prof. Dr. Devesh Gupta,
**E-mail:** drdeveshgupta@gmail.com
**Contact:** 9899000743

**Centre Name:** ESIC Medical College, NIT, NH3, Faridabad-121001
**Coordinator:** Asso.Prof.(Dr.) Monica Aggarwal
**E-mail:** monicag@rediffmail.com
**Contact:** 9811420165

**Centre Name:** Kalpana Chawla Govt. Medical College, Karnal-132001
**Coordinator:** Asso.Prof. (Dr.) Tirthankar Deb
**E-mail:** tirthdeb@gmail.com
**Contact:** 9088859953

**Centre Name:** Paras Hospital, C-1, Sushant Lok-1, Sec-43, Phase-1, Gurugram-122002
**Coordinator:** Mr. Tarun Kumar (Clinical Pharmacist)
**E-mail:** tarun.kumar@parashospitals.com
**Contact:** 9717354726

**Himachal Pradesh**

**Centre Name:** Dr. Rajendra Prasad Govt. Medical College, Kangra, Tanda-176001
**Coordinator:** Dr. Dinesh Kansal
**E-mail:** dinesh.kansal56@gmail.com
**Contact:** 9418454624
Karnataka

Centre Name: Bangalore Medical College and Research Institute, Fort, K.R. Road, Bengaluru-560002
Coordinator: Dr. C. R. Jayanthi
E-mail: bmcri@gmail.com
Contact: 09448292424

Centre Name: Belgaum Institute of Medical Sciences, Dr. B.R. Ambedkar Road, Belgaum-590001
Coordinator: Dr. Pankaj Kumar Masare
E-mail: pankajmasare@gmail.com
Contact: 09035330070

Centre Name: Bidar Institute of Medical Sciences, Bidar, Udgir Rd, Bidar- 585401
Coordinator: Dr. Chananna C.
E-mail: director@brims-bidar.in
Contact: 09448353014

Centre Name: JSS Medical College Hospital, Sri Shivarathreeshwara Nagar, Mysore-570015
Coordinator: Dr. Parthasarathi G.
E-mail: partha18@gmail.com
Contact: 09845659585

Centre Name: Karnataka Institute of Medical Sciences, P. B. Road, Vidyavanag, Hubli-580021
Coordinator: Dr. Dattatri A.N., Dr. S A Salimath
E-mail: adrrkmc@gmail.com
Contact: 09902354622, 09591073366

Centre Name: Kasturba Medical College, Madhava Nagar, Manipal-576104
Coordinator: Dr. Shalini Adiga
E-mail: shalini.adiga@manipal.edu
Contact: 09448521328, 0820 -2922543

Centre Name: Mandya Institute of Medical Sciences, District Hospital Campus, Mandya-571401
Coordinator: Dr. Nagabushan
E-mail: bushan123@rediffmail.com
Contact: 09448063431

Centre Name: SDS Tuberculosis Research Centre & Rajiv Gandhi Institute of Chest Disease, Someshwaranagar, 1st Main Road, Bengaluru-560029
Coordinator: Dr. C. Nagaraja, Director SDSTRC & RGICD
E-mail: shashidharbg@gmail.com, director.rgicd@gmail.com
Contact: 09448042579

Centre Name: St. John’s Medical College, Sarjapur Road, Bengaluru-560034
Coordinator: Dr. Padmini Devi
E-mail: p_nidhin@hotmail.com
Contact: 09844353460

Jharkhand

Centre Name: Rajendra Institute of Medical Sciences (RIMS), Bariatu, Ranchi-834009
Coordinator: Dr. Manju Gari
E-mail: amcrrims@gmail.com, manjugari@rediffmail.com
Contact: 09431558388

Centre Name: Patliputra Medical College (PMC), B.C.C.L Township, Dhanbad-826005
Coordinator: Asso.Prof.(Dr.) Asish Kumar Biswas
E-mail: drasishbiswas@hotmail.com
Contact: 09934587426

J&K

Centre Name: Govt. Medical College, Maheshpura Chowk, Bakshi Nagar, Jammu-180001
Coordinator: Dr. Vishal Tandon
E-mail: dr.vishaltandon@yahoo.com
Contact: 09419195126

Centre Name: Sher-i-Kashmir Institute of Medical Sciences, Soura, Srinagar-190011
Coordinator: Dr. Shakeel Ahmad Mir
E-mail: drshakeelahmadmir@gmail.com
Contact: 09419055375

Centre Name: Govt. Medical College, Karan Nagar, Srinagar-190010
Coordinator: Dr. Zubair Ashai
E-mail: zubairashai@yahoo.co.uk
Contact: 09419467514

Preformance Report 2017-2018
Centre Name: Vydehi Institute of Medical Sciences and Research Centre, 82, Nallurahalli, Near BMTC 18th Depot, Whitefield, Bengaluru-560066  
Coordinator: Dr. Pratibha Nadig  
E-mail: drpratibhanadig@yahoo.co.in  
Contact: 09901691964

Centre Name: Indira Gandhi Institute of Child Health, South Hospital Complex, Near NIMHANS, Hombegowda Nagar, Bengaluru-560001  
Coordinator: Dr. Basav Raj  
E-mail: basavrg@gmail.com  
Contact: 09448153754

Centre Name: M.S. Ramaiah Medical College, MSR Nagar, Gokula, Bengaluru-560054  
Coordinator: Dr. Anuradha H V (Coord), Dr. Mukunda N (Dpy Incharge)  
E-mail: drashokshahal@gmail.com  
Contact: 09418468582

Centre Name: Govt. Medical College, Maheshpura Chowk, Bakshi Nagar, Jammu-180001  
Coordinator: Dr. Vishal Tandon  
E-mail: anuradhavh@msrm.ac.in, mukundan@msrm.ac.in  
Contact: 09448847946, 09986351200

Centre Name: SDM College of Medical Sciences & Hospital, Manjushree Nagar, Sattur, Dharwad-580009  
Coordinator: Dr. Prasan R Bhandari  
E-mail: prasangeta2012@gmail.com  
Contact: 09036941910

Centre Name: ESIC-MC & PGIMSR, 3rd Block, Rajajinagar, Bangalore-560010  
Coordinator: Dr. Suchitra A.D, Dr. Niveditha  
E-mail: suchisham@hotmail.com, niveditha_1963@yahoo.co.in  
Contact: 09632229122

Centre Name: Saptagiri Institute of Medical Sciences and Research Centre,No.15,Chikkasandra, Hesaraghatta Main Road, Bangalore-560090  
Coordinator: Dr.Padma L (Coord)  
Dr. Raghunandan R (Dpy Coord)  
E-mail: lpadmagopinath@gmail.com, simspharma@gmail.com  
Contact: 09448248882

Centre Name: A.J. Institute of Medical Sciences, Kuntikana, NH-66, Mangalore-575004  
Coordinator: Dr. Sharath Kumar K.  
E-mail: docsharath@gmail.com  
Contact: 09945684880

Centre Name: S.S Institute of Medical Sciences & Research Centre, NH-4, Bypass Road, Davangere-577005  
Coordinator: Dr. Umakant N Patil  
E-mail: drunpatil@gmail.com  
Contact: 09886767811

Centre Name: Sri Devaraj Urs Medical College, Tamaka, Kolar-563101  
Coordinator: Dr. Bhuvana K  
E-mail: drbhuvana_k@yahoo.com  
Contact: 09448130159

Centre Name: Bowring & lady Curzon hospital, Lady Curzon Road, Tasker Town, Shivaji Nagar, Bengaluru-560001  
Coordinator: Ms. Shruthi  
E-mail: bowringcoe@gmail.com, shruthi.mallesh@gmail.com  
Contact: 09535544884

Centre Name: Shri B.M. Patil Medical College, BLDE University, Vijayapur-586103  
Coordinator: Dr. Anant Khot  
E-mail: anantkhot04@gmail.com  
Contact: 09591926519

Centre Name: Shivamogga Institute of Medical Sciences, Sagar Road, Shivamogga-577201  
Coordinator: Dr. S. Nagaraja Prasad  
E-mail: drnagarajaprasad@gmail.com  
Contact: 08277583078

Centre Name: M.R. Medical College, Kalaburagi-585105  
Coordinator: Dr. Santosh Kumar Jeevangi  
E-mail: mrmcalb@gmail.com, djeevangi@gmail.com  
Contact: 09945910158

Centre Name: Mysore Medical College and Research Institute, Irwin road, Mysore-570001  
Coordinator: Prof.(Dr.) Basavanna P. L  
E-mail: drbasvanannpl@gmail.com  
Contact: 09448390965

Centre Name: BGS Global Institute of Medical Sciences (BGS SIIMS), 67, BGS Health & Education City, Uttarahalli Road Kengeri, Bangalore South, Bengaluru-560060  
Coordinator: Dr. Kalpana L (Prof. & HOD)  
E-mail: Kalpu154@gmail.com  
Contact: 09880655158

Centre Name: Kasturba Medical College, Light house Hill road, Mangaluru-575001  
Coordinator: Prof.(Dr.) Ashok Shenoy K  
E-mail: ashok.shenoy@manipal.edu  
Contact: 09880530703
Centre Name: M. V. J. Medical College and Research Hospital, 30th km Milestone, National Highway 4, Hoskote, Bangalore-562114
Coordinator: Dr T V Venkatadri (Prof. & HOD)
E-mail: drtvv6@gmail.com, pharmacology@mvmc.edu.in
Contact: 09845092271

Centre Name: Akash Institute of Medical Sciences & Research Centre, Prasannahalli Road, Devanahalli, Near Kempegowda International Airport, Bengaluru-562110
Coordinator: Dr. Shubha Praveen (Prof. & HOD)
E-mail: shubhapreksa@gmail.com
Contact: 09448074489

Centre Name: Narayna Hrudalaya Hospital, 1st floor, B Block, Narayana Health City, Bommasandra Industrial Area, Bengaluru-560099
Coordinator: Dr. Alben sigamani (Head Clinical Research)
E-mail: alben.sigamani.dr@nhhospitals.org, albens@live.com
Contact: 08884431444

Centre Name: National Institute of Mental Health & Neuro Sciences (NIMHANS), Hosur Road, Lakasandra, Wilson Garden, Hosur Road, Bengaluru-560029
Coordinator: Smt. MG Sindhu (Materialvigilance - Biomedical Engineering Dept)
E-mail: sindumg@nimhans.ac.in
Contact: 09480829700

Centre Name: Pushpagiri Institute of Medical Sciences and Research Centre, Pushpagiri Medical College Hospital, Tiruvalla-689101
Coordinator: Dr. Santosh Pillai
E-mail: pem@pushpagiri.in
Contact: 09447596426

Centre Name: Amala Institute of Medical Sciences, Amala Nagar, Thrissur-68005
Coordinator: Dr. Deepu Jacob Chacko
E-mail: vigil.amala@gmail.com
Contact: 08157020222

Centre Name: Govt. T.D. medical college, Vandananam, Alappuzha-688005
Coordinator: Dr. Kala Kesavan
E-mail: drkalakesavan@yahoo.co.in
tmcalkappuzha@gmail.com
Contact: 09847034504

Centre Name: Government Medical College, Medical college,Thiruvananthapuram-695011
Coordinator: Dr Manju K Nair, Dr. Annapoorna (Dpy. Coord)
E-mail: manjusunjit@gmail.com, gmctpharmacology@gmail.com, annatvm11@yahoo.com
Contact: 09447345520

Centre Name: Amrita Institute of Medical Sciences, Kochi-68204
Coordinator: Dr. Thresiamma Thomas K.
E-mail: drthresiamma@aims.amrita.edu
Contact: 09349503287

Centre Name: Government Medical College, Palakkad-678013
Coordinator: Dr. N. Sunil
E-mail: docsunil2005@yahoo.com
Contact: 09645666189

Centre Name: Sree Gokulam Medical College & Research Foundation (S.G.M.C. & R.F.) Venjaramoodu, Thiruvananthapuram -695607
Coordinator: Dr. P. Shobha
E-mail: sgcmpharmac@gmail.com, sobhaent@gmail.com
Contact: 09895885395

Centre Name: Aster Medcity, Cheranelloor, Kochi-682027
Coordinator: Dr Priya K, Neethu Jose
E-mail: priya.karanakaran@dmhealthcare.com
Contact: 08111998041, 08111998168

Centre Name: D M Wayanad Institute of Medical Sciences, Naseera Nagar, Meppadi,Wayanad-673577
Coordinator: Dr. S. Basalingappa
E-mail: basalingappas@gmail.com
dr.sbasalingappas@dmwins.com
Contact: 0948931426, 04936-287000
Ext.-7235

Kerala
Centre Name: Sree Narayana Institute of Medical Sciences, Chalakka, P.O. North Kuthiyathodu, Ernakulam-683594
Coordinator: Asso.Prof.(Dr.). Lavanya Assa.Prof.(Dr.) Parvathy S (Dpy.Coord)
E-mail: dr.lavanya.n@gmail.com parvathyradhakrishnan86@gmail.com
Contact: 08281579844, 09946144148

Centre Name: Believers Church Medical College & Hospital, St. Thomas Nagar, Kuttapuzha, Pathanamthitta District, Thiruvalla-689103
Coordinator: Asso.Prof.(Dr.) R. S. Jacob Jesurun
E-mail: jacobjesurun@bmcch.org
Contact: 09894119472

Centre Name: Trivancore Medical College and Hospital, Mylapore, Thattamala P.O., Kollam-691020
Coordinator: Dr. Lyra K. N (Prof. & HOD) Dr. Jihana Shajahan (Dyp.Coord)
E-mail: lylakurup@gmail.com, travancoremedicalcollege@gmail.com
Contact: 09846371216

Centre Name: Rajagiri Hospital, Chunnamangvelly, Aluva-683112
Coordinator: Dr. Jerin Jose Cherian (Consultant Clinical Pharmacologist)
E-mail: jerin.cherian@rajagirihospital.com
Contact: 09895333890

Madhya Pradesh

Centre Name: Gandhi Medical College, Sultania Road, Bhopal-462001
Coordinator: Dr. Arun Srivastav
E-mail: arunsrivastav8@gmail.com
Contact: 9424983641

Centre Name: RD Gardi Medical College, Agar Road, Sarsa, Ujjain -456006
Coordinator: Dr. Sudhakar M. Parhate Dr. Sandeep Adval (Dyp. Coord)
E-mail: dr_chourishi@yahoo.co.in, dr_chourishi@hotmail.com
Contact: 09893005655

Centre Name: Sri Aurabindo Institute of Medical sciences, Ujjain Highway, Swarner Road, Indore-453555
Coordinator: Dr. Chhaya Goyal, Dr. Pooja Reddy
E-mail: chhayag@gmail.com, drpoojasreddy@gmail.com
Contact: 09827221640

Centre Name: NSCB Medical College, Medical College Colony, Jabalpur- 482003
Coordinator: Dr. K.K. Daryani, Dr. Sachin Kuchya
E-mail: nsbmc5@gmail.com, sachinkuchya@yahoo.com
Contact: 09827255744

Centre Name: All India Institute of Medical Sciences, Saket Nagar, Bhopal - 462024
Coordinator: Dr. Ratinder Jhoj, Dr. Balakrishnan S
E-mail: ratiphyarmac@aimsghp voluntary.org, head.pharmac@aimsghp voluntary.org
Contact: 0777302096

Centre Name: Gajra Raja Medical College, Veer Savarkar Marg, Gwalior-474009
Coordinator: Dr. Saroj Kothari
E-mail: sarojkothari@rediiffmail.com
Contact: 09827322002

Maharashtra

Centre Name: BJ Medical College & Sassoon General Hospital, Jai Prakash Narayan Road, Near Pune Railway Station, Pune-411001
Coordinator: Dr. Pardesi Milind Kumar Laxman Rao
E-mail: ghongane_bb@yahoo.com
Contact: 09922925590

Centre Name: Government Medical College & Hospital, Ajni Rd, Nagpur-440003
Coordinator: Dr. Ganesh N. Dakkele
E-mail: smitaavant@gmail.com, gndakkele@rediiffmail.com
Contact: 09850539353

Centre Name: Grant Medical College & Sir JJ Group of Hospitals, JJ Marg, Off Jijabho Road, Byculla Mumbai-400008
Coordinator: Dr. R.S. Gambre
E-mail: ggmc.vigil@gmail.com
Contact: 07208010660

Centre Name: Indira Gandhi Government Medical College, C.A. Road, Nagpur-440018
Coordinator: Dr. Vandana Avinash Badar
E-mail: drvandanabard@yahoo.co.in, am1_badar@yahoo.com
Contact: 09960031486

Centre Name: Lokmany Tilak Municipal Medical College & General Hospital, Dr. Babasaheb Ambedkar Road, Sion-400022
Coordinator: Dr. Sudhir R. Pawar
E-mail: dr.sudhirpawar@gmail.com
Contact: 09869111630

Centre Name: Mahatma Gandhi Institute of Medical Sciences, Nagpur Sevagram, Nagpur-442012
Coordinator: Dr. Sushil Kumar Varma
E-mail: sushil@mgims.ac.in, varmasushil9@gmail.com
Contact: 09921418999
**Centre Name:** Dr. D. Y.Patil Medical College, Sant Tukaram Nagar, Pimpri, Pune – 411018  
**Coordinator:** Dr. A.Y. Tilak  
**E-mail:** abhijeet.tilak@yahoo.com  
**Contact:** 09226145484

**Centre Name:** Aditya Birla Memorial Hospital Marg, Chinchwad, Pune-411033  
**Coordinator:** Dr. Yuvaraj Dhyanoba  
**E-mail:** yuvarajgogdand123@gmail.com  
**Contact:** 09767130114

**Centre Name:** Seth GS Medical College & KEM Hospital, Acharya Donde Marg, Parel - 400012  
**Coordinator:** Dr. Urmila Thatte  
**E-mail:** kempvpi@gmail.com, urmilathatte@gmail.com  
**Contact:** 09820198462

**Centre Name:** Swami Ramanand Teerth Rural Govt Medical College, Ambajogai, Dist. Beed- 431517  
**Coordinator:** Dr. Anand S. Kale  
**E-mail:** Kanand788@gmail.com  
**Contact:** 09890252896

**Centre Name:** TN Medical College & BYL Nair Hospital, Dr. AL Nair Road, Mumbai Central, Mumbai-400008  
**Coordinator:** Dr. Renuka Kulkarni Munshi  
**E-mail:** renuka.munshi@gmail.com  
**Contact:** 09820377409

**Centre Name:** TN Medical College & BYL Nair Hospital, Dr. AL Nair Road, Mumbai Central, Mumbai-400008  
**Coordinator:** Dr. Renuka Kulkarni Munshi  
**E-mail:** renuka.munshi@gmail.com  
**Contact:** 09820377409

**Centre Name:** Armed Forces Medical College, Opposite Race Course, Solapur Road, Pune Cantonment, Pune-411040  
**Coordinator:** Lt Col Prafull Mohan  
**E-mail:** pharmacovigilamc@gmail.com  
**Contact:** 09962966939

**Centre Name:** Government Medical College, Sangli district, Miraj-416410  
**Coordinator:** Dr. Shraddha Milind Pore  
**E-mail:** shraddha.pore7@gmail.com  
**Contact:** 09371126946

**Centre Name:** Govt. Medical College, Latur, opposite Rajasthan High School, Near minarket, Latur-413512  
**Coordinator:** Dr. Jaju J.B., Dr. Raj Solunke  
**E-mail:** ieclatur1@gmail.com, pharmacologygmclatur@gmail.com  
**Contact:** 02382-247676, 08421577155

**Centre Name:** N.K.P. Salve Institute of Medical Sciences & Lata Mangeshkar Hospital, Digdoh Hills, Hingna Road, Nagpur-440019  
**Coordinator:** Dr. Archana S. Borkar  
**E-mail:** drarchana50@gmail.com, nkpstim1@rediffmail.com  
**Contact:** 09922155782, 07104-306100

**Centre Name:** Aundh Chest Hospital, 1" Floor, Nr Sangavi Phata, Aundh camp, New Sangavi, Pune-411027  
**Coordinator:** Dr. Smita Sanjeev Shiras, Dr. Mrs. Dhavle  
**E-mail:** dphsmhpna@ntcp.org  
**Contact:** 09422356164

**Centre Name:** Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Sawangi (Meghe), Wardha-442004  
**Coordinator:** Dr. Shailesh Nagpure  
**E-mail:** drshaileshnagpure@gmail.com  
**Contact:** 09503509430

**Centre Name:** Ashwini Rural Medical College, Hospital & Research Centre, Kumbhari, Tq. South Solapur, Dist. Solapur-413006  
**Coordinator:** Dr. C. S. Waghmare  
**E-mail:** drckant@gmail.com  
**Contact:** 09766819507

**Centre Name:** Terna Medical College & Hospital, Sector-12, Phase-II, Nerul, Navi Mumbai-400706  
**Coordinator:** Dr. Sangita Sukumaran  
**E-mail:** drsangit@gmail.com  
**Contact:** 09820963663

**Centre Name:** Smt. Kashibai Navale Medical College & General Hospital, Sr. No. 49/1, Nerhe, Off Mumbai-Pune bypass, Pune-411041  
**Coordinator:** Dr. Yogita Karandikar  
**E-mail:** karandikar_yogita@yahoo.com  
**Contact:** 09922749708

**Centre Name:** Dr. Vaishampayan Memorial Govt. Medical college, Opp. District Court, Solapur-413003  
**Coordinator:** Dr. Ujwala Pramod Gawali  
**E-mail:** ujwalapagawali@gmail.com  
**Contact:** 09420492342

**Centre Name:** Hinduhridaysamrat Balasaheb Thakeray Medical College & Dr. R. N. Cooper Municipal General Hospital, Bhaktivedanta Swami Marg, Juhu, Vile Parle (West), Mumbai-400056  
**Coordinator:** Dr. Prasad R. Pandit (Prof.& HOD)  
**E-mail:** drprpandit@gmail.com  
**Contact:** 099220577678
**Centre Name:** Rural Medical College, Pravara Institute of Medical Sciences, Lon, (Near Shirdi), Tal- Rahata, Dist.- Ahmednagar-413736  
**Coordinator:** Dr. D. H. Nandak (Prof. & HOD)  
**E-mail:** contact@pmtpims.org  
**Contact:** 02422-273600, 273486

**Centre Name:** Mahatma Gandhi Mission (MGM), N-6, Cidco, Aurangabad-431003  
**Coordinator:** Asst.Prof.(Dr.) Abhijeet Bhagat  
**E-mail:** mgmpharmacovigillancecell@gmail.com, drabhhi@gmail.com  
**Contact:** 09049822869

**Centre Name:** Dr. Vasantrao Pawar Medical College, Hospital & Research Centre, Vasantdada Nagar, Adgaon, Nashik- 422003  
**Coordinator:** Dr. Pradip Barde (Prof. & HOD)  
**E-mail:** crl@dvasantraopawarmedicalcollege.com  
**Contact:** 09021416946

**Centre Name:** Dr. Shankarrao Chavan Govt. Medical College, Vishnupuri, Nanded, Maharashtara-431606  
**Coordinator:** Dr. Saleem Basha Tamboli (Prof. & HOD)  
**E-mail:** pharmacologyscgmnanded@gmail.com  
**Contact:** 09822377584

**Manipur**

**Centre Name:** Regional Institute of Medical Sciences, Lamphelpat, Imphal-795004  
**Coordinator:** Dr. S. Rita Devi  
**E-mail:** pharmacovigilance15@gmail.com, ritasanjenbam@yahoo.co.in  
**Contact:** 09612002132

**Meghalaya**

**Centre Name:** North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences, Shillong-793018  
**Coordinator:** Dr. Dhruti Kumar Brahna  
**E-mail:** ddbhriti168@gmail.com  
**Contact:** 09436766171

**Odisha**

**Centre Name:** VSS Medical College, Burla, Sambalpur-768031  
**Coordinator:** Dr. Sabita Mahapatra  
**E-mail:** dr.sabita.m@gmail.com  
**Contact:** 09238607960

**Centre Name:** M. K. C. G Medical College, Ganjam, Berhampur-760004  
**Coordinator:** Dr. Bandana Rath  
**E-mail:** drbandanarath@yahoo.co.in  
**Contact:** 09437980235

**Punjab**

**Centre Name:** Christian Medical College and Hospital, Brown Road, Ludhiana-141008  
**Coordinator:** Dr. Dinesh Kumar Badyal  
**E-mail:** dinesh@badyal@gmail.com  
**Contact:** 09815333776

**Centre Name:** Dayanand Medical College and Hospital, Tagore Nagar, Civil Lines, Ludhiana-141001  
**Coordinator:** Dr. Sandeep Kaushal  
**E-mail:** skauhgal1@yahoo.co.in  
**Contact:** 09876635367

**Centre Name:** Sri Guru Ram Das Institute of Medical Sciences & Research, Grand Trunk Rd, Amritsar-143006  
**Coordinator:** Dr. Rahat Kumar  
**E-mail:** srdlimsar@rediffmail.com, rahat_sharma66@yahoo.com  
**Contact:** 0183-2870200, 2870204

**Centre Name:** Guru Gobind Singh Medical College & Hospital, Sadiq Road, Faridkot-151203  
**Coordinator:** Dr. Harminde Singh  
**E-mail:** dr_harminderchahal@rediffmail.com  
**Contact:** 07589012024

**Centre Name:** Government Medical College, Circular Road, Amritsar-143001  
**Coordinator:** Dr. Jaswant Rai  
**E-mail:** drjaswantra@gmail.com  
**Contact:** 08146896878

**Centre Name:** Government Medical College, Patiala, New Lai Bagh, Patiala-147001  
**Coordinator:** Dr. Vijay K Sehgal, Dr. Jasbir (Dpy.Coord)  
**E-mail:** vijayksehgal@yahoo.com  
**Contact:** 09876078390, 09872197861
Centre Name: Sacred Heart Hospital, Maqsudan, Jalandhar-144008
Coordinator: Dr. Lyla Jose (Medical Supdt.)
E-mail: sr.lyla@gmail.com
Contact: 08054516699

Centre Name: Amandeep Hospital, G. T Road, Model town, Amritsar-143001
Coordinator: Manpreet kaur (Quality Coord)
E-mail: ah.qualitycontrol@amandeephospital.org
Contact: 09815335150

Rajasthan

Centre Name: Sardar Patel Medical College, SP Medical College Rd, Sardar Patel Colony, Bikaner-334001
Coordinator: Dr. R. P. Acharya
E-mail: drrpaacharya@rediffmail.com
Contact: 09214982589

Centre Name: SMS Medical College, Jawahar Lal Nehru Marg, Jaipur-302004
Coordinator: Dr. Lokendra Sharma
E-mail: dlrokendra29@gmail.com
Contact: 09414048334

Centre Name: Geetanjali Medical College and Hospital, Geetanjali Medcity, Hirar Magri Extn, Ekingpura Chouraha, Udaipur-313001
Coordinator: Dr. Jameela Tehsildar
E-mail: dr.jameelatalahasildar@yahoo.com
Contact: 09829303666

Centre Name: R.N.T Medical College Ambedkar Circle or Court Circle, SH 32, Bhopalpura, Udaipur-313001
Coordinator: Dr. Meena Atray
E-mail: drmatray@yahoo.com
Contact: 09784646478

Centre Name: NIMS Medical College, NIMS University, Shobha Nagar, Jaipur-303121
Coordinator: Dr. Manjula Bhargava
E-mail: dr.manjula.bhargava@gmail.com
Contact: 09460188488

Centre Name: All India Institute of Medical Sciences, Basini Industrial Area Phase-2, Jodhpur-342005
Coordinator: Dr. Pramod Kumar Sharma
E-mail: pramod309@gmail.com
Contact: 08003996894

Centre Name: Institute of Respiratory Diseases, SMS Medical College, Subhash Nagar, Jaipur- 302016
Coordinator: Dr. Rajendra Singhvi
E-mail: dprjdjr@rmtp.org
Contact: 09829154901, 0141-2281000 (Ext. no. 260)

Centre Name: Dr. S. N. Medical college, Residency Road, Shastri Nagar, Jodhpur-342001
Coordinator: Sr.Prof.(Dr.) Anusuya Gehlot
E-mail: medicalcollegejodhpur@yahoo.com, anusuyagehlot@gmail.com
Contact: 09413256424

Centre Name: Govt. Medical College & Associate Hospital, Rang Bari Road, Kota-324005
Coordinator: Sr.Prof.(Dr.) Laxmi Narayan Sharma
E-mail: dlaxminarayansharma58@gmail.com
Contact:

Centre Name: Jawahar Lal Nehru Medical College & Associated Hospital, Ajmer-305001
Coordinator: Dr. Sunil Kumar Mathur
E-mail: sunrinty@gmail.com, pharmacovigilance.jlnmcah@gmail.com
Contact: 09414008259

Tamil Nadu

Centre Name: Christian Medical College and Hospital, No:4, Ida Scudder road, Vellore- 632004
Coordinator: Dr.Sujith Chandy, Dr. Aswathy Rachel Mathew
E-mail: sjchandyADR@gmail.com, elle.rahal@gmail.com
Contact: 09443813800, 0416-2282690, 09791757029

Centre Name: Govt. Kilpauk Medical College, Perambur Purasawalkam, Chennai-600010
Coordinator: Dr. C. Ramachandra Bhat
E-mail: bhatcr@gmail.com
Contact: 09843126800

Centre Name: Madras Medical College, E.V.R Periyar Salai, Park Town, Chennai-600003
Coordinator: Dr. K.M Sudha
E-mail: pvpi.chennai@gmail.com, m_sudha69@yahoo.com
Contact: 09840697847

Centre Name: PSG Institute of Medical Sciences & Research, Anna Nagar, Coimbatore-641004
Coordinator: Dr. S. Ramalingam, Focal person - Dr.S.Shamugapriya
E-mail: dr.ramspsg@gmail.com, somasundaram999@rediffmail.com
Contact: 09894618450
**Centre Name:** SRM Medical College Hospital & Research Centre, Kattankulathur, Kanchipuram-603203  
**Coordinator:** Dr. Jamuna Rani, R  
**E-mail:**  
**Contact:** 09840279010

**Centre Name:** Sri Ramachandra Medical College and Research Institute, Porur, Chennai-600116  
**Coordinator:** Dr. Darling Chellathai David  
**E-mail:** pvpsismc@gmail.com, hod.pharmacology@srramachandra.edu.in  
**Contact:** 09444622698

**Centre Name:** Madurai Medical College, Alwar puram, Madurai-625020  
**Coordinator:** Dr. M. Malathi  
**E-mail:** poojamuthudch@yahoo.co.in  
**Contact:** 08760263019

**Centre Name:** Tirunelveli Medical College, Tirunelveli- 627011  
**Coordinator:** Dr. B. Meenakshi  
**E-mail:** meenakshi_b@tvmc.ac.in  
**Contact:** 09443496909

**Centre Name:** Coimbatore Medical College & Hospital, Trichi Road, Gopalapuram, Coimbatore-641014  
**Coordinator:** Dr. N. Shanthy  
**E-mail:** shanthisundarrajagan@gmail.com  
**Contact:** 09443113740

**Centre Name:** Kovai Medical Center and Hospital, Post Box No. 3209, Avanashi Road, Coimbatore – 641014  
**Coordinator:** Vijaya Kumar A  
**E-mail:** vijayakumara@kmchospitals.com  
**Contact:** 0422-4323800

**Centre Name:** Velammal Medical College Hospital and Research Institute, Anuppanadi, Madurai-625009  
**Coordinator:** Dr Rajkishore Mahato (HOD, Pharmacology)  
**E-mail:** raj_kishorek7@rediffmail.com  
**Contact:** 08489022474

**Centre Name:** Government Hospital of Thoracic Medicine, Tambaram, Chennai-600047  
**Coordinator:** Dr. R. Sridhar, Dr. A.S. Adakkalavan (Dpy.Coor)  
**E-mail:** srihema.1964@gmail.com, aadikks85@gmail.com  
**Contact:** 09444007311

**Centre Name:** Kanyakumari Govt. Medical College, Asiripalayam, Kanyakumari- 629201  
**Coordinator:** Dr. T. Ashok Kumar  
**E-mail:** drsita99@gmail.com  
**Contact:** 09443130263

**Centre Name:**  
**Coord: Govt Stanley Medical College, Old Jail road, Royapuram, Chennai-600001  
**Coordinator:** Dr. G. Hemavathy  
**E-mail:** smcppvpi16@gmail.com, hemavathy128@gmail.com  
**Contact:** 09444081969

**Centre Name:** Government Mohan Kumarmangalam medical College, Steel Plant Road, Salem-636030  
**Coordinator:** Dr. Mohamed Musthafa S. (Prof. & HOD)  
**E-mail:** gmkmcppharmacology@gmail.com, musthafaseik@gmail.com  
**Contact:** 09443025583

**Centre Name:** Karpagam Faculty of medical Sciences & Research, Pollachi main road, Othakkalmandapam, Coimbatore-641032  
**Coordinator:** Dr. A. Udayakumar (Prof. & HOD)  
**E-mail:** drudayakumar123@gmail.com  
**Contact:** 07598025301

**Centre Name:** ESIC Medical College & PGIMSR K. K. Nagar, Chennai-600078  
**Coordinator:** Dr. S. Seethalakshmi (Prof. & HOD)  
**E-mail:** seethapharmacology@gmail.com  
**Contact:** 09444176026

---

**Telangana**

**Centre Name:** Kakatiya Medical College, Rangampet Street, Warangal-506007  
**Coordinator:** Dr. Raju Devde  
**E-mail:** rajudevde_dr@yahoo.co.in  
**Contact:** 09989125124

**Centre Name:** Nizam Institute of Medical Sciences, Pun jagutta Main Road, Hyderabad-500082  
**Coordinator:** Dr. P. Usha Rani  
**E-mail:** ushapingali@yahoo.com  
**Contact:** 09849574143

**Centre Name:** Bhaskar Medical College & Bhaskar General Hospital, Yenkapally, Moinabad, Ranga Reddy, -500075  
**Coordinator:** Dr. K. Sudhakar Mr. Srinivas.A (Dpy.Coor)  
**E-mail:** docsudhakar@gmail.com, asrinivasgl1@gmail.com  
**Contact:** 09966551841, 09652169766
Uttar Pradesh

Centre Name: B.R.D Medical College & Nehru Hospital, Gorakhpur- 273013
Coordinator: Dr. Jamal Haider
E-mail: jamal001@gmail.com
Contact: 09839828358

Centre Name: GSVM Medical College, Swaroop Nagar, Kanpur- 208001
Coordinator: Dr. S.P. Singh
E-mail: singh@spgvmch.com
Contact: 09415154744

Centre Name: Institute of Medical Sciences Banaras Hindu University, Varanasi- 221005
Coordinator: Dr. B.L. Pandey
E-mail: bhp35@rediffmail.com
Contact: 09451664917, 09451440039

Centre Name: JN Medical College, Aligarh Muslim University, Aligarh- 202002
Coordinator: Dr. Mohammad Nasiruddin
E-mail: naseer_bettiah@yahoo.co.in
Contact: 09412596898

Centre Name: M.I.B. Medical College, Jhansi- 284128
Coordinator: Dr. Sadhna Kaushik
E-mail: kausik.sadhana55@gmail.com
Contact: 07897038922

Centre Name: M.L.N Medical College, Darbhanga Colony, George Town, Allahabad- 211002
Coordinator: Dr. Rakesh Chandra Chaurasia
E-mail: dr.rahesh65@rediffmail.com
Contact: 09415615064

Centre Name: Santosh Medical University, Santosh Nagar, Ghaziabad-201001
Coordinator: Dr. V. S. Chopra
E-mail: vipen.chopra@gmail.com, jhingran@yahoo.co.in
Contact: 07838961411, 09868579737

Centre Name: Uttar Pradesh University of Medical Sciences, Saifai, Etawah-206130
Coordinator: Dr. Asha Pathak
E-mail: drasha_pathak@yahoo.co.in
Contact: 09451021779

Centre Name: Muzaffarnagar Medical College & Hospital, opp. Begaipur Industrial Area, Ghaispur, Muzaffarnagar-251201
Coordinator: Dr. Suman Lata
E-mail: dr.sumanlata@yahoo.com
Contact: 09897878728

Tripura

Centre Name: Agartala Govt. Medical College, Kunjaban, Agartala-799006
Coordinator: Dr. Debasis Roy
(HOD, Pharmacology)
E-mail: contactdebasiray@gmail.com, agmc@rediffmail.com
Contact: 09436125100

Centre Name: Tripura Medical College & Dr. BRAM Teaching Hospitals, Hapania, Agartala-799014
Coordinator: Dr. Ranjib Ghosh
E-mail: ghoshranjib@rediffmail.com
Contact: 09436139660
Centre Name: School of Medical Sciences & Research, Sharda University, Greater Noida-201306
Coordinator: Prof. Qazi M. Ahmed, Dr. Ashok K Dubey
E-mail: gma49@yahoo.co.in, drakd1105@yahoo.co.in
Contact: 09313766906

Centre Name: Subharati Medical College, Subharti Puram, Nti-58, Delhi-Haridwar By Pass Road, Meerut-250005
Coordinator: Dr. Prem Prakash Khosla, Dr. H. L. Bhalia (Dpy.Coorid)
E-mail: khoslappi@yahoo.com, hirabhalla@gmail.com
Contact: 08909654319, 09761715236

Centre Name: Era’s Lucknow Medical College & Hospital, Sarfrazganj, Moosa Bagh Picnic Spot, Hardoi Road, Lucknow-226003
Coordinator: Dr. Afroz Abidi
E-mail: afrozabidi@gmail.com
Contact: 09794979717

Centre Name: Dr. Ram Manohar Lohia Institute of Medical Sciences, Vibhuti Khand, Gomti Nagar, Lucknow-226010
Coordinator: Dr. Atul Jain
E-mail: drjainatul1@gmail.com
Contact: 08191915960 09829443449

Centre Name: Sorojini Naidu (S. N) Medical College, Moti Katra, Agra-282002
Coordinator: Dr. Mona Verma
E-mail: dпущupagr@tbcsindia.nic.in, pvpi.snmc@gmail.com, dпущupagr@rntcp.org
Contact: 09997024763

Centre Name: Teerthanker Mahaveer Medical College and Research Centre, N.H-24,Bagarpur, Delhi Road, Moradabad-244001
Coordinator: Dr. Prithpal Singh Matreja
E-mail: drpmsmatreja@yahoo.co.in
Contact: 09855001847

Centre Name: Yashoda Super Specialty Hospital, H-1, Kaushambi, Ghaziabad-201010
Coordinator: Dr. G. J Singh
E-mail: dr.sunil@yashodahospital.org
Contact: 09891957745

Centre Name: National Drug Dependence Treatment Centre, Sector-19, Kamla Nehru Nagar, C. G. O Complex, Ghaziabad-201002
Coordinator: Dr Rakesh Chadda, Dr Siddharth Sarkar (Dpy.Coorid)
E-mail: drrakeshchadda@gmail.com, sidsharkar22@gmail.com
Contact: 011-26593245, 3236, 09786022145

Centre Name: Government Medical College, Chakrapanpur, Azamgarh- 276127
Coordinator: Dr. Dhananjay Pandey
E-mail: sharanshakti18@gmail.com
Contact: 09415983721, 07311100000

Centre Name: Guru Shri Gorakhnath Chikitsalaya, Gorakhnath Mandir Campus, Gorakhpur- 273001
Coordinator: Dr. Jamai Haider
E-mail: jamal001@gmail.com
Contact: 09839828358

Centre Name: Mahamaya Rajkiya Allopathic Medical College, Sadaarpur, Post-Surapur, Tehsil - Tanda, District Ambedkar Nagar, Faizabad-224227
Coordinator: Reetesh Kumar Rai, Lecturer
E-mail: reetesh3@gmail.com
Contact: 08955581688

Centre Name: Combined District Hospital, Bhinga, Shrawasti-271831
Coordinator: Dr. Ved Prakash Sharma, (CMS)
E-mail: cmsswti@gmail.com
Contact: 09839770111

Centre Name: District Hospital, Basti-272001
Coordinator: Dr. Alok Shukla, (Superintendent-In-Chief)
E-mail: dlsthosbasti000@redifffmail.com
Contact: 08005192739

Centre Name: District Hospital, Bahraich, Gurunanak Chauraha, Hospital road, Bahraich-271801
Coordinator: Dr. Dinesh Kumar Singh (CMS)
E-mail: cmsbrh2015@gmail.com, cmsbrh@gmail.com
Contact: 09454455268, 09415036818

Centre Name: District Hospital (MALE), Pratapgarh-230001
Coordinator: Dr. Prem Mohan Gupta (CMS)
E-mail: cmsgdhp2016@gmail.com
Contact: 09415215422

Centre Name: Babu Ishwar Saran District Hospital, Gonda-271001
Coordinator: Dr. Umesh Singh Yadav (CMO)
E-mail: cmsgdo2015@gmail.com, cmogdo@yahoo.com
Contact: 08050611926

Centre Name: Combined District Hospital, Sant kabir Nagar-272375
Coordinator: Dr. G. C Srivastava (CMS)
E-mail: cmskrn@gmail.com
Contact: 08543903359
Uttarakhand

Centre Name: Government Medical College, Kalpi Road, Orai, Jalua-285001
Coordinator: Dr. S. P Singh, (Prof. & HOD)
E-mail: singhdrspgmail.com
Contact: 09415134744

Centre Name: Sonjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow-226014
Coordinator: Asso.Prof.(Dr.) Rajesh Harshvardhan,
E-mail: gs_anup@rediffmail.com
Contact: 05222495365 05222495361

West Bengal

Centre Name: School of Tropical Medicine, 108, Medical College Campus Chittaranjan Avenue, Kolkata-700073
Coordinator: Dr. Santanu Tripathi
E-mail: tripathi.santanu@gmail.com
Contact: 09230566771

Centre Name: R.G. Kar Medical College, 1, Kshudiram Bose Sarani, Kolkata-700073
Coordinator: Dr. Anjan Adhikari
E-mail: addrak.pharma@gmail.com
Contact: 09831012503

Centre Name: Calcutta National Medical College, Dr Sundari Mohan Ave, Beniapukur, Kolkata-700014
Coordinator: Dr. Sushobhan Pramanik
E-mail: sushobhan.pramanik@gmail.com
Contact: 09831155886

Centre Name: Institute of Postgraduate Medical Education & Research, 244B, A.J.C Bose Road, Kolkata-700020
Coordinator: Dr. Suparna Chatterjee
E-mail: drsupch@gmail.com
Contact: 09831130980, 033-22041428

Centre Name: Burdwan Medical college, Baburbag, P.O. Rajbati-Burdwan-713104
Coordinator: Dr. Sandip Mukhopadhyay
E-mail: sandippmcl@gmail.com
Contact: 09434042425

Centre Name: Bankura Sammilani Medical College, Kenduadihi, Bankura 722101
Coordinator: Dr. Ananya Mandal
E-mail: drananyamandal@gmail.com
Contact: 09674446226

Centre Name: Niliratan Sircar Medical College, Acharya Jagdish Chandra Bose Road, Kolkata-700014
Coordinator: Prof. Nina Das
E-mail: drninadas@yahoo.com
Contact: 09433165691

Centre Name: College of Medicine & J.N.M. Hospital, Kalyani, Nadia-741235
Coordinator: Dr. Abhishek Ghosh
E-mail: drghosh.new@gmail.com , principal.cominmh.kalyani@gmail.com
Contact: 09836557042

Centre Name: Murshidabad Medical College & Hospital, Berhampore-742101
Coordinator: Dr. Mainak Ghosh
E-mail: docmainak@gmail.com
Contact: 09007924708
Centre Name: Midnapore Medical College & Hospital, Vidyasagar Road, Paschim Medinipur-721101
Coordinator: Dr. Balaram Ghosh, Dr. Souvik Ghosh
E-mail: drbrghosh@gmail.com, amc.mmch@gmail.com, souvik_ghosh78@yahoo.co.in
Contact: 09800442964, 0322-2222411, 09434183061

Centre Name: ICARE Institute of Medical Sciences & Research and Dr. Bidhan Chandra Roy Hospital, Banbhnupur, Balughata, Haldia, Dist.- Purba, Medinipur-721645
Coordinator: Dr. Sukanta Sen
E-mail: drsukam@gmail.com
Contact: 08420532336

Centre Name: Glocal Group of Hospitals, Ecospace Business Park, Action Area II, New Town, Rajarhat, Kolkata- 700156
Coordinator: Dr. Aniruddha Mukherjee, (Director, Clinical)
E-mail: anirudh.mukherjee@ghspl.com, dr.a.m.1962@gmail.com
Contact: 08017991135

Union Territory-Centre Name
Andaman & Nicobar
Centre Name: Andaman & Nicobar Islands Institute of Medical Sciences, Port Blair-744104
Coordinator: Dr. Mangesh Bankar
E-mail: drmangesh_bankar@yahoo.co.in
Contact: 09521858830

Chandigarh
Centre Name: PGIMER, Sector12, Chandigarh-160012
Status of AMC: COEART Centre
Coordinator: Dr. Bikash Medhi
E-mail: dbvikash@yahoo.com
Contact: 09914207510

Delhi
Centre Name: All India Institute of Medical Sciences (AIIMS), Ansari Nagar East, Gautam Nagar, New Delhi - 110029
Coordinator: Dr. Pooja Gupta
E-mail: drgupta.pooja@gmail.com, pvpi.ncc@gmail.com
Contact: 

Centre Name: Indraprastha Apollo Hospital, Mathura Road, Sarita Vihar, New Delhi - 110044
Coordinator: Dr. Sanjeev Sharma
E-mail: drsanjeev_sharma@apollopharmacy.org, sanjeevsham@yahoo.co.uk
Contact: 09908430005

Centre Name: Lady Harding Medical College (LHMC), C 604, Shivaji Stadium Bus Terminal Co. Place Shaheed Bhagat Singh Marg, New Delhi-110001
Coordinator: Dr. H.S. Rehan
E-mail: harmeetrehan@hotmail.com
Contact: 09811694040

Centre Name: University College of Medical Sciences, adjacent to GTB Hospital, Dilshad Garden, New Delhi - 110095
Coordinator: Dr. Rachna Gupta
E-mail: drrrachna1@rediffmail.com
Contact: 09868614063

Centre Name: Vallabhbhai Patel Chest Institute (VPCI), University of Delhi, Guru Tegh Bhadur Road, New Delhi - 110007
Coordinator: Dr. Kavita Gultati
E-mail: kavgultat2002@yahoo.com
Contact: 09899233085

Centre Name: VMMC & Safdarjung Hospital, Mahatma Gandhi Marg, Raj Nagar, Safdarjung, New Delhi – 110029
Coordinator: Dr. C.D. Tripathi
E-mail: cdttripathi@gmail.com
Contact: 09818665424

Centre Name: Hamdard Institute of Medical Sciences and Research, Hamdard Nagar, New Delhi -110062
Coordinator: Dr. Nilanjan Saha
E-mail: nilanjan.saha@jamiahamdard.ac.in
Contact: 09873013366

Centre Name: Maulana Azad Medical College and associated Lok Nayak, Govind Ballabh Pant Hospital & Guru Nanak Eye Centre, 2, B.S.Z. Marg, New Delhi - 110002
Coordinator: Dr. Vandana Roy
E-mail: roy.vandana@gmail.com
Contact: 09968604283

Centre Name: Rajan Babu Institute of Pulmonary Medicine and Tuberculosis, GTB Nagar, Kingsway Camp, New Delhi-110009
Coordinator: Dr. Anuj Bhatnagar
E-mail: anuj1968@gmail.com
Contact: 09818321353

Centre Name: National Institute of Tuberculosis and Respiratory disease (Lala Ram Sarup Institute of Tuberculosis And Respiratory Diseases) Sri Aurobindo Marg, (Near Qutab Minar), New Delhi-110030
Coordinator: Dr. Rohit Sarin
E-mail: drsarin@yahoo.com, rsarin@nitrd.nic.in, dr.khaliduk@yahoo.com
Contact: 09999971557
**Centre Name:** Institute of Liver and Biliary Sciences, D-1, Vasant Kunj, New Delhi-110070  
**Coordinator:** Dr. Kishore Singh /Dr. Shastry  
**E-mail:** kishore110092@yahoo.com  
**Contact:** 09540947006

**Centre Name:** North Delhi Municipal Corporation Medical College and Hindu Rao Hospital, Malka Ganj, Delhi-110007  
**Coordinator:** Asst.Prof.(Dr.) Yangshen Lhamo  
**E-mail:** yangshenlhamo@yahoo.com  
**Contact:** 09654833513

---

**Puducherry**

**Centre Name:** Indira Gandhi Medical College & Research Institute, Kadirkamam-605009  
**Coordinator:** Dr. Lourdu Jafirn. A , Dr. Priyadarshini R (Asso.Coord)  
**E-mail:** hiweddz@gmail.com, shalipriya85@gmail.com, adriqmcrl@gmail.com  
**Contact:** 09943732717, 09943491252

**Centre Name:** Jawaharlal Institute of Postgraduate Medical Education & Research, Dhanvantri Nagar, Gorimedu-605006  
**Coordinator:** Dr. S. Sandhiya  
**E-mail:** sandhiyaselvarajan@gmail.com  
**Contact:** 09443492922

**Centre Name:** Pondicherry Institute of Medical Sciences, Ganapathichettikulam, Kalapet, Pondicherry-605014  
**Coordinator:** Dr. Manjunatha C H  
**E-mail:** pharmacovigilance@pimsmmm.net,  
**Contact:** 09629352078
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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

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

World Health Organization

For any Other Information/Suggestions/ Query contact:
Officer In-charge Pharmacovigilance Programme of India
Email: ipclab@vsnl.net, pvpi@ipcindia.net
Website: www.ipc.gov.in