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NCC-PvPI IPC

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ADR PvPI Mobile-app

pvpi.ipc@gov.in

Indian Pharmacopoeia Commission
National Coordination Centre,
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare, Govt. of India,
Sector-23, Raj Nagar, Ghaziabad- 201002
Tel.: 0120-2783400, 2783401, 2783392
Fax: 0120-2783311

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

let us join hands with PvPI to ensure patient safety

ADR reporting Helpline (Toll Free): 1800-180-3024

Pharmacovigilance Programme of India (PvPI)

Performance Report
2016-17

Pharmacovigilance Programme of India (PvPI)

Performance Report 2016-17

INDIAN PHARMACOPOEIA COMMISSION
MINISTRY OF HEALTH & FAMILY WELFARE, GOVT. OF INDIA
SECTOR-23, RAJ NAGAR, GHAZIABAD - 201002

INDEX

ABBREVIATIONS

ADR	Adverse Drug Reaction
AE	Adverse Event
AEFI	Adverse Event Following Immunization
AIDS	Acquired Immune Deficiency Syndrome
AIIMS	All India Institute of Medical Sciences
AMC	Adverse Drug Reaction Monitoring Centre
ART	Anti-retroviral Therapy
CDSCO	Central Drugs Standard Control Organization
CIOMS	Council for International Organization for Medical Sciences
CMC	Christian Medical College
CME	Continuous Medical Education
CTP	Core Training Panel
DCG(I)	Drugs Controller General (India)
DOTS	Directly Observed Treatment-Short course
FDC	Fixed Dose Combination
FIR	First Information Report
GVP	Good Pharmacovigilance Practice
HCP	Healthcare Professional
HIV	Human Immunodeficiency Virus
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICSR	Individual Case Safety Report
IC	Information Component
IMA	Indian Medical Association
IPC	Indian Pharmacopoeia Commission
ISOP	International Society of Pharmacovigilance
KAP	Knowledge, Attitude and Practice
LoI	Letter of Intent

ABBREVIATIONS

MCI	Medical Council of India
MedDRA	Medical Dictionary for Regulatory Activities
MoHFW	Ministry of Health and Family Welfare
MoU	Memorandum of Understanding
NABH	National Accreditation Board for Hospitals & Healthcare Providers
NACO	National AIDS Control Organization
NCC	National Coordination Centre
NHP	National Health Programme
NRA	National Regulatory Authority
PGIMER	Post Graduate Institute of Medical Education and Research
Pv	Pharmacovigilance
PvPI	Pharmacovigilance Programme of India
QA-QC	Quality Assurance/Quality Control
RNTCP	Revised National Tuberculosis Control Programme
SAE	Serious Adverse Reaction
SRP	Signal Review Panel
UIP	Universal Immunization programme
WHO-ART	World Health Organisation-Adverse Reactions Terminology
WHO-DD	World Health Organisation-Drug Dictionary
WHO-UMC	World Health Organisation-Uppsala Monitoring Centre

FROM THE DESK OF SECRETARY-CUM-SCIENTIFIC DIRECTOR

The release of the Annual Performance Report of the Pharmacovigilance Programme of India (PvPI) for the Index Period 2016-17 enthuses me inasmuch as the new milestones have been laid by establishing a sustainable network of Adverse drug-reaction Monitoring Centres (AMCs) pan-India. Equally encouraging has been the progress made by spontaneous ADR-reporting, scientific collation and quality analysis of these reports, all aimed at meticulous safeguard of public health by ensuring drug safety for mass consumption.

As many as eight new AMCs have been set up during the Index Period, extending PvPI's outreach to the remotest corners of the country, including the northeast. The 210-strong nationwide AMC base provides access to Pharmacovigilance (Pv) and allied activity for patient safety to public and healthcare. During the Index Period i.e. April 2016–March 2017, the NCC-PvPI received 67,328 Individual Case Safety Reports (ICSRs), contributing in an appreciable measure to the global drug-safety database of WHO's International Drug Monitoring Programme.

Another salient feature of the Index Period has been the progressive fruition of PvPI's 'Skill Development' programme which aims at hands-on training of all stakeholders, including the pharma sector, for imbibing the values of pharmacovigilance and carrying out by standardized scientific methods and tools Pv practices to ensure drug safety for the Indian populace.

Another noteworthy development for NCC-PvPI during the Index Period has been in the sphere of Medical Devices Adverse Events Monitoring under the purview of Materiovigilance Programme of India (MvPI). For effective management of MvPI, the PvPI with its expertise and oversight has been handed the additional responsibility of monitoring and mentoring MvPI.

A landmark achievement during the Index Period has been the declaration of the Pharmacovigilance system of India as **'functional with a maturity level of 4 out of 5'** by WHO-NRA Global Benchmarking Tool (GBT). Such an international recognition is a matter of pride for me – personally and professionally.

In a major breakthrough, IPC has signed a Memorandum of Understanding (MoU) with National Accreditation Board for Hospitals and Healthcare Providers (NABH). The MoU is aimed at promotion of monitoring and reporting of ADRs by NABH-accredited hospitals to the PvPI.

The Index Period saw efforts being redoubled for the elimination of Kala-azar with enhanced cooperation between PvPI, National Vector-Borne Disease Control Programme (NVBDCP) and WHO to end the menace of this deadly disease which is at present endemic to 54 districts in the country.

I express my gratitude to the PvPI for its research and evidence-based efforts to strengthen the bond of Pharmacovigilance among all healthcare stakeholders to the eventual benefit of the common man.

Dr G N Singh
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
Ghaziabad

HIGHLIGHTS


Highlights of the Year
NCC-PvPI collaborates with Indian Council of Medical Research (ICMR) and Medical Council of India (MCI)
NRA Assessment completed successfully
Skill Development Programme: An initiative for capacity building in Pharmacovigilance
Collaboration with NABH
MoU with National Vector-Borne Disease Control Programme
Reporting of Adverse Events due to Medical Devices is now PvPI's duty
Active Surveillance for Bedaquiline begins at PvPI

Pharmacovigilance Programme of India (PvPI)

GENESIS

Adverse drug reactions (ADRs) are one of the leading causes of morbidity and mortality worldwide. The consequences of ADRs burden the healthcare system with cost of therapy and hospitalization. It is, therefore, imperative to evaluate the safety of medicines by specialized methods like Pharmacovigilance.

The World Health Organization (WHO) defines Pharmacovigilance as the science and activities related to detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. During the last decade, safety monitoring of medicines has gained global momentum by evolving various systems for monitoring adverse drug reactions.

The Pharmacovigilance Programme of India (PvPI) was initiated in July 2010 by the Central Drugs Standard Control Organisation (CDSCO) -- under the aegis of Ministry of Health and Family Welfare (MoHFW) -- with All India Institute of Medical Sciences (AIIMS), New Delhi, as the National Coordination Centre (NCC) for Pharmacovigilance. On April 15, 2011, the NCC was shifted from AIIMS to Indian Pharmacopoeia Commission (IPC). IPC is an autonomous institution of the MoHFW, Government of India (GOI), and functions as the National Coordination Centre (NCC) for PvPI. The year also saw enrolment of 22 Adverse Drug Reaction Monitoring Centres (AMCs) across the country.

With phase-wise addition of AMCs the number of ADR Monitoring Centres increased from 22 in 2011 to 210 in March 2016. These 210 AMCs include 21 Revised National Tuberculosis Control Programme (RNTCP) centres and 20 Anti-Retroviral Therapy (ART) centres for AIDS control. The 21 RNTCP centres include six Bedaquiline centres, too.

MISSION

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

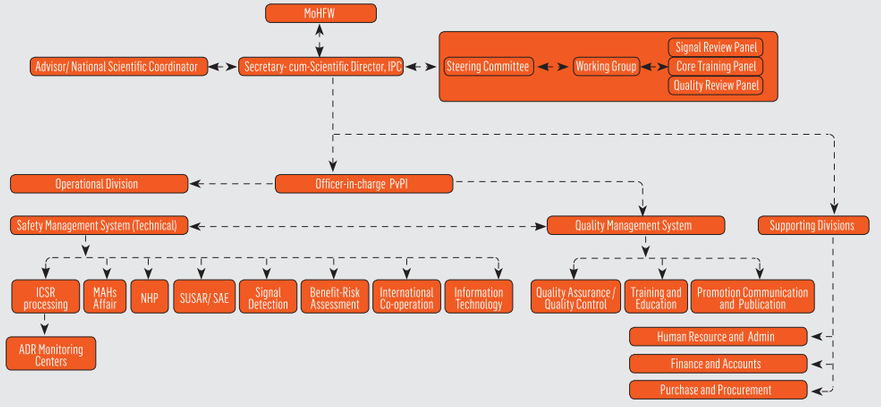
VISION

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

SCOPE AND OBJECTIVES

- To create a nation-wide system for patient-safety reporting
- To identify and analyse new signals from the reported cases
- To analyse the benefit-risk ratio of marketed medicine
- To generate evidence-based information on safety of medicine
- To support regulatory agencies in the decision-making process on use of medicine
- To communicate to various stakeholders the safety information on use of medicine so as to prevent/minimise the risk
- To emerge as a National Centre of Excellence for Pharmacovigilance
- To collaborate with other national centres for exchange of information and data management
- To provide training and consultancy support to other National Pharmacovigilance Centres across the globe
- To promote rational use of medicine

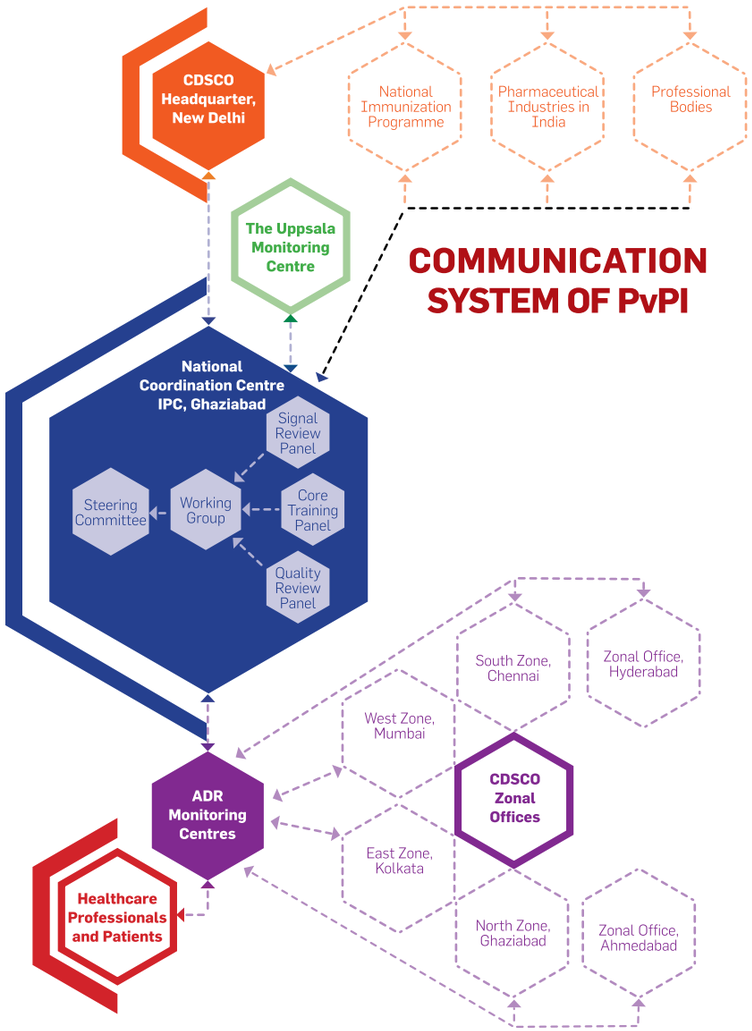
ORGANOGRAM OF NATIONAL COORDINATION CENTRE
PHARMACOVIGILANCE PROGRAMME OF INDIA (NCC-PvPI)



PvPI OVERVIEW

PVPI COMMUNICATIONS

Effective communication channels are key to successful functioning of an organization. The use of information/communication technology at NCC-PvPI and across the 210 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:



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 (SRP)

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. This panel assesses the results of computerized assessment of ICSRs for identification of potential signals from ICSRs. 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 (CTP)

The Core Training Panel (CTP) of PvPI organizes training programmes, designs training modules and conducts the training for healthcare professionals and other stakeholders. It also identifies trainers for zone-wise training centres. The CTP interacts with international agencies for participation and implementation of training programmes in Pharmacovigilance.

Channels of ADR-reporting to PvPI

Who can Report ADRs?

All healthcare professionals and others, including consumers, may report a suspected adverse drug reaction. Pharmaceutical companies may send to NCC-PvPI Individual Case Safety Reports (ICSRs) specific to their product.

PvPI OVERVIEW

Why to Report?

ADR reporting is vital to ensuring safety of patients taking medicines. The occurrence of adverse drug reactions (ADRs) needs to be reduced to a bare minimum as the risks associated with use of medicine constitute a significant economic burden on the patient, society and the nation at large. It is the primary responsibility of a vigilant healthcare professional (HCP) to report ADRs associated with use of medicines to safeguard the health of patients. India has a vast population with genetic and ethnic variability, hence a sizeable variation in disease prevalence, too. Also the use of multiple systems of medicine such as homeopathy, ayurveda, siddha and unani, etc, coupled with poor patient compliance are other contributory factors that mandate ADR-reporting due to use of these medicines. The data so generated helps make vital policy decisions regarding safe use of medicines among the Indian populace.

What to Report?

To foster the culture of reporting, PvPI encourages reporting of all types of suspected ADRs irrespective of whether they are known or unknown, serious or non-serious, frequent or rare and regardless of an established causal relationship. Although pharmacovigilance is primarily concerned with pharmaceutical drugs and vaccines, adverse reactions associated with use of traditional medicines such as herbal remedies, medical devices, contrast media and other pharmaceuticals are also monitored. Special areas of interest include the outcome associated with use of medicines during pregnancy, lactation, and in paediatric and geriatric population. Reporting is also recommended in cases where efficacy of medicines is suspect. It is also recommended to report suspected pharmaceutical inadequacies. Reporting of ADRs encountered with overdose, abuse, off-label use, misuse or occupational exposure is not currently included in the purview of PvPI.

How and Whom to Report?

All healthcare professionals, including clinicians, dentists, pharmacists, nurses, etc, can report suspected ADRs using the Suspected Adverse Drug Reaction Reporting Form. Pharmaceutical companies can use this form to send their Individual Case Safety Reports (ICSRs) specific for their product to the NCC-PvPI. The form is available on the official website of IPC (http://www.ipc.gov.in/PvPI/ ADRReportingForm.pdf) or the CDSCO (http://www.cdsco.nic.in).

Reporters are required to fill the Suspected Adverse Drug Reaction Reporting Form to report any suspected ADR. They may submit the ADR form to the nearest AMC or directly to NCC-PvPI or mail the form at pvpi.ipcindia@gmail.com.

Helpline (1800-180-3024)

Patients/Consumers/Healthcare Professionals may report suspected ADRs associated with use of medicinal products to NCC-PvPI from 9.00 am to 5.30 pm on weekdays via tollfree helpline **1800-180-3024**. An SMS acknowledgement facility has been introduced to acknowledge the valuable contribution by the reporter to the Programme, and encourage them to continue reporting ADRs.

Medicines' Side-Effect Reporting Form (For Consumers)

The Medicines' Side-Effect Reporting Form (For Consumers) ensures the direct participation of patient/consumer in PvPI. The form is at present available in 10 local languages, including Hindi, Bengali, Gujarati, Kannada, Malayalam, Marathi, Assamese, Oriya, Tamil and Telugu. ADR-reporting by consumers is a mechanism for consumer empowerment in healthcare sector.

Establishment of Adverse Drug Reaction Monitoring Centres (AMCs) under PvPI

PvPI encourages all government and non-government teaching, private, district and corporate hospitals to participate in this nationwide safety programme. Medical institutions and hospitals play a major role in both teaching and providing specialized services to patients in India. Patient safety is one of their major concerns. AMCs play a crucial role in monitoring of ADRs. 'Letter of Intent' (LoI) is required from the Head of the Institution for establishment of an AMC under PvPI. After examining the suitability, the centre concerned may be inducted as an AMC under PvPI. Subsequently, NCC communicates the details of the AMC to WHO-Uppsala Monitoring Centre (UMC), Sweden, to obtain VigiFlow® login details for submission of the ADRs. The format of LoI is available on the IPC website (www.ipc.gov.in). Alternatively, an email in this regard can be sent to PvPI at pvpi@ipcindia.net or pvpi.ipcindia@gmail.com.

The centre requesting to be inducted as an AMC is required to fulfil the following criteria:

a) It is essential for the centre to function with their own logistic and infrastructural facilities. The NCC-PvPI, IPC may provide the trained manpower, if the performance of AMC is found satisfactory.

b) The proposal may be accepted based on the significant track record of the centre in Pharmacovigilance; on the quality, quantity and frequency of Adverse Drug Reaction (ADR) reports reported directly to NCC or nearby AMCs during the past one year from the date of the said proposal.

c) Preference will be given to applications from States where no/few AMCs exist.

d) Significant track record/expertise of the proposed coordinator/deputy coordinator in the area of Pharmacovigilance.

e) The HOD/Dean/Principal of the proposed centre shall be responsible to establish/implement the PvPI activities at the centre.

f) The HOD/Dean/Principal of the institute shall be responsible for identifying new coordinator & deputy coordinator and intimating the same to NCC-PvPI in case of any change of the existing coordinator/deputy coordinator (transfer /superannuation etc).

Upon recognition, NCC-PvPI provides the regular training, skill development & technical support to the personnel engaged in PvPI activities at the AMC.

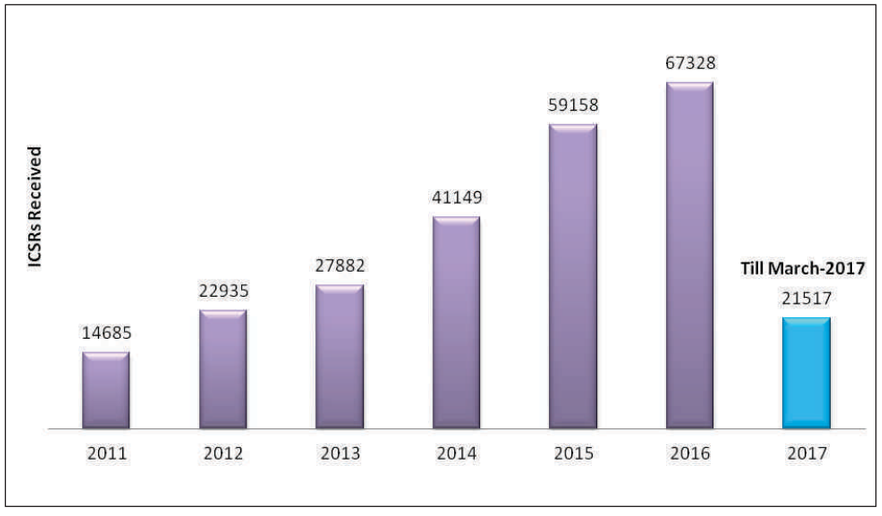
Six-Year Data of ADR Reporting

Spontaneous adverse drug reaction (ADR) reporting is the mainstay of Indian drug safety evaluation in the post-approval phase. A total 2,54,654 spontaneous reports were received at NCC-PvPI during the six-year period between January 2011 and March 2017 from various sources i.e. AMCs, non-AMCs, tollfree helpline, mobile application, etc.

ICSR DATA REPORTED IN LAST SIX YEARS

The year-wise status of reporting Individual Case Safety Reports (ICSRs) for the last six years is illustrated in Figure 1. A progressive increase in the number of reports is evident, with a near three-fold leap in the calendar year 2016 compared to the corresponding period in 2012.

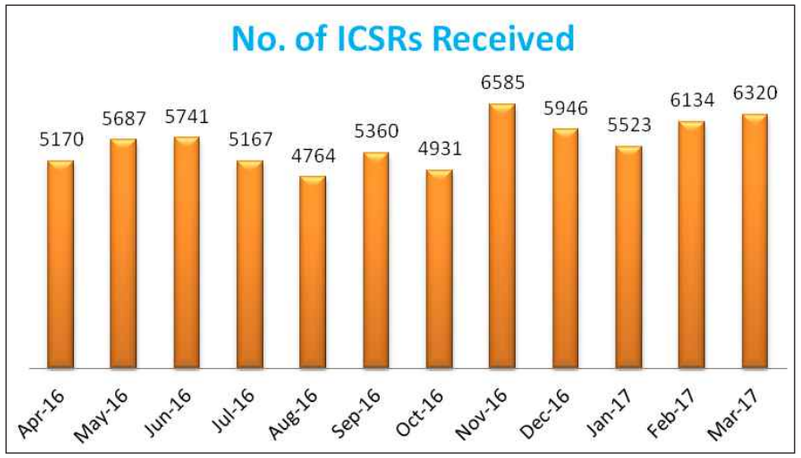
Fig 1: Individual Case Safety Reports (ICSRs) reported in past six years



Month-wise distribution of ICSRs for 2016-17

During the Index Period i.e. April 2016-March 2017, NCC-PvPI received 67,328 reports. Figure 2 illustrates the month-wise distribution of the ICSRs received at NCC-PvPI. It is evident that ICSR-reporting was well sustained throughout the year.

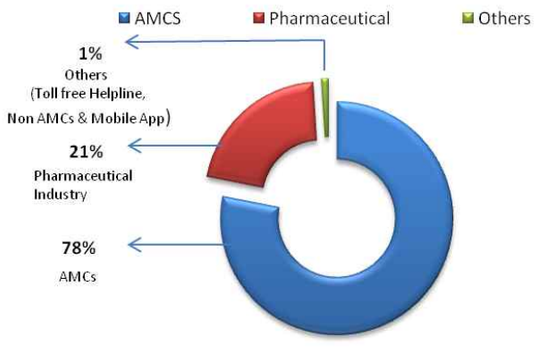
Fig 2: Month-wise distribution of ICSRs



SENDER-WISE DISTRIBUTION

Fig 3 illustrates the distribution of reports received during the index period. As many as 78% reports were received from the ADR monitoring centres (AMCs) functioning under PvPI, while the Pharma industry reported 21% and other sources 1% of the reports.

Fig 3: Sources of ICSRs received at NCC-PvPI (2016-17)

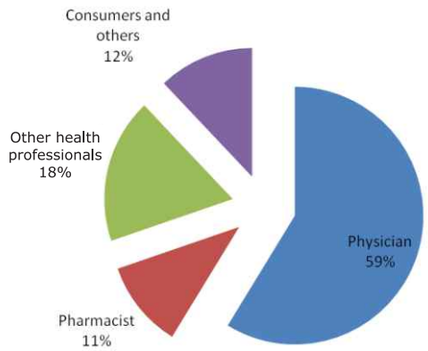


STATUS OF ADR REPORTING

REPORTER-WISE DISTRIBUTION OF ICSRs

The NCC-PvPI receives ICSRs from various stakeholders such as physicians, pharmacists, other HCPs, consumers (non-HCPs), etc. Spontaneous ADR reports from physicians (59%) continued to be the major source of reports received, followed by other healthcare professionals (18%), pharmacists (11%) and consumers and others (12%).

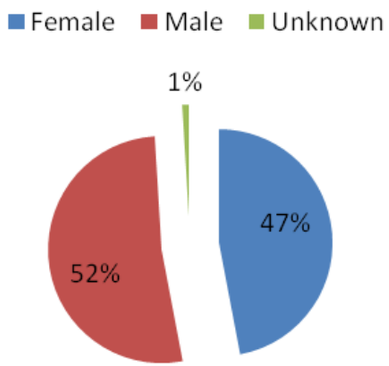
Fig 4: Reporter-wise Distribution of ICSRs received at NCC-PvPI (2016-17)



GENDER-WISE DISTRIBUTION OF ICSRs

Analysis of the ADR forms recived during the index period showed that 52% ADRs occurred in male patients and 47% ADRs were reported in female patients. No information about the gender of the patient was provided in 1% of ADR reports.

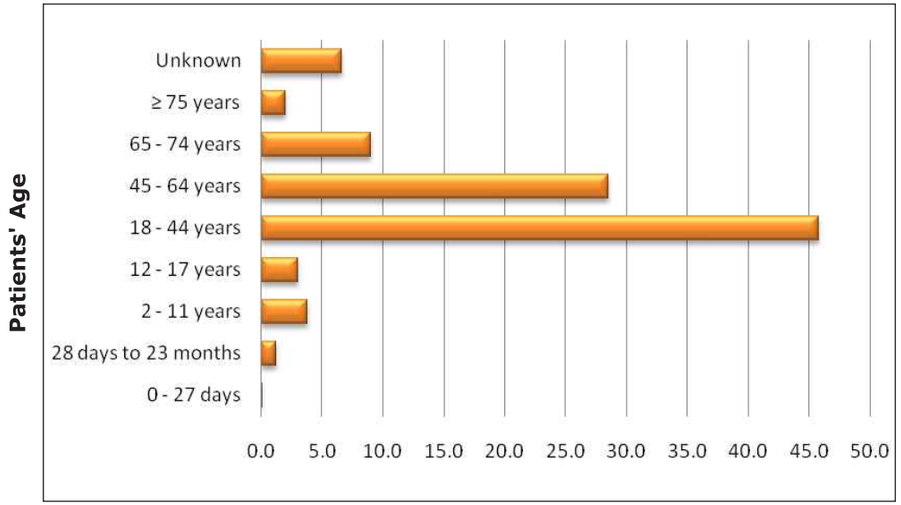
Fig 5: Gender-wise Distribution of ICSRs received at NCC-PvPI (2016-17)



AGE-WISE DISTRIBUTION OF ICSRs

Analysis of the ICSRs recived at PvPI showed that the majority of ADRs reported occurred in patients aged 18-44 years.

Fig 6: Age-wise Distribution of ICSRs received at NCC-PvPI (2016-17)

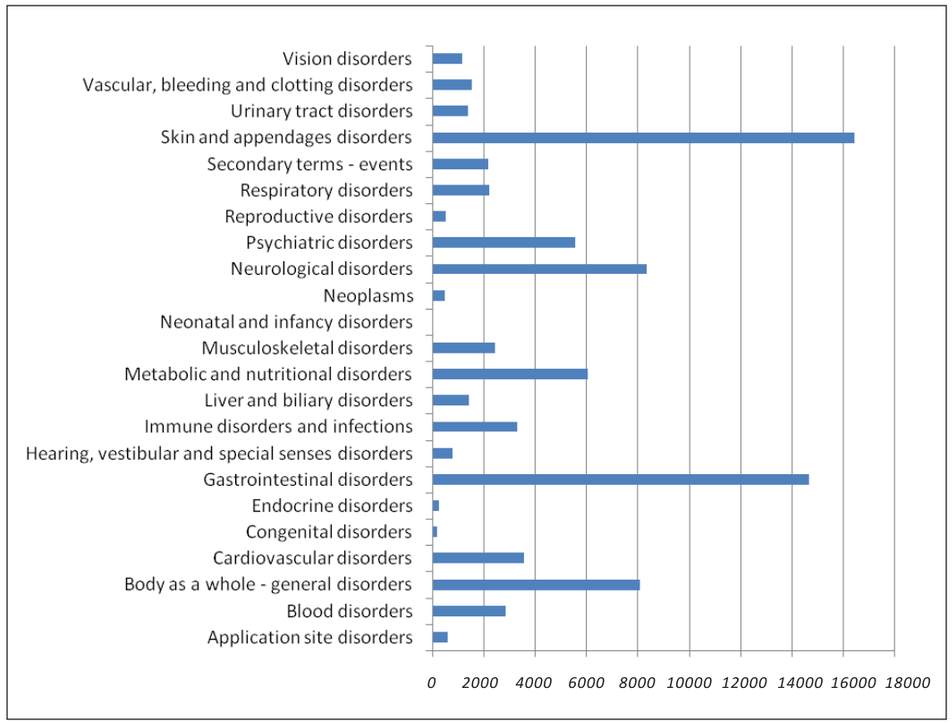


STATUS OF ADR REPORTING

SYSTEM ORGAN CLASS (SOC)-WISE DISTRIBUTION OF ADRS

The reported ADRs included a wide spectrum of clinical manifestations, which are summarized on the basis of WHO Adverse Reaction Terminology (WHO-ART) System Organ Class (SOC) i.e. the majority of the ADRs were reported in skin and appendages, gastrointestinal and neurological disorders as illustrated in the Fig 7.

Fig 7. System Organ Class (SOC) of ADRs reported during the Index Period (2016-17)



MODES OF ADR REPORTING

YARDSTICKS FOR ADR-REPORTING

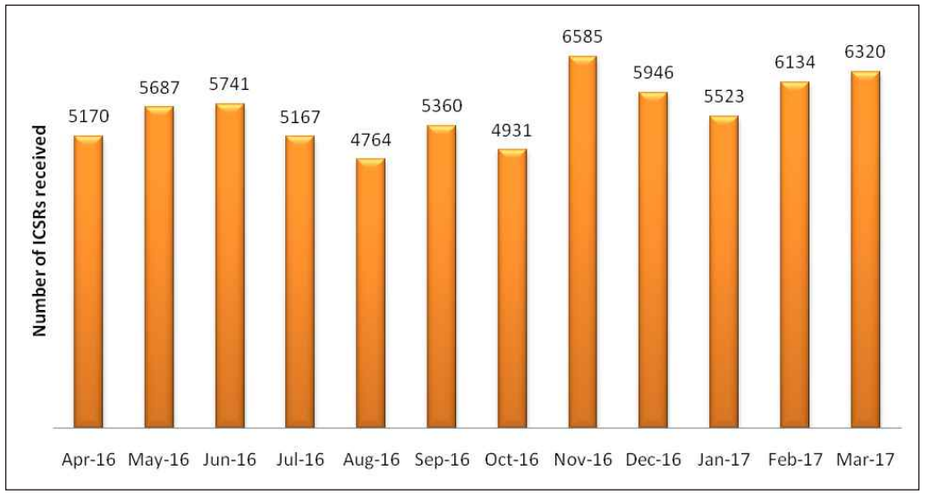
The reporting of ADRs under PvPI is classified on the basis of the mode of reporting as follows:

1. Reporting by AMCs through VigiFlow®
2. Reporting by the Pharma industry
3. Reporting through tollfree helpline
4. Reporting by non-AMCs

1. REPORTING BY AMCS THROUGH VIGIFLOW®

As many as 210 medical colleges and hospitals, State/Central/autonomous institutes, public health programmes and corporate hospitals enrolled under PvPI have been functioning as AMCs (up to March 2017). As mentioned earlier the major contribution of the ICSRs -- 78% of the total ADRs reported during the Index Period -- was by the AMCs enrolled under PvPI.

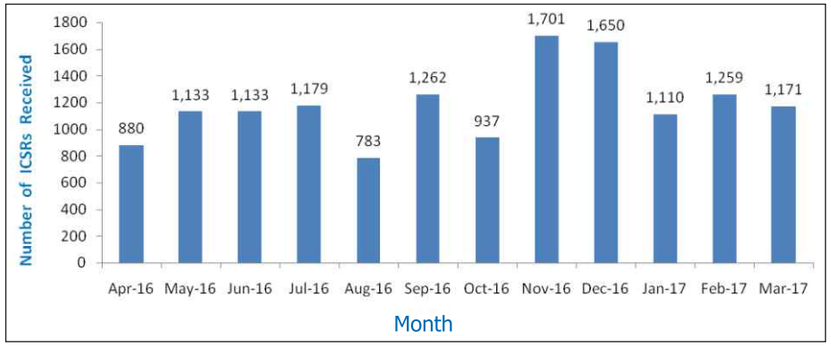
Fig 8. Month-wise distribution of ICSRs received from AMCs at NCC-PvPI (2016-17)



2. REPORTING BY THE PHARMACEUTICAL INDUSTRY

ADR reporting to NCC-PvPI by the Pharmaceutical industry has been a voluntary process as the Pharma industry is a major stakeholder in Pharmacovigilance. In order to deliberate upon challenges and issues facing Marketing Authorization Holders (MAHs), the PvPI has conducted several meetings which have resulted in an increase in reporting by MAHs.

Fig 9. Pharmaceutical Industries' ICSR Reporting Status to NCC-PvPI

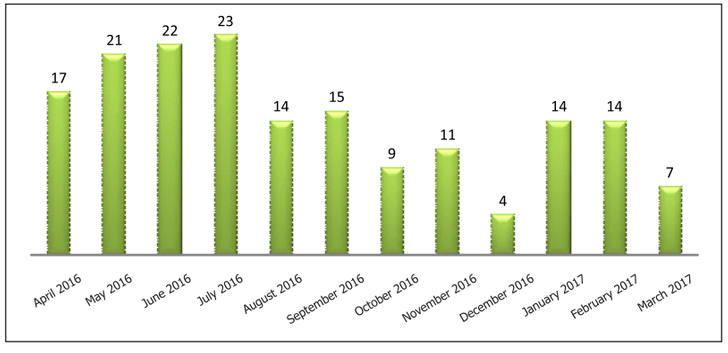


3. REPORTING THROUGH TOLLFREE HELPLINE

Following the initiation of tollfree 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 inserted into IPD and OPD prescription slips at hospitals like IGIMS, Patna and AIIMS, Patna. Calls are primarily responded to in English and Hindi on all working days between 09:00 am and 05.30 pm.

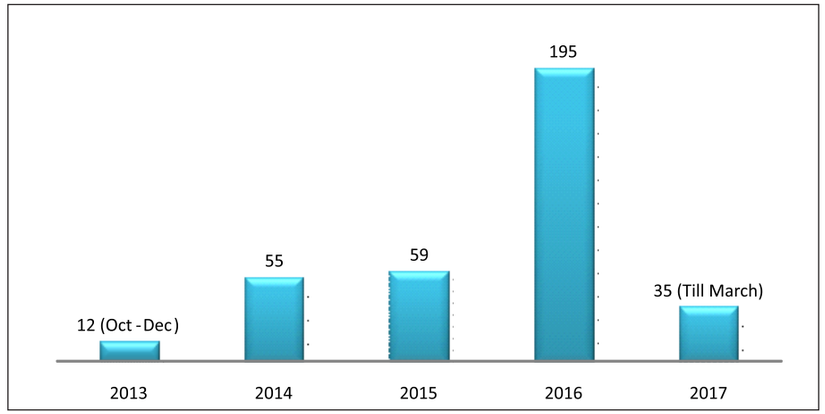
As many as 171 ADRs were reported through tollfree helpline during the Index Period, marking a significant increase over the previous index period (Figure 10).

Fig 10. ADRs reported on Tollfree Helpline (2016-17)



There has been an appreciable response in reporting by consumers ever since the installation of tollfree Helpline. Figure 11 depicts the steady increase in ADR reporting via tollfree helpline.

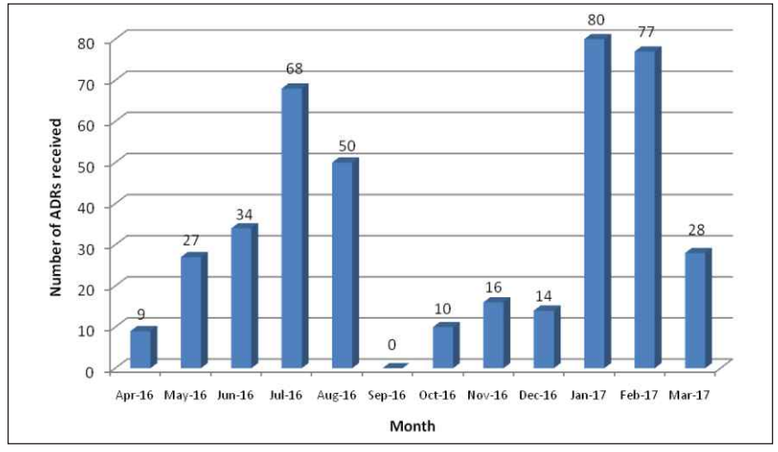
Fig 11. ADRs reported via tollfree Helpline



4. REPORTING BY THE NON-AMCS

Non-AMCs are medical colleges and hospitals, State/Central/autonomous institutes or corporate hospitals which are not enrolled under PvPI as AMCs. Reports are being received from the non-AMCs via post or email.

Fig. 12 ADRs Reported by Non-AMCs



MODES OF ADR REPORTING

5. INDIAN MOBILE APP FOR ADVERSE DRUG REACTION REPORTING AND PHARMACOVIGILANCE

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

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

Main features:

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

Fig.13. ADR Reporting Mobile Application for Android Phones

AEFI SURVEILLANCE SYSTEM AT PvPI

Adverse Event Following Immunization (AEFI) is defined as a medical event that takes place following immunization, causes concern and is believed to be caused by immunization. AEFI surveillance monitors immunization safety, detects and responds to adverse events, corrects unsafe immunization practices, reduces the negative impact of the event on health and contributes to the quality of immunization activities.

COLLABORATION OF PvPI WITH AEFI PROGRAMME (UIP-ITSU)

People's expectations of vaccine safety are high, and they are reluctant to countenance even a small risk of adverse events. Hence, vaccines safety requires AEFI Surveillance Systems for safe monitoring of vaccines used within a national immunization programme. Indian Pharmacopoeia Commission, Ghaziabad as the National Coordinating Centre for Pharmacovigilance Programme of India (PvPI) has been in collaboration with AEFI Programme since February 28, 2013, monitoring the safety of vaccines. PvPI provides technical and operational support to AEFI division of MoHFW in vaccine safety monitoring.

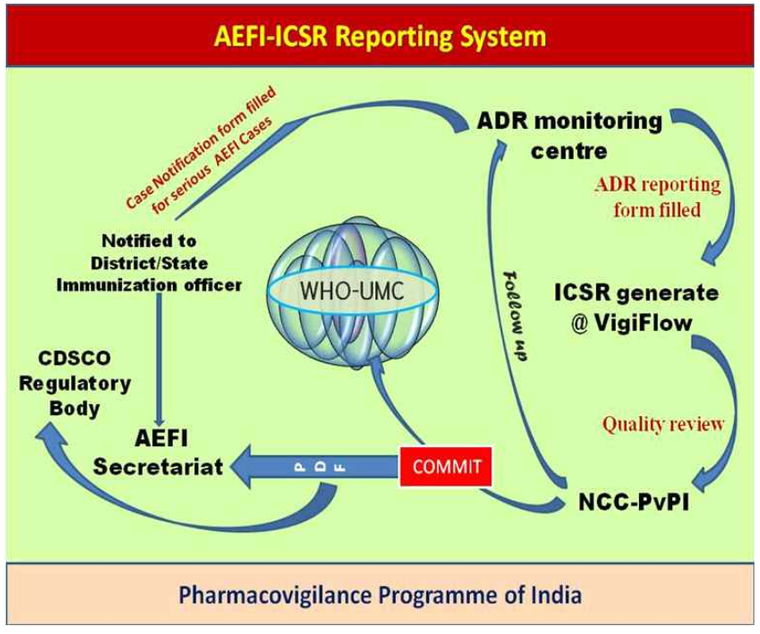
Roles and responsibilities of partners in ensuring vaccine safety for effective communication have been designed as follows:

Partners Roles and Responsibilities in Ensuring Vaccines Safety

Indian Pharmacopoeia Commission National Coordination centre-Pharmacovigilance Programme of India (NCC-PvPI)	Adverse Event Following Immunization (AEFI) Secretariat	Central Drugs Standard Control Organization (CDSCO)
1. To monitor, report, collate and analyse adverse events due to medicine & vaccines.	1. Responsible to coordinate with NCC-PvPI for the management of AEFI-ICSRs.	1. To ensure safety, efficacy & quality standards of pharmaceuticals, medical devices & vaccines.
2. AMCs shall be responsible to monitor & reporting of adverse events to NCC-PvPI and also share AEFI-ICSRs with DIO & SEPIO.	2. Responsible to coordinate with respective AMC and concerned Zonal Consultant for further follow up with SEPIO/DIO.	2. Regulatory actions are incite by CDSCO in case quality of implicated vaccines to be responsible for adverse events.
3. NCC-PvPI shall be responsible to share AEFI-ICSRs with AEFI Secretariat & CDSCO.	3. To perform causality assessment of AEFI cases.	3. Enforcement and site inspection where the AEFI occurred.
4. Communication of vaccines signals to AEFI secretariat.	4. To share reported AEFIs with CDSCO.	4. Responsible for taking appropriate regulatory decisions.

AEFI-ICSR Reporting System @ PvPI

PvPI shares the data of adverse event following vaccination reported to it by ADR Monitoring Centres (AMCs) across India, with (i) AEFI Secretariat (UIP, MoHFW) and (ii) Central Drugs Standard Control Organization (CDSCO). Medical colleges and hospitals are the cornerstone for reporting ADRs to PvPI. As AMCs they are responsible for collecting the reports and performing the follow-up to obtain necessary supplementary detailed information for scientific evaluation of the cases. The contact details of the State Expanded Programme Immunization Officer (SEPIO)/District Immunization Officer (DIO) are shared with the respective AMCs for better coordination at state/district level.



Processing and Communication of AEFI-ICSRs:

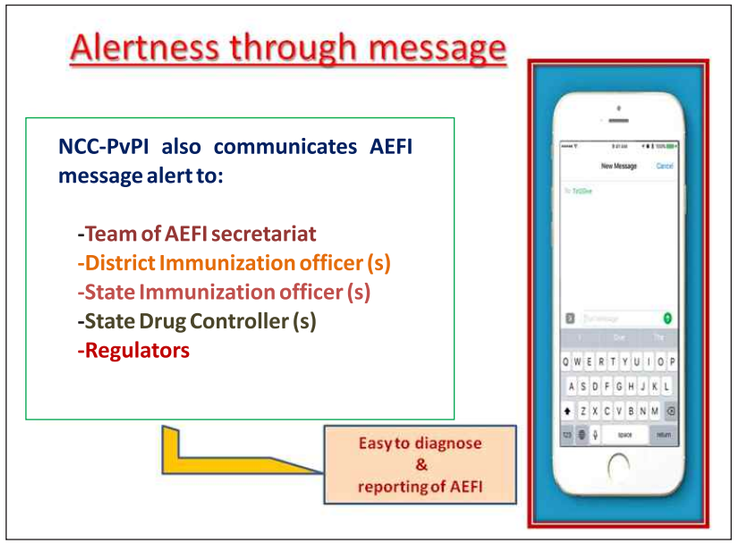
PvPI has revised its Standard Operating Procedure (SOP) for processing and communication of AEFI-ICSRs. The revised SOP includes the **"Serious AEFI Case Notification Form"** which shall be filled with "suspected ADR reporting form" for reporting of Serious AEFI which shall be notified to the DIO of the district where the vaccine was administered. This duly filled form is scanned and emailed simultaneously to SEPIO, NCC-PvPI and the AEFI Secretariat.

Serious AEFI Case Notification Form

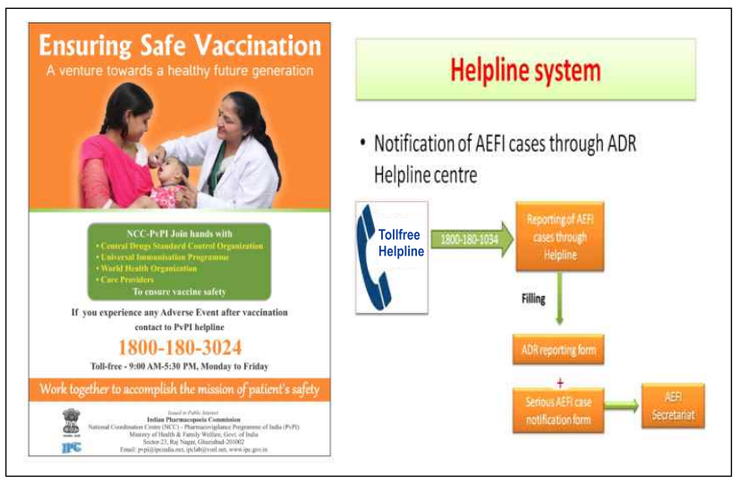
Serious AEFI Case Notification Form – ADR Monitoring Center*	
ICSR No. _____	Reporting Format No.
Name & address of ADR Monitoring center:	
Patient Name	
Age: _____	Sex: Male/Female
Complete Address of the Case with landmarks *(Street name, house number, village, block, Tehsil, PIN No., Telephone No. etc.)*	
P I N - P H O N E -	
Date of Vaccination: __ __ / __ __ / __ __ __ __	
Address of health facility where vaccinated (include name of village/urban area, block, DISTRICT and STATE)#:	

Name of vaccines with dose received (if known)																	
Date of first symptom	*D*	*D*	*M*	*M*	*Y*	*Y*	*Y*	*Y*	*Time of first symptom*	*H*	*H*	*M*	*M*	*(AM/PM)*			
Hospitalization: No/Yes Date -	*D*	*D*	*M*	*M*	*Y*	*Y*	*Y*	*Y*	*Time of Hospitalization*	*H*	*H*	*M*	*M*	*(AM/PM)*			
Name and address of hospital (if hosptilized): CR No. /MRD No. _____																	
Current status (encircle)	**Death/Still Hospitilzed/Recovered & Dishcharged with sequelae/ Recovered completely and discharged/ Left against Medical advice (LAMA)/ Not hospitilized**																
If died, date of death	*D*	*D*	*M*	*M*	*Y*	*Y*	*Y*	*Y*	Time of death	*H*	*H*	*M*	*M*	*(AM/PM)*			
Describe AEFI (Sign and symptoms)																	

#The case is to be notified to the DIO of the district where the vaccine was administered.
*This form should be scanned and emailed simultaneously to DIO, SEPIO, PVPI and AEFI Secretariat.



NOTIFICATION OF AEFI CASES THROUGH ADR HELPLINE CENTRE



Vaccine Pharmacovigilance topic is now included in PvPI Induction-cum-training programmes for newly-recruited Pharmacovigilance Associates and Skill Development Programme for stakeholders

Vaccine Awareness Through Periodic Newsletters

Periodic Newsletter of PvPI includes the chapter on AEFI updates

a. PvPI Newsletter Vol 6, Issue 15, June 2016: Adverse Event Following Immunization updates

b. PvPI Newsletter Vol 6, Issue 16, September 2016: PvPI and state AEFI secretariat cooperation in monitoring AEFI

c. PvPI Newsletter Vol 6, Issue 17, December 2016: WHO experts concede vaccine pharmacovigilance fortifies safe vaccination in India

AEFI

Coordination meeting of PvPI, CDSCO and AEFI-Secretariat:

NCC-PvPI holds regular coordination meetings with partners of AEFI surveillance to review all cases of AEFI. PvPI officials also attend **monthly coordination meeting** with CDSCO and AEFI-Secretariat to discuss technical matters. Members from NCC-PvPI and AMC coordinators regularly attend the AEFI National Coordination meeting, AEFI state-level meeting and regional-level workshop on 'AEFI reporting and investigation' and 'AEFI surveillance and causality assessment', respectively.

CDSCO, AEFI Secretariat partners in PvPI Technical Committee

- Experts from AEFI secretariat and CDSCO are members of PvPI-Signal Review Panel (SRP), the panel that works to identify new drug alert/signal/label change.
- PvPI official is a member of National AEFI Committee. AMC coordinator is also a member of the AEFI committee at the state level.
- All partners of AEFI surveillance participate in vaccine PSURs' review committee of CDSCO.

Status of Vaccine ICSRs: Reporting, Collation & Analysis

During this Index Period NCC-PvPI received 610 vaccine-related ICSRs. All the vaccine-related ICSRs were processed and analysed at NCC. Among the 610 vaccine-related ICSRs received, 133 cases were serious.

Fig.1: Serious and Non-serious vaccine-related AEFI cases

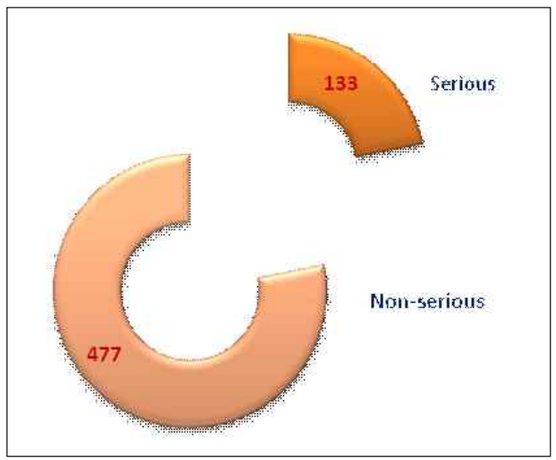


Fig. 2: Top 10 System Organ Class (SOC) of ADRs Reported with Vaccines during the Index Period

Reaction	Count
SOC: Application site disorders	66
SOC: Blood disorders	12
SOC: Body as a whole - general disorders	223
SOC: Cardiovascular disorders	6
SOC: Congenital disorders	2
SOC: Gastrointestinal disorders	68
SOC: Immune disorders and infections	65
SOC: Metabolic and nutritional disorders	3
SOC: Musculoskeletal disorders	8
SOC: Neonatal and infancy disorders	5
SOC: Neurological disorders	71
SOC: Psychiatric disorders	7
SOC: Reproductive disorders	2
SOC: Respiratory disorders	59
SOC: Secondary terms - events	25
SOC: Skin and appendages disorders	123
SOC: Urinary tract disorders	1
SOC: Vascular, bleeding and clotting disorders	2
SOC: Vision disorders	1

Distribution of Adverse Events Due to Vaccines

Subst: Diphtheria vaccine; Hepatitis B vaccine; HIB vaccine; Pertussis vaccine; Tetanus vaccine	115
Subst: Diphtheria vaccine; HIB vaccine; Pertussis vaccine; Polio vaccine; Tetanus vaccine	98
Subst: Diphtheria vaccine; Pertussis vaccine; Polio vaccine; Tetanus vaccine	1
ATC: J07BB Influenza vaccines	4
ATC: J07BC Hepatitis vaccines	22
ATC: J07BD Measles vaccines	60
ATC: J07BF Poliomyelitis vaccines	41
ATC: J07BG Rabies vaccines	150
ATC: J07BH Rota virus diarrhea vaccines	24
ATC: J07BK Varicella zoster vaccines	22
ATC: J07BL Yellow fever vaccines	1
ATC: J07BM Papillomavirus vaccines	2
ATC: J07AF Diphtheria vaccines	2
ATC: J07AG Hemophilus influenzae B vaccines	26
ATC: J07AH Meningococcal vaccines	1
ATC: J07AJ Pertussis vaccines	53
ATC: J07AL Pneumococcal vaccines	24
ATC: J07AM Tetanus vaccines	13
ATC: J07AN Tuberculosis vaccines	30
ATC: J07AP Typhoid vaccines	14

PSURs' review meetings for the following vaccines were conducted by CDSCO during the Index Period

The PSURs of vaccines submitted to CDSCO by the MAHs were reviewed during the Index Period in technical collaboration with PvPI and AEFI secretariat.

PSUR Expert Committee Meeting	Company	Reported Vaccine
7th Meeting (5-05-2016)	M/s Serum Institute of India	• IPV vaccine under the Brand name: POLIOVAC PFS
	M/s Sanofi Pasteur India Pvt. Ltd.	• Inactivated Poliomyelitis vaccine (Imovax Polio)
	M/s Shantha Biotechnics Pvt. Ltd.	• Inactivated Poliomyelitis vaccine I.P (Shan IPV)
8th Meeting (21-06-2016)	M/s Bharat Biotec Ltd.	• JE vaccine
	M/s Biological E Ltd.	• JE vaccine
9th Meeting (23-08-2016)	M/s Serum Institute of India Pvt. Ltd.	• Influenza Vaccine Live attenuated (Human) Seasonal Trivalent, Freeze Dried (Nasovac-S)
	M/s Sanofi Pasteur India Pvt. Ltd.	• Inactivated Influenza Vaccine ~(split virion) Vaxigrip
	M/s Cadila Healthcare Limited	• VAXIFLU-S, Pandemic Influenza (H1NI) 2009 Monovalent Vaccine
	M/s G C Chemie Pharma Ltd	• Inactivated Influenza Vaccine (Split-Virion) IP, Influngen
10th Meeting (02-11-2016)	M/s Bharat Biotech International	• Recombinant Hepatitis B Vaccines under two trade names i.e. Revac B+ and Revac B
	M/s GSK Asia Private Limited	• Varicella Vaccine, Live IP [VARILRIX®] and Hepatitis B Vaccine. • MMR Vaccine: • MMRV vaccine (Priorix-Tetra):
	M/s Serum Institute of India Limited	• Hepatitis BVaccine (rDNA) • MMR Vaccine
	M/s Human Biological Institute	• Hepatitis B vaccine • I Elovac-B
	M/s Biological E Limited	• Recombinant Hepatitis B Vaccine (Adsorbed)

	M/s HLL Biotech Limited	• HIVAC-B (Hepatitis B Vaccine (rDNA) I.P.)
	M/s Wockhardt Limited	• Biovac-V®-Varicella vaccine (live attenuated-aka strain) I.P, Freeze-dried
	M/s Panacea Biotech Limited	• Hepatitis-B vaccine
11th Meeting (12-01-17 & 13-01-2017)	M/s Bharat Biotech International Limited	• Typbar TCVTM (Typhoid Vi Capsular Polysaccharide) Tetanus Toxoid Conjugate Vaccine Rotavac® (Live Attenuated, Oral, IP Vero cell-derived)
	M/s Bio-Med Pvt Ltd	• BioTyph™, Peda Typh™, BI-MENINGO, QUADRIMENINGO Vaccine
	M/s Sanofi Pasteur India Pvt Ltd	• Menactra® Meningococcal (Groups A, C, Y, and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine • Shanchol® Cholera Vaccine (Inactivated, Oral) Typhoid Polysaccharide Conjugate Vaccine
	M/s Serum Institute of India Limited	• Pentavalent Vaccine (Diphtheria, Tetanus, Pertussis (whole cell), Hepatitis Band Haemophilus Influenzae type b conjugate vaccine (pentavalent, adsorbed, liquid) (DTP-HB-Hib)
	M/s GSK Asia Private Limited	• Pneumococcal Polysaccharide Conjugate Vaccine (adsorbed) Ph. Eur [Synflorix] • Human Papillomavirus Vaccine rDNA Ph Eur [Cervarix] • Live attenuated human (RIX4414 strain) rotavirus vaccine, IP [brand: Rotarix] • Pentavalent Vaccine (Quinvaxem) Rabies Vaccine (Rabipur)
	M/s MSD Pharmaceuticals Pvt Ltd	• Rotavirus vaccine (Rotateq) • Quadrivalent Human Papillomavirus Vaccine Recombinant (Gardasil) • Zostavax: Shingles (Herpes Zoster) vaccine (Live) BP Mis. MSD Pharmaceuticals Pvt. Ltd presented AEFI

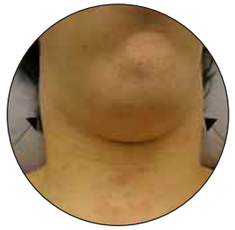
	M/s Sun Pharmaceuticals Ltd.	• Rabies Vaccine, XPRAB™
	M/s Human Biological Institute	• Rabies vaccine, Human I.P
	M/s Biological E Limited	• Liquid Pentavalent vaccine (ComBEfive)
	M/s Panacea Biotec Limited	• Pentavalent Vaccine (DTwP-Hep B-Hib-TT)
12th Meeting (18-01-17)	M/s Bharat Biotech International Limited	• Bivalent Oral Polio type 1 & type 3 Vaccine (b-OPV)
	M/s Bio-Med Pvt. Ltd.	• Bivalent Oral Polio type 1 & type 3 Vaccine (b-OPV) • Trivalent Oral Polio type 1,2 & type 3 Vaccine (t-OPV)
	M/s Sanofi Pasteur India Pvt. Ltd.	• Live attenuated Yellow Fever Vaccine Stamaril® • Tetanus Toxoid Adsorbed (ShanTT)
	M/s GSK Asia Private Limited	• dTap : Diphtheria, Tetanus and Pertussis (Acellular, Component) Vaccine (Adsorbed, Reduced Antigens Content) Ph. Eur, (Boostrix)
	M/s Human Biological Institute	• Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed) J.P. Abhay-TAG® • Tetanus Vaccine (Adsorbed) J.P. Abhay-TOX®
	M/s Biological E Limited	• Diphtheria, Tetanus and Pertussis (Whole cell) Vaccine (Adsorbed) TRIPVAC ® • Tetanus Toxoid Vaccine (Adsorbed) IP & BP
	M/s Panacea Biotec Limited	• Bivalent oral poliomyelitis vaccine-Live (Oral) bOPV
	M/s Bharat Immunological & Biological Co. Ltd	• Bivalent oral poliomyelitis vaccine -Live (Oral) bOPV

Vaccine safety initiatives by PvPI during the Index Period

BCG vaccine associated Lymphadenopathy

In India, 7 ICSRs of BCG vaccine were found associated with Lymphadenopathy. This vaccine ADR-combination had positive IC_{025} and globally it has 4,448 ICSRs.

Vaccine	Adverse event	No. of reports	Ic_{025}	Recommendation
BCG	Lymphadenopathy	7	+1.46	Prescribing information change



Recommendation and regulatory action:

During the 9th SRP meeting at CDSCO, West Zone, Mumbai, on November 28, 2016, the Signal Review Panel concluded that there was strong temporal relationship between the vaccine and the reaction (BCG vaccine-associated Lymphadenopathy), hence it be incorporated in packaging inserts of BCG vaccine marketed in India.

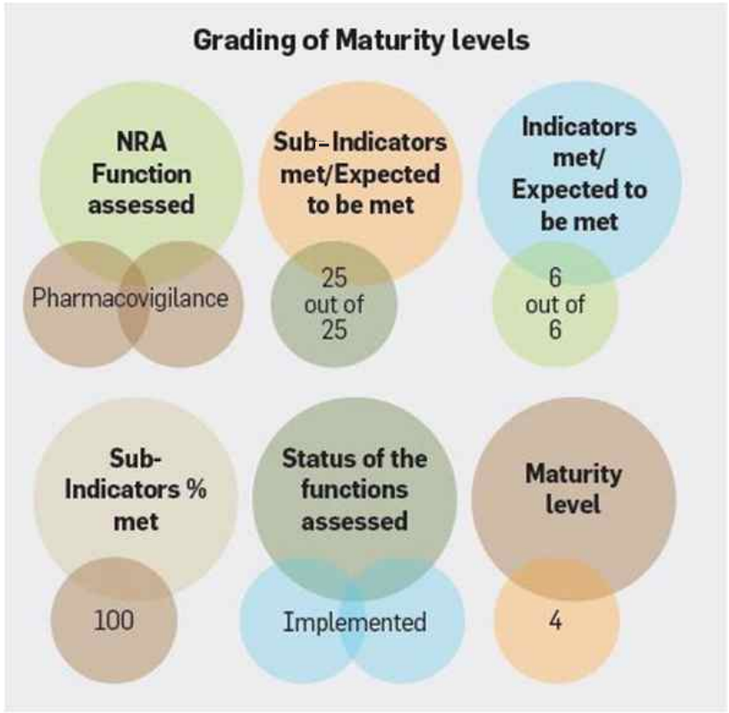
NRA meets WHO international standards for vaccine regulations

A World Health Organization (WHO)-led team of international experts from several countries has affirmed that the National Regulatory Authority (NRA) of India and its affiliated institutions meet the WHO-published indicators for the functional vaccine regulatory system.

The WHO-NRA exercise – from February 13-17, 2017 – was aimed at assessing and documenting the status of Indian vaccine regulatory system, re-benchmarking the status of the vaccine regulatory system against the WHO-NRA Global Benchmarking Tool (GBT), updating the Institutional Development Plan and measuring maturity of the system.

The NRA includes Pharmacovigilance as one of the indicators for NRA-benchmarking tool. A visit by a team of WHO experts to NCC-PvPI, Ghaziabad, on February 15, 2017, was followed by a two-day field visit by a separate team from February 14-15, 2017, to KEM, Mumbai, an ADR-monitoring centre (AMC) of Maharashtra, for reviewing the Pharmacovigilance system by using the WHO-NRA assessment tool. All sub-indicators of the Pharmacovigilance tool were fulfilled and found satisfactory. The progress was remarkable when compared with the last NRA assessment made in 2012. The assessment has been done in respect of nine different functionalities. A review meeting to this effect

was held on February 17, 2017 at MoHFW in Nirman Bhawan, New Delhi. The Pharmacovigilance system of India has been declared 'functional' with a maturity level of 4 out of 5, which is the highest level as per currently-evolved definitions.



Collaboration of PvPI with Public Health Programmes (PHP)

The World Health Organization (WHO) recommends that the national Pharmacovigilance system be integrated with public health programmes (PHPs) of the country. The PHPs are meant to treat a large number of people in an organized and structured manner. They also record the number of patients treated, drugs and dosage used, etc. The PvPI is committed to improving patient safety and safeguarding the health and welfare of Indian population by monitoring drug safety and ensuring the benefits of medicines available through PHPs outweigh the risks associated with their use. The NCC-PvPI, IPC, has collaborated with various public health programmes such as Revised National Tuberculosis Control Programme (RNTCP) and National AIDS Control Organisation (NACO) to monitor the safety of medicines used by them.

Objectives of the collaboration:

- To ensure effective implementation and integration of Pharmacovigilance with other public health programmes (PHP) in the country
- To enhance the knowledge, attitude and practice of Pharmacovigilance among healthcare professionals (HCPs) engaged in PHP

Expected outcome:

- Cohort event monitoring (CEM) (possible since the denominator values are available)
- Timely signal detection from the ICSRs received by the PvPI

Status of ICSRs: Reporting, Collation & Analysis

Integration of PHPs with PvPI has enhanced ADR Reporting/Communication system between the two entities. As many as 1,294 and 723 ICSRs were received from different RNTCP centres and antiretroviral therapy (ART) centres, respectively, during the index period April 1, 2016 to March 31, 2017. These reports were derived from the spontaneous ADR reporting system under PvPI. The reported ADRs revealed a wide spectrum of clinical manifestations and were analysed based on WHO Adverse Reaction Terminology (WHO-ART) System Organ Class (SOC), i.e. the ADRs due to suspected medication effects on organs or an organ system.

Top 10 antitubercular drugs reported to cause ADRs

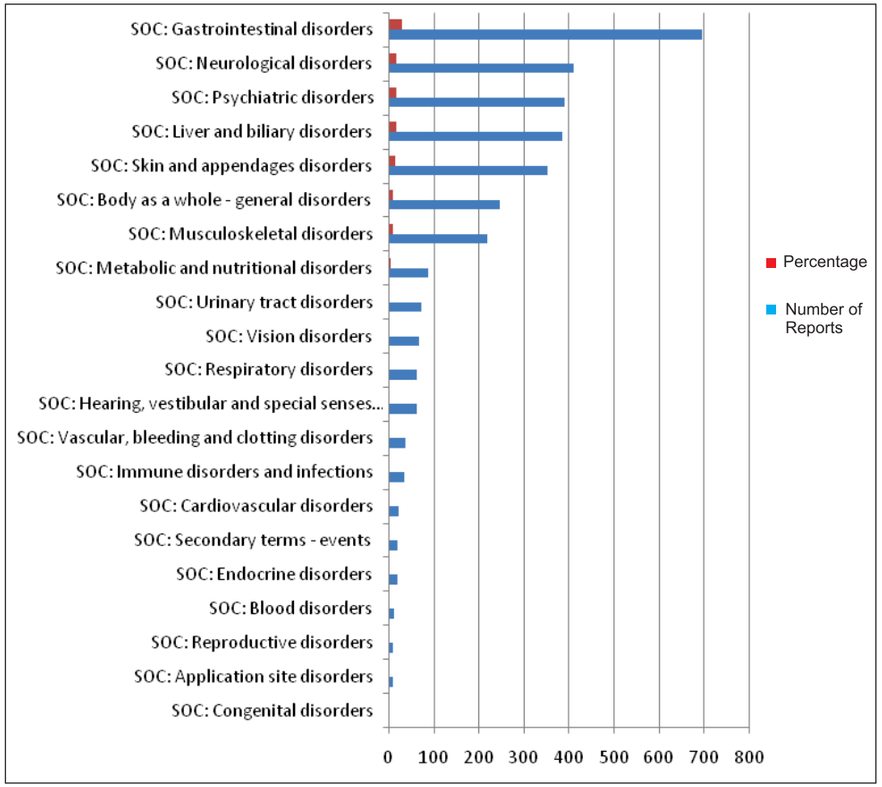
Following 10 antitubercular drugs (and/or combinations) were most commonly reported to cause ADRs during the index period:

Medication	Percentage
Subst: Bedaquiline	1.1
Subst: Cycloserine	8.3
Subst: Ethambutol	35.1
Subst: Ethionamide	9.0
Subst: Isoniazid	42.3
Subst: Pyrazinamide	44.3
Subst: Rifampicin	44.1
Subst: Streptomycin	8.3
TN: Rifampicin/Isoniazid/Pyrazinamide	0.2
TN: Rifampicin/Isoniazid/Pyrazinamide /Ethambutol Hydrochloride	8.7

Distribution of ADR reports based on System Organ Class (SOC)

Gastrointestinal adverse effects were the most frequently reported ADR with antitubercular drugs during the Index Period.

Reaction	Percentage	Reaction	Percentage
SOC: Congenital disorders	0.0	SOC: Vision disorders	3.0
SOC: Application site disorders	0.4	SOC: Urinary tract disorders	3.2
SOC: Reproductive disorders	0.4	SOC: Metabolic and nutritional disorders	3.8
SOC: Blood disorders	0.6	SOC: Musculoskeletal disorders	9.6
SOC: Endocrine disorders	0.9	SOC: Body as a whole - general disorders	10.9
SOC: Secondary terms -- events	0.9	SOC: Skin and appendages disorders	15.6
SOC: Cardiovascular disorders	1.0	SOC: Liver and biliary disorders	17.0
SOC: Immune disorders and infections	1.5	SOC: Psychiatric disorders	17.2
SOC: Vascular, bleeding and clotting disorders	1.6	SOC: Neurological disorders	18.2
SOC: Hearing, vestibular and special senses disorders	2.7	SOC: Gastrointestinal disorders	30.8
SOC: Respiratory disorders	2.8		



Top 5 antiretroviral drugs reported to cause ADRs

Following antiretroviral drugs were most frequently reported to cause ADRs, as reported during the Index period:

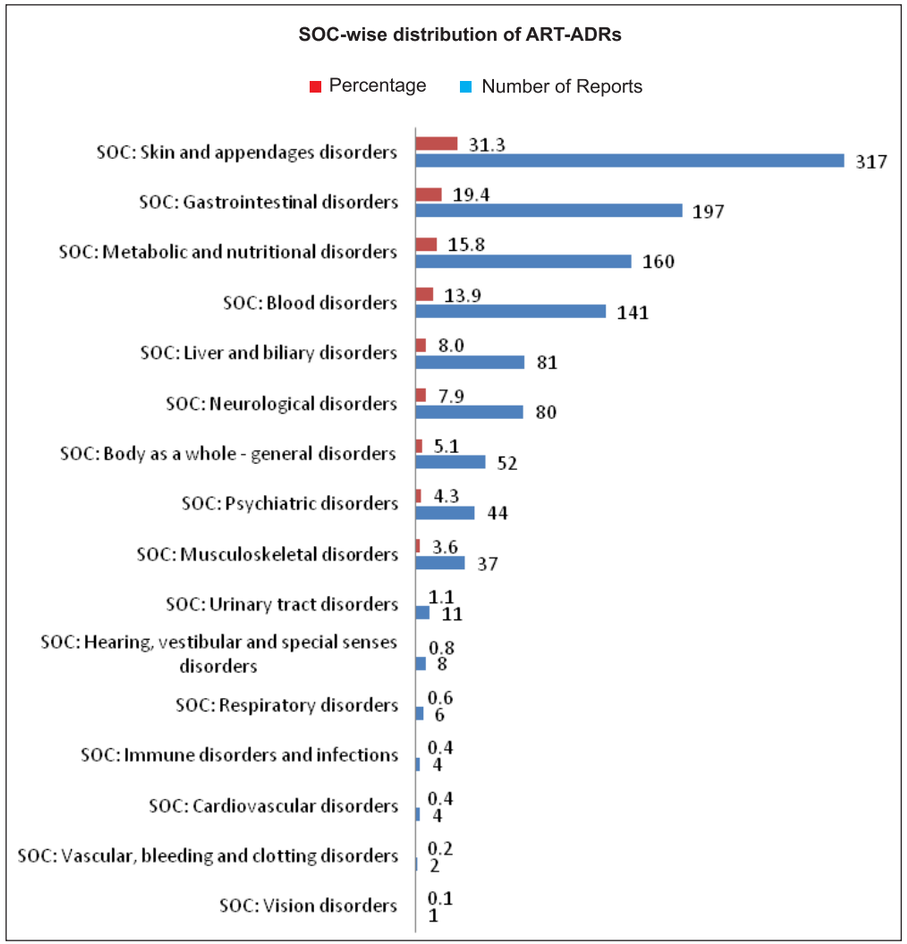
Medication	Percentage
Subst: Atazanavir; Ritonavir	9.0
TN: Lamivudine/nevirapine/zidovudine	89.2
TN: Lamivudine/Tenofovir disoproxil fumarate	1.9
TN: Lamivudine/zidovudine	0.5
TN: Tenofovir disoproxil fumarate/ lamivudine/efavirenz	0.1

Distribution of ADRs reported due to ART classified on basis of System Organ Class (SOC)

Following ADRs (as classfied on basis of SOC) were commonly observed following ART during the Index Period.

Reaction	Percentage
SOC: Vision disorders	0.1
SOC: Vascular, bleeding and clotting disorders	0.2
SOC: Cardiovascular disorders	0.4
SOC: Immune disorders and infections	0.4
SOC: Respiratory disorders	0.6
SOC: Hearing, vestibular and special senses disorders	0.8
SOC: Urinary tract disorders	1.1
SOC: Musculoskeletal disorders	3.6
SOC: Psychiatric disorders	4.3

Reaction	Percentage
SOC: Body as a whole - general disorders	5.1
SOC: Neurological disorders	7.9
SOC: Liver and biliary disorders	8.0
SOC: Blood disorders	13.9
SOC: Metabolic and nutritional disorders	15.8
SOC: Gastrointestinal disorders	19.4
SOC: Skin and appendages disorders	31.3



Training and Skill Development at PHPs under PvPI

The NCC-PvPI in collaboration with the WHO country office (India) provides a national-level training programme for healthcare professionals/experts under various PHPs such as RNTCP, NVBDCP and NACO. This initiative is specially tailored to sensitize and update the experts on how effectively to identify and report ADRs to medicines used in these programmes. The training focuses on the basics and essentials of Pharmacovigilance, medical terminology coding, and standards and procedure for entering data into VigiFlow®.

Focused Pharmacovigilance of drugs used in vector-borne diseases under NVBDCP

Several national and regional-level workshops on Pharmacovigilance for vector-borne diseases were conducted during the Index Period to promote Focused Pharmacovigilance of drugs used in vector-borne diseases under NVBDCP. Following meetings, trainings and skill development programs were held during the Index Period.

S. No	Date	Title	Organised by	Organised at	Participants/Target Audience
1.	6th – 9th Sept 2016	National Collaborative Workshop on Causality Assessment for Pharmacovigilance of Anti-Tubercular Medicines in India	WHO-RNTCP-IPC	Hotel Lalit, New Delhi	RNTCP/WHO/PvPI officials, healthcare professionals of states under the purview of CEM programme
2.	5th Dec 2016	Second Drug safety Monitoring Committee (DSMC) meeting for implementation of BDQ guidelines under RNTCP	Central TB Division (CTD)	New Delhi	CTD/RNTCP
3.	20th Dec 2016	Meeting on Quality of ICSRs for Sirturo (BEDAQUILINE) received from Janssen, Pharmaceutical companies of Johnson & Johnson	NCC-PvPI, IPC	IPC, Ghaziabad	Industry Participants/ NCC-PvPI Officials
4.	12th Apr 2017	Meeting to review the progress of ADR reporting at BDQ sites	NCC-PvPI, Ghaziabad	IPC, Ghaziabad	PvPI Officials/Pv Associates at BDQ sites, Site Coordinators
5.	18th – 19th Oct 2016	National Strategic Plan for TB Control in India (2017-23) -- Consultative Workshop	WHO India/CTD	New Delhi	Experts from hospitals/ Physicians/PvPI officials/ CTD officials/WHO consultants and other staff
6.	2nd – 4th Feb 2017	National Meeting on Accelerated Roadmap for Kala Azar Elimination -2017 and National Workshop on Pharmacovigilance for Vector-Borne Diseases	MoHFW/NHM/ NVBDCP /ICMR/ PvPI-IPC/WHO India	Hotel Grand, New Delhi	Ministry officials, health experts, physicians, data operators
7.	21st – 22nd Feb 2017	Regional Workshop on Pharmacovigilance for Vector-Borne Diseases	MoHFW/NHM/ NVBDCP/ ICMR/ PvPI-IPC/WHO India	Hotel AVN Grand, Ranchi	Ministry officials, health experts, physicians, data operators

S. No	Date	Title	Organised by	Organised at	Participants/Target Audience
8.	7th – 10th March 2017	Regional workshop on Pharmacovigilance for Vector-Borne Diseases	MoHFW/NHM/ NVBDCP/ICMR/ PvPI-IPC/WHO India	Hotel Patliputra Continental, Patna	Ministry officials, health experts, physicians, data operators
9.	21st – 23rd Feb 2017	National ToT for Expansion of Bedaquiline and Shorter MDR-TB regimen with Updated Guidelines for PMDT in India	CTD/WHO India	Ahmedabad	Physicians, trainers from Daman, Diu, Dadra Nagar Haveli, Gujarat, Chhattisgarh, Rajasthan, Maharashtra, Haryana & Goa
10.	7th – 9th March 2017	National ToT for Expansion of Bedaquiline & Shorter MDR-TB regimen with Updated Guidelines for PMDT in India	CTD/WHO India	Chennai	Physicians, trainers from Andaman & Nicobar Islands, Puducherry, Kerala, Telangana, Karnataka, Madhya Pradesh, Lakshdweep Odisha & Tamil Nadu

Drug Safety Monitoring Committee

The Drug Safety Monitoring Committee (DSMC) for use of Bedaquiline in RNTCP through Conditional Access Programme (CAP) under programmatic management of drug-resistant tuberculosis in India was constituted by the DGHS. The second meeting of this committee was held on December 5, 2016, which discussed the safety and efficacy of the drug and future plans of DSMC.

Training & Skill Development

Essence and Relevance of PvPI's Training and Education Division

The training and education division of PvPI plays an important role in fulfilling the stakeholders' expectations by imparting the requisite hands-on training in pharmacovigilance. The training report for the index period – April 1, 2016 to March 31, 2017 -- provides information on PvPI's Induction and Advance-Level Training for continued medical education (CME) organized by NCC-PvPI on its own as well as in collaboration with other partners. The training report also includes information on 'Skill Development' programmes conducted at IPC, Ghaziabad.

Training Programmes conducted by NCC-PvPI during the Index Period

As many as 13 training programmes were conducted by NCC-PvPI during the index period:

TRAINING & SKILL DEVELOPMENT

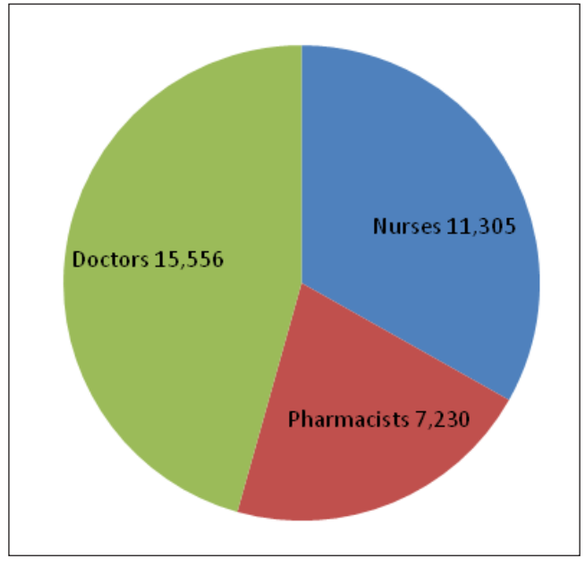
S. No	Name of Programme	Objective	Date	Place	Target Audience
1.	Advance Training Programme in Pharmacovigilance for West Zone	Training for upgradation of skills for healthcare professionals	January 20, 2016	BJMC, Ahmedabad	Healthcare Professionals
2.	CME on Pharmacovigilance and ADR Monitoring	An update on current status of PvPI, and ADR Reporting	March 31, 2016	BJMC, Ahmedabad	Post-Graduate Students of Civil Hospital, Ahmedabad
3.	CME and Awareness Programme on Pharmacovigilance	Training for upgradation of skills of ADR reporting for healthcare professionals	April 2, 2016	Andhra Medical College and NIMS, Hyderabad	Healthcare Professionals
4.	Training Programme for South Indian Healthcare Professionals	Creating awareness for patient safety and improving ADR reporting culture	April 5, 2016	JSS, Mysore, & MS Ramaiah Medical College, Bangalore	Healthcare Professionals
5.	1st National-level Meeting on Participation of Nursing Professionals in Pharmacovigilance	Training on basic knowledge of Pharmacovigilance and ADR reporting	May 6, 2016	IPC, Ghaziabad	Nursing Professionals
6.	Sensitization and Awareness on Pharmacovigilance	Creating awareness on patient safety and improving ADR reporting culture on Doctor's Day	July 1, 2016	Silchar Medical College & Hospital, Silchar	Doctors
7.	CME & Awareness Programme on Pharmacovigilance	An update on current Status on PvPI, contribution to ADR reporting by institute concerned	July 23, 2016	AIIMS, Raipur, & AIIMS, Bhopal	Healthcare Professionals
8.	Advance-Level Training for South Zone AMCs	Training for up gradation of skills of healthcare professionals	August 5-6, 2016	JSS, Mysore	Healthcare Professionals
9.	Induction-cum-Training Programme for newly-recruited Pharmacovigilance Associates	Training on basic knowledge of pharmacovigilance and hands-on training in VigiFlow	August 22-27, 2016	IPC, Ghaziabad	Newly-Recruited Pharmacovigilane Associates
10.	Advance-Level Training on Pharmacovigilance-cum-Coordinators' Meeting	Discussion and hands-on session on ADR reporting	October 8, 2016	AIIMS, Bhopal	Healthcare Professionals
11.	Pharmacovigilance Training Workshop	Training for upgradation of skills for healthcare professionals	November 28, 2016	Seth GSMC & KEM, Mumbai	Healthcare Professionals

Skill Development Programme

S. No	Name of Programme	Objective	Date	Place	Target Audience
1.	Skill Development Programme on 'Basics and Regulatory Aspects of Pharmacovigilance: Striving for Excellence'	To enhance Pharmacovigilance skills of professionals for promotion of patient safety	January 16-25, 2017	IPC, Ghaziabad	Healthcare Professionals
2.	Skill Development Programme on 'Basics and Regulatory Aspects of Pharmacovigilance: Striving for Excellence'	To enhance Pharmacovigilance skills of professionals for promotion of patient safety	March 1-10, 2017	IPC, Ghaziabad	Healthcare Professionals

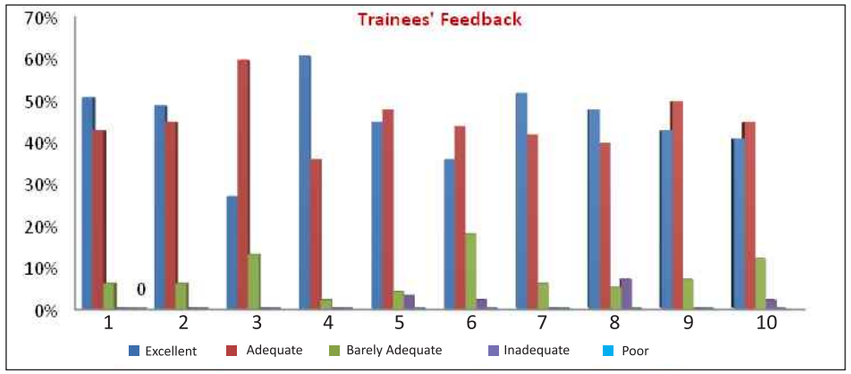
Stakeholders in Phramcovigilance Trained during the Index Period

More than 34,000 stakeholders, including doctors, nurses and pharmacists, were trained, sensitized and made aware of basic concepts of Pharmacovigilance and reporting of ADRs at 1,070 training and awareness programmes conducted by NCC and AMCs during the index period.



TRAINING & SKILL DEVELOPMENT

Trainees' feedback to Skill Development training at NCC-PvPI



Key:

1.Objective of the training at outset
2.Objective met post-training
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 confedence after training

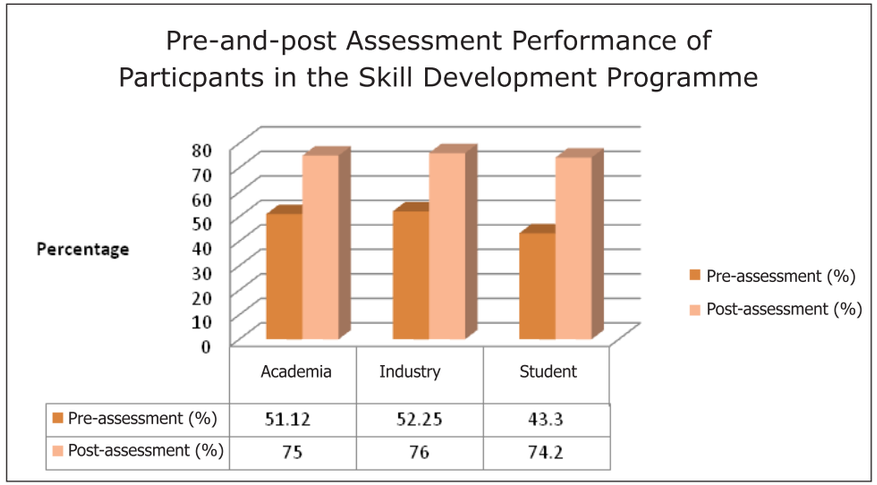
Skill Development Programme

Trainees with delegates during the 10-day (March 1-10, 2017) Skill Development Programme on 'Basics & Regulatory Aspects of Pharmacovigilance: Striving for Excellence', at IPC, Ghaziabad

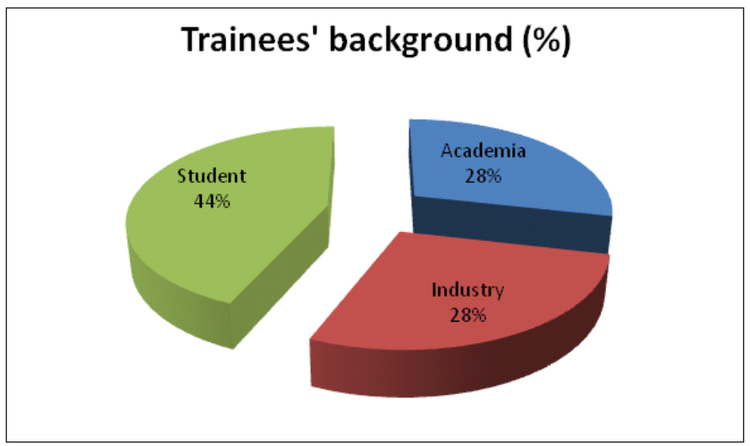
PRE-AND-POST ASSESSMENT

Pre-and-Post Assessment comparison of First Skill Development Programme of PvPI from 16th-25th January 2017

Pre-assessment of the participants was carried out at the beginning of the skill development programme to understand their basic knowledge and awareness about Pharmacovigilance. After the completion of the 10-day training programme, post-assessment was conducted to evaluate the impact and effectiveness of the training programme. The comparison of the Pre-and-Post assessment of the participants is depicted in figure below:



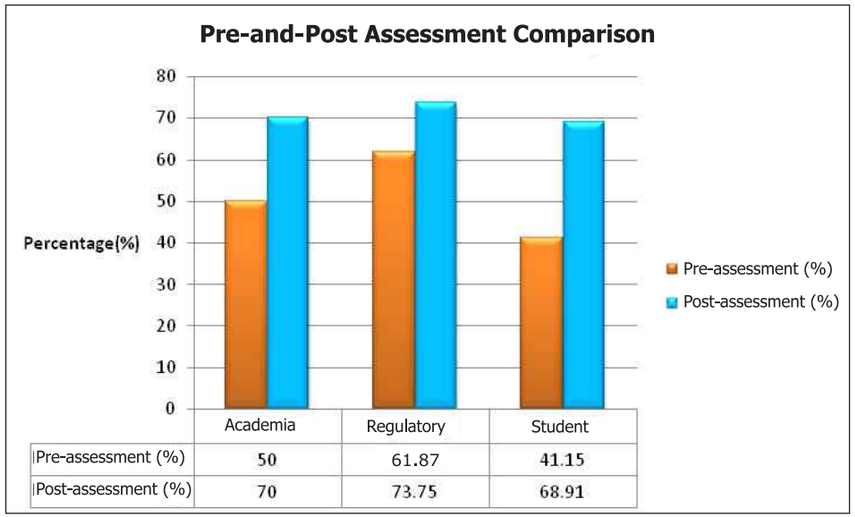
	Academia	Industry	Student
Pre-assessment (%)	51.12	52.25	43.3
Post-assessment (%)	75	76	74.2



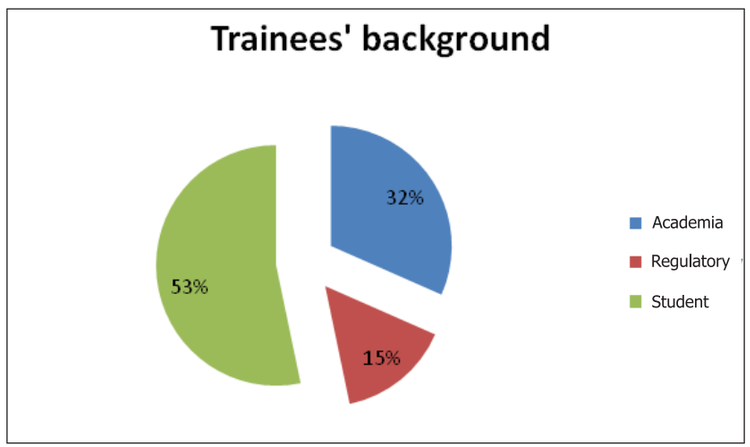
PRE-AND-POST ASSESSMENT

Pre-and-Post Assessment comparison of 2nd Skill Development Programme on Pharmacovigilance from March 1-10, 2017

A similar assessment was carried out duting the second Skill Development Programme too. The comparison of the Pre-and-Post- assessment of the participants is illustrated in figure below



	Academia	Regulatory	Student
Pre-assessment (%)	50	61.87	41.15
Post-assessment (%)	70	73.75	68.91



SIGNAL DETECTION

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) are 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:

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

The threshold values used in the PvPI for the aforementioned parameters to identify a potential signal are:

1. $IC_{025} > 0$
2. PRR ≥ 2 with the lower bound of its 95% CI > 1
3. $\chi 2$ statistics (with 1 degree of freedom) ≥ 4
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.

SIGNAL DETECTION

ACTIVITIES OF PVPI SIGNAL REVIEW PANEL (SRP)

Following signal review meetings were conducted during the Index Period.

S. No	Activities	Drug-ADR Combination Reviewed	Outcome	CDSCO Initiatives
1.	8th SRP meeting held on July 8, 2016 at CDSCO, New Delhi	• Cefixime – Acute Generalised Exanthematous Pustulosis • Itraconazole – Photosensitivity Reaction • Ibuprofen – SJS/TEN • Amoxicillin/Potassium Clavulanate – SJS/TEN • Ciprofloxacin – SJS/TEN • Sodium Valproate – Gum Hyperplasia	SRP suggested that the information be incorporated in the package insert	• In process • In process • In process • In process • In process • In process
2.	9th SRP meeting held on November 29, 2016 at CDSCO, West Zone, Mumbai	• BCG Vaccine – Lymphadenopathy • Docetaxel – Candidiasis • Furosemide – Lichenoid dermatitis • Itraconazole – Acute Generalised Exanthematous Pustulosis • Lithium Carbonate – DRESS Syndrome • Phenytoin – Acute Generalised Exanthematous Pustulosis	SRP suggested that the information be incorporated in the package insert	• In process • In process • Subject Expert Committee agreed to update the PIL • In process • Subject Expert Committee agreed to update the PIL • Subject Expert Committee agreed to update the PIL

DRUG ALERTS:

The NCC has issued drug alerts to advise the Healthcare Professionals, Patients/ Consumers to closely monitor the possibility of the following adverse events while prescribing/consuming these drugs.

S. No	Suspected drug(s)	Indication	Adverse reaction(s)
1.	Roflumilast	To reduce the risk of exacerbation of Chronic Obstructive Pulmonary Disease	Gynaecomastia
2.	Clozapine	Management of schizophrenia	Neutropenia
3.	Disulfiram	Alcohol abuse	Erythroderma
4.	Piperacillin & tazobactam	Lower Respiratory Tract Infection, Urinary Tract Infection, Intra-abdominal infection	Blurred Vision
5.	Mometasone furoate, topical	Steroid responsive dermatitis, Eczema, Atopic dermatitis	Hypertrichosis, Hirsutism, Skin depigmentation
6.	Peginterferon Alpha-2a	Chronic Active hepatitis B and C	Vasculitis
7.	Ranibizumab	Neo-vascular age-related Macular Degeneration (AMD), Visual impairment due to Diabetic Macular Edema (DME), Visual impairment due to Choroidal Neo-vascularization (CNV) secondary to Pathologic Myopia (PM)	Myocardial Infarction
8.	Amphotericin B (conventional)	Life-threatening fungal infections	Bone marrow depression
9.	Doxorubicin	Soft tissue and Bone sarcoma, Acute leukemia, Malignant lymphoma, Hodgkin's disease, Breast carcinoma	Photosensitivity reaction
10.	Crizotinib	Locally advanced or Metastatic non-small cell lung Cancer (NSCLC) that is anaplastic, Lymphoma kinase (ALK) – positive	Pneumonitis Hepatic Encephalopathy
11.	Hepatitis-B immunoglobulin (Human)	Active immunisation against hepatitis B virus (HBV) infection	Encephalopathy
12.	Lacosamide	As an adjunctive treatment for partial seizures in patients more than 17 years of age	Red-Man syndrome
13.	Dimethyl fumarate	Relapsing, remitting multiple-sclerosis encephalopathy	Osteonecrosis
14.	Cefotaxime	Infections due to sensitive gram-positive and gram-negative bacteria	Anaphylactic shock
15.	Sodium citrate/ diphenhydramine hydrochloride/ammonium chloride	Symptomatic treatment of cough	Myocardial infarction
16.	Cabergoline	Hyperprolactinemia and inhibition of lactation	Stevens-Johnson Syndrome (SJS)
17.	Amlodipine	Angina, hypertension, coronary artery disease	Alopecia
18.	Nitrofurantoin	Urinary tract infections, Cystitis	Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
19.	Atenolol	Angina, Myocardial infarction, arrhythmias, hypertension, Prophylaxis of migraine	Lichenoid dermatitis
20.	Cefixime	Otitis media, RTI, uncomplicated UTI, infections caused by *Enterobaceriaceae*, *H.influenza* species	Anal ulcer
21.	Olanzapine	Schizophrenia and other psychotic disorders, mania/mixed episode, psychomotor agitation and violent behaviour	Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
22.	Montelukast	Prophylaxis of mild to moderate asthma	Tinnitus
23.	Cefoperazone with sulbactam	Upper and Lower Respiratory Tract Infection (RTI) and Urinary Tract Infection (UTI), Septicemia	Acute generalised exanthematous pustulosis
24.	Meropenem	Nosocomial infections like septicaemia	Hypokalaemia
25.	Cefepime	For serious CRTI, uncomplicated and complicated UTI, uncomplicated skin & skin structure, infection acute exacerbation of Chronic Bronchitis & Intra-abdominal infection	Lichenoid dermatitis
26.	Losartan	Congestive heart failure, Hypertension and Myocardial infarction	Burning micturition

27.	Amisulpride	For acute and chronic schizophria	Tinnitus
28.	Carbamazepine	Partial seizures with or without secondary generalisation, Trigeminal neuralgia, Bipolar Disorder.	Bruxism
29.	Clomipramine	Obsessive Compulsion Disorder (OCD Panic disorder	Melasma
30.	Glimepiride	Type 2 Diabetes mellitus	Lichenoid drug eruption
31.	Metoprolol	Supraventricular arrhythmia, Angina Pectoris, Hypertension, Myocardial infarction, Prophylaxis of Migraine, Hyperthyroidism, Heart failure	Lichenoid drug eruption
32.	Levamisole	Roundworm and hookworm infestations	Exfoliation of skin
33.	Deferasirox	Chronic iron overload in patients with Non-Transfusion Dependent Thalassemia (NTDT) syndromes	Osteoporosis
34.	Ambroxol	All forms of Tracheobronchitis, Emphysema with Bronchitis Pneumoconiosis	Lacrimation
35.	Lurasidone	Treatment of patients with schizophrenia	Thrombocytopenia
36.	Etoricoxib	Short-term use in acute painful condition	Hyperpigmentation of skin

REGULATORY PHARMACOVIGILANCE

The process of Regulatory Pharmacovigilance ensures identifying and responding to risk-benefit issues arising out of marketed medicines, and is conducted by drug regulatory authorities and pharmaceutical companies. The objectives of regulatory pharmacovigilance are long-term monitoring of medicines, assessment of the risks and benefits of medicines, disseminating information among public to optimize safe and effective use of medicines and monitoring the impact of any action taken.

Effective Pharmacovigilance is dependent on the availability of information on possible hazards associated with medicines in clinical practice. It requires a system for collecting and monitoring suspected adverse drug reactions (ADRs).

PvPI takes all the necessary actions 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 received following ADRs associated with the quality of medicinal product during the index period:

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

MAHs' CONTRIBUTION

ROLE OF MAHs IN PvPI

As per the recent amendment to Schedule Y of the Drugs and Cosmetics Rules, 1945, Pharmacovigilance has been made a mandatory requirement for every manufacturer or marketing authorization holder (MAH). Following this mandate Pharmacovigilance Programme of India (PvPI) has initiated interactions with the pharmaceutical industry to execute the mandate.

These interactions are aimed at addressing the challenges and issues in reporting ADRs to the PvPI. Two interactive sessions were held by PvPI during the Index Period. The recommendations of these sessions are listed below:

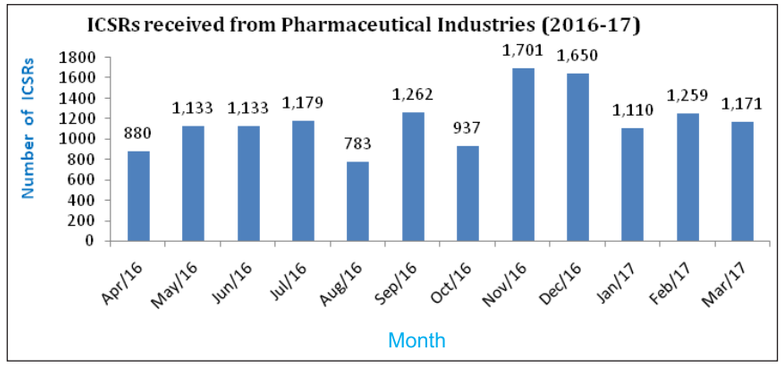
- Industries need to implement/develop a system for reporting Individual Case Safety Reports (ICSRs)/Periodic Safety Update Reports (PSUR) in XML ICH E2B format within 30 days
- The latest updated package insert leaflet (PIL) of the pharmaceutical product concerned be uploaded on the respective MAH website
- Development of the medication error module for PvPI with technical support from Lupin Pharmaceuticals Limited
- MAHs are advised to report all ADRs of their product to PvPI, including the unlisted AE/ADRs
- Training of medical representatives of MAHs to improve quality of ICSRs
- PvPI Helpline 1800-180-3024 be printed on the last page of PIL of all products

Pharmacovigilance activities of MAHs during the Index Period

Total Number of MAHs Reporting to NCC-PvPI, IPC	57
Reporting Format	CIOMS, E2B/XML
Interactive Sessions with MAHs by NCC-PvPI, IPC	2
Dedicated division for processing ICSRs submitted by MAHs	Appreciation and Acknowledgement of MAH for ADR reporting
Exclusive SOP for processing of ICSRs	-
Review of PSURs jointly by CDSCO and PvPI	Office Memorandum issued by the DCG (I)

ICSR reporting by the Pharmaceutical Industry

The voluntary reporting by MAHs has been on an increase following efforts and initiatives PvPI. As many as 14,248 ICSRs were received from the MAHs by PvPI.



Reporting of Adverse Events due to Medical Devices is now PvPI's duty

In the aftermath of Adverse Events (AEs) due to use of medical devices, the Ministry of Health and Family Welfare (MoHFW), GoI, has laid down stringent mechanisms for identifying and reporting such events throughout India. To monitor any such AEs, the Materiovigilance Programme of India (MvPI) was launched by the Drugs Controller General of India (DCGI), Dr G N Singh, at Indian Pharmacopoeia Commission, Ghaziabad, on July 6, 2015. During the launch, a Steering committee and a Working Group committee were constituted to meet the aims and objectives as also the functions of the programme. The committees recommended identification of Medical Devices Adverse Events Monitoring Centres (MDMCs), assignment of coordinators and recruitment of research associates for these centres. The MoHFW nominated Sree Chitra Tirunal Institute of Medical Sciences & Technology (SCTIMST), Thiruvananthapuram, as National Collaboration Centre (NCC) and National Health System Resource Centre (NHSRC) for providing technical support.

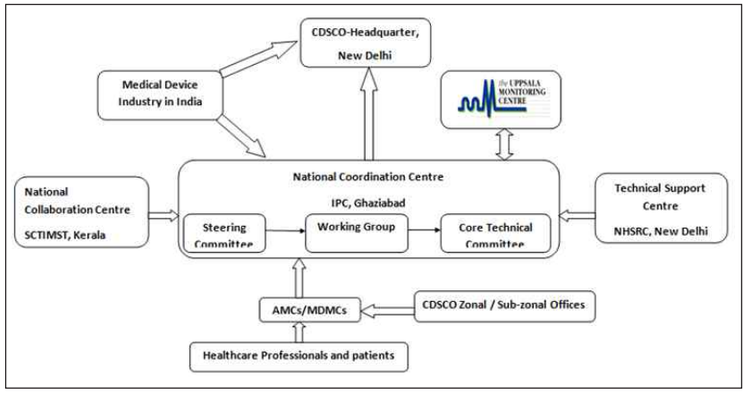
Following the recommendations by the two committees, 10 government medical colleges across the country, covering various zones, were identified as MDMCs by the NCC-PvPI and coordinators and newly-recruited research associates assigned to these centres. To train the coordinators and research associates in Materiovigilance, the NCC-PvPI held a two-day induction-cum-training programme from February 22, 2017.

To ensure effective AE reporting culture among MDMCs, clinicians, biomedical engineers, hospital technology manager, pharmacists, nurses, technicians, the MvPI has introduced various tools for AE reporting. It is pertinent to mention here that in due course the CDSCO will be able to access India-specific data on AEs related to medical devices, for making regulatory decisions.

During the steering committee's second meeting at IPC, Ghaziabad, on March 21, 2017, Dr G N Singh urged the NCC-PvPI, IPC, to shoulder all MvPI responsibilities with a view to ensuring its smooth functioning.

Dr Singh, has recently issued a circular to 210 Adverse Drug Reactions Monitoring Centres (AMCs) under PvPI, highlighting the following:

- Urgent need for reporting all adverse events due to use of medical devices
- Reporting of adverse events due to medical devices through the specifically-prescribed Medical Device Adverse Event (MDAE) reporting-form
- Need for close coordination by PvPI with cardiology, orthopaedics and dentistry departments of all AMCs to ensure urgent reporting
- PvPI to develop working relations with biomedical engineers, technical partners and healthcare professionals
- NCC-PvPI has received as many as 50 Medical Device Adverse Event (MDAE) reports, which included 39 reports due to invasive devices, five reports due to non-invasive devices and six reports related to quality of the medical device.



Key Events

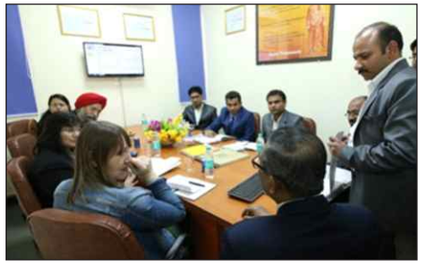
NRA Meets WHO Standards on Vaccine Regulation

A World Health Organization (WHO)-led team of international experts has certified that the National Regulatory Authority (NRA) of India and its affiliated institutions meet the WHO-published indicators for the functional vaccine regulatory system.

WHO-NRA exercise carried out from February 13-17, 2017 was aimed at assessing and documenting the status of Indian vaccine regulatory system, re-benchmarking the status of the vaccine regulatory system against the WHO-NRA Global Benchmarking Tool (GBT), updating the Institutional Development Plan and measuring maturity of the system.

The assessment includes Pharmacovigilance as one of the indicators for NRA-benchmarking tool. All sub-indicators of the Pharmacovigilance tool were fulfilled and found satisfactory. The progress was remarkable when compared with the last NRA assessment made in 2012. The assessment has been done in respect of nine different functionalities. Finally, the Pharmacovigilance system of India has been declared 'functional' with a maturity level of 4 out of 5, which is the highest level as per currently-evolved definitions.

Inaugural session of NRA Assessment 2017 at CDSCO (HQ), New Delhi



NRA reviewers during an inspection at NCC-PvPI, IPC, Ghaziabad

NURSES ARE THE CORNERSTONE OF PvPI EDIFICE

To stress the importance, and create awareness, of pharmacovigilance among nursing professionals, the NCC-PvPI organized its first national-level meeting on "Participation of Nursing Professionals in PvPI" at IPC, Ghaziabad, on May 6, 2016 as the nursing staff are one of the main stakeholders in the sphere of pharmacovigilance. Hence, the NCC-PvPI decided to play a proactive role in motivating nursing professionals to realise their role and responsibility in the detection, management, reporting and prevention of suspected ADRs and all essential activities for optimizing patient safety. During this meeting, **Dr G N Singh,** Secretary-cum-Scientific Director, IPC, said that nurses can act as a backbone for the pharmacovigilance programme and their active involvement in ADR reporting is also important from the regulatory point of view as safety information is incorporated into PIL from ADR reporting. Dr Chetna Desai, Prof B J Medical College (BJMC), Ahmedabad, in her keynote address deliberated on various topics like how to induct nurses in pharmacovigilance and the role of nurses in ADR reporting. It was recommended to form a panel of experts, including nurses to suggest ways in which ADR reporting can be implemented among nurses to include a nursing expert in the Steering Committee of PvPI. It was also recommended that Chief Nursing Staff should act as a member of PvPI panel in ADR Monitoring Centre.

Secretary-cum-Scientific Director, IPC, Dr G N Singh (centre), expounds on the role of nursing professionals in PvPI during the first national-level meeting on 'Participation of Nursing Professionals in PvPI', at IPC, Ghaziabad, on May 6, 2016

IMPORTANT EVENTS

PvPI PROGRESS: A REVIEW BY JOINT SECRETARY (REGULATIONS)

Mr K L Sharma, Joint Secretary (Regulations), and Dr G N Singh, Secretary-cum-Scientific Director, IPC, with officials of PvPI met at IPC, Ghaziabad, on May 2, 2016 to review the progress by PvPI and take situational updates of the programme. The JS (R) elaborated upon the efforts made by MoHFW to strengthen PvPI. The active engagement of pharmaceutical industries in pharmacovigilance was taken note of and the adherence to Guidance Document for MAHs will come into effect from January 2018. The JS (R) was overwhelmed by the progress and emphasized the need for value additions to PvPI with a view to improving its standing in the international arena.

JS (R), Mr K L Sharma (left), with DCG (I), Dr G N Singh (centre), and Deputy Drug Controller (India), Mr A K Pradhan, during the review meeting at IPC, Ghaziabad, on May 2, 2016

STATE DRUG REGULATION AUTHORITIES ADAPT TO PV PRACTICES

Dr Jagdish Prasad, Director General Health Services, Ministry of Health and Family Welfare (MoHFW), Government of India, has directed the State/Union Territories' (UTs) health authorities to adapt to pharmacovigilance practices in coordination with respective AMCs. Issuing a circular to this effect, he urged the authorities and officers concerned to approach nearby ADR Monitoring Centres (AMCs) functioning under PvPI for any technical support or Pharmacovigilance-related information.

Circular Highlights

- To inculcate ADR reporting culture in all healthcare professionals
- To sensitize nursing professionals for ADR reporting through state health authorities
- All state/UTs' health authorities requested to approach nearby AMC for technical support related to Pharmacovigilance

OPTIMIZING DRUG SAFETY BY RESEARCH-BASED PHARMACOVIGILANCE

To optimize drug safety through research-based Pharmacovigilance under Pharmacovigilance Programme of India (PvPI), National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI) in association with Indian Council of Medical Research (ICMR) convened its first meeting on "Optimizing the Safety of Medicines through research-based Pharmacovigilance-ICMR Institutions as Collaborating Centres" at ICMR headquarters in New Delhi on July 28, 2016.

S. No.	Name of ICMR Institute	Domain of Research
1.	National Institute of Epidemiology (NIE), Chennai	Pharmacoepidemiology and data management platforms
2.	National Institute for Research in Reproductive Health (NIRRH), Mumbai	Safety monitoring of drugs and devices for reproductive health
3.	National Institute of Nutrition (NIN), Hyderabad	Nutraceuticals' safety monitoring
4.	National Institute for Research in Tuberculosis (NIRT), Chennai	Research in tuberculosis
5.	National Institute of Cholera & Enteric Diseases (NICED), Kolkata	Safety monitoring of vaccines and drugs used in communicable diseases
6.	National AIDS Research Institute, (NARI), Pune	Monitoring the safety of Anti-HIV drugs
7.	National Institute of Malaria Research (NIMR), New Delhi	Safety of anti-malarial drugs

(From right) Secretary, DHR, & DG, Indian Council of Medical Research (ICMR), Dr Soumya Swaminathan with National Chair in Clinical Pharmacology, ICMR, Dr Nilima Kshirsagar, PSO, IPC, Dr V Kalaiselvan, and Professor and Head, Department of Pharmacology, All India Institute of Medical Sciences, New Delhi, Dr Y K Gupta

IMPORTANT EVENTS

ACTIVE SURVEILLANCE FOR BEDAQUILINE BEGINS AT PvPI

Bedaquiline (BDQ) is used for treatment of multi-drug-resistant tuberculosis (MDR-TB). At present, it is only available at six Revised National Tuberculosis Control Programme (RNTCP) centres across India as part of conditional access programme (CAP) and these centres are ADR-monitoring centres (AMCs) under PvPI. A four-day training programme on "Pharmacovigilance of antitubercular Medicines in India" was organised by NCC-PvPI, IPC, in association with RNTCP and WHO country office (India) in New Delhi from September 6 to 9, 2016. It was inaugurated by Dr Jagdish Prasad, DG, DGHS, and Mr K L Sharma, Joint Secretary (Regulation). The workshop was specially designed for six identified tertiary-care centres which are authorized to prescribe BDQ for MDR-TB treatment. The workshop was conducted for strengthening the operational and technical aspects for effective implementation of Pharmacovigilance in cohort event monitoring (CEM) of BDQ. Participants were imparted hands-on training on causality assessment, filling of CEM form (treatment initiation form and review form) and suspected ADR form for BDQ. Participants of the workshop comprised coordinators for treatment sites (clinicians), TB treatment officers, state TB officers, local causality assessment committee (CAC) members, medical officers, PvPI and WHO experts, statisticians and personnel from non-government organizations (NGOs). The workshop focused on providing in-depth training on causality assessment to RNTCP personnel.

DG, DGHS, Dr Jagdish Prasad (4th left), JS (R), MoHFW, Mr K L Sharma (5th left) and DCG (I) & Secretary-cum-Scientific Director, IPC, Dr G N Singh (4th right) with dignitaries at the inaugural session of the four-day training programme on 'Pharmacovigilance of Anti-tubercular Medicines in India', in New Delhi on September 6, 2016

IPC SIGNS MoU WITH NABH FOR ADR-REPORTING

Indian Pharmacopoeia Commission (IPC) signed a Memorandum of Understanding (MoU) with the National Accreditation Board for Hospitals and Healthcare Providers (NABH) on January 10, 2017. The objective of this MoU is to promote monitoring and reporting of ADRs by NABH-accredited hospitals to Pharmacovigilance Programme of India. The memorandum-signing ceremony was organised by IPC at CDSCO headquarters, FDA Bhawan, New Delhi.

DCG (I) & Secretary-cum-Scientific Director, IPC, Dr G N Singh with Director, NABH, Dr B K Rana (displaying copies of MoU), at CDSCO, HQ, in New Delhi on January 10, 2017

IMPORTANT EVENTS

NVBDCP AND PVPI SIGN MoU ON KALA-AZAR DRUG SAFETY

To ensure the safety of drugs used in the National Vector-Borne Disease Control Programme (NVBDCP) a memorandum of understanding (MoU) was signed between the IPC and Directorate of NVBDCP, New Delhi, on August 3, 2016. The MoU was signed by Dr G N Singh, Secretary-cum-Scientific Director, IPC, & DCG(I), and Dr A C Dhariwal, Director, NVBDCP, in presence of Dr Jagdish Prasad, DGHS. The MoU intends to foster active cooperation and exchange of information between the authorities concerned on drug safety. In the early phase, the primary objective is to monitor ADR of drugs used in treatment of Kala-azar as part of the vector-borne disease control programme.

DG, DGHS, Dr Jagdish Prasad (4th right), Secretary-cum-Scientific Director, IPC, Ghaziabad, Dr G N Singh (5th right), and Director, NVBDCP, Dr A C Dhariwal (3rd right), with experts displaying copies of NVBDCP-PvPI MoU at a meeting in New Delhi on August 3, 2016

Modes of Communication in PvPI

COMMUNICATIONS

Communicating safety information to patients and healthcare professionals is an important function of Pharmacovigilance. It is essential for achieving the objectives in terms of promoting the rational, safe and effective use of medicines, preventing harm from adverse reactions and contributing to the protection of public health. Communication aims at improving patient care, understanding ADRs/AEs, promoting transparency and

COMMUNICATIONS

accountability. NCC-PvPI is responsible for publishing/ communicating findings from its database to journals/media/online portals while other stakeholders are required to obtain prior approval from NCC to publish/communicate any data or information related to PvPI. Different modes of communications used in PvPI are:

Press and Media

This includes press releases and media briefings which are primarily intended for journalists. All activities related to PvPI are communicated to the media for raising awareness among stakeholders and the common man. PvPI also releases news to newspapers in different languages e.g. *Drug Today, Medical Times*, *Dainik Jagran, Dainik Bhaskar, Amar Ujala*, etc. in different states.

Website

A website is a key tool to disseminate information among stakeholders, including patients and healthcare professionals. NCC-PvPI strives to ensure that all important safety information is regularly published on its website.

Newsletter

NCC-PvPI publishes its *Newsletter* quarterly to communicate the findings and regulatory status of medicines in India as well as globally to the stakeholders. This newsletter is meant to disseminate information with issues of patient safety. It provides information, statistics and advice on drug safety. The quarterly issues of the *Newsletter* can be accessed from the IPC website www.ipc.gov.in

Posters and Pamphlets

Posters and pamphlets are effective modes of communication. PvPI regularly publishes posters and pamphlets that illustrate the news and views of PvPI and related drug safety information to stakeholders in India and across the globe.

Position Paper

Position paper of PvPI published during the 38th Annual Meeting of the WHO-PIDM comprises concise current scenario, landmark achievements, ongoing activities and future plans of the NCC-PvPI.

Communication through social media

LinkedIn (NCC PvPI)

LinkedIn is a business-oriented social networking service that offers visibility and access to stakeholders. The NCC-PvPI is registered on LinkedIn (ID - NCC PvPI), for better visibility and access to stakeholders.

Facebook (Ncc-PvPI IPC)

Facebook is a social networking website that allows registered users to create profiles, upload photos, videos and send messages. The facebook account of NCC-PvPI is used to share updates with users of this social media.

Twitter (@IPCNCCPvPI)

Twitter is an online social networking service that enables users to send and read short messages called "tweets". Registered users can read and post tweets regarding PvPI on the account @IPCNCCPvPI.

PvPI Achievements Highlighted in WHO-UMC Publications

PvPI outcomes are regularly shared globally through UMC and WHO publications

1. **Carbamazepine: Risk of Stevens Johnson's Syndrome**
Reference: http://apps.who.int/iris/bitstream/10665/255494/1/WPN-2016-02-eng.pdf?ua=1

2. **Piperacillin and tazobactam combination Risk of bronchospasm and hypokalaemia**
Reference: http://apps.who.int/iris/bitstream/10665/255494/1/WPN-2016-02-eng.pdf?ua=1

3. **Antirabies vaccine: Risk of erythema multiforme**
Reference: http://apps.who.int/iris/bitstream/10665/255491/1/WPN-2016-05-eng.pdf?ua=1

4. **Azithromycin: Risk of acute generalized exanthematous pustulosis**
Reference: http://apps.who.int/iris/bitstream/10665/255491/1/WPN-2016-05-eng.pdf?ua=1

5. **Betamethasone: Risk of photosensitivity reaction**
Reference: http://apps.who.int/iris/bitstream/10665/255491/1/WPN-2016-05-eng.pdf?ua=1

6. **Cefixime: Risk of acute generalized exanthematous pustulosis**
Reference: http://apps.who.int/iris/bitstream/10665/255491/1/WPN-2016-05-eng.pdf?ua=1

7. **Ceftriaxone: Risk of Stevens Johnson Syndrome**
Reference: http://apps.who.int/iris/bitstream/10665/255491/1/WPN-2016-05-eng.pdf?ua=1

8. **Cloxacillin: Risk of acute generalized exanthematous pustulosis**
Reference: http://apps.who.int/iris/bitstream/10665/255491/1/WPN-2016-05-eng.pdf?ua=1

9. **Ibuprofen: Risk of Stevens Johnson Syndrome/toxic epidermal necrolysis**
Reference: http://apps.who.int/iris/bitstream/10665/255491/1/WPN-2016-05-eng.pdf?ua=1

10. **Itraconazole: Risk of photosensitivity reaction**
Reference: http://apps.who.int/iris/bitstream/10665/255491/1/WPN-2016-05-eng.pdf?ua=1

11. **Lamotrigine: Risk of Stevens Johnsons Syndrome/toxic epidermal necrolysis**
Reference: http://apps.who.int/iris/bitstream/10665/255491/1/WPN-2016-05-eng.pdf?ua=1

12. **Mannitol: Risk of hypokalaemia**
Reference: http://apps.who.int/iris/bitstream/10665/255491/1/WPN-2016-05-eng.pdf?ua=1

13. **Ranitidine: Risk of cardiac arrest**
Reference: http://apps.who.int/iris/bitstream/10665/255491/1/WPN-2016-05-eng.pdf?ua=1

14. **Rotavirus vaccine: Risk of intussusceptions**
Reference: http://apps.who.int/iris/bitstream/10665/255491/1/WPN-2016-05-eng.pdf?ua=1

15. **Furosemide: Risk of dermatitis lichenoid**
Reference: http://apps.who.int/iris/bitstream/10665/255487/1/WPN-2017-02-eng.pdf?ua=1

16. **Itraconazole: Risk of acute generalized exanthematous pustulosis**
Reference: http://apps.who.int/iris/bitstream/10665/255487/1/WPN-2017-02-eng.pdf?ua=1

17. **Lithium carbonate: Risk of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) syndrome**
Reference: http://apps.who.int/iris/bitstream/10665/255487/1/WPN-2017-02-eng.pdf?ua=1

Scientific Publications-National Coordination Centre

S.No.	2016
1.	Kalaiselvan V, Kumar R, Kumar P, Singh GN. Reporting of adverse drug reaction under Pharmacovigilance Programme of India. International Journal of Pharma and Chemical Research. 2016; 2 (1): 25.
2.	Kalaiselvan V, Kaur I, Singh S, Singh GN. Pharmacovigilance Programme of India: System put in place to report adverse drug reaction. Inian Journal of Pharmaceutical Education and Research. 2016; 50(1): S212.
3.	Kalaiselvan V, Saurabh A, Kumar P, Singh GN. Monitoring of safety of Nutraceuticals through Pharmacovigilance Programme of India. Current trends in Nutraceuticals. 2016; 1(1): 8.
4.	Kumar P, Kalaiselvan V, Kaur I, Thota P, Singh GN. Materiovigilance Programme of India (MvPI): A step towards Patient safety for medical devices. 2016; 8(12): 497.

S.No.	2017
1.	Kalaiselvan V, Thota P, Kumar V, Rathore MS, Thota A, Singh GN. Risk of intussusceptions with Rotavirus vaccine. Indian Journal of Paediatrics . 2017; 84(2): 97.
2.	Kumar R, Kalaiselvan V, Verma R, Kaur I, Kumar P, Singh GN. Veterinary Pharmacovigilance in India: A need of hour. Indian Journal of Pharmacology. 2017; 49 (1): 2.
3.	Kumar A, Ahuja J, Shrivastava TP, Kumar V, Kalaiselvan V. Statistical Signal Process in R language in the Pharmacovigilance Programme of India. Therapeutic Innovation and Regulatory Science. 2017; 1(2): 101.

Scientific Publications-ADR Monitoring Centres (AMCs)

S.No.	2016
1.	Benjamin J, Marpaka S. 5-FU induced generalised tonic-clonic seizures in colorectal carcinoma: Case Report. European Journal of Biomedical and Pharmaceutical Sciences. 2016; 3 (9):561.
2.	Suguna A, Sravani, Prasanna. Evaluation of Knowledge, Attitude and Practice of Pharmacovigilance in Medical, Dental and BSc Nursing students of a government tertiary healthcare hospital in Telangana through Pharmacovigilance awareness programme. Journal of Dental and Medical Sciences. 2016; 15(10): 23.
3.	Raveendran A, Betkerur J. Sulfasalazine induced Toxic Epidermal Necrolysis in a Rheumatoid Arthritis Patient: A case report. Indian Journal of Pharmacy Practice. 2016; 9(1):57.
4.	Patil SB, Raikar SR. A profile of adverse drug reactions in a rural tertiary care hospital. National Journal of Physiology Pharmacology. 2016; 6(6):559.
5.	Raina R, Dimri D, Thapliyal S. Retrospective analysis on adverse drug reactions due to antimicrobials in a tertiary care hospital of Pauri Garhwal. International Journal of Pharmaceutical Research. 2016; 8 (3): 54.
6.	Reddy YVB, D. Sathish Kumar, S Sharon Sonia. Ofloxacin induced Stevens-Johnson Syndrome–Case Report. Journal of Medical and Health Research. 2016; 1 (5):56.
7.	Goyal C. Rafi M. Khan G. Anaphylaxis to parentral Ciprofloxacin in mother leading to foetal death. Indian Journal of Pharmacy and Pharmacology. 2016; 3(4):223.

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8. Bhattacharjee P, Das L, Ghosh R, Das LK. Pattern of adverse drug reactions reported at a tertiary health care teaching hospital of Tripura: A retrospective study. International Journal of Basic Clinical Pharmacology. 2016; 5 (4): 1293.

9. Thamizhvani D, Brattiya KR, Bhat RC, Stalin C. A qualitative study to analyse ADR reporting forms. International Journal of Pharmacology and Toxicology. 2016; 4 (4):208.

10. Dua M, Dua S, Gehlot A. An observatiobnal study of drug induces cutaneous reactions used in various group of patients. Scholars Academic Journal of Pharmacy. 2016; 5(3):76.

11. Pattnaik KP, Dehury S.Pain abdomen in a child aggravated after treatment with Ciprofloxacin, metronidazole and Tramadol: Case study. International Journal of Medical Research Professionals. 2016; 2(2):189.

12. Kumar M, Joe E, Shanthi, Mani. Role of Pharmacovigilance in Coimbatore Medical College and Hospital. International Journal of Pharmacy and Pharmaceutical Analysis. 2016; 1(2):11.

13. Choudhary B, Kumari S, Dhingra B, Jhaj R. A clinically suspected case of anaphylactoid reaction to Vitamin K injection in a child-Case report and review of literature. Indian Journal of Pharmacology. 2016; 48 (4): 455.

14. Jhaj R, Asati DP, Chaudhary D. Fixed drug eruption due to Levocetrizine. Journal of Pharmacology and Pharmacotherapy. 2016; 7(2):109.

15. Sharma PK, Gupta N, Hasan N, Krishnamurthy B. Hypersensitivity with inhalational Budesonide: An under recognised entity. J CLin Diagn Res. 2016; 10(10): 01.

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18. Saini R, Sharma B, Verma PK. NSAIDs: The double edge sword-Pharmacovigilance in a tertiary care hospital. IRPMS. 2016; 2 (3): 12.

19. Reddy VN, Benakppa A. Phenobarbital induced SJS in an epileptic child-Case report. 2016; 3 (4): 428.

20. Ashai ZA, Pukhta MA, Singh Z. A six month study assessing ADRs in a Nascent AMC. European Journal of Biomedical and Pharmaceutical Sciences. 2016; 3(5): 446.

21. D Sathish Kumar, Reddy YV, Swarnlatha K. Amoxicillin-Clavulanic acid induced Pemphigus vulgaris-Case report. European Journal of Biomedical and Pharmaceutical Sciences. 2016; 3(5): 579.

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23. Malladi P. Cutaneous ADRs reported to AMC at tertiary care teaching hospital–Kuppam. World Journal of Pharmacy and Pharmaceutical Sciences. 2016; 5(10):583.

24. Shanthi N, Muthukumar S, Hema P. Assessment of Pharmacovigilance–ICSR at tertiary care hospital. World Journal of Pharmacy and Pharmaceutical Sciences. 2016; 5(12):1168.

25. Malladi P. A study of ADRs reported to AMC at tertiary care teaching hospital–Kuppam. World Journal of Pharmacy and Pharmaceutical Sciences. 2016; 5(10): 804.

26. Haritha P, Sowmya D, Satish D, Reddy YV. DRESS syndrome by Dapsone and Phenytoin-Rare case report. World Journal of Pharmacy and Pharmaceutical Sciences. 2016; 5(10): 523.

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28. Jyothi A, Kiranmai R, Mounika PS, Mandava P, Kumar SD. A case report on Dapsone hypersensitivity syndrome in leprosy patient. British Journal of Pharmaceutical and Medical Research. 2016; 1(1): 63.

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31. Das L, Bhattacharjee P, Ghosh R, Das UK. KAP of Pv among doctors in tertiary care teaching hospital of Tripura. National Journal of Physiology, Pharmacy and Pharmacology. 2016; 7(2): 218.

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33. D Sathish Kumar, Sonia S, Reddy YV. Pharmacovigilance: A way for better tomorrow. Pharmacy Practice and Drug Research. 2016; 6(2): 57.

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36. Sudha KM, Devipriya S. Spontaneous adverse drug reaction reporting in a government tertiary care teaching hospital. Pharmanest. 2016; 7(3): 3100.

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2. Devadarshini S, Pattnaik KP, Samal R, Mohapatra J. Comparative analysis of cutaneous drug reaction among different Fluoroquinolones : An experimental study. International Journal of Basic and Clinical Pharmacology. 2017; 6(6): 254.

3. Chakraborty A, Ray D, Ghosh R, Roy N. Pattern of ADRs reporting to medical colleges of Tripura, India: A cross sectional study. International Journal of Basic and Clinical Pharmacology. 2017; 6(6): 1372.

4. Patel NS, Patel NK, Patel PB. Hospitalizations due to preventable Adverse reactions: Systematic review. European Journal of Clinical Pharmacology. 2017; 73(4): 385.

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6. Stalin C, Bhat CR. Adverse drug reactions profile of Penicillins and Cephalosporins: A comparative study. Inventi Rapid: Pharmacy Practice. 2017; 1: 12.

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9. Malathi M, Shanthi M, Nambi T. Adverse Drug Reaction at a Tertiary care hospital in South India-A Perspective Analysis. Journal of Medical Science and Clinical Research. 2017; 5(9): 27451.

10. Stalin C, Bhat CR, Aruna T. Analysis of anaphylaxis and anaphylaxis –like reactions: A qualitative study. MOJ Biology and Medicine. 2017; 1(4): 25.

ACTION PLAN

Action Plan 2017-18

- Extension of PvPI by enrolling district hospitals to spread coverage at micro-level
- Nation-wide campaign to enhance the outreach for public health programmes
- Development of bridge application with Nikshay (RNTCP) to access ADRs of anti tubercular drugs
- Awareness activities to enhance public engagement towards reporting adverse drug reactions
- Networking with pharmaceutical industry and other professional bodies for effective implementation of PvPI
- Aspire by professional bonding with SEARO region countries for Pharmacovigilance training and guidance
- Implementation of Quality Management System (QMS) of PvPI to ensure quality services for stakeholders
- Organizing skill development trainings for budding professionals in the field of Pharmacovigilance
- Development of indigenous IT-tools for e-reporting of adverse drug reaction in India

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Dr Pawan K. Saini, Scientific Officer

Dr Prasad Thota, Scientific Assistant

Mr Jitin Ahuja, Pharmacovigilance Associate

Mr Tarani Prakash Shrivastava, Pharmacovigilance Associate

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Dr Pramod Kumar Sharma, Associate Professor, All India Institute of Medical Sciences, Jodhpur

Dr Sushma Srivastava, Senior Consultant, IPC

Mr Ramesh Khazanchi, Editorial Consultant, IPC

Shri S C Sharma, Advisor, IPC

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

List of AMCs of PvPI

LIST OF ADR MONITORING CENTRES UNDER PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

Andhra Pradesh

Centre Name: Andhra Medical College, King George Hospital (KGH), Jagadamba Area, KGH Down Road, Maharanipeta, Visakhapatnam-530002
Coordinator: Dr. J. Sudha
Email: prabhakar2202@gmail.com
Contact: 09849903051
Recognition Status of AMCs: ART centre

Centre Name: Guntur Medical College, Kanna Vari Thota,Guntur-522004
Coordinator: Dr. A. Meena Kumari
Email: meenaphani@gmail.com
Contact: 09849133268

Centre Name: Peoples Education Society Institute of Medical Sciences and Research, Kuppam, Chittoor District-517425
Coordinator: Dr. Revanna Swamy
Email: pharmacovigilancepesimsr@gmail.com
Contact: 09845558999

Centre Name: S. V. Medical College, Alipiri Road , Tirupati, Chittoor District-517507
Coordinator: Dr. Vasundhara Devi
Email: vasuda61@yahoo.com
Contact: 09849632862

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

Centre Name: Rajivgandhi Institute of Medical Sciences, Near Balaga, Srikakulam-532001
Coordinator: Dr. D. Syamala
Email: syamala333@yahoo.com
Contact: 09866553685

Centre Name: Sri Venkateswara Institute of Medical Sciences, Sri Padmavathi Medical College for Women, Tirupati, Andhra Pradesh-517507
Coordinator: Dr. Umamaheswara Rao
Email: svimspharmacovigilance@gmail.com
Contact: 9849832292

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

Centre Name: Konaseema Institute of Medical Sciences and Research Foundation & KIMS General Hospitals, Chaitanya Health City, Amalapuram, East Godavari district-533201, Andhra Pradesh
Coordinator: Dr. Anand Acharya
Email: anand_kims@yahoo.co.in
Contact: 08297361111

Arunachal Pradesh

Centre Name: Arunachal State Hospital, Naharlagun, Arunachal Pradesh-791110
Coordinator: Dr. Dohkum Raina
Email: medicalsupt@yahoo.com
Contact: 09436041290

Centre Name: Health Training & Research Centre, Pasighat-791102
Coordinator: Dr. T Tali
Email: drjgibi@yahoo.com
Contact: 09436043020

Assam

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

Centre Name: Silchar Medical College & Hospital, Ghungoor, Silchar-788014
Coordinator: Dr. Pinaki Chakravarty
Email: dr_pinaki@yahoo.com
Contact: 09957198505
Recognition Status of AMCs: RNTCP centre

Centre Name: Jorhat Medical College & Hospital, Kushal Konwar Path, Barbheta, P.O. Jorhat-785001
Coordinator: Dr. Swapnanil Gohain
Email: nil_swapna20@yahoo.com, pharmacologyjmch@gmail.com
Contact: 09613860565

Centre Name: Assam Medical College and Hospital, Barbari, Dibrugarh, Assam-786002
Coordinator: Dr. Urmi Choudhary
Email: urmichoudhury6@gmail.com
Contact: 09864270287

LIST OF AMCs

Bihar

Centre Name: Indira Gandhi Institute of Medical Sciences, Bailey Road, Sheikhpura, Patna-800014
Coordinator: Prof. (Dr.) Harihar Dikshit
Email: dikshithariharpatna@yahoo.co.in, amcigims2015@gmail.com
Contact: 09334106381

Centre Name: All India Institute of Medical Sciences, Phulwari Sharif, Patna-801505
Coordinator: Prof. P.P. Gupta
Email: drprempgupta@gmail.com
Contact: 07763800139, 09415210579

Centre Name: Lord Buddha Koshi Medical College & Hospital, NH 107, Baijnathpur, Saharsa-852201
Coordinator: Dr. Akhilesh Kumar
Email: sykalabs@yahoo.co.in
Contact: 09431243204

Centre Name: Katihar Medical College, post box No. 23, Karimbagh, Katihar, Bihar-854105
Coordinator: Dr. C. B Choudhary
Email: drcb_choudhary@yahoo.co.uk
Contact: 09431025891

Centre Name: M. G. Memorial Medical College, Purabbali, Dinajpur Road, Kishanganj, Bihar-855107
Email: rataboli_padmanabh@rediffmail.com
Contact: 09822386263

Chhattisgarh

Centre Name: Pt. JNM Medical College, Jail Road, Raipur- 492001
Coordinator: Dr. Rajesh Hishikar
Email: rhishikar@gmail.com
Contact: 09424205700
Recognition Status of AMCs: RNTCP centre

Centre Name: All India Institute of Medical Sciences, Tatibandh, GE Road, Raipur, Chhattisgarh-492099
Coordinator: Dr. Suryaprakash Dhaneria,
Dy. Coordinator: Dr. Nitin R.Gaikwad
Email: dean@aiimsraipur.edu.in, nitingaikwad2707@gmail.com
Contact: 09826045357, 08518881725

Centre Name: C. M. Medical College and Hospital, Vill & P.O: Kachandur, Durg, Chhattisgarh-490024
Coordinator: Dr. Sunita Chandraker
Email: sunitach78@gmail.com
Contact: 07583836501

Goa

Centre Name: Goa Medical College & Hospital, NH 17, Bambolim, Tiswadi-403202
Coordinator: Dr. Padmanabh V. Rataboli

Gujarat

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

Centre Name:BJ Medical College, New Civil Hospital, Asarwa, Ahmedabad-380016
Coordinator: Dr. Mira K. Desai
Email: desaimirak@yahoo.com
Contact: 09825057107
Recognition Status of AMCs: ART-Centre, RNTCP centre

Centre Name: Government Medical College, Near State Road Transport Corporation Bus Stand, Bhavnagar-364002
Coordinator: Dr. C. B. Tripathi
Email: cbrtripathi@yahoo.co.in
Contact: 09825951678

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
Email: sachendra5@rediffmail.com, zeel_manvi@ymail.com
Contact: 09898464713, 09979596006

Centre Name: M.P. Shah Medical College, Pt. Nehru Road, Jamnagar- 361008
Coordinator: Dr. Hiren R. Trivedi
Email: drhrt13@yahoo.com
Contact: 09825210878

Centre Name: PDU Medical College, Civil Hospital Campus, Jam Nagar Road, Rajkot- 360001
Coordinator: Dr. Anil Singh
Email: docanil71@yahoo.co.in
Contact: 09426974679
Recognition Status of AMCs: ART centre

Centre Name: Gujarat Medical Education & Research Society Medical College, Gotri, Vadodara-390021
Coordinator: Dr. Prakash Bhabhor
Email: drbhabhor@gmail.com, deanmcgv@gmail.com
Contact: 09925014449

Centre Name: Pramukhswami Medical College & Shree Krishna Hospital, Gokal Nagar, Karamsad, Dist. Anand- 388325
Coordinator: Dr. Anuradha Joshi
Email: anuradhaj@charutarhealth.org
Contact: 09825828234

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

Centre Name: Gujarat Medical Education and Research Society (GMERS) Medical College, 2nd Floor, E-Block, Civil Hospital Campus, Nr. Pathikashram, Sector-12, Gandhinagar-382012
Coordinator: Dr. J. G. Buch
Email: drjgbuch@hotmail.com, deangmersmcg@gmail.com
Contact: 09426473496

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

Centre Name: GMERS Medical College, Sola, Near Gujarat High Court, S.G highway, Ahmedabad, Gujarat-380060
Coordinator: Dr. Mukesh kumar B. Vora
Email: mukeshkrutin@gmail.com
Contact: 09228117957

Haryana

Centre Name: Medanta-The Medicity Sector-38, Gurgaon-122001
Coordinator: Dr. Himanshu Baweja
Email: himanshu.baweja@medanta.org
Contact: 09990942044

Centre Name: Artemis Hospital, Sector-51, Gurgaon
Coordinator: Mr. Ankur Panchal
Email: clinicalpharmacologist@artemishealthsciences.com ankurpanchal22@gmail.com
Contact: 09990380826

Centre Name: Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences, Rohtak-124001
Coordinator: Dr. M.C. Gupta
Email: dr_mcgupta@yahoo.co.in, dr.mcgupta57@gmail.com
Contact: 09896015035
Recognition Status of AMCs: RNTCP centre

Centre Name: BPS GMC for Women, Khanpur Kalan, Sonepat-131305
Coordinator: Dr. Seema Rani
Email: Seema17march@gmail.com
Contact: 09466359666

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

Centre Name: Faculty of Medicine & Allied Health Sciences, Shree Guru Gobind Singh Tricentary University, Farukh Nagar Road, Budhera, Distt. Gurgaon, Haryana-122505
Coordinator: Dr. Naveen Kumar
Email: nk999999@rediffmail.com
Contact: 09868257149

Himachal Pradesh

Centre Name: Dr. Rajendra Prasad Govt. Medical College, Kangra, Tanda-176001
Coordinator: Dr. Dinesh Kansal
Email: dinesh.kansal56@gmail.com
Contact: 09418454624
Recognition Status of AMCs: RNTCP centre

Centre Name: Indira Gandhi Medical College, Circular Rd, Lakkar Bazar, Shimla-171001
Coordinator: Dr. A.K. Sahai
Email: drashoksahai@gmail.com
Contact: 09418468582

Jammu & Kashmir

Centre Name: Govt. Medical College, Maheshpura Chown, Bakshi Nagar, Jammu-180001
Coordinator: Dr. Vishal Tandon
Email: dr_vishaltandon@yahoo.com
Contact: 09419195126

Centre Name: Sher-i-Kashmir Institute of Medical Sciences, Soura, Srinagar-190011
Coordinator: Dr. Z.A. Wafai
Email: drzawafai@gmail.com
Contact: 09419011862

Centre Name: Acharya Shri Chander College of Medical Sciences & Hospital, N.H. Bye pass, P.O. Majeen Sidhra-180017
Coordinator: Dr. Pavan Malhotra
Email: ascomshospital@gmail.com
Contact: 09419182264

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

LIST OF AMCs

Jharkhand

Centre Name: Rajendra Institute of Medical Sciences (RIMS),
Bariatu, Ranchi-834009
Coordinator: Dr. Janardan Sharma
Email: drsharmaj@gmail.com, amcrims@gmail.com
Contact: 09431175014

Karnataka

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

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

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

Centre Name: JSS Medical College Hospital,
Sri Shivarathreeshwara Nagar, Mysore-570015
Coordinator: Dr. Parthasarathi G.
Email: partha18@gmail.com
Contact: 09845659585
Recognition Status of AMCs: ART centre

Centre Name: Karnataka Institute Of Medical Sciences,
P. B Road, Vidyanagar, Hubli-580021
Coordinator: Dr. Dattatri A.N., Dr. S A Salimath
Email: adrkmc@gmail.com
Contact: 09902354622, 09591073366
Recognition Status of AMCs: ART-Centre, RNTCP centre

Centre Name: Kasturba Medical College,
Madhava Nagar, Manipal-576104
Coordinator: Dr. K. L. Bairy
Email: kl.bairy@manipal.edu, klbairy@yahoo.com
Contact: 09449208478

Centre Name: Mandya Institute of Medical Sciences (MIMS),
District Hospital Campus, Mandya-571401
Coordinator: Dr. Nagabushan
Email: 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. Shashidhar Buggi
Email: shashidharbuggi@gmail.com, director.rgicd@gmail.com
Contact: 09448042579

Centre Name: St. Johns Medical College,
Sarjapur Road, Bengaluru-560034
Coordinator: Dr. Padmini Devi
Email: p_nidhin@hotmail.com
Contact: 09844353460

Centre Name: Vydehi Institute of Medical Sciences and
Research Centre,
82, Nallurahalli, Near BMTC 18th Depot, Whitefield, Bengalu-
ru-560066
Coordinator: Dr. Pratibha Nadig
Email: drpratibhanadig@yahoo.co.in
Contact: 09901961964

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

Centre Name: M.S. Ramaiah Medical College,
MSR Nagar, Gokula, Bengaluru-560054
Coordinator: Dr. M. C. Shiva murthy
Email: drshivamurthymc@gmail.com
Contact: 080-23605190, 23601742, 23605408

Centre Name: SDM College of Medical Sciences & Hospital,
Manjushree Nagar, Sattur, Dharwad-580009
Coordinator: Dr. Prasan R Bhandari
Email: prasangeeta2012@gmail.com
Contact: 09036941910

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

Centre Name: Sapthagiri Institute of Medical Sciences and
Research Centre, No.15, Chikkasandra,
Hesaraghatta Main Road, Bangalore-560090
Coordinator: Dr. Shubha R.
Email: shubhapreksha@gmail.com
Contact: 09448074489

Centre Name: A.J. Institute of Medical Sciences,
Kuntikana, NH-66, Mangalore-575004
Coordinator: Dr. Sharath Kumar K.
Email: 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

Email: drunpatil@gmail.com
Contact: 09886767811

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

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

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

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

Centre Name: M.R. Medical College,
Kalaburagi-585105, Karnataka
Coordinator: Dr. Santosh Kumar Jeevangi
Email: mrmcglb@gmail.com, djeevangi@gmail.com
Contact: 09945910158

Kerala

Centre Name: Govt. Medical College,
P.O- Kozhikode-673008
Coordinator: Dr. Seema. P. Mohamedali
Email: seemapharmac@gmail.com
Contact: 09497082050

Centre Name: Govt. Medical College,
Gandhinagar, Kottayam-686008
Coordinator: Dr. Ramani P.T.
Email: adrpharmac.mck@gmail.com
Contact: 09446593762

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

Centre Name: Amala Institute of Medical Sciences,
Amala Nagar, P.O Thrissur-680555
Coordinator: Dr. Deepu jacob Chacko
Email: vigil.amala@gmail.com
Contact: 08157020222

Centre Name: Govt. T.D. Medical College,
Vandanam, Alappuzha-688005
Coordinator: Dr. Kala Kesavan
Email: drkalakesavan@yahoo.co.in tdmcalappuzha@gmail.com
Contact: 09847034504

Centre Name: Government Medical College,
Medical College PO, Thiruvananthapuram-695011
Coordinator: Dr. S. Pradeep
Dy. coordinator: Dr. Annapoorna
Email: drpradeepsadasivanpillai@gmail.com,
annatvm11@yahoo.com
Contact: 09447451073
Recognition Status of AMCs: RNTCP centre

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

Centre Name: Cochin Medical College,
HMT colony P.D, kalamassery, Cochin-683503
Coordinator: Dr. S. N Veenasree
Email: veenabiju73@yahoo.com
Contact: 09995446530

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

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

Madhya Pradesh

Centre Name: Gandhi Medical College,
Sultania Road, Bhopal- 462001
Coordinator: Dr. Arun Srivastav
Email: arunsrivastav8@gmail.com
Contact: 09424983641

Centre Name: RD Gardi Medical College,
Agar Road, Surasa, Ujjain -456006
Coordinator: Dr. Ashutosh Chourishi
Email: dr_chourishi@yahoo.co.in, dr_chourishi@hotmail.com
Contact: 09893005655
Recognition Status of AMCs: RNTCP centre

LIST OF AMCs

Centre Name: SAIMS Medical College, Ujjain Highway, Sanwer Road, Indore- 453111
Coordinator: Dr. Chhaya Goyal, Dr. Pooja Reddy
Email: chhayagl@gmail.com
Contact: 09827221640

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

Centre Name: All India Institute of Medical Sciences, Saket Nagar, Bhopal- 462024
Coordinator: Dr. Ratinder Jhaj, Dr. Balakrishnan S
Email: rati.pharm@aiimsbhopal.edu.in, head.pharm@aiimsbhopal.edu.in
Contact: 07773002096

Centre Name: Gajra Raja Medical College, Veer Savarkar Marg, Gwalior, M.P-474009
Coordinator: Dr. Saroj Kothari
Email: saroj.kothari@rediffmail.com
Contact: 09827322002

Maharashtra

Centre Name: BJ Medical College & Sassoon General Hospital, Jai Prakash Narayan Road, Near Pune Railway Station, Pune-411001
Coordinator: Dr. B.B. Ghongane
Email: ghongane_bb@yahoo.com
Contact: 09922925590
Recognition Status of AMCs: ART centre

Centre Name: Government Medical College & Hospital, Ajni Rd, Nagpur-440003
Coordinator: Dr. Ganesh N. Dakhle
Email: smitaavanti@yahoo.co.in, gndakhle@rediffmail.com
Contact: 09850539353

Centre Name: Grant Medical College & Sir JJ Group of Hospital, JJ Marg, Off Jijabhoy Road, Byculla Mumbai- 400008
Coordinator: Dr. S. B. Patel
Email: pharmac.gmc@gmail.com, dr.sbpatel.gmc@gmail.com
Contact: 09821286701
Recognition Status of AMCs: ART centre

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

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

Centre Name: Mahatma Gandhi Institute of Medical Sciences, Nagpur Sevagram, Nagpur- 442012
Coordinator: Dr. Sushil Kumar Varma
Email: sushil@mgims.ac.in, varmasushil9@gmail.com
Contact: 09921418999

Centre Name: Pd. Dr. D.Y. Patil Medical College, Gaikwad Haraibhau Vinayan Rd, Pimpri, Chinchwad, Pune -411018
Coordinator: Dr. A.V. Tilak
Email: abhijeet.tilak@yahoo.com
Contact: 09226145484

Centre Name: Aditya Birla Memorial Hospital Marg, Chinchwad, Pune-411033
Coordinator: Dr. Yuvraj Dhyanoba
Email: yuvrajjogdand123@gmail.com
Contact: 09767130114

Centre Name: Seth GS Medical College & KEM Hospital, Acharya Donde Marg, Parel- 400012
Coordinator: Dr. Urmila Thatte
Email: PvPIitakem@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
Email: 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
Email: renuka.munshi@gmail.com
Contact: 09820377409

Centre Name: Armed Forces Medical College, Opposite Race Course, Solapur road, Pune Cantonment, Pune-411040
Coordinator: Dr. A.K. Gupta
Email: pharmacovigafmc@gmail.com ajayneera2007@rediffmail.com
Contact: 09765090428

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

Centre Name: Govt. Medical College, Latur, Opposite Rajasthan High School, Near Minimarket, Latur-413512
Coordinator: Dr. Jaju J.B.
Email: dean_gmchl@rediffmail.com
Contact: 02382-247676

Centre Name: N.K.P. Salve Institute of Medical Sciences & Lata Mangeshkar Hospital, Digdoh Hills, Hingna Road, Nagpur-440019

Coordinator: Dr. Archana S. Borkar
Email: drarchana50@gmail.com, nkpsims1@rediffmail.com
Contact: 09922155782, 07104-306100

Centre Name: Pandit Dindayal Upadhyay Institute of Medical Science, Research and Human Resources, Gadkari wada, Upadhye Road, Mahal, Nagpur, Maharashtra-440017
Coordinator: Dr. Viral Kamdar
Email: drviralkamdar@gmail.com
Contact: 09373105676

Centre Name: Aundh Chest Hospital, 1st Floor, Nr Sangavi Phata, Aundh camp, New Sangavi, Pune-411027
Coordinator: Dr. Smita Sanjeev Shiras, Dr. Mrs. Dhavle
Email: dpsmhpna@rntcp.org
Contact: 09422356164
Recognition Status of AMCs: RNTCP centre

Centre Name: Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Sawangi (Meghe), Wardha-442004
Coordinator: Dr. Shailesh Nagpure
Email: 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
Email: drckant@gmail.com
Contact: 09766819507

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

Centre Name: Smt. Kashibai Navale Medical College & General Hospital, Sr. No. 49/1, Narhe, Off Mumbai-Pune bypass, Pune-411041
Coordinator: Dr. Yogita Karandikar
Email: karandikar_yogita@yahoo.com
Contact: 09922747908

Manipur

Centre Name: Regional Institute of Medical Sciences, Lamphelpat, Imphal-795004
Coordinator: Dr. S. Rita Devi
Email: pharmacovigirims15@gmail.com ritasanjenbam@yahoo.co.in
Contact: 09612002132

Meghalaya

Centre Name: North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences, mawdiangdiang, shillong-793018
Coordinator: Dr. Dhriti Kumar Brahma
Email: dbdhriti168@gmail.com
Contact: 09436766171

Odisha

Centre Name: VSS Medical College, Burla, Sambalpur-768031
Coordinator: Dr. Sabita Mohapatra
Email: adr.vssmc.pharma@gmail.com
Contact: 09238607960
Recognition Status of AMCs: RNTCP centre

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

Centre Name: SCB Medical College and Hospital, Manglabag, Cuttack-753007
Coordinator: Dr. Srikanta Mohanty
Email: adr.scbmch@gmail.com, drkaliprasad@yahoo.co.in
Contact: 09437271809

Centre Name: Hi-tech Medical College & Hospital, Health Park, Pandara, Bhubaneshwar-751025
Coordinator: Dr. Parbaty Panda
Email: Parbaty.panda@gmail.com
Contact: 09437304089

Centre Name: Kalinga Institute of Medical Sciences and P.B.M Hospital, KIIT University, Bhubaneswar, Odisha-751024
Coordinator: Dr. Manjushree Mohanty
Email: drmm992014@gmail.com
Contact: 09861073471

Punjab

Centre Name: Christian Medical College and Hospital, Brown Road, Ludhiana-141008
Coordinator: Dr. Dinesh Kumar Badyal
Email: dineshbadyal@gmail.com
Contact: 09815333776

Centre Name: Dayanand Medical College and Hospital, Tagore Nagar, Civil Lines, Ludhiana-141001
Coordinator: Dr. Sandeep Kaushal
Email: skaushal1@yahoo.co.in
Contact: 09876635367

LIST OF AMCs

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

Centre Name: Guru Gobind Singh Medical College & Hospital, Sadiq Road, Faridkot-151203
Coordinator: Dr. Jasleen Kaur
Email: narulajasleen03@gmail.com
kkpharmacology@rediffmail.com
Contact: 09814917365

Centre Name: Government Medical College, Circular Road, Amritsar-143001
Coordinator: Dr. Jaswant Rai
Email: drjaswantrai@gmail.com
Contact: 08146896878

Centre Name: Government Medical College, Patiala, New Lal Bagh, Patiala, Punjab-147001
Coordinator: Dr. Anita Gupta
Email: drguptaanita@hotmail.com
gmcpharmacologypatiala@gmail.com
Contact: 09872139567
Recognition Status of AMCs: RNTCP centre

Rajasthan

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

Centre Name: SMS Medical College, Jawaharlal Nehru Marg, Jaipur-302004
Coordinator: Dr. Mukul Mathur
Email: mathur_mukul@rediffmail.com
coordPvPImsjp@rediffmail.com
Contact: 09414324182
Recognition Status of AMCs: ART centre

Centre Name: Geetanjali Medical College and Hospital, geetanjali Medicity, Hiran Magri Extn, Eklingpura Chouraha, Udaipur-313001
Coordinator: Dr. Jameela Tehshildar
Email: dr.jameelatahasildar@yahoo.com
Contact: 0929303666

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

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

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

Centre Name: Institute of Respiratory Diseases, SMS Medical College, Subhash Nagar, Jaipur- 302016
Coordinator: Dr. Rajendra Singhvi
Email: dpsrjjpr@rntcp.org
Contact: 09829154901, 0141-2281000 (Ext. no. 260)
Recognition Status of AMCs: RNTCP centre

Centre Name: Dr. S. N. Medical College, Residency Road, Shastri Nagar, Jodhpur-342001
Coordinator: Dr. Anusuya Gehlot (Senior Prof. Pharmacology)
Email: medicalcollegejodhpur@yahoo.com, anusuyagehlot@gmail.com
Contact: 09413256424

Sikkim

Centre Name: Sikkim Manipal Institute of Medical Sciences, Tadong, Gangtok-737102
Coordinator: Dr. Supratim Datta
Email: supratimdoc@gmail.com
Contact: 09434488126, 08967828551

Tamil Nadu

Centre Name: Christian Medical College and Hospital, No:4, Ida Scudder road, Vellore- 632004
Coordinator: Dr. J.V. peter
Email: peterjohnvictor@yahoo.com.au
Contact: 09626793284
Recognition Status of AMCs: ART centre

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

Centre Name: Madras Medical College, E.V.R Periyar Salai, Park Town, Chennai-600003
Coordinator: Dr. K.M Sudha
Email: PvPI.chennai@gmail.com, m_sudha69@yahoo.com
Contact: 09840697847
Recognition Status of AMCs: ART centre

Centre Name: PSG Institute of Medical Sciences & Research, Anna Nagar, Coimbatore-641004
Coordinator: Dr. S. Ramalingam
Email: drrampsg@gmail.com
Contact: 09894618450

Centre Name: SRM Medical College Hospital & Research Centre, kattankulathur, Kanchipuram-603203
Coordinator: Dr. Jamuna Rani
Email: jrs_durai@yahoo.co.in
Contact: 09840279010

Centre Name: Sri Ramachandra Medical College and Research Institute, Porur, Chennai-600116
Coordinator: Dr. Darling Chellathai David
Email: PvPIsrmc@gmail.com, hod.pharmacology@sriramachandra.edu.in
Contact: 09444622698

Centre Name: Madurai Medical College, Alwarpuram, Madurai-625020
Coordinator: Dr. M. Malathi
Email: poojamuthudch@yahoo.co.in
Contact: 08760263019

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

Centre Name: Coimbatore Medical College & Hospital, Trichy Road, Gopalapuram, Coimbatore-641014
Coordinator: Dr. N. Shanthi
Email: shanthisundarrajan@gmail.com
Contact: 09443113740

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

Centre Name: Velammal Medical College Hospital and Research Institute , Anuppanadi, Madurai-625009
Coordinator: Dr. S. Thamilaras
Email: tamilsoundar@gmail.com, Vallish.bn@gmail.com
Contact: 09443269175, 09787773793

Centre Name: Government Hospital of Thoracic Medicine, Tambaram, Chennai-600047
Coordinator: Dr. Nalini Jayanthi
Email: nalinijayanthi59@gmail.com, dpstncni@rntcp.org
Contact: 09444226783
Recognition Status of AMCs: ART Centre, RNTCP centre

Centre Name: Kanyakumari Govt. Medical College, Asaripallam, Kanyakumari District- 629201, Tamil Nadu
Coordinator: Dr. T. Ashok Kumar
Email: drsita99@gmail.com
Contact: 09443130263

Telangana

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

Centre Name: Nizam Institute of Medical Sciences, Punjagutta Main Road, Hyderabad-500082
Coordinator: Dr. P. Usha Rani
Email: ushapingali@yahoo.com
09849574143

Centre Name: Bhaskar Medical College & Bhaskar General Hospital,
Yenkapally, Moinabad, Ranga Reddy-500075
Coordinator: Dr. G. Vijay Lakshmi
Email: yadagirivijayalakshmi@yahoo.com
Contact: 08413-235447

Centre Name: Kamineni Institute of Medical Sciences, Narketpally, Nalgonda-508254
Coordinator: Dr. Y. Venkata Rao
Email: pharmacology.kimsnkp@gmail.com
Contact: 09440038529

Centre Name: Gandhi Medical College, Musheerabad, Secundrabad-500003
Coordinator: Dr. T.S. Usha Shree
Email: ushasreetakkella@yahoo.com
Contact: 09848592058
Recognition Status of AMCs: ART centre

Centre Name: Osmania Medical College, koti, Hyderabad-50019
Coordinator: Dr. V. Prasanna
Email: vprasanna@yahoo.com
pharmacologyomc@gmail.com
Contact: 09440359790

Centre Name: Chalmeda Anand Rao Institute of Medical Sciences,
Bommakal, Karimnagar, Telangana -505001
Coordinator: Dr. Santosh Kumar. B
Email: drsantoshkumar999@gmail.com
Contact: 09885767609

Tripura

Centre Name: Agartala Govt. Medical College, Kunjaban, Agartala-799006
Coordinator: Dr. Debasis Ray
Email: contactdebasisray@gmail.com, agmc@rediffmail.com
Contact: 09436125100

Centre Name: Tripura Medical College & Dr. BRAM Teaching Hospitals, Hapania, Agartala-799014
Coordinator: Dr. Tapasjyoti Ray

LIST OF AMCs

Email: tajray2007@yahoo.co.in
Contact: 09433174655, 08132803103

Uttar Pradesh

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

Centre Name: GSVM Medical College, Swaroop Nagar, Kanpur- 208001
Coordinator: Dr. S.P. Singh
Email: singhdrsp@gmail.com
Contact: 09415154744

Centre Name: Institute of Medical Sciences Banaras Hindu University, Varanasi- 221005
Coordinator: Dr. B.L. Pandey
Email: blp53@rediffmail.com
Contact: 09451964917, 09451440039
Recognition Status of AMCs: ART centre

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

Centre Name: M.L.B. Medical College, Jhansi- 284128
Coordinator: Dr. Sadhna Kaushik
Email: kaushiksadhna55@gmail.com
Contact: 07897038922

Centre Name: M.L.N Medical College, Darbhanga Colony, George Town, Allahabad- 211002
Coordinator: Dr. Rakesh Chandra Chaurasia
Email: drrakesh65@rediffmail.com
Contact: 09415615064

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

Centre Name: U.P Rural Institute of Medical Sciences and Research, Safai, Etawah-206130
Coordinator: Dr. Asha Pathak
Email: drasha_pathak@yahoo.co.in
Contact: 09451021779

Centre Name: Muzaffarnagar Medical College & Hospital, opp. Begrajpur Industrial Area, Ghasipur, Muzaffarnagar-251201
Coordinator: Dr. Suman Lata
Email: dr.sumanlata@yahoo.com
Contact: 09897878728
Recognition Status of AMCs: ART centre

Centre Name: School of Medical Sciences & Research, Sharda University, Greater Noida-201306
Coordinator: Prof. Qazi M. Ahmed, Dr. Ashok K Dubey
Email: qma49@yahoo.co.in, drakd1105@yahoo.co.in
Contact: 09313766906

Centre Name: Subharati Medical College, Subharti Puram, NH-58, Delhi-Haridwar By Pass Road, Meerut-250005
Coordinator: Dr. Prem Prakash Khosla
Dy. Coordinator: Dr. Ruchi Choudhary
Email: khoslapp@yahoo.com, ruchi.upmanyu@gmail.com
Contact: 08909654319, 09410866646

Centre Name: Eras Lucknow Medical College & Hospital, Sar - fazganj, Moosa Bagh picnic Spot, Hardoi Road, Lucknow-226003
Coordinator: Dr. Afroz Abidi
Email: afrozabidi@gmail.com
Contact: 09794979717

Centre Name: Dr. Ram Manohar Lohia Institute of Medical Sciences, Vibhuti Khand, Gomti Nagar, Lucknow-226010
Coordinator: Dr. Mukul Mishra
Email: mukul_rk_misra1@yahoo.com
Contact: 09450959088

Centre Name: Sarojini Naidu (S. N) Medical College, Moti Katra, Agra-282002
Coordinator: Dr. Mona Verma
Email: dpsupagr@tbcindia.nic.in, dpsupagr@rntcp.org PvPI.snmc@gmail.com
Contact: 09997024763
Recognition Status of AMCs: RNTCP centre

Centre Name: Teerthanker Mahaveer Medical College and Research Centre, N.H-24,Bagarpur, Delhi Road, Moradabad, U.P-244001
Coordinator: Dr. Farhan Ahmad Khan
Email: dr.farhan.k@gmail.com
Contact: 09759468300

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

Centre Name: National Drug Dependence Treatment Centre, Cector-19, Kamla Nehru Nagar, C. G. O Complex, Ghaziabad-201002
Coordinator: Dr. Sudhir K. Khandelwal
Email: sudhir_aiims@yahoo.co.uk
Contact: 011-26593675

Uttarakhand

Centre Name: Govt Medical College, Rampur Road, Haldwani-263139
Coordinator: Dr. Bhavana Srivastava
Email: bhavanaufht@yahoo.co.in

Contact: 09412017320
Recognition Status of AMCs: RNTCP centre

Centre Name: Himalayan Institute of Medical Sciences, Ram Nagar, P.O. Doiwala, Dehradun, Uttarakhand-248140
Coordinator: Dr. D.C. Dhasmana
Email: dhasmanadc@gmail.com
Contact: 09719803560

Centre Name: Veer Chandra Singh Garhwali Medical Science and Research Institute, Srinagar, Pauri Garhwal-246174
Coordinator: Dr. Getanjali Kothiyal
Email: gita.kothiyal@gmail.com
Contact: 09897272681

Centre Name: Shri Guru Ram Rai institute of Medical & Health Sciences, Sri Mahant Indresh Hospital, Patel Nagar, Post Box 80, Patel Nagar, Dehradun-248001
Coordinator: Dr. Shakti Bala Dutta
Email: sushreesoham@gmail.com
shaktibalad@gmail.com
Contact: 09456501367

Centre Name: All India Institute of Medical Sciences, Virbhadra road, Rishikesh-249201
Coordinator: Dr. Puneet Dhamija
Email: drpdhamija@gmail.com
Contact: 08475000292

West Bengal

Centre Name: School of Tropical Medicine, 108, Medical College Campus Chittaranjan Avenue, Kolkata- 700073
Coordinator: Dr. Santanu Tripathi
Email: stm.PvPI@gmail.com
Contact: 09230566771
Recognition Status of AMCs: ART centre

Centre Name: R.G. Kar Medical College, 1, Kshudiram Bose Sarani, Kolkata-700073
Coordinator: Dr. Anjan Adhikari
Email: adr.rgk.pharma@gmail.com
Contact: 09831012503
Recognition Status of AMCs: RNTCP centre

Centre Name: Calcutta National Medical College, Dr Sundari Mohan Ave, Beniapukur, Kolkata-700014
Coordinator: Dr. Sushobhan Pramanik
Email: 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
Email: drsupchat@gmail.com
Contact: 09831130980, 033- 22041428

Centre Name: Burdwan Medical College, Baburbag, P.O. Rajbati-Burdwan-713104
Coordinator: Dr. Mithilesh Haldar
Email: amc.PvPIbmc@gmail.com
Contact: 09733106803

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

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

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

Centre Name: North Bengal Medical College, PO Sushrutanagar, Siliguri, Distt. Darjeeling-734012
Coordinator: Dr. Anupam Gupta
Email: nathguptadranupam@yahoo.com
Contact: 09434686320

Centre Name: Murshidabad Medical College & Hospital, Berhampore-742101
Coordinator: Dr. Mainak Ghosh
Email: docmainak@gmail.com
Contact: 09007924708

Centre Name: Midnapore Medical College & Hospital, Vidyasagar Road, Paschim Medinipur-721101
Coordinator: Dr. Balaram Ghosh
Email: drbrghosh@gmail.com, amc.mmch@gmail.com
Contact: 09800442964, 0322-2222411

Centre Name: ICARE Institute of Medical Sciences & Research and Dr. Bidhan Chandra Roy Hospital, Banbishnupur, Balughata, Haldia, Dist.- Purba, Medinipur, W.B-721645
Coordinator: Dr. Sukanta Sen
Email: drsukant@gmail.com
Contact: 08420532336

Andaman & Nicobar

Centre Name: Andaman & Nicobar Islands Institute of Medical Sciences, Portblair-744104
Coordinator: Dr. Mangesh Bankar
Email: drmangesh_bankar@yahoo.co.in
Contact: 09531858830

LIST OF AMCs

Chandigarh

Centre Name: PGIMER, Sector12, Chandigarh-160012
Coordinator: Dr. Bikash Medhi
Email: drbikashus@yahoo.com
Contact: 09914207510
Recognition Status of AMCs: COEART centre

Delhi

Centre Name: All India Institute of Medical Sciences(AIIMS), Ansari Nagar East, Gautam Nagar, New Delhi -110029
Coordinator: Dr. Y.K. Gupta
Email: yk.ykgupta@gmail.com, PvPI.ncc@gmail.com
Contact: 09868868457
Recognition Status of AMCs: ART centre, RNTCP centre

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

Centre Name: Lady Hardinge Medical College (LHMC), C 604, Shivaji Stadium Bus Terminal Co. Place Shaheed Bhagat Singh Marg, New Delhi-110001
Coordinator: Dr. H.S. Rehan
Email: 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
Email: drrachna1@rediffmail.com
Contact: 09868140063
Recognition Status of AMCs: ART- centre

Centre Name: Vallabhbhai Patel Chest Institute (VPCI), University of Delhi, Guru Tegh Bhadur Road, New Delhi -110007
Coordinator: Prof. A. Ray
Email: arunabha14@yahoo.co.in
Contact: 09818037595

Centre Name: VMMC & Safdarjung Hospital, Mahatma Gandhi Marg, Raj Nagar, Safdarjung, New Delhi 110029
Coordinator: Dr. C.D. Tripathi
Email: cdtripathi@gmail.com
Contact: 09818665424
Recognition Status of AMCs: ART- centre

Centre Name: Hamdard Institute of Medical Sciences and Research, Hamdard Nagar, New Delhi -110062
Coordinator: Dr. Deepti Chopra
Email: drdeeptichopra@yahoo.com
Contact: 09818710237

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
Email: roy.vandana@gmail.com
Contact: 09968604283
Recognition Status of AMCs: COEART- centre

Centre Name: Rajan Babu Institute of Pulmonary Medicine and Tuberculosis, GTB Nagar, Kingsway Camp, New Delhi-110009
Coordinator: Dr. Anuj Bhatnagar
Email: anuuj1968@gmail.com
Contact: 09818321353
Recognition Status of AMCs: RNTCP centre

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
Email: drsarin@yahoo.com, r.sarin@nitrd.nic.in
Contact: 09999971557
Recognition Status of AMCs: RNTCP centre

Centre Name: Institute of Liver and Biliary Sciences, D-1, Vasant Kunj, New Delhi-110070
Coordinator: Dr. Devesh Gupta
Email: drdeveshgupta@gmail.com
Contact: 09899000743

Puducherry

Centre Name: Indira Gandhi Medical College & Research Institute, Kadirkamam-605009
Coordinator: Dr. Lourdu Jafrin. A, Dr. Priyadarshini R
Email: hiwedz@gmail.com, shalipriya85@gmail.com, adr.igmcri@gmail.com
Contact: 09943732717, 09943491252

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

Centre Name: Pondicherry Institute of Medical Sciences, Ganapathichettikulam, kalapet, Pondicherry-605014
Coordinator: Dr. Manjunatha C H
Email: drmanjunatha@pimsmmm.net
Contact: 09629352078

NEWLY-ENROLLED ADR MONITORING CENTRES

Centre Name: Narayan Medical College & Hospital, Jamuhar, Sasaram, Bihar-821305
Coordinator: Dr. Rahul Mohan
Email: braj_rahul@yahoo.co.in
Contact: 9431470647

Centre Name: Aster Medcity, Cheranelloor, Kochi, Kerala-682027
Coordinator: Dr Priya K
Email: priya.karunakaran@dmhealthcare.com
Contact: 8111998041

Centre Name: D M Wayanad Institute of medical sciences, Naseera Nagar, Meppadi (P.O),Wayanad, Kerala-673577
Coordinator: Dr. S. Basalingappa
Email: basalingappa.s@gmail.com, dr.sbasalingappa@dmwims.com
Contact: 09489391426

Centre Name: Dr. Vaishampayan Memorial Govt. Medical College, Opp. District Court, Solapur, Maharashtra-413003
Coordinator: Dr. Ujwala Pramod Gawali
Email: ujwalapgawali@gmail.com
Contact: 9420492342

Centre Name: Govt Stanley Medical College, Old Jail road, Royapuram, Chennai, Tamilnadu-600001
Coordinator: Dr. G. Hemavathy
Email: smcpvpi16@gmail.com, hemavathy128@gmail.com
Contact: 9444081969

Centre Name: Malla Reddy Institute of Medical Sciences, Survey No. 138,suraram Main Road, Quthabullapur, Jeedmetla, Hyderabad, Telangana-500055
Coordinator: Dr. M.Jamuna Rani
Email: mrimspharmacology@gmail.com, jamunadrrani@yahoo.com
Contact: 9989651706

Centre Name: Government Medical College, Chakrapanpur, Azamgarh, U.P– 276127
Coordinator: Dr. Dhananjay Pandey
Email: sharanshakti18@gmail.com
Contact: 8931083216, 8543000735

Centre Name: Mata Anandamayee Hospital, Pandit Madan Mohan Malviya Road, Shivala, Varanasi, U.P- 221001
Coordinator: Dr. (Prof.) Jannavi Tandon
Email: knjannavi@gmail.com
Contact: 9415983721, 7311100000

Centre Name: Guru Shri Gorakhnath Chikitsalaya, Gorakhnath Mandir Campus, Gorakhpur, U.P- 273001
Coordinator: Dr. Jamal Haider
Email: jamal001@gmail.com
Contact: 9839828358

Centre Name: Government Doon Medical College, Dehrakhas, Patel Nagar, Dehradun, Uttarakhand-248001
Coordinator: Dr. Rangeel Singh Raina
Email: rainarangeel@gmail.com
Contact: 9568127670

Centre Name: North Delhi Municipal Corporation Medical College and Hindu Rao Hospital, MalkaGanj, Delhi-110007
Coordinator: Dr Yangshen Lhamo
Email: yangshenlhamo@yahoo.com
Contact: 9654833513