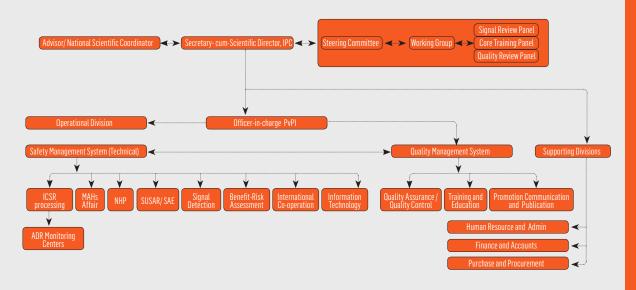
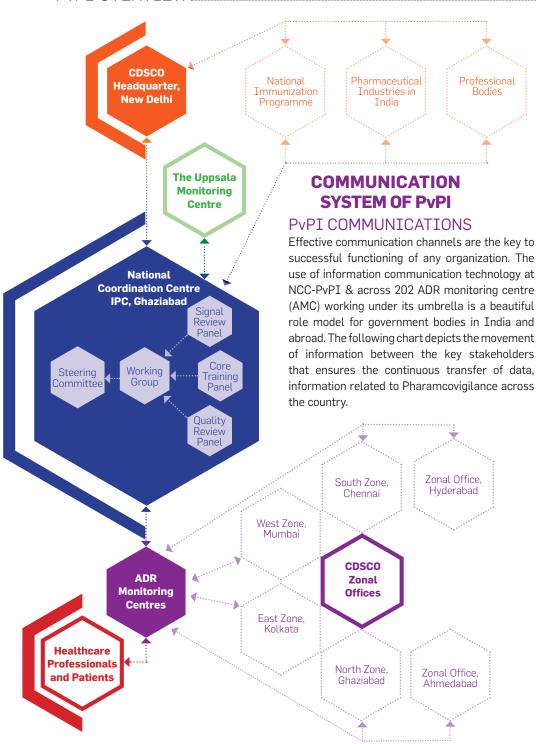
#### SCOPE AND OBJECTIVES

- 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 medications.
- To generate evidence based information on safety of medicines.
- To support regulatory agencies in the decision-making process on use of medications.
- To communicate the safety information on use of medicines to various stakeholders to prevent/ minimise the risk.
- To emerge as a National Centre of Excellence for Pharmacovigilance activities.
- To collaborate with other national centres for the 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 medicines.

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



#### PvPI OVERVIEW



#### COMMITTEES UNDER NCC-PvPI

The following committees and panels were constituted by MoHFW, Government of India (GoI) for efficient functioning of the programme:

#### **Steering Committee**

The NCC-PvPI is administered and monitored by the Steering Committee that supervises and quides the programme.

#### **Working Group**

It is constituted to approve major technical and policy issues related to establishment and implementation of the programme and provide technical inputs to CDSCO for regulatory interventions.

#### **Quality Review Panel**

It is constituted to review 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 actions after implementation of recommendations.

#### **Signal Review Panel**

SRP is constituted of experienced scientists and clinical experts affiliated to government and non-government academic institutions and hospitals, if required experts from pharmaceutical industries at times are also invited for special inputs, to collate and analyze information from ICSRs. This panel assesses the results of the computerized assessment of ICSRs for the potential signals in the field of public health & drug regulation. It also defines biostatistical methods to be followed for analysis of Drug-ADR combinations and creates standardized post analytical reports that will help in understanding the information that is derived from analysis of ADRs. It also decides upon actionable indicators.

#### **Core Training Panel**

The Core Training Panel of PvPI identifies trainers and zone wise training centers for imparting training under the PvPI. The panel interacts with international agencies for participation and implementation of training programs related to Pharmacovigilance. It organizes training, training programs and designs training modules for the stakeholders.

#### **ADR REPORTING IN PVPI**

#### Who can Report?

All healthcare professionals and others including consumers may report a suspected adverse drug reaction. Pharmaceutical companies may send report on adverse drug reaction for their product directly to the NCC-PvPI.

#### Why to Report?

The health and safety of Indian population is a matter of national concern. Occurrence of ADR constitutes a significant economic burden on the patient and the government. As a prudent and vigilant healthcare professionals (HCPs), it is the responsibility of HCPs to report adverse drug reactions associated with use of medicines to safeguard the health of patients. India has a vast population that exhibits genetic and ethnic variability, there also exists a vast variation in disease prevalence. The data so generated will help to make vital policy decisions regarding safe use of medicines in Indian population.

#### What to Report?

In order 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 to PvPI. Although Pharmacovigilance is primarily concerned with pharmaceutical medicines and vaccines, adverse reactions associated with drugs used in traditional medicine (e.g. herbal remedies), medical devices, contrast media and other pharmaceuticals are also monitored. Special areas of interest include outcomes associated with the drug use during pregnancy, lactation period, and in paediatric and geriatric populations. In addition, reporting of lack of efficacy of medicines and suspected pharmaceutical

PATIENTS/CONSUMERS/
HEALTHCARE
PROFESSIONALS MAY
REPORT SUSPECTED
ADRs ASSOCIATED WITH
THE USE OF MEDICINAL
PRODUCTS TO NCC-PvPI
VIA HELPLINE
1800-180-3024
FROM 9:00 A.M. TO 5:30 P.M.

defects are also recommended to report. 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 (clinicians, dentists, pharmacists, nurses, etc.) can report adverse drug reactions 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 directly to the NCC. The form is available on the official website of IPC (http://www.ipc.gov.in) or the CDSCO (http://www.cdsco.nic.in).

#### CHANNELS OF ADR REPORTING



#### **Suspected ADR form**

Reporters may fill the 'Suspected Adverse Drug Reaction Reporting Form' available on the official website of IPC (www.ipc.gov.in) or the CDSCO (www.cdsco.nic.in) to report any ADR. Reporters may submit the ADR form to the nearest AMC or directly to NCC of PvPI or mail the duly filled form at PvPI. ipcindia@gmail.com.

#### Helpline (1800-180-3024)

Patients/Consumers/Healthcare Professionals may report suspected

ADRs associated with the use of medicinal products to NCC-PvPI via toll-free helpline 1800-180-3024 from 9:00 A.M. to 5:30 P.M. on working days. An SMS acknowledgement facility has been introduced to acknowledge the reporter of his valuable contribution to the programme and to encourage them for further ADR

#### **Mobile Application**

reporting.

An android mobile application for Adverse Drug Reaction (ADR) reporting was launched on 22nd May 2015. It is a joint venture of IPC (NCC) and NSCB Medical College, Jabalpur. It is expected that this application will provide a platform for the private healthcare professionals to report ADRs. The mobile application includes inbuilt functions and features for reporting ADRs such as customization of reporter details, auto-entry of drug details and WHO algorithm based causality assessment.



#### **Medicines Side Effect Reporting Form (For Consumers)**

The form ensures direct participation of patients/ consumers in PvPI and this in turn helps in safeguarding the health of Indian population. The form is now available in ten local languages i.e. Hindi, Bengali, Gujarati, Kannada, Malayalam, Marathi, Assamese, Oriya, Tamil and Telugu. This channel of reporting ADR may be regarded as a mechanism for consumer empowerment in healthcare sector.

The reporter is free to choose his own choice to report the Adverse Drug Reactions.

## Pharmacovigilance in Drugs & Cosmetics Rules, 1945

#### Pharmacovigilance System Mandate for Drug Manufacturers

ue to emerging need of pharmacovigilance and monitoring of drug safety profile, Ministry of Health and Family Welfare, Government of India amended the Schedule Y appended to Drugs & Cosmetics Rules, 1945, vide G.S.R. 287 (E) dated 08.03.2016.

The said notification created a mandate of Pharmacovigilance system in place for reporting ADR to licensing authority by every manufacturer or market authorization holder.

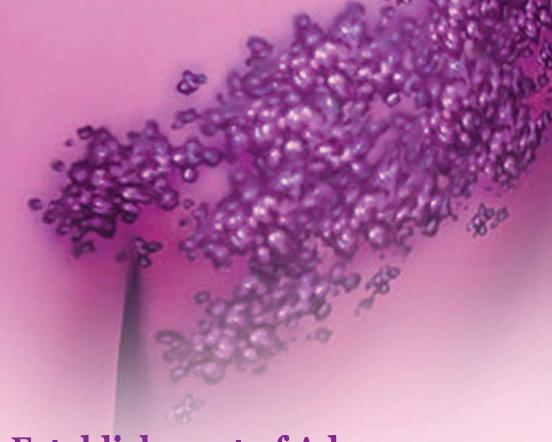
The substance of G.S.R. 287 (E) dated 08.03.2016 is reproduced below:

#### "4. Post Marketing Surveillance-

1. The applicant shall have a Pharmacovigilance system in place for collecting, processing and forwarding the report to the licensing authority for information on adverse drug reactions emerging from the use of the drugs manufactured or marketed by the applicant in the country.



- **1 (a)** The system shall be managed by qualified and trained personnel and the officer in-charge of collection and processing of data shall be a medical officer or a pharmacist trained in collection and analysis of adverse drug reaction reports.
- **1 (b)** Subsequent to approval of the product, new drug shall be closely monitored for its clinical safety once it is marketed.
- 1 (c) The applicant shall furnish Periodic Safety Update Reports (PSURs) in order to-
  - (a) Report all relevant new information from appropriate sources;
  - (b) Relate the data to patient exposure;
  - (c) Summarise the market authorisation status in different countries and any significant variations related to safety; and
  - (d) Indicate whether changes shall be made to product information in order to optimise the use of product."



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

vPI encourages all government and non government teaching hospitals, private hospitals, district hospitals, 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 the major concerns for them. Monitoring of ADRs is very important in this aspect and the AMCs plays a very crucial role in it.

A 'Letter of Intent' (LoI) is required from the Head of the Institution to participate in the PvPI. After examining the suitability, the concerned centre may be inducted as an AMC under PvPI. Subsequently, NCC communicates the AMC details to WHO-Uppsala Monitoring Centre (UMC), Sweden to obtain VigiFlow® login details. The format of LoI is available on the IPC website (www.ipc.gov.in) or an email in this regard may be sent to PvPI at PvPI@ipcindia.net or PvPI.ipcindia@gmail.com.

#### ADR MONITORING CENTRES

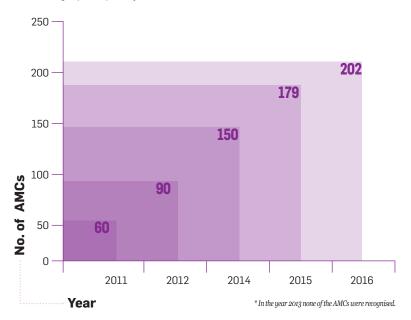
The centre requesting for the participation should fulfill the following criteria to be accepted as an AMC:

- a) It is essential for the center to function with their own logistic and infrastructural facilities. If the proposed centre is accepted as an AMC, NCC-PvPI, IPC may provide the trained manpower if its performance was found satisfactory.
- b) Preference will be given to the applications from States where no/few AMCs exist.
- c) The proposal may be accepted based on the past track record of the centre on Pharmacovigilance.
- d) The acceptance of the centre as an AMC is based on the quality, quantity and frequency of Adverse Drug Reaction (ADR) reports reported directly to NCC or nearby AMCs in the past one year from the date of the said proposal for enrollment as an AMC.
- e) Significant track record/expertise of the proposed coordinator/deputy coordinator in the area of Pharmacovigilance.
- f) The HOD/Dean/Principal of the proposed centre shall be responsible to establish/ implement the PvPI activities at the centre.
- g) The HOD/Dean/Principal of the institute shall be responsible to identify new coordinator & deputy coordinator and to intimate the same to NCC-PvPI in case of any change (transfer/ superannuation etc).

If the centre fulfills the above mentioned criteria it may be accepted as an AMC under PvPI. Upon recognition, NCC-PvPI provides them the regular training, skill development & technical support to the personnel engaged in PvPI activities.

#### **AMCs enrolled under PvPI**

At present, there are 202 ADR monitoring centres (AMCs) enrolled under PvPI. The graph depicts year wise enrolment of AMCs.



#### Categorization of Adverse Drug Reaction Monitoring Centres (AMCs) functioning under Pharmacovigilance Programme of India (PvPI)

	Categorization of AMCs					
S. No.	Medical Colleges/ Hospitals	No.				
1.	Government Teaching Hospitals/ART Centres/ RNTCP Centres	109				
2.	Non Government Teaching Hospitals	84				
3.	Corporate Hospitals	06				
4.	Specialized Hospitals	03				
	Total no. of AMCs	202				

## **Status of ADR Reporting**

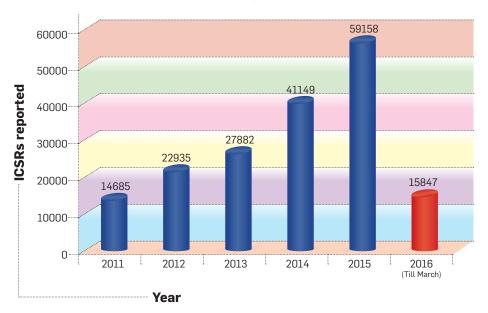
## 1,81,656 ADR reports have been received at NCC-PvPI during April 2011 – March 2016

total of 1,81,656 reports were received at NCC-PvPI during April 2011 – March 2016 from various sources i.e. AMCs, Non AMCs, via Toll free helpline number, Mobile application etc. Spontaneous adverse drug reaction (ADR) reporting is the mainstay of Indian drug safety evaluation in the post approval phase.

#### ICSR DATA REPORTED IN LAST 5 YEARS

The year wise status of the reporting of Individual Case Safety Reports (ICSRs) in the last 5 years is illustrated in Figure 1. A progressive increase in the number of reports is evident, with a two fold increase which was observed in the year 2015, as compared to the year 2013.

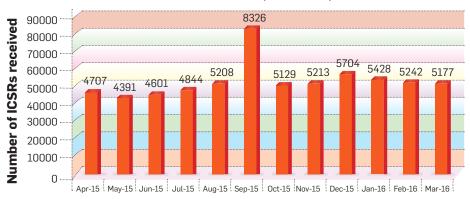
Fig.1 Individual Case Safety Reports (ICSRs) reported in past 5 years



#### ICSR'S MONTH WISE (2015-16) DISTRIBUTION

During the index period i.e. April 2015 – March 2016 NCC-PvPI received a total of 63,970 reports. Month wise distribution of the reports received at NCC-PvPI during the index period shows that the ICSRs reporting is well sustained throughout the year. A sudden increase in the month of September reporting was seen due to contribution of massive industrial reports.

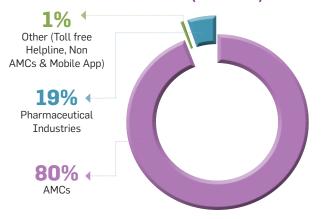
Fig.2 Month wise distribution of ICSRs received at NCC-PvPI (2015-16)



## SOURCE WISE DISTRIBUTION

The figure 3, depicts distribution the the reports received during the index period. 80% reports were reported by the ADR monitoring centres (AMCs) functioning under PvPI, Pharmaceutical industry reports summed to 19% and other sources contributed 1%.

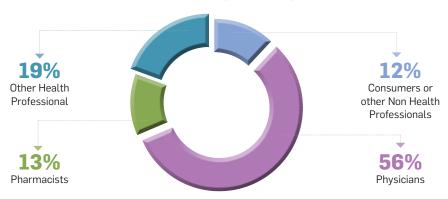
Fig. 3 Sources of ICSRs received at NCC-PvPI (2015-16)



#### REPORTER WISE DISTRIBUTION

The NCC-PvPI receives ICSRs from the physicians, pharmacists, other HCPs, consumers (non HCPs) etc. Spontaneous ADR reports from the Physicians (56%) remained a big source of received reports, followed by the other healthcare professionals (19%), pharmacists (13%) and consumers or other non-healthcare professionals (12%).

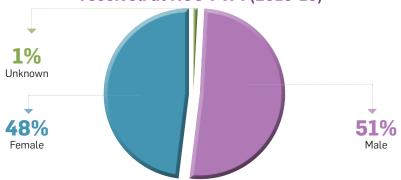
Fig. 4 Reporter wise Distribution of ICSRs received at NCC-PvPI (2015-16)



#### GENDER WISE DISTRIBUTION

As per data, 51% ADRs occurred in male patients and 48% ADRs were reported in female patients.

Fig. 5 Gender wise Distribution of patients in ICSRs received at NCC-PvPI (2015-16)

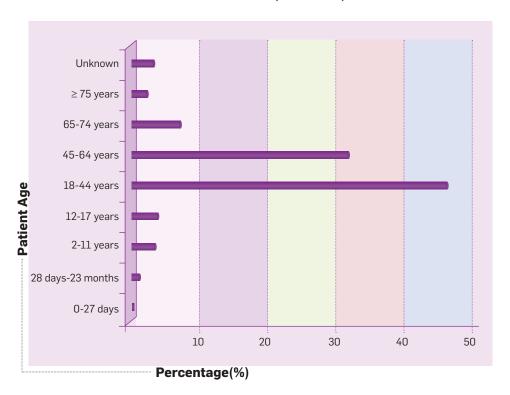


 $<sup>^{\</sup>star}$  Unknown refers to the cases in which no option was marked against the gender field.

#### AGE WISE DISTRIBUTION OF ADRS

The majority of the reported cases occurred in patients aged 18-44 years.

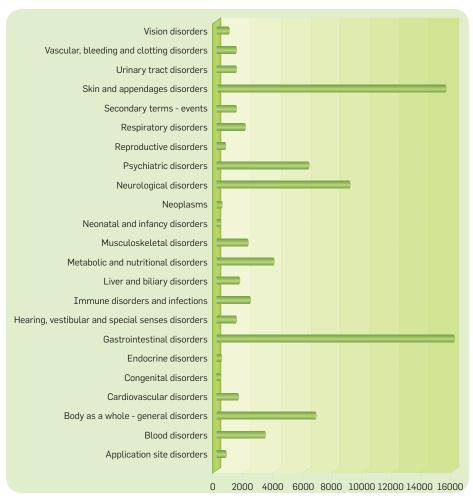
Fig. 6 Age wise Distribution of patients in ICSRs received at NCC-PvPI (2015-16)



#### DISTRIBUTION OF ADRs—SYSTEM ORGAN CLASS (SOC) WISE

The reported ADRs included 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 reported cases were gastrointestinal, skin & appendages and neurological disorders as shown in the Fig.7.

Fig. 7 System Organ Class (SOC) of ADRs reported at NCC-PvPI (2015-16)



#### MODES OF ADR REPORTING

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

- 1. Reporting by AMCs through VigiFlow®.
- Reporting by the Pharmaceutical industry.
- 3. Reporting through Toll free helpline.
- 4. Reporting by the Non-AMCs.

3400

5. ADR Reporting via Mobile Application.

#### 1. REPORTING BY AMCs THROUGH VIGIFLOW®

A total of 202 Medical Colleges & Hospitals, Medical/Central/Autonomous Institutes, Public Health Programmes or Corporate Hospitals enrolled under PvPI are functioning as AMCs (upto March 2016). As previously mentioned the major contribution of the ICSRs was made by the AMCs enrolled under PvPI i.e. 80%, during the index year.

**Number of ICSRs received** 4800 -4666 4559 4565 4515 4503 4600 4281 4400 4282 4149 4098 4200 3986 4000 ---3892 3938 3800 3600 -

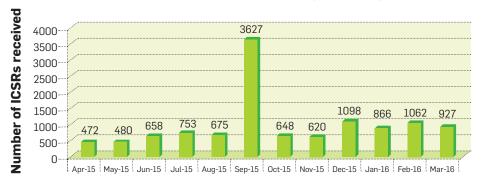
Fig. 8 Month wise distribution of ICSRs received from **AMCs at NCC-PvPI (2015-16)** 

#### 2. REPORTING BY THE PHARMACEUTICAL INDUSTRY

Pharmaceutical industry is an important stakeholder in PvPI. NCC-PvPI planned and executed several rounds of meeting with the industry experts for data sharing arrangements between CDSCO, NCC-PvPI and marketing authorization holders (MAHs). As a net result of these efforts, MAHs has started voluntary reporting to NCC-PvPI.

Apr-15 May-15 Jun-15 Jul-15 Aug-15 Sep-15 Oct-15 Nov-15 Dec-15 Jan-16 Feb-16 Mar-16

Fig. 9 ICSRs received from Pharmaceutical Industries (2015-16)



#### 3. REPORTING THROUGH TOLL FREE HELPLINE:

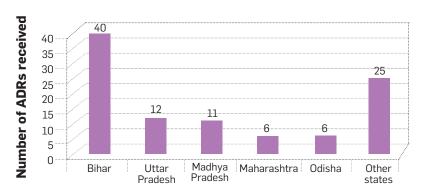
On 11<sup>th</sup> October, 2013, the NCC-PvPI launched a Toll Free Helpline Number i.e. 1800-180-3024 for the consumers to report ADRs to NCC-PvPI. Besides ADR reporting, consumers can collect other relevant information from this helpline e.g. about how, what and whom to report ADRs in the country. Calls are primarily responded in English & Hindi on all working days between 09:00 A.M. - 05:30 P.M. and beyond these timings, a caller can drop a voice message. The call is returned by PvPI, the next working day.

During the index period total 100 ADRs were reported through Toll Free Helpline Number.

Fig. 10 ADRs reported on Toll free Helpline (2015-16)



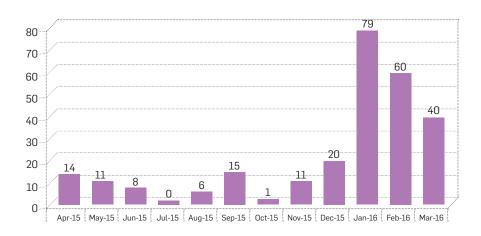
Fig. 11 State wise distribution of ADRs reported on Toll free Helpline (2015-16)



#### 4. REPORTING BY THE NON-AMCs

Non-AMCs are the Medical Colleges & Hospitals, Medical/Central/Autonomous Institutes or Corporate Hospitals which are not enrolled under PvPI. Reports are being received from the Non-AMCs via post or e-mail.

Fig. 12 ICSRs received from Non-AMCs (2015-16)



#### 5. ADRs REPORTING VIA MOBILE APPLICATION

ADR reporting application is a smart phone application for android users that was launched on  $22^{\rm nd}$  May, 2015. With the help of this application physician, pharmacists and other healthcare professionals can instantly report ADRs from across the country. The application can be downloaded and installed from the google play store in any android smart phone. The mobile application comprises of the following key features:

- 1. Customized for every reporter, that is to say the reporter information needs to be filled only once.
- Auto-entry feature a drug once reported goes into the database and gets displayed upon next reporting.
- 3. ADR's due to Fixed Dose Combinations(FDC) can be reported with a single entry regarding their dosage regimen, labeling details & indications.
- 4. Paperless and instantaneous submission.
- Algorithm based causality assessment, based on WHO criteria.
- Option to choose nearest or preferred AMC.
- An auto generated copy of duly filled ADR Form as .pdf file is sent as acknowledgement to the reporters email account for the purpose of record, review and research.

The report received via mobile application directly goes to the nearest or preferred AMC. Then, the AMC validates & reviews the report and forwards the same to NCC-PvPI.

Fig.13. Mobile App



## Technical Support to Strengthen the AEFI Surveillance System

## The PvPI provides technical and operational support to AEFI division of MoHFW in vaccine safety monitioring

COLLABORATION OF PVPI WITH UNIVERSAL IMMUNIZATION PROGRAMME(UIP) TO MONITOR VACCINE SAFETY IN INDIA

Adverse Event Following Immunization (AEFI) is defined as a medical event that takes place after 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. IPC, NCC-PvPI collaborated with AEFI Programme on 28th February 2013 to monitor the safety of vaccines. The PvPI shares the data of adverse event following vaccination that are reported from AMCs across India, with the Immunization Technical Support Unit (ITSU) and AEFI- CD-SCO. ITSU is a multidisciplinary team of experts and advisors established by Public Health Foundation of India (PHFI) in collaboration with the Ministry of Health & Family Welfare (MoHFW). ITSU provide technical support to the MoHFW to implement Universal Immunization Programme (UIP).

1. AEFI Data Management System in PvPI and exchange of information among all the partners:

- PvPI shares data of all reported serious adverse events (SAEs) on daily basis and non serious adverse events on monthly basis with the ITSU and AEFI- CDSCO.
- PvPI has also revised its Standard Operating Procedure (SOP) for processing and communication of AEFI-ICSRs.
- For better coordination at state level between AMCs and State Expanded Programme Immunization Officer (SEPIO) the PvPI shares the contact details of SEPIO with Pharmacovigilance Associate (previously known as, Technical Associate).

- 2. Coordination meeting with PvPI, CDSCO and ITSU:
- PvPI officials attend the monthly coordination meeting of PvPI, CDSCO and AEFI and share the information among all the partners of AEFI surveillance.
- NCC-PvPI holds regular coordination meetings with AEFI division of UIP, MoHFW and CDSCO to review all the AEFI cases.
- Members from NCC-PvPI and AMC coordinators regularly attend the AEFI National coordination meeting and AEFI state level & regional level workshop on 'AEFI reporting and investigation' and 'AEFI surveillance and causality assessment', respectively.
- For better insights, for the first time PvPI team attended an internal audit as a part of AFFI Secretariat.
- AMC coordinator is also a member of the AEFI committee at the state level.

#### STATUS OF ICSRs OF VACCINES: REPORTING, COLLATION & ANALYSIS

During this index period NCC received a total 637 vaccines related ICSRs. All the vaccine ICSRs were processed and analysed at NCC. Among the 637 cases, 108 cases were serious. Out of the 637 cases, the pentavalent (Tetanus/Diphtheria/Pertussis/Hepatitis B/Haemophilus influenza type B) vaccine was found to cause highest numbers of ADRs during the index period.

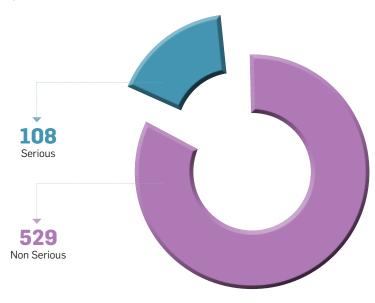


Fig.14: Serious and Non serious vaccine cases

Fig.15: Distribution of adverse event due to Vaccines

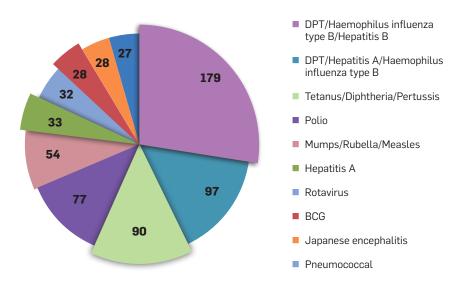
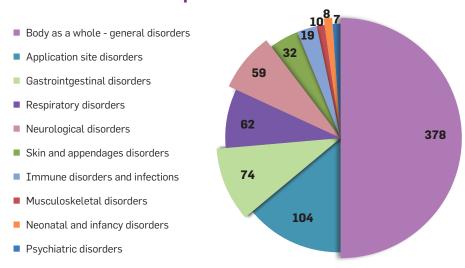


Fig.16: Top Ten System Organ Class (SOC) of ADRs Reported with Vaccines



#### **REVIEW OF VACCINES PSURs**

The PSURs of vaccines submitted to CDSCO by the MAHs are reviewed during the index period in technical collaboration with PvPI.

## During the index period three vaccine PSURs review meetings were conducted by CDSCO:

PSUR Expert Committee Meeting	Company	Reported Vaccine (Brand Name)	Period of Reporting	CDSCO Outcomes
4th Meeting (10 <sup>th</sup> June 2015)	MSD	Rotateq®	28-05-2010 to 23-04-2015	PSUR (PBRER format) submission should be continued on 6 monthly basis.
5th Meeting (13 <sup>th</sup> October 2015)	Glaxo SmithKline	Rotarix®	01-06-2008 to 11-07-2015	All serious cases shall be reported within 15 days of information to the CDSCO.
6 <sup>th</sup> Meeting (27 <sup>th</sup> January 2016)	Glaxo SmithKline	Cervarix®	01-04-2009 to 31-12-2015	The firm shall submit SOP for active surveillance to monitor adverse event of post vaccination.
				The company should provide the causality assessment of all the ICSRs.

#### VACCINE SAFETY INITIATIVES IN PVPI:

**Intussusception due to Rota Vaccine:** The vaccine has been approved by the National Regulatory Authority in India to protect children from Rota virus infection. It is also equally important to protect the health of this vulnerable population by ensuring safety of vaccine. In India, out of 15 ICSRs due to Rota vaccine; 10 suspected cases of intussusceptions were reported from 2011 to April 2015.

**Recommendation and Regulatory Action:** These cases were reviewed by the Signal Review Panel (SRP), which concluded that there was a strong temporal relationship between the vaccine and the AE and hence, it should be incorporated in package inserts of drug marketed in India. The matter was approved by Subject Expert Committee (SEC) for label change in CDSCO.

#### **Rabies Vaccine Associated Risk of Erythema Multiforme:**

The mild systemic Adverse Event Following Immunizations (AEFIs) reported with its use are headache, malaise, nausea and fever. Pain and/or swelling may occur at the site of injection, particularly following intradermal administration. Serious AEFIs including that of allergic or neurological nature rarely occur. NCC-PvPI has received two AE reports of rabies vaccine till August 2015.

**Recommendation and Regulatory Action:** The SRP concluded that there was a strong temporal relationship between the vaccine and the reaction (Anti rabies Vaccine and Erythema Multiforme) and hence it should be incorporated in package inserts of suspected marketed vaccine domestically. The matter was approved by Subject Expert Committee (SEC) of CDSCO to change the label accordingly.

#### **AEFI SURVEILLANCE**

The PvPI has included a topic on AEFI monitoring into its technical training sessions intended for induction cum training programmes for newly recruited technical associates and other stakeholders.

## NCC-PvPI focused on the importance of AEFI monitoring during the training/meeting organized during the index period.

S. No	Name	Date	Place	Participants			
NATION	NATIONAL AEFI COMMITTEE						
1	National level training workshop on AEFI monitoring and causality assessment	2015	New Delhi	IPC, CDSCO, ITSU and WHO officials			
MONTH	ILY AEFI-PHARMACOVIGILANC	E PARTNERS M	EETING				
2	Monthly meeting of IPC, CDSCO and AEFI	Monthly	Nirman Bhawan, New Delhi	IPC, CDSCO and ITSU, WHO Country office (India) officials			
OTHER	INTERACTIVE SESSIONS:						
3	Induction-cum-Training Programme for the Newly Recruited Technical Associates under PvPI	16 <sup>th</sup> to 20 <sup>th</sup> February, 2015	IPC, Ghaziabad	New Technical Associates			
4	Induction cum Training Programme for Newly Recruited Technical Associates	18 <sup>th</sup> to 22 <sup>nd</sup> August 2015	IPC, Ghaziabad	New Technical Associates			
5	Induction cum Training Programme for Newly Recruited Technical Associates	24 <sup>th</sup> - 28 <sup>th</sup> August 2015	IPC, Ghaziabad	New Technical Associates			
6	Induction cum Training Programme on Pharmacovigilance for Coordinators of Newly recognized AMCs under PvPI	3 <sup>rd</sup> - 4 <sup>th</sup> September 2015	IPC, Ghaziabad	Coordinators			
7	First internal audit in AEFI division	2015	AEFI Secretariat	PvPI as a part of AEFI Secretariat at Immunization Technical Support Unit (ITSU).			

#### KNOWLEDGE SHARING:

Documentation and Publications of PvPI with emphasis on AEFI Surveillance

- 1. PvPINewsletterVol.5 April Issue 11, 2015: Intussusceptions due to Rota vaccine: A matter of risk concern under Drug Safety information.
- 2. PvPI Newsletter Vol.5 August Issue 12, 2015: 'Risk of erythema multiforme associated with use of rabies vaccine' published under Vaccine safety initiatives.
- 3. Poster on "Role of the Partners in AEFI Monitoring"
- 4. Chapter: National Drug Regulatory Authority of India and its affiliated institution, published in AEFI Surveillance and Response Operational Guidelines, 2015.



## Pharmacovigilance in Public Health Programmes (PHP)

Several initiatives are taken to enhance the ADR Reporting from PHP.

#### BACKGROUND

As per the recommendation of WHO the national pharmacovigilance system should be integrated with public health programmes (PHP) in their countries, because public health programmes treat a large number of population, in an organized and structured fashion, and record the number of patients treated, drugs used, doses given, etc.

Therefore, NCC-PvPI, IPC had collaborated with the several public health programmes such as Revised National Tuberculosis Control Programme (RNTCP) and National AIDS Control Organization (NACO) to monitor the safety of drugs used in their respective programmes.



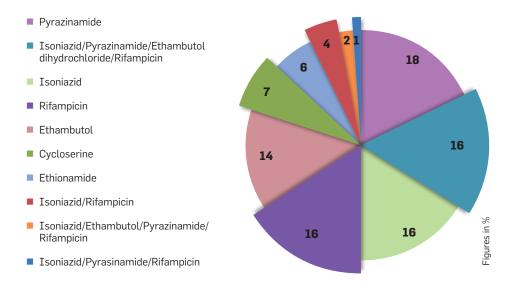
- ♦ Revised National Tuberculosis Control Programme
- National AIDS Control Organization
- Adverse Event Following Immunization
- ♦ National Vector Borne Disease Control Programme
- Indian Council for Medical Research
- ◆ Indian Medical Association

#### STATUS OF ICSRs: REPORTING, COLLATION & ANALYSIS

Several initiatives have been taken to enhance the ADR Reporting from PHPs. During the index period a total of 3429 ICSRs were received from different AMCs & RNTCP centres and 3549 ICSRs from AMCs & ART centres. These reports were derived entirely from the spontaneous ADR reporting system under the PvPI. The reported ADRs include a large spectrum of clinical manifestation, which are summarized based on WHO Adverse Reaction Terminology (WHO-ART) System Organ Class (SOC), i.e. the ADRs due to the suspected medication affects both single organ as well as multiple organs.

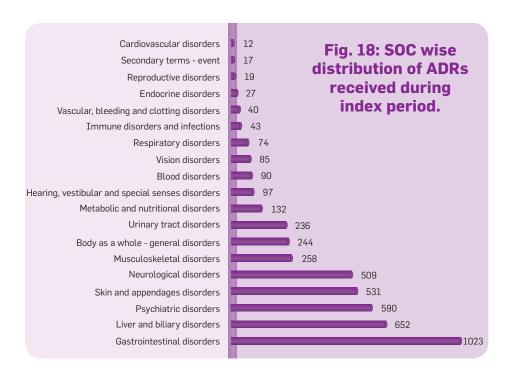
#### ANTITUBERCULAR DRUGS REPORTED TO CAUSE ADRS

Fig. 17: Anti Tubercular Drugs causing maximum ADRs.



## DISTRIBUTION OF ADR REPORTS BASED ON SYSTEM ORGAN CLASS (SOC)

During the index period, with the use of Anti-tubercular drugs maximum number of gastrointestinal disorder ADRs were reported.

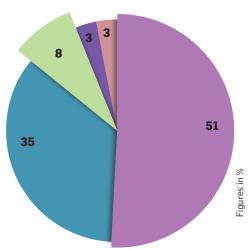


#### ANTIRETROVIRAL DRUGS MAXIMUM TO CAUSE ADRS

During the index period, the top five antiretroviral drugs that caused ADRs were:



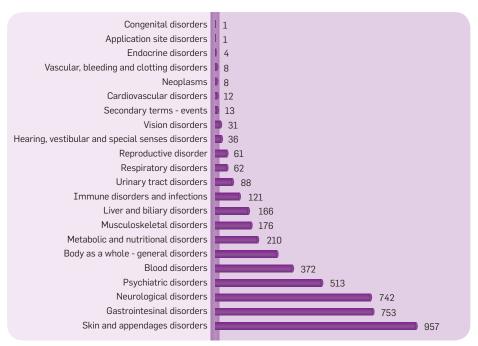
- Lamivudine/Efavirenz/Tenofovir disoproxil fumarate
- Zidovudine/Nevirapine/Lamivudine
- Zidovudine/Lamivudine
- Lamivudine/Tenofovir disoproxil fumarate
- Ritonavir/ Atazanavir



## DISTRIBUTION OF ADR REPORTS BASED ON SYSTEM ORGAN CLASS

During the index period, with the use of Antiretroviral drugs maximum number of skin & appendages disorder ADRs were reported.

Fig. 20. SOC wise distribution of ADRs received during index period.



#### TRAINING AND SKILL DEVELOPMENT IN PHPs UNDER PvPI

The NCC-PvPI teamed up with the WHO Country Office (India) to provide the national level training programme for team of healthcare professionals/ experts under various PHPs such as RNTCP and NACO programme. This initiative was specially tailor made to sensitize and update the experts on how to effectively identify and report ADRs arising from the use of the drugs used in these programmes. The training focused on basic and essentials of Pharmacovigilance, medical terminology coding, standards and procedure for entering data into the VigiFlow® (web based ICSR management system) and causality assessment.

#### PvPI & RNTCP joint venture to promote the safety of antitubercular drugs

S. No.	Date	Title	Organised by	Organised at	Participants/Target Audience
1.	10-23 <sup>th</sup> April 2015	Joint Monitoring Mission	Central TB Division/ PvPI	Hotel Lalit, New Delhi	RNTCP/WHO/PvPI officials, all healthcare professionals of states under purview of JMM
2.	21 <sup>st</sup> May 2015	Meeting on Bedaquiline-CAP	Central TB Division/ PvPI	Nirman Bhavan, New Delhi	RNTCP/WHO/PvPI Officials
3.	1-3 <sup>rd</sup> July 2015	National Workshop on Bedaquiline-CAP	Central TB Division/ PvPI	Hotel Taj, New Delhi	MoHFW/RNTCP/PvPI Officials
4.	7 <sup>th</sup> January 2016	National Training of Trainers (TOT) on Implementation of Bedaquiline	Central TB Division/ PvPI	NTI Bangalore	RNTCP/WHO/PvPI Officials
5.	3 <sup>rd</sup> February 2016	Launch of newer initiatives under RNTCP and NACO	Central TB Division/ PvPI	Hotel Oberoi, New Delhi	MoHFW/RNTCP/PvPI Officials
6.	8 <sup>th</sup> February 2016			NITRD & RBIPMT, New Delhi	NITRD/RBIPMT/RNTCP/ PvPI Officials
7.	15 <sup>th</sup> to 17 <sup>th</sup> February 2016	Site and Key district staff training for Bedaquiline Conditional Access Programme Central	Control TP	KEM Hospi- tal –Mumbai, Maharashtra	KEM Hospital Staff/RNTCP/ PvPI Officials
8.	17 <sup>th</sup> to 19 <sup>th</sup> February 2016		Division	BJMC, Ahmedabad, Gujrat	BJMC/ RNTCP/ PvPI Officials
9.	3 <sup>rd</sup> to 5 <sup>th</sup> March 2016			GHTM Tambaram, Tamil Nadu	GHTM Tambaram/ RNTCP/ PvPI Officials
10.	7 <sup>th</sup> to 9 <sup>th</sup> March 2016			GMC Guwahati, Assam	GMC/ RNTCP/ PvPI Officials
11.	21 <sup>st</sup> March 2016	World TB Day; Release of Guideline and Launch of Bedaquiline	Central TB Division	Hotel Taj, New Delhi	MoHFW/RNTCP/PvPI Officials

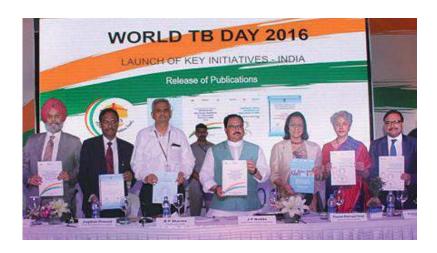
## PvPI AS A CORE COMPONENT OF JOINT MONITORING MISSION (JMM) OF REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

MoHFW and WHO Country Office (India) along with other technical partners conducted a JMM to review India's RNTCP from  $10^{th}$  April 2015. Since the programme's inception, there have been five such missions. The last one was undertaken in August 2012.

#### Objectives of JMM:

- Review India's progress in implementation of the National Strategic Plan and followup on the recommendations of JMM 2012.
- Review the country's progress towards universal access to TB care, challenges and plans for TB control efforts, and to advice GoI and partners on the pathway towards strategies in line with End TB Strategy.

The Joint Monitoring Mission (JMM) took place in a context characterized by the recent adoption of the 'End TB strategy' by the Member States to end the TB epidemic in the world and India's experience with implementation of its ambitious strategies. Central TB division, MoHFW, GoI and WHO recognized PvPI efforts by including it as a member of review team of JMM for RNTCP. The JMM was held from  $10^{\text{th}}$ - $23^{\text{rd}}$  April 2015 at New Delhi, to evaluate the functioning of the programme and interacting with the directly observed treatment, short course (DOTS) providers at the field level which strengthened the mutual activities between PvPI and RNTCP. NCC-PvPI recommended to focus and to provide training to the DOTS providers on Pharmacovigilance.



## BEDAQUILINE – NEW DRUG FOR MULTI DRUG RESISTANT TB

World TB Day is designed to build public awareness about the global epidemic of tuberculosis (TB) and efforts to eliminate the disease was observed here on 21st March 2016. Befitting the occasion Hon'ble Health Minister Shri J.P. Nadda along with officials

# BEDAQUILINE IS BEING INTRODUCED AT SIX IDENTIFIED TERTIARY CARE CENTRES ACROSS INDIA

of MoHFW released 'Guidelines for Prevention and Management of Adverse reactions associated with Anti TB drug' and launched Bedaquiline – new drug for Multi Drug-Resistant TB as part of the Revised National Tuberculosis Control Programme (RNTCP). The drug is being introduced at six identified tertiary care centres across India, having advanced facilities for laboratory testing and intensive care for patients. Bedaquiline will be given to multi-drug resistant TB patients with resistance to either all fluoroquinolone and/or all second line injectables and extensive drug resistant TB.

PvPI in technical collaboration with RNTCP and WHO started on active surveillance on bedaquiline

## FOCUSED PHARMACOVIGILANCE ON DRUGS USED IN VECTOR BORNE DISEASE UNDER NATIONAL VECTOR BORNE DISEASE CONTROL PROGRAMME (NVBDCP)

Directorate of National Vector Borne Disease Control Programme (NVBDCP) is the central nodal agency for the prevention and control of vector borne diseases (VBDs) i.e. Malaria, Dengue, Lymphatic Filariasis, Kala-azar, Japanese Encephalitis and Chikungunya in India. The NCC- PvPI, IPC has a mandate to monitor the ADRs and also to improve patient safety and welfare in Indian population by monitoring drug safety. A close collaboration between IPC, NCC – PvPI and NVBDCP is necessary to collect, monitor, collate & analysis of ADRs due to drugs used in NVBDCP. Both institutions have intiated a dialogue to begin safety of drug through focused Pharmacovigilance by specifically monitoring drugs used in treatment of VBDs. They have formally agreed to work together as a part of larger PvPI with the objective to setup Pharmacovigilance system in NVBDCP.

#### ICMR INSTITUTIONS TO JOIN HANDS WITH PVPI

A two days workshop on Pharmacovigilance and Pharmacoepidemiology was held on 4-5<sup>th</sup> March 2016 at National Institute for Research in Tuberculosis (NIRT), Chennai.

The objective of this workshop was to gain a better understanding of the onGoIng programme and challenges in reporting of ADRs in anti-TB treatment. It was also aimed to develop an operational research protocol related to daily anti-TB treatment.

The ICMR institutions expressed their deep interest to collaborate with PvPI in improving the pharmacovigilance standards in India, basic knowledge & skills of healthcare professionals (HCPs) to ensure the safety of the vulnerable population while exposed to different drug regimen. In near future, ICMR Institutions will be declared as PvPI collaborating centres.

#### WORKING GROUP - 38TH ANNUAL MEETING OF WHO - PIDM

The Union Minister of Health & Family Welfare, Govt. of India, Shri J. P. Nadda inaugurated the 38th Annual Meeting of the National Pharmacovigilance Centres participating in the World Health Organization Programme for International Drug Monitoring (WHO-PIDM) in New Delhi. The meeting was jointly organised by Indian Pharmacopoeia Commission and WHO Country Office (India). Valuable recommendations were made as an outcome of the working groups in 38th Annual Meeting of WHO – PIDM organized to discuss various challenges/issues and initiatives regarding pharmacovigilance in RNTCP & NACO.

Following are the challenges/issues and initiatives regarding pharmacovigilance at RNTCP & NACO:

- Integration of E-NIKSHAY with VigiFlow®.
- Creating options for grading of severity of reactions in the VigiFlow<sup>®</sup>.

#### E-NIKSHAY

To keep a track of the TB patients across the country, the Govt. of India has introduced a system called *NIKSHAY*. The word is combination of two Hindi words *NI* and *KSHAY* meaning eradication of tuberculosis. *NIKSHAY* (www.nikshay.gov.in) is a web based solution for monitoring of TB patients.

#### INTEGRATION OF E-NIKSHAY WITH VIGIFLOW

Integration of E-Nikshay with the UMC's VigiFlow® (web-based Individual Case Safety Report (ICSR) management system) so that NIKSHAYID field column to be made available in VigiFlow® which will bridge the gap between E-Nikshay and VigiFlow® to track TB patient's data. This data will be used for active surveillance and identifying the adverse reactions from the data.

## CREATING OPTIONS FOR GRADING OF SEVERITY OF REACTIONS IN THE VIGIFLOW

Currently grading the severity of reactions is done in free text column. PvPI suggested the UMC to provide an option to enter the severity grading in VigiFlow® This will not only improve the qualitative reporting but also holsters the causality assessment process.

#### DRUG SAFETY MONITORING COMMITTEE

A Drug safety monitoring committee (DSMC) for the use of Bedaquiline within RNTCP through Conditional Access Programme under Programmatic management of Drug resistant tuberculosis in India has been constituted with the approval of DGHS. The first meeting of this committee was held on 11<sup>th</sup> March 2016, to discuss the roles and responsibilities and future plans of DSMC.

#### CONSTITUTION OF CAUSALITY ASSESSMENT COMMITTEE (CAC)

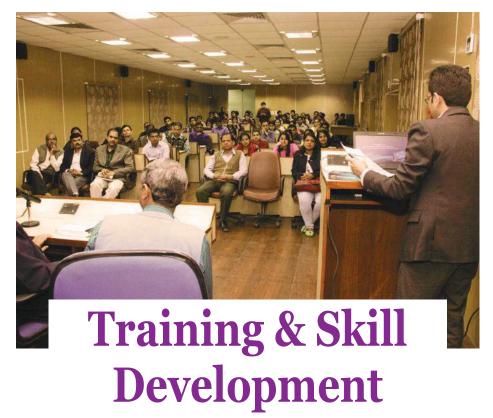
As per the recommendation of first meeting of Drug Safety Monitoring Committee (DSMC) on the use of Bedaquiline held on 11<sup>th</sup> March 2016, at New Delhi all AMCs for Bedaquiline under PvPI shall constitute a Causality Assessment Committee (CAC) to establish a causal relationship between adverse events and drug/s reported in ICSRs.

#### **Proposed activities**

- 1. To ensure proper implementation and integration of Pharmacovigilance with other public health programmes in India.
- 2. To integrate ADR analytical tools used in public health programmes with the Pharmacovigilance tools in order to avoid the duplicity in reporting.
- 3. To expand the knowledge, attitude and practice of Pharmacovigilance among the healthcare professionals engaged in the PHPs.

The following are expected outcomes:-

- The cohort event monitoring (CEM) is possible since the denominator values are available.
- b. Timely signal detection is possible.



The training & education division of PvPI play an important role in imparting education and training on drug safety.

he training and education division of PvPI play an important role in fulfilling the stakeholders expectations by imparting education and training. The training report for the index period provides information on PvPI training (Induction & advanced level) i.e. CMEs organized by the NCC, and in collaboration with other partners.

DETAILS OF TRAINING PROGRAMMES CONDUCTED DURING THE INDEX PERIOD

During this index period, the NCC-PvPI has organized 13 training programmes.

S No.	Name of Programme	Date	Place	Target Audience	Objective (s)
1.	PvPI Sensitization Programme	24 <sup>th</sup> June 2015	V.S.S. Medical College, Burla, Odisha	Health care professionals, postgraduate and undergraduate students of medical colleges and hospitals	Knowledge, Awareness & Practice (KAP) of Pharmacovigilance
2.	Refreshment Course on Updates on PvPI for Existing Technical Associates	20 <sup>th</sup> & 21 <sup>st</sup> July 2015	IPC, Ghaziabad	Technical Associates	Acquaint the technical associates with the recent development/ updates in PvPI.
3.	Induction cum Training Programme for Newly Recruited Technical Associates	18 <sup>th</sup> to 22 <sup>nd</sup> August 2015	IPC, Ghaziabad	New Technical Associates	Training on Basic Knowledge of Pharmacovigilance and Hands on Training in VigiFlow®
4.	CME on Pharmacovigilance	22 <sup>nd</sup> August 2015	R. D. Gardi Medical College Ujjain, M.P	Healthcare professionals working under Integrated counselling and Testing Centre, National AIDS Control Organization (ICTC-NACO)	Create awareness related to patient safety and to improve ADR reporting culture.
5.	Induction cum Training Programme for Newly Recruited Technical Associates	24 <sup>th</sup> to 28 <sup>th</sup> August 2015	IPC, Ghaziabad	New Technical Associates	Training on Basic Knowledge of Pharmacovigilance and Hands on Training in VigiFlow®
6.	Induction cum Training Programme on Pharmacovigilance for Coordinators of Newly recognized AMCs under PvPI	3 <sup>rd</sup> & 4 <sup>th</sup> September 2015	IPC, Ghaziabad	Coordinators of Newly recognized AMCs under PvPI	Training on Basic Knowledge of Pharmacovigilance and Hands on Training in VigiFlow®
7.	Joint Signal Detection Workshop	5 <sup>th</sup> to 8 <sup>th</sup> October 2015	IPC, Ghaziabad	Staff of NCC- PvPI & Drug inspectors of CDSCO	Training on Basic Knowledge of Signals & its assessment

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#### TRAINING & SKILL DEVELOPMENT

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S No.	Name of Programme	Date	Place	Target Audience	Objective (s)		
8.	38 <sup>th</sup> Annual Meeting of Representatives of National Pharmacovigilance Centres participating in the WHO programme for International Drug Monitoring	4 <sup>th</sup> - 6 <sup>th</sup> November 2015	New Delhi	Staff of NCC-Pv- PI, WHO & UMC Officials, CDSCO Officials & Representatives of National Phar- macovigilance Centres	Meeting acts as a platform for coun- tries to discuss current issues and concerns in Phar- macovigilance.		
9.	East Zone training programme	27 <sup>th</sup> November 2015	IPGMER- Kolkata	For special invite & delegates	KAP of Pharma- covigilance		
10.	Training & Awareness programme on Pharmacovigilance	8 <sup>th</sup> – 9 <sup>th</sup> December 2015	PGIMER, Chandigarh	Healthcare Professionals	KAP of Pharma- covigilance		
11.	Training for Nursing Professionals	5 <sup>th</sup> February 2016	Jaypee Hospital, Noida	Nursing Staff	KAP of Pharma- covigilance		
12.	Induction cum Training Programme on Pharmacovigilance for Coordinators of Newly recognized AMCs under PvPI	15 <sup>th</sup> - 19 <sup>th</sup> February 2016	IPC, Ghaziabad	New Coordinators	Training on Signal assessment		
13.	Advanced Level training in Pharmacovigilance	19 <sup>th</sup> March 2016	Seth GSMC & KEM Hospital, Mumbai	Existing Coordi- nators & Techni- cal Associates of west zone	Training for up -gradation of Skills of Coordinators & TAs		

In order to cater to the needs of education and training in Pharmacovigilance for the HCPs engaged in AMCs, Corporate Hospitals, District level hospitals etc, the NCC recognized five Regional Training Centres (RTCs) in addition to four existing.

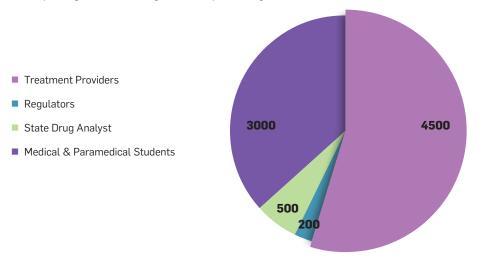
#### LIST OF REGIONAL TRAINING CENTRES (RTCs):

Regional Training Centres	States/UTs under purview
1. PGIMER, Chandigarh, Punjab	Chandigarh, Uttarakhand, Punjab, Haryana, Delhi, Jammu and Kashmir, Himachal Pradesh
Seth GS Medical College     & KEM, Mumbai, Maharashtra	Maharashtra, Goa, Dadra and Nagar Haveli
JSS Medical College     & Hospital, Mysuru, Karnataka	Kerala, Karnataka, Puducherry, Tamil Nadu Lakshadweep
4. IPGMER, Kolkata, West Bengal	West Bengal, Odisha, Jharkhand, Bihar, Andaman & Nicobar
5. All India Institute of Medical Sciences, Bhopal, Madhya Pradesh	Madhya Pradesh, Chhattisgarh
6. <b>B J Medical College, Ahmedabad, Gujarat</b>	Gujarat, Rajasthan, Daman & Diu
7. Institute of Medical Sciences, Varanasi, Uttar Pradesh	Uttar Pradesh, Bihar
8. Nizam's Institute of Medical Sciences, Hyderabad, Telangana	Telangana, Andhra Pradesh
9. Silchar Medical College & Hospital, Silchar, Assam	Assam, Arunachal Pradesh, Manipur, Meghalaya, Mizoram, Nagaland, Tripura, Sikkim

#### TRAINING & SKILL DEVELOPMENT

#### DETAILS OF STAKEHOLDERS TRAINED DURING THE INDEX PERIOD

More than eight thousand stakeholders were trained on basic concepts of Pharmacovigilance and reporting of ADRs during the index period is given as follows:



A Pre and Post training assessment was carried out in order to assess the impact & quality of training on the trainees. An improvement was found in knowledge, awareness and skill development was observed before and after the training.

78.4 80 65.07 65.17 62.43 60.05 Figure in percentage 60 47.7 40 20 Pre Post Pre Post Post Knowledge Skill Development Awareness Assessment Criteria

Fig. 21: Qualitative Analysis of impact of Training & Skill Development

#### FEEDBACK AND SUGGESTIONS OF TRAINEES

Following suggestions were received from the participants during the training programs. The follow up actions, as relevant are also mentioned.

S. No.	Suggestions	Follow Up action plan
1.	To conduct zone wise training for Healthcare Professionals (HCPs) to improve Knowledge, Awareness and practice (KAP) on Pharmacovigilance	Suggestion under evaluation
2.	Number of training programmes for Technical Associates (TAs) should be increased.	Suggestion under evaluation
3.	Time duration for the hands on training on Vigi-Flow® software should be increased	Implemented
4.	Duration for the field level training should be increased	Implemented
5.	Identification of pool of trainers & Training of Trainers	Suggestion under evaluation
6.	Include Pharmacovigilance in medical, pharmacy & nursing curriculum	Partially completed
7.	To create awareness by using All India Radio & Doordarshan Services	Partially completed
8.	To make reporting of ADRs mandatory for the doctors	Plan underway to seek the approval of the Medical Council of India (MCI) for the same
9.	Awards/certificate of appreciation to the clinicians & other significant contributors to the PvPI to motivate and encourage reporting	Accepted & implemented.

#### Advanced level training on signal detection



Faculties and trainees at signal detection workshop organised by PvPI on 13 October, 2015

### **Signal Detection**

The WHO has defined 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"

ignal detection and clinical assessment of Individual Case Safety Reports (ICSRs) is an inseparable domain of Pharmacovigilance. The 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".

NCC-PvPI is engaged in identifying potential signals from the India specific ICSRs with the technical assistance of experts in the signal review panel (SRP).

#### METHODS USED FOR SIGNAL DETECTION IN PVPI

Various methods are used for signal detection. The following four parameters were proposed to identify a new signal from Indian ICSRs:

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

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

- 1. IC<sub>025</sub>>0
- 2. PRR  $\geq$  2 with the lower bound of its 95% CI > 1
- 3.  $\chi^2$  statistics (with 1 degree of freedom)  $\geq 4$  and
- 4.  $N_{comb} \ge 3$ , to highlight potential signals.

At least two out of four of these parameters are required to be fulfilled to consider a specific Drug-ADR combination as a potential signal.



#### ACTIVITIES OF SIGNAL REVIEW PANEL (SRP) OF THE PVPI

List of the signal review meetings conducted during the index period (April 2015 to March, 2016) is given below.

S No.	Activities	Drug-ADR combination reviewed	Outcome
1	5 <sup>th</sup> SRP Meeting held on 9 <sup>th</sup> May, 2015 at CDSCO, East Zone, Kolkata	Four Drug-ADR combinations were reviewed  Mannitol – Hypokalaemia  Piperacillin and Tazobactum – Hypokalaemia  Pipreracillin and Tazobactum – Bronchospasm  Rota Vaccine – Intussusception	Suggested to Marketing Authorization Holders to incorporate the same in package insert.
2	6 <sup>th</sup> SRP Meeting held on 6 <sup>th</sup> Octo- ber, 2015 at IPC, Ghaziabad	Three Drug-ADR Combinations were reviewed  ■ Ranitidine – Cardiac Arrest  ■ Anti Rabies Vaccine – Erythema Multiforme  ■ Surfactant – Pulmonary Hemorrhage	Suggested to MAHs to incorporate the same in the package insert.
3	IPC-UMC's Joint Signal Detection workshop	A total 168 Drug - ADR Combinations were reviewed	Seven Drug-ADR combination identified as signal:  Citicholine-Hallucination  Azithromycin- Acute Generalized Exanthematous pustulosis (AGEP)  Cloxacillin- AGEP  Amikacin-Drug Hypersensitivity Syndrome  Artemisinin derivatives- Stevens Johnson Syndrome  Phenytoin-Vestibular Disorder  Betamethasone- Photosensitivity
4	7 <sup>th</sup> SRP Meeting held on 1 <sup>st</sup> March, 2016 at Central Drugs Standard Control Organization, New Delhi	Five Drug-ADR Combinations were reviewed  Ceftriaxone - Stevens Johnson Syndrome (SJS)  Lamotrigine - Stevens Johnson Syndrome (SJS)/ Toxic Epidermal Necrolysis (TEN)  Betamethsone -Photosensitivity Reaction  Azithromycin - Acute Generalised Exanthematous Pustulosis (AGEP)  Cloxacillin - Acute Generalised Exanthematous Pustulosis (AGEP)	Suggested to MAHs to incorporate the same in package insert.

#### SIGNAL DETECTION

### PvPI RECOMMENDATIONS AND REGULATORY ACTIONS DURING THE INDEX PERIOD:

NCC-PvPI has made several evidence based recommendations to the Indian regulatory authority, CDSCO for regulatory actions after an in-depth analysis and discussion in the SRP. Three meetings of SRP were held during the index period and total 11 recommendations on drug safety in Indian population have been submitted to CDSCO for appropriate regulatory actions.

#### RECOMMENDATIONS OF PVPI TO THE CDSCO.

S. No	Drugs : Adverse Drug Reaction(s)	Recommendations of PvPI to the CDSCO	CDSCO initiatives
1	Lamotrigine : Stevens Johnson Syndrome, Toxic Epidermal Necrolysis	For label change	In Process
2	Ceftriaxone : Stevens Johnson Syndrome	For label change	In Process
3	Betamethasone : Photosensitivity Reaction	For label change	In Process
4	Azithromycin : Acute Generalized Exanthematous Pustulosis	For label change	In Process
5	Cloxacillin : Acute Generalized Exanthematous Pustulosis	For label change	In Process
6	Ranitidine : Cardiac Arrest	For label change	In Process
7	Anti Rabies Vaccine: Erythema Multiforme	For label change	In Process
8	Surfactant: Pulmonary Haemorrhage	For label change	In Process
9	Mannitol: Hypokalaemia	For label change	Approved in the Subject Expert Committee (SEC) of CDSCO
10	Piperacillin & Tazobactum : Hypokalaemia, Bronchospasm	For label change	Approved in the SEC of CDSCO
11	Rota Vaccine: Intussusception	For label change	Approved in the SEC of CDSCO

In addition to drug safety recommendations to CDSCO, the NCC through its drug alert column also advises Healthcare Professionals, Patients/Consumers to closely monitor the possibility of the following adverse events while prescribing/consuming these drugs.

S.No	Suspected Drug	Indications	Adverse Reactions
1	Phenytoin	Generalized tonic-clonic seizures; partial seizures; status epilepticus	Angioedema
2	Phenytoin	Generalized tonic-clonic seizures; partial seizures; status epilepticus	Osteoporosis
3	Nicorandil	Angina Pectoris, Vasodialator	Risk of ulcer complication
4	Olanzapine	Schizophrenia, acute mania episodes in bipolar disorder	Hyponatraemia
5	Crizotinib	Locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-Positive	Risk of cardiac failure

#### **SUMMARY**

Signal Detection related activities held during the index period	Numbers
Number of SRP Meetings	03
Number of Signal Detection Workshop	01
Number of Drug-ADR combinations discussed	180
Number of Signals identified	07
Number of recommendations made regarding Drug-ADR combination to the CDSCO for label change	11

# Recommendations to CDSCO for Regulatory Intervention

PvPI recommended to the CDSCO to insert the adverse reaction Hypokalaemia and Bronchospasm due to Fixed Dose Combination (FDC) Piperacillin and Tazobactum.

### RECOMMENDATIONS TO CENTRAL DRUGS STANDARD CONTROL ORGANIZATION (CDSCO) FOR REGULATORY INTERVENTION

In order to support the decision-making process of the CDSCO, NCC-PvPI regularly coordinates with the CDSCO, New Delhi. Several meetings were held in between the officials of National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI) and CDSCO for better coordination. Based on the ICSRs data analysis and deliberations in Signal Review Panel (SRP) meetings, following recommendations were submitted to the CDSCO.

- Lamotrigine : Stevens Johnson Syndrome, Toxic Epidermal Necrolysis
- Ceftriaxone : Stevens Johnson Syndrome
- Betamethasone : Photosensitivity Reaction
- Azithromycin : Acute Generalized Exanthematous Pustulosis
- Cloxacillin : Acute Generalized Exanthematous Pustulosis
- Ranitidine : Cardiac Arrest
- Anti Rabies Vaccine : Erythema Multiforme
- Surfactant : Pulmonary Haemorrhage
- Mannitol : Hypokalaemia
- Piperacillin & Tazobactum : Hypokalaemia, Bronchospasm
- Rota Vaccine : Intussusception

#### **ACTION TAKEN BY CDSCO**

#### Piperacillin & Tazobactum: Hypokalaemia, Bronchospasm

PvPI recommended to the CDSCO to include the adverse reaction Hypokalaemia and Bronchospasm occurring due to Fixed Dose Combination (FDC) of Piperacillin and Tazobactum.

This proposal was further discussed by Subject Expert Committee (SEC) i.e. Antimicrobial, Antiparasitic, Antifungal and Antiviral committee in its meeting held on  $26^{\text{th}}$  Oct, 2015. The committee recommended that all the manufacturers of above said FDC product should be instructed to include these two adverse reactions in their package insert as well as any other promotional literature.

The recommendation of the SEC were considered by Drugs Controller General (India) and further instructed market authorization holders (MAHs) to include these two adverse reactions i.e. Hypokalaemia & Bronchospasm in their package insert.

#### SEC OF CDSCO APPROVED FOLLOWING DRUG-ADR COMBINA-TIONS FOR FURTHER ACTION BY DCG (I)

#### 1. Rota Vaccine: Intussusception

PvPI recommended to the CDSCO to insert the adverse reaction Intussusception occurring due to use of Rota Vaccine. The proposal for potential signal & recommendation for the label change for the same was approved in the SEC of CDSCO.

# Important Events of NCC - PvPI

Shri JP Nadda underlined the importance of pharmacovigilance and ADR monitoring in the country and reiterated that India has made considerable progress in this field in the past five years.....

#### MOBILE APP FOR ADR REPORTING

Under reporting of ADRs is widespread and a matter of serious concern in spontaneous/ voluntary reporting. The NCC-PvPI has taken intiative in collaboration with NSCB Medical College, Jabalpur to launch an android mobile application for the HCPs to report ADRs.

The facility was launched by Shri B. P. Sharma, Secretary, Ministry of Health & Family Welfare, Government of India on  $22^{nd}$  May, 2015 at Nirman Bhawan. New Delhi.

The mobile application enables HCPs to report ADRs instantly. It is a simple, paperless tool that also provides algorithm based causality assessment.





Shri. B. P. Sharma, the then Secretary Health and officials of MoHFW, Govt. of India during launch the Android Mobile App for ADR reporting (22<sup>nd</sup> May, 2015, Nirman Bhawan, New Delhi)

#### VISIT OF JOINT SECRETARY MoHFW, GoI TO IPC-PvPI:

Shri K.L. Sharma, Joint Secretary (Regulation), MoHFW, GoI, visited IPC on 4th June, 2015 to address the induction training for the Assistant Drugs Controller (ADC), CDSCO. He interacted with technical staff of PvPI and emphasized that PvPI is progressing in the right direction to ensure medicine safety in the country. He also reviewed the functioning of ICSR processing, toll free helpline services and others activities of PvPI. He appreciated the commitment of staff of NCC-PvPI and the progress of PvPI.



Shri K. L. Sharma, JS(R) along with Dr. G. N. Singh, DCG(I), Dr. Surinder Singh, Director, NIB and IPC officials (4<sup>th</sup> June, 2015, IPC, Ghaziabad)

#### IMPORTANT EVENTS

#### MEDICAL DEVICE SAFETY MONITORING

Materiovigilance Programme of India (MvPI) was launched on 6<sup>th</sup> July, 2015 by Dr. G. N. Singh, DCG(I) at IPC, Ghaziabad to monitor the safety of medical devices in the country. He emphasized that safety of medical devices cannot be ignored and should be monitored critically; and stakeholder and healthcare provides should be committed to the cause. He stated that IPC as a National Coordinating Centre for MvPI, will provide all the necessary support for effective implementation of this program. National Health System Resource Centre (NHSRC), New Delhi will provide technical support. He congratulated Sree Chitra Tirunal Institute of Medical Sciences & Technology (SCTIMST), Thiruvananthapuram for being designated as the National Collaborating Centre for MvPI. The materiovigilance reporting form has been developed in consultation with the stakeholders and is now available in the public domain.



Experts during the launch of MvPI (6th July 2015, IPC, Ghaziabad)

# THE 38<sup>th</sup> ANNUAL MEETING OF REPRESENTATIVES OF NATIONAL PHARMACOVIGILANCE CENTRES PARTICIPATING IN THE WHO PROGRAMME FOR INTERNATIONAL DRUG MONITORING

The Union Minister for Health & Family Welfare, Government of India, Shri J.P. Nadda, inaugurated the 38th Annual Meeting of National Pharmacovigilance Centres participating in the World Health Organization (WHO) Programme for International Drug Monitoring (PIDM) in New Delhi. The meeting was jointly organised by Indian Pharmacopoeia Commission (IPC) and the WHO (Country Office India). Several international delegates representing different countries participated in the meeting. Hon'ble Minister, Shri Nadda, underlined the importance of Pharmacovigilance, and ADR monitoring in the country and reiterated that India has made considerable progress in this field in the past five years, including setting up of Pharmacovigilance system for tuberculosis and HIV-AIDS related public health programmes.



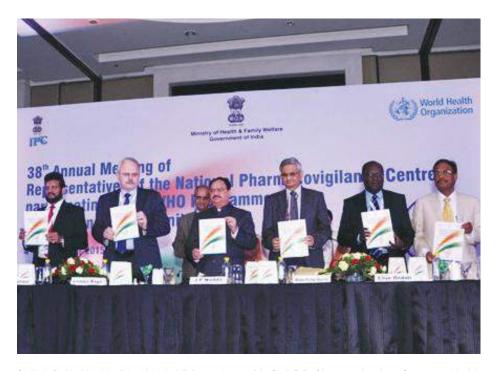
Shri J. P. Nadda, Hon'ble Union Minister for Health, MoHFW, GoI addressing the delegates at the 38<sup>th</sup> Annual Meeting of Representatives of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring (4-6<sup>th</sup> November 2015, New Delhi).

#### IMPORTANT EVENTS

Hon'ble Minister applauded the IPC, NCC-PvPI which serve as a platform for knowledge transfer and act as catalysts for developing the next level Good Pharmacovigilance Practices and for improving awareness about ADR reporting.

While addressing the delegates he said that "IPC is set to become the **first WHO** Collaborating Centre for Safety of Medicines and Vaccines in the South-East Asia Region."

He also emphasised the importance of creating a nation-wide system for patient safety reporting, to identify and analyse risk benefit ratio of marketed medicines, to generate evidence on safety of medicines and to support regulatory agencies in decision making.



Shri J. P. Nadda, Hon'ble Health Minister along with Shri B.P. Sharma, the then Secretary Health, Dr. Jagdish Prasad, DG, DGHS, Shri K.B. Agarwal, Additional Secretary, MoHFW, GoI, Dr. Lambit Rago, WHO, Geneva along with other dignitaries releasing the Position Paper of Pharmacovigilance Programme of India on 4<sup>th</sup> Nov, 2015.

#### INAUGURATION OF BENEFIT-RISK ASSESSMENT CELL

The PvPI Benefit- Risk Assessment Cell was inaugurated by Shri J.P. Nadda, Union Minister for Health on 14th Nov, 2015 at NCC-PvPI, IPC, Ghaziabad. Risk Management Plan (RMP) is a documented plan that describes the risks (adverse drug reactions and potential adverse reactions) associated with the use of a drug and how they are being handled (warning on drug label or on packet inserts of possible side effects). The overall goal of RMP is to ensure a positive benefit-risk profile once the drug has been marketed.

Benefit-Risk Assessment aims at minimizing the risks while maximizing the beneficial effects of a medicine by ensuring its proper use by the patients. If the overall balance of benefits and risks is judged to be negative, then the medicine may be withdrawn unless risk reduction strategies can be identified to reduce the risk associated with the drug.



Shri J. P. Nadda, Hon'ble Health Minister, inaugurating the Benefit-Risk Assessment cell of PvPI (14th Nov, 2015, IPC-PvPI, Ghaziabad)

#### **New Partners of PvPI in Pharmacovigilance:**

#### INDIAN MEDICAL ASSOCIATION (IMA)

The Indian Medical Association (IMA) and IPC have agreed to work together to enhance the ADR reporting. While signing the formal LoI, Dr. S. S. Agrawal, President, IMA and Dr. G. N. Singh, Secretary-cum-Scientific Director, IPC expressed their mutual commitment for the cause. While speaking on the occasion Dr. K. K. Agrawal, Secretary, IMA said that IMA shall accelerate the process and practice of ADRs reporting by the clinicians to PvPI.

Following steps will be taken to accelerate the participation of clinicians in PvPI:-

- Regular training and advocacy to the doctors on Pharmacovigilance.
- IMA- Nodal centres as patient safety monitoring centres.
- Declare a "National Patient Safety Day".
- Familiarize the clinicians with the process of ADR reporting.

IMA-PvPI patient safety monitoring cell is being set up at IMA-HQ, New Delhi

This cell aims to mobilize physicians about ADRs reporting ADRs received at safety monitoring cells will be forwarded to NCC-PvPI for assessment The cell is equipped with skilled manpower and a dedicated helpline number for ADR reporting and other logistics



Dr. G. N. Singh, DCG(I) & Secretary-cum-Scientific Director, IPC and Dr. S. S. Agarwal, President, IMA signing and exchanging the LoI (6<sup>th</sup> January, 2016).

#### INVOLVEMENT AND RESPONSIBILITIES OF CORPORATE AND DISTRICT HOSPITALS IN PVPI

The participation of corporate hospitals in PvPI is paramount because the newly introduced drugs are more frequently used in the corporate hospitals than in the public hospitals. The current Adverse Drug Reaction Monitoring Centres (AMCs) under PvPI are Government teaching hospitals as well as private medical colleges. Also the range and number of drugs used in private sector is higher than in the public sector. Nearly 80% of the patient care is provided by corporate hospitals, and hence there is a huge potential to promote patient safety through these hospitals. Therefore, the NCC-PvPI recognized the need to collaborate with the corporate hospitals to monitor the safety of new drugs available in the market. A meeting was held on 11th Jan, 2016 at IPC, under the chairmanship of Dr. K.K. Kalra, CEO, NABH, who urged the corporate hospitals to come forward to support the PvPI. He also informed that the ADR reporting by the corporate hospitals is mandatory for NABH accreditation of hospitals or its subsequent renewal.



Meeting with representatives of the Corporate Hospitals to promote ADR reporting and patient safety (11th January, 2016, NCC-PvPI, IPC, Ghaziabad)

#### ICMR INSTITUTIONS TO JOIN HANDS WITH PVPI

The ICMR & PvPI collaborated during a two day workshop on pharmacovigilance and pharmacoepidemiology in RNTCP. The workshop was held on 4-5th March, 2016 at the National Institute for Research in Tuberculosis (NIRT), Chennai.

The objective of this workshop was to gain a better understanding of the onGoIng Programme and the challenges in reporting of adverse drug reactions to anti-TB treatment. It also aimed to develop an operational research protocol related to daily anti-TB treatment.



Dr. Soumya Swaminathan, Director General, ICMR & Secretary (DHR) along with participants of workshop on Pharmacovigilance and Pharmacoepidemiology.  $(4-5^{th}$  March, 2016).

The meeting was attended by more than 70 experts of PvPI, TB treatment providers & researchers. While addressing the gathering Dr. Soumya Swaminathan, Secretary, Department of Health Research (DHR) & Director General (DG), ICMR emphasized that PvPI & ICMR must work together to improve the basic knowledge & skills of Health Care Professional (HCPs) in pharmacovigilance, in ensuring the safety of the vulnerable population exposed to different drug regimens. The ICMR institutions such as National AIDS Research Institution (NARI), Pune, National Institute for Research in Reproductive Health (NIRRH), Mumbai, National Institute of Cholera and Enteric Diseases (NICED), Kolkata, National Institute of Nutrition (NIN), Hyderabad, National Institute of Epidemiology (NIE), Chennai, National Institute of Malaria Research (NIMR), Delhi, have expressed their deep interest to collaborate with PvPI.

#### THE ROLE OF NURSING PROFESSIONALS IN PVPI- A NEED OF THE HOUR

Nurses can play an important role in ADRs reporting, as they are in direct contact with the patients and have good knowledge of diagnosis, symptoms, drugs and ADRs. Given their unique position in patient care and recording side effects, nurses are well-placed to monitor the patients' response to drugs. They are often the primary source in alerting the responsible physician about possible ADRs. There is thus an obvious reason to involve nurses and encourage them to contribute to the ADR reporting system.



Nursing Staff, Jaypee Hospital Noida participating in training-cum-interactive session (5th February, 2016 – Jaypee Hospital, Noida)

PvPI intiatives during the index period to enhance nurses participation

- AMCs are encouraged to educate nurses to detect and prevent ADRs.
- Regular meetings with stakeholders, including office bearers of Nursing Council of India.
- Newsletters for Nurses to promote their participation in PvPI.
- Meeting with President, Nursing Council of India to percolate the concept of PvPI among the educating, practicing nursing community.
- Inclusion of nursing professionals in PvPI technical committees.
- Published scientific article in nursing journal.
- Dialogue between PvPI and state nursing councils.

# Modes of Communication in PvPI



#### COMMUNICATION

Communicating safety information to patients and healthcare professionals is an important function in the field of Pharmacovigilance and 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 to improve patient care, understand ADRs/ AEs, promote transparency and accountability. NCC is responsible for publishing/ communicating any findings from NCC database to journals/ media/online-web whereas 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 as follows:



#### Press and Media communication

This includes press releases and press briefings which are primarily intended for journalists. All activities related to PvPI are communicated to media to generate awareness among stakeholders. PvPI also releases news in different news papers e.g. drug today, medical times, dainik jagran, dainik bhaskar, amar ujala, united bharat etc. in different states and in local languages across language barriers to reach a wider population.



#### Website

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



#### Newsletter

NCC-PvPI publishes the "PvPI Newsletter" quarterly to communicate the findings and regulatory status of medicines in India as well as globally to the stakeholders. This newsletter is intended for anyone concerned with the issues of patient safety. It provides practical information and advice on drug safety and information on emerging safety issues. Past issues of the newsletter may be accessed from the IPC website www.ipc.gov.in.



#### Posters and Pamphlets

Posters and pamphlets are effective mode 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.

#### COMMUNICATION



#### Position Paper

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

#### COMMUNICATION THROUGH SOCIAL MEDIA



#### LinkedIn (NCC PvPI)

LinkedIn is a well known 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.



#### WhatsApp (7042343309)

WhatsApp Messenger is a cross-platform mobile messaging application, which allows you to exchange messages, information and documents with others. The NCC-PvPI has a dedicated WhatsApp number i.e. **7042343309** for this purpose.



#### Facebook (Ncc-PvPI Ipc)

Facebook is a popular free 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 on the account @IPCNCCPvPI.

# PvPI achievements reflected in the WHO-UMC publications

PvPI outcomes are regularly shared globally through UMC and WHO publications



# WHO Pharmaceuticals NEWSLETTER

<sup>2016</sup> No. **2** 

Prepared in collaboration with the WHO Collaborating Centre for International Drug Monitoring, Uppsala Sweden

Risk of Stevens Johnson syndrome with carbamazepine

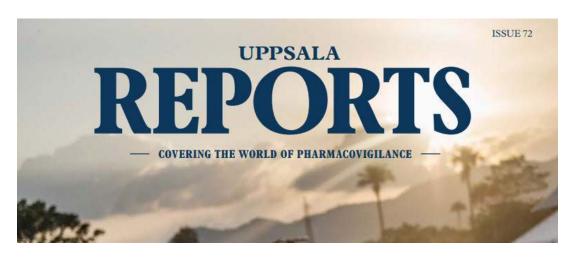
(http://www.who.int/medicines/ publications/PharmaNewsletter2\_16/en/)



Risk of bronchospasm and hypokalaemia with a combination of piperacillin and tazobactam

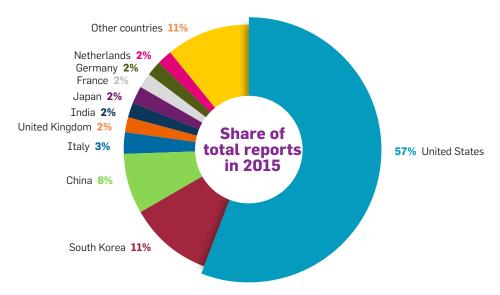
(http://www.who.int/medicines/publications/PharmaNewsletter2\_16/en/)





In late 2015, the number of individual case safety reports (ICSRs) in VigiBase® (WHO international database for adverse drug reactions) passed 12 million - and increase of about 1.7 million reports during last year alone.

### The contribution of PvPI to global drug safety database was reflected in the UMC report Issue 72



### ERYTHEMA MULTIFORME/STEVENS JOHNSON SYNDROME WITH RABIES VACCINE

The association of rabies vaccine and erythema multiforme (EM) stands out disproportionally in the WHO Global Individual Case Safety Report (ICSR) Database, VigiBase®.

#### REPORTS IN VIGIBASE®

The combination of rabies vaccine and erythema multiforme (EM) stands out disproportionally in the WHO Global Individual Case Safety Report (ICSR) Database, VigiBase® (with an IC: 1.00, IC025: 0.44 and observed number of reports/expected number of reports of 30/15). After removal of duplicates we identified 29 reports listing Erythema multiforme (27 cases) and Stevens Johnson syndrome (2) after administration of rabies vaccine, originate from Vietnam (1 case), Thailand (3), Australia (1), the United States (14), India (2), Denmark (1), Germany (3), the United Kingdom (3) and Tunisia (1) and refer to 20 male and 8 female patients. One report did not state the gender. The patients concerned were mostly young; the age ranged between 5 months and 80 years (median 34 years) with only three patients over 50. In 20 cases the patients were reported to have received only rabies vaccine. In 11 reports the brand of the vaccine was not mentioned, the remaining 18 mentioned different brands but none were identified as a nervous tissue vaccine. Co-suspect vaccines or drugs that have been associated with EM/SJS were mentioned in nine reports. The time of onset was mentioned in all but two reports and was consistent with skin lesions appearing within 14 days (median time to onset four days) and with two outliers at 20 and 30 days respectively

## NCC-PvPI Scientific Publication 2015-16

## PvPI outcomes are published in peer reviewed national and international journals.

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- **2.** Kalaiselvan V, Bhardwaj V, Kumar R, Singh G.N. Participation of nursing professionals in pharmacovigilance programme of india, Research & Reviews: A Journal of Pharmacology. (2015); (5): No 2
- 3. Kalaiselvan V, Kumar R, Thota P, Saurabh A, Kumar R, Tripathi A, Bhardwaj V. Adverse Drug Reaction Associated With Vitamins: An Analysis Of Spontaneous Reports From Pharmacovigilance Programme of India Database, Research & Reviews: A Journal Of Pharmacology. 2015; (5): No 3.
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Kalaiselvan, Ranvir Kumar, Prasad Thota, Archanu Saurabh, shi Kumar, Arunabh Tripathi, Vaishali Bhardwaj Indun Pharmoopoca Commission, Raj Nagar, Ghazinbad, U.P., India

# **AMC-PvPI Scientific Publication 2015-16**

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- **3.** Gupta M, Khanna J, Mathur R, Mittal N. Lamotrigine-induced fulminant hepatic failure: an unusual presentation. International Journal of Basic & Clinical Pharmacology. 2015;4(2):379.
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- 17. Sharma J., Verma S., Gupta M.C.. Atracurium-induced anaphylaxis and angioedema: a case report. International Journal of Basic & Clinical Pharmacology. 2015; 4(4): 802-804.
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# International Visitors at the NCC-PvPI

9<sup>th</sup> FEB 2016: MR. NANA ANSAH, MEDICINES QUALITY AND SAFETY SPECIALIST, FOOD AND DRUGS AUTHORITY GHANA- VISITED THE IPC



Mr. Nana Ansah Adjei , interacting with the personnel at PvPI helpline section

Mr. Nana Ansah Adjei, Medicines Quality and Safety Specialist, Food and Drugs Authority Ghana visited IPC, NCC-PvPI on 9th Feb, 2016. He discussed the importance of Pharmacovigilance in patient safety and envinced keen interest on behalf of Ghana FDA to work together with PvPI. He was also apprised with the logistics of PvPI, leadership and communications, insight into operations with respect to data collection, and use of analytical and executive Pharmacovigilance tools. He appreciated the skill, knowledge, competence and collaborative mindset of NCC. He was particularly appreciative about the PvPI helpline, an unique facility in India, for reporting ADRs and expressed his desire to introduce this facility in Ghana too.

#### 2<sup>nd</sup> MARCH 2016: INTERACTION OF CDSCO WITH SWEDISH COUNTERPARTS MR. BACKMAN CHRISTER AND MRS.KARIN GRONDAL TO PROMOTE PATIENT SAFETY



Mr. Backman Christer and Mrs. Karin Grondahl, Medical Product Agency, Sweden participated in the meeting held on 2<sup>nd</sup> March 2016 at CDSCO Headquarter.

The CDSCO organized a meeting on 2<sup>nd</sup> March, 2016 at CDSCO (HQ), New Delhi to discuss the Memorandum of Intent (MoI) between India and Sweden to understand and to update various issues related to regulatory affairs and Pharmacovigilance. Mr. Backman Christer and Mrs. Karin Grondahl, on behalf of Swedish Medical Product Agency, participated and provided information about the National Regulatory Authority (NRA) of their country. The progress in various areas of CDSCO were also presented by respective officials of various departments. This was second deliberation for the PvPI with Swedish NRA (the first meeting was held on 25th Nov 2014). It was emphasized that while the progress at PvPI is commendable, the signal detection in PvPI can be strengthened further.

### Action Plan 2016-17

HE PHARMACOVIGILANCE PROGRAMME OF INDIA has emerged over time as an essential part of public health programmes, but it encounters certain challenges. A proactive system is being developed in order to adapt to modern technology and the growing need of healthcare professionals/ consumers.

The PvPI has been evolving and gradually implementing strategies to enhance the system to meet the future challenges. Pharmacovigilance network has been expanded further to cover broader regions in need for proactive monitoring and reporting.

PvPI is already emerging in the country and globally as well. It is intended to become a advanced programme. The action plan for 2016-17 is as follows:

- Pharmacovigilance system to implement active surveillance on Bedaquiline.
- Lauching of skill development programme for young professionals of pharmacy / medical and other cources on pharmacovigilance
- Publication of pharmacovigilance guidelines for the marketing authorization holders.
- Identifying and Establishing new AMCs.
- Establishment/Integration of Pharmacovigilance in vector borne disease programme.
- Engagement of research institutions in PvPI for research based Pharmacovigilance.

Although a considerable progress has been made by the programme, there is yet a long way to go.....

In words of Robert Frost "Miles to go before we sleep......"

**SINCERELY ACKNOWLEDGE** the efforts and contribution of the following members of my team for compiling and meticulously preparing this Performance Report.

Dr. V. Kalaiselvan, Principal Scientific Officer

Dr. Pawan Saini, Scientific Officer

Dr. Prasad Thota, Scientific Assistant

Ms. Archana Saurabh, Pharmacovigilance Associate

Mr. Jitin Ahuja, Pharmacovigilance Associate

All PvPI team at National Coordination Centre (NCC) & ADR Monitoring Centres (AMCs).

I also gratefully acknowledge the contribution and expertise provided by the following in preparing and reviewing this report:

Dr. Chetna Desai, Professor of Pharmacology, BJ Medical College, Ahmedabad, Gujarat.

Dr. Sushma Srivastava, Senior 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

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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, Kur-

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

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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: medicalsunt@vahoo.com Contact: 09436041290

Centre Name: Health Training & Research Centre,

Pasighat-791102 Coordinator: Dr. T Tali Email: drigibi@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@vahoo.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

#### 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

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Contact: 09826045357, 08518881725

**Centre Name:** C. M. Medical College and Hospital, Vill & P.O: Kachandur, Durg, Chhattisgarh-490024 **Coordinator:** Dr. Sunita Chandraker

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#### Goa

Centre Name: Goa Medical College & Hospital, NH 17,

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#### Gujarat

Centre Name: SMT NHL Municipal Medical College,

Ellise Bridge, Ahmedabad-380006 Coordinator: Dr. Supriya D. Malhotra Email: supriyadmalhotra@gmail.com

Centre Name: BJ Medical College, New Civil Hospital,

Asarwa, Ahmedabad-380016 Coordinator: Dr. Mira K. Desai Email: desaimirak@yahoo.com Contact: 098/5057107

Contact: 09727760262

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

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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

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# Haryana

Centre Name: Medanta-The Medicity Sector-38,

Gurgaon-122001

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Centre Name: Artemis Hospital, Sector-51, Gurgaon

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Centre Name: Pandit Bhagwat Dayal Sharma Post Graduate

Institute of Medical Sciences, Rohtak-124001

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Recognition Status of AMCs: RNTCP centre

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

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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@vahoo.co.uk

## **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

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Contact: 09449208478

Centre Name: Mandya Institute of Medical Sciences (MIMS),

District Hospital Campus, Mandya-571401
Coordinator: Dr. Nagabushan
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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. John's Medical College, Sarjapur Road, Bengaluru-560034 Coordinator: Dr. Padmini Devi

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Centre Name: Vydehi Institute of Medical Sciences and

Research Centre

82, Nallurahalli, Near BMTC 18th Depot, Whitefield, Bengalu-

ru-560066

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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,

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Coordinator: Dr. Suchitra A.D, Dr. Niveditha

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Contact: 09632229122

Centre Name: Sapthagiri Institute of Medical Sciences and

Research Centre, No.15, Chikkasandra, Hesaraghatta Main Road, Bangalore-560090

Coordinator: Dr. Shubha R.
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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

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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: mrmcqlb@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

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
Emall: 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

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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

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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

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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

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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, Nag-

pur-440019

Coordinator: Dr. Archana S. Borkar

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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 Emall: karandikar\_yogita@yahoo.com Contact: 09922747908

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# Manipur

Centre Name: Regional Institute of Medical Sciences,

Lamphelpat, Imphal-795004 Coordinator: Dr. S. Rita Devi

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# Meghalaya

Centre Name: North Eastern Indira Gandhi Regional

Institute of Health & Medical Sciences, mawdiangdiang, shillong-793018 **Coordinator:** Dr. Dhriti Kumar Brahma

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## 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

 $\textbf{Email:} \ adr.scbmch@gmail.com, drkaliprasad@yahoo.co.in$ 

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

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# 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

**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

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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

Centre Name: SMS Medical College, Jawaharlal Nehru Marg, Jaipur-302004 Coordinator: Dr. Mukul Mathur Email: mathur\_mukul@rediffmail.com coordPvPImsjp@rediffmail.com Contact: 19414324182

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: drrampsq@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@sriram-

achandra.edu.in Contact: 09444622698

Centre Name: Madurai Medical College,

Alwarpuram, Madurai-625020 Coordinator: Dr. M. Malathi Email: poojamuthudch@yahoo.co.in

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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

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Centre Name: Velammal Medical College Hospital and Research Institute, Anuppanadi, Madurai-625009

Coordinator: Dr. S. Thamilaras

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Centre Name: Government Hospital of Thoracic Medicine, Tambaram, Chennai-600047

Coordinator: Dr. Nalini Jayanthi

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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

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Centre Name: Nizam Institute of Medical Sciences. Punjagutta Main Road, Hyderabad-500082

Coordinator: Dr. P. Usha Rani Email: ushapingali@yahoo.com

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Centre Name: Bhaskar Medical College & Bhaskar General

Hospital.

Yenkapally, Moinabad, Ranga Reddy-500075 Coordinator: Dr. G. Vijay Lakshmi Email: yadagirivijayalakshmi@yahoo.com

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Centre Name: Kamineni Institute of Medical Sciences.

Narketpally, Nalgonda-508254 Coordinator: Dr. Y. Venkata Rac

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

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# Tripura

Centre Name: Agartala Govt. Medical College,

Kunjaban, Agartala-799006 Coordinator: Dr. Debasis Ray

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Contact: 09436125100

Centre Name: Tripura Medical College &

Dr. BRAM Teaching Hospitals, Hapania, Agartala-799014

Coordinator: Dr. Tapasjyoti Ray

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#### 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@cmail.com

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Centre Name: M.L.N Medical College, Darbhanga Colony,

George Town, Allahabad- 211002

Coordinator: Dr. Rakesh Chandra Chaurasia

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Coordinator: Dr. V. S. Chopra

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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

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Centre Name: Subharati Medical College, Subharti Puram, NH-

58, Delhi-Haridwar By Pass Road, Meerut-250005 **Coordinator:** Dr. Prem Prakash Khosla

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Centre Name: Era's Lucknow Medical College & Hospital, Sarfazganj, Moosa Bagh picnic Spot, Hardoi Road, Lucknow-226003

Coordinator: Dr. Afroz Abidi Email: afrozabidi@gmail.com Contact: 09794979717

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Moti Katra, Agra-282002 Coordinator: Dr. Mona Verma

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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, Kau-

shambi, 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

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#### Uttarakhand

Centre Name: Govt Medical College, Rampur Road,

Haldwani-263139

**Coordinator:** Dr. Bhavana Srivastava **Email:** bhavanaufht@yahoo.co.in

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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

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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

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Centre Name: School of Tropical Medicine, 108, Medical Col-

lege Campus Chittaranjan Avenue, Kolkata- 700073

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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

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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

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Contact: 09733106803

Centre Name: Bankura Sammilani Medical College, Kenduadihi,

Bankura 722101

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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

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Centre Name: North Bengal Medical College, PO Sushrutana-

gar, Siliguri, Distt. Darjeeling-734012 Coordinator: Dr. Anupam Gupta Email: nathguptadranupam@yahoo.com

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Centre Name: Murshidabad Medical College & Hospital,

Berhampore-742101

Coordinator: Dr. Mainak Ghosh Email: docmainak@gmail.com Contact: 09007924708

Centre Name: Midnapore Medical College & Hospital, Vidyas-

agar 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,

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Coordinator: Dr. Sukanta Sen Email: drsukant@gmail.com Contact: 08420532336

## Andaman & Nicobar

Centre Name: Andaman & Nicobar Islands Institute of Medi-

cal Sciences, Portblair-744104 Coordinator: Dr. Mangesh Bankar Email: drmangesh\_bankar@yahoo.co.in

# 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@

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**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), Univer-

sity 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

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Recognition Status of AMCs: ART- centre

Centre Name: Hamdard Institute of Medical Sciences and

Research, Hamdard Nagar, New Delhi -110062

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**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

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igmcri@gmail.com

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# About the IPC and NCC-PvPI

Indian Pharmacopoeia Commission (IPC), Ghaziabad is an autonomous institution under the aegis of Ministry of Health & Family Welfare (MoHFW), Government of India. At IPC, Ghaziabad we strive hard to achieve its mission "To promote public and animal health in India by bringing out authoritative and officially accepted standards for quality of drugs including active pharmaceutical ingredients, excipients and dosage forms, used by health professionals, patients and consumers." The vision of IPC is "To promote the highest standards of drugs for use in human and animals within practical limits of the technologies available for manufacture and analysis."

The IPC is functioning as the National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI) since the year 2011. The mission of PvPI is to safeguard the health of Indian population by ensuring that the benefit of use of medicines outweighs the risks associated with their use. The programme is an important initiative of MoHFW for improving patient safety and welfare of Indian population by monitoring drug safety and minimizing the risk associated with the use of medicines. It also aims to bolster the regulatory mechanisms in India by utilising the drug safety database for identifying signals and providing support for appropriate regulatory interventions. The programme seeks support from all stakeholders including the physicians, pharmacists, patients, pharmaceutical industry and the consumers.



#### **Indian Pharmacopoeia Commission**

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