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.
**PvPI OVERVIEW**

**COMMUNICATION SYSTEM OF PvPI**

PvPI COMMUNICATIONS

Effective communication channels are the key to successful functioning of any organization. The use of information communication technology at NCC-PvPI & across 202 ADR monitoring centre (AMC) working under its umbrella is a beautiful role model for government bodies in India and abroad. The following chart depicts the movement of information between the key stakeholders that ensures the continuous transfer of data, information related to Pharmacovigilance across the country.
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 guides 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 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 reporting.

**Mobile Application**
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.
Due 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

PvPI 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 play 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)

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Medical Colleges/ Hospitals</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Government Teaching Hospitals/ART Centres/ RNTCP Centres</td>
<td>109</td>
</tr>
<tr>
<td>2.</td>
<td>Non Government Teaching Hospitals</td>
<td>84</td>
</tr>
<tr>
<td>3.</td>
<td>Corporate Hospitals</td>
<td>06</td>
</tr>
<tr>
<td>4.</td>
<td>Specialized Hospitals</td>
<td>03</td>
</tr>
<tr>
<td><strong>Total no. of AMCs</strong></td>
<td><strong>202</strong></td>
<td></td>
</tr>
</tbody>
</table>
A 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

<table>
<thead>
<tr>
<th>Year (Till March)</th>
<th>ICSRs reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>14685</td>
</tr>
<tr>
<td>2012</td>
<td>22935</td>
</tr>
<tr>
<td>2013</td>
<td>27882</td>
</tr>
<tr>
<td>2014</td>
<td>41149</td>
</tr>
<tr>
<td>2015</td>
<td>59158</td>
</tr>
<tr>
<td>2016</td>
<td>15847</td>
</tr>
</tbody>
</table>
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 the distribution of 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)
STATUS OF ADR REPORTING

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)**

- **19%**: Other Health Professional
- **56%**: Physicians
- **13%**: Pharmacists
- **12%**: Consumers or other Non Health Professionals

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)**

- **48%**: Female
- **51%**: Male
- **1%**: Unknown

* 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)**

The bar chart shows the percentage of ADR cases reported across different age groups. The highest percentage of cases is observed in the 18-44 years age group, followed by the 0-27 days and 2-11 years age groups.
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)

- Vision disorders
- Vascular, bleeding and clotting disorders
- Urinary tract disorders
- Skin and appendages disorders
- Secondary terms - events
- Respiratory disorders
- Reproductive disorders
- Psychiatric disorders
- Neurological disorders
- Neoplasms
- Neonatal and infancy disorders
- Musculoskeletal disorders
- Metabolic and nutritional disorders
- Liver and biliary disorders
- Immune disorders and infections
- Hearing, vestibular and special senses disorders
- Gastrointestinal disorders
- Endocrine disorders
- Congenital disorders
- Cardiovascular disorders
- Body as a whole - general disorders
- Blood disorders
- Application site disorders
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®.
2. Reporting by the Pharmaceutical industry.
3. Reporting through Toll free helpline.
4. Reporting by the Non-AMCs.
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.

![Fig. 8 Month wise distribution of ICSRs received from AMCs at NCC-PvPI (2015-16)](image)

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.
3. REPORTING THROUGH TOLL FREE HELPLINE:

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

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 22nd 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.
2. 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.
5. Algorithm based causality assessment, based on WHO criteria.
6. Option to choose nearest or preferred AMC.
7. 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.
Technical Support to Strengthen the AEFI Surveillance System

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

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-CDSCO. 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 AEFI 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](image_url)
**Fig. 15: Distribution of adverse event due to Vaccines**

- DPT/Haemophilus influenza type B/Hepatitis B: 179
- DPT/Hepatitis A/Haemophilus influenza type B: 28
- Tetanus/Diphtheria/Pertussis: 32
- Polio: 54
- Mumps/Rubella/Measles: 77
- Hepatitis A: 90
- Rotavirus: 28
- BCG: 28
- Japanese encephalitis: 27
- Pneumococcal: 97

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

- Body as a whole - general disorders: 378
- Application site disorders: 62
- Gastrointestinal disorders: 59
- Respiratory disorders: 32
- Neurological disorders: 19
- Skin and appendages disorders: 10
- Immune disorders and infections: 7
- Musculoskeletal disorders: 104
- Neonatal and infancy disorders: 74
- Psychiatric disorders: 32
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:**

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

**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.

<table>
<thead>
<tr>
<th>S. No</th>
<th>Name</th>
<th>Date</th>
<th>Place</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NATIONAL AEFI COMMITTEE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>National level training workshop on AEFI monitoring and causality assessment</td>
<td>2015</td>
<td>New Delhi</td>
<td>IPC, CDSCO, ITSU and WHO officials</td>
</tr>
<tr>
<td>2</td>
<td>MONTHLY AEFI-PHARMACOVIGILANCE PARTNERS MEETING</td>
<td>Monthly</td>
<td>Nirman Bhawan, New Delhi</td>
<td>IPC, CDSCO and ITSU, WHO Country office (India) officials</td>
</tr>
<tr>
<td>3</td>
<td>OTHER INTERACTIVE SESSIONS:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Induction cum Training Programme for Newly Recruited Technical Associates</td>
<td>18th to 22nd August 2015</td>
<td>IPC, Ghaziabad</td>
<td>New Technical Associates</td>
</tr>
<tr>
<td>7</td>
<td>Induction cum Training Programme on Pharmacovigilance for Coordinators of Newly recognized AMCs under PvPI</td>
<td>3rd - 4th September 2015</td>
<td>IPC, Ghaziabad</td>
<td>Coordinators</td>
</tr>
<tr>
<td>8</td>
<td>First internal audit in AEFI division</td>
<td>2015</td>
<td>AEFI Secretariat</td>
<td>PvPI as a part of AEFI Secretariat at Immunization Technical Support Unit (ITSU).</td>
</tr>
</tbody>
</table>

KNOWLEDGE SHARING:
Documentation and Publications of PvPI with emphasis on AEFI Surveillance

3. Poster on “Role of the Partners in AEFI Monitoring”
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.
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.

- Pyrazinamide
- Isoniazid/Pyrazinamide/Ethambutol dihydrochloride/Rifampicin
- Isoniazid
- Rifampicin
- Ethambutol
- Cycloserine
- Ethionamide
- Isoniazid/Rifampicin
- Isoniazid/Ethambutol/Pyrazinamide/Rifampicin

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:

Fig. 19: Antiretroviral Drugs causing maximum ADRs.

- 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.**

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congenital disorders</td>
<td>1</td>
</tr>
<tr>
<td>Application site disorders</td>
<td>1</td>
</tr>
<tr>
<td>Endocrine disorders</td>
<td>4</td>
</tr>
<tr>
<td>Vascular, bleeding and clotting disorders</td>
<td>8</td>
</tr>
<tr>
<td>Neoplasms</td>
<td>8</td>
</tr>
<tr>
<td>Cardiovascular disorders</td>
<td>12</td>
</tr>
<tr>
<td>Secondary terms - events</td>
<td>13</td>
</tr>
<tr>
<td>Vision disorders</td>
<td>31</td>
</tr>
<tr>
<td>Hearing, vestibular and special senses disorders</td>
<td>36</td>
</tr>
<tr>
<td>Reproductive disorder</td>
<td>61</td>
</tr>
<tr>
<td>Respiratory disorders</td>
<td>62</td>
</tr>
<tr>
<td>Urinary tract disorders</td>
<td>88</td>
</tr>
<tr>
<td>Immune disorders and infections</td>
<td>121</td>
</tr>
<tr>
<td>Liver and biliary disorders</td>
<td>166</td>
</tr>
<tr>
<td>Musculoskeletal disorders</td>
<td>176</td>
</tr>
<tr>
<td>Metabolic and nutritional disorders</td>
<td>210</td>
</tr>
<tr>
<td>Body as a whole - general disorders</td>
<td></td>
</tr>
<tr>
<td>Blood disorders</td>
<td></td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td></td>
</tr>
<tr>
<td>Neurological disorders</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
</tr>
<tr>
<td>Skin and appendages disorders</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Date</th>
<th>Title</th>
<th>Organised by</th>
<th>Organised at</th>
<th>Participants/Target Audience</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>10-23&lt;sup&gt;th&lt;/sup&gt; April 2015</td>
<td>Joint Monitoring Mission</td>
<td>Central TB Division/ PvPI</td>
<td>Hotel Lalit, New Delhi</td>
<td>RNTCP/WHO/PvPI officials, all healthcare professionals of states under purview of JMM</td>
</tr>
<tr>
<td>2.</td>
<td>21&lt;sup&gt;st&lt;/sup&gt; May 2015</td>
<td>Meeting on Bedaquiline-CAP</td>
<td>Central TB Division/ PvPI</td>
<td>Nirman Bhavan, New Delhi</td>
<td>RNTCP/WHO/PvPI Officials</td>
</tr>
<tr>
<td>3.</td>
<td>1-3&lt;sup&gt;rd&lt;/sup&gt; July 2015</td>
<td>National Workshop on Bedaquiline-CAP</td>
<td>Central TB Division/ PvPI</td>
<td>Hotel Taj, New Delhi</td>
<td>MoHFW/RNTCP/PvPI Officials</td>
</tr>
<tr>
<td>4.</td>
<td>7&lt;sup&gt;th&lt;/sup&gt; January 2016</td>
<td>National Training of Trainers (TOT) on Implementation of Bedaquiline</td>
<td>Central TB Division/ PvPI</td>
<td>NTI, Bangalore</td>
<td>RNTCP/WHO/PvPI Officials</td>
</tr>
<tr>
<td>5.</td>
<td>3&lt;sup&gt;rd&lt;/sup&gt; February 2016</td>
<td>Launch of newer initiatives under RNTCP and NACO</td>
<td>Central TB Division/ PvPI</td>
<td>Hotel Oberoi, New Delhi</td>
<td>MoHFW/RNTCP/PvPI Officials</td>
</tr>
<tr>
<td>6.</td>
<td>8&lt;sup&gt;th&lt;/sup&gt; February 2016</td>
<td></td>
<td>NITRD &amp; RBIPMT, New Delhi</td>
<td></td>
<td>NITRD/RBIPMT/RNTCP/PvPI Officials</td>
</tr>
<tr>
<td>7.</td>
<td>15&lt;sup&gt;th&lt;/sup&gt; to 17&lt;sup&gt;th&lt;/sup&gt; February 2016</td>
<td>Site and Key district staff training for Bedaquiline Conditional Access Programme</td>
<td>Central TB Division</td>
<td>KEM Hospital – Mumbai, Maharashtra</td>
<td>KEM Hospital Staff/RNTCP/PvPI Officials</td>
</tr>
<tr>
<td>8.</td>
<td>17&lt;sup&gt;th&lt;/sup&gt; to 19&lt;sup&gt;th&lt;/sup&gt; February 2016</td>
<td></td>
<td>BJMC, Ahmedabad, Gujrat</td>
<td></td>
<td>BJMC/RNTCP/PvPI Officials</td>
</tr>
<tr>
<td>9.</td>
<td>3&lt;sup&gt;rd&lt;/sup&gt; to 5&lt;sup&gt;th&lt;/sup&gt; March 2016</td>
<td></td>
<td>GHTM Tambaram, Tamil Nadu</td>
<td></td>
<td>GHTM Tambaram/RNTCP/PvPI Officials</td>
</tr>
<tr>
<td>10.</td>
<td>7&lt;sup&gt;th&lt;/sup&gt; to 9&lt;sup&gt;th&lt;/sup&gt; March 2016</td>
<td></td>
<td>GMC Guwahati, Assam</td>
<td></td>
<td>GMC/RNTCP/PvPI Officials</td>
</tr>
<tr>
<td>11.</td>
<td>21&lt;sup&gt;st&lt;/sup&gt; March 2016</td>
<td>World TB Day; Release of Guideline and Launch of Bedaquiline</td>
<td>Central TB Division</td>
<td>Hotel Taj, New Delhi</td>
<td>MoHFW/RNTCP/PvPI Officials</td>
</tr>
</tbody>
</table>
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 10th 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 follow-up 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 10th-23rd 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.
World TB Day is designed to build public awareness about the global epidemic of tuberculosis (TB) and efforts to eliminate the disease were observed here on 21st March 2016. Befitting the occasion Hon’ble Health Minister Shri J.P. Nadda along with officials 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 initiated 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 4-5th 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®.

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 NIKSHAY ID 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 11th 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 11th 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:—

a. The cohort event monitoring (CEM) is possible since the denominator values are available.

b. Timely signal detection is possible.
The 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.
<table>
<thead>
<tr>
<th>S No.</th>
<th>Name of Programme</th>
<th>Date</th>
<th>Place</th>
<th>Target Audience</th>
<th>Objective(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>PvPI Sensitization Programme</td>
<td>24th June 2015</td>
<td>V.S.S. Medical College, Burla, Odisha</td>
<td>Health care professionals, postgraduate and undergraduate students of medical colleges and hospitals</td>
<td>Knowledge, Awareness &amp; Practice (KAP) of Pharmacovigilance</td>
</tr>
<tr>
<td>2.</td>
<td>Refreshment Course on Updates on PvPI for Existing Technical Associates</td>
<td>20th &amp; 21st July 2015</td>
<td>IPC, Ghaziabad</td>
<td>Technical Associates</td>
<td>Acquaint the technical associates with the recent development/updates in PvPI.</td>
</tr>
<tr>
<td>6.</td>
<td>Induction cum Training Programme on Pharmacovigilance for Coordinators of Newly recognized AMCs under PvPI</td>
<td>3rd &amp; 4th September 2015</td>
<td>IPC, Ghaziabad</td>
<td>Coordinators of Newly recognized AMCs under PvPI</td>
<td>Training on Basic Knowledge of Pharmacovigilance and Hands on Training in VigiFlow®</td>
</tr>
<tr>
<td>7.</td>
<td>Joint Signal Detection Workshop</td>
<td>5th to 8th October 2015</td>
<td>IPC, Ghaziabad</td>
<td>Staff of NCC-PvPI &amp; Drug inspectors of CDSCO</td>
<td>Training on Basic Knowledge of Signals &amp; its assessment</td>
</tr>
</tbody>
</table>

Continued on next page
### TRAINING & SKILL DEVELOPMENT

Continued from previous page

<table>
<thead>
<tr>
<th>S No.</th>
<th>Name of Programme</th>
<th>Date</th>
<th>Place</th>
<th>Target Audience</th>
<th>Objective(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.</td>
<td>38th Annual Meeting of Representatives of National Pharmacovigilance Centres</td>
<td>4th - 6th November 2015</td>
<td>New Delhi</td>
<td>Staff of NCC-PvPI, WHO &amp; UMC Officials &amp; Representatives of National Pharmacovigilance Centres</td>
<td>Meeting acts as a platform for countries to discuss current issues and concerns in Pharmacovigilance.</td>
</tr>
<tr>
<td>9.</td>
<td>East Zone training programme</td>
<td>27th November 2015</td>
<td>IPGMER-Kolkata</td>
<td>For special invite &amp; delegates</td>
<td>KAP of Pharmacovigilance</td>
</tr>
<tr>
<td>10.</td>
<td>Training &amp; Awareness programme on Pharmacovigilance</td>
<td>8th – 9th December 2015</td>
<td>PGIMER, Chandigarh</td>
<td>Healthcare Professionals</td>
<td>KAP of Pharmacovigilance</td>
</tr>
<tr>
<td>11.</td>
<td>Training for Nursing Professionals</td>
<td>5th February 2016</td>
<td>Jaypee Hospital, Noida</td>
<td>Nursing Staff</td>
<td>KAP of Pharmacovigilance</td>
</tr>
<tr>
<td>12.</td>
<td>Induction cum Training Programme on Pharmacovigilance for Coordinators of Newly recognized AMCs under PvPI</td>
<td>15th - 19th February 2016</td>
<td>IPC, Ghaziabad</td>
<td>New Coordinators</td>
<td>Training on Signal assessment</td>
</tr>
<tr>
<td>13.</td>
<td>Advanced Level training in Pharmacovigilance</td>
<td>19th March 2016</td>
<td>Seth GSMC &amp; KEM Hospital, Mumbai</td>
<td>Existing Coordinators &amp; Technical Associates of west zone</td>
<td>Training for up-gradation of Skills of Coordinators &amp; TAs</td>
</tr>
</tbody>
</table>
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):**

<table>
<thead>
<tr>
<th>Regional Training Centres</th>
<th>States/UTs under purview</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. PGIMER, Chandigarh, Punjab</td>
<td>Chandigarh, Uttarakhand, Punjab, Haryana, Delhi, Jammu and Kashmir, Himachal Pradesh</td>
</tr>
<tr>
<td>2. Seth GS Medical College &amp; KEM, Mumbai, Maharashtra</td>
<td>Maharashtra, Goa, Dadra and Nagar Haveli</td>
</tr>
<tr>
<td>3. JSS Medical College &amp; Hospital, Mysuru, Karnataka</td>
<td>Kerala, Karnataka, Puducherry, Tamil Nadu Lakshadweep</td>
</tr>
<tr>
<td>4. IPGMER, Kolkata, West Bengal</td>
<td>West Bengal, Odisha, Jharkhand, Bihar, Andaman &amp; Nicobar</td>
</tr>
<tr>
<td>5. All India Institute of Medical Sciences, Bhopal, Madhya Pradesh</td>
<td>Madhya Pradesh, Chhattisgarh</td>
</tr>
<tr>
<td>6. B J Medical College, Ahmedabad, Gujarat</td>
<td>Gujarat, Rajasthan, Daman &amp; Diu</td>
</tr>
<tr>
<td>7. Institute of Medical Sciences, Varanasi, Uttar Pradesh</td>
<td>Uttar Pradesh, Bihar</td>
</tr>
<tr>
<td>8. Nizam’s Institute of Medical Sciences, Hyderabad, Telangana</td>
<td>Telangana, Andhra Pradesh</td>
</tr>
<tr>
<td>9. Silchar Medical College &amp; Hospital, Silchar, Assam</td>
<td>Assam, Arunachal Pradesh, Manipur, Meghalaya, Mizoram, Nagaland, Tripura, Sikkim</td>
</tr>
</tbody>
</table>
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:

- Treatment Providers: 3000
- Regulators: 200
- State Drug Analyst: 500
- Medical & Paramedical Students: 4500

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.

![Fig. 21: Qualitative Analysis of impact of Training & Skill Development](image)
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.

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

**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”.

Signal 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 ($N_{comb}$).

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

1. $IC_{0.025} > 0$
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. $N_{comb} \geq 3$, 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.

<table>
<thead>
<tr>
<th>S No.</th>
<th>Activities</th>
<th>Drug-ADR combination reviewed</th>
<th>Outcome</th>
</tr>
</thead>
</table>
| 1     | 5th SRP Meeting held on 9th 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     | 6th SRP Meeting held on 6th October, 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  
- Phenyltoin-Vestibular Disorder  
- Betamethasone-Photosensitivity | |
| 4     | 7th SRP Meeting held on 1st 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. |
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.

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

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

**SUMMARY**

<table>
<thead>
<tr>
<th>Signal Detection related activities held during the index period</th>
<th>Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of SRP Meetings</td>
<td>03</td>
</tr>
<tr>
<td>Number of Signal Detection Workshop</td>
<td>01</td>
</tr>
<tr>
<td>Number of Drug-ADR combinations discussed</td>
<td>180</td>
</tr>
<tr>
<td>Number of Signals identified</td>
<td>07</td>
</tr>
<tr>
<td>Number of recommendations made regarding Drug-ADR combination to the CDSCO for label change</td>
<td>11</td>
</tr>
</tbody>
</table>
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 26th 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 COMBINATIONS 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.
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 initiative 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 22nd 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 MoHW, Govt. of India during launch the Android Mobile App for ADR reporting (22nd 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 (4th June, 2015, IPC, Ghaziabad)
MEDICAL DEVICE SAFETY MONITORING

Materiovigilance Programme of India (MvPI) was launched on 6th 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 providers 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 38th 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.
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 4th 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.

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

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 initiatives 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.


COMMUNICATION

Modes of Communication in PvPI

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

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

![Pie chart showing the share of total reports in 2015 across countries]

- **United States**: 57%
- **China**: 8%
- **South Korea**: 11%
- **India**: 2%
- **Japan**: 2%
- **Italy**: 3%
- **United Kingdom**: 2%
- **Germany**: 2%
- **France**: 2%
- **Netherlands**: 2%
- **Other countries**: 11%
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.

SCIENTIFIC PUBLICATIONS AT NCC


AMC-PvPI Scientific Publication 2015-16


Most Common Cause of Cutaneous Adverse Drug Reactions in an Outpatient Department of a Tertiary Care Hospital. JCDR. 2015; Vol-9(11): FC17-FC20


International Visitors at the NCC-PvPI

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

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 enmoved 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.

Mr. Nana Ansah Adjei, interacting with the personnel at PvPI helpline section
2nd MARCH 2016: INTERACTION OF CDSCO WITH SWEDISH COUNTERPARTS MR. BACKMAN CHRISTER AND MRS.KARIN GRONDAL TO PROMOTE PATIENT SAFETY

The CDSCO organized a meeting on 2nd 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

The 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 an advanced programme. The action plan for 2016-17 is as follows:

- Pharmacovigilance system to implement active surveillance on Bedaquiline.
- Launching of skill development programme for young professionals of pharmacy/medical and other courses 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....”*
ACKNOWLEDGEMENT

I 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:** prabhu2202@gmail.com  
**Contact:** 09849903051  
**Recognition Status of AMCs:** ART centre

<table>
<thead>
<tr>
<th>Centre Name</th>
<th>Addresses</th>
<th>Coordinator</th>
<th>Email</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andhra Medical College, KGH</td>
<td>Jagadamba Area, KGH Down Road, Maharanipeta, Visakhapatnam-530002</td>
<td>Dr. J. Sudha</td>
<td><a href="mailto:prabhu2202@gmail.com">prabhu2202@gmail.com</a></td>
<td>09849903051</td>
</tr>
</tbody>
</table>

## Arunachal Pradesh

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

<table>
<thead>
<tr>
<th>Centre Name</th>
<th>Addresses</th>
<th>Coordinator</th>
<th>Email</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jorhat Medical College &amp; Hospital</td>
<td>Kushal Konwar Path, Barbheta, P.O. Jorhat-785001</td>
<td>Dr. Swapnani Gohain</td>
<td><a href="mailto:nil_swapnapa20@yahoo.com">nil_swapnapa20@yahoo.com</a>, <a href="mailto:pharmacologyjymch@gmail.com">pharmacologyjymch@gmail.com</a></td>
<td>08613880565</td>
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</table>

## Assam

**Centre Name:** Assam Medical College and Hospital, Barbari, Dibrugarh, Assam-786002  
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<th>Centre Name</th>
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**Haryana**

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**Recognition Status of AMCs**:

**ART centre**

**ART-Centre, RNTCP centre**

**ART-Centre**

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Recognition Status of AMCs: RNTCP centre
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- **Centre Name**: All India Institute of Medical Sciences, Saket Nagar, Bhopal- 462024  
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- **Centre Name**: Gajra Raja Medical College, Veer Savarkar Marg, Gwalior, M.P-474009  
  **Coordinator**: Dr. Saroj Kothari  
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- **Centre Name**: Government Medical College & Hospital, Ajni Rd, Nagpur-440003  
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  **Contact**: 09892292590  
  **Recognition Status of AMC’s**: ART centre

- **Centre Name**: Grant Medical College & Sir JJ Group of Hospitals, JJ Marg, Off Jijabhooy Road, Byculla Mumbai- 400008  
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- **Centre Name**: Lokmanyatilak Municipal Medical College & General Hospital, Dr. Babasaheb Ambedkar Road, Sion- 400022  
  **Coordinator**: Dr. Sudhir R. Pawar  
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- **Centre Name**: PD. Dr. D.Y. Patil Medical College, Gaikwad Harabhai Vinayan Rd, Pimpri, Chinchwad, Pune - 411018  
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  **Coordinator**: Dr. Urmila Thatte  
  **Email**: Pvi.tilakem@gmail.com, urmilathatte@gmail.com  
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- **Centre Name**: TN Medical College & Byl Nair Hospital, Dr. AL Nair Road, Mumbai Central, Mumbai- 400008  
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Centre Name: Pandit Dindayal Upadhyay Institute of Medical Science, Research and Human Resources, Gadkari wada, Upadhye Road, Mahal, Nagpur, Maharashtra-440017  
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Recognition Status of AMCs: RNTCP centre

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Centre Name: Ashwini Rural Medical College, Hospital & Research Centre, Kumbhari, Tq. South Solapur, Dist. Solapur-413006  
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Coordinator: Dr. Dhriti Kumar Brahma  
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Recognition Status of AMCs: RNTCP centre

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Centre Name: SCB Medical College and Hospital, Manglabag, Cuttack-753007  
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Recognition Status of AMCs: RNTCP centre

Sikkim

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Recognition Status of AMCs: ART centre

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Centre Name: Gandhi Medical College, Musheerabad, Secunderabad-500003  
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**Centre Name:** GSVM Medical College, Swaroop Nagar, Kanpur- 208001  
**Coordinator:** Dr. S.P. Singh  
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**Centre Name:** Institute of Medical Sciences Banaras Hindu University, Varanasi- 221005  
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**Centre Name:** M.L.B. Medical College, Jhansi- 284128  
**Coordinator:** Dr. Sadhna Kaushik  
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**Uttarakhand**

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Recognition Status of AMCs: COEART centre

Delhi

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Recognition Status of AMCs: ART centre, RNTCP centre

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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
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Recognition Status of AMCs: COEART- centre

Centre Name: Rajan Babu Institute of Pulmonary Medicine and Tuberculosis, GTB Nagar, Kingsway Camp, New Delhi-110009
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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
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Recognition Status of AMCs: RNTCP centre

Puducherry

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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.

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