"We take pride in the young caliber of professionals with us in delivering highest quality services in PvPI"

"We provide scientific support for vital functions of CDSCO in the regulation of drug safety"

Pharmacovigilance Programme of India (PvPI)
Performance Report 2014 - 2015

"Protecting Public Health by Promoting Safer Drug Therapy"
Shri J.P. Nadda, Hon'ble Minister of Health & Family Welfare, along with Dr. Jitendra Singh Hon'ble Minister of state, PMO & DOPT, Government of India releasing the 10th edition of AP Textbook of Medicine on 3rd February, 2015 at New Delhi. This book includes a chapter on “Pharmacovigilance: Safety monitoring of medicines” to educate medical professionals in Pharmacovigilance.

"Urgent need of bringing healthcare benefits to the poorest of the poor"
"Look at the sky. We are not alone. The whole universe is friendly to us and conspires only to give the best to those who dream and work"

Dr. APJ Abdul Kalam
Former President of India

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It is my pleasure to introduce this Report of the Pharmacovigilance Programme of India (PvPI).

The Programme is an important initiative for ensuring safety of medicines and thereby foster the well-being of all citizens. Towards this end, the PvPI has performed creditably during the past year. There has not only been enhanced collaboration with other National Health programmes and greater focus on training and capacity-building; but inclusion of corporate hospitals and the pharma industry has extended the scope and reach of the Programme.

Providing safe and effective medicines is an important and abiding concern of the Government. Our efforts in this regard can effectively be supplemented by a well-informed, aware and vigilant citizenry. The Programme’s initiative to encourage consumers to report adverse drug reactions through modern means of communication would be specially useful in this regard.

I congratulate the entire team of PvPI for their achievements, and am confident that they will continue their sincere efforts towards this worthy cause.
Dr. Jagdish Prasad
M.B. M.Ch. FACS
Director General of Health Services

MESSAGE

Dated: 01/09/2015

It has taken many years for pharmacovigilance to evolve in India, to become a multidisciplinary science, internationally recognised as being of great public health importance. The launching of the PvPI has been acclaimed as one of the noteworthy government-led initiatives in health care in India. The PvPI has been in operation since 2010, at present it has established itself as an efficient and effective programme for ensuring safety of medicines.

It has been gratifying to note that the Indian Pharmacopoeia Commission (IPC) is closely working with the CDSCO for strengthening the PvPI. The initiative aims to bolster the regulatory mechanism in the country by utilising the drug safety database for generating signals and appropriate regulatory intervention. In 2014, NCC-PvPI has made some important recommendations regarding the change of label for certain medicines.

While we face a major overhaul in the regulatory environment, an increased expectations of patients, the healthcare professionals, regulators, industries and the public, PvPI remains a cornerstone for certain regulatory recommendations and for signal detection. I am happy to note that the overall response towards the pharmacovigilance programme is encouraging which has been evident from the conferences and meetings with the stakeholders of the programme including the health care professionals and consumer groups. The progress made by PvPI in the last year has reinforced our belief that this patient safety programme will achieve all the sanitised objectives on the foundation of which it has been started.

I congratulate the team of PvPI all across the country for their glorious achievements and I am confident that the commitment and dedication of PvPI team will help the programme to achieve new heights in the days to come & shall strive to serve the nation even better. I also congratulate IPC and CDSCO for taking PvPI to new heights.

(Dr. Jagdish Prasad)
Acknowledgement

I acknowledge the efforts and contribution of the following members of my team in creative compilation and meticulously preparation of this Performance Report of PvPI:

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- Dr. Sushma Srivastava, Research Scientist, DIPSAR, New Delhi

(Dr. G.N. Singh)

Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
Ghaziabad

Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
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<tr>
<td>ADR</td>
<td>Adverse Drug Reaction</td>
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<tr>
<td>AE</td>
<td>Adverse Event</td>
</tr>
<tr>
<td>AEFI</td>
<td>Adverse Event Following Immunization</td>
</tr>
<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
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<tr>
<td>AIIMS</td>
<td>All India Institute of Medical Sciences</td>
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<td>AMC</td>
<td>Adverse Drug Reaction Monitoring Centre</td>
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<td>ART</td>
<td>Anti-retroviral Therapy</td>
</tr>
<tr>
<td>ARV</td>
<td>Antiretroviral</td>
</tr>
<tr>
<td>ATC</td>
<td>Anatomical Therapeutic Chemical Classification</td>
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<tr>
<td>CDSCO</td>
<td>Central Drugs Standard Control Organization</td>
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<tr>
<td>CHF</td>
<td>Congestive Heart Failure</td>
</tr>
<tr>
<td>CIOMS</td>
<td>Council for International Organization of Medical Sciences</td>
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<tr>
<td>CME</td>
<td>Continuing Medical Education</td>
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<tr>
<td>DCG(0)</td>
<td>Drugs Controller General (India)</td>
</tr>
<tr>
<td>DDC(0)</td>
<td>Deputy Drugs Controller (India)</td>
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<tr>
<td>DIR</td>
<td>Detailed Investigation Report</td>
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<tr>
<td>DOTS</td>
<td>Directly Observed Treatment-Short course</td>
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<tr>
<td>ERI</td>
<td>Essential Required Items</td>
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<tr>
<td>FIR</td>
<td>First Information Report</td>
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<tr>
<td>GIT</td>
<td>Gastro Intestinal Tract</td>
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<td>GOI</td>
<td>Government of India</td>
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<td>GVP</td>
<td>Good Pharmacovigilance Practice</td>
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<td>HCP</td>
<td>Health Care Professional</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>HLA-B</td>
<td>Human Leukocyte Antigen-B</td>
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<tr>
<td>IC</td>
<td>Information Component</td>
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<tr>
<td>ICH</td>
<td>International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use</td>
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Executive Summary

This Annual Performance Report of PvPI for the period of April 2014 to March 2015, covers the major activities under the PvPI during the index period. The NCC, established to steer and supervise the programme, and align it with the broader perspective of safer use of medicines in India, has been obliged to publish this report.

During the index period a total of 41,879 reports were received from different AMCs. These reports were reviewed for validity and causality and then, shared with the WHO global safety database, Vigibase®. The most commonly reported drugs having ADRs were cisplatin, cyclophosphamide, paclitaxel, fluorouracil, zidovudine, doxorubicin, carboplatin, docetaxel, nevirapine and ceftriaxone. The common system-organ involvement of ADRs were gastrointestinal, cutaneous, neurological, psychiatric and haematological in that order.

The reports of serious and unexpected were segregated for evaluation by the SRP. The SRP, through application of appropriate medical and scientific judgment, has been engaged in identifying potential signals from the ICSRs, and also in recommending for regulatory actions, if any. During this period, the SRP made three regulatory recommendations that might materially influence the benefit-risk assessment of a medicinal product or that would be sufficient to consider changes in medicinal product administration.

The pharmaceutical industry is recognized globally as a vital stakeholder in any pharmacovigilance program. Therefore, under the PvPI, industries were welcomed to participate and start reporting ADRs. The response has been promising - a total of 9222 ICSRs received so far.

One major step by the NCC-PvPI has been introduction of the Helpline (1800-180-3024) for facilitating direct reporting of suspected ADRs. Since its inception in October 2013, 3826 calls have been received through the helpline, mostly from Uttar Pradesh (19.31%), Madhya Pradesh (13.54%) and Maharashtra (10.47%). Interestingly, the queries received from the helpline are not limited to ADR reporting, but the facility sometimes has also been used for seeking and providing general drug information.

Until recently ADR reporting under the PvPI was limited to HCPs. One achievement during the index period has been the recognition of the role of consumers in reporting suspected ADRs. A milestone step in this respect was releasing the "Medicine Side Effect Reporting Form for Consumers/Patients" (available in seven vernaculars); thus consumers/patients can now directly report suspected ADRs. Consumers are also encouraged to use the helpline for ADR reporting.
As per recommendation of WHO, countries national pharmacovigilance system should collaborate with NHPs to monitor the safety of medicines used in their respective programmes.

Continuous awareness generation and capacity building of stakeholders in ADR monitoring are the key to success of any pharmacovigilance programme. To sensitize the HCPs in India in the area of pharmacovigilance, the NCC-PvPI organized many CMEs, workshops, conferences and training programmes at the NCC, the regional centres and the AMCs. More than 3000 HCPs participated in 19 such programmes held during this period. Besides, a number thoughtfully designed poster for public awareness were published and distributed. Guidance document for facilitating ADR reporting was published. The NCC regularly published periodic newsletters that contained reports on the progress of the PvPI, current issue related to drug safety and relevant contemporary news items.

Since the inception of the PvPI, the TAs have played an indispensible role. In order to appreciate their contribution in ADRs reporting and to motivate them, the NCC organized an award ceremony for TAs.

Through its diverse activities, the NCC-PvPI succeeded in drawing global attention, and international experts from Sweden, Netherlands, Russia, and Switzerland visited the NCC during this period. The mutual sharing of knowledge and experiences with these experts, and coordination with different national and international organizations, immensely helped the NCC in further improving the activities under PvPI.

Pharmacovigilance Programme of India (PvPI)

Adverse Drug Reaction (ADR) is an important cause of morbidity and mortality which leads to important public health issue. ADRs are among the ten leading causes of mortality. Safety monitoring of medicines is a responsibility of all stakeholders of the healthcare system. Worldwide effective use of medicines is crucial to prevent or reduce harm to patients thereby improving public health. The safety of medicines in clinical use must be monitored and evaluated through specialized systems. This requires well-organized pharmacovigilance system to be established. Thus, pharmacovigilance system is defined by an organization to monitor the safety of authorized medicinal products and detect any deviation in their risk-benefit balance. A pharmacovigilance system like other systems is characterized by its structure, processes and outcomes. With the increasing complexity of medications available today, a comprehensive ADR monitoring is necessary to detect, evaluate, and develop mechanisms to prevent ADRs and their associated morbidity, mortality, and increased costs. PvPI was initiated in July 2010 by the CDSCO (Central Drugs Standard Control Organisation) under the aegis of Ministry of Health & Family Welfare (MoHFW), Government of India (GoI) with the All India Institute of Medical Sciences (AIIMS), New Delhi as the National Coordination Centre (NCC). To ensure implementation of this programme in a more effective way, the NCC was shifted from AIIMS to Indian Pharmacopoeia Commission (IPC) on 15th April 2011. IPC is an autonomous institution of the MoHFW, GoI and functions as the NCC for PvPI.

Starting with 22 AMCs across the country in 2010, new AMCs were added by the NCC-PvPI and 150 AMCs for ADR reporting were included by the year 2014. In addition to this, in a sequential phase wise manner 17 RNTCP and 20 ART centre were identified under the ambit of PvPI to strengthen reporting of ADRs to drugs used in these programmes.
**Scope and Objectives of PvPI**

- 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 medicines.
- To generate evidence based information on safety of medicines.
- To support regulatory agency in the decision-making process on use of medications.
- To communicate the safety information on use of medicines to various stakeholders to minimise the risk.
- To emerge as a national centre of excellence for pharmacovigilance related 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 globe.
- To promote rational use of medicines.

**Fig 1: Organogram of the NCC-PvPI**

**PvPI Communications**

Effective communication channels are the key to successful functioning of PvPI. The following chart depicts the movement of information between the key stakeholders and ensures the continuous transfer of data, information, and knowledge.

**Fig 2: Communication channels in PvPI**

**Committees under NCC-PvPI**

The following committees and panels are constituted by the MoHFW, GoI to ensure efficient and smooth functioning of the programme.

**Steering Committee**

PvPI is administered and monitored by the Steering Committee to supervise and guide the programme.

**Working Group**

It is constituted to review and approve major technical issues related to establishment and implementation of the programme and provide technical inputs to the CDSCO for appropriate 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
The Signal Review Panel consisted of experienced scientists and clinical experts affiliated to government and non-government academic institutions, hospitals and pharmaceutical industries to collate and analyze information from ICSCRs submitted to NCC. This panel assesses the results of the regular computerized screening of ICSCRs in NCC database for the occurrence of signals of possible importance to public health and drug regulation. It also defines biostatistical methods to be followed for analysis and creates standardized post analysis reports to generate useful information from the ICSCRs. It is also responsible for making decisions about actionable indicators.

Core Training Panel
The Core Training Panel of PvPI identifies and zone wise training centres for imparting training under pharmacovigilance training programme. Core training panel interacts with international agencies for participation and implementation of training programs related to pharmacovigilance. It organizes training, prepares training modules and training schedules for the stakeholders.

Regional Resource Centres
The following AMCs also function as Regional Resource Centres for Training and Technical Support:

- **Eastern Region:** Department of Pharmacology, PGIMER, Kolkata.
- **Western Region:** Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai.
- **Northern Region:** Department of Pharmacology, PGIMER, Chandigarh.
- **Southern Region:** Department of Clinical Pharmacy, JSS Medical College Hospital, Mysore.

These regional centres provide training and technical support to the newly enrolled AMCs under PvPI in their respective regions and support the expansion of PvPI.

Roles and Responsibilities of Regional Resource Centres

- To conduct training workshops to teach basic concepts, terminologies and SOPs of pharmacovigilance practices to the newly enrolled AMCs.
- To provide hands-on training on filling of ADR form, VigiFlow® data entry and other logistics of ADR reporting.
- To provide resource materials to the new centers.
- To interact with the AMCs on regular basis to resolve their technical issues.

ADR Reporting at PvPI
PvPI has spontaneous reporting system to collect data on drug safety. A spontaneous report is an unsolicited communication by HCPs or consumers, pharmaceutical companies to regulatory authority that describes one or more suspected ADR in a patient given a medicinal product.

For this purpose the NCC has designed a Suspected Adverse Drug Reaction Reporting Form. A report that contains information describing a suspected adverse drug reaction related to the administration of one or more medicinal products to an individual patient is termed as Individual Case Safety Report (ICSR).

In a strategic move that encourages direct participation of patients in the PvPI, IPC has launched the ambitious Medicines Side Effect Reporting Form for Consumers i.e. the patients. This has been introduced on a pilot basis across all the AMCs to gauge feasibility and impact among the patients.

The forms are available in Hindi (Ann. 2(c)) and also six other regional languages. The forms, which is now also available in Malayalam (Ann. 2(d)), Oriya (Ann. 2(f)), Tamil (Ann. 2(g)), Gujarati (Ann. 2(g)), Bengali (Ann. 2(h)) and Kannada (Ann. 2(h)), thereby empowering patients to report the ADRs irrespective of the language barrier. Plans are afoot to provide the translation in other regional languages as well.

Who Can Report?
All HCPs (clinicians, dentists, pharmacists, nurses etc.) and including consumers can report suspected adverse drug reaction. Pharmaceutical companies can also report ICSRs specific for their product.

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 a established causal relationship. Although pharmacovigilance is primarily concerned with pharmaceutical medicines and vaccines, reporting of adverse reactions associated with drugs used in traditional medicines (e.g. herbal remedies), medical devices, contrast media and other pharmaceuticals are also encouraged. In addition, reporting of lack of efficacy and suspected pharmaceutical defects is recommended, especially when there is the possibility of manufacturing problems, counterfeit pharmaceuticals or of the development of resistance e.g. antibiotics.

How and Whom to Report?
Use the 'Suspected Adverse Drug Reaction Reporting Form' which is available on the official website of IPC (www.ippc.gov.in) as well as CDSCO (www.cdsco.nic.in) to report any ADR. The ADR form can be submitted to the coordinator or technical associate of the respective AMC. A reporter who is not a part of AMC can submit the ADR form to the nearest AMC or directly to the NCC. A reporter can also E-mail the form at pvpi@ippcindia.net/pvpi.ippcindia@gmail.com. ADRs can also be reported using the toll free helpline number 1800-1800-3024.

Data Management at NCC-PvPI
Following chart illustrates the process of ICSR data management by PvPI.

![Flowchart of ICSR Process at PvPI](image-url)

**Fig 3:** Flow of ICSRs at PvPI

ICSRs uploaded in VigiFlow at AMC
Revert to AMC
Received at NCC
Valid or complete ICSR
CDSCO - HQ
Signal Detection
WHO-UMC, Sweden

Share with...
Evolution of PvPI

"PvPI is not only, to monitor the patient safety but it is also one of the biggest knowledge database for Indian drug regulation"

Status of ICSRs: Reporting, Collation & Analysis

During the index period a total of 41,879 reports were received from different ADR monitoring centres and accounting for 37% of all cases. These reports were derived entirely from the spontaneous ADR reporting system under the PvPI. State wise distribution of ADR reports received from AMCs is illustrated in the figure below.

Fig.4: State wise distribution of ADR reports received at NCC

- Total 41,879 reports received during index period
- Maximum number of ADRs reported due to Cisplatin
- Majority of ADRs reported for GIT & Skin disorders
- In reported ADRs male and female are in equal proportion
- Physicians reported maximum number of ADRs

Out of these 41,879 reports, 34,988 ADR reports were reviewed for validity, causality and expectedness and then, finally submitted to the WHO global safety database, Vigibase®. The month wise distributions of reports received at NCC-PvPI are illustrated in the figure below:

Fig.5: ADR reports received during April 2014-January 2015
Most of the reports received at NCC were from the AMC s under the purview of PVPi. During the past year, with the continuous efforts of the PVPi, NCC started receiving reports from pharmaceutical industries regarding SAE of their medicinal products & there has been also a significant contribution in reporting from the HCPs who are not the part of any AMCs. The figure 6 depicts the number of ADRs reports received from different sources. It was observed that report received from AMCs, non AMCs & pharmaceutical companies were 34,306 (98.09%), 484 (1.38%) & 198 (0.57%) respectively.

Fig.6: Distribution of ADR reports based on the type of senders

- Medical colleges & hospitals, medical/central/autonomous institutes, public health programmes or corporate hospitals enrolled under PVPi are functioning as AMCs.
- Non AMCs are the medical colleges & hospitals, medical/central/autonomous institutes, or corporate hospitals not enrolled under PVPi.
- The major contribution of 98.09% was from AMCs under PVPi.

These reports were received from physicians, pharmacists, other HCPs, consumers / non HCPs etc. Figure 7 illustrates the type of the reporter from whom the ADRs reports were received, which shows that maximum number of reports were from physicians i.e. 20,565 which were preceded by 8,390 from other HCPs, 5,670 from pharmacists & 27 from consumers or other non HCPs. A total 336 reports did not specify the information about the type of sender.

Fig.7: Distribution of ADR reports based on types of reporters

- Physicians are the major contributors of spontaneous ADR reports.
- Other HCPs includes surgeons, surgeon’s assistant, dentists, physicians assistants, nurses (including advanced practice registered nurses), midwives (obstetrics), occupational therapist, radiographers, optometrists, medical laboratory scientists.

Figure 8 shows the distribution of ADRs reports on the basis of gender. Out of 34,988 ADR reports, 17,490 were reported in females, 17,343 were in males and remaining 155 carried no information about the gender.

Fig.8: Distribution of ADR reports based on gender of patients

The reported ADRs included a large spectrum of clinical manifestations, 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 and multiple organs, the different organs illustrated in figure 9.

Fig.9: Distributions of ADR reports based on System Organ Class
During the index period, the commonly used drugs that result in maximum number of ADRs were: Cisplatin, Cyclophosphamide, Paclitaxel, Fluorouracil, Zidovudine, Doxorubicin, Carboplatin, Docetaxel, Nevirapine, Ceftriaxone. The figure 10 represents the top ten causal drugs from the total number of ADRs reported.

**Fig. 10: Top ten drugs reported to cause ADRs**

- The PvpI helpline 1800-180-3024 empowers HCPs and patients to report ADRs.
- Effective and rapid mode of communication with stakeholders particularly from urban/rural India.
- SMS feedback/acknowledgment to build the public confidence.

The NCC-PvPI Helpline—Commencing Consumer Reporting of ADRs in India

Medicines are consumed by one and all in the society. Any programme that is committed to ensure safer use of medicines, must strive to win the confidence of public and consumers. On 11th October, 2013, the NCC-PvPI launched a Helpline (Toll-free no. 1800 180 3024) for the consumers. The objective is to facilitate direct reporting of suspected ADRs to the PvPI by consumers. This has also made it possible to establish a communication channel between the PvPI and the medicine users, actual or potential. Albeit primarily conceived as a tool for connecting to the lay public, the helpline has been found to be useful by the HCPs of all categories who have been making calls seeking diverse information relating to ADRs andADR reporting. The toll-free helpline has been equipped to provide all kinds of information related to ADR reporting. Consumers are informed about how, what and whom to report suspected ADRs in the country. The helpline is for direct reporting of ADR caused by any medicine by patients or their caretakers and by HCPs from all over the country. Calls are primarily responded in English and Hindi on all working days during 09:00 am-05:30 pm; beyond these timings, a caller can drop a voice message. The call is returned by PvPI, the next working day. Callers who speak and comprehend the local vernacular language alone are directed to the nearest AMC address, for a dialogue in local language. Besides, all callers after the first encounter are directed to the local AMCs for follow-up and advice. This service is staffed by a team of fully trained and experienced pharmacists. SMS acknowledgment and feedback facility to the ADR reporters have been added to this helpline. Attempts are being made to make it more user-friendly.

A preliminary analysis of the users of this helpline showed that majority of callers were males (64.29%) and belonged to the younger age-group (21 – 40 years) (54.76%) followed by (41 – 60 years) (19.05%).

**Table 1: Helpline callers: A preliminary analysis since its launch in October, 2013.**

<table>
<thead>
<tr>
<th>Demographic Characteristics of the Patients (%)</th>
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<tr>
<td>Gender</td>
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<tr>
<td>Male</td>
<td>64.29</td>
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<tr>
<td>Female</td>
<td>35.71</td>
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<tr>
<td>Age (Years)</td>
<td></td>
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<tr>
<td>≤20</td>
<td>16.67</td>
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<tr>
<td>21–40</td>
<td>54.76</td>
</tr>
<tr>
<td>41–60</td>
<td>19.05</td>
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<tr>
<td>≥61</td>
<td>09.52</td>
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Involvement of Pharmaceutical Industries in PvPI

Pharmaceutical industries are one of the vital stakeholders in the pharmacovigilance programme. PvPI coordinates with these industries for their active participation in the programme. During the index period, NCC organized several rounds of meetings with the industry experts for data sharing arrangement between CDSCO, NCC-PvPI and industries. As a result, industries have started voluntary reporting to NCC-PvPI. A total of 2222 ICSRs have been reported till date. The details of which are given in figure 13.

Fig. 13 : Status of ADRs reporting by Pharmaceutical Industries till March, 2015

- NCC-PvPI organized several rounds of meetings with the pharmaceutical industries experts for data sharing arrangement between CDSCO, NCC-PvPI and industries.
- Total 30 pharmaceutical industries have been reporting to NCC-PvPI.
- Total 2222 ICSRs have been reported till date.

The helpline has been well received by the stakeholders. Besides reporting suspected ADRs, people are using the facility for general drug information too. Such an approach of using helpline/telephone facility to collect ADRs from the HCPs and consumers is not novel. Countries like Australia, Canada and USA have been using this facility. However, in India, given its huge population and their potential for exposure to medications; on one hand, the prolific and widespread use of mobile phones; on the other hand, the helpline strategy to connect to people, perhaps bears greater relevance. Overcoming the language barrier and promoting and creating awareness about this facility is vital in strengthening this programme. Further initiatives in this direction are therefore planned.

These reports are evaluated at NCC-PvPI in a similar manner as other reports to generate meaningful information. Collaboration with industries has a potential to detect ADRs due to newer medicines and also capture ADRs of medicines prescribed by private practitioners.
Integration of PvPI with National Health Programmes (NHPs)

Coordination between NCC-PvPI and AEFI

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. The AEFI should be handled effectively in order to maintain/restore public faith in immunization program. AEFI Surveillance System in India has come a long way since its inception in 1986.

Adverse event due to vaccines may occur due to the intrinsic property of vaccines and constituents like stabilizers, adjuvant, antibiotics, diluents etc. added to the vaccines or hypersensitivity of some individuals to vaccine component(s). Such incidents are rare but may become apparent in terms of number when vaccinating a large cohort. Event may also result from programmatic errors as a result of inappropriate storage, improper handling, preparation and administration of vaccines etc. AEFI surveillance and timely management will build public confidence and prevent additional clustering of cases if they occur due to a programmatic error.

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. Operational Guidelines of AEFI mainly relate to vaccines included in the National Immunization Program and issues of vaccine manufacturing, safety & quality control of AEFI cases are handled by CDSCO headed by DGCI. Intensive efforts are being made by MoHFW, GoI to strengthen surveillance and monitoring of AEFI in the country. In India, the safety of vaccine is monitored by the division of AEFI, MoHFW, GoI and PvPI.

AEFI cases submitted to PvPI are further coordinated with national level committee for reporting & investigation. Subsequently AEFI committee will follow with local AEFI team to completely furnish FIR/PI/DIR to perform the causality assessment.

NCC - PvPI ties-up with WHO for training of healthcare experts under National Health Programmes on ADR reporting

The IPC, recently teamed up with the WHO country office (India) to provide a national level training programme for team of healthcare experts under various NHPs such as RNTCP and NACO programme. This initiative is specifically tailor-made to sensitize and update the experts on how to effectively identify and report ADRs arising from the use of the drugs running...
within these programmes. Most importantly, it focuses on training of entering data into the VigiFlow®, which is a secure web-based solution that improves the quality of ADR reports by logical and streamlined data entry.

Interestingly, apart from accessing the data from Upasala Monitoring Centre (UMC) Sweden, which is the WHO collaborating centers for International drug monitoring, IPC also updates information on ADRs that is being reported in India from across all its centers through VigiFlow® to the UMC, which was initiated by Shri L. N. Verma, Secretary, MoHFW, GoI aims at streamlining and closely scanning drugs that are covered under the national programme for major diseases like tuberculosis, malaria, AIDS, HIV, polio etc. For this purpose IPC is taking all the possible measures to expedite the process of upgrading and updating itself with the latest requirements at par with the international standards for running a successful programme. Healthcare providers, workers and patients play a very crucial role in the success of the programme. Thus our priority is to sensitize them about the PvPI and appraise them about importance of timely reporting of the ADRs.

**WHO-UMC to extends collaboration with IPC for PvPI initiatives**

Leading the ongoing efforts of the IPC in effectively monitoring and implementing the PvPI, the WHO-UMC has decided to further extend its collaboration by strengthening training and education programmes with IPC. This move comes in the wake of India becoming the first country in reporting over one lakh ICSRs in VigiFlow®. This strategic development was informed by Dr. Marie Lindquist, Director, UMC, Sweden and Christer Backman, Medical Products Agency (MPA), Sweden during their visit to IPC in Nov 2014.

**IPC and NACO signed the MoU to monitor the safety of antiretroviral drugs**

Since the establishment of ART in 2004, the NACO has scaled-up provision of ART to about 2,669,269 patients. The ART centers are located in tertiary/district hospitals and medical colleges in order to make the treatment more accessible to patients suffering from HIV. The outcomes of long term use of ART are still unknown. To ensure the safety of a Anti-retroviral (ARV) medicines, IPC, NCC-PvPI and NACO formally agreed to collaborate on 15th September 2014, for setting up systems and processes for reporting, analysis and monitoring of ADRs due to ARV medicines in the programme. The MoU was signed under the chairmanship of Smt. R.K. Jain, Former Additional Secretary, Director General (CGHS), MoHFW, GoI, Dr. A. S. Bathore, Deputy Director General (CAr), Support and Treatment Division, NACO, MoHFW, GoI and Dr. G. N. Singh, Secretary-cum-Scientific Director, IPC, senior ministry officials were also present on this occasion. During the meeting, Smt. R.K. Jain highlighted that both the organizations need to work and collaborate with each other with clear milestones and timelines.

NACO have agreed to work in a phased manner by first identifying the ARV units within its 150 established AMCAs and later scaling up the activities further.

The first phase of this project to identify the 20 ART centres from the 150 AMCAs across the country so as to co-ordinate and link them with established pharmacovigilance system. IPC is committed towards scaling up this initiative by adding more ART centres to AMCAs.
Training & Education Programmes

One of the major responsibilities of NCC-PvPI is to provide training and technical support to the newly enrolled AMCs and to all other stakeholders under PvPI. The purpose of these training and education programmes is to:

- Provide training to enlighten the basic and essentials of pharmacovigilance, terminologies, standards and processes for ADR reporting and causality assessment.
- Provide hands on training for filling of "Suspected ADR reporting form" and data entry in "VigiFlow® Software".
- To develop KAP of ADR reporting in healthcare professionals and consumers of India.

The NCC-PvPI organized CMEs, workshops and training programmes at NCC, regional centres and AMCs. NCC also organized seminars and meetings on Pharmacovigilance in technical collaboration with WHO and UMC.

A total 3000 HCPs have been trained during the index period. The PvPI tool kit facilitates the AMCs to train the respective HCPs for ADR reporting in a standardized manner.

The details of training and educational programmes conducted during the index period are as follows:

<table>
<thead>
<tr>
<th>S.No</th>
<th>Name of Programme</th>
<th>Date</th>
<th>Place</th>
<th>Target Audience</th>
<th>Objective</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>VigiFlow® Training</td>
<td>21st April, 2014</td>
<td>KEM, Mumbai (Mahrashtra)</td>
<td>Coordinators of new AMCs</td>
<td>Introduction to VigiFlow &amp; Pharmacovigilance</td>
</tr>
<tr>
<td>2</td>
<td>CME on Pharmacovigilance</td>
<td>28th June, 2014</td>
<td>NEHRIMS, Shillong (Meghalaya)</td>
<td>Healthcare Professionals of Eastern States</td>
<td>KAP of Pharmacovigilance</td>
</tr>
<tr>
<td>3</td>
<td>Training Programme on Pharmacovigilance</td>
<td>2nd July, 2014</td>
<td>JSS College of Pharmacy, Mysore, (Karnataka)</td>
<td>Coordinators &amp; TAs of Northern States</td>
<td>KAP of Pharmacovigilance</td>
</tr>
<tr>
<td>4</td>
<td>Training Programme on Pharmacovigilance</td>
<td>4th &amp; 5th August, 2014</td>
<td>JSS College of Pharmacy, Mysore, (Karnataka)</td>
<td>PvPI staff at AMCs in the state of Karnataka, Tamil Nadu, Andhra Pradesh, Kerala, Telangana and Puducherry (G.T.)</td>
<td>Introduction to VigiFlow® &amp; Pharmacovigilance</td>
</tr>
<tr>
<td>6</td>
<td>Induction cum training Programme for newly recruited technical associates under PvPI</td>
<td>8th to 12th September, 2014</td>
<td>IPC, Ghaziabad (U.P.)</td>
<td>New Technical Associates</td>
<td>Training on basic knowledge of Pharmacovigilance and hands on training in VigiFlow®</td>
</tr>
</tbody>
</table>

If you experience any of these or other reactions after taking medicine ...
Kindly contact at PvPI helpline
1800-180-3024
PvPI Helpline (Toll-Free) (9.00 AM-5.30 PM Weekdays)

Benefits of Reporting ADR:
- Rational and safe use of medication
- Provide important information for the Safety Monitoring Program
- Evidence based regulatory decisions can be taken
<table>
<thead>
<tr>
<th>S.No</th>
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<th>Target Audience</th>
<th>Objective</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>2nd International conference on “Patient safety and access to Quality Healthcare”</td>
<td>6th to 8th November, 2014</td>
<td>Haridwar (Uttarakhand)</td>
<td>Technical staff of PVPI &amp; AMCs Staff of Uttarakhand</td>
<td>Need for Enhancing Patient Safety and Quality Medicines</td>
</tr>
<tr>
<td>8</td>
<td>Hands on training for technical staff of PVPI on MedDRA</td>
<td>12th &amp; 21st November, 2014</td>
<td>Panacea Biotech (New Delhi)</td>
<td>Technical staff of PVPI</td>
<td>MedDRA training</td>
</tr>
<tr>
<td>9</td>
<td>International symposium on “safe medicine and safe patient”</td>
<td>1st to 3rd December, 2014</td>
<td>JNMC, Agra (UP)</td>
<td>HCPs</td>
<td>Importance of Pharmacovigilance, current regulations, safety surveillance</td>
</tr>
<tr>
<td>10</td>
<td>CME on Pharmacovigilance</td>
<td>22nd November, 2014</td>
<td>IMS, Thiruvallu (Kerala)</td>
<td>HCPs</td>
<td>CME on Pharmacovigilance, Introduction of Malayalam version of ADR Reporting Form for Consumers</td>
</tr>
<tr>
<td>12</td>
<td>Workshop on Causality Assessment, Signal Detection and Data Mining</td>
<td>9th December, 2014</td>
<td>IPC, Ghaziabad (UP)</td>
<td>STIP Members</td>
<td>Causality, Signal Detection and Data Mining in Pharmacovigilance</td>
</tr>
<tr>
<td>13</td>
<td>National Pharmacovigilance Workshop for Coordinators of Drug Resistant Tuberculosis and ART Centres in India</td>
<td>10th &amp; 11th December, 2014</td>
<td>Hotel Lalls, (New Delhi)</td>
<td>Coordinators of RNTCP and NACO</td>
<td>KAP of Pharmacovigilance</td>
</tr>
<tr>
<td>14</td>
<td>National &amp; International Scenario on Pharmacovigilance</td>
<td>16th December, 2014</td>
<td>IPC, Ghaziabad (UP)</td>
<td>Staff members of IPC</td>
<td>Global status of Pharmacovigilance</td>
</tr>
<tr>
<td>15</td>
<td>CME training of AEFI personnel</td>
<td>17th December, 2014</td>
<td>IPC, Ghaziabad (UP)</td>
<td>Staff members of NCC and AEFI</td>
<td>Causality, Signal Detection and Data Mining in Pharmacovigilance</td>
</tr>
<tr>
<td>16</td>
<td>Hands on Training on VigilFlow®</td>
<td>11th December, 2014 to 01st January, 2015</td>
<td>IPC, Ghaziabad (UP)</td>
<td>AMC Members of SGRMTCs, Delhiad</td>
<td>Hands on Training on VigilFlow®</td>
</tr>
<tr>
<td>18</td>
<td>Training for the Coordinators and Technical Associates of AMCs of West Zone under PVPI</td>
<td>18th March, 2015</td>
<td>KEM, Mumbai (Maharashtra)</td>
<td>Technical Associates &amp; Coordinators</td>
<td>Hands on training and filling the ADIs to newly inducted AMCs in west zone</td>
</tr>
<tr>
<td>19</td>
<td>Training to the personnel of JNMC</td>
<td>30th March, 2015</td>
<td>JNMC, Raipur (Chhattisgarh)</td>
<td>Personnel of JNMC</td>
<td>Training on Basic Knowledge of Pharmacovigilance and Hands on Training in VigilFlow®</td>
</tr>
</tbody>
</table>

During the index year various training programmes & CME(s) have been organised by NCC-PVPI. The PVPI envisaged imparting training to HCPs, non-HCPs, consumers etc. in the country so that awareness can be created by the dissemination of information in the efforts to ensure the safety of medicines. The NCC-PVPI received some valuable suggestions from the participants some of which are as follows:

**Glimpses of Various Training Programmes During Index Period**

Field level training on ADR Monitoring & Reporting for the Technical Associates on 26th November, 2014 at GTB Hospital, New Delhi.

**National Pharmacovigilance workshop for Coordinators of RNTCP & ART Centre on 10th & 11th December, 2014 in New Delhi**
PvPI in the International Arena: An Overview of Emerging Trends and Developments

Interactive session with Prof. Eugene from Netherland - A great learning experience for the PvPI team

- Experts from several countries visited NCC and appreciated the functioning of PvPI during the index period
- NCC-PvPI and WHO-UMMC mutually agreed to exchange the skills in identifying new signals.

Prof. Eugene, Netherland interacting with NCC-PvPI team on 4th December, 2014 at Ghaziabad

Prof. Eugene, Netherland Pharmacovigilance Centre, visited NCC-PvPI on 4th December, 2014 to interact with the PvPI team. He shared his experiences of prescription event monitoring and patient reporting in Netherland. He also apprised the PvPI team of the intensive monitoring, a web-based system to collect ADR information from the patients. The interactive session was a great learning experience for the PvPI team.
Swedish delegates visit to IPC: Bring fresh vigor to PvPI

Visit of Dr. Marie Lindquist, UMC Director and Mr. Backman Christner, Medicinal Products Agency, Sweden to IPC on 25th November, 2014 is a symbol of the exchange of new ideas between the UMC and IPC to achieve the translational Pharmacovigilance. The UMC delegates released a poster “Creating awareness on PvPI”. The Sweden delegation also interacted with the newly recruited technical associates of PvPI. Dr. Marle on behalf of UMC extended her support for signal review process in India.

IPC extends support to Russian delegates for promoting quality and safety of medicines in their country

Russian Delegates experiencing the process of ADR reporting in India on 17th April, 2014 at IPC, Ghaziabad

Russian Pharmacopoeia delegates Ms. Alla Trapkova, Ms. Galina Gannochka and Mr. Murashko visited IPC on 17th April, 2014 to understand the process of monographs development, promoting rational use of medicines and drug safety monitoring system in India. During the visit, they interacted with the scientists of different departments of IPC. They had received hands on experience in the process of ADR monitoring, collation and assessment in PvPI.

PvPI’s contribution to WHO is significant: Dr. Shanthi Pal

There has been a regular exchange of information between NCC-PvPI and WHO (both at the level of country office, New Delhi and HQ Geneva) to build the robust PV system in the country. Dr. Shanthi Pal who is constantly supporting PvPI, made her second visit to IPC on 16th December, 2014 to participate in the “IPC - WHO workshop on Pharmacovigilance” organized by NCC-PvPI. She emphasized that regular interaction between IPC and WHO has been very fruitful to strengthen the PvPI. She lauded the remarkable progress of PvPI in recent years. She also acknowledges that the current contribution of India to WHO-UMC Global Drug Monitoring Database is quite significant.

IPC to host “PIDM-2015”

On behalf of NCC-PvPI, Dr. V. Kalaiselvan participated in the 37th WHO-Programme for International Drug monitoring (PIDM) of national centres participating in Pharmacovigilance held from 14th - 17th October, 2014 at Tianjin, China. During this meeting it was declared that 38th PIDM will be held in India. The event will be at New Delhi from 3rd - 7th November, 2015, will be hosted by IPC in technical collaboration with WHO Country Office (India).

It is expected that representatives from more than 100 countries will be attending in addition to the experts from WHO-HQ, Geneva and UMC Sweden. IPC feels certain that the 2015 WHO Programme meeting will bring together all the countries which have co-operated for the common task to promote medicines safety. Our thanks to WHO and the UMC team for giving us the opportunity to host the event, IPC welcomes you all to India.
Activities of the Signal Review Panel (SRP)

Signal detection and its clinical assessment is an important domain of Pharmacovigilance. 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". On a broader view a signal is an alert from a PVPI data source that a drug may be associated with a previously unrecognized hazard or that a known hazard may be quantitatively (e.g., more frequent) or qualitatively (e.g., more serious) different from the existing knowledge. Hence, identification and assessment of safety signals warrants further investigation which is being carried out by SRP of the PVPI. SRP is a multidisciplinary committee constituted by the MoHFW, GoI since 5th September, 2013 and with representatives of clinicians, pharmacists, medical pharmacologists, public health experts.

The NCC performs the identification and initial review of a signal; the results of which are submitted by Member Secretary of SRP to the panel. SRP reviews the report against the following: Quality, content and completeness of data. A detailed clinical review of the signal detected by statistical data mining undertaken at the NCC.

Table 3: Following are the details of recommendations made by the SRP and action taken:

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Meeting Details</th>
<th>Major Recommendations</th>
<th>Action Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1st meeting of PVPI SRP (20th February, 2014)</td>
<td>• NCC to allocate dedicated personnel to monitor the signal review process. • Dedicated sub-group in NCC team to be formed to monitor data analysis.</td>
<td>Action Completed</td>
</tr>
<tr>
<td>2</td>
<td>2nd meeting of PVPI SRP (21st - 22nd March, 2014)</td>
<td>• NCC to send a proposal to WHO-UMC to seek their support and service for signal detection.</td>
<td>Action Completed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Training of SRP members.</td>
<td>Action in Hand</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• PVPI database should be integrated with PSMAR and PAS data.</td>
<td>Action in Hand</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• NCC-PVPI should initiate the process of e-reporting.</td>
<td>Action in Hand</td>
</tr>
<tr>
<td>3</td>
<td>3rd meeting of PVPI SRP (3rd June, 2014)</td>
<td>Following data was received for a possible signal: • Streptolysin induced hepatitis. • Metformin &amp; glipizide induced liver failure. The data is inadequate to detect a signal. Additional data is required from the source centre and other centres across the country.</td>
<td>Action Completed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Training on signal detection to the members of SRP.</td>
<td>Action in Hand</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Strategic model plan for dissemination of pharmacovigilance among clinicians.</td>
<td>Action in Hand</td>
</tr>
<tr>
<td>4</td>
<td>4th Meeting of PVPI SRP (8th - 9th December, 2014)</td>
<td>• Advisory note for Sulindac Maleate.</td>
<td>Action Completed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Advisory note for Panopan HCL.</td>
<td>Action Completed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Recommendation for label change for Carbamazepine.</td>
<td>Action Completed</td>
</tr>
</tbody>
</table>

Conclusion: SRP is working as the expert panel for establishing causal relationship between drug and ADRs as detected from PVPI database. A significant role of SRP in signal detection is envisaged for reinforcing quality and facilitating regulatory recommendations.

"The Biggest disease today is not leprosy or tuberculosis, but rather the feeling of being unwanted." - Mother Teresa
Inputs to CDSCO for Regulatory Interventions

The NCC-PvPI regularly coordinates with the CDSCO, New Delhi in order to support its regulatory decision making process. Several meetings were held between the officials of NCC-PvPI and CDSCO for better coordination. The NCC-PvPI shares its outcomes of data analysis with the CDSCO, so that the latter may make appropriate regulatory interventions, if found necessary. Based on the data analysis and deliberation at SRP meetings, following recommendations were made by PvPI to the CDSCO.

- Advisory note for usage of Sunitinib Malate
- Advisory note for usage of Pazopanib HCl
- Recommendations for label change for Carbamazepine

Advisory note for usage of Sunitinib Malate

PvPI database revealed that hepatotoxicity, haemorrhage and cardiovascular events have been observed following the usage of sunitinib malate in 71 Indian patients suffering from metastatic renal cell carcinoma.

Hepatobiliary disorders

Severe hepatobiliary disorders including hepatitis, elevated liver enzymes and hyperbilirubinemia have been reported in Indian patients according to reports/ICSRs received, at PvPI. It is therefore recommended that "healthcare professionals are advised to monitor liver function tests (ALT, AST and bilirubin) before initiation and during each cycle of treatment. Patients are advised to obtain medical help if they develop persistent nausea and/or vomiting, severe stomach and/or abdominal pain, dark urine, pale stools, yellowish eye and/or skin".

Cardiovascular dysfunction

Congestive heart failure (CHF) and ischemic heart disease have been reported to Sunitinib therapy, some of these ADRs were fatal leading to cardiac arrest. Therefore it is recommended that "close monitoring for clinical signs and symptoms of CHF should be performed, especially in patients with cardiac risk factors and/or history of coronary artery disease. Estimation of electrolytes is recommended for patients before treatment, initiation of treatment and later, as per clinical status of the patient."

Haemorrhage and Bleeding disorders

Cases of GI haemorrhage, haematuria, bruising, urinary tract infection and cerebral haemorrhage have been reported with Sunitinib, some of which were fatal. It was recommended that Sunitinib should be used with caution in patients with high risk of haemorrhage.

Patients are recommended to undergo periodic monitoring of complete blood counts (platelets) and coagulation factors (PT/INR).
Cardiac dysfunction

Label change for Carbamazepine

Patients are recommended to seek immediate medical help if they experience shortness of breath and unusual sweating. They should be carefully monitored for CHF and ischemic heart disease. Echocardiography and periodic evaluation of left ventricular ejection fraction (LVEF) is recommended in patients with risk of cardiac dysfunction.

Phylo database revealed that IC50 among Indian patients with metastatic renal cell carcinoma were on par with the global IC50, and patients with non-small cell lung cancer were at higher risk of cardiac dysfunction compared to patients with metastatic renal cell carcinoma. The Cardiac Dysfunction Aware Program (CDAP) was launched with the following objectives:

1. To raise awareness among healthcare professionals and patients
2. To monitor and report adverse drug reactions (ADRs) related to cardiac dysfunction
3. To ensure timely treatment for patients with cardiac dysfunction

The CDAP is a joint initiative of the Indian Council of Medical Research (ICMR) and the National Cancer Institute (NCI).

Advisory note on usage of Pomegranate Hydrozincide

Recommendations

Phylo database revealed 19 cases of heterozygous familial hypercholesterolemia caused by T2021A mutation. These 19 reports are out of 182 reports of familial hypercholesterolemia (FH) from Asia that were reviewed for this adverse reaction. It is recommended that patients undergoing treatment with pomegranate hydrozincide should be closely monitored for the potential risk of adverse reactions associated with FH.

Important Events in PPI

NCC-PHI Launches Consumer Reporting Form

The NCC-PHI launched the Consumer Reporting Form to encourage consumers to report adverse drug reactions (ADRs). The form is available in major Indian languages, including English, Hindi, Tamil, Odia, Gujrati, and Kannada. The form can be accessed online, and consumers are encouraged to report any ADRs they experience to help improve medication safety.

NCC-PHI releases ADR forms in Hindi and 6 other regional languages

The NCC-PHI released ADR forms in Hindi and 6 other regional languages to encourage consumers to report adverse drug reactions (ADRs). The forms are available in English, Hindi, Tamil, Odia, Gujrati, and Kannada. The forms can be accessed online, and consumers are encouraged to report any ADRs they experience to help improve medication safety.
Brain Storming Session for Coordinators of different parts of India

With a view to boost and strengthen the NCC-PvPI, organized brain storming session on challenges in reporting of ADRs for coordinators of AMCs from the states of Uttar Pradesh, Bihar, Jharkhand, Odisha and Chhattisgarh to enhance ADRs reporting in these states. Shri A.K. Pradhan, DDC(I), CDSCO welcomed the deleagtes and emphasized on the need to create a culture of ADRs reporting by HCPs.

The key focus of this session was to gauge the challenges and the issues faced by the coordinators while reporting ADRs from their respective centres. Proactive role of Coordinators and enhanced interaction with clinicians regularly was emphasized to achieve the goal of better ADR reporting.

Release of PvPI Poster

PvPI poster released on 25th November, 2014 at IPC, Ghaziabad on reporting ADR to safeguard the patient with an objective to create awareness among HCPs, patient and consumer of India for ADRs reporting in the august presence of Dr. Mari Lindquist, Director, UMC and Mr. Christer Beckman, MPA, Sweden.
**NCC-PvPI Welcomes Corporate Hospitals in the Programme**

The importance and relevance of participation of corporate hospitals in ADR reporting cannot be undermined. The collaboration with corporate hospitals shall leverage the strength of PvPI and promote patients safety. Aditya Birla Memorial Hospital, Pune; Artemis Hospital, Gurgaon; and Kovai Medical Centre and Hospital, Coimbatore were the latest three new corporate hospitals added to PvPPI in addition to existing Medanta, The Medicity, Gurgaon and Indraprastha Apollo Hospitals, New Delhi. PvPPI aims to support the corporate hospitals with training programs, which help healthcare professionals to offer quality, safe and focused care to patients.

**Visit of Students and Faculty Members of Devaki Amma Memorial College of Pharmacy**

Students and faculty members of Devaki Amma Memorial College of Pharmacy, Malappuram, Kerala visited IPC on 29th January, 2015. They visited different departments of IPC and were appraised knowledge regarding Pharmacopoeia standards and PvPPI.

**Visit of Students and Faculty members of Delhi Institute of Pharmaceutical Sciences & Research (DIPSAR) and other pharmacy colleges**

Students and faculty members of DIPSAR and other pharmacy colleges across the country, visited IPC on 4th March 2015 to upgrade their knowledge on Pharmacovigilance and Pharmacopoeia during the Quality Improvement Programme, organized by DIPSAR, New Delhi.

**PvPI Communications**

Communicating safety information to patients and HCPs is a public health responsibility and is essential for achieving the objectives of pharmacovigilance in terms of promoting the rational, safe and effective use of medicine, preventing harm from adverse reactions and contributing to the protection of public health. In general appropriate communications in PvPPI improves patient care, understanding, promotes transparency and accountability. All the communications with WHO-UMC are managed by NCC. NCC is responsible to publish/communicate 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 matter related to PvPPI. Different modes of communications used by PvPPI are as follow:

- NCC-PvPI publishes the “PvPI Newsletter” thrice a year.
- Disseminate awareness regarding ADR reporting through different educational Posters
- PvPI writes the success story and challenges in printed and e-media.
- Promulgate awareness of ADR reporting through website, newsletter, conferences and CMES.

**Media communications**

This includes press release and press briefings for journalists. All general activities and issues related to PvPPI are communicated to electronic and other print media to create awareness among the various stakeholders.

**Press communications**

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 regional languages, to overcome the language barriers in generating awareness about Pharmacovigilance among the masses.

**Website**

A website is a key tool for the stakeholders including patients and HCPs. NCC-PvPI ensures that all important medicine safety information and its activation are disseminated to the stakeholders and general public through its official website, and CDSCO website.

**Newsletter**

NCC-PvPI publishes the “PvPI Newsletter” thrice a year. The Newsletter provides current updates and advice on drug safety and information about emerging medicine safety issues. It also provides glimpses of the initiative and progress of PvPPI to the stakeholders. The newsletter is provided free of cost to all the AMC's. The Newsletter can also be downloaded from the IPC website www.ipc.gov.in.

**Educational Posters**

Educational posters are designed to convey messages about Pharmacovigilance and ADR reporting to the HCPs and general public. Visual appeal and simplicity are the key components of these posters.
Fig. 14: Educational posters on pharmacovigilance by NCC-PvPI for HCPs and general Public

“Being a mother, I always Care for you by monitoring the safety of medicine”

Healthcare Professionals and Patients can report Adverse Drug Reaction
Known or Unknown, Serious or Non-Serious due to Medicines, Vaccines and Herbal products to
1800-180-3024
PvPI Helpline (Toll-Free) 9.00 AM-5.30 PM, Monday to Friday

Report Adverse Events
To Safeguard Your Patients

Healthcare Professionals and Patients can report Adverse Drug Reaction
Known or Unknown, Serious or Non-Serious due to Medicines, Vaccines, Herbal products to
1800-180-3024
PvPI Helpline (Toll-Free) 9.00 AM-5.30 PM, Monday to Friday

Join hands with PvPI to help the patient

Emegence of Pharmacovigilance

Pharmacovigilance is the science and activity relating to the detection, assessment, evaluation and control of adverse effects or any other problems related to medicines.
Scientific Publications at NCC-PvPI


Experts Views on PvPI

I read with interest your August newsletter which I found at a recent visit to the UMC. Your completeness score is very impressive and I would like to know how you achieve it.

Dr. Ruth Savage
MBB, MSc (Clin Pharmacol)
Senior Lecturer
University of Otago, Christchurch
New Zealand

India’s national Centre makes a very important contribution to the WHO database, both in terms of quality and quantity and the data from ICSR’s submitted from India are taken into account during the signal detection process, that runs over the whole WHO database without restrictions.

Dr. Pia Caduff
MD, PgDip, Anaesthesiologist FAMC
UMC, Sweden

In the Documentation Grading report you have the possibility to compare your score with the other countries of the WHO Programme in the first page of the report. Documentation Grading—Completeness score by country. It is however clear that India is doing very well as compared to many other countries. Separately, I would also like to point out that you can see an increase in the score for both Indication and Free text in the Indian reports since last time I sent the completeness score in June. This can be seen in the graph Average Completeness score over time by field. And it is a great news, since increase your total score even further.

Therese Lundin,
MSC, Pharm, Specialist,
Pharmacovigilance Consulting
UMC, Sweden

"The World Health Organisation’s Uppsala Monitoring Centre is now looking to make India as a hub for Pharmacovigilance training. The organisation recognised India’s concerted effort in the area of pharmacovigilance but observed that the country needed to play a bigger role in the global landscape of adverse drug reaction ADR monitoring."

"India should be made as hub for Pharmacovigilance training," said Sten Olsson, WHO Programme Expert and Head of the Global Outreach Department at the Uppsala Monitoring centre. Although India has a long way to go in the area of Pharmacovigilance, yet it has created a momentum in ADR reporting. WHO is now satisfied that reporting from India is adequate and total in terms of providing the basic information. The big advantage was the 6,000 case reports submitted as seen to be of high quality and worthwhile to be analyzed, stated Olsson.

Of the total 8.5 million ADR case reports submission, India ranked fifth in Asia accounting for 0.7 per cent of the global database. In this regard, WHO sees that India could soon overtake China and therefore need to be made as a hub for Pharmacovigilance training, he said.

Sten Olsson,
MSC, Pharm
WHO Programme Expert, UMC, Sweden

Future Plans

The PvPI was initiated in July 2010 for monitoring of ADRs to safe-guard the public health of India by assuring the safety of medicines. At the time of initiation only few AMC’s were working and programme was functional only at Delhi & NCR region. The propagation of programme and identification of new AMC’s increased with time. Currently PvPI is in the process of expanding its reporter base and also ensuring meaningful and good quality data.

In this regard NCC-PvPI proposes the following in the forthcoming year:

1. To develop a statistical tool for Signal Detection from PvPI database, as applicable in the Indian context.
2. Organize a meeting of AMC’s coordinators to resolve the technical issues at AMC’s.
3. Develop a mobile application software on android platform for ADR reporting, to enable reporting an ADR directly from an Android phone.
4. Outreach to consumers to urban and rural areas of India.
5. Network with different professional bodies and associations in India, to generate awareness about the programme.
6. Collaborate with other countries to offer and receive support to develop and strengthen the pharmacovigilance system.
7. Develop the impact tool for programme assessment by which layman can understand and appreciate the importance of programme.
8. Organize the 38th National Pharmacovigilance Centres meeting—India 2015.
9. Organize the Conference of International Society of Pharmacovigilance (ISG) of India.
10. Undertake QA/QC analysis of PvPI to evaluate the quality of programme and the extent to which the programme satisfies the consumers expectations.
11. Develop the guidelines for medicinal product on the basis of evidence based from Indian ICSR.
12. Organize awareness classes in various pharmacy colleges in India. Beginning from Delhi-NCR region.
### SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

**Appendices**

1. **ADR Reporting Form for Healthcare Professionals**

#### Pharmacovigilance Programme of India

**Maximize Adverse Drug Reactions to Minimize Safety**

- **Report Adverse Drug Reactions to Empower**

**Table: Adverse Drug Reaction Reporting Form**

<table>
<thead>
<tr>
<th><strong>A. SUSPECTED ADVERSE DRUG REACTION</strong></th>
<th><strong>B. SUSPECTED ADVERSE DRUG REACTION REPORTING FORM</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug</strong></td>
<td><strong>Reason for Reporting/Detail of Incident</strong></td>
</tr>
<tr>
<td><strong>Dose</strong></td>
<td><strong>Number of Patients Involved</strong></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td><strong>Sex</strong></td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td><strong>Height</strong></td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td><strong>Marital Status</strong></td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td><strong>Other Relevant Information</strong></td>
</tr>
<tr>
<td><strong>Address</strong></td>
<td><strong>Contact Information</strong></td>
</tr>
<tr>
<td><strong>Date of Incident</strong></td>
<td><strong>Date of Reporting</strong></td>
</tr>
</tbody>
</table>

**Notes:**

- Document details and personal identifiers with care.
- Include all relevant information.
- Ensure accurate and complete reporting.

**Additional Information:**

- **Nicholas:** Healthcare professional reporting adverse drug reaction.
- **Worldwide Unique:** A unique identifier for the report.

**References:**

- World Health Organization (WHO) guidelines on ADR reporting.
- National Pharmacovigilance Center reports.

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*Pharmacovigilance Programme of India (PPhPI)*
2. ADR Reporting form for Consumers in different vernaculars

2 (b) Gujarati

MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

This reporting is voluntary, has no legal implication and aims to improve patient safety. Your active participation is valuable. The information provided in this form will be forwarded to APDR Monitoring Centre for follow-up. You are requested to cooperate with the programme officials when they contact you for more details.

Special Instructions to Consumers:
- Please describe the event in as many details as possible so that it can be matched with similar cases and help in future investigation.
- Please include names of family members, friends and neighbours who have received the same product at the same time.
- For more details, please contact APDR Monitoring Centre on 011-23456789 or visit www.apdr.gov.in

1. Patient Details/Name of Patient:
- First Name
- Last Name
- Date of Birth
- Address
- Telephone No.
- Email ID

2. Health Information:
- Age
- Sex
- Weight
- Height
- Occupation

3. Details of Medicines Taking/Taken:
- Name of Medicines Taking/Taken
- Dose
- Frequency
- Duration

4. Details of Side Effect:
- Date of Onset
- Duration
- Description
- Severity

5. Outcome:
- Resolution

6. Additional Information:
- Other details

Please note: You may be contacted by APDR Monitoring Centre for further information.

Pharmacovigilance Programme of India (PvPI)
### MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

**2 (c) Hindi**

**Version 1.0**

**Medical Programme of India (PPI)**

**Performance Report 2014-2015**

| Details of Person Reporting the Side Effect | 
|---|---|
| Name: | [Name] |
| Address: | [Address] |
| Telephone No.: | [Number] |

**4. Details of Medicine Taking/Other**

**Name of Medicines**

| Name of Medicine/ 
|---|---|
| (in case of powder/ 
|---|---|
| in case of liquid/ 
|---|---|
| in case of tablet/ 
|---|---|
| in case of capsule/ 
|---|---|
| in case of injection/ 
|---|---|
| in case of other forms/ 
|---|---|

**Dosage form/packaging of the Medicine:**

<table>
<thead>
<tr>
<th>Dosage form/packaging of the Medicine</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Tablets</td>
<td>[Quantity]</td>
</tr>
<tr>
<td>Capsules</td>
<td>[Quantity]</td>
</tr>
<tr>
<td>Injection</td>
<td>[Quantity]</td>
</tr>
<tr>
<td>Oral Liquids</td>
<td>[Quantity]</td>
</tr>
</tbody>
</table>

**5. About the Side Effect:**

- **When did the side effect start?**
- **When did the side effect stop?**
- **The side effect continued?**

**6. How was the Side Effect?**

- **Did the side effect occur regularly?**
- **Did the side effect occur frequently?**
- **Did the side effect occur during the day or at night?**
- **Did the side effect occur at home or in the hospital?**

**7. What do you do to manage the side effect?**

- **What caused the side effect?**

**Note:**

This reporting is voluntary, has no legal implication and aims to improve patient safety. Your active participation is valuable. The information provided in this form will be forwarded to AIDC Monitoring Centre for follow-up. You are requested to cooperate with the programme officials when they contact you for more details. Please do report even if you do not have all the information.

---

### MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

**2 (d) Kannada**

**Version 1.0**

**Medical Programme of India (PPI)**

**Performance Report 2014-2015**

| Details of Person Reporting the Side Effect | 
|---|---|
| Name: | [Name] |
| Address: | [Address] |
| Telephone No.: | [Number] |

**4. Details of Medicine Taking/Other**

**Name of Medicines**

| Name of Medicine/ 
|---|---|
| (in case of powder/ 
|---|---|
| in case of liquid/ 
|---|---|
| in case of tablet/ 
|---|---|
| in case of capsule/ 
|---|---|
| in case of injection/ 
|---|---|
| in case of other forms/ 
|---|---|

**Dosage form/packaging of the Medicine:**

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<td>[Quantity]</td>
</tr>
<tr>
<td>Oral Liquids</td>
<td>[Quantity]</td>
</tr>
</tbody>
</table>

**5. About the Side Effect:**

- **When did the side effect start?**
- **When did the side effect stop?**
- **The side effect continued?**

**6. How was the Side Effect?**

- **Did the side effect occur regularly?**
- **Did the side effect occur frequently?**
- **Did the side effect occur during the day or at night?**
- **Did the side effect occur at home or in the hospital?**

**7. What do you do to manage the side effect?**

- **What caused the side effect?**

**Note:**

This reporting is voluntary, has no legal implication and aims to improve patient safety. Your active participation is valuable. The information provided in this form will be forwarded to AIDC Monitoring Centre for follow-up. You are requested to cooperate with the programme officials when they contact you for more details. Please do report even if you do not have all the information.

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Please refer to the guide to the medicined form.
MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

Indian Pharmacopoeia Commission, National Coordination Centre - Pharmacovigilance Programme of India,

Ministry of Health & Family Welfare, Government of India.

1. Patient Details

Patient Initials: [ ] Gender: [ Male ] [ Female ] [ Other ]
Age (Year or Month): [ ]

2. Health Information

a. Reason(s) for taking medicine(s)/Disease/Symptoms:

b. Medicines Advised by (If): [ ] Doctor [ ] Pharmacist [ ] Friends/Relatives [ ] Self (Past disease experienced/No past disease experienced):

3. Details of Person Reporting the Side Effect

Name (Optional): [ ] Address: [ ]

Telephone No: [ ] Email: [ ]

4. Details of Medicine Taken/Taken/Purchased/Since

5. About the Side Effect

When did the side effect start? [ ]
Side Effect is still Continuing? [ Yes/No ]

6. How bad was the Side Effect? [ Please if the boxes that Apply ]

7. Describe the Side Effect [ What did you do to manage the side effect(s)? ]

This reporting is voluntary, has no legal implication and aims to improve patient safety. Your active participation is valuable. The information provided in this form will be forwarded to AIIMS Monitoring Centre for follow-up. You are expected to cooperate with the programme officials when they contact you for more details. Please do report even if you do not have all the information.

Please turn this page to read the instructions.
"The doctor of the future will give no medicine, but will educate his patients in the care of the human frame, in diet, and in the cause and prevention of disease."  

Thomas Edison

<table>
<thead>
<tr>
<th>No.</th>
<th>State</th>
<th>Name of AMC</th>
<th>Address</th>
<th>Contact Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Tamil Nadu</td>
<td>Madras Medical College</td>
<td>Chennai</td>
<td>91-1234567890</td>
</tr>
<tr>
<td>2.</td>
<td>Andhra Pradesh</td>
<td>Osmania Medical College</td>
<td>Hyderabad</td>
<td>91-9876543210</td>
</tr>
<tr>
<td>3.</td>
<td>Maharashtra</td>
<td>Seth GS Medical College</td>
<td>Mumbai</td>
<td>91-1234567890</td>
</tr>
<tr>
<td>4.</td>
<td>Karnataka</td>
<td>Vijaya College of Medical Sciences</td>
<td>Bangalore</td>
<td>91-9876543210</td>
</tr>
<tr>
<td>5.</td>
<td>Uttar Pradesh</td>
<td>Dr. Ram Manohar Lohia Medical College</td>
<td>Lucknow</td>
<td>91-9876543210</td>
</tr>
<tr>
<td>6.</td>
<td>Rajasthan</td>
<td>JLN Medical College</td>
<td>Jaipur</td>
<td>91-9876543210</td>
</tr>
</tbody>
</table>

**AMCs Under Pharmacovigilance Programme of India (PhvPi)**

1. **Pharmaceuticals**
   - Headquarter: Centre of Excellence, ICMR, New Delhi, IN-110021
   - Contact: 11-98-76-543210

2. **NDMA**
   - Headquarter: New Delhi, IN-110021
   - Contact: 11-98-76-543210

3. **NDMA**
   - Headquarter: New Delhi, IN-110021
   - Contact: 11-98-76-543210

4. **NDMA**
   - Headquarter: New Delhi, IN-110021
   - Contact: 11-98-76-543210

5. **NDMA**
   - Headquarter: New Delhi, IN-110021
   - Contact: 11-98-76-543210

6. **NDMA**
   - Headquarter: New Delhi, IN-110021
   - Contact: 11-98-76-543210