



Pharmacovigilance Programme of India (PvPI)

Performance Report 2014 - 2015

*"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"*



Indian Pharmacopoeia Commission

National Coordination Centre, Pharmacovigilance Programme of India
Ministry of Health & Family Welfare, Govt. of India
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**"Protecting Public Health by
Promoting Safer Drug Therapy"**



INDIAN PHARMACOPOEIA COMMISSION

Ministry of Health & Family Welfare, Govt. of India

Sector-23, Raj Nagar, Ghaziabad-201002



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 API Text book 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"



Shri Narendra Modi
Hon'ble Prime Minister of India





“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.

Table of Content

Message	01
Preface	03
Acknowledgement	04
Abbreviations	05
Executive Summary	07
Pharmacovigilance Programme of India (PvPI): An Introduction	09
Status of ICSRs: Reporting, Collation & Analysis	15
The NCC-PvPI Helpline	19
Involvement of Pharmaceutical Industries in PvPI	21
Integration of PvPI with National Health Programmes (NHPs)	23
Training & Education Programmes	27
PvPI in the International Arena	31
Activities of the Signal Review Panel	35
Inputs to CDSCO for Regulatory Interventions	37
Important Events in PvPI	39
PvPI Communications	43
Scientific Publications at PvPI	47
Future Plans	49
Appendices	57



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2nd June 2015

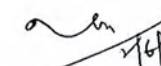
MESSAGE

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.


(B.P. Sharma)

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दिनांक/Dated.....

Dated: 01/06/2015



MESSAGE

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 sanctified 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)

Preface

It is my privilege to introduce the performance report of PvPI for the index period of April, 2014 – March, 2015. The report describes the varied activities of the PvPI during the year and also documents the different initiatives taken.

Beginning to operate with few ADR Monitoring Centres (AMCs) in July 2010, the PvPI has now expanded to 150 AMCs across the country and we expect these numbers to grow further in the next year. It has been a year of significant challenges, but also one of substantial progress. It is heartening to note that during the index period, the PvPI has contributed around 41,879 ICSRs to the global drug safety database of WHO International Drug Monitoring Programme with completeness grading score of 0.91, this marked an improvement of 11 % as compared to previous years.

With an objective to ensure the medicines and patients safety in public health programs, the NCC-PvPI has collaborated with the RNTCP and NACO. Since ADRs are associated with significant social and economic consequences, there is a need to continuously engage healthcare professionals, in this well structured programme. The NCC-PvPI organized several CMEs and training programmes for this purpose. A guidance document has been released for all the stakeholders under PvPI to ensure an uniform reporting culture.

To empower and encourage the consumers to report ADRs and other medicine related problems, a medicines side effect reporting form has been introduced in different regional languages. The scope of an android phone application for ADR reporting is being explored.

The NCC-PvPI has extended its purview of activities to the pharmaceutical industries, to keep pace with the rapid induction of NCEs and high tech pharma products in the market, it is vital to monitor both the known and hitherto unknown side effects of such products, that are consumed by a large population in India.

Based on the analysis of ICSRs received in the last year and review of the signals detected, the NCC-PvPI identified some newer safety concern that might guide regulatory decisions.

I am grateful to the PvPI staff at the NCC and the Coordinators & Technical Associates at the AMCs for their efforts, dedication and support that enabled the PvPI to successfully meet its commitments. I look forward to their continued support and cooperation that would go a long way in fostering safer use of medicines in India.

(Dr. G. N. Singh)

Secretary-cum- Scientific Director
Indian Pharmacopoeia Commission
Ghaziabad

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

- Dr. V. Kalaiselvan, Principal Scientific Officer
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- Mr. Ranvir Kumar, Technical Associate
- Ms. Vaishali Bhardwaj, Technical Associate
- Mrs. Madhvi Rathore, Technical Associate
- Sh. S.A. Alishah, Advisor, IPC and other Technical, Administrative and Financial Staff of IPC
- All PvPI teams at ADR Monitoring Centres (AMCs)

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- Dr. Santanu K. Tripathi, Professor & Head, Department of Clinical & Experimental Pharmacology, School of Tropical Medicine, Kolkata, West Bengal
- Dr. Sushma Srivastava, Research Scientist, DIPSA, New Delhi



(Dr. G.N. Singh)

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Abbreviations

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

ICSR	Individual Case Safety Report
IMA	Indian Medical Association
IPC	Indian Pharmacopoeia Commission
ISoP	International Society of Pharmacovigilance
KAP	Knowledge, Attitude and Practice
LIM	Lareb Intensive Monitoring
MedDRA	Medical Dictionary for Regulatory Activities
MoHFW	Ministry of Health and Family Welfare
MoU	Memorandum of Understanding
MPA	Medical Product Agency
NACO	National AIDS Control Organization
NCC	National Coordination Centre
NCE	New Chemical Entity
NHP	National Health Programme
PIR	Preliminary Investigation Report
PV	Pharmacovigilance
PvPI	Pharmacovigilance Programme of India
QA-QC	Quality Assurance- Quality Control
QMS	Quality Management System
RNTCP	Revised National Tuberculosis Control Programme
SAE	Serious Adverse Event
SOC	System Organ Class
SoPI	Society of Pharmacovigilance of India
SRP	Signal Review Panel
TA	Technical Associate
WHO-ART	World Health Organization- Adverse Reactions Terminology
WHO-DD	World Health Organization -Drug Dictionary
WHO-HQ	World Health Organization-Head Quarter
WHO-UMC	World Health Organization-Uppsala Monitoring Centre

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 judgement, 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 recognised globally as a vital stakeholder in any pharmacovigilance programme. Therefore, under the PvPI, industries were welcomed to participate and start reporting ADRs. The response has been promising-a total 2222 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 programme 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 has played an indispensable 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, Netherland, 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.

Introduction

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.

Mission of PvPI

Safeguard the health of the Indian population by ensuring that the benefits of use of medicine outweigh the risks associated with their use.

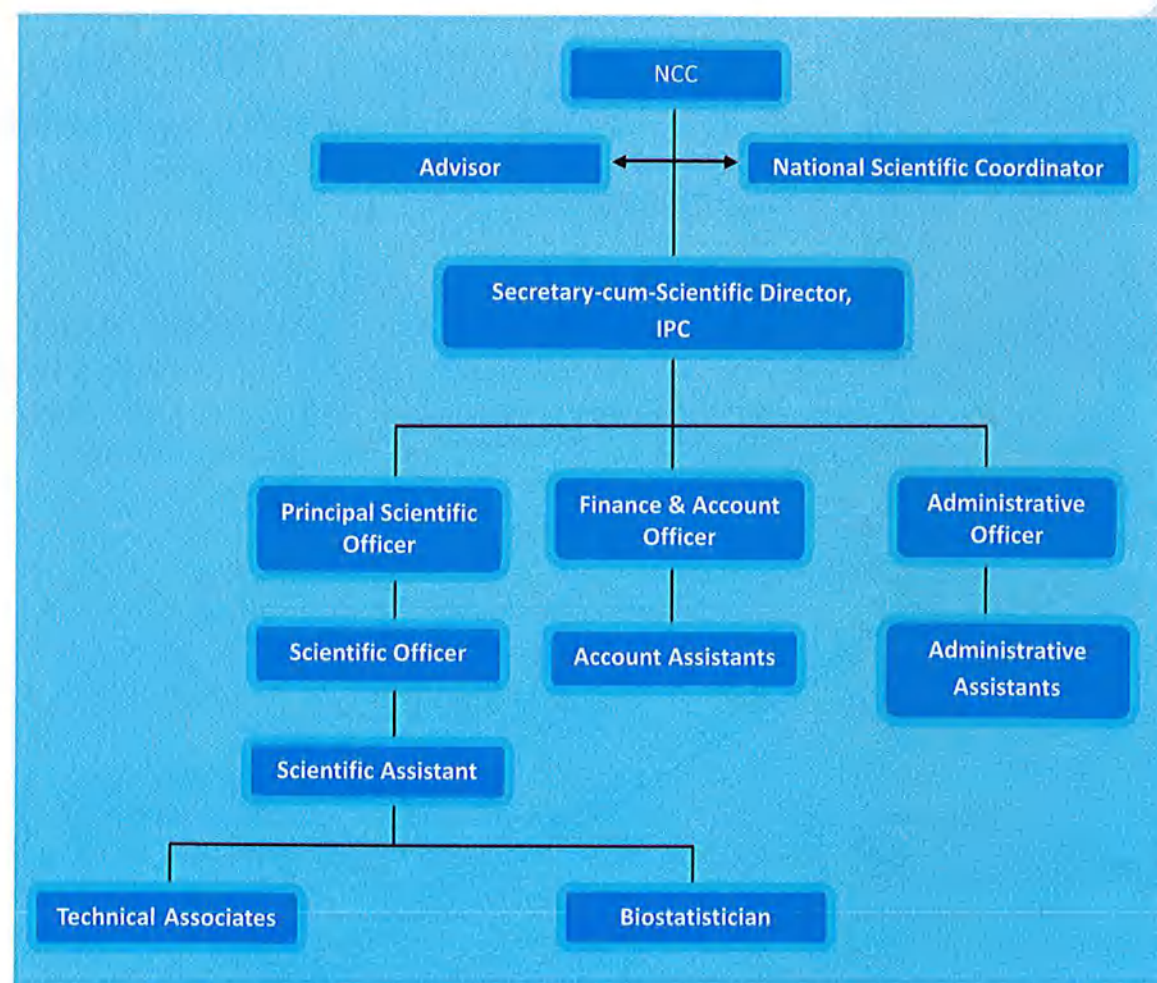
Vision of PvPI

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

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.

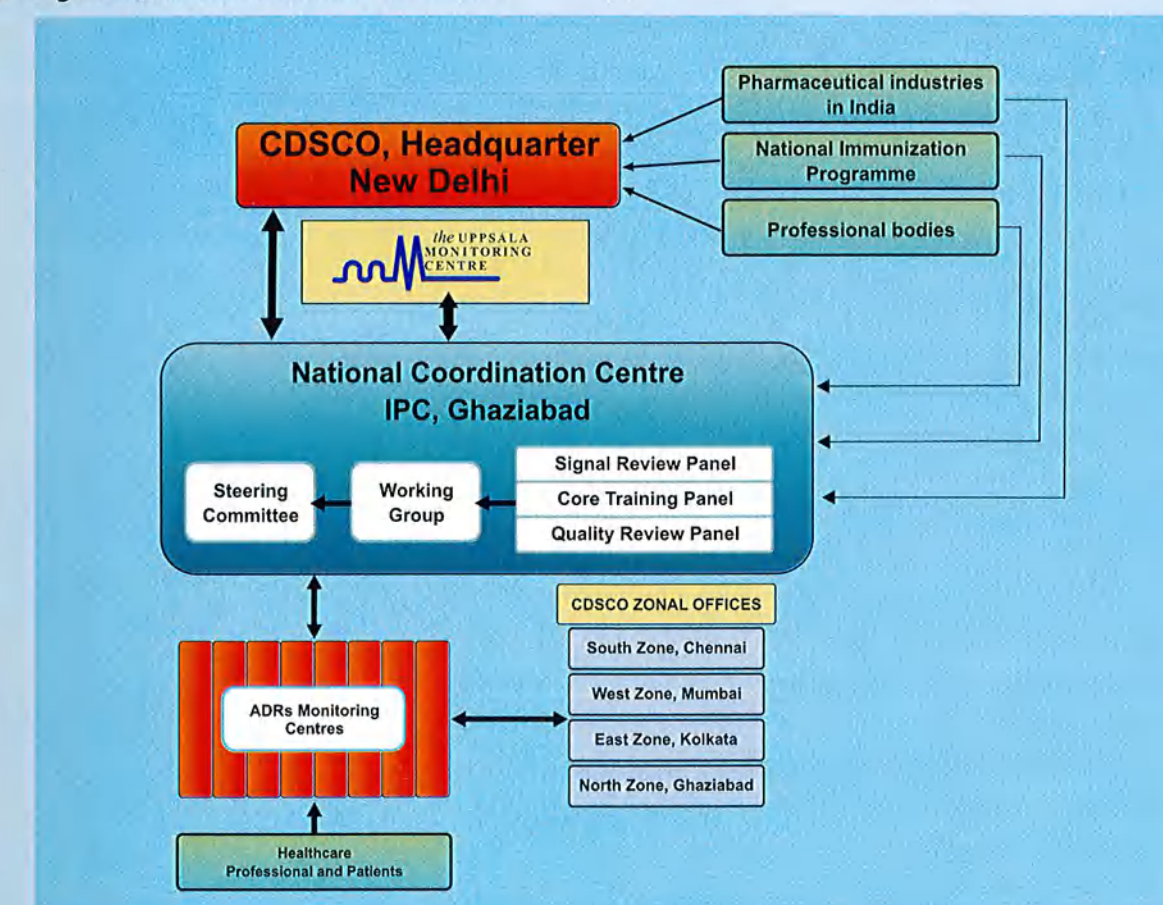
Fig 1: Organogram of the NCC-PvPI



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 constituted of experienced scientists and clinical experts affiliated to government and non-government academic institutions, hospitals and pharmaceutical industries to collate and analyze information from ICSRs submitted to NCC. This panel assesses the results of the regular computerized screening of ICSRs 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 ICSRs. It is also responsible for making decisions about actionable indicators.

Core Training Panel

The Core Training Panel of PvPI identifies trainers 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, IPGIMER, 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 centers provide training and technical supports 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 workshop 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(e)], Oriya [Ann.-2(f)], Tamil [Ann.-2(g)], Gujarati [Ann.-2(b)], Bengali [Ann.-2(a)] and Kannada [Ann.-2(d)], 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, the 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.

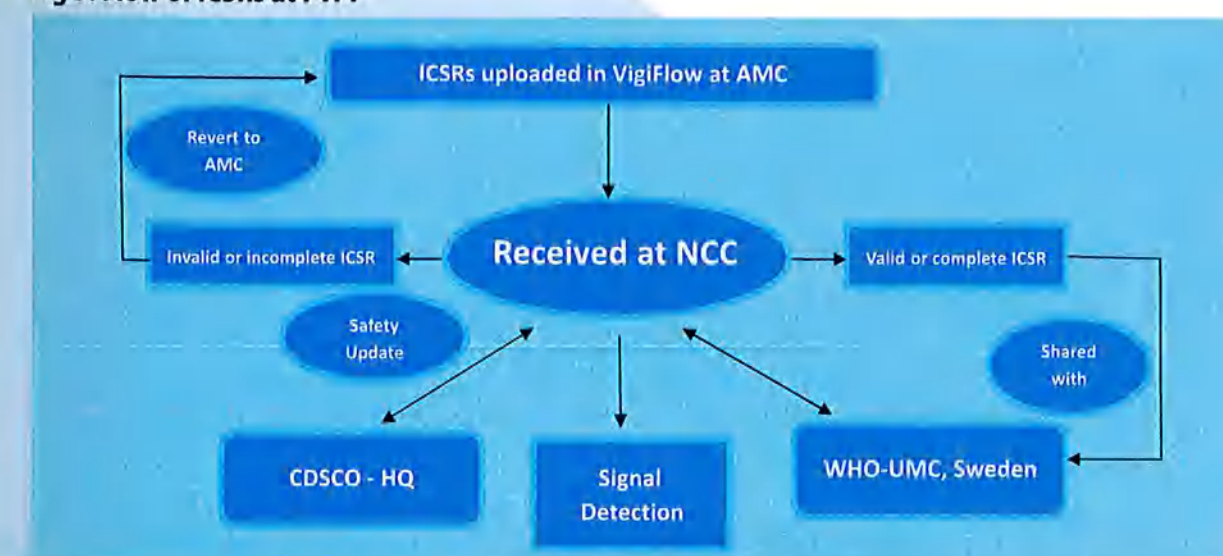
How and Whom to Report?

Use the 'Suspected Adverse Drug Reaction Reporting Form' which is available on the official website of IPC (www.ipc.gov.in) as well as CDSCO (www.cdsc.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@ipcindia.net / pvpi.ipcindia@gmail.com. ADRs can also be reported using the toll free helpline number **1800-180-3024**.

Data management at NCC-PvPI

Following chart illustrates the process of ICSR data management by PvPI

Fig 3: Flow of ICSRs at PvPI



Evolution of PvPI



Patient
"Key Stakeholder in
Reporting ADR"



Healthcare Professionals
"Monitoring and Reporting
Adverse Drug Reactions"



National Coordination Centre
"Coordinating Pharmacovigilance Programme of India"

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



**WHO-Uppsala
Monitoring Centre**
"International Drug Monitoring"



Communication
"To Generate a Strong Network of
Pharmacovigilance All Over the Country"



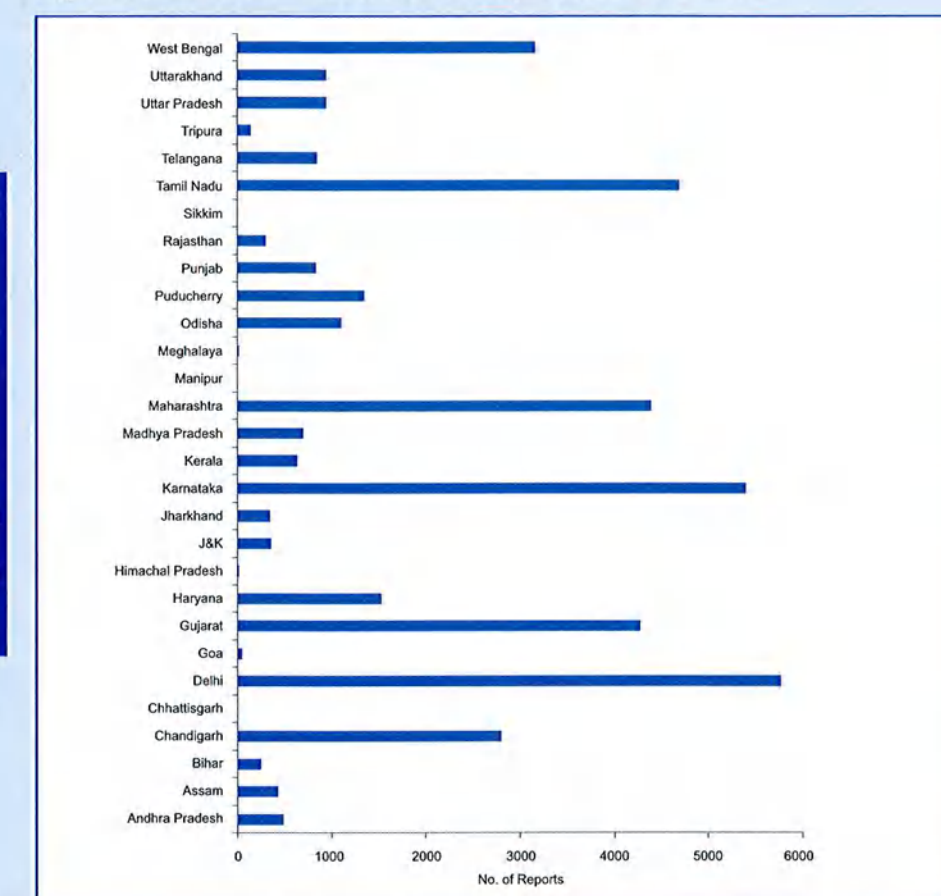
CDSCO
"Regulatory Intervention
on Medicines"

- 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

Status of ICSRs : Reporting, Collation & Analysis

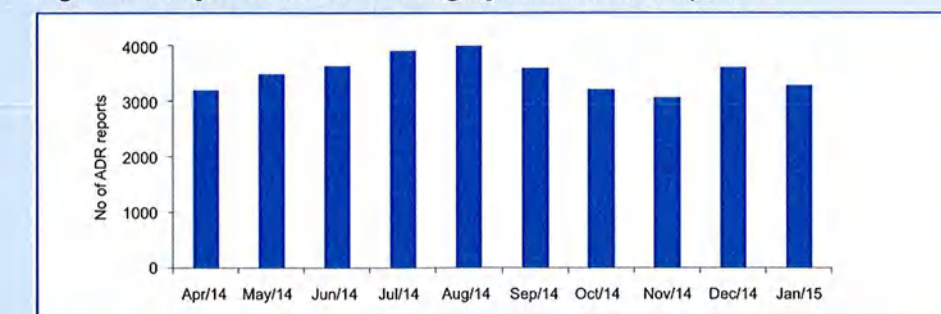
During the index period a total of 41,879 reports were received from different ADR monitoring centres and accounting for 37% of all cases. These reports were derived entirely from the spontaneous ADR reporting system under the PvPI. State wise distribution of ADR reports received from AMCs is illustrated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

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



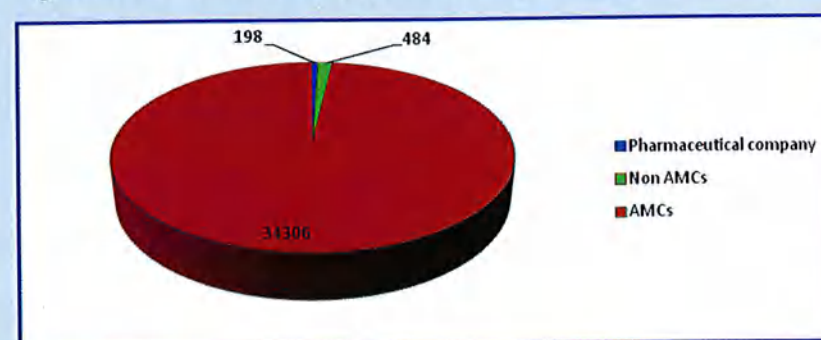
Out of these 41,879 reports, 34,988 ADR reports were reviewed for validity, causality and expectedness and then, finally submitted to the WHO global safety database, VigiBase®. The month wise distributions of reports received at NCC-PvPI are illustrated in the figure below:-

Fig.5: ADR reports received during April 2014-January 2015



Most of the reports received at NCC were from the AMCs under the purview of PvPI. During the past year, with the continuous efforts of the PvPI, NCC started receiving reports from pharmaceutical industries regarding on 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 (98.05%), 484 (1.38%) & 198 (0.57%) respectively.

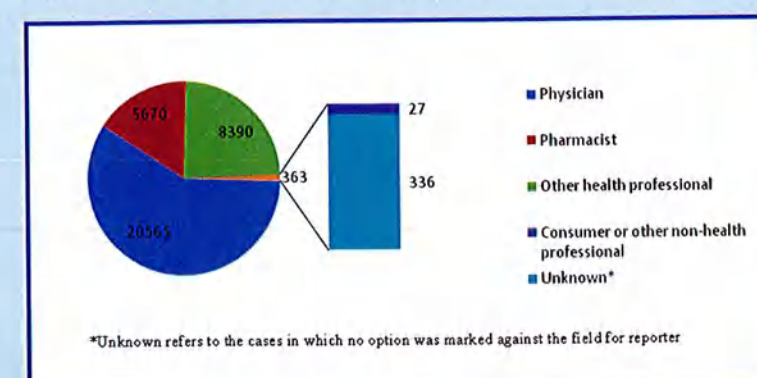
Fig.6: Distribution of ADR reports based on the type of senders



- 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 98.05% 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.

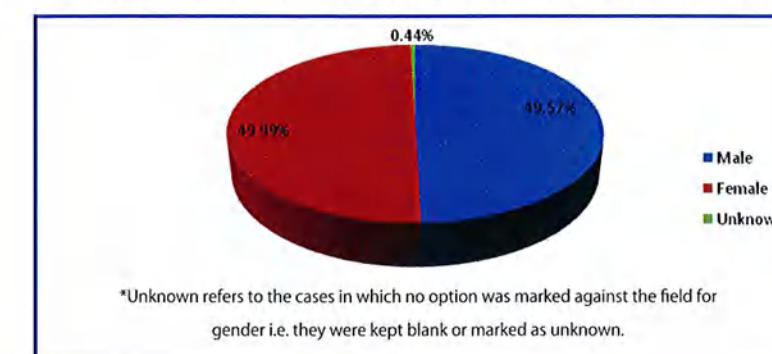
Fig.7: Distribution of ADR reports based on types of reporters



- 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.

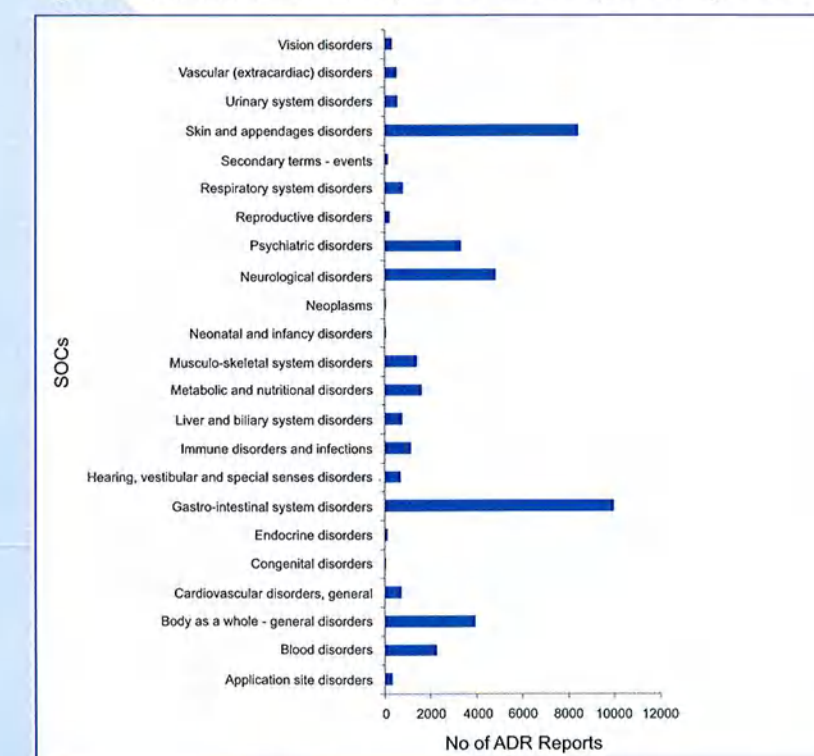
Figure 8 shows the distribution of ADRs reports on the basis of gender. Out of 34,988 ADR reports, 17,490 were reported in females, 17,343 were in males and remaining 155 carried no information about the gender.

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



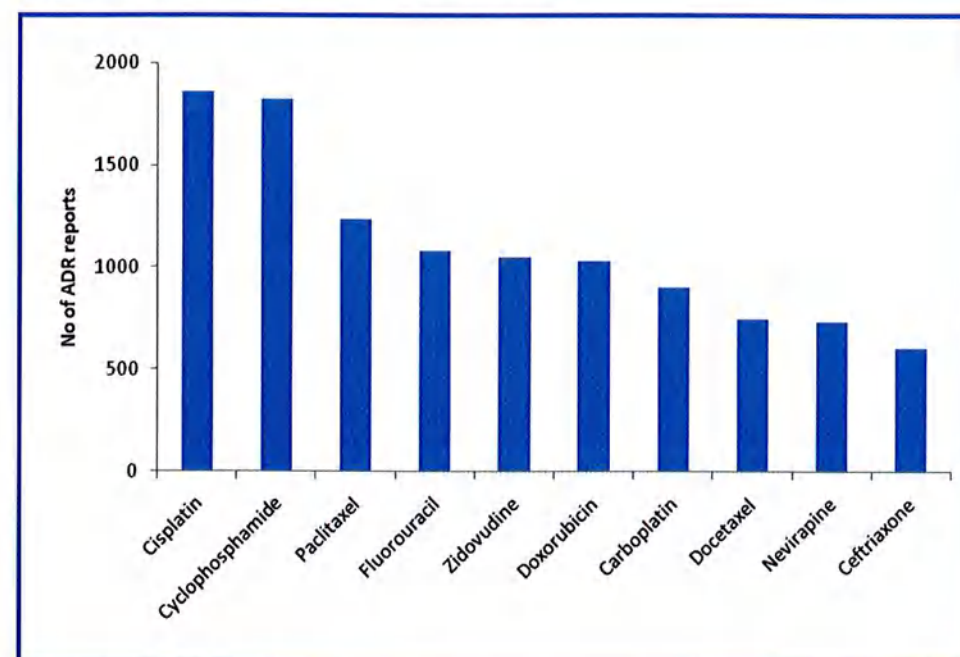
The reported ADRs included a large spectrum of clinical manifestations, which are summarized based on WHO Adverse Reaction Terminology (WHO-ART) System-Organ Class (SOC). i.e. the ADRs due to the suspected medication affects both single organ and multiple organs, the different organs illustrated in figure 9.

Fig.9: Distributions of ADR reports based on System Organ Class



During the index period, the commonly used drugs that results 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 NCC-PvPI Helpline-Commencing Consumer Reporting of ADRs in India

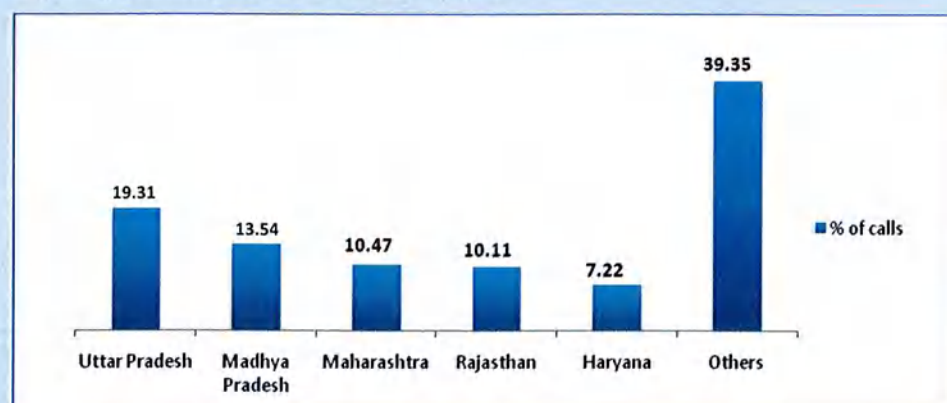
Medicines are consumed by one and all in the society. Any programme that is committed to ensure safer use of medicines, must strive to win the confidence of public and consumers. On 11th October, 2013, the NCC-PvPI launched a Helpline (Toll-free no. 1800 180 3024) for the consumers. The objective is 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 and ADR 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.

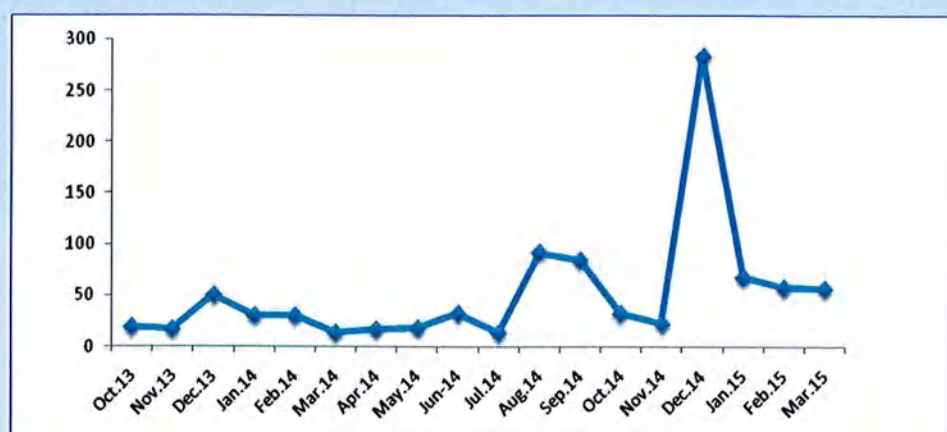
Demographic Characteristics of the Patients (%)		
Gender	Male	64.29
	Female	35.71
Age (Years)	≤20	16.67
	21-40	54.76
	41-60	19.05
	≥61	09.52

Fig.11: Calls received – State wise (%)



Maximum number of calls were received from Uttar Pradesh (19.31%) followed by Madhya Pradesh (13.54%) and Maharashtra (10.47%). Uttar Pradesh recorded the highest number of calls and Kerala and Tamil Nadu the least, which was surprising because the literacy rates in these latter states are better compared to other states. However people are more aware about this helpline facility in Uttar Pradesh and Madhya Pradesh because of the information published in the national as well as local newspapers.

Fig.12 : Calls received - A month wise analysis (Total call received - 3826)

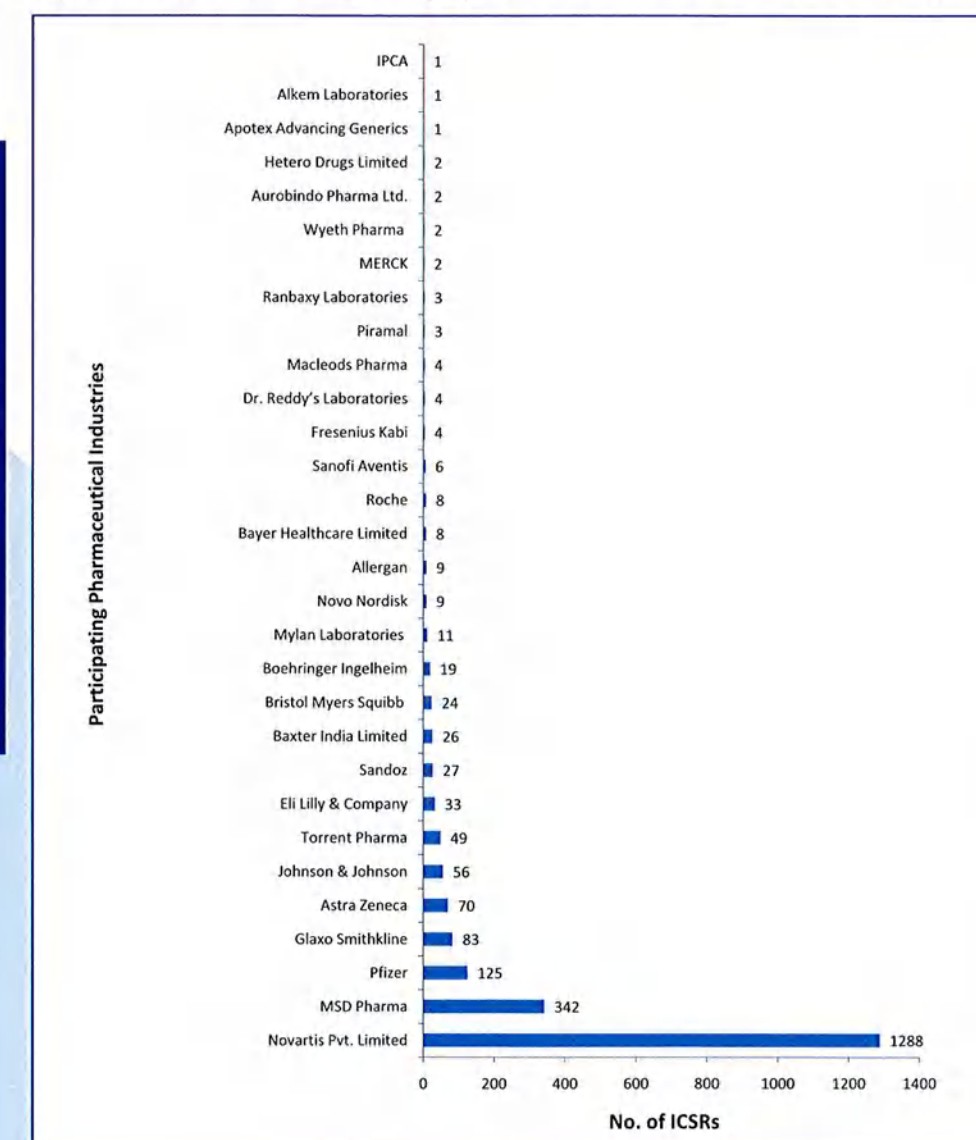


The helpline has been well received by the stakeholders. Besides reporting suspected ADRs, people are using the facility for general drug information too. Such an approach of using helpline/telephone facility to collect ADRs from the HCPs and consumers is not novel. Countries like Australia, Canada and 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 the 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.

Involvement of Pharmaceutical Industries in PvPI

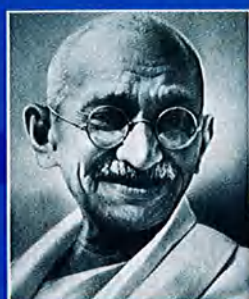
Pharmaceutical industries are one of the vital stakeholders in the pharmacovigilance programme. PvPI coordinates with these industries for their active participation in the programme. During the index period, NCC organized several rounds of meetings with the industry experts for data sharing arrangement between CDSCO, NCC-PvPI and industries. As a net result, industries have started voluntary reporting to NCC-PvPI. A total 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.

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.



"Strength does not come from physical capacity. It comes from an indomitable will"

Mahatma Gandhi
Father of Nation

- NCC-PvPI ties-up with WHO for training of healthcare professionals under National Health Programmes on ADR reporting.
- NCC-PvPI join hands with AEFI, RNTCP & NACO for ADR reporting.
- Total 37 ART & RNTCP centers recognized for ADR reporting under PvPI.

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 DCGI. Intensive efforts are being made by MoHFW, Gol to strengthen surveillance and monitoring of AEFI in the country. In India, the safety of vaccine is monitored by the division of AEFI, MoHFW, Gol 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/PIR/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 Uppsala 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 Lov 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

Lauding 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 796,269 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 Sri R.K. Jain, Former Additional Secretary, Director General (CGHS), MoHFW, GoI. Dr. A. S. Rathore, Deputy Director General, Care, Support and Treatment Division, NACO, MoHFW, GoI and Dr. G. N. Singh, Secretary-cum-Scientific Director, IPC, senior ministry



Meeting to sign the MoU between IPC and NACO to monitor the safety of antiretroviral drugs on 15th September 2014, in the august presence of Shri R. K. Jain, Additional Secretary & Director General (CGHS), MoHFW, GoI along with other ministry officials at New Delhi

officials were also present on this occasion. During the meeting, Shri 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 AMCs and later scaling up the activities further.

The first phase of this project to identify the 20 ART centres from the 150 AMCs 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 AMCs.

Reporting Adverse Events, Safeguarding Patients

"Step Ahead for Better Patient Safety"

Vomiting



Stomach pain



Itching



Rash



Headache



Fever



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

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:

- More than 3000 HCPs were trained on Pharmacovigilance during the index period.
- Quality and quantity of reporting enhanced.
- Opportunity for skill development.
- Strengthen the network between AMCs and NCC.

- 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 2: Training and Education Programmes on Pharmacovigilance during Index Period

S.No	Name of Programme	Date	Place	Target Audience	objective
1	VigiFlow® Training	21st April, 2014	KEM, Mumbai (Maharashtra)	Coordinators of new AMCs	Introduction to VigiFlow & Pharmacovigilance
2	CME on Pharmacovigilance	28 th June, 2014	NEIGRIMS, Shilong (Meghalaya)	Healthcare Professionals of Eastern States	KAP of Pharmacovigilance
3	Training Programme on Pharmacovigilance	2 nd July, 2014	Kasauli, (Himachal Pradesh)	Coordinators & TAs of Northern States	KAP of Pharmacovigilance
4	Training Programme on Pharmacovigilance	4 th & 5 th August, 2014	JSS College of Pharmacy, Mysore, (Karnataka)	PvPI staff at AMCs in the state of Karnataka, Tamil Nadu, Andhra Pradesh, Kerala, Telangana and Puducherry (U.T.)	Introduction to VigiFlow® & Pharmacovigilance
5	Workshop on Pharmacovigilance	30 th August, 2014	IMS Law College, Noida (U.P.)	Law Students	Introduction of PvPI in context of Patient Safety
6	Induction cum training Programme for newly recruited technical associates under PvPI	8 th to 12 th September, 2014	IPC, Ghaziabad (U.P.)	New Technical Associates	Training on basic knowledge of Pharmacovigilance and hands on training in VigiFlow®

S.No	Name of Programme	Date	Place	Target Audience	Objective
7	2 nd International conference on "Patient safety and access to Quality Healthcare"	6 th to 8 th November, 2014	Haridwar (Uttarakhand)	Technical staff of PvPI & AMC Staff of Uttarakhand	Need for Enhancing Patient Safety and Quality Medicines
8	Hands on training for technical staff of PvPI on MedDRA	19 th & 21 st November, 2014	Panacea Biotech (New Delhi)	Technical staff of PvPI	MedDRA training
9	International symposium on "safe medicine and safe patient"	1 st to 3 rd December, 2014	JNMC, Aligarh (U.P.)	HCPs	Importance of Pharmacovigilance, current regulations, safety surveillance
10	CME on Pharmacovigilance	22 nd November, 2014	PIMS, Thiruvalla (Kerala)	HCPs	CME on Pharmacovigilance, Introduction of Malayalam version of ADR Reporting Form for Consumers
11	Induction cum Training Programme for Newly Recruited Technical Associates under PvPI	24 th to 28 th November, 2014	IPC, Ghaziabad (U.P.)	New Technical Associates	Training on Basic Knowledge of Pharmacovigilance and Hands on Training in VigiFlow®
12	Workshop on Causality Assessment, Signal Detection and Data Mining	9 th December, 2014	IPC, Ghaziabad (U.P.)	SRP Members	Causality, Signal Detection and Data Mining in Pharmacovigilance
13	National Pharmacovigilance Workshop for Coordinators of Drug Resistant Tuberculosis and ART Centres in India	10 th & 11 th December 2014	Hotel Lalit, (New Delhi)	Coordinators of RNTCP and NACO	KAP of Pharmacovigilance
14	National & International Scenario on Pharmacovigilance	16 th December, 2014	IPC, Ghaziabad (U.P.)	Staff members of IPC	Global status of Pharmacovigilance
15	QMS training of AEFI personnel	17 th December, 2014	IPC, Ghaziabad (U.P.)	Staff members of NCC and AEFI	Causality, Signal Detection and Data Mining in Pharmacovigilance
16	Hands on Training on VigiFlow	31 st December, 2014 to 01 st January, 2015	IPC, Ghaziabad (U.P.)	AMC Members of SGRRTS, Dehradun	Hands on Training on VigiFlow®
17	Induction cum Training Programme for the Newly Recruited Technical Associates under PvPI	16 th to 20 th February, 2015	IPC, Ghaziabad (U.P.)	New Technical Associates	Training on Basic Knowledge of Pharmacovigilance and Hands on Training in VigiFlow®
18	Training for the Coordinators and Technical Associates of AMCs of West Zone under PvPI	18 th March, 2015	KEM, Mumbai (Maharashtra)	Technical Associates & Coordinators	Hands on training and filling the ADRs to newly inducted AMCs in west zone
19	Training to the personnel of JNMC	30 th March, 2015	JNMC, Raipur (Chhattisgarh)	Personnel of JNMC	Training on Basic Knowledge of Pharmacovigilance and Hands on Training in VigiFlow®

During the index year various training programmes & CME(s) have been organised by NCC - PvPI. The PvPI envisages 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:

Time duration for the hands on training on VigiFlow® software should be increased.

Duration for the training at AMC should be increased.

Training should be periodically organised to acquire newer skills & knowledge continuously.

Session regarding Biostatistical tools used in PV should be more elaborate.

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



National Pharmacovigilance workshop for Coordinators of RNTCP & ART Centre on 10th & 11th December, 2014 in New Delhi



Participants during causality assessment, signal detection and data mining workshop on 8th December, 2014 at IPC, Ghaziabad



Induction cum training programme for the technical associates at IPC, Ghaziabad held on 20th February, 2015



Induction cum training programme for the technical associates at IPC, Ghaziabad held on 25th November, 2014.

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-UMC mutually agreed to exchange the skills in identifying new signals.



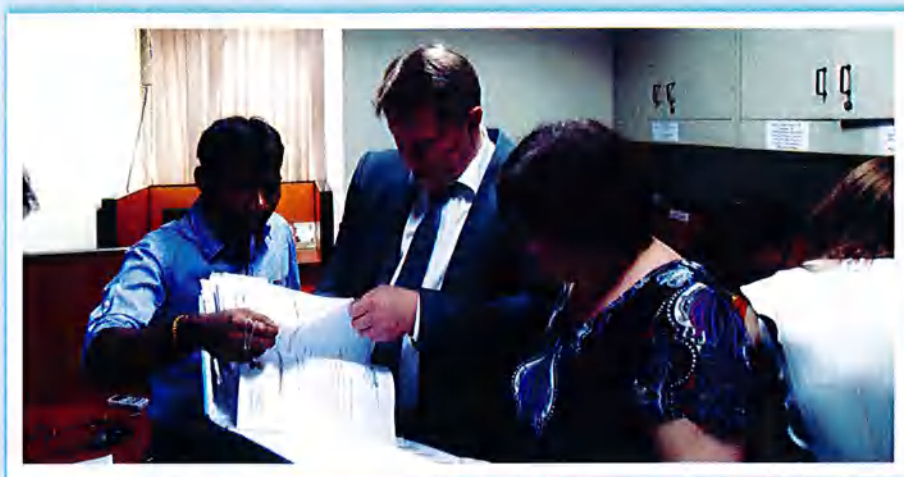
Prof. Eugene, Lareb, Netherland interacting with NCC- PvPI team on 4th December, 2014 at Ghaziabad

Prof. Eugene, Lareb, The 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 about 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

Dr. G. N. Singh (1st from left), along with Dr. S.K. Gupta (1st from right) briefing the progress of PvPI to Dr. Marie Lindquist (2nd from right) and Mr. Backman Christer (2nd from left) during their visit to NCC-PvPI on 25th November, 2014

Visit of Dr. Marie Lindquist, UMC Director and Mr. Backman Christer, Medicinal Products Agency, Sweden to IPC on 25th November, 2014 is a symbolic 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. Marie 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

Dr. Shanthi Pal (Medicines Safety Programme Manager, WHO-HQ) during her presentation on Pharmacovigilance in one day workshop on "National & International Scenario on Pharmacovigilance" on 16th December, 2014 at IPC, Ghaziabad

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, this 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 feel 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 welcome you all to India.



"The Biggest disease today is not leprosy or tuberculosis, but rather the feeling of being unwanted."

Mother Teresa

- Signal is unreported ADR of any particular drug
- SRP consists of medical doctors of various specializations clinical pharmacologist, pharmacists experts from drug regulation and scientists
- Two SRP meetings were held during index period
- Important outcomes of the meetings are
 - Recommended to link PvPI with PSURs.
 - Recommended CDSCO for making changes in the prescribing information of Carbamazepine, Sunitinib Malate & Pazopanib Hydrochloride
 - Strategic model plan for dissemination of pharmacovigilance among clinicians

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.

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 representations 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 the 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:

S.No.	Meeting Details	Major Recommendations	Action Taken
1	1 st meeting of PvPI SRP (20 th February, 2014)	• NCC to allocate dedicated personnel to monitor the signal review process. • Dedicated sub group in NCC team to be formed to monitor data analysis.	Action Completed
2	2 nd meeting of PvPI SRP (21 st -22 nd March 2014)	• NCC to send a proposal to WHO-UMC to seek their support and service for signal detection. • Training of SRP members. • PvPI database should be integrated with PSUR and PMS data. • NCC-PvPI should initiate the process of e-reporting.	Action Completed Action in Hand
3	3 rd meeting of PvPI SRP (6 th June , 2014)	Following data was received for a possible signal • Streptokinase induced hepatitis. • Metformin & glimepiride induced Lichen planus. The data is inadequate to detect a signal. Additional data is required from the source centre and other centres across the country. • Training on signal detection to the members of SRP. • Strategic model plan for dissemination of pharmacovigilance among clinicians.	Action Completed Action in Hand
4	4 th Meeting of PvPI SRP (8 th -9 th December, 2014)	• Advisory note for Sunitinib Malate. • Advisory note for Pazopanib HCl. • Recommendation for label change for Carbamazepine.	Action Completed



*"Wherever the art of medicine is loved,
there also is love of humanity."*

Hippocrates

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 data base 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 with 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).

Advisory note for usage of Pazopanib Hydrochloride

Cardiac dysfunction

PvPI database revealed that 47 ICSRs among Indian patients with metastatic renal cell carcinoma who were on pazopanib hydrochloride therapy, cardiac dysfunction sometimes fatal nature were also reported. These include reports of congestive heart failure and ischemic heart disease leading to death.

"Patients are recommended to seek immediate medical help if they experienced fast irregular heartbeat, dizziness, fainting, chest pain, radiating to jaw/left arm, shortness of breath and unusual sweating. Patient should be carefully monitored for CHF and ischemic heart disease. Base line and periodic evaluation of left ventricular ejection fraction (LVEF) is recommended in patients with a risk of cardiac dysfunction".

Label change for Carbamazepine

PvPI database revealed 119 ICSRs of life threatening or fatal skin reactions (Stevens Johnson Syndrome, Toxic Epidermal Necrolysis) may have been caused by carbamazepine. These 119 reports are out of 1887 reports of carbamazepine induced ADRs from India reported to VigiBase® till the end of 2014.

An increased association of HLA-B* 1502 with carbamazepine induced stevens johnson syndrome has been reported in Indian population.

Recommendations

Based on these facts, it is recommended that the following statement is added to the package insert of carbamazepine containing products:

"It is also recommended that patients may be screened for HLA-B*1502 prior to initiating treatment with carbamazepine since it is a known risk factor for carbamazepine induced stevens johnson syndrome. Patients testing positive for this allele should not be treated with carbamazepine unless the benefit clearly outweighs the risk".

Important Events in PvPI

Launch of Consumer Reporting Form

NCC- PvPI launches medicines adverse effect reporting form for consumers/patients.



Release of consumer side effects reporting form (English) on 1st August 2014

The medicines side effect reporting form for consumers/patients was launched for direct participation of patients in the PvPI. This will be carried out on a pilot basis across the 150 AMCs to gauge its impact created among the consumers/patients and on whether they are comfortable with the reporting of ADRs. The ADR reporting form was launched during a national conference held in Ghaziabad to sensitize the consumers/patients and their vital role in the PvPI programme directly to achieve grand success of this programme.

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



Release consumer reporting forms in different regional languages on 16th December 2014

To broaden the scope of the PvPI through direct involvement of the patients, the NCC-PvPI released consumer reporting form. The reporting forms are available in English, Hindi and six regional languages viz Malayalam, Tamil, Oriya, Gujarati, Bengali and Kannada to encourage and facilitate direct consumer participation in PvPI.

Brain Storming Session for Coordinators of different parts of India



Brain storming session for coordinators of different states of India held on 30th May, 2014 at IPC, Ghaziabad

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 delegates 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



Release of PvPI poster on 25th November, 2014, at IPC, Ghaziabad

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. Marie Lindquist, Director, UMC and Mr. Christer Backman, MPA, Sweden.

Release of Guidance Document for PvPI



Release of guidance document in the presence of Health Secretary Sh. Lov Verma on 30th July, 2014 at New Delhi

The first version of "Guidance Document for PvPI" has been published by NCC-PvPI, IPC. The guidance document was formally released by Shri Lov Verma, Secretary, MoHFW, GOI during the 47th Drug Consultative Committee (DCC) meeting held on 30th July, 2014 at New Delhi. The Guidance document will act as a point of reference to ensure the best practices with respect to ADRs to help streamline the process in a uniform manner.

Certificate and Award of Appreciation for the Technical Associates working at AMCs under PvPI



Technical Associates of various AMCs appreciated by Secretary-cum-Scientific Director on 15th August 2014 at IPC Ghaziabad for their excellent work and outstanding contribution to PvPI

The NCC-PvPI presented certificate and award of appreciation to the technical associates working in various AMCs based on their length of service, quality and quantity of reporting ADRs, significant contribution for expanding the programme and feedback from their respective coordinators.

Dr. G. N. Singh, Secretary-cum-Scientific Director, IPC, Ghaziabad, appreciated their efforts and awarded the certificate in a function held on 15th August, 2014.

Following technical associates were awarded the appreciation certificate:

- Mr. Amitabh Ranjan, University College of Medical Sciences (UCMS), New Delhi
- Mr. Sachin Kumar, All India Institute of Medical Sciences (AIIMS), New Delhi
- Ms. Rachel Ranjini Paul, Christian Medical College (CMC), Vellore
- Mr. Ratan J. Lihite, Guwahati Medical College (GMC), Guwahati

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 PvPI in addition to existing Medanta, The Medicity, Gurgaon and Indraprastha Apollo Hospitals, New Delhi. PvPI 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 Pharmacopoeial standards and PvPI.



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 PvPI 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 PvPI. Different modes of communications used by PvPI are as follow:

Media communications

This includes press release and press briefings for journalists. All general activities and issues related to PvPI 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 PvPI to the stakeholders. The newsletter is provided free of cost to all the AMCs. 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.

- 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.

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

Issued in Public Interest
Indian Pharmacopoeia Commission
National Coordination Centre, Pharmacovigilance Programme of India,
Ministry of Health & Family Welfare Govt. of India,
Sector-23, Raj Nagar, Ghaziabad-201002
Email: pvpipi@ipcindia.net, ipcinfo@vsnl.net, www.ipc.gov.in

**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

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Pharmacovigilance Programme of India (PvPI)
To ensure safety of medicines
Over the years, PvPI has setup the benchmark to promote patients safety

ADRs Monitoring Centers Set up to monitor Adverse Drug Reactions (ADRs)	Patient empowerment Dedicated Helpline (toll free) & ADRs reporting forms in Hindi & other regional languages	Collaboration with National Health Programmes (NHP) Ensuring safety of medicines & vaccines	Training & Education More than 10,000 Health Care Professionals trained	Regulatory Intervention Evidence based recommendations to National Regulatory Bodies
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Join hands with PvPI to help the patient



Issued in Public Interest
Indian Pharmacopoeia Commission
National Coordination Centre, Pharmacovigilance Programme of India,
Ministry of Health & Family Welfare Govt. of India,
Sector-23, Raj Nagar, Ghaziabad-201002
Email: pvpipi@ipcindia.net, ipcinfo@vsnl.net, www.ipc.gov.in

PvPI Helpline (Toll-Free)
1800-180-3024
9:00 AM-5:30 PM, Monday to Friday

"WE BELIEVE IN INDIA"



- Where all citizens have right to access medical facility
- Where medicines are affordable for the entire population
- Where all healthcare professionals & patients can report adverse reactions with pharmaceutical products, as a concern of safety
- Where risk due to adverse event with medicine can be prevented
- Where the health of Indian population is ensured by minimizing the risks associated with use of medicines

We have started a journey of Pharmacovigilance, for saving lives

We invite you to join us
Pharmacovigilance Programme of India
1800-180-3024
PvPI Helpline (Toll-Free)
9:00 AM-5:30 PM, Monday to Friday

Issued in Public Interest
Indian Pharmacopoeia Commission
National Coordination Centre, Pharmacovigilance Programme of India,
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Emergence of Pharmacovigilance
"Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems"



Thalidomide Disaster
Many children in the 1960's, pictured here, were born with phocomelia as an adverse effect of the drug thalidomide, resulting in the shortening or absence of limbs.

"After Thalidomide Tragedy, WHO established International Drug Monitoring Programme to improve patient safety in 1961"

Pharmacovigilance Programme of India established with the vision to improve patient safety and welfare in Indian population by monitoring drug safety and thereby reducing the risk associated with use of medicines.

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Indian Pharmacopoeia Commission
National Coordination Centre, Pharmacovigilance Programme of India,
Ministry of Health & Family Welfare Govt. of India,
Sector-23, Raj Nagar, Ghaziabad-201002
Email: pvpipi@ipcindia.net, ipcinfo@vsnl.net, www.ipc.gov.in

- Safety of more than 1.27 billion population is a concern
- Usage of multi-model practices
- Genetic and ethnic variability
- Prevalence of different diseases
- Drug manufacturing process
- Medicines usage and availability



- Medicines safety is established in limited number of patients in clinical trials
- Less than 5000 human subjects are involved in clinical trials which allows to detect only common ADR
- Need to establish safety of medicines in special population that is children, elderly & pregnant women
- Even one ADR of a medicine in 10,000 population is considered as unsafe

**WE
INDIAN
PHARMACOPOEIA
COMMISSION
HELP TO PROMOTE
QUALITY AND SAFETY
OF MEDICINES**



- Indian Pharmacopoeia is the official book of standards for the drugs
- Guidance document for the healthcare professionals to promote rational use of generic medicines
- Pharmacovigilance Programme of India is to ensure the safety of medicines
- Collaboration with National and International organizations/partners for patient safety



 **Indian Pharmacopoeia Commission**
National Co-ordinating Centre, Pharmacopoeia in Programme of
Ministry of Health & Family Welfare Govt. of India
Room No. 23, Raj Bhawan, Ghazalabad 201002
Website: www.ipc.gov.in ipchindiabot.com www.ipc.gov.in

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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
MBBS, 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 ICSRs 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, PgDPV, Anaesthesiologist FMH,
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 great news, since it increases your total score even further.

Therése 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 that the 62,000 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 AMCs were working and programme was functional only at Delhi & NCR region. The propagation of programme and identification of new AMCs 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 AMCs coordinators to resolve the technical issues at AMCs.
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 lay man 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 (ISoP) 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 ICSRs.
12. Organize awareness classes in various pharmacy colleges in India. Beginning from Delhi-NCR region.

Minimize Adverse Drug Reactions Maximize Patient Safety

Iron Sucrose Induced
Angioedema



Tretinoin Induced
Retinoid dermatitis



Ofloxacin/Ornidazole
Induced Fixed Drug Eruption



Lamotrigine Induced
Rash and Fever



Amlodipine Induced
Pedal edema



Phenytoin Induced
Steven Johnson Syndrome



Report Adverse Drug Reactions to
Empower
Pharmacovigilance Programme of India

Appendices

1. ADR Reporting form for Healthcare Professional

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by healthcare professionals

INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India) Ministry of Health & Family Welfare Government of India Sector-23, Raj Nagar, Ghaziabad-201002 www.ipc.nic.in										(AMC/ NCC Use only)	
										AMC Report No.	
										Worldwide Unique	
A. PATIENT INFORMATION										12. Relevant tests / laboratory data with dates	
1. Patient Initials		2. Age at time of Event or date of birth		3. Sex ☐ M ☐ F							
				4. Weight ___ Kgs							
B. SUSPECTED ADVERSE REACTION										13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)	
5. Date of reaction started (dd/mm/yyyy)											
6. Date of recovery (dd/mm/yyyy)											
7. Describe reaction or problem											
										14. Seriousness of the reaction	
										☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly ☐ Life threatening ☐ Required intervention to prevent permanent impairment / damage ☐ Hospitalization/prolonged ☐ Other (specify) ☐ Disability	
										15. Outcomes	
										☐ Fatal ☐ Recovering ☐ Unknown ☐ Continuing ☐ Recovered ☐ Other (specify)	
C. SUSPECTED MEDICATION(S)											
S.No	8. Name (brand and /or generic name)	Manufacturer (if known)	Batch No./ Lot No. (if known)	Exp. Date (if known)	Dose used	Route used	Frequency	Therapy dates (if known, give duration)		Reason for use of prescribed for	
								Date started	Date stopped		
i.											
ii.											
iii.											
iv.											
S.No As per C	9. Reaction abated after drug stopped or dose reduced					10. Reaction reappeared after reintroduction					
	Yes	No	Unknown	NA	Reduced dose	Yes	No	Unknown	NA	If reintroduced dose	
i.											
ii.											
iii.											
iv.											
11. Concomitant medical product including self medication and herbal remedies with therapy dates (exclude those used to treat reaction)										D. REPORTER (see confidentiality section on first page)	
										16. Name and Professional Address : _____	
										Pin code: _____ E-mail _____	
										Tel. No. (with STD code): _____	
										Occupation _____ Signature _____	
17. Causality Assessment										18. Date of this report (dd/mm/yyyy)	

2. ADR Reporting form for Consumers in different vernaculars

2 (a) Bengali



MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

ঔষধের পার্শ্বক্রিয়া রিপোর্টিং ফর্ম (উপোভোক্তার জন্য)

Indian Pharmacopoeia Commission, National Coordination Centre- Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Government of India.

ভারতীয় ফার্মাকোপীয়া কমিশন, ভারতের জাতীয় সমন্বয় কেন্দ্র- জাতীয় ঔষধ সতর্কতার কর্মসূচী, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রালয়, ভারত সরকার

Version 1.0
সংস্করণ 1.0

1. Patient Details/ রোগীর বিবরণ				
Patient Initials/ রোগীর আদ্যক্ষর:	Gender/ লিঙ্গ (V): Male/ পুরুষ ☐ Female/ মহিলা ☐	Age (Year or Month)/ বয়স (বছর বা মাস):		
2. Health Information/ স্বাস্থ্য সংক্রান্ত তথ্য				
a. Reason(s) for taking medicine(s) (Disease/Symptoms)/ ঔষধ নেওয়ার কারণ (গুলি) (রোগ/উপসর্গ):				
b. Medicines Advised by/ ঔষধের পরামর্শদাতা (V): Doctor/ ডাক্তার ☐ Pharmacist/ ফার্মাসিস্ট ☐ Friends/Relatives/ বন্ধু/আত্মীয় ☐				
Self (Past disease experienced/No past disease experienced)/ বিগত রোগের অভিজ্ঞতা/বিগত রোগের কোনো অভিজ্ঞতা নেই ☐				
3. Details of Person Reporting the Side Effect/ পার্শ্বক্রিয়া প্রতিবেদনকর্তা				
Name (Optional)/ নাম (ঐচ্ছিক):				
Address/ ঠিকানা:				
Telephone No/ টেলিফোন নং:		Email/ ইমেইল:		
4. Details of Medicine Taking/Taken/ নেওয়া/নিচ্ছেন ঔষধের বিবরণ				
Name of Medicines/ ঔষধের নাম	Quantity of Medicines taken (e.g. 250 mg, Two times a day)/ নেওয়া ঔষধের পরিমাণ (যেমন 250 মিলিগ্রাম, দিনে দুই বার)	Expiry Date of Medicines/ ঔষধের মেয়াদ শেষ হওয়ার তারিখ	Date of Start of Medicines/ ঔষধ নেওয়া শুরু করার তারিখ	Date of Stop of Medicines/ ঔষধ নেওয়া বন্ধ করার তারিখ
Dosage form/ প্রকার (V): Tablet/ ট্যাবলেট ☐ Capsule/ ক্যাপসুল ☐ Injection/ ইনজেকশন ☐ Oral Liquids/ মৌখিক তরল ☐				
If Others (Please Specify)...../অন্য যদি কিছু থাকে (দয়া করে উল্লেখ করুন.....)				
5. About the Side Effect/ পার্শ্বক্রিয়ার সম্বন্ধে				
When did the side effect start?/ পার্শ্বক্রিয়া কখন থেকে শুরু হয়?		Side Effect is still Continuing (Yes/No)/ পার্শ্বক্রিয়া অব্যাহত রয়েছে (হ্যাঁ/না):		
When did the side effect stop?/ পার্শ্বক্রিয়া কবে থেকে বন্ধ হয়েছে?				
6. How bad was the Side Effect? (Please V the boxes that Apply)/ পার্শ্বক্রিয়া কতটা খারাপ ছিল? (প্রযোজ্য বাক্সে V প্রয়োগ করুন)				
☐ Did not affect daily activities/ দৈনন্দিন কাজকর্ম কে প্রভাবিত করে নি		☐ Affect daily activities/ দৈনন্দিন কাজকর্ম কে ব্যাহত করে		
☐ Admitted to hospital/ হাসপাতালে ভর্তি করা হয়		☐ Death/ মৃত্যু		
☐ Others/ অন্যান্য				
7. Describe the Side Effect (What did you do to manage the side effect?)/ পার্শ্বক্রিয়া বর্ণনা করুন (পার্শ্বক্রিয়া কে সামলানোর জন্য আপনি কি করতে হয়েছে?)				

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 ADR 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.

এই রিপোর্টিং স্বৈচ্ছিক, এতে কোন আইনি সংশ্লিষ্টতা নেই এবং রোগীর নিরাপত্তা উন্নত করাই এর উদ্দেশ্য। এই ফর্ম নেওয়া তথ্য পরবর্তী ব্যবস্থার জন্য এ. ডি. আর. মনিটরিং সেন্টার কে পাঠানো হবে। আপনার কাছে প্রগ্রাম কর্মকর্তাদের সঙ্গে সহযোগিতা করতে অনুরোধ করা হচ্ছে, যখন তারা আরো বিস্তারিত বিবরণের জন্য আপনার সাথে যোগাযোগ করবেন। আপনার কাছে সমস্ত তথ্যের বিবরণ না থাকলেও দয়া করে রিপোর্ট করুন।

Please turn the page to read the instructions
নিশ্চয়ই পরের পাতা পড়ুন

2 (b) Gujarati



MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

દવાઓની આડઅસરનું અહેવાલ ફોર્મ (ગ્રાહકો માટે)

Indian Pharmacopoeia Commission, National Coordination Centre- Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Government of India.

ભારતીય ઔષધસંગ્રહ પંચ (ઇન્ડિયન ફાર્માકોપીયા કમિશન), રાષ્ટ્રીય સંકલન કેન્દ્ર - ભારત ઔષધસતર્કતા કાર્યક્રમ (ફાર્માકોવિજિલન્સ પ્રોગ્રામ ઓફ ઇન્ડિયા), આરોગ્ય અને કુટુંબ કલ્યાણ મંત્રાલય, ભારત સરકાર.

Version 1.0
વર્ઝન 1.0

1. Patient Details/દર્દીની વિગત				
Patient Initials/દર્દીના પ્રથમ અક્ષરો:	Gender/ જાતિ (V): Male/ પુરુષ ☐ Female/ મહિલા ☐ Other/ અન્ય ☐	Age (Year or Month)/ ઉંમર (વર્ષ કે મહિના):		
2. Health Information/ આરોગ્યની માહિતી				
a. Reason(s) for taking medicine(s) (Disease/Symptoms)/ દવા (દવાઓ) લેવા માટેનું કારણ(કારણો) (રોગ/લક્ષણો):				
b. Medicines Advised by/ દવા લેવાની સલાહ આપનાર (V): Doctor/ ડોક્ટર ☐ Pharmacist/ ફાર્માસિસ્ટ ☐ Friends/Relatives/ મિત્રો/સંબંધી ☐				
Self (Past disease experienced/No past disease experienced)/ પોતે (અગાઉ રોગનો અનુભવ/અગાઉ રોગનો અનુભવ નહીં) ☐				
3. Details of Person Reporting the Side Effect/ આડઅસર જણાવતા હોય તે વ્યક્તિની વિગત				
a. Name (Optional)/ નામ (વૈકલ્પિક):				
b. Address/ સરનામું:				
Telephone No./ ટેલીફોન નંબર:		Email/ ઇમેઇલ:		
4. Details of Medicine Taking/Taken/ દવાઓ લેતા હો/લીધી હોય તેની વિગત				
Name of Medicines/ દવાઓનું નામ	Quantity of Medicines taken (e.g. 250 mg, Two times a day)/ લીધેલ દવાનું પ્રમાણ (દા. ત. 250 મિલીગ્રામ, દરરોજ બે વખત)	Expiry Date of Medicines/ દવાઓની એક્સપાયરી તારીખ	Date of Start of Medicines/ દવાઓ શરૂ કર્યાની તારીખ	Date of Stop of Medicines/ દવાઓ બંધ કર્યાની તારીખ
Dosage form/ દવાનું સ્વરૂપ (V): Tablet/ ગોળી ☐ Capsule/ કેપ્સ્યુલ ☐ Injection/ ઇન્જેક્શન ☐ Oral Liquids/ મુખ વાટે પ્રવાહી ☐				
If Others (Please Specify)...../ જો અન્ય (સ્પષ્ટ કરો.....)				
5. About the Side Effect/ આડઅસર વિશે				
When did the side effect start?/ આડઅસર ક્યારે શરૂ થઈ હતી?		Side Effect is still Continuing (Yes/No)/ આડઅસર ચાલુ છે (હા/ના)		
When did the side effect stop?/ આડઅસર ક્યારેય બંધ થઈ હતી?				
6. How bad was the Side Effect? (Please V the boxes that Apply)/ આડઅસર કેટલી ખરાબ હતી? (મહેરબાની કરીને લાગુ પડે તે બોક્સ પર V કરો)				
☐ Did not affect daily activities/ રોજિંદી કામગીરી પર અસર કરતી નહોતી		☐ Affect daily activities/ રોજિંદી કામગીરીને અસર થઈ હતી		
☐ Admitted to hospital/ હોસ્પિટલમાં દાખલ કર્યા હતા		☐ Death/ મૃત્યુ		
☐ Others/ અન્ય				
7. Describe the Side Effect (What did you do to manage the side effect?)/ આડઅસર જણાવો (આડઅસર નિવારવા તમે શું કર્યું હતું?)				

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આ રિપોર્ટિંગ સ્વૈચ્છિક છે, કોઈ કાયદેસર સૂચિતાર્થ સામેલ નથી અને દર્દીની સલામતી સુધારવાનો હેતુ છે. તમારી સહયોગીતા મૂલ્યવાન છે. આ ફોર્મમાં આપવામાં આવતી માહિતી રોગોપચ માટે એડીબાર મોનિટરિંગ સેન્ટરને મોકલવામાં આવશે. તેઓ વધુ વિગત માટે તમારી સંપર્ક કરે ત્યારે સહકાર આપવા તમને વિનંતી છે. તમામ માહિતી ન હોય તો પણ મહેરબાની કરીને જરૂરી માહિતી હોય તે આપો.

Please turn the page to read the instructions
સુચનો વાંચવા મહેરબાની કરીને પાનું ફેરવો

2 (c) Hindi



MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

औषधि दुष्प्रभाव सूचना फॉर्म (उपभोक्ताओं के लिए)

Indian Pharmacopoeia Commission, National Coordination Centre- Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Government of India.

भारतीय भेषज संहिता आयोग, राष्ट्रीय समन्वय केंद्र - भारतीय फार्माकोविजिलेंस कार्यक्रम, स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार।

Version 1.0
संस्करण 1.0

1. Patient Details/ रोगी का विवरण

Patient Initials/ रोगी के आद्याक्षर: Gender/ लिंग (V): Male/ पुरुष ☐ Female/ स्त्री ☐ Age (Year or Month)/ आयु (वर्ष या माह):

2. Health Information/ स्वास्थ्य संबंधी जानकारी

a. Reason(s) for taking medicine(s)/ दवा(दवाएं) लेने का कारण (रोग/लक्षण):

b. Medicines Advised by/ दवाई की सलाह देने वाला (V): Doctor/ डॉक्टर ☐ Pharmacist/ फार्मासिस्ट ☐ Friends/Relatives/ मित्र/ रिश्तेदार ☐ Self (Past disease experienced/No past disease experienced)/ स्वयं (पूर्व बीमारी का अनुभव/पूर्व बीमारी का कोई अनुभव नहीं) ☐

3. Details of Person Reporting the Side Effect/ दुष्प्रभाव की सूचना देने वाले व्यक्ति का विवरण

Name (Optional)/ नाम (वैकल्पिक):

Address/ पता:

Telephone No/ टेलीफोन नं.: Email/ ईमेल:

4. Details of Medicine Taking/Taken/ ली जा रही है / ली जा चुकी दवाई का विवरण

Name of Medicines/ दवाइयों के नाम	Quantity of Medicines taken (e.g. 250 mg, Two times a day)/ ली गई दवाई की मात्रा (उदाहरण के लिए 250 मिग्रा, एक दिन में दो बार)	Expiry Date of Medicines/ दवा के निष्क्रिय होने की तिथि	Date of Start of Medicines/ दवाइयां आरंभ करने की तिथि	Date of Stop of Medicines/ दवाइयां रोकने की तिथि

Dosage form/खुराक का स्वरूप (V): Tablet/ गोली (टेबलेट) ☐ Capsule/ कैप्सूल ☐ Injection/ इंजेक्शन ☐ Oral Liquids/ मौखिक तरल ☐ If Others (Please Specify)...../यदि अन्य (कृपया निर्दिष्ट करें).....

5. About the Side Effect/ दुष्प्रभाव के बारे में

When did the side effect start?/ दुष्प्रभाव की शुरुआत कब हुई थी? Side Effect is still Continuing (Yes/No)/ दुष्प्रभाव अभी भी जारी है (हां/नहीं): ☐ हां ☐ नहीं

When did the side effect stop?/ दुष्प्रभाव कब समाप्त हुआ था? क्या दुष्प्रभाव जारी है (हां/नहीं): ☐ हां ☐ नहीं

6. How bad was the Side Effect? (Please V the boxes that Apply)/ दुष्प्रभाव कितने हानिकारक थे? (कृपया जो लागू हो, उस पर V का निशान लगाएं)

☐ Did not affect daily activities/ दैनिक गतिविधियां प्रभावित नहीं हुई थी ☐ Affect daily activities/ दैनिक गतिविधियां प्रभावित हुई

☐ Admitted to hospital/ अस्पताल ले जाना पड़ा ☐ Death/ मृत्यु

☐ Others/ अन्य

7. Describe the Side Effect (What did you do to manage the side effect?)/ दुष्प्रभाव की व्याख्या करें (आपने दुष्प्रभावों से छुटकारा प्राप्त करने के लिए क्या किया)?

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यह रिपोर्टिंग स्वैच्छिक है, कोई कानूनी निहितार्थ नहीं है और इसका लक्ष्य मरीज की सुरक्षा में सुधार करना है। आपकी सक्रिय भागीदारी मूल्यवान है। इस फॉर्म में दी गई जानकारी की अनुवर्ती कार्रवाई हेतु एडीआर निगरानी केंद्र को भेजा जाएगा। आपसे अनुरोध है कि आप कार्यक्रम के अधिकारियों का सहयोग करें जब वे अधिक जानकारी प्राप्त करने के लिए आपसे संपर्क करें। कृपया पूर्ण जानकारी न होने पर भी सूचित करें।

Please turn the page to read the instructions
निर्देशों को पढ़ने के लिए कृपया पेज पलटें

2(d) Kannada



MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

ಔಷಧಿಗಳ ಅಡ್ಡಪರಿಣಾಮದ ವರದಿಯ ಫಾರ್ಮ್ (ಗ್ರಾಹಕರಿಗೆ)

Indian Pharmacopoeia Commission, National Coordination Centre- Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Government of India.

ಭಾರತೀಯ ಔಷಧ ಶಾಸ್ತ್ರ ಆಯೋಗ, ರಾಷ್ಟ್ರೀಯ ಸಮನ್ವಯ ಕೇಂದ್ರ - ಭಾರತೀಯ ಔಷಧ ಸಹ ಶಾಂತಿಪಾಲನಾ ಕಾರ್ಯಕ್ರಮ, ಆರೋಗ್ಯ ಮತ್ತು ಕುಟುಂಬ ಕಲ್ಯಾಣ ಸಚಿವಾಲಯ, ಭಾರತ ಸರ್ಕಾರ.

Version 1.0

1. Patient Details/ ರೋಗಿಯ ವಿವರ

Patient Initials/ ರೋಗಿಯ ವಿವರ: Gender/ ಲಿಂಗ (V): Male/ ಪುರುಷ ☐ Female/ ಸ್ತ್ರೀ ☐ Age (Year or Month)/ ವಯಸ್ಸು (ವರ್ಷ ಅಥವಾ ಮಾಸ):

2. Health Information/ ಆರೋಗ್ಯ ಮಾಹಿತಿ

a. Reason(s) for taking medicine(s)/ ಔಷಧ ತೆಗೆದುಕೊಳ್ಳಲು ಇರುವ ಕಾರಣ (ಗಳು) (ರೋಗ/ಲಕ್ಷಣಗಳು):

b. Medicines Advised by/ ಔಷಧಿಗಳನ್ನು ಸೂಚಿಸಿದವರು (V): Doctor/ವೈದ್ಯರು ☐ Pharmacist/ಔಷಧ ವ್ಯಾಪಾರಿ ☐ Friends/Relatives/ ಸ್ನೇಹಿತರು / ಸಂಬಂಧಿಗಳು ☐ Self (Past disease experienced/No past disease experienced)/ ಸ್ವತಃ (ಹಿಂದಿನ ರೋಗದ ಅನುಭವ / ಯಾವುದೇ ಹಿಂದಿನ ರೋಗದ ಅನುಭವ ಇಲ್ಲ) ☐

3. Details of Person Reporting the Side Effect/ ಅಡ್ಡ ಪರಿಣಾಮವನ್ನು ವರದಿ ಮಾಡುವ ವ್ಯಕ್ತಿಯ ವಿವರಗಳು

Name (Optional)/ ಹೆಸರು (ಐಚ್ಛಿಕ):

Address/ ವಿಳಾಸ:

Telephone No/ ದೂರವಾಣಿ ಸಂಖ್ಯೆ: Email/ ಇಮೇಲ್:

4. Details of Medicine Taking/Taken/ ತೆಗೆದುಕೊಳ್ಳುತ್ತಿರುವ/ತೆಗೆದುಕೊಂಡ, ಔಷಧ ವಿವರಗಳು

Name of Medicines/ ಔಷಧಿಗಳ ಹೆಸರು	Quantity of Medicines taken (e.g. 250 mg, Two times a day)/ ತೆಗೆದುಕೊಂಡ ಔಷಧಿಗಳ ಪ್ರಮಾಣ (ಉದಾ 250 ಮಿಗ್ರಾಂ, ದಿನಕ್ಕೆ ಎರಡು ಬಾರಿ)	Expiry Date of Medicines/ ಔಷಧಿಗಳ ಕೊನೆಯ ದಿನಾಂಕ	Date of Start of Medicines/ ಔಷಧಿಗಳನ್ನು ಆರಂಭಿಸಿದ ದಿನಾಂಕ	Date of Stop of Medicines/ ಔಷಧಿಗಳನ್ನು ನಿಲ್ಲಿಸಿದ ದಿನಾಂಕ

Dosage form/ ಡೋಸೇಜ್ ಫಾರ್ಮ್ (V): Tablet/ಟ್ಯಾಬ್ಲೆಟ್ ☐ Capsule/ಕ್ಯಾಪ್ಸುಲ್ ☐ Injection/ಇಂಜೆಕ್ಷನ್ ☐ Oral Liquids/ ಬಾಯಿಯ ದ್ರವ ☐ If Others (Please Specify)...../ ಇತರೆ ಇದ್ದಲ್ಲಿ (ದಯವಿಟ್ಟು ಸೂಚಿಸಿ).....

5. About the Side Effect/ಅಡ್ಡ ಪರಿಣಾಮದ ಬಗ್ಗೆ

When did the side effect start?/ ಅಡ್ಡ ಪರಿಣಾಮ ಯಾವಾಗ ಆರಂಭವಾಯಿತು? Side Effect is still Continuing (Yes/No)/ ಅಡ್ಡ ಪರಿಣಾಮ ಮುಂದುವರಿದಿದೆ (ಹೌದು/ಇಲ್ಲ): ☐ ಹೌದು ☐ ಇಲ್ಲ

When did the side effect stop?/ ಅಡ್ಡ ಪರಿಣಾಮ ಯಾವಾಗ ನಿಂತಿತು? ಅಡ್ಡ ಪರಿಣಾಮ ಮುಂದುವರಿದಿದೆ (ಹೌದು/ಇಲ್ಲ): ☐ ಹೌದು ☐ ಇಲ್ಲ

6. How bad was the Side Effect? (Please V the boxes that Apply)/ ಅಡ್ಡ ಪರಿಣಾಮ ಎಷ್ಟು ಹಾನಿಕಾರಕವಾಗಿತ್ತು (ಅನ್ವಯವಾಗುವ ಪಟ್ಟಿಗಳನ್ನು ದಯವಿಟ್ಟು V ಮಾಡಿ)

☐ Did not affect daily activities/ ದೈನಂದಿನ ಚಟುವಟಿಕೆಗಳ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರಲಿಲ್ಲ ☐ Affect daily activities/ ದೈನಂದಿನ ಚಟುವಟಿಕೆಗಳ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರಿದೆ

☐ Admitted to hospital/ ಆಸ್ಪತ್ರೆಗೆ ದಾಖಲಾಗಿದೆ ☐ Death/ ಮರಣ

☐ Others/ ಇತರೆ

7. Describe the Side Effect (What did you do to manage the side effect?)/ ಅಡ್ಡ ಪರಿಣಾಮವನ್ನು ನಿವಾರಿಸಲು ನೀವು ಏನು ಮಾಡಿದಿರಿ?

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 ADR 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.

ಈ ವರದಿಯು ಸ್ವಯಂಚ್ಛೇಷ್ಠವಾಗಿದೆ, ಯಾವುದೇ ಕಾನೂನು ತೀರ್ಮಾನಗಳನ್ನು ಹೊಂದಿಲ್ಲ ಮತ್ತು ರೋಗಿಯ ಆರೋಗ್ಯವನ್ನು ಸುಧಾರಿಸುವ ಗುರಿ ಹೊಂದಿದೆ. ನಿಮ್ಮ ಸಕ್ರಿಯ ಸಹಭಾಗಿತ್ವ ಮಹತ್ವದ್ದಾಗುತ್ತದೆ. ಈ ಸಮಸ್ಯೆಯಲ್ಲಿ ಎದುರಿಸಿದ ಮಾಹಿತಿಯನ್ನು ಮುಂದಿನ ಪ್ರಕ್ರಿಯೆಗಾಗಿ ವಿಶಿಷ್ಟ ಮಾಹಿತಿಗಾಗಿ ಸೇರಿಕೊಳ್ಳುವುದಾಗಿರುತ್ತದೆ. ಹೆಚ್ಚಿನ ವಿವರಗಳಿಗಾಗಿ ಕಾರ್ಯಕ್ರಮ ಅಧಿಕಾರಿಗಳು ನಿಮ್ಮನ್ನು ಸಂಪರ್ಕಿಸಿದಾಗ ದಯವಿಟ್ಟು ಸಹಕರಿಸಲು ನಿಮ್ಮನ್ನು ಕೋರಲಾಗಿದೆ. ನಿಮ್ಮಲ್ಲಿ ಏನೂ ಮಾಹಿತಿ ಇಲ್ಲದಿದ್ದಾಗಲೂ ಸಹ ದಯವಿಟ್ಟು ಅದನ್ನು ವರದಿ ಮಾಡಿ.

Please turn the page to read the instructions

2(e) Malayalam



ഉപഭോക്താക്കൾക്ക് മരുന്നുകളുടെ പാർശ്വ ഫലങ്ങൾ അറിയിക്കുവാനുള്ള

ഫോറം

ഇന്ത്യൻ ഫാർമക്കോപ്പിയോ കമ്മീഷൻ, ദേശീയ ഏകോപന കേന്ദ്രം, ഇന്ത്യൻ ഫാർമക്കോ വിജിലൻസ് പ്രോഗ്രാം, ആരോഗ്യ കുടുംബക്ഷേമ മന്ത്രാലയം, ഭാരത് സർക്കാർ

1. രോഗിയെ സംബന്ധിച്ച വിവരങ്ങൾ

പേരും ഇനിയും ആണ് ☐ പെൺ ☐ ഇതരം ☐ വയസ്സ് (ജനന തീയതി) :

2. രോഗിയെ സംബന്ധിച്ച വിവരങ്ങൾ

എ) മരുന്നുകൾ കഴിക്കുന്നത് റായ് കാര്യങ്ങൾ (രോഗം/ലക്ഷണങ്ങൾ) :

ബി) മരുന്ന് നിർദ്ദേശകൻ () : ഡോക്ടർ ☐ ഫാർമസിസ്റ്റ് ☐ സുഹൃത്തുക്കൾ/ബന്ധുക്കൾ ☐ സ്വയം ☐

3. പാർശ്വ ഫലങ്ങൾ അറിയിക്കുന്ന വ്യക്തിയെ സംബന്ധിച്ച വിവരങ്ങൾ

പേര് :

മേൽവിലാസം :

4. കഴിക്കുന്ന/കഴിച്ച് മരുന്നുകളെ സംബന്ധിച്ച വിവരങ്ങൾ

മരുന്നിന്റെ പേര്	ഉപയോഗിച്ച മരുന്നുകളുടെ എണ്ണം ഉദാ 250 മി ഗ്രാം 5 മില്ലി 2 നേരം	കാലാവധി	ഉപയോഗം തുടങ്ങിയ ദിവസം	ഉപയോഗം നിർത്തിയ ദിവസം

ഏത് തരം മരുന്ന് () : ഗുളിക ☐ ക്യാപ്സുൾ ☐ കുത്തി വെയ്പ്പ് ☐ മറ്റുള്ളവ ☐

5. പാർശ്വ ഫലവിവരങ്ങൾ

എപ്പോൾ തുടങ്ങി ഇപ്പോഴും തുടരുന്നു ☐ ഓ

എപ്പോൾ അവസാനിച്ചു

6. പാർശ്വ ഫലത്തിന്റെ ഗുരുതരത

- ☐ ദൈനംദിന പ്രവർത്തിയെ ബാധിച്ചു ☐ ദൈനംദിന പ്രവർത്തനങ്ങളെ ബാധിച്ചില്ല
- ☐ ആശുപത്രിയിൽ പ്രവേശിപ്പിച്ചു ☐ മരണം സംഭവിച്ചു
- ☐ മറ്റ് പാർശ്വ ഫലങ്ങൾ ഉണ്ട് ☐ ഹൃദയം

7. പാർശ്വ ഫലത്തെ കുറിച്ച് വിവരിക്കുക

ഈ റിപ്പോർട്ട് സമയത്ത് നൽകുന്നതാണ്. പ്രത്യേക നിയമ വ്യവസ്ഥയൊന്നും ബാധകമല്ല. രോഗിയുടെ സുരക്ഷയാണ് ലക്ഷ്യം. ഇതിൽ ഏതൊരു മരുന്നും സജീവ പങ്കാളിത്തം ആവശ്യമാണ്. ഈ ഫോറം വഴി നൽകിയിട്ടുള്ള വിവരങ്ങൾ എഡിത്ത് നിരീക്ഷണ കേന്ദ്രത്തിലേക്ക് അയക്കുന്നതാണ്. ഈ പദ്ധതിയുമായി ബന്ധപ്പെട്ട ഉദ്യോഗസ്ഥർ സമീപിക്കുമ്പോൾ കൂടുതൽ വിവരങ്ങൾ നൽകുവാനും പൂർണ്ണമായ വിവരങ്ങൾ ലഭ്യമാക്കിയിട്ടില്ലാത്ത പാർശ്വഫലങ്ങൾ അറിയിക്കുവാനും താൽപ്പര്യപ്പെടുന്നു.

2(f) Oriya

Version 1.0

വ്ഷ 1.0



MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

ଔଷଧର କୁପ୍ରଭാവ ସୂଚନା ଫର୍ମ (ଉପଭୋକ୍ତାଙ୍କ ନିମନ୍ତେ)

Indian Pharmacopoeia Commission, National Coordination Centre - Pharmacovigilance Programme of India,
Ministry of Health & Family Welfare, Government of India.

ଭାରତୀୟ ଲେଖକ ଆୟୋଗ, ରାଷ୍ଟ୍ରୀୟ ସହଯୋଗ କେନ୍ଦ୍ର, ଭାରତ ଲେଖକ ସଂଗଠନ ଏବଂ ପାର୍ମାବୋରିଜିନାଲ୍ କାର୍ଯ୍ୟକ୍ରମ, ସ୍ୱାସ୍ଥ୍ୟ ଏବଂ କଲ୍ୟାଣ
ମନ୍ତ୍ରାଳୟ, ଭାରତ ସରକାର ।

୧. ରୋଗୀର ବିବରଣୀ

ରୋଗୀର ହସ୍ତାକ୍ଷର: ଲିଙ୍ଗ (V): ପୁ. ☐ ଶ୍ରୀ. ☐ ଅନ୍ୟ ☐ ବୟସ (ବର୍ଷ କିମ୍ବା ମାସ):

୨. ଔଷଧ ସୂଚନା

(କ) ଔଷଧ ସେବନ ର କାରଣ (ରୋଗ/ଲକ୍ଷଣ):

(ଖ) ଔଷଧ ପରୀକ୍ଷା ଦାତା (V): ଡାକ୍ତର ☐ ପାର୍ମାଣିକ ☐ ବନ୍ଧୁ/ସମ୍ପର୍କୀୟ ☐ ନିଜେ (ଅତୀତ ରୋଗର ଅଭିଜ୍ଞତା / ଅତୀତ ରୋଗର ଅଭିଜ୍ଞତା ନାହିଁ) ☐

୩. କୁପ୍ରଭାବ ରିପୋର୍ଟ କରୁଥିବା ବ୍ୟକ୍ତି ର ବିବରଣୀ

ନାମ (ଲକ୍ଷ୍ମୀ):

ଠିକଣା:

ଟେଲିଫୋନ୍ ନମ୍ବର :

ଇମେଲ୍ :

୪. ଔଷଧ ସେବନ କରିଥିବା/କରୁଥିବା ସମ୍ପର୍କ ବିବରଣୀ

ଔଷଧର ନାମ	ଔଷଧ ର ପରିମାଣ (ଉଦାହରଣ ୨୫୦ ମି.ଗ୍ରା. ଟବ୍ଲେଟ୍ ୨ ଥର)	ଔଷଧ ସମାପ୍ତ (ସଂପୂର୍ଣ୍ଣ) ର ତାରିଖ	ଔଷଧ ସେବନ ଆରମ୍ଭ କରିବାର ତାରିଖ	ଔଷଧ ସେବନ ବନ୍ଦ କରିବାର ତାରିଖ

ଖୁରାକ ର ପ୍ରକାର (V): ବଡ଼ ☐ କ୍ୟାପସୁଲ୍ ☐ ଇନ୍‌ଜେକ୍ସନ୍ ☐ ସିରସ୍ ☐ ଯଦି ଅନ୍ୟକିଛି (ଦୟାକରି ବର୍ଣ୍ଣନା କରନ୍ତୁ)

୫. କୁପ୍ରଭାବ ସମ୍ବନ୍ଧୀୟ

କୁପ୍ରଭାବ ଆରମ୍ଭ କେବେ ହେଲା ? କୁପ୍ରଭାବ ଲାଗି ଅଛି (ହଁ/ନା):

କୁପ୍ରଭାବ ବନ୍ଦ କେବେ ହେଲା ?

୬. କୁପ୍ରଭାବ ର ଖ୍ୟାତୀକାରିତା ? (ଦୟାକରି କୋଠାରୁ ରେ / ବିଅନ୍ତ)

☐ ଦୈନନ୍ଦିନ କାର୍ଯ୍ୟରେ ପ୍ରଭାବିତ ହେଉନଥିଲା ☐ ଦୈନନ୍ଦିନ କାର୍ଯ୍ୟରେ ପ୍ରଭାବିତ ହେଉଥିଲା

☐ ଡାକ୍ତରଖାନାରେ ଭର୍ତ୍ତି ହେଉଥିଲେ ☐ ପୁରୁଷ

☐ ଅନ୍ୟ

୭. କୁପ୍ରଭାବ ର ବର୍ଣ୍ଣନା (କୁପ୍ରଭାବ କୁ ଲୋକିକା ପାଇଁ କ'ଣ କରିଛନ୍ତି?)

ଏହି ସୂଚନା ସ୍ୱେଚ୍ଛାସ୍ତ୍ରରେ ଅଟେ, ଏହାର କିଛି ବୈଧ ସମ୍ବନ୍ଧ ନାହିଁ । ରୋଗୀର ସୁରକ୍ଷା ହେଉଛି ଏହାର ଲକ୍ଷ୍ୟ । ଆପଣଙ୍କ ସ୍ୱାସ୍ଥ୍ୟ ଓ ଅନ୍ୟ ସମ୍ପର୍କୀୟ ସମସ୍ତ ସୂଚନା ପ୍ରତିବଦ୍ଧ ଔଷଧ ପ୍ରଭାବ କେନ୍ଦ୍ର କୁ ଅନୁସନ୍ଧାନ ପାଇଁ ପଠାଯିବ । ଯେତେବେଳେ କାର୍ଯ୍ୟକାରୀ ଅଧିକ ସୂଚନା ପାଇଁ ଯୋଗାଯୋଗ କରିବେ ଆପଣଙ୍କୁ ସହଯୋଗ ପାଇଁ ଅନୁରୋଧ । ଆପଣଙ୍କ ପାଖରେ ସମ୍ପର୍କୀୟ ସୂଚନା ନଥିଲେ ମଧ୍ୟ ରିପୋର୍ଟ କରନ୍ତୁ ।

ସୂଚନା ପଢ଼ିବା ପାଇଁ ଦୟାକରି ପୃଷ୍ଠା ପଢନ୍ତୁ ।

2(g) Tamil



MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

மருந்துகளின் பக்க விளைவுகள் குறித்து புகார் அளிப்பதற்கான படிவம் (நுகர்வோர்களுக்கானது)

Indian Pharmacopoeia Commission, National Coordination Centre- Pharmacovigilance Programme of India,
Ministry of Health & Family Welfare, Government of India.

இந்திய மருந்தியல் ஆணையம், தேசிய ஒருங்கிணைப்பு மையம் - இந்திய மருந்தியல்சார் புலனாய்வுத் திட்டம்,
சுகாதாரம் & குடும்ப நல அமைச்சகம், இந்திய அரசு.

Version 1.0
பதிப்பு 1.0

1. Patient Details/ நோயாளியின் விவரங்கள்

Patient Initials/நோயாளியின் முதலெழுத்துக்கள்: Gender/ பால (V): Male/ஆண் ☐ Female/பெண் ☐ Other/ பிறர் ☐ Age (Year or Month)/ வயது (ஆண்டு அல்லது மாதம்):

2. Health Information/ உடல்நலம் பற்றிய தகவல்

a. Reason(s) for taking medicine(s) (Disease/Symptoms)/ மருந்து(கள்) உட்கொள்வதற்கான காரணங்கள் (நோய் கு அறிகுறிகள்):

b. Medicines Advised by/ மருந்துகளை உட்கொள்ள பரிந்துரைத்தவர் (V): Doctor/ டாக்டர் ☐ Pharmacist/ மருந்தாணை ☐ Friends/Relatives/ நண்பர்/உறவினர்கள் ☐ Self (Past disease experienced/No past disease experienced)/ சுயமாக (முன்னர் ஏற்பட்ட நோயின் அனுபவம் / நோய் முன்னர் ஏற்பட்ட அனுபவம் இல்லை) ☐

3. Details of Person Reporting the Side Effect/ பக்க விளைவுகள் குறித்து புகார் அளிக்கும் நபரின் விவரங்கள்

a. Name (Optional)/ பெயர் (விருப்பப்பட்டால்):

b. Address/ முகவரி:

Telephone No./ தொலைபேசி எண்: Email/ இ-மேயில்:

4. Details of Medicine Taking/Taken/ எடுத்துக் கொள்ளும் / எடுத்துக் கொண்ட மருந்தின் விவரங்கள்

Name of Medicines/ மருந்துகளின் பெயர்கள்	Quantity of Medicines taken (e.g. 250 mg, Two times a day)/ எடுத்துக் கொண்ட மருந்துகளின் அளவு(எ.க. 250மிகி, ஒரு நாளைக்கு இரு முறை)	Expiry Date of Medicines/ மருந்துகளின் காலாவதி தேதி	Date of Start of Medicines/ மருந்துகளை உட்கொள்ள தொடங்கிய தேதி	Date of Stop of Medicines/ மருந்துகளை நிறுத்திய தேதி

Dosage form/ மருந்தின் வடிவம் (V): Tablet/ மாத்திரை ☐ Capsule/ கேப்சூல் ☐ Injection/ ஊச ☐ Oral Liquids/ வாய்வழி திரவம் ☐ If Others (Please Specify.....)/ பிற(தயவுசெய்து குறிப்பிடவும்)

5. About the Side Effect/ பக்க விளைவுகள் பற்றிய விவரம்

When did the side effect start?/ பக்க விளைவு எப்போது இருந்து ஆரம்பித்தது? Side Effect is still Continuing/ பக்க விளைவு தொடர்கிறதா(ஆம் / இல்லை) ☐

When did the side effect stop?/ பக்க விளைவு எப்போது நின்றது?

6. How bad was the Side Effect? (Please v the boxes that Apply)/ பக்க விளைவு எந்த அளவிற்கு மேலமானதாக இருந்தது (பொருத்திலும் பெட்டியில் தயவு செய்து V செய்யவும்)

☐ Did not affect daily activities/ தினசரி நடவடிக்கைகளைப் பாதிக்கவில்லை	☐ Affect daily activities/ தினசரி நடவடிக்கைகளைப் பாதித்தது
☐ Admitted to hospital/ மருத்துவமனையில் சேர்ந்தேன்	☐ Death/ மரணம்
☐ Others/ பிற	

7. Describe the Side Effect (What did you do to manage the side effect?)/ பக்க விளைவு பற்றிய தகவல்களை விவரித்து எழுதவும் (பக்க விளைவை சமாளிக்க நீங்கள் என்ன செய்தீர்கள்?)

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 ADR 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.

இந்த அறிக்கை தன்னார்வமானது. சட்டபூர்வ நடவடிக்கை எவ்வு இது நோக்கம் அல்ல. இதை நோக்கம் நோயாளியின் பாதுகாப்பை மேம்படுத்துவது மட்டுமே. உங்களின் ஆர்வமான பங்கேற்பு மதிப்பிடப்படும். இந்தப் படிவத்தில் தகவல் தொடர்பு கண்காணிக்கப்படுவதற்காக ஏடிஆர் மையத்திற்கு அனுப்பி வைக்கப்படும். கூடுதல் விவரங்களுக்கு உங்களைத் திட்ட அலுவலர்கள் தொடர்பு கொள்ளும்போது ஒத்துழைப்பை உங்களைக் கேட்டுக் கொள்கிறோம். எல்லா தகவல்களும் இல்லை என்றாலும்கூட இப்படிவத்தைக் கொண்டு அறிக்கையை பதிவு செய்ய சமர்ப்பிக்கலாம்.

Please turn the page to read the instructions
நிரப்புவதற்கான வழிகாட்டி குறிப்புகளைப் படிப்பதற்கு தயவுசெய்து அடுத்த பக்கத்தைப் பார்க்கவும் என

2 (h) English



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.

Version 1.0

1. Patient Details

Patient Initials: Gender (V): Male ☐ Female ☐ Other ☐ Age (Year or Month) :

2. Health Information

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

b. Medicines Advised by (V): 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 Taking/Taken

Name of Medicines	Quantity of Medicines taken (e.g. 250 mg, Two times a day)	Expiry Date of Medicines	Date of Start of Medicines	Date of Stop of Medicines
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy

Dosage form (V) : Tablet ☐ Capsule ☐ Injection ☐ Oral Liquids ☐ If Others (Please Specify.....)

5. About the Side Effect

When did the side effect start? Side Effect is still Continuing (Yes/No): ☐

When did the side effect stop?

6. How bad was the Side Effect? (Please v the boxes that Apply)

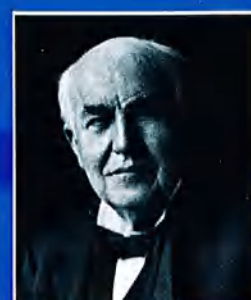
☐ Did not affect daily activities	☐ Affect daily activities
☐ Admitted to hospital	☐ Death
☐ Others	

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

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 ADR 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.

Please turn the page to read the instructions

AMCs Under Pharmacovigilance Programme of India



"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

S. No	State	Name of AMCs	S. No	State	Name of AMCs
1.	Andhra Pradesh	Andhra Medical College, King George Hospital (KGH), Jagadamba Area, KGH Down Rd, Maharajpet, Visakhapatnam-530002	40.	Karnataka	Karnataka Institute Of Medical Sciences, P. B. Road, Vidyanagar, Hubli-580021
2.		Guntur Medical College, Kanna Vari Thota, Guntur-522004	41.		Kasturba medical College, Light House Hill Road, Manipal-575001
3.		Peoples Education Society Institute of Medical Sciences and Research, Kuppam, Chittoor District-517425	42.		Mandya Institute of Medical Sciences (MIMS), District Hospital Campus, Mandya-571401
4.		S. V. Medical College, Alipiri Road, Tirupati, Chittoor District-517507	43.		SDS Tuberculosis Research Centre & Rajiv Gandhi Institute of Chest Disease, Someshwaranagar 1st Main Road, Bengaluru-560029
5.		Kurnool Medical College, Budhawarpet, Kurnool-518002	44.		St. John's Medical College, Sarjapur Road, Bengaluru-560034
6.		Rajiv Gandhi Institute of Medical Sciences, Near Balaga, Srikakulam-532001	45.		Vydehi Institute of Medical Sciences and Research Centre, 82, Nallurahalli, Near BMT 18th Depot, Whitefield, Bengaluru-560066
7.	Assam	Govt. Medical College, Narakachal Hill Top, Guwahati-781032	46.	Karnataka	Indira Gandhi Institute of Child Health, South Hospital Complex, Near NIMHANS, Hombegowda Nagar, Bengaluru-560001
8.		Silchar Medical College & Hospital, Chungoor, Silchar-788014	47.		M.S. Ramiah Medical College, MSR Nagar, Gokula, Bengaluru-560054
9.		Jorhat Medical College & Hospital, Kushal Konwar Path, Barbheta, P.O. Jorhat-785001	48.		SDM College of Medical Sciences & Hospital, Manjushree Nagar, Sattur, Dharwad-580009
10.	Bihar	Indira Gandhi Institute of Medical Sciences, Bailey Road, Sheikhpura, Patna-800014	49.	Kerala	Govt. Medical College, P.O. Kozhikode-673008
11.		All India Institute of Medical Sciences, Phulwari Sharif, Patna-801505	50.		Govt. Medical College, Gandhinagar, Kottayam-686008
12.		Lord Buddha Koshi Medical College & Hospital, NH 107, Bajinathpur, Saharsa-852201	51.		Pushpagiri Institute of Medical Sciences and Research centre, Pushpagiri Medical College Hospital, Tiruvalla-689101
13.	Chhattisgarh	Pt. JNM Medical College, Jail Road, Raipur-492001	52.		Amala Institute of Medical Sciences, Amala Nagar, P.O. Thrissur-680555
14.	Goa	Goa Medical College & Hospital, NH 17, Bambolim, Tiswadi-403202	53.		Govt. T.D. medical college, vandanam, Alappuzha-688005
15.	Gujarat	SMT NHL Municipal Medical College, Ellise Bridge, Ahmedabad-380006	54.		Government Medical College, Medical College PO, Thiruvananthapuram-695011
16.		BJ Medical College, New Civil Hospital, Asarwa, Ahmedabad-380016	55.	Madhya Pradesh	Amrita Institute of Medical Sciences, Kochi, Kerala-68204
17.		Government Medical College, Near State Road Transport Corporation Bus Stand, Bhavnagar-364002	56.		Gandhi Medical College, Sultanla Road, Bhopal-462001
18.		Surat Municipal Institute of Medical Education & Research, Ring Road, Near Sahara Darwaja, Opposite Bombay Market, Umarwara, Bharat Nagar, Surat-395010	57.		RD Gardi Medical College, Agar Road, Surasa, Ujjain-456006
19.		M.P. Shah Medical College, Pt. Nehru Road, Jamnagar-361008	58.	Maharashtra	SAIMS Medical College, Ujjain Highway, Sanwer Road, Indore-453111
20.		PDU Medical College, Civil Hospital Campus, Jam Nagar Road, Jam Nagar Road, Rajkot-360001	59.		NSCB Medical College, Medical College Colony, Jabalpur-482003
21.	Haryana	Gujarat Medical Education & Research Society Medical College, Gotri, Vadodra-390021	60.	Maharashtra	All India Institute of Medical Sciences, Saket Nagar, Bhopal-462024
22.		Pramukhswami Medical College & Shree Krishna Hospital, Gokal Nagar, Karamsad, Dist. Anand-388325	61.		BJ Medical College & Sassoon General Hospital, Jai Prakash Narayan Road, Near Pune Railway Station, Pune-411001
23.		Government Medical College, Baroda, Anandpura, Vadodra-390001	62.		Government Medical College & Hospital, Ajni Rd, Nagpur-440003
24.	Haryana	Medanta-The Medicity Sector-38, Gurgaon-122001	63.		Grant medical college & Sir JJ Group of Hospital, JJ Marg, Off Jijabhoy Road, Byculla Mumbai-400008
25.		Artemis Hospital, Sector-51, Gurgaon	64.		Indira Gandhi Government Medical College, C.A. Road, Nagpur-440018
26.		Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences, Rohtak-124001	65.		Lokmanya Tilak municipal Medical College & General Hospital, Dr. Babasaheb Ambedkar Road, Sion-400022
27.		BPS GMC for women, Khanpur Kalan, Sonapat-131305	66.		Mahatma Gandhi Institute of Medical Sciences, Nagpur Sevagram, Nagpur-442012
28.	Himachal Pradesh	Maharishi Markandeshwar Institute of Medical Sciences and Research, Mullana, Ambala-133207	67.		Pd. Dr. D.Y. Patil Medical College, Gaikwad Haralbhau Vinayam Rd, Pimpri, Chinchwad, Pune-411018
29.		Dr. Rajendra Prasad Govt. Medical College, Kangra, Tanda-176001	68.		Aditya Birla Memorial hospital Marg, Chinchwad, Pune-411033
30.	Jammu & Kashmir	Indira Gandhi Medical College, Circular Rd, Lakkar Bazar, Shimla-171001	69.		Seth GS Medical College & KEM Hospital, Acharya Donde Marg, Parel-400012
31.		Govt. Medical College, Maheshpura Chowk, Bakshi Nagar, Jammu-180001	70.		Swami Ramanand Teerth Rural Govt Medical College, Ambajogal, Dist. Beed-43151
32.	Jharkhand	Sher-i-Kashmir Institute of Medical Sciences, Soura, Srinagar-190011	71.		TN Medical College & B.Y. Nair Hospital, Dr. AL Nair Road, Mumbai Central, Mumbai-400008
33.		Acharya Shri Chander College of Medical Sciences & Hospital, N.H. Bye pass, P.O. Majee Sidhra-180017	72.	Odisha	Armed Forces Medical College, Opposite Race Course, Solapur road, Pune Cantonment, Pune-411040
34.	Karnataka	Govt. Medical College, Karan Nagar, Srinagar-190010	73.		Government Medical College, Sangli district, Miraj-416410
35.		Rajendra Institute of Medical Sciences (RIMS), Barilatu, Ranchi-834009	74.		Govt. Medical College, Iatur, opposite rajasthan high school, near minimarket, Iatur-413512
36.	Karnataka	Bangalore Medical College and Research Institute, Fort, K.R. Road, Bengaluru-560002	75.	Manipur	Regional Institute of Medical Sciences, Lamphelpat, Imphal-795004
37.		Belgaum Institute of Medical Sciences, Dr. B.R. Ambedkar Road, Belgaum-590001	76.	Meghalaya	North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences, mawdiang, shillong-793018
38.		Bidar Institute of Medical Sciences, Bidar, Udgir Rd, Bidar-585401	77.	Odisha	VSS Medical College, Burla, Sambalpur-768031
39.		JSS Medical College Hospital, Sri Shivarathreshwara Nagar, Mysore-570015	78.		M. K. C. G Medical College, Ganjam, Berhampur-760004
			79.	Odisha	SCB Medical College and Hospital, Mangalabag, Cuttack-753007
			80.		Hi-tech Medical College & Hospital, Health Park, Pandara, Bhubaneswar-751025

S. No	State	Name of AMCs
81.	Punjab	Christian Medical College and Hospital, Brown Road, Ludhiana-141008
82.		Dayanand Medical College and Hospital, Tagore Nagar, Civil Lines, Ludhiana-141001
83.		Sri Guru Ram Das Institute of Medical Sciences & Research, Grand Trunk Rd, Amritsar-143006
84.		Guru Gobind Singh Medical College & Hospital, Sadq Road, Faridkot-151203
85.	Rajasthan	Government Medical College, Circular Road, Amritsar-143001
86.		Sardar Patel Medical College, SP Medical College Rd, Sardar Patel Colony, Bikaner- 334001
87.		SMS Medical College, Jawaharlal Nehru Marg, Jaipur-302004
88.		Geetanjali Medical College and Hospital, geetanjali Medicity, Hiran Magri Extn, Eklingspura Chouraha, Udaipur-313001
89.		R.N.T Medical College Ambedkar Circle or Court Circle, SH 32, Bhopalpur, Udaipur-313001
90.	Sikkim	NIMS Medical College, NIMS University, Shobha Nagar, Jaipur-303121
91.		All India Institute of Medical Sciences, Basni Industrial Area Phase-2, Jodhpur-342005
92.		Sikkim Manipal Institute of Medical Sciences, Tadong, Gangtok-737102
93.		Christian Medical College, Thorapadi P. O., Vellore-632002
94.	Tamilnadu	Govt. Kilpauk Medical College, Perambur Purasawalkam, Chennai-600010
95.		Madras Medical College, E.V.R Periyar Salai, Park Town, Chennai-600003
96.		PSG Institute of Medical Sciences & Research, Anna Nagar, Coimbatore-641004
97.		SRM Medical College Hospital & Research Centre, kattankulathur, Kanchipuram-603203
98.		Sri Ramachandra Medical College and Research Institute, Porur, Chennai-600116
99.		Madurai Medical College, Alwarpuram, Madurai-625020
100.		Tirunelveli Medical College, Tirunelveli-627011
101.		Coimbatore Medical College & Hospital, Trichy Road, Gopalapuram, Coimbatore-641014
102.		Koval Medical Center and Hospital, Post Box No. 3209, Avanaishi Road, Coimbatore - 641014
103.		Kakatiya Medical College, Rangampet Street, Warangal-506007
104.	Telangana	Nizam Institute of Medical Sciences, Punjagutta Main Road, Hyderabad-500082
105.		Bhaskar Medical College & Bhaskar General Hospital, Yenkapally, Moimabad, Ranga Reddy-500075
106.		Kamineni Institute of Medical Sciences, Narketpally, Nalgonda-508254
107.		Gandhi Medical College, Musheerabad, Secunderabad-500003
108.	Tripura	Osmania medical College, koti, Hyderabad-50019
109.		Agartala Govt. Medical College, Kunjaban, Agartala-799006
110.	Uttar Pradesh	Tripura Medical College & Dr. BRAM Teaching Hospitals, Hapania, Agartala-799014
111.		B.R.D Medical College & Nehru Hospital, Gorakhpur- 273013
112.		GSVM Medical College, Swaroop Nagar, Kanpur- 208001
113.		Institute of Medical Sciences Banaras Hindu University, Varanasi-221005
114.	Uttar Pradesh	JN Medical College, Aligarh Muslim University, Aligarh- 202002
115.		M.L.B. Medical College, Jhansi- 284128
116.		M.L.N Medical College, Darbhanga Colony, George Town, Allaha- bad- 211002

S. No	State	Name of AMCs
117.	Uttar Pradesh	Santosh Medical University, Santosh Nagar, Ghaziabad-201001
118.		U.P Rural Institute of Medical Sciences and Research, Safai, Etawah-206130
119.		Muzaffarnagar Medical College & Hospital, opp. Begrajpur Indus- trial Area, Ghasipur, Muzaffarnagar-251201
120.		School of Medical Sciences & Research, Sharda University, Greater Noida-20130
121.	Uttar Pradesh	Subharati Medical College, Subharti Puram, NH-58, Delhi-Haridwar By Pass Road, Meerut-250005
122.		Era's Lucknow Medical College & Hospital, Sarfazanji, Moosa Bagh picnic Spot, Hardoi Road, Lucknow-226003
123.		Central Drug research Institute, Sector 10, Jankipuram Extension, Sitapur Road, Lucknow-226031
124.		Dr. Ram Manohar Lohia Institute of Medical Sciences, Vibhuti Khand, Gomti Nagar, Lucknow-226010
125.	Uttarakhand	Govt Medical College, Rampur Road, Haldwani-263139
126.		Himalayan Institute of Medical Sciences, Ram Nagar, P.O. Doiwala, Dehradun, Uttarakhand-248140
127.		Veer Chandra Singh Garhwali Medical Science and Research Institute, Srinagar, Pauri Garhwal-246174
128.		Shri Guru Ram Rai institute of Medical & Health Sciences, Sri Mahant Indresh Hospital, Patel Nagar, Post Box 80, Patel Nagar, Dehradun-248001
129.	West Bengal	All India Institute of Medical sciences, Virbhadra road, Rishikesh-249201
130.		School of Tropical Medicine, 108, Medical College Campus Chittaranjan Avenue, Kolkata- 700073
131.		R.G. Kar Medical College, 1, Kshudiram Bose Sarani, Kolkata-700073
132.		Calcutta National Medical College, Dr Sundari Mohan Ave, Beniapu- kur, Kolkata-700014
133.	West Bengal	Institute of Postgraduate Medical Education & Research, 244B, A.J.C Bose Road, Kolkata-700020
134.		Burdwan Medical college, Baburbag, P.O. Rajbati-Burdwan-713104
135.		Bankura Sammilani Medical College, kenduadihi, Bankura -722101
136.		Nilratan Sircar Medical College, Acharya Jagdish Chandra Bose Road, Kolkata-700014
137.	Chandigarh	College of Medicine & J.N.M. Hospital, Kalyani, Nadia-741235
138.		North Bengal Medical College, PO Sushrutnagar, Siliguri, Distt. Darjeeling-734012
139.		Murshidabad Medical College & Hospital, Berhampore-742101
140.		PGIMER, Sector12, Chandigarh-160012
141.	Delhi	All India Institute of Medical Sciences(AIIMS), Ansari Nagar East, Gautam Nagar, New Delhi -110029
142.		Indraprastha Apollo Hospital Mathura Road, Sarita Vihar, New Delhi -110044
143.		Lady Hardinge Medical College (LHMC), C 604, Shivaji Stadium Bus Terminal Co. Place Shaheed Bhagat Singh Marg, New Delhi-110001
144.		University College of Medical Sciences, adjacent to GTB Hospital, Dilshad Garden, New Delhi -110095
145.	Delhi	Vallabhbhai Patel Chest Institute(VPCI), University of Delhi, Guru Tegh Bhadur Road, New Delhi -110007
146.		VMMC & Safdarjung Hospital, Mahatma Gandhi Marg, Raj Nagar, Safdarjung, New Delhi -110029
147.		Hamdard Institute of Medical Sciences and Research, Hamdard Nagar, New Delhi -110062
148.		Maulana Azad Medical College and associated Lok Nayak, Govind Ballabh Pant Hospital & Guru Nanak Eye Centre, 2, B.S.Z. Marg, New Delhi -110002
149.	Puducherry	Indira Gandhi Medical College & Research Institute, Kadirkamam -605009
150.		Jawaharlal Institute of Postgraduate Medical Education & Research,, Dhanvantri Nagar, Gorimedu-605006

Network of ADR Monitoring Centers (AMCs) under PvPI



This map is for illustrative purposes and does not imply the expression of any opinion on the part of the public or their sponsors concerning the legal status of any country or territory or concerning the delimitation of frontiers or boundaries.