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सत्यमेव जयते

IPC

Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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OVER THE COUNTER

Community Pharmacists best care to encounter the safety of Over the Counter medicines is an emerging need

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Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare, Government of India

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सत्यमेव जयते

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निर्माण भवन, नई दिल्ली - 110011
Government of India
Ministry of Health & Family Welfare

Greetings to All Readers,

It gives me immense pleasure to note rapid momentum in the field of Pharmacovigilance practices, patient safety and the role played by National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI) under the aegis of Indian Pharmacopoeia Commission (IPC) in creating effective communication with stakeholders.

While a few policy level changes have been brought into Schedule 'Y' appended to Drugs & Cosmetics Rules, 1945, a Pharmacovigilance system has been made mandatory for manufacturers and Marketing Authorization Holders (MAHs). As pharmaceutical industry is an important stakeholder in the process of bolstering the regulatory framework, this decision will have far reaching impact on drug safety.

I am happy to note that NCC-PvPI in IPC is working closely with Pharmacy Council of India to bring Pharmacovigilance into Pharmacy curriculum. I am also delighted to note the initiatives taken at NCC-PvPI together with Indian Council of Medical Research (ICMR) and its affiliated institutions to optimise drug safety through research based Pharmacovigilance.

There is a need to address massive challenges such as public awareness, outreach to primary health centres, participation of physicians and allied healthcare professionals in pharmacovigilance. I urge various stakeholders to work at all levels with strong commitment towards promoting PvPI.

(K. B. Agarwal)

SAFETY PROFILE OF OVER-THE-COUNTER (OTC) DRUGS

A Need of Pharmacist Care and Vigilance

Pharmacists play a crucial role in the health-care system due to their easy access by the public for self-care or self-medication with non-prescription OTC drugs or medicines. Currently, India ranks 11th position in the global OTC market size and it is expected to grow USD 6.6 billion by 2016 due to expansion of more number of pharmaceutical companies and chemist shops in the rural market. The total revenue of OTC medicines in India constitutes 21% of total market revenue of USD 20 billion.

In general, OTC drug market is increased due to the establishment of more pharmacies, especially in rural areas, increased availability of OTC drugs and also rural population shows higher tendency to self-medicate. Hence, community pharmacists have a critical role providing great care during OTC drugs sale and must educate the patients about adverse drug reactions (ADRs) of medication and precautions required.

NCC-PvPI has observed growing evidence of ADRs from its database in the last 5 years due to OTC drugs. Therefore, it is a primary responsibility of NCC-PvPI to analyze the scientific data and communicate to the healthcare professionals and public.

SALIENT FEATURES OF STUDY

Study Design

- The study period was from July 2011 to June 2016
- Study based on analysis of Individual Case Safety Reports (ICSRs) available in VigiFlow
- A total of 76 drugs were identified from National Formulary of India (NFI) 2016 (Published by IPC)
- Adverse events of 76 OTC drugs were retrieved from PvPI database
- A search criterion includes single active substance (Drug name) or salt form of single active substance. Similarly, herbal drugs based Ayurvedic, Siddha, Unani and Homoeopathic medicines ICSRs were retrieved from VigiBase database.

Study Outcome

- OTC drugs share 18.59% of ICSRs, Scheduled drugs share 81.28% of ICSRs and herbal drugs share 0.12% of ICSRs.
- Serious ADRs were noticed in 3000 (14.95%) ICSRs, Non-serious ADRs were noticed in 16064 (80.06%) ICSRs and absence of ADRs were noticed in 999 (4.97%) ICSRs of allopathic OTC drugs.

An allopathic OTC drugs in India mostly falls under Schedule H and H1. As per D&C Act 1940 and thereunder Rules 1945, these drugs should be sold against prescription only. Similarly, very less number of ICSRs are reported for single or combination of herbal drugs, Ayurvedic and Homoeopathic medicines in the last 5 years. The Ayurvedic medicines were reported with high incidence of serious ADRs (65.67 %). However, no ICSRs are available for Siddha and Unani medicines in the VigiBase database.

The present study reveals that safety of OTC drugs is a matter of grave concern. Therefore stringent safety monitoring and regulations are needed.

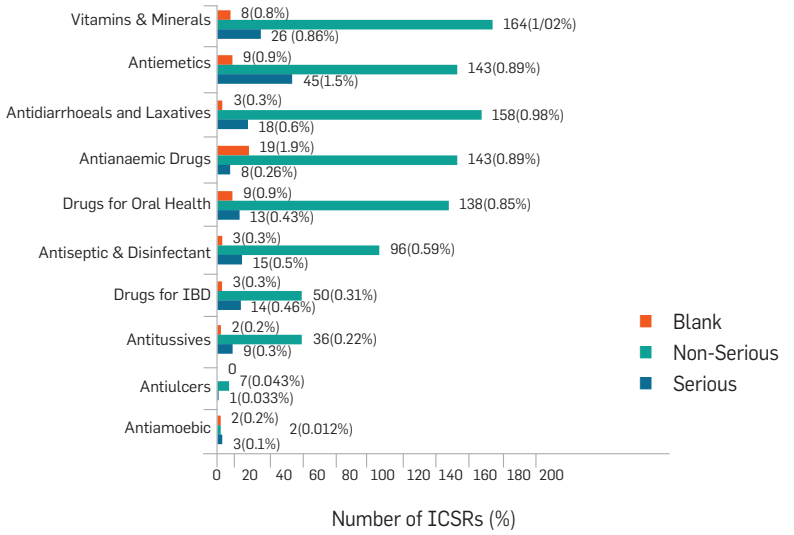
JOINT VENTURE

- Community Pharmacists are encouraged to participate in PvPI by reporting ADRs.
- Pharmacists and AMCs are required to work together to promote patient safety.
- PvPI urges the Pharmacy Council of India (PCI) to empower the pharmacists for ensuring safety of medicines.
- State regulators are invited to join hands with PvPI.
- Consumers are advised to report ADRs to Physicians/ Pharmacists/ nearest AMCs/NCC.

KEY MESSAGE:

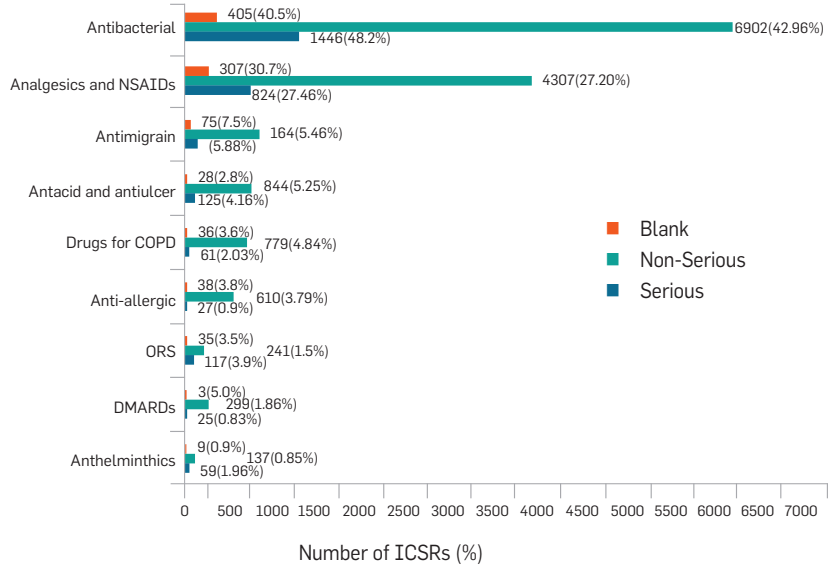
- PvPI will continue to evaluate the safety concern for the use of OTC drugs.
- PvPI recommends CDSCO to constitute an advisory committee of experts to provide inputs regarding the safety of OTC drugs.

ICSRs OF ALLOPATHIC OTC DRUGS



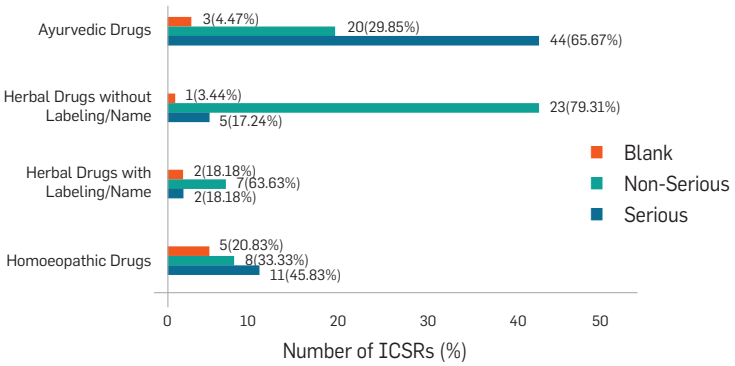
IBD-Inflammatory Bowel Diseases

ICSRs OF ALLOPATHIC OTC DRUGS



NSAIDS: Non-Steroidal Anti Inflammatory Diseases, COPD: Chronic Obstructive Pulmonary Diseases, ORS: Oral Rehydration Salts, DMARDs: Disease Modifying Anti-Rheumatic Diseases

ICSRs OF HERBAL DRUGS

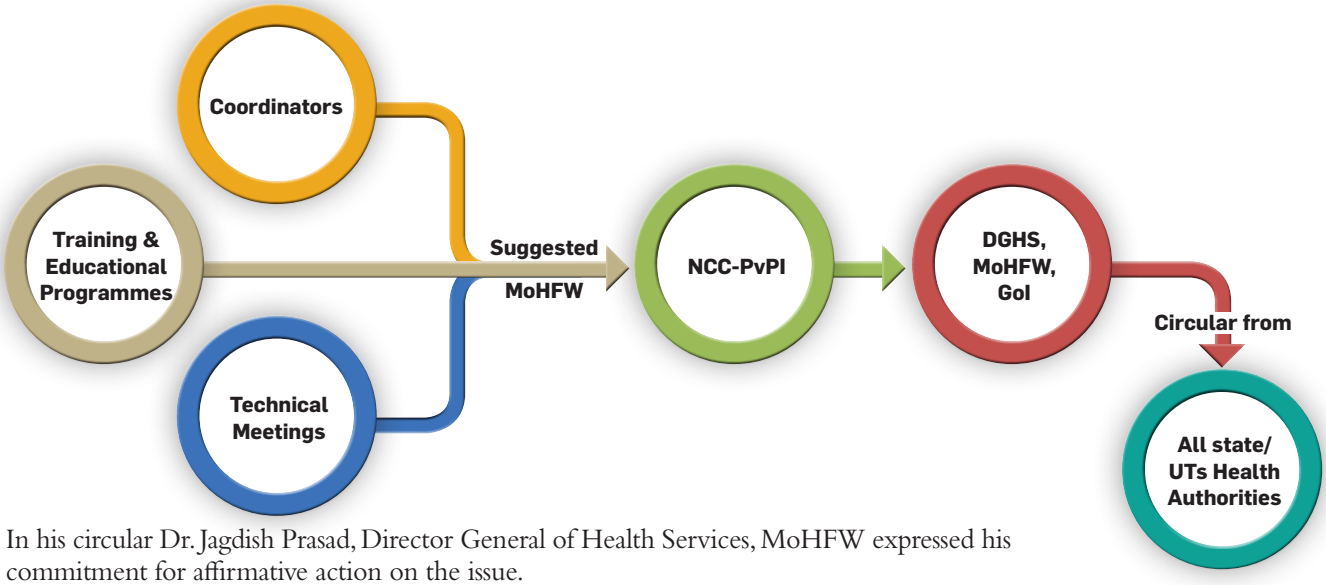


PvPI Implements Pharmacovigilance with Support of State Drug Regulation Authorities

Dr. Jagdish Prasad directs the State/ Union Territories (UTs) Health Authorities to adopt pharmacovigilance practices and also urges the authority to work in close coordination with AMCs

Addressing the states/ UTs health authorities Dr. Jagdish Prasad Director General (DG), Directorate General of Health Services (DGHS), Ministry of Health and Family Welfare (MoHFW), Government of India (GoI) reiterated the 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' and apprised the authorities and all concerned officers to approach the nearby ADR Monitoring Centres (AMCs) functioning under PvPI for any technical support or to collect Pharmacovigilance related information.

He assured full cooperation of state health authorities and emphasized their role in public awareness and effective implementation of PvPI.



In his circular Dr. Jagdish Prasad, Director General of Health Services, MoHFW expressed his commitment for affirmative action on the issue.

CIRCULAR HIGHLIGHTS

- To inculcate ADR reporting culture in all the healthcare professionals.
- To sensitize nursing professionals for ADR reporting through state health authorities.
- All state/UTs health authorities were requested to approach nearby AMC for any technical support related to Pharmacovigilance.
- In light of feedback received from the coordinators, NCC approached DGHS to address the issue.

Optimising Drug Safety through Research Based Pharmacovigilance

A discussion on focused monitoring, Pharmacoepidemiology in Pharmacovigilance, Cohort Event Monitoring

In an important step to optimise drug safety through research based Pharmacovigilance under Pharmacovigilance Programme in India (PvPI), the Indian Pharmacopoeia Commission (IPC), National Coordination Centre- Pharmacovigilance Programme in India (NCC-PvPI) in association with Indian Council of Medical Research (ICMR) convened first meeting on 'Optimising the Safety of Medicines through Research based Pharmacovigilance-ICMR institutions as Collaborating Centres' at ICMR Headquarter, New Delhi on 28th July, 2016. The meeting was chaired by Dr. Soumya Swaminathan, Secretary DHR & Director General, ICMR.

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

The proposals from ICMR institutions (NIE, Chennai; NIRRH, Mumbai; NIN, Hyderabad; NIRT, Chennai; NICED, Kolkata; NIMR, New Delhi; NARI, Pune) as "PvPI Collaborating" was accepted in principle. Experts from various ICMR institutions agreed to provide all necessary infrastructure and expertise to up-scale the Programme.

A discussion on focused monitoring, Pharmacoepidemiology in Pharmacovigilance and Cohort Event Monitoring (CEM) under PvPI also aligned in the meeting.

Strengthening of Pharmacovigilance System in Eastern Uttar Pradesh

A meeting on "Strengthening of Pharmacovigilance system and ensuring patient safety in Eastern Uttar Pradesh" was convened on 25th July, 2016 under the chairmanship of Mr. Bejon Misra, Consumer Policy Expert. The objective of the meeting was to address the challenges and issues in strengthening Pharmacovigilance system in Eastern Uttar Pradesh (U.P.). The committee deliberated several issues related to Pharmacovigilance system such as:

1. Strengthening of existing AMCs in Eastern U.P.
2. Identification of potential AMCs in the region
3. Challenges in creating public awareness
4. Enhance the participation of stakeholders such as

physicians, community pharmacists, consumers etc.

This meeting has given platform for unique ideas of promoting PvPI in the rural parts of state. The ideas put forth to committee were sensitization of Accredited Social Health Activist (ASHA) workers and health workers from district level hospitals to primary health centres on ADR reporting, inclusion of PvPI helpline number in footnote of prescriptions, & initiation of Pharmacovigilance activities at individual level.

The committee reiterated the commitment for safer therapies by ensuring patient drug safety.

CURRENT SCENARIO AND ACTION PLAN

Action Plan: 1

EXISTING AMCs

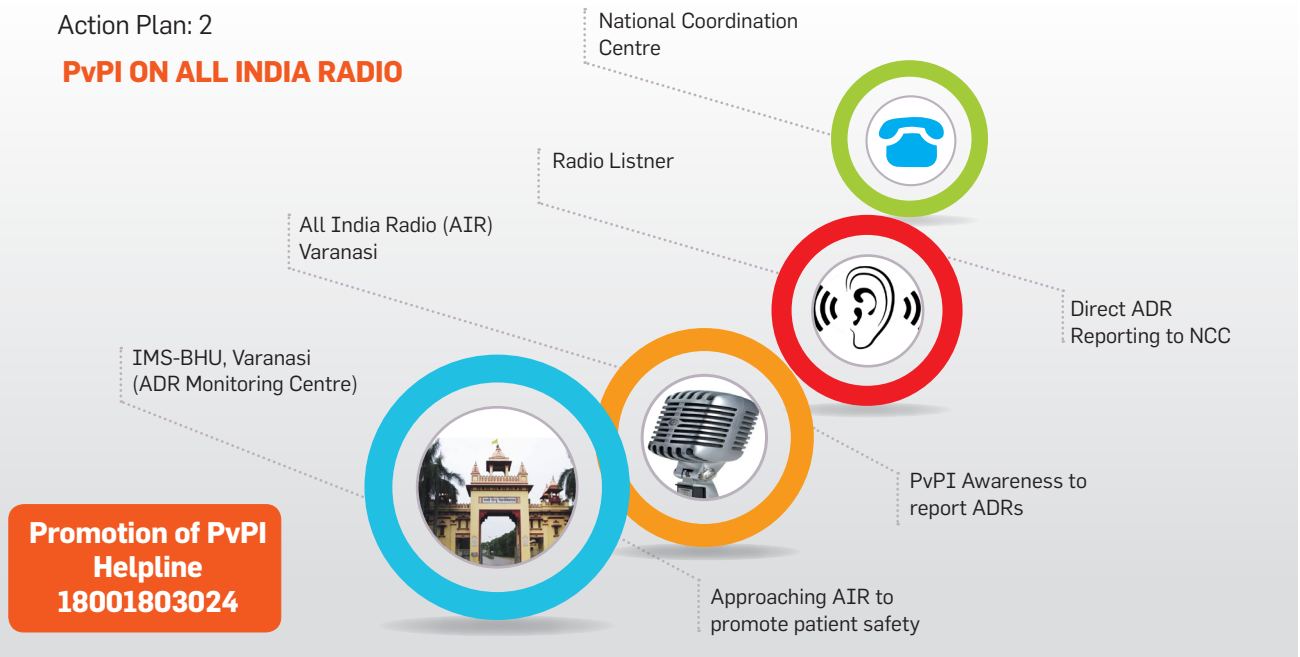
1. B.R.D Medical College & Nehru Hospital, Gorakhpur
2. Institute of Medical Sciences-Banaras Hindu University, Varanasi
3. M.L.N Medical College, Allahabad (In orange & blue combination.)

UPCOMING AMCs

1. Mata Anandamayee Hospital, Varanasi
2. Guru Shri Gorakhnath Chikitsalaya, Gorakhpur
3. Government Medical College, Azamgarh

Action Plan: 2

PvPI ON ALL INDIA RADIO



Action Plan: 3

Mapping of Healthcare Professionals in Pharmacovigilance

Eastern Uttar Pradesh ➲ District Mirzapur ➲ Tehsil (4) ➲ Block (12)

Total Population-24,96,970

District Health Organizational Structure | **Healthcare Professionals**

- Primary Health Centres (45)
- Community Health Centres (7)
- Family Welfare Centres (17)
- Family Welfare Sub-Centres (263)
- Other Hospitals (10)
- Ayurvedic, Unani and Homeopathic Pharmacies (79)

- Chief Medical Officer
- Deputy CMOs
- Medicals Officers Incharge(9)
- Medical Superintendents (7)
- Medical Officers (35)
- Pharmacists (13)
- Nurses (14)

ACTION PLAN 4

In order to carry out all these activities effectively BRD Medical College, Gorakhpur will coordinate & make bridges between hospitals/ institutions of Eastern UP & NCC-PvPI.

DRUG SAFETY IN KALA-AZAR TREATMENT

A MoU between National Vector Borne Disease Control Programme and PvPI

Aims to foster active cooperation and information exchange on safety of medicines used during Kala-azar treatment in initial phase

In an important step towards ensuring the safety of drugs used in the National Vector Borne Disease Control Programme (NVBDCP), a Memorandum of understanding (MoU) was signed between the IPC and Directorate of NVBDCP, New Delhi on 03rd August, 2016.

The MoU was signed between Dr. G.N. Singh, Secretary-cum-Scientific Director, IPC & DCG (I) and Dr. A.C. Dhariwal, Director, NVBDCP, MoHFW in the presence of Dr. Jagdish Prasad, DG, DGHS. The MoU intend to foster active cooperation and exchange of information between aforementioned authorities on drug safety. In the early phase primary objective is to monitor ADR of drugs used in Kala-azar treatment as part of the Vector borne disease control programme

Dr. Jagdish Prasad, DG, DGHS, Dr. G.N. Singh, Secretary-cum-Scientific Director, IPC, Ghaziabad, Dr. A.C. Dhariwal, Director, NVBDCP along with experts on the occasion held on 3rd August 2016.

Active Surveillance for Bedaquiline Begins in PvPI

National Workshop on Pharmacovigilance of Anti-tubercular Medicines: An active surveillance for Bedaquiline

Dr. Jagdish Prasad, DGHS, Sh. K.L. Sharma, JS (R), Dr. G.N. Singh, DCG (I) & Secretary-cum-Scientific Director, IPC along with dignitaries on inaugural session of workshop on 6th to 9th September 2016 at New Delhi.

Bedaquiline (BDQ) is an approved drug in India to treat multi-drug resistant tuberculosis (MDR-TB). It is available in six Revised National Tuberculosis Control Programme (RNTCP) centres only across India as part of conditional access programme and these Centres are ADR monitoring Centres under PvPI. A four day training programme on "Pharmacovigilance of Anti-tubercular Medicines in India" was organised by IPC, NCC-PvPI in association with RNTCP and WHO, country office (India) from 06th - 09th September 2016 at New Delhi. It was inaugurated by Dr. Jagdish Prasad, DG, DGHS, MoHFW, GoI and Shri K.L. Sharma, Joint Secretary (Regulation), MoHFW, GoI. This workshop was specially designed for six identified tertiary care centres which are prescribing BDQ to treat MDR-TB.

The workshop was aimed to strengthen the operational and technical aspects to effectively implement Pharmacovigilance for CEM of BDQ. Hands on training was given to participants for the causality assessment, filling of CEM form (treatment initiation form & review form) and suspected ADR form for BDQ.

In this workshop, participants were Coordinators of treatment sites (clinicians), TB treatment officers, state TB officers, local causality assessment committee members, medical officers, PvPI and WHO team, statisticians, personnel from non-government organizations (NGOs). The training was focused to provide in depth training on concepts of Causality Assessment to the RNTCP personnel including filling the forms in NIKSHAY.

Dr. Jagadish Prasad, DG, DGHS, MoHFW, GOI Speaking on the occasion on 06th September 2016

HIGHLIGHTS OF DIRECTOR GENERAL'S SPEECH

- RNTCP officials need to use effectively PvPI helpline number to report ADRs.
- Pharmacovigilance and drug safety monitoring of newer drugs such as BDQ is of pivotal importance for improving treatment support and adherence-particularly among drug resistant TB cases.
- BDQ CEM team need to effectively monitor & report ADRs so that signal(s), if any can be identified promptly.
- PvPI to have similar kind of collaboration with other national health programmes.
- An effective coordination between NCC-PvPI, RNTCP & WHO is vital for success of mission i.e. TB eradication.

Shri K.L. Sharma, JS (R), MoHFW, GoI, delivered speech on growth of PvPI at New Delhi

HIGHLIGHTS OF JOINT SECRETARY (REGULATION) SPEECH

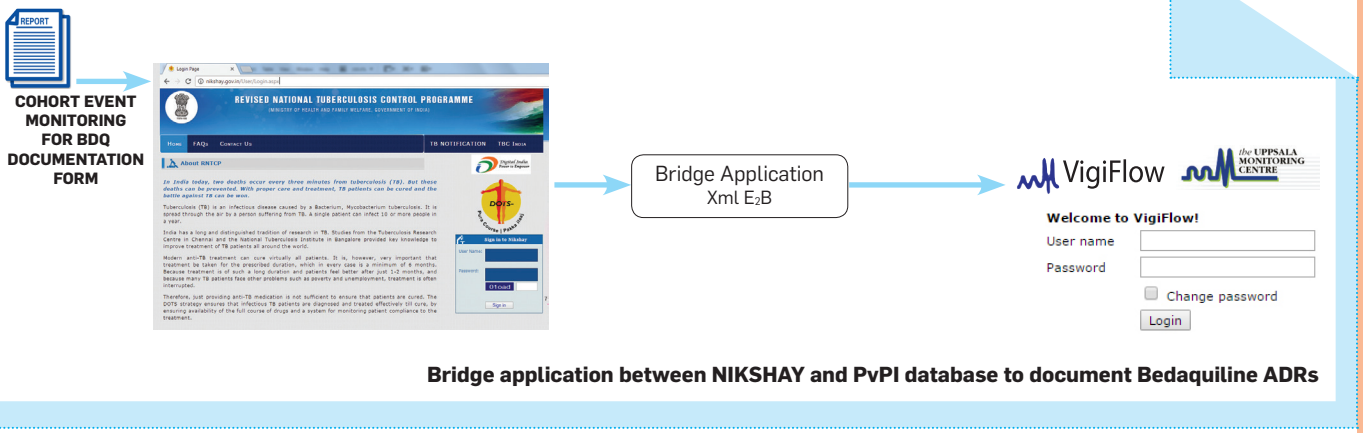
- Dynamic growth of PvPI and its integration with public health programmes has been impressive.
- Partnership between PvPI, RNTCP & WHO (India) is bound to succeed.
- PvPI is effectively utilizing Information Communication Technology (ICT) for the development of bridge application and seamless data flow with support of WHO.

Dr. Sunil D. Khaparde, DDG (TB), Dr. V. S. Salhotra, Addl. DDG (TB), Dr. Madhur Gupta, WHO India, Dr. Malik Parmar, WHO India, other Senior RNTCP and IPC officials and Coordinators of the ADR monitoring centres were present durng the training programme.

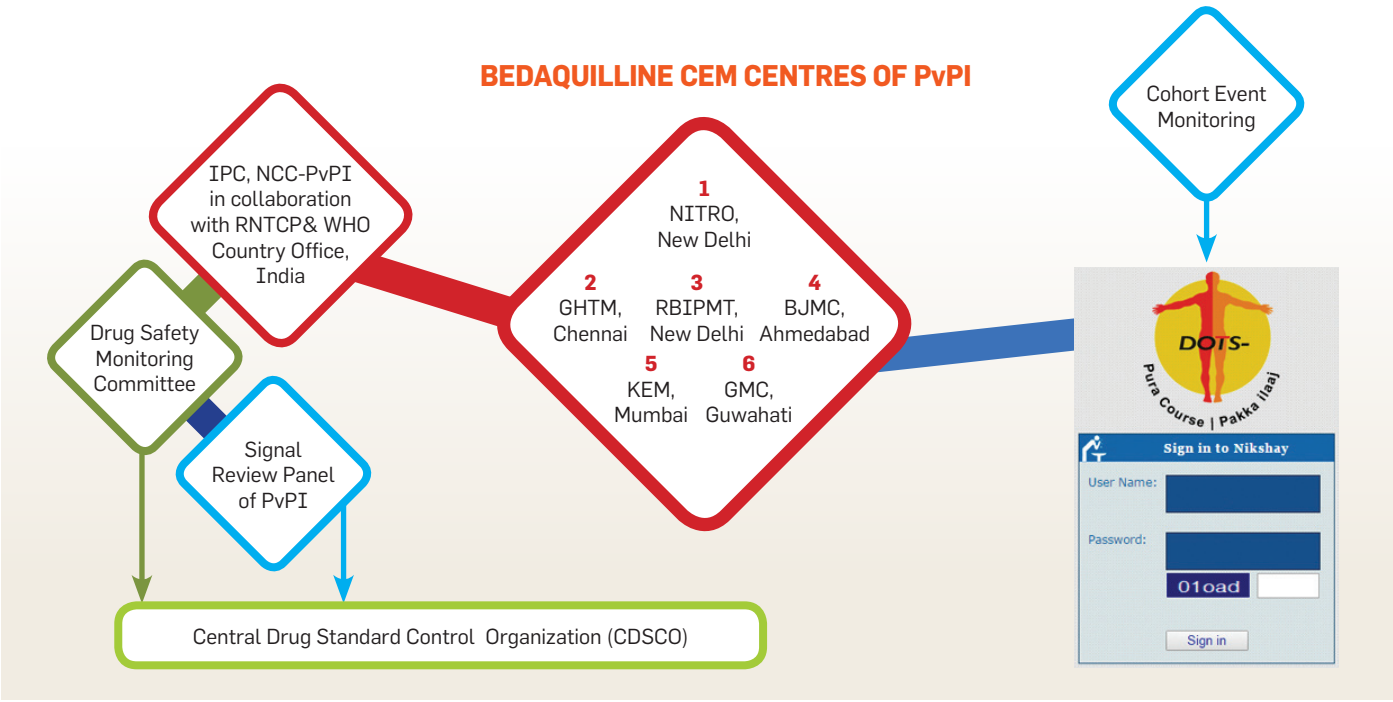
Causality assessment in Pharmacovigilance should not be done casually otherwise, it may increase casualties.
– Dr. Pinaki Chakravarty, Silchar Medical College & Hospital, Assam.

This is an impotant initative of PvPI in line of active surveillance– Dr. Meera Desai, BJMC Medical College, Ahmedabad, Gujarat

PvPI in the technical support of RNTCP and WHO developed a bridge application to ensure seemless data flow



Bridge application between NIKSHAY and PvPI database to document Bedaquiline ADRs



Pharmacovigilance: An Important Benchmarking Tool for Upcoming NRA Assessment

Pharmacovigilance is one of the key indicators of NRA benchmarking tool

National Regulatory Authority (NRA) is responsible for ensuring the products released for public distribution (normally pharmaceuticals and biological products such as vaccines) are safe and ensures the functioning of regulatory authority of the country. To strengthen the regulatory functioning and to harmonize the NRA benchmarking tool, WHO - CDSCO jointly organized International Workshop on Good Regulatory Practices for National Regulatory Authorities from 20-21st July 2016 New Delhi. This was preliminary meeting held under the chairmanship of Mr. K. L. Sharma, Joint Secretary (R) MoHFW & Dr Nicole Seguy WHO Representative to India. Subsequently Secretary level meetings were convened to review the preparedness of forthcoming WHO-NRA assessment.

Health Ministry, WHO, IPC officials on the preliminary meeting of NRA Assessment from 20-21st July 2016, New Delhi

Pharmacovigilance is identified as one of the key indicators of NRA benchmarking tool. PvPI urges all the AMCs to comply with NRA indicators for effective assessment.

Training & Skill Development Programme

PvPI ENGAGES A DIVERSIFIED TEAM

PvPI always look out for qualified, competative and dynamic professionals to derive maximum value and measurable outcomes

Newly recruited PvAs on Induction cum Training Programme at NCC-PvPI, IPC from 22nd Aug 2016 to 27th Aug 2016

- NCC engages young and talented pharmacovigilantes to bring innovative thoughts and ideas.
- Pharmacovigilance Associates (PvAs) are basic workforce of PvPI.
- PvPI is strengthened by appointing total of 46 PvAs in the programme.
- An Induction-cum-Training Programme was conducted by NCC from 22nd Aug 2016 to 27th Aug 2016 to improve the skills and knowledge of PvAs in pharmacovigilance.
- Trained PvAs are posted at different AMCs located from Kashmir to Kanyakumari.
- PvPI looks for similarities among professionals rather than looking for differences to attain maximum benefit.

Induction-cum-training programme for 28 new AMCs coordinators at IPC on 26-27th July 2016

- 23 new AMCs were identified which brought the total number of AMCs to 202. The induction-cum-training programme for the new coordinators of these AMCs was conducted on 26th and 27th July 2016 at IPC.
- These training addressed the various issues like understanding the technical and operational process of ADRs monitoring and reporting. A total of 28 coordinators participated in this training.
- Dr. G.N. Singh, DCG (I) urged to new AMCs Coordinators to execute their commitments to the needs of PvPI.

Drug Safety Alerts for July-September 2016

The preliminary analysis of Suspected Unexpected Serious Adverse Reactions (SUSARs) from ICSRs documented in PvPI database reveals that the following drugs are associated with the risks

HEPATITIS B IMMUNOGLOBULIN (HUMAN)

Indication: Active immunisation against Hepatitis B virus (HBV) infection in subjects considered at risk of exposure to HBV-positive material.

Event/ Reaction: Encephalopathy

LACOSAMIDE

Indication: As an adjunctive treatment of partial onset seizures in patients > 17 years of age.

Event/ Reaction: Red Man Syndrome

DIMETHYL FUMARATE

Indication: For Relapsing remitting multiple sclerosis Encephalopathy

Event/ Reaction: Osteonecrosis

CEFOTAXIME

Indication: Infections due to sensitive gram-positive and gram-negative bacteria such as bacteraemia, cellulitis, Intra-abdominal infections, gonorrhoea, bone or joint infections, skin infections, urinary tract infections, septicaemias, surgical prophylaxis, endometritis, life threatening resistant/hospital acquired infections, infections in immune-compromised patients, Haemophilus epiglottitis and meningitis.

Event/ Reaction: Anaphylactic Shock

SODIUM CITRATE/ DIPHENHYDRAMINE HYDROCHLORIDE/ AMMONIUM CHLORIDE

Indication: For Symptomatic treatment of cough.

Event/ Reaction: Myocardial infarction

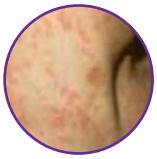
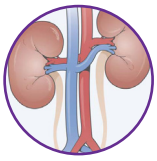
Healthcare professionals, patient/consumers are advised to closely monitor the possibility of adverse events of above suspected drugs. Also, it is advised to report adverse events to NCC-PvPI either by filling of Suspected Adverse Drug Reaction Reporting Form for Healthcare Professional or Medicine Side Effect Reporting Form for Consumer through the IPC website. (http://www.ipc.gov.in) or through PvPI Helpline No. 1800-180-3024.

RECOMMENDATION OF 8TH SIGNAL REVIEW PANEL

The 8th Signal Review Panel (SRP) Meeting was held on 8th July, 2016 at CDSCO Headquarters, New Delhi with an objective to detect Signal from Indian Database and promote patient safety. In this meeting, potential signals reported in the ICSRs were scientifically evaluated and SRP recommended following:

S.No	Drugs	Adverse Drug Reactions	Recommendations
1	Cefixime	Acute generalized exanthematous pustulosis (AGEP)	For Signal
2	Itraconazole	Photosensitivity reaction	For Drug Safety Label change
3	Ibuprofen	Steven-Johnson Syndrome / Toxic Epidermal Necrolysis	For Drug Safety Label change
4	Amoxicillin/Clavulanate Potassium	Steven-Johnson Syndrome /Toxic Epidermal Necrolysis	To Harmonize the Drug Safety Label
5	Ciprofloxacin	Steven-Johnson Syndrome / Toxic Epidermal Necrolysis	To Harmonize the Drug Safety Label
6	Sodium Valproate	Gum Hyperplasia	To Harmonize the Drug Safety Label

Comparative status of Global Drug Alerts with PvPI Database

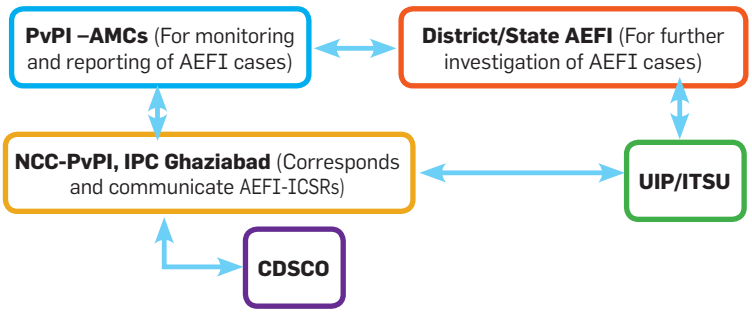
NAME OF DRUG	RISK WARNING	INTERNATIONAL STATUS	INDIA STATUS
CHLORHEXIDINE ANTISEPTIC NON-PRESCRIPTION TOPICAL PRODUCT	 Serious Allergic reaction	Health Canada safety review on topicalchlorhexidine (2-4%) revealed occurrence of serious allergic anaphylactic reactions when used in the mouth, on open wounds, or immediately before or during surgery. The symptoms of a serious allergic reaction, including anaphylaxis, may include itchy hives with swelling of the face, eyes, lips, mouth or throat; difficulty in breathing; throat tightness or hoarseness; and fainting. An anaphylactic reaction is a serious and potentially life-threatening hypersensitivity reaction.	NCC-PvPI received one report of allergic reaction
FLUOROQUINOLONE ANTIBACTERIAL DRUGS	 Restricting use	US FDA has issued advice based on the benefit-harm assessment for the useof fluoroquinoloneanti-bacterial and in certain types of infections. The FDA safety review has shown that systemic use of fluoroquinolones is associated with serious adverse effects which involve tendons, muscles, joints, nerves and central nervous system. These adverse effects outweigh the benefits of fluoroquinolone when used for acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections. FDA recommends that fluoroquinolones should be reserved for those with no alternative treatment options.	NCC-PvPI keen on monitoring ADR report of fluoroquinolone in the acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections from healthcare professionals.
METFORMIN	 Warnings for certain patients with reduced kidney function	Metformin is used in type-2 diabetes alongside diet and exercise. Diabetes can lead to kidney damage, hence current labelling strongly recommends against use of metformin in patients with renal impairment due to risks of developing lactic acidosis. A review of studies published in the medical literature concluded that metformin can be used safely in patients with mild impairment in kidney function and in some patients with moderate impairment in kidney function. Metformin is contraindicated inpatients with an eGFR below30mL/minute/1.73 m2 and initiation of metformin in patients with an eGFR between30-45mL/minute/1.73 m2 is not recommended. US FDA recommended for metformin containing medicines product label to expand its use in patients with mild or moderately impaired kidney function.	NCC- PvPI received three report of renal failure
OLANZAPINE	 Risk of serious skin reactions	FDA has received 23 cases of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) with olanzapine use. Hence, FDA has announced that drug labels for olanzapine containing products will be updated to include an additional warning describing DRESS. The FDA recommends that healthcare professionals stop treatment with olanzapine immediately if DRESS is suspected and they should inform patients of the signs and symptoms of severe skin reactions, instructing them to seek medical care immediately, should they occur.	NCC-PvPI received two reports of DRESS

Healthcare professionals are sensitized to carefully monitor the above mentioned alerts, if any event related to these drugs is to be reported to NCC-PvPI.

PvPI & State AEFI Secretariat Cooperation in Monitoring AEFI

Representative from AEFI Secretariat, Immunization Technical Support Unit (ITSU), Bhopal recently visited AIIMS, Bhopal which is an AMC under PvPI

AMCs across India are imperative means of collecting, collating & monitoring adverse reaction occurring due to drugs/ vaccines. Data of serious Adverse Event Following Immunization (AEFI) cases are shared with state AEFI secretariat District Immunization Officer (DIO) for the further investigation of AEFI cases.



STATE AEFI SECRETARIAT VISITS PvPI AMC

In response to the circular dated February 3, 2016 regarding monitoring and reporting of both serious (immediately) and non-serious adverse event due to immunization to the State Expanded Programme Immunization Officer (SEPIO) and NCC-PvPI, recently Regional Training Centre (RTC), AIIMS Bhopal has taken a number of initiatives to promote better collaboration between the AMCs and state AEFI committees.

Mr. Deepak Polpakara Representative from AEFI Secretariat, Immunization Technical Support Unit (ITSU), Bhopal recently visited AIIMS, Bhopal which is an AMC under PvPI. He had discussed the importance of AEFI reporting and its impact on paediatrics population. He also discussed National guidelines for AEFI cases reporting to state secretariat. Also Dr. Santosh Shukla, SEPIO & Secretary, State AEFI Committee discussed ways to ensure active participation of AIIMS, Bhopal in AEFI reporting.

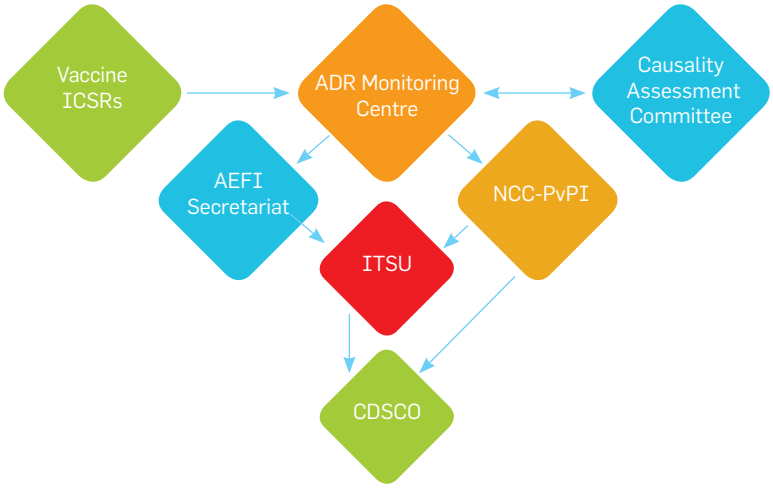
Further, the PvPI team of AIIMS, Bhopal attended a State AEFI Committee Meeting of National AEFI Committee, on 28th June 2016, at Bhopal.

RECOMMENDATIONS OF MEETING:

Committees: State AEFI committees' visit required to be more frequent and the Zonal Consultant needs to follow up if possible by visit and/or phone calls to the AMC.

PvPI team: The National AEFI Committee Meetings (at least 2 out of 3) needs to be conducted at regional centre instead of national centre.

PvPI team of Government Medical College (GMC), Miraj, with State AEFI: Four serious adverse events were communicated to state AEFI committee by GMC, Miraj in 2016. The centre is actively monitoring adverse reactions occurring due to drugs and vaccines in rural population. The details are given.

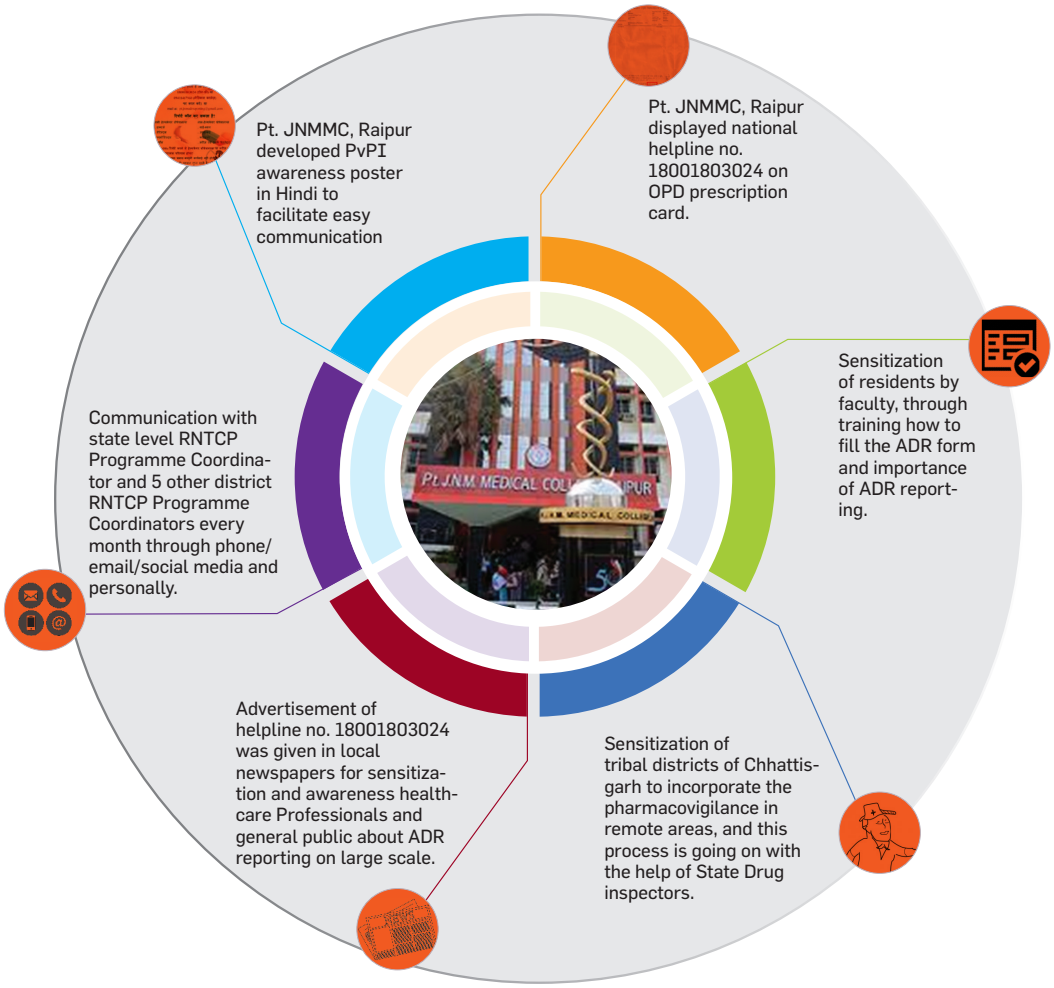


S. No.	Age	Sex	ADR	Seriousness criteria	Vaccine name	Outcome
1	2 year old	Female	Erythema	Hospitalization	DPT	Recovering
2	5 months old	Male	Encephalitis	Hospitalization	DPT	Recovering
3	5 months old	Male	Impending abscess	Hospitalization	DPT	Not recovered
4	5 months old	Male	Focal convulsions	Hospitalization	DPT	Recovered

Pandit Jawahar Lal Nehru Memorial Medical College, Raipur- Shoots up PvPI in Chhattisgarh

Pandit Jawaharl Lal Nehru Memorial Medical College (Pt. JNMMC), Raipur was established on 9th September 1963. Pt. J.N.M. Medical College, Raipur is the only tertiary level medical college with 700 bedded hospital and health institution which provides specialty health services to approximately 2 crore population of Chhattisgarh. An average attendance in outpatient department (OPD) is more than 900 patients per day and more than 100 major and minor surgical procedures are performed daily in 11 fully equipped operation theatres. In May 2014, it was established as an ADR monitoring centre under the leadership of Dr. Abha Singh, Dean, Pt. JNMMC and Dr. Rajesh Hishikar, Professor & HOD, as a Coordinator for NCC-PvPI. The Pharmacovigilance Associate Ms. Preeti Singh was appointed by NCC-PvPI in this AMC.

ACTIVITIES OF AMC

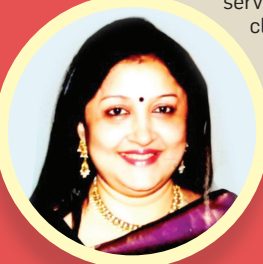


Pharmacovigilance activities at our centre is concerned with all clinical and non-clinical departments are well connected in terms of ADR monitoring and reporting.

Dr. Rajesh Hishikar, Professor & HOD, Pt. JNMMC, Raipur

In providing high quality medical care, drug safety monitoring is essential in effective use of medicines; Pharmacovigilance is recognised as a clinical discipline that provides an opportunity to evaluate the safety of these drugs and it serves as an indicator of the standards of clinical care practised within a country.

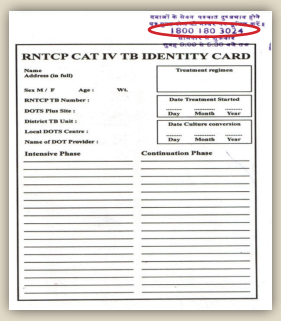
Dr. Abha Singh, Dean, Pt. JNMMC, Raipur



Pharmacovigilance is the need of well-established health care system that ensures the patient safety. The technical support provided by NCC-PvPI is of utmost importance to sensitize the healthcare professionals for ADR reporting.

Professor Vivek Chaudhary
Medical Superitendent, Pt. JNMMC, Raipur.

Sarojini Naidu Medical College (SNMC), Agra- Unwavering Toil with PvPI



PvPI-Helpline number in the RNTCP Identity card

Prof. SAROJ SINGH
M.S. FICOG, FICMCH, FIAJAGO, MAMS
Principal, Dean & Chief of Hospital, Sarojini Naidu Medical College (SNMC), Agra, Uttar Pradesh.

Patient safety is our prime focus and one of our core principles. SNMC has the honour of being one of the first three Medical Colleges in India. It has a well-equipped hospital with indoor sections having 976 beds, with an admission of about 39,000 patients every year and an outdoor section treating about 4,00,000 patients per annum. The clinical findings from study of ICSRs submitted to PvPI can be used for generating hypothesis and signals for further investigation. As a healthcare professional one can play an important role in the ongoing safety of medicines and vaccines by reporting adverse events. Pharmacovigilance is an important tool for patient safety and medicine safety. We will be focusing to improve ADR reporting by involving all healthcare professionals and regular sensitization of general public.

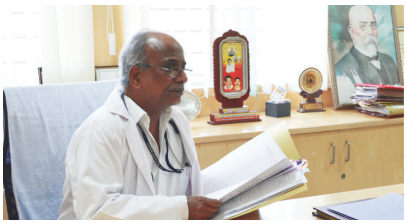
Dr. MONA VERMA
Coordinator - PvPI
Senior Medical Officer DRTB Center, TB & Chest Department, Sarojini Naidu Medical College, Agra

We have been working effectively to carry forward the agenda of PvPI of implementing a uniform reporting culture in SNMC. We have succeeded in sensitizing all the clinical departments through regular quarterly meetings and personal interaction and by means of posters, newsletters and seminars. Today we stand way ahead from where we had started. The PvPI Toll-free number has already been displayed in OPD slips and ADR reporting form will be included in In-patient files. Dr. Santosh Kumar (HOD, TB & Chest) has provided valuable inputs and supported us unconditionally.
Our future goals will be focused on involving all healthcare professionals for good pharmacovigilance practice and sensitize private practitioners and district hospital for ADR reporting.

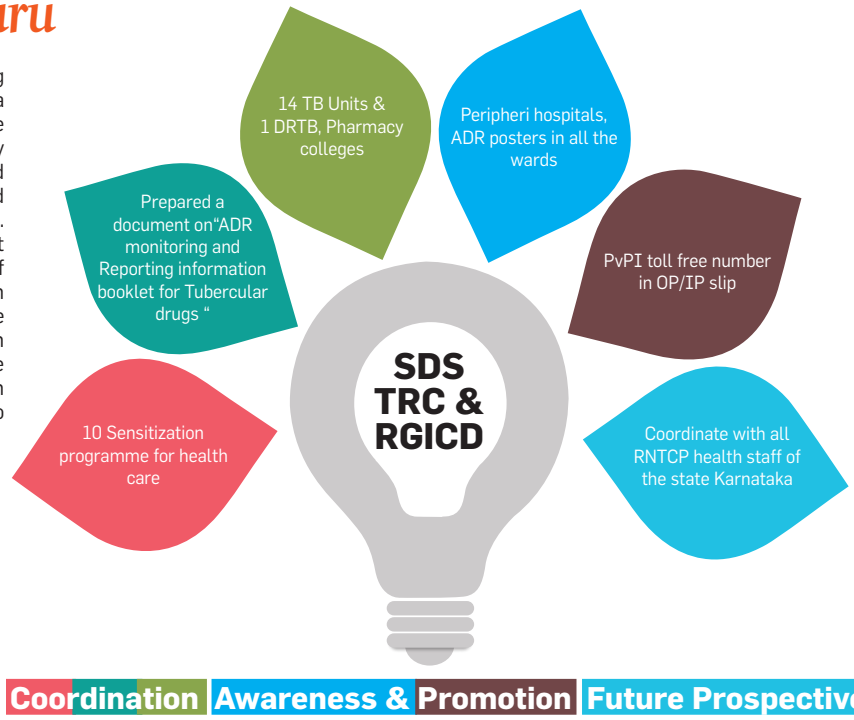
Pharmacovigilance Experience at Shantabai Devarao Shivaram Tuberculosis Research Centre and Rajiv Gandhi Institute of Chest Diseases, Bengaluru

It is my privilege and honour to head one of the leading chest institutions in Karnataka. The institution is a 470 bedded teaching autonomous institute having the department of Pulmonary Medicine and Thoracic Surgery which caters to about 100 out patients every day with bed occupancy rate over 60%. The hospital has established AMC under the PvPI in 2013 and is effectively functioning.

Any institution which cares for wellness of the patient will coordinate and cooperate with all the activities of ADR monitoring centre. Shantabai Devarao Shivaram Tuberculosis Research Centre and Rajiv Gandhi Institute of Chest Diseases (SDS TRC & RGICD) is working with this principle; hence the activities of ADR are being done effectively at this institution which will in turn help in overall patient care & management of safety drug use to the needy patients.



Dr.Shashidhar Buggi, Director, SDS TRC & RGICD & AMC Coordinator



Approved New Drugs in India

The following new drugs were approved during the period from July to September 2016 by the CDSCO

S.No	DRUG	INDICATION
1	Acotiamide Hydrochloride Bulk & Tablet 100mg	For the treatment of bloating after meals, epigastric bloating and early satiety in functional dyspepsia
2	Sacubutril+ Valsartan film coated tablets 50mg/100 mg/200mg	To reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction.
3	Lurasidone Hydrochloride Bulk & Lurasidone Hydrochloride Tablets 40mg/80mg	For the treatment of Patients with Schizophrenia
4	Fenticonazole Nitrate Vaginal Capsule 600 mg	For the treatment of vulvovaginal candidiasis
5	Palbociclib Capsules 75mg/100mg/125 mg	Palbociclib is a kinase inhibitor indicated in combination with Letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-Positive, human epidermal growth factor receptor 2 (HER2)-Negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease
6	Midodrine Hydrochloride 2.5 mg Tablet	For the treatment of symptomatic orthostatic hypotension
7	Phospholipids Fraction from Bovine Lung (surfactant) 50 mg/vial	Preventive use in premature neonates with a high risk of respiratory Distress Syndrome

- Healthcare professionals are urged to closely monitor the safety of these drugs.
- ADRs if any to be reported to PvPI.

PvPI in International Arena

Showcase of PvPI in International Pharmaceutical Federation (FIP)

This year 76th FIP World Congress of Pharmacy and Pharmaceutical Sciences 2016 took place in Buenos Aires, Argentina from 28th August to 1st September 2016. The Drug regulators, Hospital Pharmacists, Community Pharmacists, Academicians, Military and Emergency Pharmacists etc. across the globe participated in the congress. PvPI outreach was exhibited through posters and discussions in the different forums of the running sessions shed light on all key achievements of the programme as capturing of ADR through helpline, android app etc and its contribution to WHO-UMC database. South East Asian Region Pharm Forum also highlighted the success of PvPI. Pharmacist contribution to improve patient adherence in Pharmacovigilance will be the face of change in pharmacovigilance activities.

NEWS DIGEST

PvPI Exposition in WHO Newsletter to Bolster the Action Plan

Cohort Event Monitoring of BDQ has been launched across the six TB treatment centres in the country with the first patient enrolled in June 2016. To ensure the smooth functioning and effective monitoring of this new product WHO-RNTCP in collaboration with IPC organized National workshop in September 2016. It is important to capture even all the ADRs of this new product for further recommendation through two of the designed reporting forms i.e a treatment initiation form and a treatment review form for use at every follow-up visit or event.

WHO has also marked to capture pre-marketing safety and efficacy data from the manufactures.

ACKNOWLEDGEMENT

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सत्यमेव जयते

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let us join hands with PvPI to ensure patient safety

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