



Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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**Data
Mining is
pivotal to**

PV

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Secretary-cum-Scientific Director's Message



Dear Readers,

The Pharmacovigilance Programme of India (PvPI) in conjunction with its sister flagship, the Materiovigilance Programme of India (MvPI), and allied PV ventures such as those in Phytopharmaceuticals and Neutraceuticals are turning over a new leaf at Indian Pharmacopoeia Commission (IPC). The arena of research and collection-evaluation-analysis of scientific data by way of ICSR/PSUR, Signal Review and Drug Alerts has acquired a new dimension with the application of state-of-the-art tools of ADR/MDAE reporting and processing.

The proverbial sifting of the dross from the gold in the field of safe use of drugs and its propagation among the masses and healthcare stakeholders, including MAHs, is in full swing with the necessary oversight by PvPI/MVPI, IPC.

One of the landmark achievements by the Indian Pharmacopoeia Commission in the Index Period Jan-March 2019 has been the conduct of the fifth "Asia-Pacific Pharmacovigilance Training Course" at

Ghaziabad. In collaboration with Uppsala Monitoring Centre (UMC), Sweden, the event showcased the skills and expertise IPC has acquired and honed in Pharmacovigilance. With experts from 14 countries across the world in attendance, it was aimed at capacity-building in PV for public health programmes of WHO member-countries.

I feel vindicated by reposing trust in the scientific, technical and field staff at IPC and its affiliated units at AMCs for their contribution to making Pharmacovigilance a buzzword at the grassroots level as well as in the health sector at large.

I wish success to all concerned in raising the PV benchmark across the country.

Dr G N SINGH

Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare
Government of India

ICSR Data Analysis for 2018



VigiFlow is a web-based Individual Case Safety Report (ICSR) management system that is available for use by national pharmacovigilance centres of the WHO Programme for International Drug Monitoring.

VigiLyze is an online resource that delivers useful search and analysis functions and provides a quick and clear overview of VigiBase.

Pharmacovigilance Programme of India has been rapidly growing since its inception in April 2011. We have been receiving reports from healthcare professionals, industry and consumers (helpline and mobile application). VigiBase data indicates that in 2018 as many as 61,104 ICSRs were reported from all over the country. The suspected adverse events were mainly reported between the age group of 18 and 44 years.

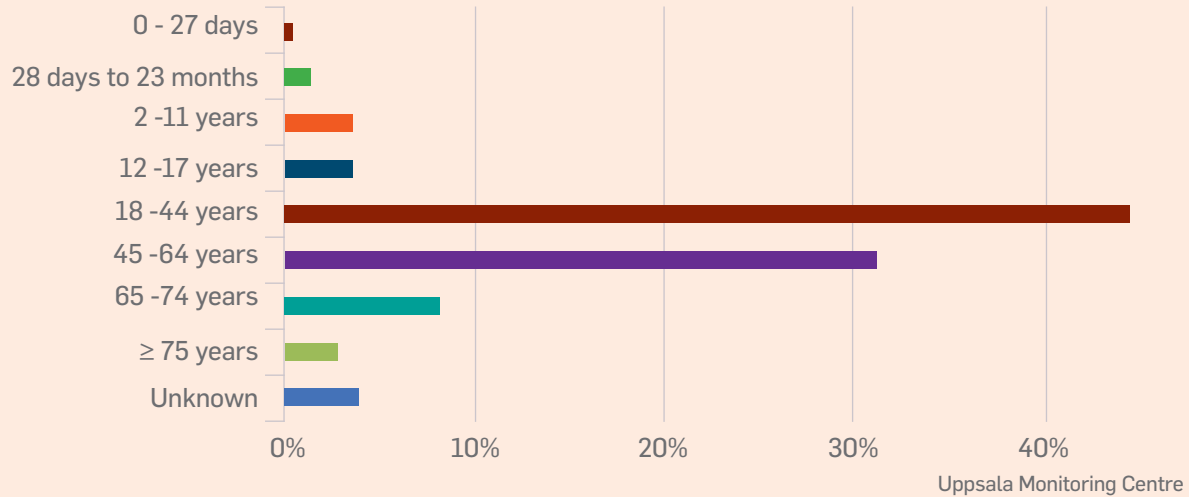
Gender-wise analysis of database reveals that of the total ICSRs submitted by PvPI in VigiBase, 29,211 were reported from male and 31,164 from female. The statistics of the total ICSRs summarizes that physicians contributed to 57% of ICSRs, similarly, pharmacists and other healthcare professionals together contributed to nearly 18% of ICSRs, and consumers contributed to nearly 7% of ICSRs in PvPI database. The analysis also points to the major role by regional

pharmacovigilance centres (ADR Monitoring Centres) in reporting suspected adverse events. Of the 61,104 ICSRs submitted in 2018, as many as 52,587 were reported by AMCs, 7,569 by pharmaceutical companies, 1,261 by healthcare professionals, and 28 by the regulatory authorities.

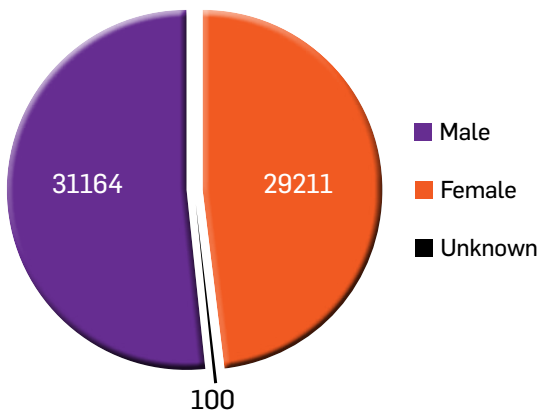
Data-mining was done by VigiLyze to identify the most occurring reactions with associated medicines. After a determined analysis of database we came to know that gastrointestinal and skin were often reported as associated System Organ Class (SOC) for suspected adverse events. Majority of suspected adverse reactions originated from anti-infective class as anti-retroviral drugs (Lamivudine, Efavirenz and Tenofovir).

As a WHO member, PvPI contributes to ensuring public health by regularly monitoring the safety of medicines used by Indian populace. PvPI consistently sensitizes all stakeholders by regularly issuing Drug alerts and conducting PV training across the country. In recent years PvPI has gained momentum owing to the enhanced contribution by, and support of, healthcare professionals and pharmaceutical companies which help boost the enthusiasm at PvPI to ensure patient safety through transparent approach and quality services, focused on scientific innovation and rationality.

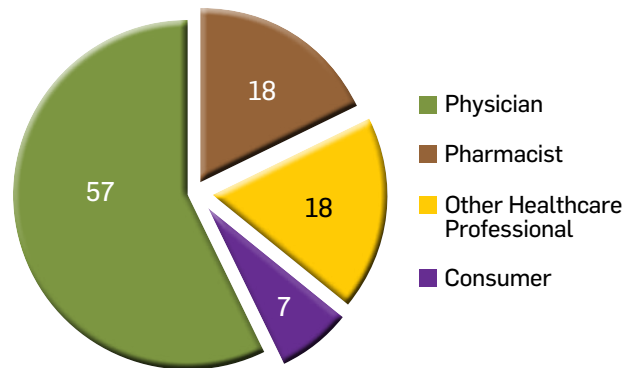
Patient age



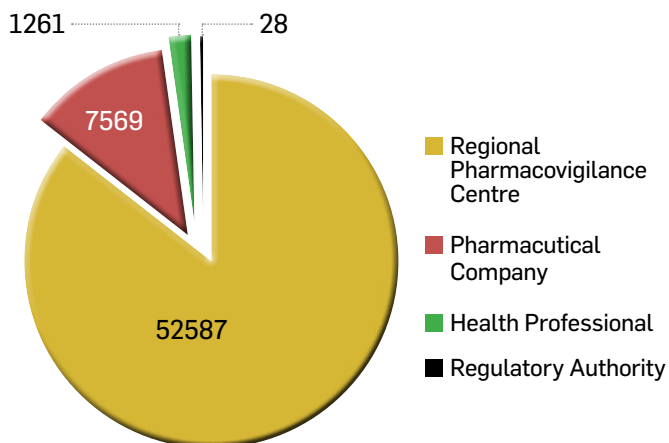
Gender-wise distribution of ICSRs



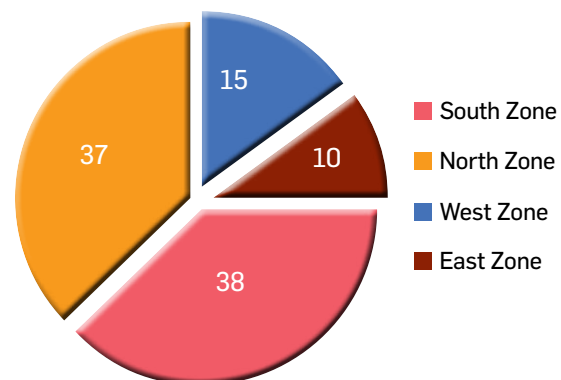
Reporter-wise distribution of ICSRs



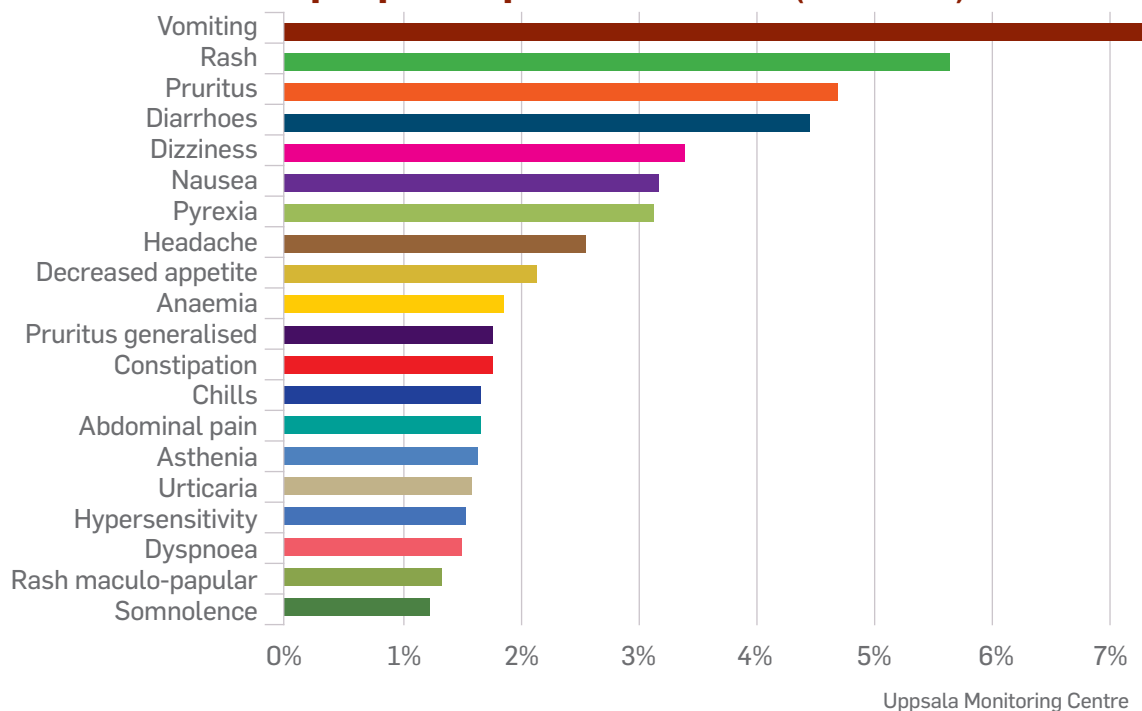
Sender-wise distribution of ICSRs



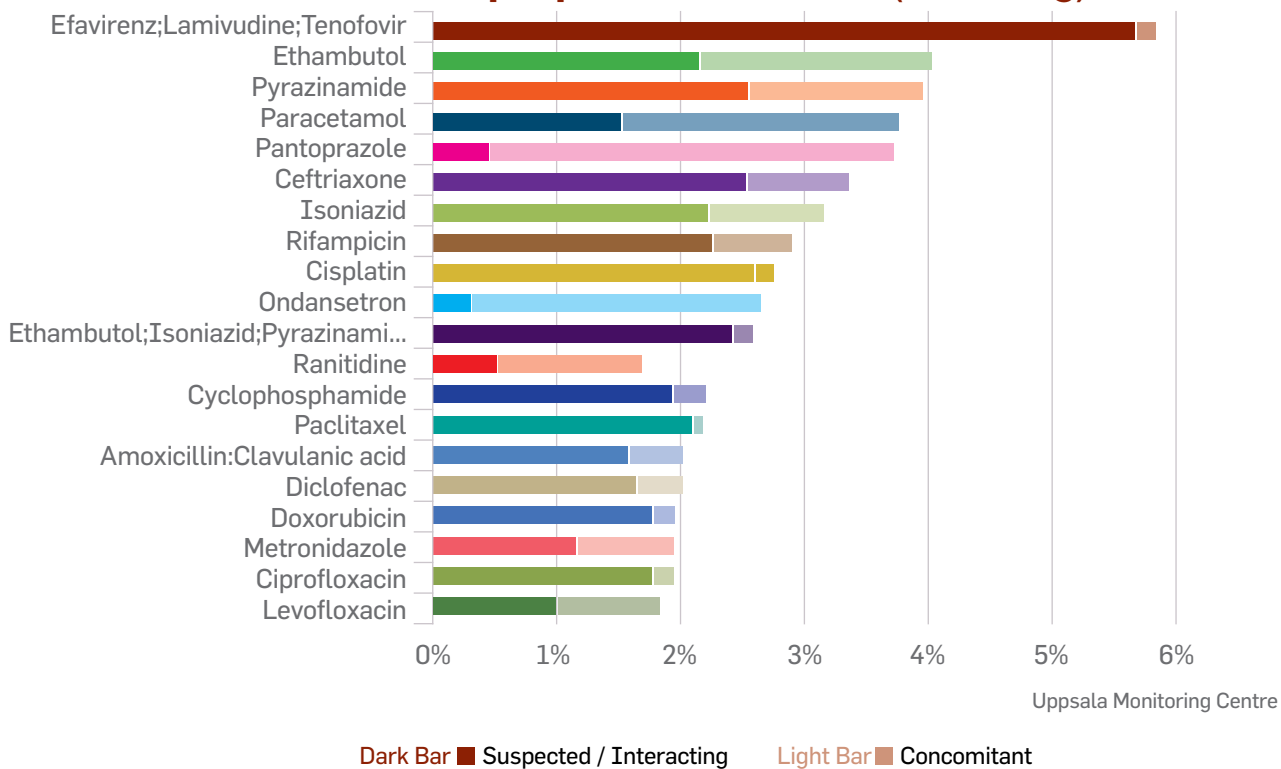
Zone-wise distribution of ICSRs



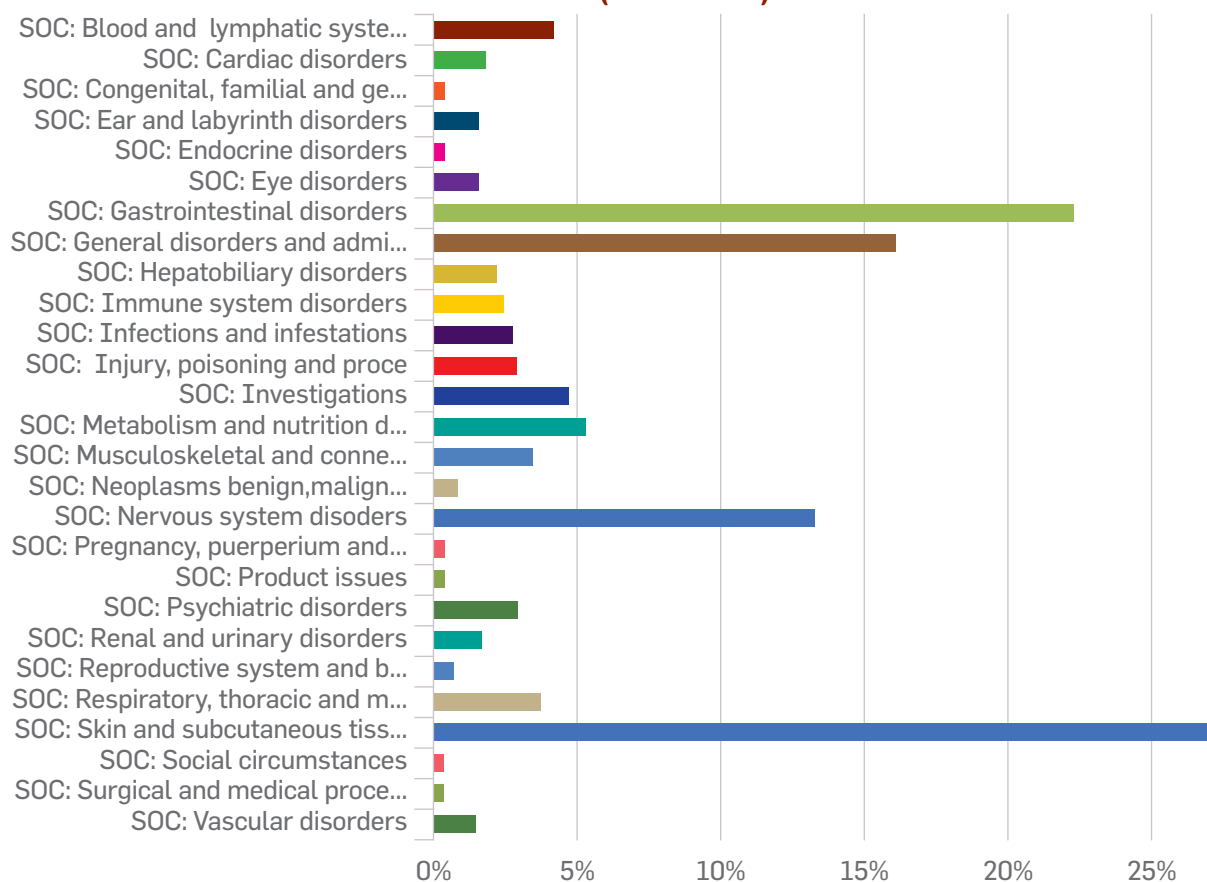
Top reported preferred terms (MedDRA)



Top reported substances (WHODrug)

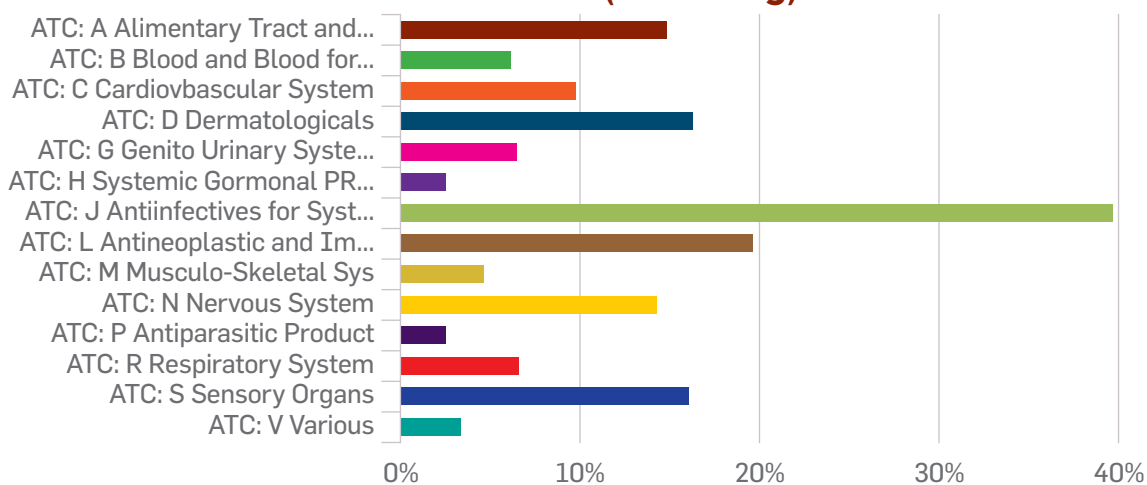


Reaction (MedDRA)



Uppsala Monitoring Centre

Medication (WHODrug)



Uppsala Monitoring Centre

Asia-Pacific PV Training course



Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare, Government of India in collaboration with Uppsala Monitoring Centre (UMC), Sweden, organized the fifth “Asia-Pacific Pharmacovigilance Training Course” from March, 4-15, 2019 at Hotel Fortune, Ghaziabad. At the programme inaugural Dr G N Singh, Secretary-cum-Scientific Director, IPC assured that IPC was committed to extending Pharmacovigilance Training & Technical Support to WHO member-countries besides ensuring sustainable Pharmacovigilance development in India. As many as 30 participants from 14 countries, including Sweden, Zimbabwe, Malawi, Congo, Swaziland, Bangladesh, Vietnam, Maldives, Botswana, Oman,

Philippines, Malaysia, Ethiopia, and India, attended the training programme.

The purpose of the course was to further develop effective and sustainable Pharmacovigilance practices for member-countries of the WHO Programme for Drug Monitoring and individuals involved in the field by creating a unique opportunity for learning and collaboration. The training programme was designed to meet regional needs and challenges unique to Pharmacovigilance. International Pharmacovigilance experts from WHO, WHO-Collaborating Centres, MHRA, UMC, Drug Regulatory Authorities, academic institutions, IPC and pharmaceutical industries addressed technical sessions blended by hands-on training.



FOCAL POINTS

- Participants acquired adequate knowledge and skills for establishing and strengthening Pharmacovigilance system at their respective organization/country
- Enhanced potential for capacity-building in PV for public health programmes of participating countries
- Training programme was conducted on a no-profit-no-loss basis
- Revenue in terms of course fee -- INR 30 lakh
- Helped enhance global reputation of Indian Pharmacopoeia Commission
- Served as a platform for capacity-building and updating skills of participating staff of PvPI

Review of identified ICSRs @ 14th SRP meeting

The 14th Signal Review Panel meeting was held at IPC, Ghaziabad on February 28, 2019. Chaired by Prof Urmila Thatte, the meeting was attended by its members, including Dr Jai Prakash, Prof G Parthasarathi, Dr K K Aggarwal, Dr M Ramesh, Dr Mira K Desai, Dr Supeme Chatterjee, Dr Sachendra Srivastava, Ms Rubina Bose, Dr V Kalaiselvan, Dr Shashi Bhushan, Dr R S Ray, and Mr Vipin Kumar, Mr Sandeep Kumar and Ms Shivangi,

SALIENT FEATURES

- Discussed nine Drug-ADR combinations which were reported to PvPI and not listed in Indian PIL.
- Signal Review Panel (SRP) recommended PvPI to suggest CDSCO to take necessary steps for four Drug-ADR combinations to incorporate suspected ADR into the PIL of respective medication.
- Discussed Draft Signal validation and Signal assessment form containing essential data which need to be filled up and kept ready before the meeting.

ICSR software development meet

CC-PvPI, IPC officials, including Dr Shashi Bhushan, Senior scientific officer, Mr Vipin Kumar, Senior Pharmacovigilance Associate, PvPI, IPC, held a meeting with C-DAC and SUN Pharma PV teams at SUN Pharmaceuticals Industry Ltd, Gurgaon on January 16, 2019. The objective of the meeting was to develop software for longterm use, validation of the software using GAMP 5V Model, 21CFR (Part 11)-compliant global safety databases, and validation certification so as to make it more robust from the existing software available in the market.

SALIENT FEATURES

- An audit trail system in the software for tracking ICSR process
- WHO-DD is internationally accepted & updated
- Software is inbuilt with E2B(R3)-compliant for transmission of the data to other database
- Updated software as automation of case narrative for the ICSR and finding duplicate report in database.
- Addition of new features such as field for BMI, Separation of reports by ethnic group, and Optical Character Recognition (OCR) are inbuilt in the system



PV partners' monthly meet

A Pharmacovigilance partner meet was held at Deputy Commissioner Room, UIP Division in Nirman Bhawan, New Delhi on Jan 28, 2019 to review the progress of PvPI. The meeting was chaired by Dr M K Aggrawal with Dr Shashi Bhushan, Senior Scientific Officer and Mr Pankaj Bhatt, Senior Pharmacovigilance Associate, representing IPC. Other partners included Dr Arti Garg, Dr Deepak Polpakara, AEFI Secretariat, New Delhi, Dr Vikas Madaan, Mr Somnath Basu, ADC (I), CDSCO (HQ), New Delhi, Dr Vineet Goyal, WHO India, Mr Rajesh Nallamothu, Mr Shaktivel P and Dr Krishna Kumar.

MOOT POINTS

- Follow-up on Institutional Development Plan activities, including plan for Joint Assessment Visit
- Vac-Safe (formerly VAEIMS) updates
- Audio-visual training for all stakeholders with the screening of vaccine-associated anaphylactic shock and adrenaline administration
- Meeting of CDAC and WHO officials for



development/update of indigenous PvPI-ADR reporting software

- Reporting of AEFI cases through notification form by AMCs
- Preparation of checklist to assess AEFI processes at state, district and planning unit level

IPC at CDSCO workshop on bolstering PvPI

A two-day workshop on “Strengthening Pharmacovigilance Systems and Supporting the Collaboration of Regulators, Pharmacovigilance Programme of India and Immunization



Programme of India” was held at CDSCO (HQ), FDA Bhawan, New Delhi on February 4-5, 2019. Dr Jai Prakash, Sr Principal Scientific Officer, Dr V Kalaiselvan, Principal Scientific Officer and Mr Vipin Kumar, Senior Pharmacovigilance Associate represented IPC, Ghaziabad.

WHO, CDSCO, AEFI Secretariat, PvPI and rotavirus Marketing Authorization Holders (MAHs) had an interactive session at the workshop to plan effective implementation of Pharmacovigilance system at MAH-level. The workshop also focused on generation of signals from VigiFlow ICSR database for rotavirus vaccine.

SALIENT FEATURES

- Dr Viola Macolic Technical Officer, WHO-HQ presented WHO programme for international drug monitoring comprising VigiBase, VigiLyze, VigiAccess and its linkage with the national

PV system, E2B features in ADR reporting and importance of MedDRA coding in ICSRs for better signal detection activities

- Dr Madhur Gupta, Technical Officer, WHO-India discussed the roles and responsibilities of all stakeholders for Pharmacovigilance in India with specific focus on AEFI surveillance system
- Dr Jai Prakash and Dr V Kalaiselvan deliberated on PV guidelines covered under guidance documents of Pharmacovigilance for MAHs and reporting system of ICSRs by MAHs to PvPI
- CDSO representatives briefed on regulatory requirement of Pharmacovigilance for MAHs in India, focusing on the current situation of Post-Authorization Safety Studies (PASS) with case study
- MAH representatives from GSK, MSD, Bharat Biotech and Serum companies made presentations on routine Pharmacovigilance activities for vaccine ADR collection and reporting.
- Challenges and proposals to meet the regulatory



requirements for reporting all collected vaccine ADRs to the regulators. Describe the process in the company from collecting to coding and sending ICSRs to PvPI

- MHRA/UK representatives also shared their experiences with MAHs for collection, reporting, sharing ADR reports and access to database for signal detection

5th Core Training Panel Meet

PvPI organised the fifth Core Training Panel (CTP)-cum Fourth Regional Training Centres (RTCs) Coordinators' meeting at IPC, Ghaziabad on January 31, 2019. The meeting was chaired by Dr Nilima Kshirsagar, National Chair, Clinical Pharmacology, ICMR.

HIGHLIGHTS

- Goals and targets in training and education for 2019
- Designing competency-based training programmes and data-driven research in the area of Pharmacovigilance
- Challenges in sensitizing clinicians and conducting training programmes/awareness activities
- Panel members suggested training for sensitizing nursing and paramedical staff/ institutions and



other healthcare professionals to Pharmacovigilance

- Structured schedule and format of training agenda to maintain uniformity among all RTCs
- Chairperson Dr Nilima Kshirsagar suggested that NCC-PvPI provide technical support/ Pharmacovigilance Associate to ICMR institutions for establishment of Pharmacovigilance system and facilitating Pharmacovigilance-centric research.



IPC @PV meet in Shobhit varsity, Saharanpur

A national conference on “Recent Advances in Pharmacovigilance Measures Affecting Drug Development and Industry Output” was organised by Adarsh Vijendra Institute of Pharmaceutical Sciences at Shobhit University in Gangoh, Saharanpur, UP on February 12, 2019. Dr V Kalaiselvan, Principal Scientific Officer with Pharmacovigilance Associates Ms Shavya Singh and Dr V Lokesh Reddy attended the conference. Dr Kalaiselvan delivered a lecture on “Pharmacovigilance: Current Status & Challenges”, covering the key elements of effective and efficient functioning of PvPI, IPC for promoting patient safety in India. Ms Shavya

Singh deliberated on “Pharmacovigilance: Methods for Reporting Adverse Events”. Dr Lokesh Reddy expounded on “Introduction of Suspected ADR Form and Hands-on Training with Case Examples”.

OUTCOME

- Sensitized students and healthcare professionals to the basics of Pharmacovigilance and reporting of ADRs
- Experts at the conference suggested that Pharmacy institutes make it mandatory for their students to use PvPI-ADR mobile app for reporting ADRs



National AEFI Committee meet

National Adverse Event Following Immunization (AEFI) Committee meeting was held at NIHFW in New Delhi on February 25, 2019. Signal review for all AEFI cases was discussed and evaluated by committee

members. A presentation on signal identification of drugs was made by Mr Vipin Kumar, Senior Pharmacovigilance Associate, IPC. The Committee also recommended to CDSCO that regular meetings be held with MAHs for vaccine PSUR.

National workshop on PSUR & RMP assessment for regulatory authorities



A four-day workshop on Periodic Safety Update Report (PSUR) and Risk Management Plan (RMP) assessment was organized by WHO in collaboration with National Regulatory Authority of India (NRA) at Hotel Royal Plaza, New Delhi, India between March 5-8, 2019.

The workshop was organized with an objective of providing training to the regulatory authorities' representatives on legislative framework of PSURs and RMPs in India. Further this training also included a dedicated hands-on training for successful writing of PSUR & RMPs for all the MAHs of India.

The workshop was attended by Dr V Kalaiselvan, Principal Scientific Officer, IPC and Pharmacovigilance Associates Mr Pankaj Bhatt, Mr Amit and Ms Swati Thapliyal. Dr R Chandrashekar, Deputy Drugs Controller (India), Dr Deepak Polpakara, AEFI Secretariat, Delhi. Representatives of CDSCO, WHO, MHRA and vaccine MAHs were also present during the workshop. .

MOOT POINTS

- Discussed legislation and guidelines for RMP, PSUR and regulatory practices in India, also discussed medicines which required RMP submission
- Timelines on RMP submission, modules and Good Pharmacovigilance Practices (GvP) guidelines on RMP were highlighted
- Case studies related to RMP assessment for medicines and vaccines were discussed
- Updated guidelines for the industries in India on submission of RMP and PSURs.
- CDSCO officials delivered a presentation on how to write RMP and PSUR for medicines and vaccines

OUTCOME

- Participants updated their understanding on various aspects of RMP and PSUR.
- Hands-on training to all vaccine-safety stakeholders for assessment of RMP and PSUR documents
- Focused approach to good vigilance practices for patient safety

5th Technical Committee meet on Kala-Azar

5th Internal Technical Committee meeting on updating ADR reporting of anti Kala-azar drugs such as Miltefosine, Ambisome, etc. was conducted at Department of National Vector-Borne Disease Control Programme (NVBDCP), DGHS in New Delhi on February 26, 2019. Mr Pankaj Bhatt, Senior Pharmacovigilance Associate, PvPI, IPC

represented Pharmacovigilance Programme of India. He made a presentation on ADR reporting status of Kala-azar drugs from 58 NVBDCP centres. ADR reporting status for Miltefosine and Ambisome was shared with the technical committee members and adverse drug reactions were discussed in terms of their seriousness, gender, age group and affected system organ class.

PV training for Ayush coordinators

A two-day training programme for the coordinators of Pharmacovigilance Centres of Ayurveda, Siddha, Unani and Homoeopathy Centres was conducted by All India Institute of Ayurveda (AIIA), Sarita Vihar, New Delhi in collaboration with Indian Pharmacopoeia Commission (IPC), Ghaziabad on March 19-20, 2019. The inaugural session was attended by Dr K R C Reddy, Director, PCIM and Prof Sujata Kadam, Dean, PG Studies, AIIA, Dr GVR Joseph, Director, HPL, Ghaziabad, Dr Jai Prakash, Senior Principal Scientific Officer, IPC, Ghaziabad and Dr V Kalaiselvan, Principal Scientific Officer, IPC, Ghaziabad. The training was attended by 41 coordinators from across the country.

Dr Kavita Gulati, Vallabhbhai Patel Chest Institute, University of Delhi, Dr Ashwini, Medrix, Prof G P Mahanta, Annamalai University, Annamalai Nagar; Dr V Kalaiselvan, Principal Scientific Officer, IPC, Ghaziabad, Dr Pooja Gupta, AIIMS, New Delhi, Dr Santhanu Tripathi, School of Tropical Medicine, Kolkata, Dr Rachna Paliwal, Ministry of AYUSH, New Delhi were the experts who addressed the technical sessions. The emphasis during the two-day session was on:



- Basic introduction and concept of Pharmacovigilance in ASU & H drugs
- Terminology and methods used in Pharmacovigilance
- Building-up of an effective Pharmacovigilance Communication system for AYUSH products
- Challenges and lessons learnt from Pharmacovigilance Programme of India (PvPI) and Way forward for AYUSH systems
- Functioning of a Peripheral Centre in monitoring safety of AYUSH products.
- Surveillance of misleading advertisements of AYUSH drugs



CME on vaccine safety



A Continued Medical Education (CME) programme on “Academic Clinical Trial and Vaccine Safety” was jointly organised by ADR Monitoring Centre, Guwahati, Department of Pharmacology, Department of Community Medicine, Guwahati Medical College & Hospital, at Guwahati on March 23, 2019. The symposium was addressed by AMC Coordinators Prof Bikash Medhi and Prof Santanu Kumar Tripathi and WHO expert Dr Subhajit Bhattacharjee.

The CME focused on vaccine safety, AEFI and how to report ADR for vaccine, role of PvPI in AEFI data collection, filling up of ICSR form and proposed joint work with WHO for AEFI reporting. Seventy-five members, including faculty and students of the various medical colleges of Assam, attended the CME. The CME was a success with eminent persons sharing their knowledge and expertise.

MvPI Jan-Mar 2019 progress report

Development of Resource Material and Reporting Tools

National Coordination Centre (NCC)-MvPI on February 8, 2019 launched at IPC its recently-developed reporting tools and reference documents for ensuring effective implementation of MvPI as well as promoting safety of Medical Devices. Reporting tools and reference documents

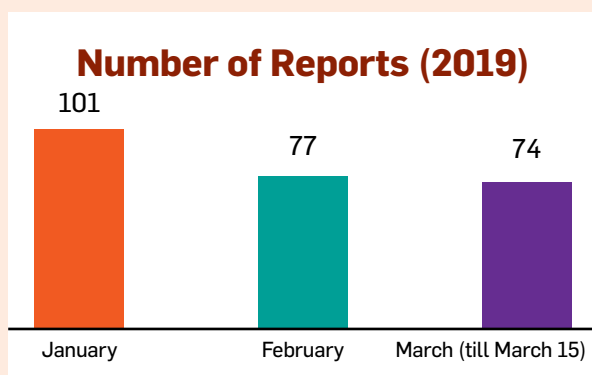
available on IPC website and are as follows:

- An updated Medical Devices Adverse Event Reporting Form (version 1.1)
- A Field Safety Corrective Action (FSCA) Form
- Registered Medical Devices Information Sharing Portal (www.mvpi.co.in)
- A Reference Manual for Medical Devices
- A Handbook for MvPI



MDAEs reported Jan-Mar 2019

NCC-MvPI received as many as 1,213 Medical Devices Adverse Event (MDAE) reports from across the country since 2014. However, for the Index Period – January 1 to March 15, 2019) -- MvPI received 252 reports which were duly processed.



ICSRs reported January-March 2019



New MDAE Centre

During Index Period, NCC-MvPI recognised School of Tropical Medicine, Kolkata as one of the Medical Devices Adverse Events Monitoring Centres under MvPI.

MvPI Partners' meet

Monthly partners meeting -- an initiative by NCC-MvPI to discuss serious adverse events and other in-house technical documents with MvPI partners i.e.

SCTIMST, Kerala, CDSCO and NHSRC, New Delhi – has been started recently and conducted once each in January 2019 and February 2019. A synopsis of the MvPI partners meeting follows herein:

Month/Year	Outcome
January 2019	<p>The reported Adverse Events in December were assessed and it was concluded that they were not related to Medical Devices. The reported incidents might have been the result of clinical conditions of the patient and/or procedural issues</p> <p>Constitution of subject expert committee and criteria for selection of subject experts were decided</p>
February 2019	<p>The reported Adverse Events in January were assessed and it was concluded that they were not related to Medical Devices except for a few cases in which trend-monitoring is suggested for final conclusion</p>

Workshop at PGIMER, Chandigarh

A workshop on “Clinical Pharmacology and Therapeutics” was conducted by Department of Pharmacology, PGIMER, Chandigarh on March 2, 2019. The workshop was attended by nearly 50 participants from diverse backgrounds, including scientists, physicians, postgraduate students and research scholars. IPC was represented by Dr Jai Prakash, Senior Principle Scientific Officer, IPC, Dr R S Ray, Scientific Officer, IPC and Mr Sandeep Kumar,

Pharmacovigilance Associate, PvPI. Dr Jai Prakash delivered a talk on “Pharmacovigilance Programme of India: Current Scenario”. The participants were sensitized to the need and importance of Pharmacovigilance and briefed on the modes of reporting ADRs, Causality Assessment and tools of ADR reporting within the country. He also highlighted the achievements of IPC, NCC-PvPI in promoting patient safety and sensitized the audience to the regular Skill Development Programme at IPC.

Training for MvPI advancement

NCC-MvPI- on January 30, 2019 organized a training programme on the Role of Biomedical Engineers in Assessment of Medical Devices Adverse Events. Held at IPC Regional Office, Hyderabad, it was aimed at developing workforce to meet the challenges in implementing MvPI's core objectives.



Workshop on Alternative Methods of Animal Testing

A three-day workshop on “Alternative Methods of Animal Testing” was organised by Department of Biomedical Sciences, Shaheed Rajguru College of Applied Sciences for Women, University of Delhi on March 29, 2019. The workshop was attended by eminent scientists, research scholars, faculty and students. Dr R S Ray, Scientific

Officer, IPC represented IPC and on the last day of the workshop delivered a talk on “Pharmacovigilance: Ensuring Safe Use of Medicines”. He highlighted the scientific modules applied by NCC-PvPI, IPC in promoting patient safety, stressing how the training by Skill Development Programme at IPC promoted the culture of ADR reporting among all HCPs.

Approved New Drugs in India

New drugs approved by CDSCO during January- March 2019

S. No	DRUG	INDICATION
1	Fenspiride hydrochloride film-coated extended release tablet 80 mg and Fenspiride hydrochloride Bulk	For treatment of Acute Rhinosinusitis and Moderate persistent asthma as an add-on therapy
2	Bilastine tablets 20 mg and Bilastine Bulk	For symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria in adults
3	Iguratimod film-coated tablets 25 mg and Iguratimod Bulk	For treatment of active rheumatoid arthritis symptoms

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

Source: on 29/03/2019 https://cdsco.gov.in/opencms/opencms/en/Approval_new/Approved-New-Drugs/

Drug Safety Alerts for January-March 2019

Preliminary analysis of Suspected Unexpected Serious Adverse reactions (SUSARs) from the PvPI database reveals that the following drugs are associated with the risks as given below:

Suspected Drugs: Levetiracetam

Indication: (i) As monotherapy in partial onset seizures with or without secondary generalisation in newly diagnosed patients above 16 years

(ii) As adjunctive therapy for myoclonic seizures in adults and in adolescents above 12 years

(iii) For primary generalised tonic-clonic seizures in adults and adolescents above 12 years with idiopathic generalised epilepsy

ADR: Anencephaly

Suspected Drugs: Cetirizine

Indication: For treatment of seasonal/perennial allergic rhinitis & chronic idiopathic urticaria in infants & children

ADR: Tachycardia

Suspected Drugs: Dabigatran

Indication: For prevention of stroke, systemic embolism and reduction of vascular mortality in adult patients with atrial fibrillation

ADR: Alopecia













Suspected Drugs: Sertraline

Indication: Major depressive disorders, Obsessive Compulsion Disorders (OCD), panic disorders

ADR: Maculopathy

Healthcare professionals, Patients/Consumers are advised to closely monitor the possibility of the above ADRs associated with the use of above drugs. If such reactions are encountered, please report to the NCC-PvPI either by filling of Suspected Adverse Drug Reactions Reporting Form/Medicines Side-Effect Reporting Form for Consumer (<http://www.ipc.gov.in>) or by PvPI **Helpline # 1800-180-3024**.

Comparative status of Global Drug Alerts with PvPI Database

NAME OF DRUG	RISK WARNING	INTERNATIONAL STATUS	INDIA STATUS
EPINEPHRINE	 Pulmonary Oedema	 America – 56 Europe – 07 Asia – 05	 Two ICSRs of Pulmonary oedema reported in PvPI database
FLUCONAZOLE	 DRESS Syndrome	 America – 15 Europe – 43 Asia – 10	 One ICSR of Dress Syndrome reported in PvPI database
DABIGATRAN	 Alopecia	 America – 226 Europe – 53 Asia – 3	 One ICSR of Alopecia reported in PvPI database
SERTRALINE	 Maculopathy	 America – 13 Europe – 10 Oceania – 2	 One ICSR of Maculopathy reported in PvPI database

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

Stellar role in PV by CMCH-Ludhiana

Established in 1894, Christian Medical College and Hospital (CMCH), Ludhiana is one of the premier medical institutes in the Punjab region. This tertiary care hospital has 775-bed occupancy, providing speciality health facilities under dynamic leadership of the Director, Dr William Bhatti. CMCH, Ludhiana was enrolled as an Adverse drug reaction Monitoring Centre (AMC) under Pharmacovigilance Programme of India (PvPI) in 2012. Pharmacovigilance activities of AMC are carried out effectively under the stewardship of Dr Dinesh K Badyal, AMC Coordinator and Professor, Department of Pharmacology. The institute has constituted a CAC (Casualty Assessment Committee) and Pharmacovigilance committee for strengthening pharmacovigilance and sensitizing healthcare professionals to PV. It has been steadfast



in the implementation of Pharmacovigilance programme in the college and associated hospitals.

ACTIVITIES AND ACHIEVEMENTS

- Drug alerts, MDAE (Medical Device Adverse Event) reporting form and NCC-PvPI toll-free number incorporation in the in-house quarterly bulletin of drug updates “Pharmascan” & circulation among all HCPs
- Coordination with peripheral hospitals for active ADR-reporting as Punjab Institute of Medical Sciences, Jalandhar & Satguru Partap Singh Apollo Hospitals, Ludhiana
- Awareness of PvPI among medical students, faculty and other HCPs through models at annual pharmacology quiz competition “Pharmiz”
- Sensitization by a seminar on “Pharmacovigilance ADR-reporting” for nursing staff in May 2018
- ADR collection through ADR reporting registers from different department OPDs. Implementing practices and sharing ideas with other departments as well
- Dissemination through PvPI awareness posters and pamphlets in all OPD wards and ICUs
- Poster display of rare case reports in CME “Modernizing Medical Education: Replacing Animal Use with Superior Simulation Technologies” at CMCH, Ludhiana
- Research project on focused pharmacovigilance of first line anti-tubercular drugs in tertiary care hospital

RDGMC-Ujjain at its best in PV

RD Gardi Medical College (RDGMC) is the first private medical college in Madhya Pradesh. Established in 2001, it is recognized by the Medical Council of India and Ministry of Health & Family Welfare, Govt of India. Its 800-bed hospital provides patients medical services free of cost. RDGMC, Ujjain has been functioning as an Adverse Drug Reactions Monitoring Center (AMC) under Pharmacovigilance Programme of India since 2011. The programme has been picked

up pace since the deputation of Mr Sunil Kumar Thakur, Patient Safety Pharmacovigilance Associate, NCC-PvPI, IPC, Ghaziabad. Steps taken by AMC RDGMC for boosting Pharmacovigilance include:

- Quarterly CMEs on PV for all faculties, consultants and resident doctors for updating on recent advancements
- Regular sensitization of nurses, medical, paramedical and pharmacy staff by seminars and workshops



- Actively participated in “Simhashth Kumbh 2016” for mass sensitization of public on Pharmacovigilance. A minute-long awareness video was made by AMC and played on giant screens at various locations of the Kumbh Mela
- Regular visits to NABH-accredited hospitals in

and around Ujjain for sensitizing the staff on PV-system set-up at hospitals

- Liaison the UHCs, PHCs and CHCs with district health administration to facilitate pharmacovigilance
- AMC proactive in starting a systematic pharmacovigilance system for healthcare facilities in MP. Health secretary of MP appointed Deputy Drug Controller of the state as Nodal Officer for Pharmacovigilance who will look after the state pharmacovigilance system. An action plan to start state pharmacovigilance system was presented to the health commissioner of the state
- An exclusive OPD dedicated to pharmacovigilance has been started to facilitate direct consumer reporting and patient counseling on rational use of drugs
- Drug Alert Cards issued to the patients for minimizing the occurrence of ADRs

MMC-Madurai adapts to PV practices

Established in 1954, Madurai Medical College is a Government Medical college located in Madurai, Tamil Nadu. The college is attached with Government Rajaji Hospital with the in-patient capacity of around 3000 patients. It was designated as an AMC under PvPI in January 2014. Currently, the AMC at MMC, Madurai is functional under the supervision of Dr K M S Susila, Director. MMC, Madurai. Dr M Malathi is leading the activities of AMC as Coordinator and Mr T Thirumalai Nambi is appointed by PvPI as Senior Pharmacovigilance Associate.

AMC ACTIVITIES

- Contribution of more than 2500 ICSRs to PvPI database since inception
- Regular sensitization and training programmes



for all the departments of Madurai Medical College and associated hospitals

- Dedicated trainings for pharmacy and nursing students in nearby colleges
- Inclusion of above 300 mobile numbers of HCPs in national database to receive drug safety SMS alerts
- Raised alarm for quality issues of medicinal products/medicines such as infusion sets, Imatinib tablets, Metronidazole Injection, Bupivacaine Injection etc.
- Active vigilance of medical devices
- Drug Alert Cards issued to the patients as ADR-risk minimizing measures

STAKEHOLDERS' FEEDBACK

Dr. MEGHA SHARMA, Associate Professor, Department of Pharmacology, R. D. Gardi Medical College Ujjain, (M P), India, Researcher, Global Health- Health Systems and Policy, Department of Public Health Sciences, Karolinska Institutet, Stockholm, Sweden

Pharmacovigilance program of India (PvPI) is an important surveillance system to monitor drug safety and rational use of medicines. The wide varieties of inexpensive reporting methods give flexibility to the program and provide better patient care. Regular training and active participation of the healthcare providers is crucial for the program. At RDGMC the students and staff is being regularly trained under PvPI. The focal area of RDGMC PvPI has been expanded and state level training seminars have been conducted at the center.



Dr. DINESH K BADYAL, Professor, Department of Pharmacology (AMC Coordinator), Christian Medical college and Hospital, Ludhiana, "Heartiest congratulations to NCC-PvPI, Ghaziabad for its success".

Pharmacovigilance Programme of India (PvPI) has put international impact in the area of ADR reporting significantly. The constant encouragement & motivation provided by the PvPI have improved the ADR reporting scenario in India. Private sector, national health programmes and also pharmaceutical industry into the programme have helped in achieving of new milestones in the field of Pharmacovigilance. It has been a pleasure to work with and to see the growth of PvPI since its embryonic stage. We, as a team look forward to working with PvPI for many more years to come."

Dr. MONIKA SHARMA, MBBS, MD (Pediatrics), CMCH, Ludhiana

"Pharmacovigilance program is the need of the hour. Besides being a check on improper prescription practices, the PVPI program has helped create awareness about newer drug effects amongst doctors. Physicians are now more alert to the possibility of yet unrecognized adverse reactions to drugs. Having a designated 'ADR Officer' in our institute has enhanced adverse reaction reporting."



Dr. ANURADHA BHATIA, Associate Professor, MBBS, MD (Dermatology), Member of PV Committee, CMCH, Ludhiana

Pharmacovigilance programme of India is a very important tool for all medical professionals and is need of the hour. Since the incidence of drug reactions are on the rise in the recent years, this programme sensitizes all medical professionals regarding the various adverse drug events and helps in regulating the safety of drugs.

Dr. ABHILASHA WILLIAMS, Associate Professor, MBBS, MD (Dermatology), Member of PV Committee, CMCH, Ludhiana

Pharmacovigilance programme of India has made our doctors, nurses and paramedical staff more sensitive in patient safety. The entire team headed by Dr. Dinesh Badyal (AMC coordinator at CMCH, Ludhiana) is quite active and vigilant in reporting the adverse drug reactions. The entire AMC team has put their hard work to improve the drug safety profiles in our health institution.



Dr. SHAILENDRA SHARMA, Professor-Surgery & Medical Superintendent, RD Gardi Medical College, Ujjain.

Statistics from US and other developed countries have shown very large number of people suffer and even die from the adverse effects of drugs. The pharmaceutical companies are more powerful than armament industry and will never easily disclose the adversity cause by molecules marketed by them. It is so sad to watch even the mainstream doctors either lack the knowledge or concerns about the adverse effects of molecules they are prescribing. In this darkness the Pharmacovigilance Programme of India in monitoring the adverse reaction is doing a great service in medicines safety. ADR Monitoring center RD Gardi Medical College under stewardship of Mr. Sunil Kumar Thakur is doing a great job in identifying such drugs and making clinicians aware of such adverse effects in addition to creating a database and contributing it for national body. My best wishes to all who are rendering this vital service to medicines.

Dr. ARTI JULKA, Professor Pulmonary Medicine, RD Gardi Medical College, Ujjain

Pharmacovigilance program of India (PvPI) is the need of the hour providing useful information about the adverse effects of drugs and devices being used in the country. This is especially important with polypharmacy being practiced and increasingly complex drug interactions being experienced. Let us all participate and strengthen the program for providing better and safer care to our patients.



Dr. B. L. BAMBORIYA, Professor, Dept. of Medicine, R D Gardi Medical College Ujjain

The Pharmacovigilance Programme of India is doing a great job to improve the patient safety through CMEs, timely drug alerts, having own signal detection system and dedicated personals for it. Despite all these laudable efforts, to be content with the pace of growth in pharmacovigilance for such a large population like India is unacceptable. Still there is an inadequate level of pharmacovigilance awareness among healthcare professionals and so many challenges in adverse drug reactions reporting need to be overcome. I believe for a robust pharmacovigilance system to take shape in the clinical settings, it is of immense importance that a pharmacovigilant culture needs to be inculcated right from the student days. The MCI mandate for all medical colleges to have a pharmacovigilance department is a great initiative, but there is a need to give more emphasis in the Pharmacovigilance especially in the subject of Pharmacology to engage the students in the Pharmacovigilance practice during their clinical assignments.



Dr. G. GEETHA RANI, Professor & HOD, Department of Dermatology, Madurai Medical College, Madurai

Adverse drug reactions are often under reported and sometimes under diagnosed, especially in late reactions. The frequent use of non prescription drugs and the entry of newer drug in to the market make it more challenging. The genetic background plays an important role in the differing clinical pattern of ADR of a particular drug from country to country. The database collected may reveal this difference. Madurai medical college is participating actively in the PvPI programme and will continue to contribute effectively for fulfilling its objectives.



Dr. P.N.RAJASEKARAN, Professor & H.O.D., Medical Oncology, Madurai Medical College, Madurai

Pharmacovigilance ensures therapeutic discipline. When a series of breast cancer patients started on chemotherapy failed to develop alopecia in our institution, a PvPI intervention was triggered. Thus we picked up substandard Doxorubicin which was one among the long list of substandard consumables found to be defective by PvPI. This programme continues to be successful only because of simple reporting format and good coordination by Pharmacovigilance staff at all levels. As a logical next step, Active Pharmacovigilance by regular and random sample lifting from end users for quality assurance will further augment the PvPI.



Dr. P.V.BALAMURUGAN, CAC Member, Department of General Medicine, Madurai Medical College, Madurai

Pharmacovigilance (PV) aims at safer and more effective use of medicines for everyone. The most important step to achieve this aim is to increase the level of awareness among health care providers (HCPs) and making them spontaneously report adverse events (ADEs). The spontaneous reporting systems provide highest volume of information at the lowest maintenance cost and hence helps in the early detection of patient safety issues.



Dr. R.PRABHAKARAN, Professor & Head, Department of Respiratory Medicine, Madurai Medical College, Madurai.

PvPI plays a vital part in ADR monitoring and preventive measures. As far as our department concerned, we have utilized medical devices recall as per FDA/TGA in a meticulous way to service the Bronchovideoscope at free of cost. We thank PvPI & MvPI for concern about the patient safety. The ADR monitoring is very essential in patients who are on multiple regimens like anti tuberculosis drugs and anti retroviral drugs. These drugs tend to cause more serious hepatic, renal toxicity and drug resistance. The ADR monitoring in these patients really help us to minimize the patient sufferings from ADR and further morbidity.



Dr. K.M.S.SUSILA, Director & H.O.D., Institute of Pharmacology, Madurai Medical College, Madurai.

Delivering safe care in complex pressurized fast moving environment is the greatest challenges faced by health sector. The preventable errors can and should be avoided and PvPI has the key to the door to safeguard the patients from ADR. Hence it is very imperative to extend this programme in health care students curriculum which will help us to go long way in therapeutics.



Dr. M.MALATHI, Coordinator, AMC., Institute of Pharmacology, Madurai Medical College, Madurai.

With growing recognition of harms caused by healthcare products comes the need for medical professionals to learn how to deliver safe care, which is the key principle of PvPI. It doesn't stop short with collection, analysis and assessment of ADR, but the scope extends to substandard, counterfeit drugs, vaccines and Materiovigilance. The improvement in computing capabilities have provided opportunities to automat signal detection and giving drug safety alert to all stake holders. Our institute has encouraged the Pharmacy students to do projects in ADR monitoring to create awareness on PvPI among those students.



दवाईयों से होने वाले प्रतिकूल प्रभाव/दुष्प्रभाव की निगरानी एवं मरीजों की सुरक्षा के प्रति जागरूकता

फॉर्माकोविजिलेंस प्रोग्राम ऑफ़ इंडिया, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार द्वारा जनहित में जारी

जैसा कि हम सभी जानते हैं कि दवाईयों (टैबलेट्स, कैप्सूल, सीरप, इंजेक्शन, टीके इत्यादि) के उपयोग से किसी न किसी प्रकार के प्रतिकूल प्रभाव/दुष्प्रभाव की सम्भावना रहती है इसको ध्यान में रखते हुए स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार ने एक विशेष कदम उठाया एवं इस कदम के अंतर्गत फॉर्माकोविजिलेंस प्रोग्राम ऑफ़ इंडिया को नवीकृत किया, जिसका राष्ट्रीय समन्वय केंद्र भारतीय भेषज संहिता आयोग, राजनगर, गाज़ियाबाद, उत्तर प्रदेश में स्थित है। इस समन्वय केंद्र का मुख्य कार्य दवाओं से होने वाले प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी ए.डी. आर. मॉनीटरिंग सेंटर के द्वारा एकत्रित करके उसका ऑकलन एवं विश्लेषण करना है जिससे किसी भी दवा के फायदे एवं नुकसान की जानकारी अग्रिम कार्यवाही हेतु केन्द्रीय औषधि मानक नियंत्रण संगठन, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार को प्रेषित की जा सके।

“फॉर्माकोविजिलेंस का अर्थ है औषधि सतर्कता”, यदि किसी मरीज या व्यक्ति को दवाई लेने के बाद कोई प्रतिकूल प्रभाव/दुष्प्रभाव जैसे कि त्वचा संबंधित परेशानी, डायरिया, जी मिचलाना, उल्टी, बुखार, रक्तचाप (उच्च/निम्न), सिरदर्द या अन्य कोई दुष्प्रभाव प्रतीत होता है तो ऐसी स्थिति में अपने चिकित्सक से या नजदीकी अस्पताल में जाकर चिकित्सक से परामर्श लें।

राष्ट्रीय समन्वय केंद्र फॉर्माकोविजिलेंस प्रोग्राम ऑफ़ इंडिया, में दवाईयों के प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी एकत्रित करने हेतु विभिन्न सुवधाजनक माध्यम उपलब्ध हैं, जैसे कि:

- निःशुल्क हेल्पलाइन नम्बर 1800-180-3024
(सोमवार से शुक्रवार प्रातः 9:00 बजे से सायं 5:30 बजे तक)
- मोबाइल ऐप (ADR PvPI)

- ए.डी.आर. मॉनीटरिंग सेंटर
- ए.डी.आर. रिपोर्टिंग फॉर्म

(ए.डी.आर. मॉनीटरिंग सेंटर एवं फॉर्म की जानकारी भारतीय भेषज संहिता आयोग की वेबसाइट www.ipc.gov.in पर उपलब्ध है)

अगर आपको पहले किसी दवा से किसी भी प्रकार की कोई असुविधा हुई हो तो अपने चिकित्सक को इसकी सूचना अवश्य दें, जिससे चिकित्सक को आपका उपचार बेहतर ढंग से करने में सहायता मिले।

यदि कोई चिकित्सक, फॉर्मासिस्ट, नर्स या अन्य कोई स्वास्थ्यकर्म प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी देता है तो उनके विरुद्ध किसी प्रकार की कार्यवाही नहीं की जाती है बल्कि इससे दवाईयों के प्रभाव को बेहतर ढंग से समझने में एवं रोगी के उचित उपचार में सहायता मिलती है इसलिए अपने मन से इस प्रकार के समस्त डर व भ्रमों को दूर करके जनहित में स्वास्थ्य संबंधित इस महान कार्य में अपना सहयोग दें।

वर्तमान में भारत के अधिकतर राज्यों में ए.डी.आर. मॉनीटरिंग सेंटर कार्यरत हैं एवं राष्ट्रीय समन्वय केंद्र द्वारा फॉर्माकोविजिलेंस विषय पर वर्ष भर कौशल विकास कार्यक्रम का आयोजन किया जाता है। इस कार्यक्रम की पूर्ण जानकारी भारतीय भेषज संहिता आयोग की वेबसाइट पर उपलब्ध है।

राष्ट्रीय समन्वय केंद्र द्वारा फॉर्माकोविजिलेंस प्रोग्राम ऑफ़ इंडिया आप सभी से अनुरोध करता है कि दवाओं के सेवन से हुए सभी प्रकार के प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी अवश्य दें जिससे कि दवाओं का सुरक्षित उपयोग सभी के लिए सुनिश्चित किया जा सके।



Indian Pharmacopoeia Commission
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Pharmacovigilance Programme of India
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Let us join hands with PvPI to ensure patient safety
ADR reporting Helpline (Tollfree): 1800-180-3024