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Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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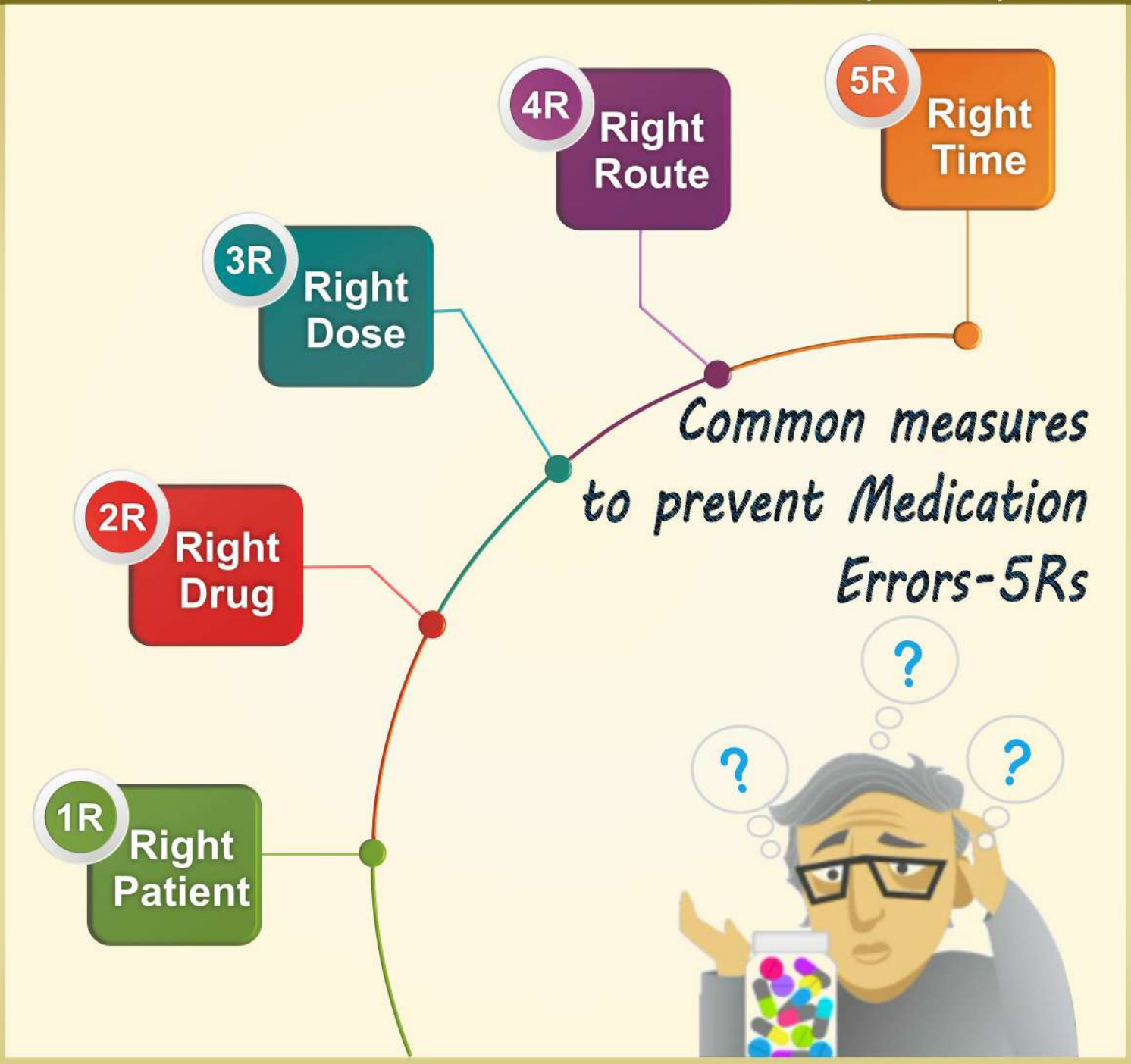

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National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI),
Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare, Government of India

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Message from the Desk of
Secretary-cum-Scientific Director

Dear Readers,

I am delighted to release the Pharmacovigilance Programme of India (PvPI) Newsletter Volume 12, Issue 2 for the index period from April, 2022 to June, 2022. This issue highlights the role of PvPI in preventing medication errors.

In this quarter, 33 new Adverse Drug Reaction Monitoring Centres (AMCs) have been enrolled under PvPI and total number of AMCs became 567 from 534 across the country. As on date, a total of 5.76 Lakh Individual Case Safety Reports have been reported to PvPI.

The PvPI is regularly sensitizing the stakeholders about the pharmacovigilance and reporting of adverse events through awareness programmes, trainings, workshops, skill development programmes, Continuing Medical Education (CME) etc. The PvPI has organized a total of 4502 training programmes and trained a total of 224918 participants in the area of pharmacovigilance.

The NCC-PvPI has continuously organised regional trainings and interactive sessions with MAHs/Pharmaceutical Industries to resolve their issues & challenges about the reporting of AEs to PvPI.

The drug safety advisories/drug safety alerts are being sent to our AMCs and healthcare professionals for the focussed pharmacovigilance and reporting of such adverse reactions to PvPI, if encountered with the use of drugs.

As a team, we will continue to work towards building patient safety culture in India. I, congratulate the PvPI team, AMCs and subject experts for their ceaseless efforts, cooperation and contribution in strengthening of robust pharmacovigilance system in India.

(Dr. Rajeev Singh Raghuvanshi)
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
(Ministry of Health & Family Welfare,
Govt. of India)
Ghaziabad-201002

Medication Errors: Reasons and Possible solutions

As defined by National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP), "A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer". It can happen anytime whenever a drug is prescribed by a doctor, when medication chart is prepared by nurses, when drugs are indented, when the drugs are dispensed, when the drugs are administered to the patient, or when the proper monitoring of drug is not done.

Common reasons of Medication Errors

1. Illegible prescription: When prescriptions are not written in capital letter it causes difficulty in reading the contents of prescription which leads to errors.
2. Error prone abbreviations: When doctors use error prone abbreviations (abbreviations which may lead to errors), incorrect use of decimal points in dose of drugs (missing leading zero/unnecessary trailing zero) it leads to errors.
3. Incomplete prescription: When all the important directions on the use of drugs are not present in the prescription/medication chart of the patient or when dose, frequency, or route is missing it leads to errors.
4. When drugs are not transcribed properly in the nursing chart by nurses it leads to administration of wrong drug or wrong dose.
5. Poor pharmacy and dispensing practice: If look-alike drug and sound-alike drugs are not properly stored, it will lead to dispensing of wrong drug.
6. Medication reconciliation: All the ongoing medications of the patient should be properly record and should be added along with the list of current medications of the hospitalised patients to avoid administration of wrong drug or omission of any drug.

Possible Solutions to prevent Medication Errors

1. Computer generated prescriptions: CPOE- Computerised Physician Order Entry will avoid errors arising due to legibility of the prescriptions, spelling mistakes, error prone abbreviations.
2. If medication chart is checked twice before indenting or administering any drug will help to avoid transcription and administration error.
3. Proper reading of the prescription before dispensing the medicines, pharmacist should double check the drug order before dispensing and look-alike and sound-alike drugs should be kept according to the guidelines to avoid dispensing error.
4. The 5 Rights of Medication Administration should be followed: The rights of medication errors if followed properly will reduce the harm caused by medication errors. They are:
   - Right Patient: Two identifiers (name of patient and unique hospital ID) should be used to identify patients before administration of drugs.
   - Right Drug: Name of the drug on the prescription and name of the drug should be matched properly.

- Right dose: Dose of the drug should be properly calculated before administering any drug (especially in case of antibiotics and anti-tuberculosis drugs)
- Right Route: Route prescribed must be confirm before administering.
- Right Time: Prescribed drugs should be given at the correct time and frequency should match with the order.

Why it should be reported to PvPI?

The medication errors are of concern for patient safety. They can cause significant Adverse Events or Adverse Drug Reactions and impact the quality of life of patients and many even may lead to morbidity and mortality.

If healthcare professional report events of medication errors, it will help to understand the reasons behind the errors and this will help to take appropriate corrective actions and also to prevent them in future to improve the safety of the patients. Confidentiality of the reporter is maintained, name of hospitals or any healthcare professionals is not disclosed in any way.

So, Before you Prescribe, Transcribe, Dispense or Administer any Drug ...STOP and CHECK properly...!! Patient safety is in our hands...!!

References:

1. National Formulary of India, 6th Edition 2021
2. https://www.nccmerp.org/consumer-information accessed on 30th September, 2022 at 11:00 AM
3. Tariq RA, Vashisht R, Sinha A, Scherbak Y. Medication Dispensing Errors and Prevention. In: StatPearls. StatPearls Publishing, Treasure Island (FL); 2021. PMID: 30085607.

Enrollment of new AMCs

By enrolling of 33 new Adverse Drug Reaction Monitoring Centres (AMCs), the total number of AMCs has been increased from 534 to 567 AMCs across the country. The list of newly enrolled AMCs is mentioned below;

S. No.	State	Name of Hospital/Medical college/Institute	Status
1	Andhra Pradesh	Mahatma Gandhi Cancer Hospital & Research Institute Pvt. Ltd. (A unit of Vizag cancer hospital & research centre Pvt.Ltd.), 1/7, MVP colony, Visakhapatnam- 5300017	Private
2		Dr. Pinnamaneni Siddhartha Institute of Medical Sciences & Research Foundation, Chinoutpally, Gannavaram, Krishna- 521286	Private
3	Bihar	Big Apollo Spectra Hospital, Sheetla Mandir Road, Near Sump House, Agamkuan, Patna- 800007	Private
4	Chhattisgarh	Rajmata Shrimati Devendra Kumari Singhdeo Govt. Medical College, Ambikapur, Surguja, Chhattisgarh - 497001	Government
5	Haryana	Adesh Medical College & Hospital, Dept. of Pharmacology, Mohri, Kurukshetra - 136135	Private
6		Medeor Hospital Limited, Plot - P - 2, Sector - 5, IMT Manesar, Gurugram – 122051	Private
7	New Delhi	Medeor Hospital, B-33, 34 Qutab Institutional Area, New Delhi- 110016	Private
8	Karnataka	People Tree Hospitals, A unit of TMI healthcare Pvt. Ltd., No- 2, Tumkur Road, Goraguntepalya, Yeshwantpur, Bangalore – 560022	Private
9		Dr. Janu Mankikars Memorial Hospital Maternity & Nursing Home, A/652/8 Subhash Road, Kumta Taluk, Uttar Kannada, Karnataka - 581343	Private

S. No.	State	Name of Hospital/Medical college/Institute	Status
10	Kerala	Noorul Islam Institute of Medical Science & Research Foundation, (NIMS Medicity), Aralummoodu P.O. Neyyatinkara, Thiruvananthapuram – 695123	Private
11		Iqra International Hospital & Research Centre, Malaparamba, Calicut- 673009	Private
12	Madhya Pradesh	MGM medical college, Dept. of Pharmacology, A. B. Road, Infront of Suyash Hospital, Indore – 452001	Private
13	Maharashtra	Ashoka Medicover Hospitals, Indira Nagar, Wadala Road, Nashik- 422009	Private
14		Prakash Institute of medical sciences & research, Vrun - Islampur - 415409	Private
15	Rajasthan	Krishna Heart & General Hospital, 138, Prem Niwas, Gopalpura Bypass, Jaipur - 302019	Private
16		Heart & General Hospital, 7- Vivekand Marg, C-Scheme, Ashok Nagar, Jaipur - 302001	Private
17		District TB Clinic, Opposite AKH, Bewar (Ajmer) - 305901	Government
18	Tamil Nadu	Pankajam Memorial Hospital, C-3, 4th Cross Street, Near Ranga Theatre, Hindu Colony, Nanganallur, Chennai - 600061	Private
19		Govt. Thanjavur Medical College & Hospital, Dept. of Pharmacology, Thanjavur - 613004	Private
20		Govt. Medical College, Dept. of Pharmacology, Ariyalur - 621713	Government
21		National Institute of Research in Tuberculosis, No. 1, Mayor Sathiyamoorthy Road, Chetpet, Chennai, 600031	Government

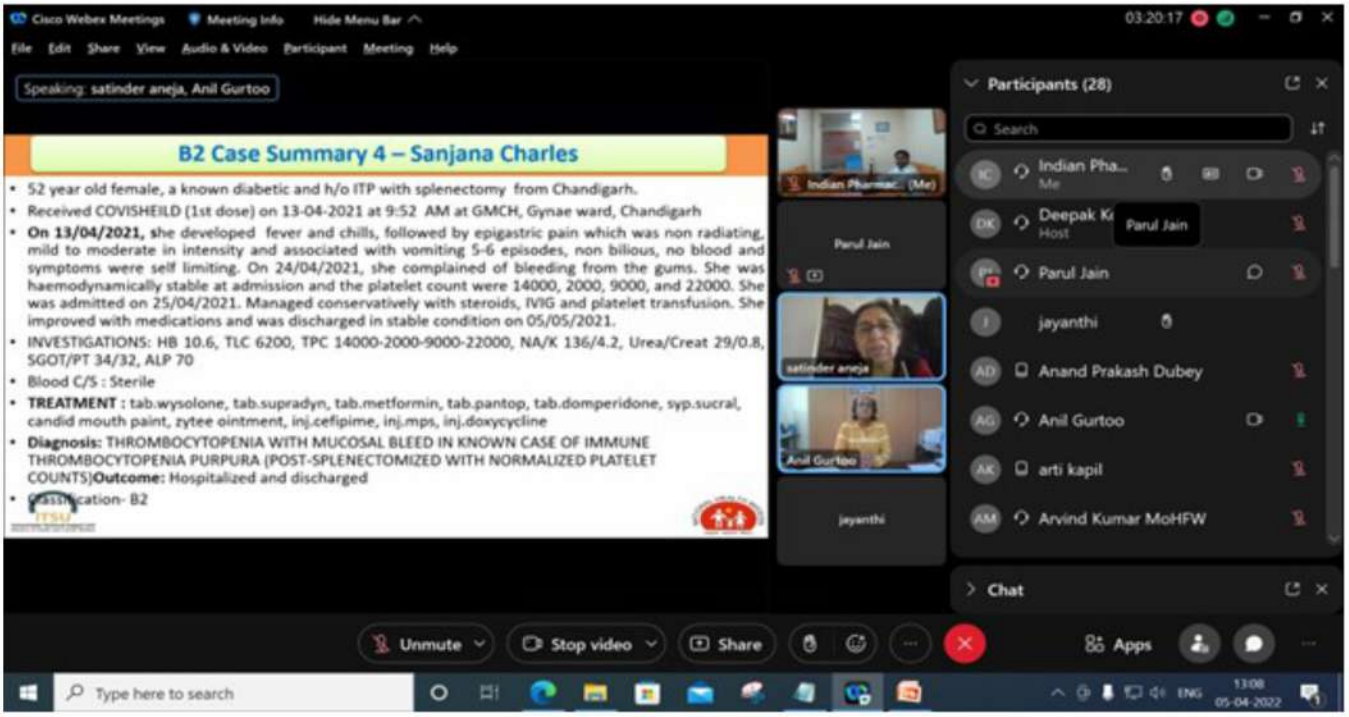
S. No.	State	Name of Hospital/Medical college/Institute	Status
22	Uttar Pradesh	Vivekananda Polyclinic and Institute of Medical Sciences, Vivekananda Puram, Lucknow - 226007	Private
23		Autonomous State Medical College, S. N. M. Hospital & TB Sanitorium, Near Jain Mandir, Subhash Tiraha, Firozabad - 283203	Government
24		Sharma Medicare Pvt. Ltd. NH - 19 / A, L - Block Delta - 2, Greater Noida - 201308	Private
25		Bhardwaj Hospital, NH- 1, Sec - 29, Noida, Gautam Buddha Nagar, - 201301	Private
26		Maharshi Vashishtha Autonomous State Medical College, Basti, Village - Rampur - 272124	Government
27		Ivory Hospital Pvt. Ltd., NH - 25, Pocket - E, Sector - 36 (RHO - 1) Greater Noida – 201310	Private
28		S. N. Medical College, Dept. of Pharmacology, Academic block, Agra – 282002	Government
29		F. H. Medical College, Near Railway Bridge NH - 2, Tundla, Firozabad – 283204	Private
30	West Bengal	Narayana Multispeciality Hospital, Barasat 78, Jessore RD, South, Kolkata – 700127	Private
31		Deben Mahata Government Medical College & Hospital, Hatuara, Purulia, Vivekananda Nagar - 723147	Government
32		B. M. Birla Heart Research Centre - A unit of the Calcutta Medical Research Institute, 1/1 National Library Avenue, Kolkata – 700027	Private
33	UT of Dadra and Nagar Haveli & Daman and Diu	Namo medical education and research institute and Shri Vinoba Bhave Civil Hospital, S. R. Delkar Marg, Saily Road, Silvassa – 396230	Government

Letter of Intent renamed as Enrollment Form

The NCC-PvPI, IPC has revised the Letter of Intent for the enrollment of new ADR Monitoring Centres under PvPI and renamed as "Enrollment Form for new ADR Monitoring Centre under PvPI", which is available on the web portal of NCC-PvPI, IPC (https://www.ipc.gov.in/ images/Enrollment_form _for_ new_ADR_monitoring_centre_under_PvPIpdf.pdf).

National AEFI committee meeting

The NCC-PvPI officials have participated in the National AEFI committee meeting held on April 5, 2022 through video conferencing (WebEx) aimed to approve the causality assessment classification of the AEFI cases reported post COVID 19 vaccinations. This was organized by the AEFI Secretariat under the chairmanship of Dr. S Aneja, Professor and Head, Deptt of Paediatrics, School of Medical Sciences and Research, Sharda University, Greater Noida. A total of 28 participants from various organizations have attended this meeting.



Review meeting for kala-azar elimination programme

The National Centre for Vector Borne Diseases Control (NCVBDC) in collaboration with WHO has organized National Review Meeting for Kala-azar elimination Programme from 29-30 April, 2022 at Ranchi, Jharkhand. The progress made by the states of Bihar, Jharkhand, West Bengal & Uttar Pradesh, in last few years in elimination of Kala-Azar was reviewed. Total number of kala-azar cases were 1345 and the number of blocks above elimination threshold were 8 out of 633 till December 2021.

The target to achieve the elimination is one kala-azar case per ten thousand of population. This meeting was attended by various participants including PvPI representative.

WHO-CC Activities

- WHO-SEARO has organized a conference on "Addressing challenges of regulatory COVID-19 medical products in South-East Asia" from 11-12 April, 2022. Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific, Director, IPC has participated in this conference.

- WHO-SEARO office, New Delhi has organized a meeting for the heads of National Regulatory Authorities (NRAs), South-East Asia Regulatory Network (SEARN) from 7-8 June, 2022. Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific, Director, IPC has participated as a Chairman for Working Group -3 (vigilance for medical products).

Handholding meeting on VigiFlow for newly recognized AMCs

Handholding meeting on Vigiflow software for newly recognized AMCs enrolled under PvPI was conducted on 23rd May, 2022 and 28th June, 2022 at Indian Pharmacopoeia Commission by Ms. Shilpa Bhardwaj, Team Lead-ICSR Division. In this meeting a total of 43 participants including Coordinators, Deputy-Coordinators of AMCs across the country were trained on how to enter the ICSRs into the VigiFlow software.

Global Pharmacovigilance Congress

A two days global pharmacovigilance congress having theme on current advancement in pharmacovigilance training programme was organized by MKCG Medical College & Hospital, Berhampur, Odisha, in collaboration with NCC-PvPI - IPC, Ghaziabad virtually from 10th June to 11th June 2022. It was attended by galaxy of experts throughout the country. In this congress, Dr Rajeev Singh Raghuvanshi was invited as the Chief Guest and Dr Jai Prakash delivered a presentation on "Progressive Journey of Pharmacovigilance Programme of India".

Interactive meetings

The objective of the following interactive meetings were to address the basic concepts of Pharmacovigilance and how the Pharmacovigilance system can be effectively implemented at MAHs/Pharmaceutical industries. It also focussed on the issues/challenges related to the quality submission of ICSRs in E2B, xml format to PvPI.

Date	Title	No. of Participants
19-04-2022	Interactive meeting on improving the quality of ICSRs received from JB Chemicals	3
25-04-2022	Interactive meeting on improving the quality of ICSRs received from Macleods Pharmaceticals Limited	6
24-05-2022	Interactive meeting on improving the quality of ICSRs received from NOVO Nordisk India Pvt Limited	3
03-06-2022	Interactive training with Wipro Healthcare Ltd. Officials Regarding Improving the quality of ICSRs.	1
06-06-2022	Interactive meeting on improving the quality of ICSRs received from Merck Pvt Limited, India	2

ADR reporting Status

ADR PvPI App

01

S. No	Month	Number of reports received
1.	April 2022	14
2.	May 2022	48
3.	June 2022	49

Non AMCs

02

S. No	Month	Number of reports received
1.	April 2022	95
2.	May 2022	110
3.	June 2022	120

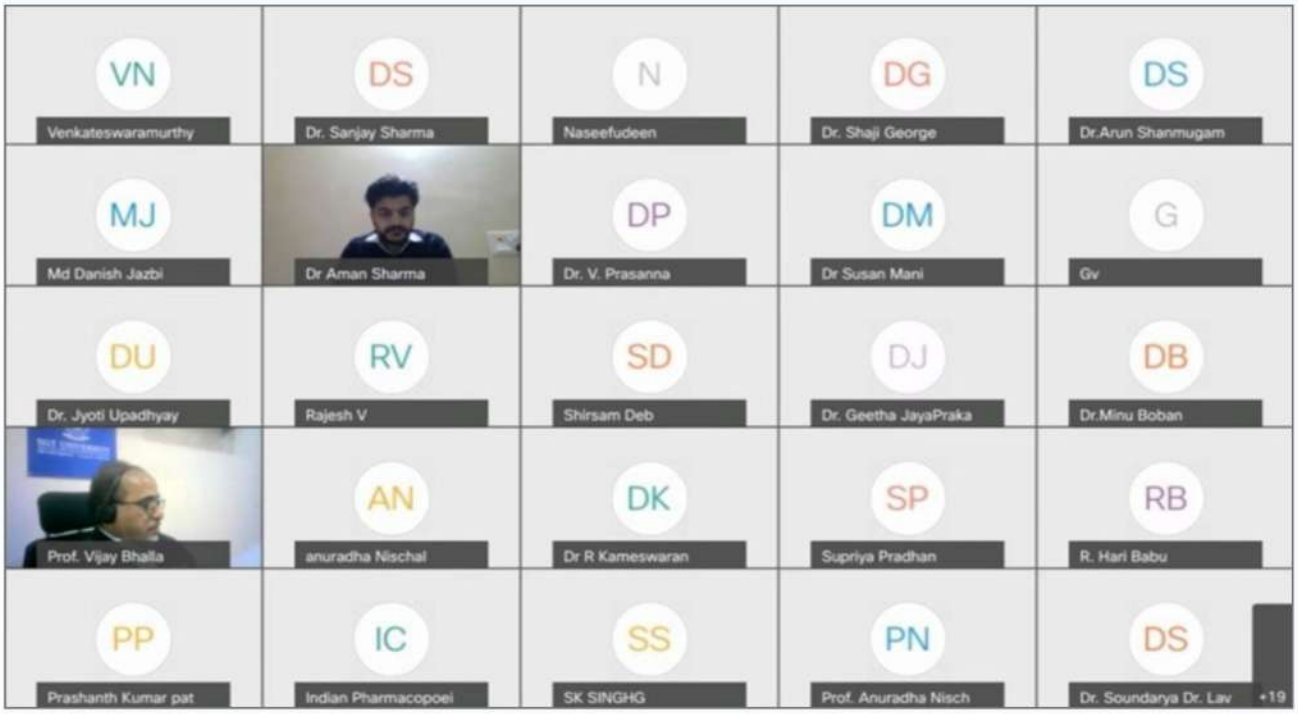
PvPI-Helpline (Toll-free No. 1800 180 3024)

03

S. No	Month	Number of reports received
1.	April 2022	34
2.	May 2022	22
3.	June 2022	12

Induction-cum-Training Programmes

1. The Induction-cum-Training Programme on Pharmacovigilance for coordinators/deputy coordinators of newly recognized AMCs and newly recruited Pharmacovigilance Associates at AMCs through video conferencing was held from 06th April to 08th April 2022. A total of 60 participants have attended this programme. This training programme was started with welcome address by Dr Shashi Bhushan, Senior Scientific Officer, IPC Ghaziabad. During the 3 days of Induction Programme, a total of 15 technical sessions were conducted on various topics of Pharmacovigilance.

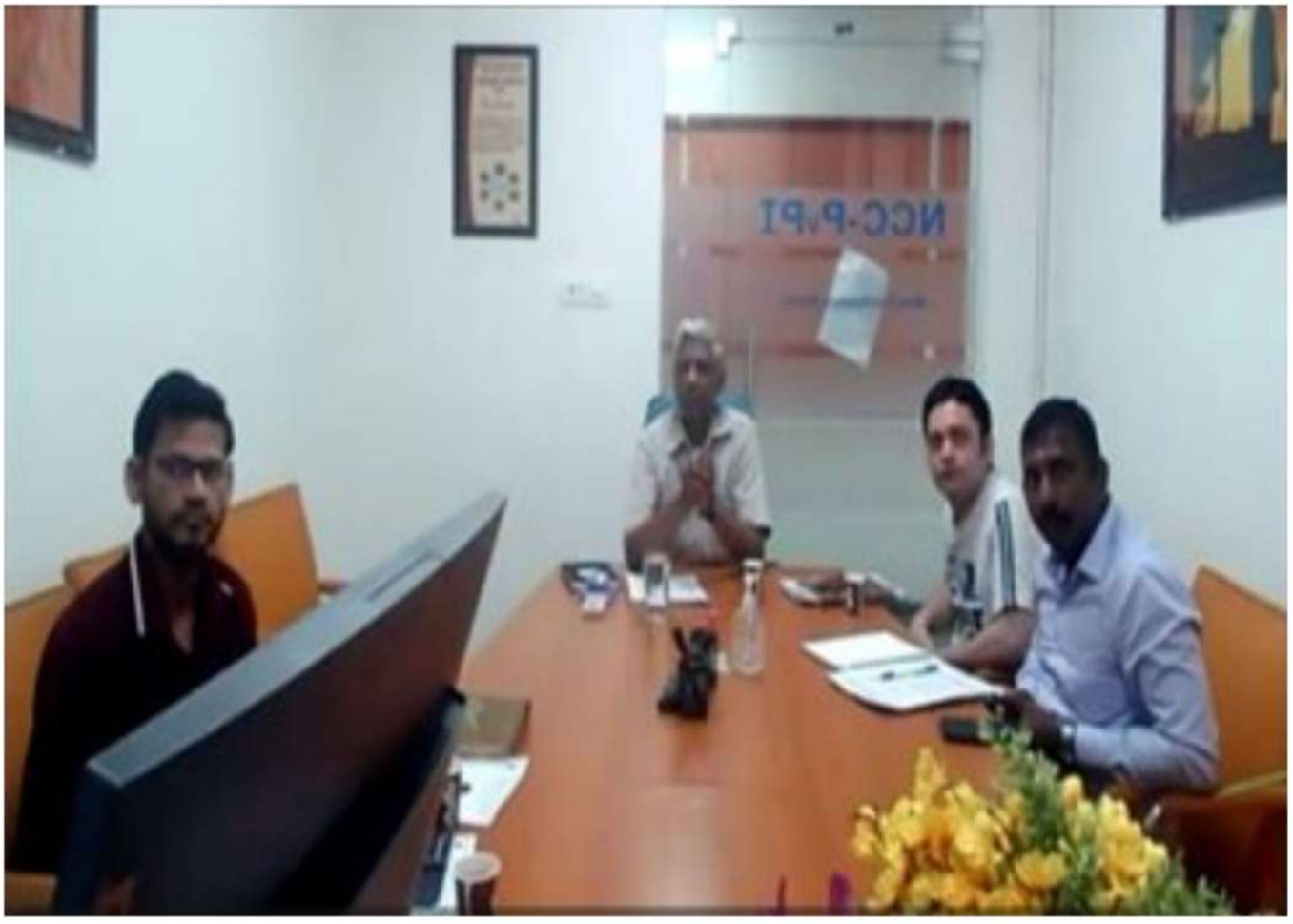


06th April – 08th April 2022 Induction-cum-training Photograph

2. Similarly, another Induction-cum-Training Programme on pharmacovigilance for coordinators/deputy coordinators of newly recognized AMCs and newly recruited pharmacovigilance associates at AMCs through video conferencing was held from 30th May to 1st June 2022. A total of 33 participants have attended this programme.

30th May to 01st June 2022 Induction-cum-Training

21st Skill Development Programme



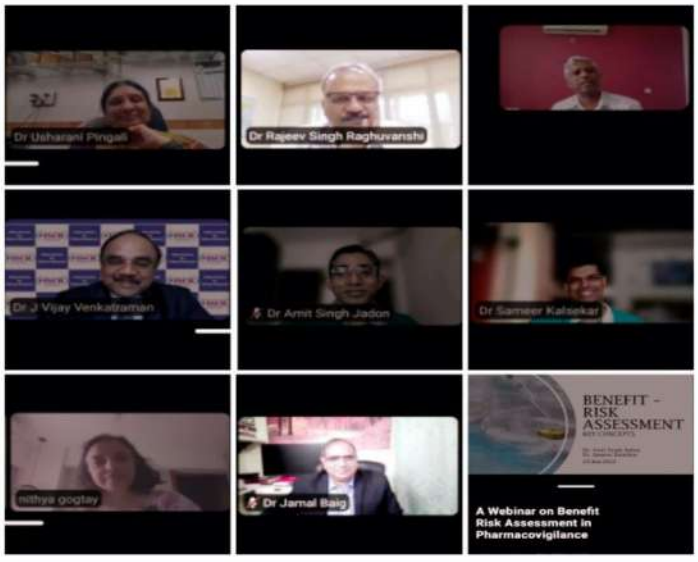
21st Skill Development Programme held on 13th - 17th June 2022

21st Skill Development Programme on Pharmacovigilance of Medical Products was held from 13th to 17th June 2022 through virtual mode. A total of 120 participants have attended this SDP including Industry Professionals, Physician, Academicians, Pharmacy Students, Medical Students, Pharmacist across the country. The training programme was started with welcome address by Dr. Jai Prakash, Officer-in-Charge PvPI, Sr. Principal Scientific Officer, IPC. He extended his warm greetings & best wishes to all the participants. During the 5 days of SDP, a total of 19 technical sessions were conducted on various topics of Pharmacovigilance. The technical sessions were delivered by experts from the Pharmaceutical Industries, Academic & Research Institutions. The training sessions covered the basics of Pharmacovigilance and in-depth signal detection method and regulatory intervention/outcomes.

Advance Level Trainings

1. One day Advance level training programme was organized by MMC Chennai, in collaboration with NCC-PvPI - IPC, Ghaziabad on 27th April 2022. In this training programme, Dr R S Ray, Scientific Assistant, PvPI-IPC had participated and delivered a talk on "Current Status of Pharmacovigilance Program of India.

27th April 2022 MMC Chennai ALT



24th June 2022 NIMS Hyderabad ALT

2. Another one-day Coordinators meeting-cum-Advance level training programme was organized by NIMS Hyderabad, in collaboration with NCC-PvPI - IPC, Ghaziabad with on 24th June 2022. In this training programme, Dr Rajeev Singh Raghuvanshi, Secretary-cum-Scientific-Director, IPC was invited for addressing the gathering. Dr Jai Prakash, Officer-incharge, has also participated as a panelist. An effective panel discussion was held on "Understanding Risk-Benefit from a Quantitative Perspective- The Concept of NNT for Benefit and Harm".

New Drugs Approved in India

The following new drugs were approved by CDSCO during this tenure:-

S. No.	Drugs	Indications
1.	Liothyronine sodium bulk and Liothyronine sodium tablets 5 mcg & 20 mcg	To treat some of the more severe conditions in which the thyroid does not produce enough thyroxine and balance the effect of medicines used to treat an overactive thyroid
	Polyhexamethylene guanidine hydrochloride 1.000 lit	For surface disinfection
2.	Finerenone 10 mg/20 mg film coated tablets	Indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 Diabetes (T2D)
3.	Sugammadex sodium bulk and Sugammadex injection 100 mg/ml (single dose vial for bolus injection, IV)	Reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults undergoing surgery
4.	Nirmatrelvir bulk and Combi pack of Nirmatrelvir 300 mg tablets (2x150 mg tablets) and Ritonavir tablets 100 mg	For treatment of adult patients with COVID19, with SpO2 >93% and who have high risk of progression of the disease including hospitalization or death, in light of Covid 19 outbreak for restricted emergency use in the country
5.	Aviptadil bulk and Aviptadil injection (Each ml vial contains Aviptadil 15 mcg)	For treatment of patients with severe COVID19 with Acute Respiratory Distress Syndrome (ARDS), in light of COVID19 outbreak for restricted emergency use in the country

6.	Bempedoic acid bulk and Bempedoic acid tablet 180 mg	Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with eterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. Limitation of use: The effect of the drug on cardiovascular morbidity and mortality has not been established.
7.	rdESAT-6 bulk; rCFP-10 bulk and rdESAT-6 and rCFP-10 (Cy-Tb) injection-Each vial (10 dose vial, single dose of 0.1ml) contains: rdESAT-6:0.05 mcg; rCFP-10:0.05	For detection of Latent TB for population of 18 years and above
8.	Pralsetinib Capsule 100 mg	• Indicated for the treatment of adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer. • Indicated for the treatment of adult and paediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer who require systemic therapy. • Indicated for the treatment of adult and paediatric patients 12years of age and older with advanced or metastatic RET-fusion positive thyroid cancer who require systemic • Therapy and who are radioactive iodine refractory (if radioactive iodine is appropriate).

☞ **Healthcare Professionals (HCPs), patients/consumers are advised to closely monitor the above mentioned new drugs. If any reactions are encountered, please report to the PvPI, IPC by filling up Suspected Adverse Drug Reactions Reporting Form for HCPs/ Medicine Side Effect Reporting Form for the Consumer (download from http://www.ipc.gov.in), through Android Mobile App "ADR PvPI" and PvPI Helpline No. 1800-180-3024 (Toll-Free)**

Drug Safety Alerts

Identified & issued by PvPI during this tenure

S. No.	Issuing Date	Suspected Drugs	Indications	Adverse Drug Reactions
1.	28th April, 2022	Cefuroxime	• Antibiotic- indicated for lower & upper respiratory tract infection, UTI, gynaecological infection, skin or soft tissue infection etc. • Antibiotic- indicated in the treatment of respiratory tract infections, UTI, ENT soft tissue infections etc.	Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
2.	30th May, 2022	Itraconazole	• Systemic aspergillosis and candidiasis, cryptococcosis, sporotrichosis, Paracoccidioidomycosis, blastomycosis and other rarely occurring systemic or tropical mycoses. • Empiric therapy of febrile neutropenic patients with suspected fungal infections.	Symmetrical Drug Related-Intertriginous and Flexural Exanthema (SDRIFE)
3.	17th June, 2022	Trimetazidine	• Ischaemic heart disease, angina pectoris, sequalae of infarction. • Cardiac drug indicated in the treatment of angina pectoris and intermittent claudication.	Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)

☞ **Healthcare Professionals (HCPs), patients/consumers are advised to closely monitor the above mentioned ADRs associated with the use of the above suspected drugs. If such reactions are encountered, please report to the PvPI, IPC by filling up Suspected Adverse Drug Reactions Reporting Form for HCPs/ Medicine Side Effect Reporting Form for the Consumer (download from http://www.ipc.gov.in), through Android Mobile App "ADR PvPI" and PvPI Helpline No. 1800-180-3024 (Toll-Free)**

Drug Safety Alerts issued by other countries and status of ICSRs in PvPI database

S. No.	Suspected Drugs	Adverse Drug Reactions	Total No. of ICSRs in other Countries	Total No. of ICSRs in PvPI	Reference
1.	Ceftriaxone	Potential risk of hepatitis	295	08	WHO Pharmaceuticals Newsletter No. 2, 2022
2.	Brolucizumab	Intra-ocular inflammation	101	05	
3.	Clindamycin	Risk of acute kidney injury	351	02	

PvPI in Press Media

IPC cautions healthcare professionals to watch out for Cefuroxime induced DRESS syndrome

Laxmi Yadav, Mumbai
Saturday, May 7, 2022, 08:00 Hrs [IST]

The Indian Pharmacopoeia Commission (IPC), which is the National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI), has flagged drug safety alert revealing that second-generation cephalosporin antibiotic, Cefuroxime is associated with drug reaction with Eosinophilia and Systemic Symptoms (DRESS) syndrome.

This came to light after the preliminary analysis of adverse drug reactions (ADRs) from the PvPI database.

Cefuroxime is a bactericidal agent that acts by inhibition of bacterial cell wall synthesis. Cefuroxime has activity in the presence of some beta-lactamases, both penicillinases and cephalosporinases, of gram-negative and gram-positive bacteria. Cefuroxime was patented in 1971, and approved for medical use in 1977. It is on the World Health Organization's List of Essential Medicines.

The antibiotic is indicated for lower and upper respiratory tract infection, urinary tract infections (UTIs), gynaecological infection, skin infection or soft tissue infection. The drug is also indicated for ENT soft tissue infection etc.

As per drug safety alert issued by IPC in last week of April 2022, Cefuroxime is linked with Drug reaction with Eosinophilia and Systemic Symptoms (DRESS) syndrome which is an idiosyncratic, drug-induced hypersensitivity reaction that presents with skin rash, involvement of internal organs like liver, lung, or kidney, lymphadenopathy, and haematological manifestations such as eosinophilia and atypical lymphocytes.

Healthcare professionals and patients have been advised to closely monitor the possibility of the above ADR associated with the use of Cefuroxime. If such a reaction is encountered, it needs to be reported to the NCC-PvPI for suitable action.

IPC had earlier also flagged drug safety alerts revealing that beta-lactam antimicrobials, cephalosporins and anti-inflammatory drug, ibuprofen were associated with adverse event known as fixed drug eruption while Cefazolin, a cephalosporin antibiotic, was associated with acute generalized exanthematous pustulosis (AGEP).

Besides this, it had earlier also flagged drug safety alerts revealing that popular blood pressure drug, Losartan was associated with muscle spasm while diclofenac, a NSAID, was linked to skin hyperpigmentation.

Dimethyl fumarate, used for relapsing-remitting multiple sclerosis, was associated with adverse drug reaction alopecia, according to the preliminary analysis of ADRs from the PvPI database.

PvPI was implemented by the CDSCO in July 2010 across the country. Since then, IPC has been mandated to establish clinical evidence between the drug and the ADR event through a robust system of causality assessment.

Reference: ***http://www.pharmabiz.com/NewsDetails.aspx?aid=149603&sid=1***

Medical Dialogues
.....Daily Dose of Health & Medical News

Drug Safety Alert: IPC Flags Adverse Drug Reaction Linked To Itraconazole

Written By Susmita Roy — Published On 2 June 2022 5:42 PM | Updated On 2 June 2022 5:42 PM

New Delhi: The Indian Pharmacopoeia Commission (IPC), through its recently issued drug safety alert for the month of May, has revealed that popular antifungal drug Itraconazole is linked with Adverse Drug Reactions (ADRs) named Symmetrical Drug Related Intertriginous and Flexural Exanthema (SDRIFE).This came after preliminary analysis of Adverse Drug Reactions (ADRs) from the...

Itraconazole is an antifungal agent used for the treatment of various fungal infections in immunocompromised and non-immunocompromised patients, such as pulmonary and extrapulmonary blastomycosis, histoplasmosis, and onychomycosis.

Itraconazole interacts with 14-α demethylase, a cytochrome P-450 enzyme necessary to convert lanosterol to ergosterol. As ergosterol is an essential component of the fungal cell membrane, inhibition of its synthesis results in increased cellular permeability causing leakage of cellular contents. Itraconazole may also inhibit endogenous respiration, interact with membrane phospholipids, inhibit the transformation of yeasts to mycelial forms, inhibit purine uptake, and impair triglyceride and/or phospholipid biosynthesis.

Itraconazole is indicated for the treatment of Systemic aspergillosis and candidiasis, cryptococcosis, sporotrichosis, Paracoccidioidomycosis, blastomycosis and other rarely occurring systemic or tropical mycoses.

In addition, the drug is also indicated tfor Empiric therapy of febrile neutropenic patients with suspected fungal infections.

Following the preliminary analysis of Adverse Drug Reactions (ADRs) from the PvPI database, it is reported that Itraconazole can lead to Symmetrical Drug Related Intertriginous and Flexural Exanthema (SDRIFE).

Symmetrical drug-related intertriginous and flexural exanthema (SDRIFE) or (Baboon syndrome) is a symmetrical erythematous rash on the flexures after systemic exposure to a drug. This is distinct from other cutaneous drug reactions owing to its typical morphology, distribution, and absence of systemic findings. However, real pathogenetic mechanisms of symmetrical drug-related intertriginous and flexural exanthema are still unclear, but it has been suspected to develop as a result of a type IV delayed hypersensitivity immune response.

In light of the above, the Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, has advised Healthcare Professionals, Patients/Consumers to closely monitor the possibility of the above ADRs associated with the use of above suspected drugs.

Further, the safety alert added, "If such reaction is encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form/Medicines Side Effect Reporting Form for Consumer (http://www.ipc.gov.in), through Android Mobile App "ADR PvPI App" and PvPIHelpline No. 1800-180-3024 (Toll Free)."

Reference: ***https://medicaldialogues.in/news/industry/pharma/drug-safety-alert-ipc-flags-adverse-drug-reaction-linked-to-itraconazole-93875?from-login=774631***

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Drug-Makers To Add AGEP As Adverse Effect In Patient Information Leaflet Of Itraconazole: CDSCO Panel

Written By **Susmita Roy** — Published On 31 May 2022 4:43 PM | Updated On 31 May 2022 4:43 PM

New Delhi: The Subject Expert Committee (SEC) functional under the Central Drugs Standard Control Organization (CDSCO) has recommended that CDSCO may request State Drugs Controllers to direct the manufacturers of Itraconazole to include Acute Generalized Exanthematous Pustulosis (AGEP) as adverse effect in the corresponding Patient Information Leaflet (PIL) of the drug.

Acute generalized exanthematous pustulosis (AGEP) is a severe, usually drug-related reaction, characterized by an acute onset of mainly small non-follicular pustules on an erythematous base and spontaneous resolution usually within two weeks.

Reference: ***https://medicaldialogues.in/news/industry/pharma/drug-makers-to-add-agep-as-adverse-effect-in-patient-information-leaflet-of-itraconazole-cdsco-panel-93805?from-login=259420***

Aakash Healthcare Super Speciality Hospital New Delhi

Aakash Healthcare Super Speciality Hospital in Dwarka, New Delhi, is a non-AMC but continues to support PVPI towards achieving its goal of patient safety.

Pharmacovigilance activities are carried out by Mr. Vipin Kumar, Clinical Pharmacist under the supervision of Dr Jyoti Mishra, Medical Superintendent & Unit Head and supported by Dr Ajit, DMS and Ms Ankita Bhatt, Quality. They attended 21st Skill Development Program on "Pharmacovigilance for Medical Products" from 13th June to 17th June, 2022. They have also organised an event on "Current updates of the Pharmacovigilance Programme of India" on 4th May, 2022 to create awareness amongst their hospital staff and covered following topics-

- Need of Pharmacovigilance
- Pharmacovigilance Programme of India
- Minimum requirements to report ADR
- Data Flow of PvPI
- ADR Reporting Status of India
- Channels for reporting ADRs in PvPI
- Global Status of ICSRs reported in India

Father Muller Medical College Mangalore

Father Muller Medical College was recognised as an AMC by PvPI in February 2021. As per the requirement of AMC, a causality assessment committee was formed in April 2021. They have active Pharmacovigilance committee since July 2011.

ADR reporting is done by spontaneous reporting as well as by active searching of ADRs in the wards. All the pharmacovigilance activities are carried out under the supervision of AMC coordinator and pharmacovigilance committee. Many sensitization programmes on identification and reporting of ADRs have been organised for nurses and doctors. Along with creating pharmacovigilance awareness they also sensitized doctors, nursing and pharmacy staff about medication errors and ways to prevent these. They celebrated National Pharmacovigilance Week last year from 17th to 23rd September 2021. During which, an e-poster competition was organised for 2nd MBBS students, and a sensitization programme on pharmacovigilance was conducted for Pharm D students of neighbouring pharmacy colleges.

GMERS Medical College Gandhinagar

Gujarat Medical & Education Research Society (GMERS), Gandhinagar is an ADR Monitoring Centre under PvPI. The AMC is in the pharmacology department of this institute. In very short time this centre has succeeded not only to establish pharmacovigilance set up but also has maintained it.

Regular conduct of sensitization and awareness sessions are organized for different stakeholders including clinicians, nursing staff, pharmacists, intern doctors and other paramedical staff. Research regarding the pharmacovigilance activities has also been promoted by this institute for undergraduate & postgraduate students as well as faculties. Out of many awareness activities conducted by this institute one such noteworthy activity was too aware the pharmacists of different pharmacy shops in the city by distributing ADR information flyer and counselling them to foster ADR reporting.

Feedback on PvPI

Pharmacovigilance is a very good programme, as clinicians will be more careful while prescribing the drugs to the patient and hence patient will be benefited by less exposure of adverse drug reaction.

Dr. ILA Pahwa,
Professor & Head Department of Medicine

Promoting safe use of medicines is a priority of Pharmacovigilance Programme of India. Recognizing and reporting of ADRs is a critical step towards better drug safety. Muzaffarnagar Medical College has a well-established AMC, where we sensitize health care professionals to voluntarily report ADRs in the interest of patient safety.

Dr. Meenakshi Jindal
Professor & Head Department of Pharmacology

Dr. Darshan J. Dave
Professor & Head in Pharmacology

For an effective and efficient functioning of pharmacovigilance system, all the stake holders need to be alert and attentive throughout the life cycle of a medicinal product in the market. The stronger the national ADR reporting system, the more likely reasonable regulatory decisions will be made for the early release of new drugs and optimum usage of existing agents with the promise of therapeutic advances and better treatment outcome. This will play a pivotal role to decrease the health care expenditure. The long-term aim of this AMC is to provide healthy, outcome centred platform where all the stake holders will equally contribute towards the reporting of suspected ADRs.

12th -16th September 2022	17th -23rd September 2022	14th -18th November 2022
22nd Skill Development Programme & Pharmacovigilance of Medical Products	2nd National Pharmacovigilance Week	23rd Skill Development Programme & Pharmacovigilance of Medical Products
Last Date of Registration 6th September 2022	Last Date of Registration 11th September 2022	Last Date of Registration 7th November 2022

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

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

जैसा कि हम सभी जानते हैं कि दवाईयों (टैबलेट्स, कैप्सूल्स, 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 फॉर्माकोविजीलैंस 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 आँकलन 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।

"फॉर्माकोविजीलैंस 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, फॉर्माकोविजीलैंस प्रोग्राम ऑफ़ इंडिया, में दवाइयों के प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी एकत्रित करने हेतु विभिन्न सुविधाजनक माध्यम उपलब्ध है, जैसे कि:

- निःशुल्क हेल्पलाइन नम्बर 1800-180-3024 (सोमवार से शुक्रवार प्रातः 9:00 बजे से सांय 5:30 बजे तक)• मोबाइल ऐप, (ए.डी.आर पी वी पी आई)
- 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 स्वास्थ्यकर्मी 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 फॉर्माकोविजीलैंस 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, फॉर्माकोविजीलैंस 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।

कोविड-१९ महामारी के दौरान उपयोग होने वाली औषधियों से होने वाले दुष्प्रभाव की जानकारी कहाँ और कैसे दें

इसकी जानकारी आप फॉर्माकोविजीलैंस प्रोग्राम ऑफ़ इंडिया के अंतर्गत किसी भी निकटवर्ती ऐ॰ डी॰ आर॰ मॉनिटरिंग सेंटर पर दे सकते हैं। इस सम्बन्ध में एक विशेष फॉर्म - Suspected Adverse Drug Reaction Reporting Form (For Drugs used in Prophylaxis/ Treatment of COVID-19) भी डिज़ाइन किया गया है, जो www.ipc.gov.in पर उपलब्ध है ।

सत्यमेव जयते
IPC

Indian Pharmacopoeia Commission
National Coordination Centre,
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare, Govt. of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392

For any other information/Suggestion/ Query, please contact:
Officer Incharge
Pharmacovigilance Programme of India
Email: lab.ipc@gov.in, pvpi.ipc@gov.in
Website: www.ipc.gov.in

Let us join hands with PvPI to ensure patient safety