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IPC

Newsletter

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Role of Pharmacovigilance in Drug-Drug Interactions

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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 4 for the index period from October, 2022 to December, 2022. This Issue highlights the PvPI activities including Role of Pharmacovigilance in drug-drug interaction.

In this quarter, 46 new Adverse Drug Reaction Monitoring Centres (AMCs) have been enrolled under PvPI and total number of AMCs became 652 from 606 across the country. By the end of this quarter, a total of 6.6 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 5537 training programmes and trained a total of 298254 participants in the area of pharmacovigilance.

The Development Partnership Administration (DPA) division of Ministry of External Affairs (MEA), Government of India has identified IPC to provide the capacity building training in the area of Pharmacovigilance to partner countries. In this context, NCC-PvPI, IPC conducted 20 hours (5 days x 4 hours) training programme virtually from 5th to 9th December 2022 focused on Pharmacovigilance system capacity building, basic tools applied for Adverse Drug Reporting/Monitoring, methods used in Pharmacovigilance and impact of Pharmacovigilance practices on post COVID19 pandemic.

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

Role of Pharmacovigilance in Drug-Drug Interaction

Drug-Drug interaction (DDI) is a reaction between two (or more drugs), when they either concomitantly administered or administered within a short time interval and constitute an important concern for patient safety in Post Marketing Surveillance. The DDIs may cause Adverse Drug Reactions (ADRs) by exposing patients to higher risks and impact the public healthcare system. Identification of possible DDIs causing harm to the population and communicating risk to take risk minimization measures are major concerns for Pharmacovigilance Programme of India (PvPI).

The main types of DDIs include Pharmacokinetic and Pharmacodynamic. The pharmacokinetic interactions can affect the drug bioavailability through Absorption, Distribution, Metabolism and Excretion. Examples of these interactions are the administration of a drug that increases the motility of the intestine decreasing the absorption of the other drug, competition for the same plasma protein transporter, inhibition of the action of a metabolizing enzyme or even interaction at excretion level affecting the elimination of one drug by other drugs. On the other hand, pharmacodynamic interactions can occur at receptor level with both drugs interacting with the same protein, at the signaling level affecting different signaling pathways or at the effector levels causing different pharmacological responses. The action of DDIs can be synergistic or antagonistic or a novel effect. The possible risk factors for DDIs are as follows;

- Ease of availability of drugs
- Polypharmacy
- Multiple prescribers
- Comorbidity
- Genetic variations
- Narrow therapeutic index drugs
- Other risk factors like smoking, consuming alcohol etc.

NCC-PvPI has done the data mining to identify DDIs from PvPI data received from the different types of stakeholders across the country. Some of the important DDIs supported by ICSRs are as follows :-

S. No.	Suspected Drugs	Concomitant Drugs	Effects of Interactions	No. of ICSR(s)
1.	Meropenem	Valproic acid	Serum Valproic Acid concentration is decreased.	02
2.	Phenytoin	Dabigatran	Phenytoin will decrease the level or effect of dabigatran by P-glycoprotein (Multidrug Resistance Mutation-1) efflux transporter. Avoid or Use Alternate Drug. Avoid coadministration. P- glycoprotein inducers reduce systemic exposure of dabigatran	02
3.		Diazepam/ Ondansetron	Phenytoin will decrease the level or effect of diazepam/Ondansetron by affecting hepatic/intestinal enzyme CYP3A4 metabolism.	08
4.		Paracetamol	Phenytoin decreases levels of Paracetamol by increasing metabolism. Enhanced metabolism increases levels of hepatotoxic metabolites.	01
5.	Tacrolimus	Voriconazole	Tacrolimus and voriconazole both increase QTc interval.	14
6.		Mycophenolate	Mycophenolate and tacrolimus both increase immunosuppressive effects; risk of infection.	04
7.		Itraconazole	itraconazole and tacrolimus both increase QTc interval.	05
8.		Prednisolone	Tacrolimus will increase the level or effect of prednisolone by P-glycoprotein (MDR1) efflux transporter.	01
9.	Valproic Acid	Carbamazepine	Enhanced toxicity without corresponding increase in ant-epileptic effect; plasma concentration of Valproic Acid often lowered; plasma concentration of active metabolite of Carbamazepine often raised.	06
10.		Lamotrigine	Valproic acid increases levels of lamotrigine by decreasing metabolism. Modify Therapy/Monitor Closely.	07

Enrollment of New AMCs

By enrolling 46 new Adverse Drug Reaction Monitoring Centres (AMCs), the total number of AMCs has increased from 606 to 652. The list of newly enrolled AMCs is mentioned below:

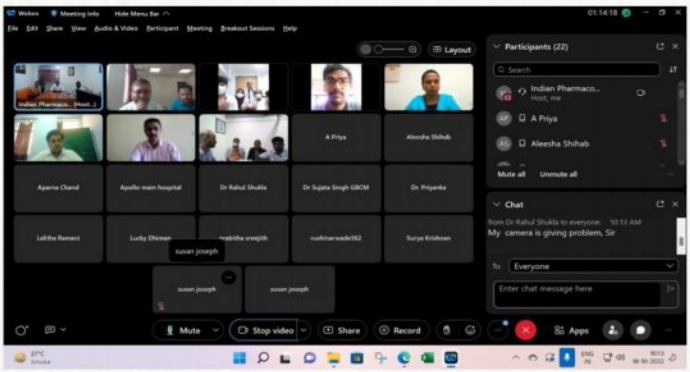
S. No.	States/UT	Name of Hospitals/Medical Colleges/Institutes	Status
1	Andhra Pradesh	Rajiv Gandhi Institute of Medical Sciences (RIMS), 5th Lane, Bhagya Nagar, Ongole, Andhra Pradesh - 523001	Government
2		Siddhartha Medical College, Vijayawada, Andhra Pradesh - 520008	Government
3		Sri Venkateshwara Institute of Cancer Care & Advanced Research, Alipiri road, Tirupati, Andhra Pradesh - 517501	Private
4		Government Medical College & Hospitals, Ananthapuram, Anantapur, Andhra Pradesh - 515001	Government
5	Delhi	Goyal Hospital & Urology Centre, E-4/8, Krishna Nagar, Delhi - 110051	Private
6		Atal Bihari Vajpayee Institute of Medical Sciences & Dr. RML hospital, Connaught Place, New Delhi-110001	Government
7		Park Hospital West Delhi 12, Meera Enclave, New Delhi - 110018	Private
8	Gujarat	Banas Medical College & Research Institute, Oriya Village, Banaskantha, Gujarat - 385001	Private
9		Kanba Hospital - Unit of Lakhani Hospitals Pvt. Ltd, Ahmedabad, Gujarat - 382350	Private
10		Bhailal Amin General Hospital, Vadodara, Gujarat - 390003	Private
11		SGVP Holistic Hospital, SGVP Campus, Opp. Nirma University, Ahmedabad, Gujarat - 382481	Private
12	Haryana	Sarvodaya Multispeciality and Cancer Hospital, Opp. Red Cross Bhawan, Hisar, Haryana - 125001	Private
13		Anand Orthopadic Centre, Opp. Theme Park, Near Panorama, Thanesar, Kurukshetra, Haryana - 136118	Private
14		Shantidevi GI Institute & Advanced Endoscopy Centre, Hisar, Haryana - 125001	Private
15		Aarvy Healthcare Super Specialty Hospital, Gurgaon, Haryana - 122505	Private

S. No.	States/UT	Name of Hospitals/Medical Colleges/Institutes	Status
16	Karnataka	Togari Veeramallappa Memorial College of Pharmacy, Ballari, Karnataka - 583104	Government
17	Kerala	Chazhikattu Hospital Pvt Ltd, Idukki, Kerala - 685584	Private
18		SP Fort Hospital, Fort Anakottil Lane, Distt-Thiruvanathapuram, Kerala -695023	Private
19	Madhya Pradesh	Suyash Hospital Pvt. Ltd., AB Road, Indore, Madhya Pradesh - 452001	Private
20	Maharashtra	Krupamayi Hospitals, Railway Station Road, Aurangabad, Maharasthra - 431001	Private
21		School of Pharmacy, Dr. Vishwanath Karad MIT World Peace University, Pune, Maharashtra - 411038	Private
22		Alexis Multispeciality Hospital, Koradi Road, Nagpur, Maharashtra - 440030	Private
23	Mizoram	Mizoram State Cancer Institute (MSCI), Aizawl, Mizoram - 776017	Government
24	Punjab	EMC Super Speciality Hospitals Pvt Ltd, Green Avenue, Amritsar, Punjab - 143001	Private
25		Orison Super Speciality Hospital Infertility and Trauma Centre, Ludhiana, Punjab - 49012	Private
26	Rajasthan	Rungta Hospital, Malviya Nagar, Jaipur, Rajasthan - 302017	Private
27		Saket Medicare & Research Center, Mansarovar, Jaipur, Rajasthan 302020	Private
28		Healthcare Global Hospital, Mansarovar, Jaipur, Rajasthan - 302020	Private
29		Eternal Hospital (EHCC) Eternal Health Care Centre & Research Institute, Jagatpura, Jaipur, Rajasthan -302017	Private
30		Imperial Hospital & Research Centre, Shastri Nagar, Jaipur, Rajasthan - 302006	Private
31		Mittal Hospital & Research Centre, Ajmer, Rajasthan - 305004	Private
32	Tamil Nadu	Apollo Speciality Hospitals, Madurai, Tamil Nadu - 625020	Private
33		Kauvery Hospital, Tiruchirapalli, Tamil Nadu -620001	Private
34		Scudder Memorial Hospital, Ranipet, Tamil Nadu -632401	Private

S. No.	States/UT	Name of Hospitals/Medical Colleges/Institutes	Status
35	Telangana	Government Medical College, Sangareddy, Telangana - 502001	Government
36		Omni Hospitals, H. No. 11-9-46, Opp. To Pvt Market, Kothapet, Dilsukhnagar, Hyderabad, Telangana - 500035	Private
37		Udai Omni Hospitals, Fateh Maidan, Abids, Hyderabad, Telangana- 500001	Private
38		Prathima Hospitals, Kochiguda Hyderabad, Telangana - 500027	Private
39		Pace Hospital, Hitech City, Hyderabad, Telangana - 500081	Private
40	Uttar Pradesh	St. Joseph Hospital, Gomti Nagar, Lucknow, U.P. 226010	Private
41		All India Institute of Medical Sciences, Dalmau Road, Raebareli, U.P. 229405	Government
42		SJM Super Speciality Hospital, Sec-63, Noida, U.P. 201307	Private
43		Yatharth Super Speciality Hospital and Heart Centre, Sec-110, Noida, U.P. 201304	Private
44		Government Medical College Kannauj (Tirwa), U.P. 209732	Government
45		Ajanta Hospital and IVF Centre Pvt Ltd, Alambag Lucknow, U.P. 226005	Private
46	West Bengal	Narayana Super Speciality Hospital, Shibpur, Howrah, West Bengal - 711103	Private

Continuing Medical Education Programme organized by KEM, Mumbai

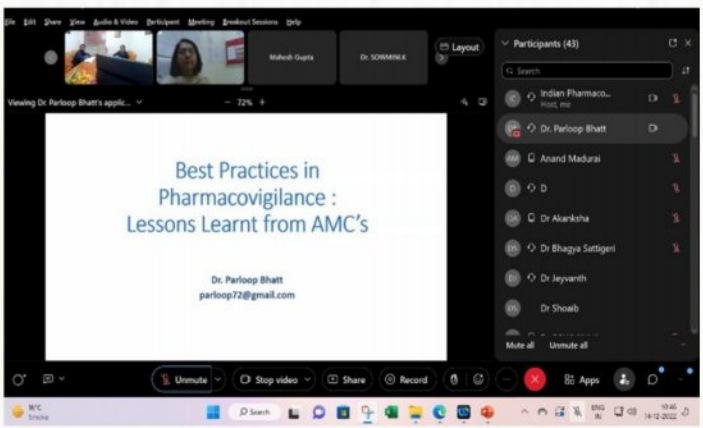
Dr. Nithya Gogtay, Coordinator, Dr. Mahesh Belhekar, Deputy Coordinator and Ms. Ujwala Mahajan, PV Associate at Seth GS Medical College & KEM Hospital, Mumbai have organized CME on "Assessing the safety of warfarin using pharmacogenetics" on 12th October 2022 at their hospital. A total of 14 participants from Department of Clinical Pharmacology & Pediatrics staff members attended this training programme.



Induction-cum-Training Programmes on Pharmacovigilance

NCC-PvPI conducted 3 days Induction-cum-Training Programme on Pharmacovigilance for Coordinators/ Deputy Coordinators of newly recognized AMCs and newly recruited Pharmacovigilance Associates at AMCs from 18th to 20th October 2022 through virtual platform at IPC. The objective of this training programme was to enhance the Pharmacovigilance skills of the newly recognized AMCs Coordinators, Deputy Coordinators & Pharmacovigilance Associates in order to promote patient safety. A total of 85 participants participated in this training programme.

NCC-PvPI conducted another 3 days Induction-cum-Training Programme on Pharmacovigilance from 12th to 14th December 2022 through virtual platform at IPC. A total of 95 participants participated in this training programme.



Continuing Medical Education Programme organized by AIIMS, Bathinda

Dr. Abhinav Kanwal, Coordinator, All India Institute of Medical Sciences (AIIMS), Bathinda, Dr. Mintu Pal, Deputy Coordinator & Dr. Gazal, Pharmacovigilance Associate has conducted the Continuing Medical Education (CME) on creating awareness among the Health Care Professionals regarding the reporting of Adverse Drug Reactions in Dermatology Department of AIIMS, Bathinda on October 21, 2022. A total of 10 participants participated in this training programme. This training was focused on convenient ways to report the ADRs by distributing the hard copies of suspected ADR reporting forms and this should be available on the website of AIIMS, Bathinda.

PvPI participated in celebration of Medsafety Week

NCC-PvPI has participated in Medsafety Week campaign organized by the Uppsala Monitoring Centre (UMC), Sweden from 7th to 13th November 2022. The theme of this year's campaign was "How patients and healthcare professionals make safety work". The main objective of this campaign was to raise the awareness among the public about reporting of Adverse Drug Reactions in national reporting systems .

NCC-PvPI in this campaign sensitized its AMCs across the country and disseminated the campaign's material to them. During this campaign, e-mail banner was added in the signatures of the e-mail, animations, social-media cards. Posters were shared in the social media platforms like Twitter, Facebook and LinkedIn.

22nd Signal Review Panel Meeting

NCC-PvPI, IPC has organized 22nd Signal Review Panel (SRP) Meeting on 22nd November 2022 through hybrid mode. The objective of this meeting was to confirm Signals/Prescribing Information Leaflet changes and issuing drug safety advisory from the reported drug safety data of Indian population in PvPI. In this meeting, the Individual Case Safety Reports (ICSRs) for Signal/Prescribing Information Leaflet changes/drug safety advisory were scientifically evaluated and the SRP has recommended the following for incorporating in the PIL;

S. No.	Drugs	Adverse Drug Reactions	SRP Recommendations
1	Paracetamol	Fixed Drug Eruption	Signal to be included in Prescribing Information Leaflet (PIL) of Paracetamol
2	Losartan	Muscle Spasm	To include in PIL of Losartan
3	Piroxicam	Fixed Drug Eruption	To include in PIL of Piroxicam
4	Albendazole	Diarrhea	To issue as an advisory to the Programme Division & DCG(I)

The NCC-PvPi acknowledges the following ADR Monitoring Centres for their contribution for submitting above SRP recommendations related data :-

Drug-ADR Combinations	Adverse Drug Reactions Monitoring Centers
Piroxicam – Fixed Drug Eruption	Madras Medical College-Chennai, MVJ Medical College and Research Hospital-Bangalore, AIIMS-Mangalagiri, Kalinga Institute of Medical Sciences - KIMS Hospital-Bhubaneswar, Royalcare Super Speciality Hospital Limited-Sulur, Christian Medical College-Vellore, Government Kilpauk Medical College-Chennai, Government Medical College-Srinagar, Dr. Rajendra Prasad Government Medical College-Tanda, Konaseema Institute of Medical Sciences-Amlapuram, Government T D Medical College-Alappuzha, Maharaja Krushna Chandra Gajapati Medical College and Hospital-Brahmapur, SRM Medical College Hospital and Research Centre-Kattankulathur, Sree Gokulam Medical College and Research Foundation-Trivandrum, AIIMS-Bhopal, Rangaraya Medical College-Kakinada, JSS-Mysuru, Calcutta School of Tropical Medicine-Kolkata, Christian Medical College-Ludhiana, PSG Institute of Medical Sciences and Research-Coimbatore, RG Kar Medical College and Hospital-Kolkata

Drug-ADR Combinations	Adverse Drug Reactions Monitoring Centers
Paracetamol – Fixed Drug Eruption	Pt. Jawahar Lal Nehru Memorial Medical College-Raipur, Subharti Medical College-Meerut, Rabindranath Tagore Medical College-Udaipur, AIIMS-Mangalagiri, Ashwini Rural Medical College, Hospital & Research Centre-Solapur, AIIMS-Bhopal, Calcutta National Medical College & Hospital-Kolkata, Sri Jagannath Medical College and Hospital-Puri, Government Medical College-Nagpur, Bhaskar Medical College and General Hospital-Hyderabad, Guru Gobind Singh Medical College & Hospital-Faridkot, Osmania Medical College-Hyderabad, Amala Institute of Medical Sciences-Thrissur, Silchar Medical College and Hospital-Silchar, Jorhat Medical College & Hospital-Jorhat, JSS-Mysuru, Government Medical College-Bhopal, Gajra Raja Medical College-Gwalior, Lady Hardinge Medical College-Delhi, AIIMS-Bhubaneswar, GMERS Medical College and Hospital-Ahmedabad, Royalcare Super Speciality Hospital Limited-Sulur, Government Medical College-Thoothukudi, Sardar Patel Medical College-Bikaner, Sriram Chandra Bhanj Medical College & Hospital-Cuttack, GMERS Medical College-Vadodara, Government Medical College-Vadodara, Sri Venkateshwara Medical College-Tirupati, Government Medical College-Guntur, AIIMS-Bhopal, ESIC Medical College-Faridabad, P.E.S. Institute of Medical Sciences and Research-Kuppam, Sri Aurobindo Institute of Medical Sciences-Indore, Kakatiya Medical College-Warangal, Jawaharlal Nehru Medical College-Ajmer, Rangaraya Medical College-Kakinada, Kalpana Chawla Government Medical College-Karnal, Armed Forces Medical College-Pune, Rural Institute of Medical Sciences & Research-Etawah
Losartan – Muscle Spasm	Smt. B. K. Shah Medical Institute & Research Centre-Waghodia, Nil Ratan Sircar Medical College and Hospital-Kolkata, Tirunelveli Medical College-Tirunelveli, Institute of Post Graduate Medical Education and Research-Kolkata.
Albendazole - Diarrhea	Madras Medical College-Chennai, Government Medical College-Vadodara, Bhaskar Medical College and General Hospital-Hyderabad, Kalpana Chawla Government Medical College-Karnal, Osmania Medical College-Hyderabad, Tripura Medical College & Dr. B.R. Ambedkar Memorial Teaching Hospital-Agartala, Dr Y. S. Parmar Government Medical College-Sirmour, Believers Church Medical College Hospital-Thiruvalla, Government Medical College-Miraj, Shree Guru Gobind Singh Tricentenary University-Gurgaon, Government Doon Medical College-Dehradun, Andaman and Nicobar Islands Institute of Medical Sciences-Port Blair, Indira Gandhi Medical College & Research Institute-Puducherry, Kalpana Chawla Government Medical College-Karnal, Byramjee Jeejeebhoy Medical College-Ahmedabad, King Edward Memorial Hospital-Mumbai, Santosh Medical College-Ghaziabad, Lokmanya Tilak Municipal Medical College and General Hospital-Mumbai, Nathiba Hargovandas Lakhmichand Municipal Medical College-Ahmedabad, Sawai Man Singh Medical College-Jaipur, Veer Chandra Singh Garhwali Government Institute Of Medical Science and Research-Pauri Garhwal, Silchar Medical College and Hospital-Silchar, Tripura Medical College & Dr. B.R. Ambedkar Memorial Teaching Hospital-Agartala, Tomo Riba Institute of Health & Medical Sciences-Naharlagun

All ADR Monitoring Centres under PvPI are encouraged to submit ICSRs that may contribute to signals.

Advanced level training programme organized by AIIMS, Bhopal

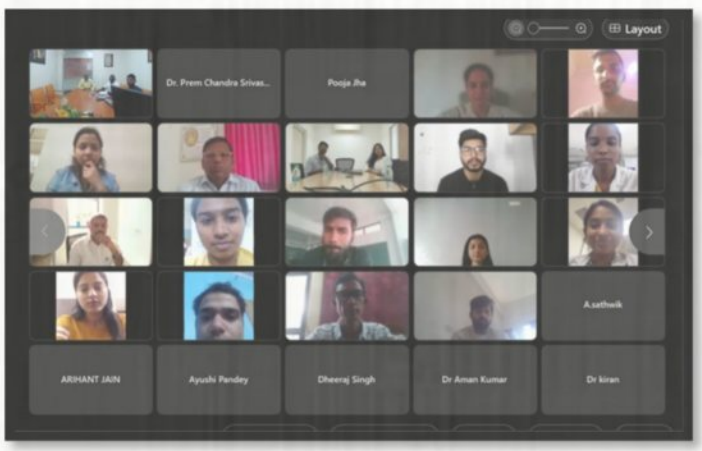
Prof. Ratinder Jhaj, Coordinator, All India Institute of Medical Sciences (AIIMS), Dr. Balakrishnan S, Deputy Coordinator, AIIMS, Bhopal & Ms. Deepa Choudhary, PV Associate conducted 6th advanced level training in Pharmacovigilance-cum-Coordinators meeting for participants from Madya Pradesh and Chhattisgarh on 11th November 2022 at AIIMS, Bhopal. The objective of this training was to sensitize coordinators, deputy coordinators and PV Associates about recent updates in PvPI, medication error & their reporting, ADRs due to Anti-Tubercular Therapy and reporting of AEFI due to COVID-19 vaccines. A total of 41 participants participated in this training programme as follows;

S. No.	Participants Details	Number of Participants
1	Coordinators	07
2	Deputy Coordinators	10
3	Pharmacovigilance Associates	05
4	NCC-PvPI representative	01
5	CDSCO Sub zonal office representative	01
6	Medical officer, NTEP DOTs, AIIMS, Bhopal	01
7	Prof. & Head Forensic Medicine and Toxicology, AIIMS, Bhopal	01
8	Other HCPs	15

23rd Skill Development Programme

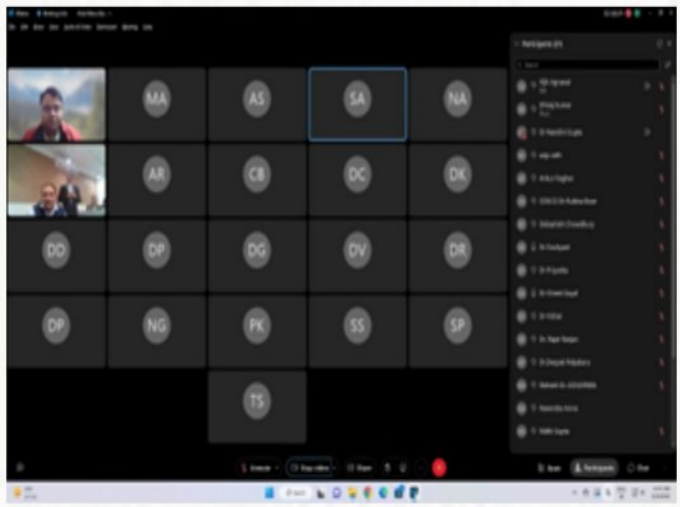
The NCC-PvPI, IPC has organized 5 days 23rd Skill Development Programme (SDP) on Pharmacovigilance of Medical Products from 14th to 18th November, 2022 through virtual mode at IPC. The objective of the Skill development Programme (SDP) was to enhance the Pharmacovigilance skills of the healthcare professionals in order to promote the patient safety in India. A total of 106 participants attended this SDP as follows:

S. No.	Participants details	Number of Participants
1	Associate Professor/ Assistant Professor/ Professor & HOD	32
2	Students (B Pharm, Pharm D, MBBS)	16
3	Industry Professional	8
4	Doctor/ Dental Surgeon	10
5	Pharmacist	5
6	Other	35
Total	106	



National AEFI Committee Meetings

The National AEFI committee meetings were held virtually on 24th November 2022 and 9th December, 2022 respectively to approve the causality assessment classification of the reported AEFI cases. Both meetings were organized by the AEFI Secretariat under the chairmanship of Prof. S. Aneja, Head of the Department of Pediatrics, School of Medical Sciences and Research, Sharda University, Greater Noida. Dr. Vijit Agrawal, Sr. PV Associate, PvPI had attended these meetings.

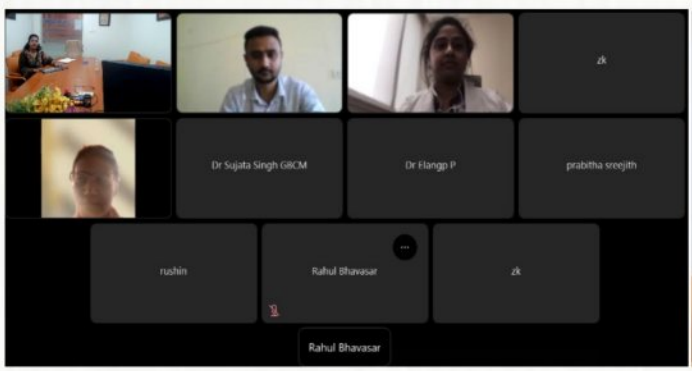


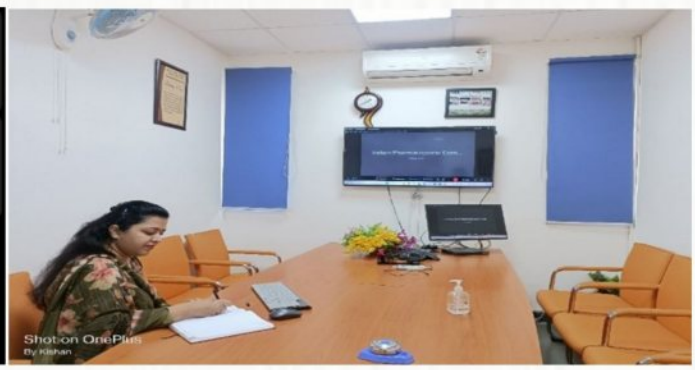
Participation of PvPI in MSN Conclave organized by Indian Medical Association

Dr. R.S Ray, Scientific Assistant and Mr. Hamad Ali, Pharmacovigilance Associate, PvPI participated in Medical Students Network (MSN)-The Way & Beyond organized by the Indian Medical Association on 27th November 2022 at New Delhi. Dr. R.S Ray briefed the gathering on "Current Status of PvPI" in this event.

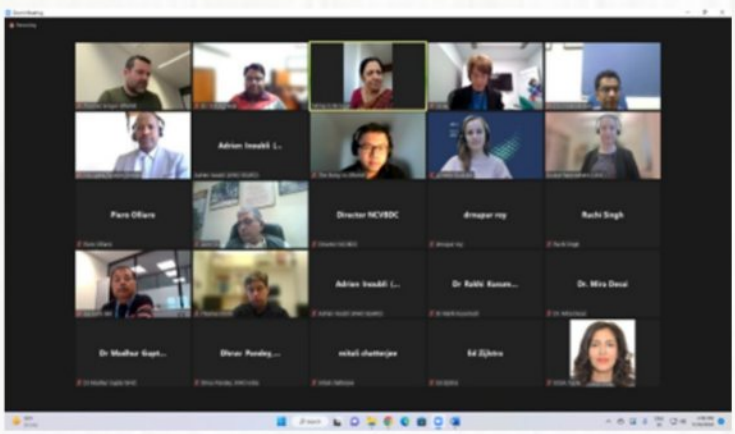
Virtual handholding session on VigiFlow for newly recognized AMCs

NCC-PvPI had organized handholding sessions on VigiFlow software to train the Coordinators, Deputy-Coordinators and Pharmacovigilance Associates of newly recognized AMCs under PvPI on 29th November 2022 at IPC. Ms. Shilpa Bhardwaj, Team Lead-ICSR division made presentation on "How to enter the ICSRs into the VigiFlow software?" and a total of 13 participants participated in this handholding session from AMCs across the country.





WHO-Multidisciplinary Technical Group (MTG) meeting on Miltefosine



The representatives from PvPI, IPC have participated as observers in a WHO-Multidisciplinary Technical Group (MTG) meeting organized by the WHO Regional Office for South-East Asia (SEARO), New Delhi on Ocular Events reported with the administration of Miltefosine on 30th November 2022 through virtual mode. In this meeting, discussion focused on the Causality Assessment, Risk Minimization Measures & its Communication, remaining uncertainties and need of further studies for Miltefosine associated Ocular Events.

Sensitization of Wipro GE Healthcare Pvt. Ltd.

NCC-PvPI sensitized the officials of Wipro GE Healthcare Pvt. Ltd. about the Pharmacovigilance Programme of India on 30th November 2022 through virtual mode at IPC, Ghaziabad. A total of 70 participants participated in this sensitization event.

Continuing Medical Education Programme organized by Madaras Medical College, Chennai

Dr C. Ramachandra Bhatt, Coordinator, MMC and Mrs. Siddiraju Devipriya, PV Associate organized CME Programme on "ADR Reporting-Basics to Advanced" in collaboration with PvPI, IPC on 2nd December 2022 through hybrid mode. A total of 224 participants attended this CME Programme as follows:

S. No.	Participants details	Number of Participants
1	Doctors	173
2	Pharmacist	01
3	Pharmacy Faculty	02
4	Pharmacovigilance Associates	04
5	Students	44

e-ITEC course on International Pharmacovigilance Training

The Development Partnership Administration (DPA) Division of Ministry of External Affairs (MEA), Govt. of India has identified IPC to provide the capacity building training in the area of Pharmacovigilance to partner countries for capacity building.

In this context, PvPI, IPC organized 20 hours (5 days x 4 hours) training programme virtually from 5th-9th December 2022 on Pharmacovigilance, basic tools applied for Adverse Drug Reporting/Monitoring, methods used in Pharmacovigilance and impact of Pharmacovigilance practices on post COVID19 pandemic. This International training also focused on to:

- The basic need and scope of Pharmacovigilance system.
- Understand and strengthen the Pharmacovigilance post COVID19 pandemic.
- Establishing Causality Assessment of Drug-Event combination.
- Group exercise along with discussion for the participants to resolve their issues on topics.

A total of 27 participants were from seven countries - Egypt, Mauritius, Morocco, Myanmar, Nicaragua, Sri Lanka & Tunisia registered through the e-ITEC portal of Ministry of External Affairs, Government of India.

Advanced Level Training organized by IPGME&R, Kolkata

Prof. Suparna Chatterji, Coordinator conducted an advanced level training on "Risk Benefit & Assessment & Communication in Pharmacovigilance" on 8th December 2022 through hybrid mode. Prof. M. Bandopadhyay, Director, IPGME&R, Kolkata also addressed the participants and appreciated the organizers. The IPGME&R is an East Zone Regional Centre under PvPI for providing training and technical supports to the AMCs in their zone. The training was structured to cover the emerging topics in Pharmacovigilance. A total of 158 participants from AMCs of East & North East Zone under PvPI participated in this training either in person or online. The overall experience of this training programme was good as reflected in feedback provided by the participants and such feedback will encourage to organize more such trainings in future.

Advanced level training organized by B. J. Medical College, Ahmedabad

Dr. Chetna Desai, Regional Training Centre Coordinator, B. J. Medical College, Ahmedabad in collaboration with PvPI conducted an advanced level training in Pharmacovigilance from 12th to 13th December 2022 through hybrid mode. The objective of this training was to impart knowledge and skills in Pharmacovigilance and Materiovigilance to the participants. A total of 339 participants had registered from Gujarat (148), Rajasthan (22) and other states (169) in this training programme.

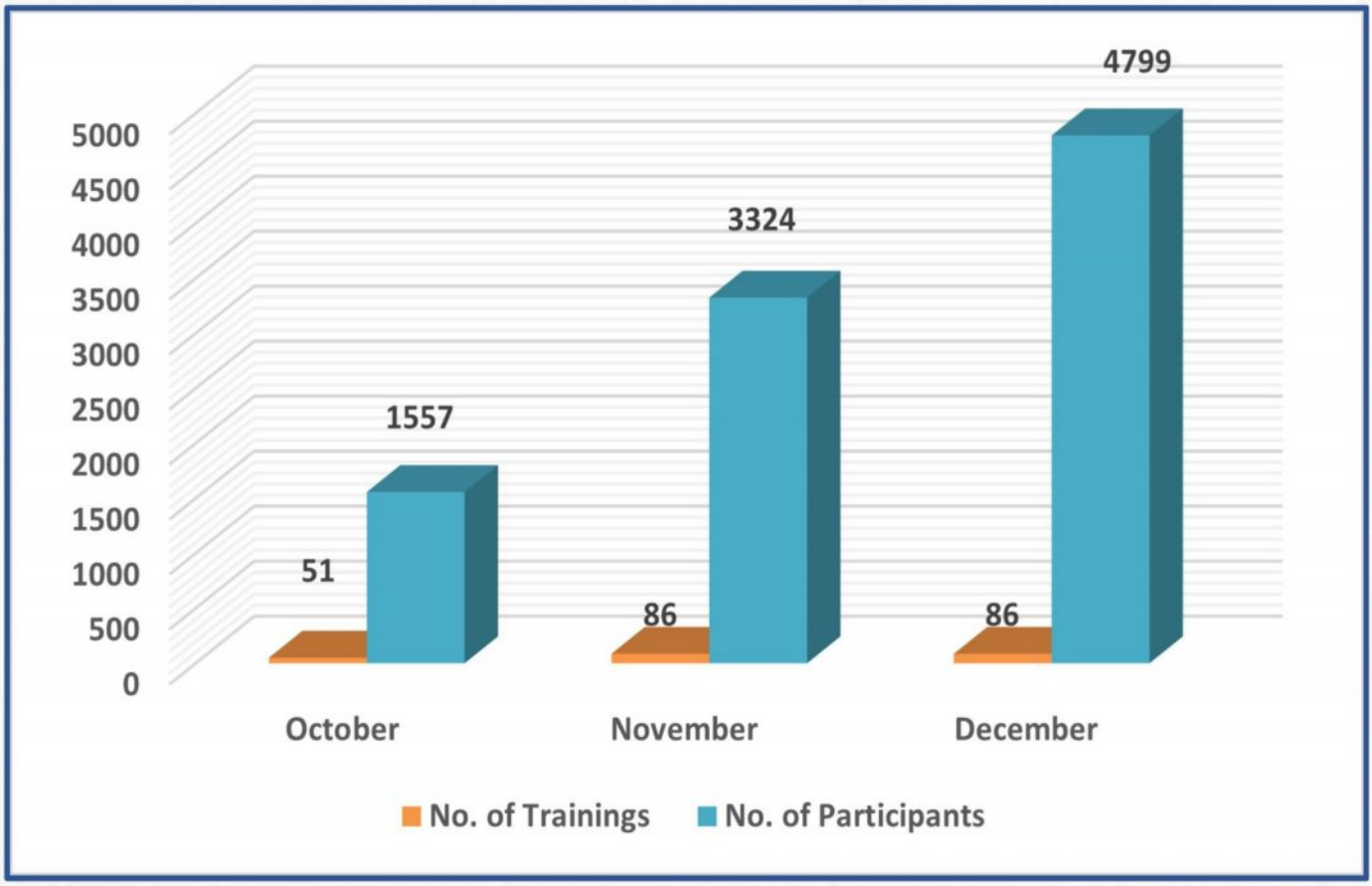
Pharmacovigilance awareness programme organized by RKGIT, Ghaziabad

Ms. Rituparna Palit, Assistant Professor, Raj Kumar Goel Institute of Technology (RKGIT), Ghaziabad and Ms. Archana Ojha, Assistant Professors, RKGIT conducted an awareness programme about the functioning of Pharmacovigilance Programme of India to promote the patient safety on 22nd December 2022 at college campus.

Dr. Jai Prakash, PvPI officer In-charge & Ms. Deepti Sachdeva, PV Associate joined this event. A total of 140 undergraduate & postgraduate students of Pharmacy participated in this awareness programme. This session ended with presenting a memento to experts by Dr. Laxman Prasad, Group Advisor - RKG Group of Institutions, Dr. Monika Sachdeva, Principal Pharmacy, and Dr. Umesh Kumar Singh, Director R&D Pharmacy.

Total training Programmes conducted during index period

NCC-PvPI has organized a total of 223 training programmes like skill development programmes, continuing medical educations, advanced level training programmes, Induction-cum-training programmes etc. and trained 9680 participants in pharmacovigilance during this quarter. The month wise details are given below:



NCC-PvPI issued the following drug safety alerts during this tenure and shared with AMCs through email for the sensitizations of healthcare professionals.

S. No.	Issuing Date	Suspected Drugs	Indication	Adverse Drug Reactions
1.	17th October, 2022	Amoxicillin	For treatment of urinary tract infections, upper respiratory-tract infections, bronchitis, pneumonia, otitis media, dental abscess, osteomyelitis, Lyme diseases in children, endocarditis prophylaxis, post-splenectomy prophylaxis, gynaecological infections, gonorrhoea, helicobacter pylori eradication enteric fever.	Fixed Drug Eruption
2.	28th November, 2022	Norfloxacin	• Antibacterial- Indicated in the treatment of acute uncomplicated/complicated chronic, recurrent urinary tract infections, including pyelonephritis, cystitis, urethritis & gonococcal infections. • Wide variety of infections caused by susceptible Gram +ve and Gram -ve organism including mixed infection in poultry.	Skin Hyperpigmentation

3.	26th December 2022	Minoxidil	For the treatment of alopecia (male pattern baldness in men).	Folliculitis

Source:

https://www.ipc.gov.in/mandates/pvpi/pvpi-updates/8-category-en/931-drug-alerts-2022.html

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 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 ICSR (s) in PvPI	References
1	Selective Serotonin Reuptake Inhibitors (SSRI)	Risk of suicidal ideation	7878	32	WHO Pharmaceuticals Newsletter No. 4, 2022, published on November 17, 2022.
2	Crizotinib	Vision disorder	169	03	hpra-drug-safety-newsletter-edition-109.pdf
3	Gabapentin	Toxic Epidermal Necrolysis	58	04	hpra-drug-safety-newsletter-edition-110.pdf

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)

PvPI in Press & Media

IPC alerts healthcare professionals about norfloxacin induced skin hyperpigmentation

Laxmi Yadav, Mumbai
Wednesday, December 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 antibacterial norfloxacin is associated with adverse event known as skin hyperpigmentation.

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

Norfloxacin is used to treat a variety of bacterial infections. This medication belongs to a class of drugs known as quinolone antibiotics. It is indicated in the treatment of acute uncomplicated/complicated chronic, recurrent urinary tract infections, including pyelonephritis, urethritis and gonococcal infections. It is also indicated in a wide variety of infections caused by susceptible gram positive and gram-negative organisms including mixed infection in poultry.

Norfloxacin's mode of action depends on blocking of bacterial DNA replication by binding itself to an enzyme called DNA gyrase, which allows the untwisting required to replicate one DNA double helix into two. Notably the drug has 100 times higher affinity for bacterial DNA gyrase than for mammalian.

As per drug safety alert issued by IPC last week of November, norfloxacin is linked with skin hyperpigmentation. Hyperpigmentation refers to patches of skin that become darker than the surrounding areas of skin. It occurs when the skin produces excess melanin, the pigment that gives skin its colour.

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

IPC flags drug safety alert against Minoxidil due to adverse event known as folliculitis

Shardul Nautiyal, Mumbai
Friday, December 16, 2022, 08:00 Hrs [IST]

The Indian Pharmacopoeia Commission (IPC) has flagged drug safety alert to the Drugs Controller General of India (DCGI) revealing that Minoxidil is associated with adverse event known as folliculitis. IPC is the National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI).

Minoxidil topical solution has been approved in India for the treatment of hair loss in men. It has also been authorised by the US Food and Drug Administration (FDA) for the treatment of hair loss in both men and women.

Folliculitis is often caused when hair follicles are infected with bacteria like Staphylococcus aureus (staph). It may also be caused by viruses, fungi, parasites, medications or physical injury. However healthcare practitioners say that Minoxidil does not cause folliculitis. Scalp has to be examined and proper diagnosis has to be done for further treatment.

Dr. Reddy's Laboratories had launched the prescription drug Minoxidil topical solution USP 2% and 5% for the treatment of female pattern hair loss (FPHL) in September 2021 under the brand names Mintop 2% and Mintop Eva 5% respectively.
The DCGI had given the first-ever approval for the use of Minoxidil topical solution USP 2% and 5% for the treatment of female pattern hair loss (FPHL) in India.

Minoxidil topical solution is available as a first-line treatment option for FPHL in India. While Minoxidil topical solution has been approved in India for the treatment of male pattern baldness, there are presently no other drugs approved for the treatment of FPHL.

Female pattern hair loss is the most common cause of hair loss in women and its prevalence increases with advancing age, often leading to psychological distress.

The launch follows the first-ever approval of the additional indication by the Central Drugs Standard Control Organization (CDSCO) in India for the use of Minoxidil topical solution USP 2% and 5% for treatment of FPHL.

Minoxidil topical solution will become available as first-line treatment option for FPHL in India. While Minoxidil topical solution has been approved in India for the treatment of alopecia in men (male pattern baldness), there were no other drugs approved for the treatment of FPHL in India.

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.

Image

नवभारत
छत्तीसगढ़ • ओडिशा
Raipur Main - 30 Dec 2022 - 30page3
epaper.navabharat.news

देश की दवा व टीका फैक्ट्रियों में अब फार्माकोविजिलेंस जरूरी

एहतियाती कदम : औषधि महानियंत्रक ने जारी किया आदेश, फैक्टरियों को साझा करनी होगी जानकारी

नई दिल्ली। सरकार ने सभी दवा, टीका फैक्ट्रियों में फार्माकोविजिलेंस सिस्टम स्थापित करने पर जोर दिया है। नई दवाएं व नैदानिक परीक्षण 2019 अधिनियम के तहत प्रत्येक दवा निर्माता कंपनी को अपने यहां फार्माकोविजिलेंस सिस्टम शुरू करना है, जिसमें एक मेडिकल ऑफिसर और फार्मासिस्ट रहेगा। ये हर माह अपने उत्पादों की सुरक्षा, गुणवत्ता और प्रतिकूल प्रभावों के बारे में जानकारी एकत्रित कर सरकार के साथ साझा करेंगे। इनकी रिपोर्ट पर सरकार ऑडिट कराएगी और जांच में दोषी मिलने पर उक्त कंपनी के खिलाफ सख्त कार्रवाई होगी। देश में मौजूदा समय में 4,500 से अधिक दवा व टीका निर्माता कंपनियां हैं, जिनकी 10,500 से अधिक फैक्ट्रियां मौजूद हैं। 23 दिसंबर को भारत के औषधि महानियंत्रक डॉ. वीजी सोमानी ने दवा, टीका निर्माता और निर्यातक कंपनियों को आदेश जारी करते हुए फार्माकोविजिलेंस सिस्टम के बारे में जानकारी मांगी है।

4,500 से अधिक दवा व टीका निर्माता कंपनियां हैं, मौजूदा समय में देश में

- केंद्रीय औषधि मानक नियंत्रण संगठन (सीडीएससीओ) के वरिष्ठ अधिकारी के मुताबिक, नई दवाएं और नैदानिक परीक्षण 2019 अधिनियम के तहत सभी दवा-टीका कंपनियों में फार्माकोविजिलेंस स्थापित करने के लिए कहा है। नए आदेशानुसार, कंपनियों को फार्माकोविजिलेंस शुरू करने के साथ-साथ उसकी जानकारी सरकार के साथ साझा करने के निर्देश भी दिए हैं।

इसलिए जरूरी है यह सिस्टम

- जेनेरिक दवाएं, ओवर-द-काउंटर दवाएं, थोक दवाएं, टीके, अनुबंध अनुसंधान और विनिर्माण, बायोसिमिलर और बायोलॉजिक्स भारतीय फार्मा उद्योग के कुछ प्रमुख खंड हैं।
- भारत में सबसे अधिक संख्या में फार्मास्युटिकल निर्माण सुविधाएं हैं जो यूएस फूड एंड ड्रग एडमिनिस्ट्रेशन (यूएसएफडीए) के अनुपालन में हैं। 500 एपीआई उत्पादक हैं जो दुनियाभर में एपीआई बाजार का लगभग 8% हिस्सा है।

भारतीय दवाएं जांची-परखीं विश्वसनीय : विदेश मंत्रालय

बागची बोले- उज्बेकिस्तान जैसे मामले देश की छवि धूमिल कर रहे

नई दिल्ली। कफ सिरप के सेवन से उज्बेकिस्तान में 18 बच्चों की मौत मामले में विदेश मंत्रालय ने अपना बयान जारी किया है। विदेश मंत्रालय के प्रवक्ता अरिंदम बागची ने बृहस्पतिवार को कहा कि भारतीय दवा उद्योग दुनिया भर के देशों के लिए एक विश्वसनीय आपूर्तिकर्ता रहा है और यहां की दवाएं पूरी तरह जांची गई हैं। कथित तौर पर उज्बेकिस्तान में भारतीय कंपनी मैरियन बायोटेक द्वारा बनाई गई खांसी की दवाई डॉक1 मैक्स के कारण मौतों की खबर दुखद है। ऐसे मामले दुनिया में भारत की छवि को धूमिल कर रहे हैं।

विदेश मंत्रालय के प्रवक्ता अरिंदम बागची ने कहा, जब ये घटनाएं सामने आती हैं तो हम इन्हें बहुत गंभीरता से लेते हैं। एजेंसी

Feedback on PvPI

PvPI has been at the helm of all pharmacovigilance activities across India. The various outreach activities, trainings and observance of National Pharmacovigilance Week, have generated an unprecedented awareness on pharmacovigilance among healthcare professionals and the public. The entire healthcare scenario is improving due to timely ADR detection and vigilance for prevention of ADR by healthcare professionals. We are extremely grateful for the immense support and guidance given to our AMC, and earnestly look forward for future roles and avenues with PvPI.

Prof. Dr Jacob Jesurun RS

HOD, Department of Pharmacology, Coordinator, Deputy Director, Believers Church Medical College Hospital, Thiruvalla, Kerala

Patient safety is of paramount importance in healthcare system to avoid harm to the population. Pharmacovigilance is an important scientific tool for the purpose of safe and effective use of medicines to identify and decrease the chances of adverse events with the use of marketed drugs. The Pharmacovigilance Programme of India (PvPI) is an initiative of the Ministry of Health and Family Welfare, Government of India through Indian Pharmacopoeia Commission that functions as the National Coordination Center to ensure the safe use of medicines and trains the healthcare professionals on this key topic and further joins the WHO-UMC initiative to sustain the health safety across the globe.

NIPER Hajipur is proud to be a part of this initiative and participate as an active adverse drug reaction monitoring centre in Bihar State.

Dr. Sameer Dhingra

Associate Professor and Head, Department of Pharmacy Practice, NIPER- Hajipur, Bihar, Coordinator

Forthcoming Events

10th January 2023	Celebration of 15th Foundation Day of IPC.
11th - 13th January 2023	Induction-cum-training programme on Pharmacovigilance for Coordinators/Deputy Coordinators of newly recognized AMCs and newly recruited Pharmacovigilance Associates at AMCs
19th January 2023	Training on "Narrative Writing"
6th - 10th February 2023	24th Skill Development Programme on Pharmacovigilance of Medical Products
15th February 2023	Training on "Basics of Causality Assessment"
5th March 2023	Workshop-cum-Training Programme on Pharmacovigilance for NABH accredited hospitals

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

औषधि सतर्कता कार्यक्रम (फार्माकोविजिलैंस प्रोग्राम ऑफ़ इंडिया) क्या है?

फार्माकोविजिलैंस प्रोग्राम ऑफ़ इंडिया, स्वास्थ्य एवं परिवार कल्याण मंत्रालय के अंतर्गत कार्य करता है जिसका नोडल कार्यालय, भारतीय भेषज संहिता आयोग में स्थित है। मैटीरियोविजिलैंस प्रोग्राम ऑफ़ इंडिया जिसका नोडल कार्यालय भी भारतीय भेषज संहिता आयोग में स्थित है तथा हीमोविजिलैंस प्रोग्राम ऑफ़ इंडिया जिसका नोडल कार्यालय राष्ट्रीय जैविक संस्थान, नॉएडा में स्थित है, वे भी इसी के भाग हैं।

उद्देश्य

राष्ट्रीय औषधि सतर्कता सप्ताह का उद्देश्य औषधियों से होने वाले दुष्प्रभाव के प्रति जागरूकता फैलाना व इनसे होने वाले दुष्प्रभावों को फार्माकोविजीलैंस प्रोग्राम ऑफ़ इंडिया को रिपोर्ट करना है।

औषधि सतर्कता क्या है?

सामान्य मात्रा में किसी औषधि अथवा दवा का सेवन करने से होने वाले प्रतिकूल प्रभाव अथवा दुष्प्रभाव का पता लगाने, उसका मूल्यांकन करने, समझने व रोकथाम से सम्बंधित विज्ञान एवं गतिविधियों को औषधि सतर्कता विज्ञान कहते हैं तथा इस विषय में सजग/ सतर्क रहने को औषधि सतर्कता कहते हैं।

दवा प्रतिक्रिया/ एडवर्स ड्रग रिएक्शन (एडीआर)

औषधियों का वह प्रभाव जो हानिकारक और अनअपेक्षित है और जो आमतौर पर मनुष्यों में बीमारी की रोकथाम, निदान या उपचार के लिए या शारीरिक कार्य के संशोधन के लिए उपयोग की जाने वाली खुराक पर होती है, को दवा प्रतिक्रिया/ एडवर्स ड्रग रिएक्शन कहते हैं।

औषधि दुष्प्रभावों को कौन रिपोर्ट कर सकता है?

सभी स्वास्थ्य कर्मचारी (चिकित्सक, दंत चिकित्सक, फार्मासिस्ट, नर्स और उपभोक्ताओं सहित गैर-स्वास्थ्य देखभाल कर्मचारी) दवाओं के दुष्प्रभाव को रिपोर्ट कर सकते हैं।

औषधि दुष्प्रभावों को रिपोर्ट क्यों करें?

स्वास्थ्य कर्मचारी के रूप में सार्वजनिक स्वास्थ्य की सुरक्षा के लिए औषधि उत्पादों से जुड़े प्रतिकूल प्रभावों को रिपोर्ट करना एक नैतिक जिम्मेदारी है।

क्या रिपोर्ट करें?

औषधियों से होने वाले किसी भी प्रकार की प्रतिक्रियाएं भले ही ज्ञात हों या अज्ञात, गंभीर हों या अगंभीर, अक्सर हो या दुर्लभ, ऐसी सभी प्रतिक्रियाओं की रिपोर्टिंग कर सकते हैं।

कैसे और किसे रिपोर्ट करें?

1. हेल्पलाइन नंबर 1800-180-3024 पर कॉल करके (सोमवार से शुक्रवार सुबह 9:00 बजे से सायं 5:30 बजे)।
2. हमारी वेबसाइट www.ipc.gov.in पर औषधि दुष्प्रभाव सूचना फॉर्म डाउनलोड करके व उचित तरीकें से भरकर ई-मेल करें।
3. हमारी ई-मेल आई डी है pvpi.ipc@gov.in, pvpi.compat@gmail.com
4. यह सुविधा गूगल प्ले स्टोर पर मुफ्त उपलब्ध है।
5. आप "ADR PvPI" App डाउनलोड कर सकते हैं।

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