



Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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3rd National Pharmacovigilance Week - 2023



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A WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services

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Government of India



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Message from the Desk of Secretary-cum-Scientific Director



I am privileged to release the Pharmacovigilance Programme of India (PvPI) Newsletter Volume 13, Issue 3 for the index period from July, 2023 to September, 2023. During the index period, NCC-PvPI celebrated 3rd National Pharmacovigilance Week 2023 (NPW 2023) on the theme “Boosting Public Confidence in Pharmacovigilance”. The Adverse Drug Reaction Monitoring Centres (AMCs) in medical colleges, hospitals, academic institutes and Pharmaceuticals Industries have also shown interest in celebration of 3rd NPW 2023. During 3rd NPW, 861 trainings/workshops/awareness programmes were conducted and trained/sensitized 95974 participants across the country.

In this quarter, 82 New AMCs have been enrolled under PvPI and total number of AMCs became 842 across the country. As on 30th September, 2023, a total of 7.36 Lakh Individual Case Safety Reports have been reported to PvPI. The PvPI is regularly sensitizing its 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 7515 training programmes and trained a total of 460331 participants in the area of pharmacovigilance so far.

The NCC-PvPI, IPC has issued a total of 157 drug safety alerts so far for the sensitization of healthcare professionals and reporting of such adverse drug reactions to PvPI, if encountered with the use of such drugs (for details, please refer the website www.ipc.gov.in).

At global level, the NCC-PvPI, IPC being a World Health Organization-Collaborative Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services is regularly sharing the latest information on safety and regulatory actions of medical products to the SEARN Countries. NCC-PvPI, IPC has also organized one day International Webinar on “Updates on VigiFlow & Optimum Use of VigiLyze for Signal Detection” on 20th September 2023 for South East Asia Regional countries and WHO Member States participating in the Programme for International Drug Monitoring (PIDM).

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

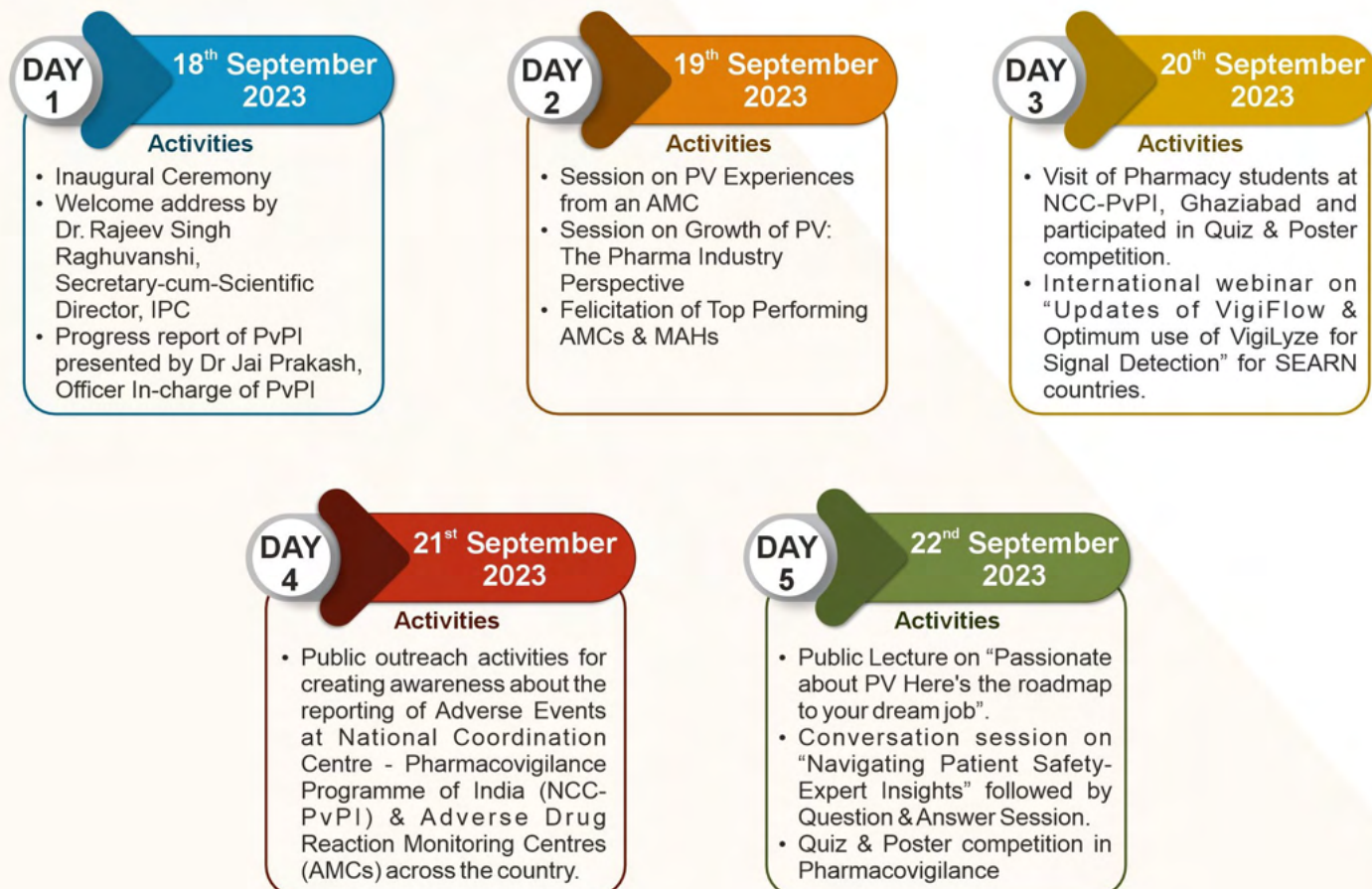
(Dr. Rajeev Singh Raghuvanshi)
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
(Ministry of Health & Family Welfare,
Govt. of India)
Ghaziabad - 201002



3rd National Pharmacovigilance Week 2023

The National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) celebrated 3rd National Pharmacovigilance Week (NPW) from 17th-23rd September 2023 across the country. The theme of this NPW was “Boosting Public Confidence in Pharmacovigilance”. The Adverse Drug Reaction Monitoring Centres (AMCs) in medical colleges, hospitals, academic institutes and Pharmaceuticals Industries have also shown interest in celebration of 3rd NPW 2023. Various modes like Workshops, Conferences, Quiz competition, Poster competition etc. were used during entire week for creating the awareness at hospitals, medical colleges and academia across the country. A total of 861 trainings/workshops/awareness programmes related to Pharmacovigilance were conducted and trained/sensitized 95974 participants across the country.

During the 3rd NPW 2023, NCC-PvPI team took the initiative to visit various schools in Ghaziabad district for educating the students about the reporting of Adverse Events with the use of medical products and also distributed the pamphlets & resource materials to the teachers & students. The major activities organized by NCC-PvPI during this week were as follows;

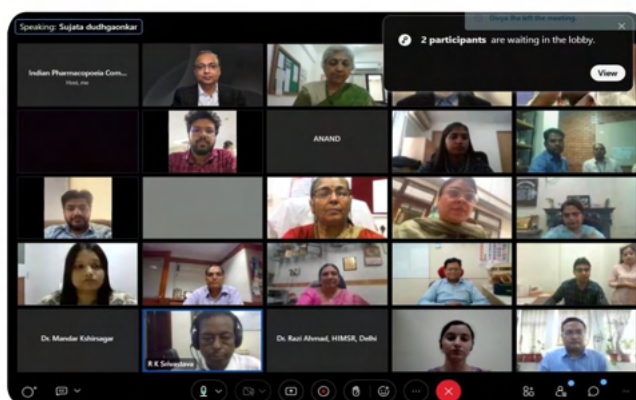




COVER STORY

Pharmacovigilance Programme of India (PvPI)

The Adverse Drug Reaction Monitoring Centres (AMCs) in medical colleges, hospitals and academic institutions under PvPI across the country have actively participated in 3rd National Pharmacovigilance Programme (NPW) 2023. The glimpses of the celebration of 3rd NPW 2023 are as follows;





Enrolment of New AMCs

NCC-PvPI, IPC has enrolled 82 new AMCs in 20th Phase of PvPI expansion. The total number of AMCs enrolled by the end of this quarter were 842 across the country. The list of newly enrolled AMCs is mentioned below:

S. No.	States/UTs	Name of Hospitals/Medical Colleges/Institutes	Status
1.	Andhra Pradesh	Sri Balaji Medical College Hospital & Research Institute Near Airport Road, Renigunta (Chittoor), Andhra Pradesh - 517520	Non-Government
2.		Viswabharathi Medical College Hospital R.T. Nagar, Penchikalapadu, Kurnool, Andhra Pradesh - 518467	
3.		St. Ann's Hospital 38-1-28/2, Punammathota, Vijayawada, NTR DT, Andhra Pradesh - 520028	
4.	Assam	Lakhimpur Medical College and Hospital Chowkham, Saboti, North Lakhimpur, Assam - 787051	Government
5.	Bihar	MGM Hospital & Research Centre Pvt. Ltd. Jagat Narayan Lal Road, East Lohanipur Kadamkuan, Patna, Bihar - 800003	Non-Government
6.	Chandigarh	Jindal IVF & Sant Memorial Nursing Home 3050 Sector-20D, Chandigarh- 160020	Non-Government
7.	Chhattisgarh	Shri Balaji Institute of Medical Sciences Shri Balaji Hospital Campus, Mowa, Raipur, Chhattisgarh - 492001	
8.	Delhi	Metro Hospital & Cancer Institute 21 Community Centre, Preet Vihar, East Delhi, Delhi - 110092	Non-Government
9.		Kailash Deepak Hospital 5&6, Institutional Area, Vikas Marg Extn., Shahdara, Delhi - 110092	
10.	Gujarat	GMERS Medical College Kharvad Medan, Sipor Road, Vadnagar, Gujarat - 384355	Non-Government
11.		Kiran Multi Super Speciality Hospital & Research Centre Vasta Devdi Road, Near Sumul Dairy Road, Katargam, Surat, Gujarat - 395004	



IMPORTANT ACTIVITIES

12.		Synergy Superspeciality Hospital (A unit of Saurashtra Medicare LLP) Rajkot, Gujarat-360005	
13.		Unique Hospital Multispecialty and Research Centre Opp. Kiran Motors, Civil Char Rasta, Sosyo Circle, Surat, Gujarat-395017	
14.		Shri Atal Bihari Vajpayee Government Medical College Chhainsa, Faridabad, Haryana - 121004	Government
15.		Amrita School of Medicine Mata Amritanandamayi Marg, Sector - 88, Faridabad, Haryana - 121002	
16.		Mittal Surgical & Maternity Hospital Opp - PNB Bank, Ambala Road, Kaithal, Haryana - 136027	
17.		Arpana Hospital (A Unit of Arpana Research & Charities Trust) Madhuban, Karnal, Haryana - 132037	
18.	Haryana	Pratap Heart & Chest Hospital Near Mejban Chowk, Charkhi Dadri, Haryana- 127306	Non-Government
19.		Agarwal Nursing Home Kurukshetra, Haryana - 136118	
20.		Kaddam Multispeciality Hospital Bhiwani, Haryana - 127021	
21.		Malik Hospital 145, Hansi, Hisar, Haryana- 125033	
22.		Mission Hospital & Medical Research Center Pvt Ltd. Main Rohtak Delhi Road, Near Bahadurgarh City Metro Station. Jhajjar, Haryabna-124507	
23.	Himachal Pradesh	Civil Hospital Ponta Sahib, Sirmaur, Himachal Pradesh - 173025	Government
24.		Karan Hospital Ward No.12, Palampur, Kangra, Himachal Pradesh - 176061	Non-Government
25.	Jammu and Kashmir	Government Medical College Udhampur Dhar Road Near Sailan Talab, Udhampur, Jammu & Kashmir - 182101	Government
26.	Karnataka	Koppal Institute of Medical Sciences Gangavathi Road, Koppal, Karnataka - 583231	Government



27.	Kerala	Sun Medical & Research Centre S. T. Nagar, Kannamkulangara, Thrissur, Kerala - 680001	Non-Government
28.		Nyle Institute of Medical Science (P) Ltd. Kaiparambu (PO), Kozhikode Road, Thrissur, Kerala - 680546	
29.		Aster Mother Hospital Areekode, Vazhakkad Road, Ugrapuram, Malappuram, Kerala - 673639	
30.		The Dale View College of Pharmacy and Research Centre Punalal, P.O. Poovachal, Trivandrum, Kerala - 695515	
31.		M.A.J. Hospital Market Road, Edappally, Kochi, Ernakulam, Kerala - 682024	
32.	Ladakh	Mahabodhi Karuna Charitable Hospital P.O. Box 22, Leh, Ladakh - 194101	Non-Government
33.	Madhya Pradesh	Anant Nursing Home Pvt. Ltd Madan Mahal Railway Station Road, Wright Town, Jabalpur, Madhya Pradesh - 482002	Non-Government
34.	Maharashtra	Kamalnayan Bajaj Hospital Gut no. 43, Bajaj Marg, Beed Bypass Road, Satara Parisar, Aurangabad, Maharashtra- 431005	Non-Government
35.		CritiCare Asia Multispeciality Hospital and Research Centre Kirol Road, Opp. Lal Bahadur Shastri Road., Ali Yavar Jung, Kurla (West), Mumbai, Maharashtra - 400070	
36.		Arneja Institute of Cardiology Pvt. Ltd. 123, Ramdaspath, Behind Somalwar High School, Nagpur, Maharashtra - 440010	
37.		Jupiter Hospital Pune, Lane - 3, Baner - Balewadi Road, Prathamesh Park, Baner, Pune, Maharashtra - 411045	
38.		Bharatratna Atalbihari Vajpayee Medical College and Hospital Baburao Sanas Campus, Thakre Chowk, Mangalwar Peth, Pune, Maharashtra - 411011	
39.		Lifeline Superspeciality Hospital (Solapur) Maharashtra -413304	
40.		Medicover KLE Hospitals Near Pavani Apartment, Sector - 1, Indrani Nagar, Bhosari, Pune, Maharashtra-411019	



IMPORTANT ACTIVITIES

41.		New Age Six Sigma Medicare & Research Ltd. Satguru's, Maharastra, Nashik, 422007	
42.		Synergy Multispeciality Hospital LLP, 10247 A/5, Near ST. Workshop, Chandan wadi, Sangli, Miraj Road,- 416410 / 416416	
43.	Nagaland	Christian Institute of Health Science and Research 4th Mile, P.B No-31, PO-ARTC, Chumoukedima, Nagaland - 797115	Non- Government
44.	Odisha	Vikash Multi Speciality Hospital AH-46, Barahaguda Canal Chowk, Bargarh, Odisha- 768040	Non- Government
45.	Puducherry	Sri Lakshmi Narayana Institute of Medical Sciences Osudu Agaram Village, Villianur Commune, Koodapakkam Post, Puducherry - 605502	Non- Government
46.	Punjab	Chawla Nursing Home and Maternity Hospital Lajpat Nagar, Link Road, Jalandhar, Punjab - 144001	Non- Government
47.		Mann Medici Superspeciality Hospital Near TV Tower, Adda Khambra, Nakodar Road, Jalandhar, Punjab - 144002	
48.		Park Hospital, (A Unit of Park Medicity World Pvt. Ltd.) Urban Estate, Phase-I, Opp. New Bus Stand, Patiala, Punjab - 147002	
49.		My Hospital Super Speciality Care Sector - 69, Mohali, Punjab - 160069	
50.		Indus Hospital SCF-98-100, Phase-3B2, Mohali, Punjab-160059	
51.		Indus International Hospital Derabassi, S.A.S Nagar, Punjab -140507	
52.		K D Ganesha Hospital Pvt Ltd. 7 Circular Road, Near Medical College, Amritsar, Punjab -143001	
53.		Mahajan Hospital Opposite Bharat Gas Godown, College Road, Batala, Gurdaspur, Punjab - 143505	
54.		EVA Hospital 40 New Lajpat Nagar, Pakhowal Road, Punjab, Ludhiana-141001	
55.	Rajasthan	Vijay Hospital Near Kanjoli Line Railway Over Bridge, Drigh Road, Bharatpur, Rajasthan - 321001	Non- Government



56.		Pacific Institute of Medical Sciences Ambua road, Umarda, Girwa, Udaipur, Rajasthan-313015	Non- Government
57.		J. W. Global Hospital & Research Centre Delwara Road, Mount Abu, Sirohi, Rajasthan - 307501	
58.		SCR (Sir Chotu Ram) Hospital and Research Centre S-1, S Block, Sirsi Road, RFC Colony, Hanuman Nagar Extension, Krishna Nagar, Vaishali Nagar, Jaipur, Rajasthan - 302021	
59.		The Solanki Hospital Pushp Vatika Colony, Fatehpur, Sikar Road, Bharatpur, Rajasthan - 321001	
60.		Ramaya Surgical Centre 67/144, Jagriti Road, Pratap Nagar, Sector-6, Jaipur, Rajasthan - 302033	
61.		Pradeep Hospital & Fracture Clinic Be Narayan Gate, Bharatpur, Rajasthan - 321001	
62.		Shri Brij Fracture Hospital 143 Bal Vihar, Near 200 feet Bypass Kalwar Road, Jhotwara, Jaipur, Rajasthan - 302012	
63.		Siyaram Hospital and Research Centre Pvt. Ltd. 22-B, Chand Bihari, Khatipura Road, Jaipur, Rajasthan - 302012	
64.		Dr Manjeet Institute of Critical i care & Trauma Centre Pno. 14 Sec 10 (Institutional Block) Vidhyadhar Nagar, Jaipur, Rajasthan- 302039	
65.	Tamil Nadu	Government Medical College No.1 Manalmedu, Taluk, Orathur, Nagapattinam, Tamil Nadu -611108	Government
66.		Government Medical College Near Amma Park, Kadampa Nagar, Ramanathapuram, Tamil Nadu - 623503	
67.		Government Medical College and Hospital Kallakurichi, Tamil Nadu - 606213	
68.		K.A.P. Viswanatham Government Medical College and Mahatma Gandhi Memorial Government Hospital Trichy, Tamil Nadu - 620001	



IMPORTANT ACTIVITIES

69.		Arunai Medical College and Hospital Velu Nagar, Thenmathur, Thiruvannamalai, Tamil Nadu - 606603	Non-Government
70.		A.C.S Medical College & Hospital Velappanchavadi, Chennai, Tamil Nadu - 600077	
71.		NTC Hospitals and NTC Institute of Medical Sciences (NIMS) 187, Thathaneri Main Road, Near ESI Hospital Vaithiyanathapuram, Madurai - 625018	
72.	Telangana	Sree Lakshmi Gayathri Hospitals Pvt. Ltd. SLG Circle, No.306, Nizampet Road, Bachupally, Hyderabad, Telangana - 500090	Non-Government
73.		Yashoda Hospitals Nalgonda X Roads, Near New Market Metro Station, Malakpet, Hyderabad, Telangana-500036	
74.		Medicover Hospital 05-11-744 Yellammagutta, Nizamabad, Beside LIC Building, Telangana, India-503001	
75.	Uttar Pradesh	Metro Hospital & Heart Institute 47/G-5, Boundary Road, Lal Kurti, Meerut Cantt., Meerut, Uttar Pradesh - 250001	Non-Government
76.		Shanti Gopal Hospital Plot No-01, Ahinsa Khand-II, Indirapuram, Ghaziabad, Uttar Pradesh - 201014	
77.		Jaswant Rai Speciality Hospital Opp. Sports Stadium, Mawana Road, Saket, Meerut, Uttar Pradesh - 250001	
78.		Chandra Laxmi Hospital Plot No 336,337,338, Sec-4, Vaishali, Ghaziabad, Uttar Pradesh - 201010	
79.		HCL Avitas Pvt. Ltd. A-5, Sec. 24, Noida, Gautam Budh Nagar, Uttar Pradesh-201301	
80.		Royal Cancer Institute and Research Centre (A unit of Oncocare Medicals Pvt. Ltd.) Uttar Pradesh-208002	
81.	Uttarakhand	Premasukh Hospital & Dialysis Centre 23/18, P.G. Tandon Marg, Laxman Chowk, Dehradun, Uttarakhand - 248001	Non-Government
82.	West Bengal	KPC Medical College & Hospital, 1F, Raja SC Mullick Road, Jadavpur, Kolkata, West Bengal - 700032	Non-Government



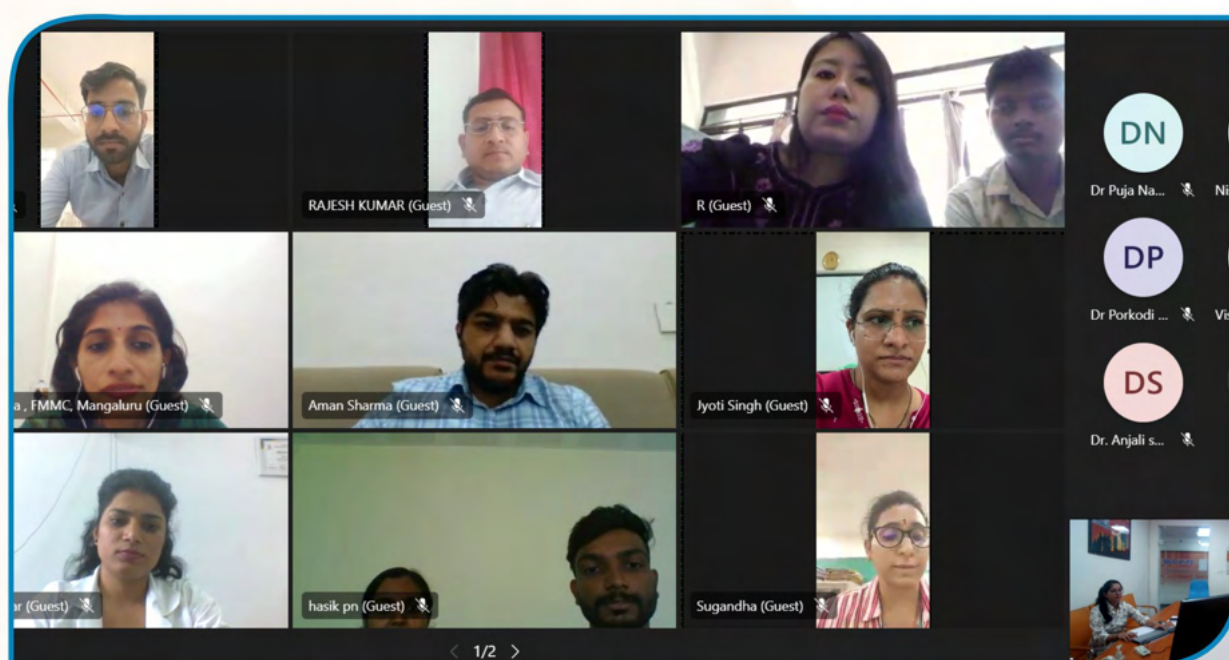
GMERS Medical College and Civil hospital organised Sensitization and Basic training Programme in Pharmacovigilance



Prof. Mukesh Kumar B Vora, Coordinator, Prof. Krina Patel, Deputy Coordinator & Dr. Payal M Patel, PV Associate, Gujarat Medical Education and Research Society (GMERS) Medical College and Civil Hospital, Ahmedabad an AMC under PvPI organised 3 hours "Sensitization and Basics training in Pharmacovigilance" from 12th -14th July 2023 and 18th July 2023 respectively. A total of 142 Interns doctors participated in this event.

Handholding meeting organized by PvPI, IPC

NCC-PvPI, IPC organized handholding meeting virtually on "VigiFlow Software" for Coordinators, Deputy-Coordinators, Junior Pharmacovigilance Associates of newly enrolled AMCs under PvPI on 25th July 2023. Ms Deepti Sachdeva, PV Associate demonstrated the entry of collected drug safety data at AMCs into VigiFlow software. A total of 86 participants have attended this meeting.





TRAINING & EDUCATION

Hands on training organized by Kalpana Chawla Government Medical College, Karnal



Prof. Tirthankar Deb, Coordinator, Kalpana Chawla Government Medical College (KCGMC), Karnal, Dr Arun Pandey, HOD of Psychiatry, Dr Savita Chahal, Associate Prof. and Dr Ritu beniwal, PV Associate organized hands-on training on “Safe & rational use of medicines and vigilant approach to Adverse Drug Reaction reporting” on 25th July 2023. A total of 24 participants including Doctors, Nursing staff, patients and other staff have attended this workshop.

Interactive Meetings with Marketing Authorization Holders (MAHs)

The objective of the following interactive meetings held virtually was to address the basic concepts of Pharmacovigilance and how the Pharmacovigilance system can be effectively implemented at MAHs/Pharmaceutical Industry? and also focussed on the issues/challenges related to the quality submissions of Individual Case Safety Reports (ICSRs) in E2B, xml format to PvPI.

Date	MAH/Pharmaceutical Industry	No. of Participants
31 st July 2023	Glenmark Pharmaceuticals Ltd.	23
28 th August 2023	Macleods Pharmaceuticals Ltd.	11

26th Skill Development Programme on Pharmacovigilance



NCC-PvPI, IPC has virtually conducted 5 days “26th Skill Development Programme (SDP) on Pharmacovigilance” from 7th – 11th August 2023. The objective of the SDP was to develop and enhance the Pharmacovigilance skills in the healthcare professionals in order to promote the patient safety. A total of 209 participants including representatives from Pharmaceutical Industries, Physicians, Academicians, Medical & Paramedical Students, Pharmacists and Drug Regulators across the country participated in this programme.



Pharmacovigilance Partners Meeting

The Pharmacovigilance Partners meeting was organized by Adverse Event Following Immunization (AEFI) Secretariat on 22nd August 2023 at Nirman Bhawan New Delhi. Dr Jai Prakash, Officer In-charge PvPI & Dr. Vijit Agrawal, Sr. PV Associate, PvPI have attended this meeting.

National AEFI Committee Meeting

Adverse Event Following Immunization (AEFI) Secretariat organized the National AEFI committee meeting virtually on 31st August 2023 to approve the causality assessment of the reported AEFI cases in Universal Immunization Programme (UIP) vaccines. This meeting was chaired by Dr S. Aneja, Professor and Head, Department of Paediatrics, School of Medical Sciences and Research, Sharda University to approve the. NCC-PvPI, IPC officials participated in this event.

Workshop-cum-Training Programme on Pharmacovigilance for NABH Accredited Hospitals

Sri Aurobindo Institute of Medical Sciences (SAIMS), Indore, an AMC under PvPI organised one day Workshop-cum-Training Programme on Pharmacovigilance for NABH Accredited Hospitals through hybrid mode on 24th August 2023. The objective of this training Programme was to enhance the Pharmacovigilance skill in healthcare professionals working at NABH Accredited Hospitals in order to promote the patient safety. A total of 195 participants have attended this event.





Continuing Medical Education (CME) Programme organized by All India Institute of Medical Sciences, Bhopal



All India Institute of Medical Sciences (AIIMS), Bhopal is one of the Regional Training Centres under PvPI. Dr Ratinder Jhaj, Coordinator, Dr Balakrishnan, Deputy Coordinator & Ms. Deepa Chaudhary, PV Associate organised CME on “Pharmacovigilance - What every Healthcare Professionals should know?” at AIIMS, Bhopal on 25th August 2023. A total of 120 participants including Physicians, Nurses, Pharmacist and other healthcare professionals were participated in this event.

Experts Meetings for reviewing Pharmacovigilance Guidance Document for MAHs of Pharmaceutical Products

The National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) in coordination with Central Drugs Standard Control Organization (CDSCO) had released first publication of Pharmacovigilance Guidance Document for MAHs of Pharmaceutical Products. The objective of this document was to provide the guidance for MAHs to set-up and implement the Pharmacovigilance System at their site.

NCC-PvPI, IPC has constituted a experts committee to revise this Guidance document and following review meetings were held through hybrid mode during this tenure;

S. No.	Date	Review Meetings
1.	7 th July 2023	2 nd Review meeting Pharmacovigilance Guidance document for MAHs of Pharmaceutical Products
2.	7 th – 8 th August 2023	3 rd Review meeting Pharmacovigilance Guidance document for MAHs of Pharmaceutical Products

Note: We look forward for the comments of stakeholders with proper justification by the end of 31st December 2023. The comments obtained after the due date will not be accepted. The existing Pharmacovigilance Guidance Document for MAHs of Pharmaceutical Products is available at link [76 Page.cdr \(ipc.gov.in\)](https://www.cdr.gov.in/76Page.cdr)



International Webinar organized by NCC-PvPI for SEARN Countries & WHO-PIDM Member States

NCC-PvPI, IPC being a World Health Organization (WHO) organized one day International Webinar on “Updates on VigiFlow & Optimum Use of VigiLyze for Signal Detection” on 20th September 2023 for South East Asia Regional countries and WHO Member States participating in the Programme for International Drug Monitoring (PIDM). Dr Adrien Inoubli, Regional Advisor, WHO-SEARO Office, Ms. Paulina Nakielny, Product manager, Uppsala Monitoring Centre (UMC), Sweden; Mr. Magnus Ekelo, Education & Training Specialist, UMC, Sweden; Prof. Mira Desai, SRP Member, PvPI delivered talks on various topics in Pharmacovigilance. A total of 55 participants from 9 countries (Bangladesh, Egypt, Indonesia, Myanmar, Nigeria, Mauritius, Sri Lanka, Bhutan and Zimbabwe) have participated in this webinar.



Continuing Medical Education (CME) Programme organized by All India Institute of Medical Sciences, Patna

The Department of Pharmacology, All India Institute of Medical Sciences, Patna, an AMC under PvPI organised CME on “Adverse Drug/Device Reaction Reporting: Ensuring Patient Safety” on 23rd September 2023. A total of 79 participants including Physicians, Nurses, Pharmacist and other healthcare professionals participated in this event.





TRAINING & EDUCATION

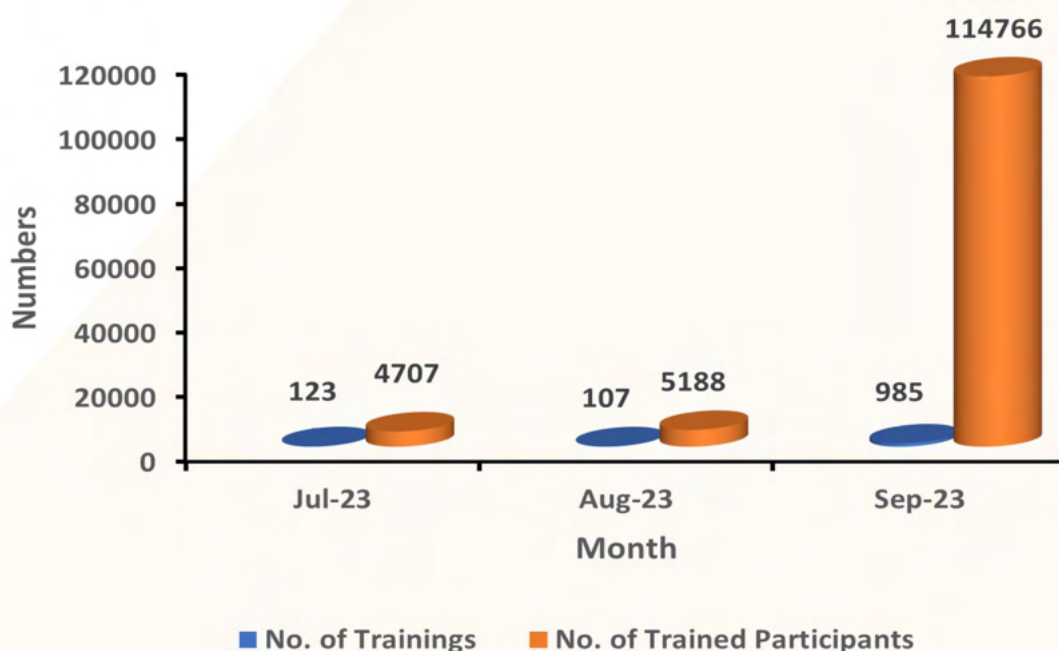
Continuing Medical Education (CME) Programme organized by All India Institute of Medical Sciences, Mangalagiri



Dr. Arup Kumar Misra, Coordinator, Dr Gaurav Manikrao Rangari, Deputy Coordinator and Dr Saggurthi Pavani, Pharmacovigilance Associate organised CME on “Awareness and Sensitization on Pharmacovigilance & ADR reporting” on 30th September 2023 at All India Institute of Medical Sciences (AIIMS), Mangalagiri, Andhra Pradesh, an AMC of PvPI. A total of 24 participants including Physicians, Nurses, Pharmacist and other healthcare professionals participated in this event.

Monthly trend of training programmes

The monthly trend of the trainings organized in this quarter is shown below. NCC-PvPI, IPC organised a total of 1215 training programmes like Skill Development Programmes, Continuing Medical Education, Advanced Level Training Programmes etc. and trained a total number of 124661 participants in the area of Pharmacovigilance across the country.





Sensitization on SGLT2 inhibitors related Genital Infections

The Health Canada and US Food and Drug Administration (USFDA) made safety announcements on July 20, 2018, wherein Health Canada addressed the potential risk of inflammation of the pancreas (acute and chronic pancreatitis), and USFDA on August 29, 2018 issued a warning of serious rare infection called necrotizing fasciitis of the perineum also referred to as Fournier's Gangrene.

The NCC-PvPI sensitized the AMCs under the PvPI for monitoring and reporting of Adverse Reactions related to the use of SGLT2 inhibitors through email on February 26, 2021, August 10, 2021 & April 13, 2022 respectively. An official letter also sent to all AMCs by PvPI on July 15, 2019 for the sensitization of Healthcare Professionals (HCPs) concerned to closely monitor incidence of Genital Infections associated with use of Sodium-Glucose Cotransporter-2 (SGLT2) inhibitors. A formal communication was issued following a warning letter issued by the Central Drugs Standard Control Organization (CDSCO) vide its letter No. 12-74/13-DC dated March 25, 2019.

In this context, once again, healthcare professionals are requested to closely monitor Adverse Events associated with the use of SGLT2 inhibitors and report such AEs/ADRs to National Coordination Centre for PvPI.

Sensitization for monitoring & reporting of Adverse Events/Reactions related to the use of Botulinum neurotoxin type A (BoNT/A)

The World Health Organization (WHO) identified & issued Threat : Multicounty Outbreak of Iatrogenic Botulism, Threat Assessment No. 1/2023, dated 17th April 2023, (<https://www.who.int/health-topics/substandard-and-falsified-medical-products>) that 71 suspected cases of iatrogenic botulism with the use of endoscopic (intra-gastric) injection of Botulinum neurotoxin type A (BoNT/A) have been reported in the European region since 28th Feb. 2023. All cases are adults and most cases are middle-aged women. The symptoms of botulism can be very severe, requiring intensive-care treatment as well as the administration of specific anti-toxins.

In view of the above, healthcare professionals are requested to closely monitor Adverse Events to ensure the early detection of Iatrogenic botulism suspected to be associated with the endoscopic (intra-gastric) injection of Botulinum neurotoxin type A (BoNT/A) and report such AEs/ADRs to National Coordination Centre for PvPI.





New Drugs Approved in India

The following new drugs were approved by the CDSCO during this index period;

S. No	New Drugs	Approved Indication(s)
1.	Treprostinil Bulk Drug and Treprostinil Solution for infusion 1mg/ml & 10mg/ml	For the treatment of idiopathic or heritable pulmonary arterial hypertension (PAH) to improve exercise tolerance and symptoms of disease in patients classified as New York Heart Association (NYHA) functional class III
2.	Icaridin API and Icaridin 20% w/v Spray	Indicated for mosquito and insect repellent
3.	Inclisiran solution for injection in prefilled syringe 284 mg/1.5 ml	Inclisiran is indicated in adults with primary hypercholesterolemia (heterozygous familial and nonfamilial) or mixed dyslipidaemia, as an adjunct to diet: - in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL-C goal with the maximum tolerated dose of a statin, or – alone or in combination with other lipid lowering therapies in patients who are statin intolerant, or for whom a statin is contraindicated
4.	Relugolix Bulk Drug and Relugolix Tablet 120mg	For the treatment of adult patients with advance prostate cancer
Healthcare Professionals (HCPs), patients/consumers are advised to closely monitor the safety profile of above mentioned new drugs. If any adverse reaction is encountered, please report to the NCC-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

NCC-PvPI, IPC issued the following drug safety alerts and shared with AMCs through email for the sensitization of healthcare professionals, thereby strengthening the reporting of ICSRs to PvPI. PvPI, IPC being a WHO Collaborative Centre also shared the drug safety alerts with South-East Asia Regional Network (SEARN) Countries through email.

S. No.	Issue Date	Suspected drugs	Indication(s)	Adverse Drug Reactions
1.	28 th July 2023	Colistimethate Sodium	For the treatment of some serious infections caused by Gram-negative bacteria, including those of the lower respiratory tract and urinary tract, when more commonly used systemic antibacterial agents may be contraindicated or may be ineffective because of bacterial resistance.	Bartter's like Syndrome
2.	22 nd August 2023	Levonorgestrel	- Used as emergency Contraceptive. - For Control of Fertility. - For the treatment of Contraception, Menorrhagia & Endometrial Hyperplasia during Estrogen replacement therapy in women	Deep Vein Thrombosis
3.	27 th September 2023	Esomeprazole	- GERD, erosive reflux esophagitis, prevention of relapse of esophagitis & helps in eradication of H. Pylori associated peptic ulcer. - For the treatment of GERD, gastric and duodenal ulcer, Zollinger-Ellison syndrome.	Hyperprolactinaemia
 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 NCC-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)				



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Drug Safety Alert: Indian Pharmacopoeia Commission Flags Adverse Reactions Linked To Colistimethate Sodium

Written By Susmita... Published On 31 July 2023 6:00 PM | Updated On 31 July 2023 6:00 PM



Medical News & Guidelines ▾ Health News ▾ AYUSH ▾ State News ▾ Medical Education ▾ Industry ▾ MDTV

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Drug Safety Alert: Indian Pharmacopoeia Commission Reveals ADR Linked To Contraceptive Drug Levonorgestrel

Written By Susmita... Published On 25 Aug 2023 6:00 PM | Updated On 25 Aug 2023 6:00 PM



World Health Organization

WHO Pharmaceuticals NEWSLETTER

2023
No. 3

Paracetamol

Risk of fixed drug eruption

India. The CDSCO has approved the recommendation from the National Coordination Centre – Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) to revise the prescribing information leaflet (PIL) for paracetamol to include fixed drug eruption as an adverse drug reaction.

Paracetamol is indicated for the symptomatic treatment of pain and fever.

The NCC-PvPI, IPC reviewed 480 Individual Case Safety Reports (ICSRs) of paracetamol associated fixed drug eruption and a causal

Losartan

Risk of muscle spasm

India. The Central Drugs Standard Control Organization (CDSCO) has approved the recommendation from the National Coordination Centre – Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) to revise the prescribing information leaflet (PIL) for losartan to include muscle spasm as an adverse drug reaction.

Losartan is indicated for the treatment of mild to moderate hypertension.

The NCC-PvPI, IPC reviewed 10 Individual Case Safety Reports (ICSRs) of losartan associated muscle spasm and a causal relationship between them was found.

Piroxicam

Risk of fixed drug eruption

India. The CDSCO has approved the recommendation from the National Coordination Centre – Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) to revise the prescribing information leaflet (PIL) for piroxicam to include fixed drug eruption as an adverse drug reaction.

Piroxicam is indicated for the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, cervical spondylitis and other musculoskeletal disorder.

The NCC-PvPI, IPC reviewed 31 Individual Case Safety Reports (ICSRs) of Piroxicam associated fixed drug eruption and a causal relationship between them was found.



Felicitation of Top 10 Performing ADR Monitoring Centres/MAHs in 2022-23 during 3rd NPW 2023

The following Adverse Drug Reactions Monitoring Centres were identified as a top performer without human resources provided by PvPI;

AMCs	Coordinators	Deputy coordinators
Believers Church Medical College & Hospital Thiruvalla	Dr. Jacob Jesurun RS	Dr. Swetha Reba Mathews
M.S. Ramaiah Medical College Bengaluru	Dr. Anuradha H V	Dr. Mukunda N
Vijaya Medical & Educational Trust Vadapalani	Dr. Shajahan O.M	Dr. K. Mukesh
Lady Hardinge Medical College New Delhi	Dr. Harmeet Singh Rehan	---
PSG Institute of Medical Sciences & Research Coimbatore	Dr. K. Bhuvaneswari	Dr. S. Shanmugapriya
Chalapathi Institute of Pharmaceutical Sciences Guntur	Dr. Venkata Rama Rao Nallani	Dr. Gavin Sivabharath
Iqraa International Hospital & Research Centre Calicut	Dr. Muhammed Thoyyib	Dr. Muhammed Anas V. K.
Maulana Azad Medical College New Delhi	Dr. Vandana Roy	Team
Father Muller Medical College Mangaluru	Dr. Chandralekha.N	Dr. Akshata Aroor
National Institute of Pharmaceutical Education and Research Hajipur	Dr. Sameer Dhingra	Dr. Krishna Murti



The following Adverse Drug Reactions Monitoring Centres were identified as a top performer with human resources provided by PvPI;

AMCs	Coordinators	Deputy Coordinators	PV Associates
Post Graduate Institute of Medical Education & Research Chandigarh	Dr. Bikash Medhi	Dr. Ajay Prakash	Mr. Benjamin
JSS Medical College & Hospital Mysore	Dr. M. Ramesh	Dr. Sri Harsha Chalasani	Dr. Ascharya Chintalapati
Seth GS Medical College & KEM Hospital Mumbai	Dr. Nithya Gogtay	Dr. Mahesh Belhekar	Ms. Pratiksha Dyaneshwar Thombare
Rajagiri Hospital Aluva	Dr. Dinu Varghese	Dr. Eldho Mathew Paul	Ms. Aparna Chand.O
Amrita Institute of Medical Sciences Kochi	Dr. Princy Louis Palatty	Dr. M.P. Narmadha	Ms. Tinu.T .S.
Kurnool Medical College Kurnool	Dr. Pusuloori Rajesh	Dr. M.Rajanikanth	Mr. Doreddulla Satish Kumar
Nizam Institute of Medical Sciences Hyderabad	Dr. P. Usha Rani	Ms. M. Padmaja	Mr. Amal Sajeev
All India Institute of Medical Sciences Bathinda	Dr. Abhinav Kanwal	Dr. Rohit Kumar	Dr. Gazal Gagneja
School of Tropical Medicine Kolkata	Dr. Santanu Munshi	---	Ms. Shatavisa Mukherjee
Institute of Postgraduate Medical Education & Research Kolkata	Dr. Suparna Chatterjee	Dr. Avijit Hazra	Ms. Manjari Bhattacharya

The top performing MAHs were felicitated in terms of submitting ICSRs to PvPI;

S. No.	MAHs
1.	Novartis India Limited
2.	Pfizer Limited
3.	Roche Products (India) Private Limited
4.	Baxter (India) Private Limited
5.	Sanofi India Limited



Winners of e-Poster Competition from AMCs

WINNER OF 1ST PRIZE



Dr. Kavita Dhar Bagati
(AMC- Coordinator)

**Saraswati Institute of Medical Science (SIMS),
Hapur**



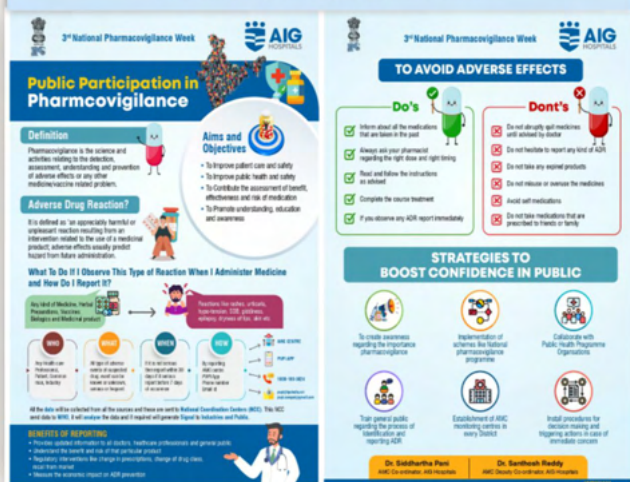
WINNERS OF 2ND PRIZE



Dr. Siddhartha Pani
(AMC-Coordinator)

Dr. Santhosh Reddy
(Deputy Coordinator)

AIG Hospitals, Hyderabad



WINNERS OF 3RD PRIZE



Sanjit Kalita
(B. Pharm Student)

Rajdeep Bhuyan
(B. Pharm Student)

**NETES Institute of Pharmaceutical Science
(NIPS- Kamrup)**





Winners of e-Poster Competition for Pharmacy Students visited at NCC-PvPI, IPC



1st Prize
Diya Sharma
B. Pharm - 4th Year
Apeejay Satya University
Gurugram



2nd Prize
Nishita Rathi
B. Pharm - 4th Year
ITS College of Pharmacy
Ghaziabad



3rd Prize
Puneet Mishra
B. Pharm- 4th Year
Sunder Deep Pharmacy College
Ghaziabad



**Winners of Pharmacovigilance Quiz Competition
from NCC-PvPI, IPC**

**Winners of
1st Prize**



Tripti Purohit
Jr. PV Associate

**Winners of
2nd Prize**



Shatrúnajay Shukla
Scientific Assistant

**Winners of
3rd Prize**



Tejesvi Mishra
Jr. PV Associate



Rishi Kumar
Scientific Assistant



Neha Nasim
Jr. PV Associate



Atul Tiwari
Jr. PV Associate



Pratibha Verma
Jr. PV Associate



Shweta Wachaspati
Pharmacopoeial Associate



Pooja Gond
Jr. PV Associate



Winners of Pharmacovigilance Quiz Competition for Pharmacy Students visited at NCC-PvPI, IPC

Winners of 1st Prize



Aman Kumar
Sehar Khajuria
Tannu Priya
B. Pharm - 4th Year
Raj Kumar Goel Institute of
Technology (Pharmacy)
Ghaziabad

Winners of 2nd Prize



Subham
Megha
Pooja Pandita
M. Pharm
Delhi Institute of
Pharmaceutical Sciences and
Research (DIPSAR) New Delhi

Winner of 3rd Prize



Khushi Varshney
B. Pharm - 3rd Year
Galgotia College of Pharmacy
Greater Noida



NCC-PvPI, IPC has planned to organize the following events through virtual mode;

FORTHCOMING EVENTS

**20th - 24th
November 2023**

**27th Skill
Development
Programme on
Pharmacovigilance**



**29th November
2023**

**Introduction to
MedDRA Coding**



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

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

औषधि सतर्कता कार्यक्रम

(फार्माकोविजिलेंस प्रोग्राम ऑफ़ इंडिया) क्या है?

फार्माकोविजिलेंस प्रोग्राम ऑफ़ इंडिया, स्वास्थ्य एवं परिवार कल्याण मंत्रालय के अंतर्गत कार्य करता है जिसका नोडल कार्यालय, भारतीय भेषज संहिता आयोग में स्थित है। मैटीरियोविजिलेंस प्रोग्राम ऑफ़ इंडिया जिसका नोडल कार्यालय भी भारतीय भेषज संहिता आयोग में स्थित है तथा हीमोविजिलेंस 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 फार्माकोविजिलेंस 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 तरीके 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 फार्माकोविजिलेंस 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।



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