



Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

VOL 14 | ISSUE 2 | 2024

Before you prescribe...

-  **THINK**
-  **KNOW**
-  **CHECK**
-  **ASK**

Look-alike Sound-alike



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National Coordination Centre - Pharmacovigilance Programme of India

A WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory
Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare,
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 14, Issue 2 for the index period from April, 2024 to June, 2024 on the theme "Look -alike and sound-alike (LASA) drugs". Addressing this issue is not just a matter of improving healthcare outcomes; it is a critical step towards ensuring that India's healthcare system remains one of the most robust and reliable in the world.

In this quarter, 81 New Adverse Drug Reaction Monitoring Centres (AMCs) have been enrolled under PvPI and the total number of AMCs were 976 across the country. A total of 8.5 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 339 training programmes and trained a total of 16219 participants in the area of pharmacovigilance in this quarter.

In this quarter, a capacity building programme on "Pharmacovigilance Audits & Inspections" was organised by National Coordination Centre (NCC)-PvPI, Indian Pharmacopoeia Commission (IPC) on 27th June 2024 through hybrid mode at IPC for the PvPI staff posted at NCC and AMCs across the country.

The NCC-PvPI, IPC has issued 166 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.

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 taken by the CDSCO based on PvPI recommendations to the SEARN Countries.

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

(Dr. Rajeev Singh Raghuvanshi)
Secretary-cum-Scientific Director
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(Ministry of Health & Family Welfare,
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Look-alike and Sound-alike Drugs



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Drugs whose names look alike (orthographic similarity) and/or sound alike (phonetic similarity) are called look-alike and sound-alike (LASA) drugs. The look-alike and/or sound-alike names may be proprietary/brand or non-proprietary/generic names.

| Features | Non-proprietary/generic names |
|----------------------|--|
| Sound Alike | Sertraline/Cetirizine |
| Look Alike | Propranolol/Prednisolone Prochlorperazine/Promethazine Amiloride/Amlodipine/Amiodarone |
| Look and Sound Alike | Cycloserine/Cyclosporine Bupropion/Buspirone Dopamine/Dobutamine |

At global level, US FDA and the Institute for Safe Medication Practices (ISMP) maintain an online, free to download list of LASA drugs⁽¹⁾. LASA drugs are prone to lead to medication errors, that is a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient⁽²⁾. Medication errors due to LASA may occur at any level of the medication use process, that is storage, prescription, dispensing, preparation or administration⁽³⁾. The Sound alike drugs are particularly prone to medication errors when prescriptions transmitted verbally or over phone, while look alike drugs are more liable to cause errors, when prescriptions are handwritten. In case of look and sound alike medicines, both handwritten as well as oral / telephonic prescriptions can cause errors. Similar strength, dosage form or packaging increase the risk of error, while differences may help in avoiding mix-ups.

RISK MINIMISATION

Since LASA drugs pose a risk to the patient safety by being mixed up, we need to be vigilant about them at all stages of medicine use, in fact right from the process of naming a drug. Drug Names: The WHO, in its guidance on devising new INN⁽⁴⁾ recommends that INNs should be distinctive in sound and spelling, and not be liable to confusion with names in common use. European Medicines Agency's Name Review Group (NRG) assesses the degree of orthographic and/or phonetic similarity and the risk of cognitive error in the suggested name of a new drug compared with already approved names⁽⁵⁾.

Storage: To minimise errors during storage and dispensing, FDA and ISMP have recommended the use of "tall man letters." for labelling of LASA drugs to emphasize differences in medications e.g. DOPamine and DOBUTamine, metFORMIN and metoPROLOL. In addition, warning labels for look-alike medicines may be used on storage shelves and medication trolleys. LASA drugs should also be stored separate from each other, whenever possible⁽³⁾.

Prescribing: Prescriptions should be written legibly, and include name of medication, dosage form, dose indication. Whenever possible, drug names in Computerised Prescriber Order Entry (CPOE) should incorporate Tall Man lettering. In case of verbal/telephonic prescription, drug name should be pronounced clearly, and ideally spelled out. Also, digits for dosages should be sounded out (e.g, two-five instead of twenty-five). Verbal/telephonic orders should be limited to emergency situations only⁽³⁾.

Dispensing: Medication labels should be read carefully at all dispensing stages and triangle check should be performed to check actual medicines against the medicines' labels and against the prescription. Double checking should be conducted during the dispensing process.

Administration: Patients, caregivers as well as HCPs need to be aware of potential errors with LASA medicines, and be vigilant about such errors.

References:

- (1) ISMP_Confused Drug Names 2024. Available from:
http://online.ecri.org/hubfs/ISMP/Resources/ISMP_ConfusedDrugNames.pdf
- (2) Aronson JK. Medication errors:
What they are, how they happen, and how to avoid them. QJM. 2009 Aug 1;102(8):513–21.
- (3) WHO. Medication safety for look-alike, sound-alike medicines. 2023
- (4) WHO. Guidance on the Use of International Non-Proprietary Names (INNs) for Pharmaceutical Substances. 2017
- (5) European medicines Agency. Good practice guide on risk minimisation and prevention of medication errors. 2015. Available from
<https://www.google.com/search?q=European+medicines+Agency.++Good+practice+guide+on>

Artificial Intelligence and Machine Learning: A Pragmatic Approach in Pharmacovigilance

Dr. Manoj Sharma, Ph.D, Fellowship in Pharmacovigilance and Pharmacoepidemiology (Univ. Bordeaux, France) Head & QPPV-Global Pharmacovigilance Department, Win-Medicare Pvt. Ltd, New Delhi, India



Pharmacovigilance is the science that deals with the collection and management of adverse drug reactions, identification of important risks and communicating these risks to the stakeholders for safe use of medicines. During the past decade the significance of pharmacovigilance has expanded from pharmaceuticals to biologicals, medical devices, cosmetics, and phytopharmaceuticals. Consequently, this has led to generation of large amount of drug safety information on a daily basis and a challenge for data processing, as majority of the data is received with incomplete information thereby further making the analytics a challenging task. This makes the role of Artificial Intelligence (AI) and machine learning (ML) necessary and pertinent as AI and ML can handle complex PV tasks where there is a high degree of uncertainty and inferences need to be drawn from the vast global data which cannot be analyzed manually, otherwise. In PV, the application of AI/ML is majorly required during the process of importing a large amount of data from multiple sources into a single, cloud-based storage medium and signal detection activity. AI tools such as semantic searching enhance the accuracy of the search field; optical character recognition identify text in scanned documents; text mining transforms unstructured text to structure data. ML which is considered a branch of AI enhances the computer working without being explicitly programmed. This is imperative particularly in the situation where the computer processes need to learn from data rather than relying solely on a set of pre-defined rule(s). Natural language processing (NLP) of the computer system can understand human language and interpret it. NLP and ML algorithms are cognitive services that can be used in combination to solve tasks when human intelligence requires. Drug safety professionals working on the AI/ML applications need to possess communication skills and analytical assessment skills with a desire to learn the advances in the updated algorithm.

In India, AI is making a significant impact in pharmacovigilance as it has grossly reduced human error and sped up the process of risk assessment. With advances in natural language understanding and image recognition, AI has facilitated the quality of data generated in drug studies, and further fast decision making for any drug safety issue. AI and ML has enabled sophisticated analysis of large datasets to identify adverse drug reaction trends and patterns which can help regulatory authority and marketing authorisation holders make decisions more quickly. During the recent past with the rapid expansion of AI and ML, the pharma industry is looking for an integrated solution that allows them to manage end-to-end monitoring of drug safety issues from hidden data and using automation for efficiency.

Enrolment of New AMCs

The NCC-PvPI, IPC has enrolled 81 new AMCs in 23rd Phase of PvPI expansion. The total number of AMCs enrolled by the end of this quarter were 976 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 | Government Medical College Near Old Bus Stand, Eluru-534001, Andhra Pradesh | Government |
| 2. | | A.C. Subba Reddy Govt. Medical College Nellore, Andhra Pradesh-524004 | |
| 3. | | Government Medical College Vidya Nagar, Rajamahendravaram, East Godavari, Andhra Pradesh-533105 | |
| 4. | | Trust Multispeciality Hospitals 11-427, Madhavapatnam Road, Kakinada, Andhra Pradesh-533005 | Non-Government |
| 5. | | Swatantra Hospitals (Multispeciality) Pvt. Ltd. Opposite to Income Tax Office, Kambala Cheruvu, Rajamahendravaram, Andhra Pradesh-533105 | |
| 6. | | Good Samaritan Cancer & General Hospital Jose Nagar, Sai Nagar, Vangayagudem, Eluru, Duggirala, Andhra Pradesh-534001 | |
| 7. | | GSL Trust Cancer Hospital Kambal Cheruvu, East Godavari, Andhra Pradesh-533105 | |
| 8. | | Sai Hospital Aryapuram, D. No.- 12-20-4/1, Rajamahendravaram, East Godavari, Andhra Pradesh-533104 | |
| 9. | | Andhra Hospitals (Bhavani Puram) Pvt. Ltd. 16-72/1, Opp. High School, Gollapudi, Vijayawada, NTR. Andhra Pradesh-521225 | |

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|-----|------------|---|----------------|
| 10. | Assam | Kokrajhar Medical College & Hospital Rangalikhata, Kokrajhar, Assam-783370 | Government |
| 11. | | Dhubri Medical College & Hospital R.K Mission Road, Jhagarpar, Dhubri-783325 | |
| 12. | Bihar | Ford Hospital & Research Center Pvt. Ltd. NH30, New Bypass, Khemnichak, Ramakrishna Nagar, Patna, Bihar-800027 | Non-Government |
| 13. | Chandigarh | Government Medical College & Hospital Sector 32, Chandigarh-160030 | Government |
| 14. | Delhi | Ramlal Kundanlal Orthopaedic Hospital & R.K Maternity Home East Delhi-110092 | Non-Government |
| 15. | | Aakash Healthcare Super Speciality Hospital Road No. 201, Sector-3, Dwarka, New Delhi-110075 | |
| 16. | | Divya Prastha Hospital RZ-37, Main Road, Raj Nagar-I, Palam Colony, South West, New Delhi-110045 | |
| 17. | | Neonest Hospital A-1/3, Prasant Vihar, Rohini, New Delhi-110085 | |
| 18. | | B M Gupta Hospital Pvt. Ltd H-5, 8 to 15,21,22,26 Uttam Nagar, South West, New Delhi-110059 | |
| 19. | | National Heart Institute 49-50, Community Centre, East of Kailash, New Delhi-110065 | |
| 20. | Gujarat | GMERS Medical College 6th Floor, National Health Mission Bhavan, Civil Hospital Campus, Sector 12, Gandhinagar-382016, Gujarat | Government |
| 21. | | Govt. Spine Institute, Physiotherapy College Ahmedabad, Gujarat-380016 | |
| 22. | | Spandan Multispeciality Hospital 1/A 2/A Nandigram Society, Sindhwai Mata Road, Manjalpur, Vadodara, Gujarat-390011 | Non-Government |

IMPORTANT ACTIVITIES

| | | | |
|-----|---------|---|----------------|
| 23. | Haryana | Kirti Hospital 1315/4 Park Road, Kaithal, Haryana-136027 | Non-Government |
| 24. | | VK Neurocare and Trauma Research Hospital N-159, Model Town, Hisar, Haryana-125005 | |
| 25. | | Primus Hospital Opp. Bank of Baroda, Near Shiv Chowk, Sanoli Road, Panipat, Haryana-132103 | |
| 26. | | Soni Burn & Plastic Surgery Hospital Sec -15 A, Kanari Road, Hisar, Haryana-125001 | |
| 27. | | Gobind Nursing Home 120- Hetram Park, Opposite Jat College, Hisar, Haryana-125001 | |
| 28. | | Sri Onkar Eye & ENT Care Centre 1402/677, New Model Colony, Ambala, Haryana-134003 | |
| 29. | | Asha Kiran The Criti Care Hospital Dhaud Chowk, Kanwar Singh Colony, Jhajjar, Haryana-124103 | |
| 30. | | Park Hospital CHD City, NH-1, Sector 45, Karnal-132116, Haryana | |
| 31. | | Ahooja Eye & Dental Institute 560/1, Dayanand Colony, New Railway Road, Gurugram, Haryana-122001 | |
| 32. | | CDAS Superspeciality Hospital Malibu Town, Sec 47, Gurugram, Haryana-122018 | |
| 33. | | Dr Jale's Life Care Hospital Near Kailash Ashram, Subhash Nagar, Model Town, Rohtak, Haryana-124001 | |
| 34. | | Pushpanjali Hospital Rajesh Pilot Chowk, Rewari, Haryana-123401 | |

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|-----|-------------|--|----------------|
| 35. | | Jaspal Nursing Home 69 Model Town, Ambala City, Haryana-134003 | |
| 36. | | NP Rawal Hospital Pvt. Ltd. 786, Jernaily Colony, Near Dyal Singh College Road, Karnal, Haryana-132001 | |
| 37. | | MM College of Medical Sciences & Research (MMCMSR) Sadopur, Ambala, Haryana-134007 | |
| 38. | | Bhagwan Das Hospital Block E, Omaxe City, Sector 18, Sonipat, Haryana-131001 | |
| 39. | J&K | Triveni Nursing Home 8-C/C, Gandhi Nagar, Jammu, J&K-180004 | Non-Government |
| 40. | Karnataka | Raja Rajeswari Medical College & Hospital Kambipura, Mysore Road, Bangalore, Karnataka-560074 | Non-Government |
| 41. | | Sahyadri Narayana Multispeciality Hospital Shimoga, Karnataka-577202 | |
| 42. | Kerala | Ahalia School of Pharmacy Palakkad, Kerala-678557 | Non-Government |
| 43. | Ladakh | PHC-Bogdang Near Bogdang, Bridge, Leh, Ladakh-194401 | Government |
| 44. | Maharashtra | Sadhu Vaswani Mission's Medical Complex Pune, Maharashtra-411001 | Non-Government |
| 45. | | Sri Dhaneshwari Manav Vikas Mandal's Private Medical College RP Hospital & Research Centre, Pedgaon, Parbhani, Maharashtra-431537 | |
| 46. | | Sancheti Institute for Orthopaedics & Rehabilitation 16, Shivajinagar, Pune-411005 | |
| 47. | | Sahayog Hospital (A unit of Ramade Memorial Medicare & Research Institute LLP), Rani Awantibai Chowk, Ring Road, Gondia, Maharashtra-441614 | |

IMPORTANT ACTIVITIES

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| 48. | Odisha | Dharanidhar Medical College and Hospital Keonjhar, Odisha-758002 | Government |
| 49. | | Hi Tech Medical College & Hospital Rourkela, Odisha-769004 | Non-Government |
| 50. | Punjab | Healthsure Multispeciality Hospital Ludhiana Highway Road, Gharwan, SAS Nagar, Punjab-140413 | Non-Government |
| 51. | | Grecian Hospital Sector 69, SAS Nagar, Mohali, Punjab-160062 | |
| 52. | | Aggarwal Liver & Gut Super Speciality Hospital 275-276, JP Nagar, Near BSNL Exchange, Jalandhar, Punjab-144001 | |
| 53. | | HP Orthocare Hospital Santokh Pura, Jalandhar, Punjab-144004 | |
| 54. | | Parmar Hospital Bela Road, Ropar, Punjab-140001 | |
| 55. | | The Corporate Hospital Batala Road, Amritsar Punjab-143001 | |
| 56. | | Sant Ishar Singh ji Memorial Hospital Village Rara Sahib, Punjab-141417 | |
| 57. | | NHS Hospital (A Unit of NASA Brain and Spine Centre) 128 Guru Nanak Nagar, Opposite Sports College, Kapurthala Road, Jalandhar, Punjab-144008 | |

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| 58. | Rajasthan | Shri Ram Hospital, (A Unit of Shri Ram Super Speciality Surgical Centre Pvt. Ltd.) Opp. Mahamandir Railway Station, Jodhpur, Rajasthan-342006 | Non-Government |
| 59. | | Advance Amcure Hospital Pvt. Ltd. Jaipur, Rajasthan-302029 | |
| 60. | | Shree Rana Hospital & Charitable Medical Institution 317/318, Vaishali Nagar, Ajmer, Rajasthan-305001 | |
| 61. | | Manglam Plus Medicity Hospital Shipra Path, Mansarovar, Sector-5, Jaipur, Rajasthan-302020 | |
| 62. | | Dana Shivam Hospital Plot No. 2, Central Spine Sector-2, Vidyadhar Nagar, Jaipur-362023 | |
| 63. | | GBH American Hospital 101, Kothi Bagh, Bhatt Ji Ki Bari, Meera Girls College Road, Udaipur, Rajasthan-313001 | |
| 64. | Tamil Nadu | Government Medical College Tiruppur, Dharapuram Road, Tamil Nadu-601608 | Government |
| 65. | | Government Medical College & ESI Hospital Tamil Nadu-641015 | |
| 66. | | Vels Medical College & Hospital 12/123, Velan Nagar, Periyapalayam Road, Manjankaranai Village, Uthukottal Taluk, Tiruvallur, Tamil Nadu- 601102 | Non-Government |
| 67. | | T.N.K.H.N.U. Charity Fund Hospital, No.23, NRT Road, Theni, Tamil Nadu-625531 | |

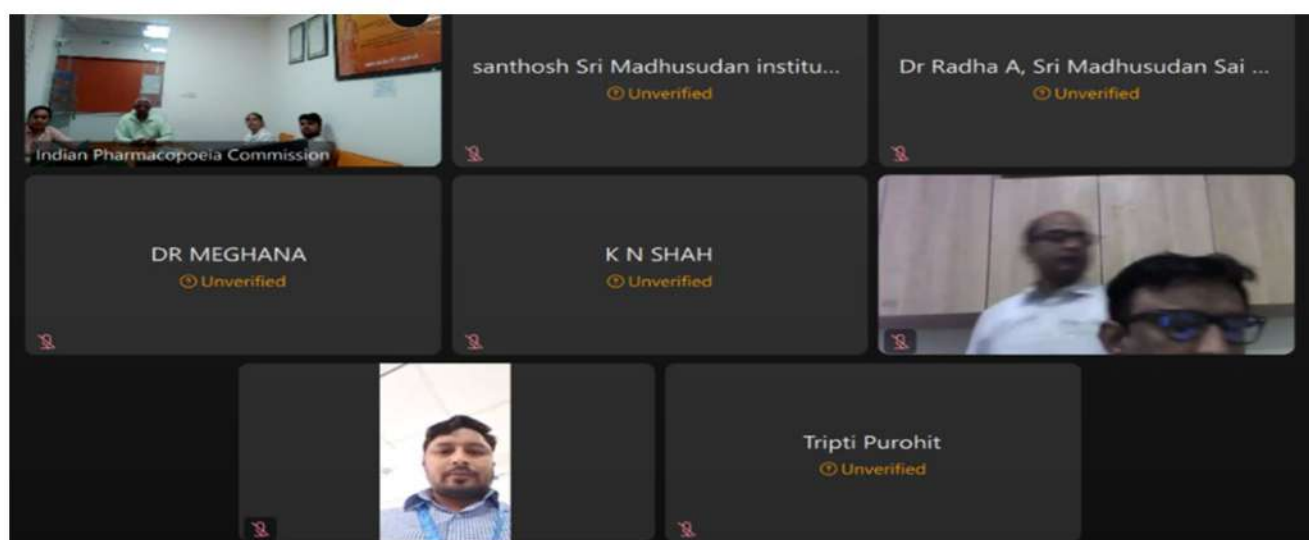
IMPORTANT ACTIVITIES

| | | | |
|-----|---------------|---|----------------|
| 68. | Telangana | Government Medical College, Vikarabad, Biladakala alampally, Vikarabad, Telangana-501101 | Government |
| 69. | | Medicover Women & Child Hospitals Beside Shilparamam, Opp. Hitex Charminar, HITECHCITY Hyderabad, Telangana-500081 | Non-Government |
| 70. | | Prathima relief Institute of Medical Sciences H. No. 51 -3-630, Sahasra Nagar, Near Ayyappa Swamy and Iskon Temple, Mulugu Road, Telangana-506007 Warangal | |
| 71. | Uttar Pradesh | Government Medical College Badaun, Gunera, Wazidpur, Sirsauli, Uttar Pradesh-243601 | Government |
| 72. | | Metro Hospital & Heart Institute, Cardiology Wing, X-1, Sector 12, Noida, Gautam Bhudha Nagar, Uttar Pradesh-201301 | Non-Government |
| 73. | | Navin Hospital (A Unit of Navin Medicare Pvt. Ltd.) NH-3, Pocket-F, Alpha-2, Greater Noida, G.B. Nagar, Uttar Pradesh-201308 | |
| 74. | | Noida International Institute of Medical Sciences Plot No.1, Sector-17 A, Yamuna Expressway, Opp. F1 Track, Gautam Budh Nagar, Uttar Pradesh-203201 | |
| 75. | | Charak Hospital and Research Centre, Lucknow, UP-226003 | |
| 76. | | Atlanta Mediworld Multispeciality Hospital & Research Centre (A Unit of RRM Services) Sector-14, Vasundhara, Ghaziabad-201012 | |

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|-----|-------------|---|----------------|
| 77. | | Mayo Medical Centre Pvt Ltd Vikas Khand-2, Gomti Nagar, Lucknow, Uttar Pradesh-226010 | |
| 78. | | Krush Divine Hospital (A unit of Ramraj Wellness Pvt. Ltd.) G.B. Nagar, Uttar Pradesh-203207 | |
| 79. | Uttarakhand | Graphic Era Institute of Medical Sciences Dehradun, Uttarakhand-248001 | Non-Government |
| 80. | West Bengal | Amri Hospitals Dhakuria, P-4 & 5, CIT Scheme, Gariahat Road, Kolkata, West Bengal-700029 | Non-Government |
| 81. | | Neotia Getwel (A unit of Ambuja Healthcare Venture Limited), Uttorayon Behind, City Centre Matigara, Siliguri, Darjeeling, West bengal-734010 | |

Induction-cum-Training Programme organised by NCC-PvPI, IPC

The NCC-PvPI, IPC conducted four days online “Induction-cum-Training Programme on Pharmacovigilance” for Coordinators/Deputy Coordinators of newly recognised Adverse Drug Reaction Monitoring Centres (AMCs) from 9th to 12th April 2024. The objective of this training programme was to train the participants on Pharmacovigilance activities performed at their AMCs. A total of 22 participants attended this training programme.



Advanced Level Training Programme organised by Madras Medical College, Chennai

The Madras Medical College, Chennai as a Regional Training Centre (RTC) organized Advanced Level Training Programme in Pharmacovigilance under the supervision of Dr K. M. Sudha, Coordinator and



Mrs. Siddiraju Devipriya, Pharmacovigilance Associate, MMC, Chennai on 24th April 2024 through hybrid mode. This event was started by inauguration & welcome address by Dr C Ramachandra Bhat, Director & Professor, MMC, felicitation by Dr M Kavitha, Vice Principal, MMC and presidential address by Dr E. Theranirajan, Dean, MMC, Chennai. In this training programme, Dr Jai Prakash, Officer In-charge of PvPI highlighted the current

updates on PvPI. A total of 148 participants including coordinators, deputy coordinators, pharmacovigilance associates and other faculty associates participated in this training programme.

Continuing Medical Education (CME) Training Programme organised by PGIMER, Chandigarh

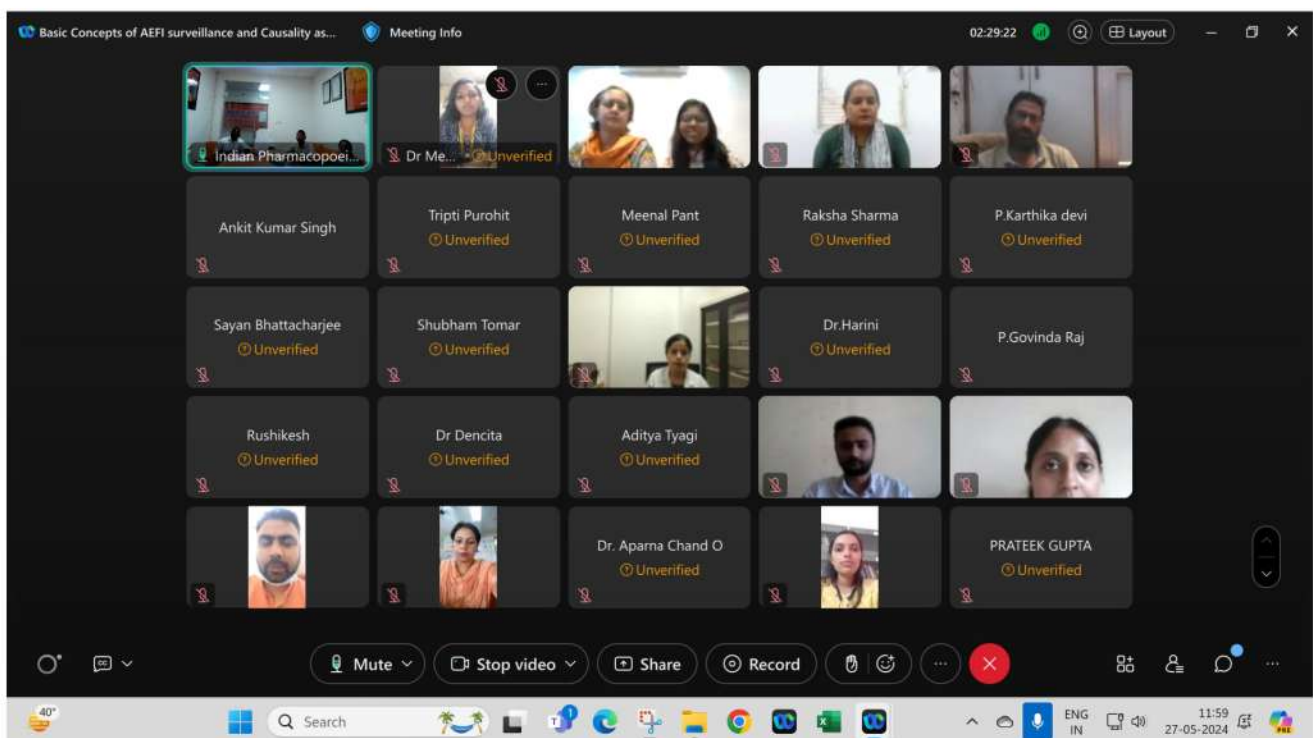
The Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh as a Regional Training Center (RTC) has organised one day Continuing Medical Education (CME) Training Programme on Pharmacovigilance and Materiovigilance for coordinators, deputy coordinators, pharmacovigilance associates, and hospital residents (Junior and Senior Residents) at PGIMER, Chandigarh on 25th May 2024. The CME was started with a welcome address & inauguration by Prof. Bhavneet Bharti, Director, AIMS, Mohali, Punjab, Prof. Y. K. Gupta, National Scientific Coordinator, PvPI and Dr Rajeev Singh Raghuvanshi, Drugs Controller General of India. This event was conducted under the supervision of Prof. Bikash Medhi, Coordinator and Dr Ajay Prakash, Deputy Coordinator, PGIMER, Chandigarh. In this event, Dr Jai Prakash, Officer In-charge of PvPI and Dr V. Kalaiselvan Officer In-charge of MvPI provided updates on the Pharmacovigilance and Materiovigilance Programs of India.



This training programme highlighted the significance of AE reporting, current status of the vigilance system in India, essential role of healthcare professionals and patients in reporting AE and Medical Device Adverse Events (MDAEs). A total of 382 participants participated in this event through hybrid mode.

Webinar organised by NCC-PvPI, IPC on “Basic Concepts of AEFI Surveillance and Causality Assessment of AEFI cases”

A webinar on “Basic Concepts of Adverse Event Following Immunization (AEFI) Surveillance and Causality Assessment of AEFI cases” was organised by NCC-PvPI, IPC for Pharmacovigilance Associates posted at NCC and AMCs across the country on 27th May 2024. In this webinar, Dr Rajashree Roy, Sr. Programme Manager, AEFI Secretariate and Dr Farishta H. D Singh, Sr. Programme Officer, AEFI Secretariate explained the procedure for Causality Assessment of AEFI cases. A total of 124 participants attended this training programme.



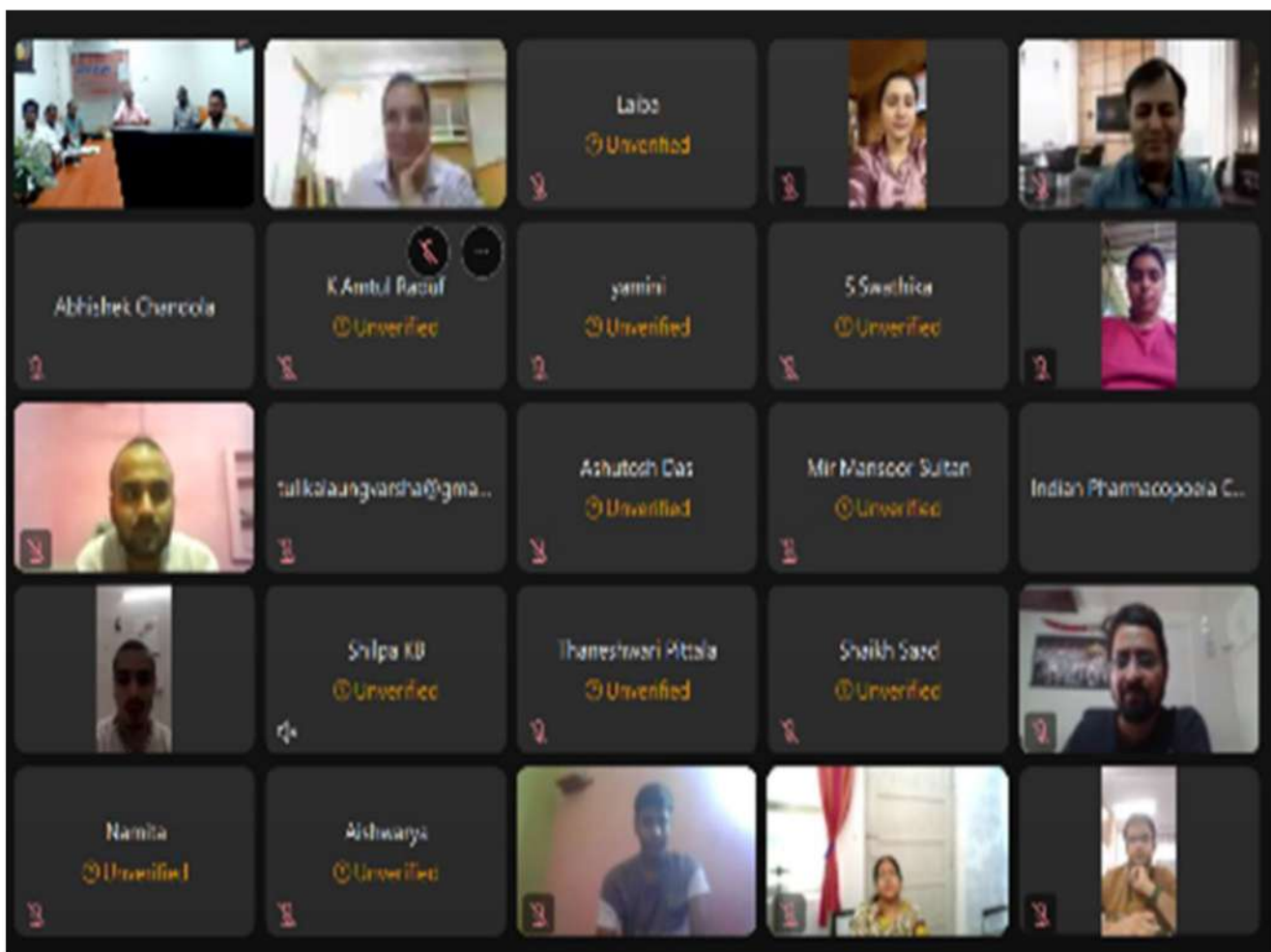
Training Programme organised by Sikkim Manipal Institute of Medical Sciences, Sikkim

The Sikkim Manipal Institute of Medical Sciences, Sikkim organised one day training programme on Pharmacovigilance in collaboration with PvPI and National Institute of Pharmaceutical Education & Research (NIPER), Guwahati under the supervision of Dr Sushrut Varun Satpathy, Coordinator on 31st May 2024 at SMU auditorium. Dr Jai Prakash, Officer In-charge of PvPI, Dr Shashi Bushan, Sr. Scientific Officer and Mr. Vipin Sharma, Team Lead, Signal Division, PvPI, IPC attended this training Programme. Dr Jai Prakash in detail explained “Role of PvPI in shaping patient safety” and Mr Vipin Sharma explained “Tools for AE reporting” including hands on training on ADR reporting for the participants. A total of 100 participants participated in this event.



29th Skill Development Programme on Pharmacovigilance organized by NCC-PvPI, IPC

The NCC-PvPI, IPC conducted 5 days “29th Skill Development Programme on Pharmacovigilance” virtually from 3rd to 7th June 2024 at Mini Conference Hall, IPC, Ghaziabad. The objective of this training programme was to enhance the pharmacovigilance skills of the healthcare professionals to promote the patient safety. A total of 260 participants including Pharmaceutical Industry Professionals, Physician, Academicians, Pharmacy/Medical Students and Pharmacists across the country participated in this training programme.



Training Programme organised by NCC-PvPI, IPC on 'Pharmacovigilance Audits & Inspections'

A capacity building programme on "Pharmacovigilance Audits & Inspections" was organised by the NCC-PvPI, IPC on 27th June 2024 through hybrid mode at IPC for the PvPI staff posted at NCC and AMCs across the country. In this training programme, Mr Moin Don, Founder & CEO, PVCON CONSULTING has given a detailed presentation on "Pharmacovigilance Audits & Inspections" and answered the questions of the participants.



Advanced Level Training Programme organised by JSS Medical College & Hospital, Mysuru

The JSS Medical College & Hospital, Mysuru as a Regional Training Centre (RTC) organized a webinar by Prof. M. Ramesh, Coordinator on "Advancing, Excelling & Mastering in Pharmacovigilance" for Coordinators, Pharmacovigilance Associates and Healthcare Professionals (HCPs) from various institutions located across the country on 29th June 2024. The objective of the webinar was to provide an insight into Pharmacovigilance with special emphasis on:

- Advanced strategies for enhancing patient safety,
- Empowering various stakeholders in Pharmacovigilance for the future,
- Developing and strengthening the skills, competencies and abilities in pharmacovigilance,
- Advancing Pharmacovigilance practices through innovative approaches

In this webinar, Dr Jai Prakash, Officer in-Charge of PvPI delivered a keynote address on “Pharmacovigilance–Regulatory Perspectives” followed by a detailed presentation on “Enhancing Pharmacovigilance: Developing Skill Set, Competencies & Capacity Building”. Dr Ray R S, Scientific Assistant, PvPI, IPC has also delivered a talk on “Excelling in Pharmacovigilance: Enhancing Patient Safety through Advanced Strategies”. A total of 272 participants have participated in this webinar.



Interactive meeting with Marketing Authorization Holders (MAHs)

The Interactive meetings with following MAHs held virtually to address the basic concepts of Pharmacovigilance and how the Pharmacovigilance system can be effectively implemented at MAHs/Pharmaceutical Industry and

| Date | MAHs | No. of Participants |
|-----------------------------|-----------------------------|---------------------|
| 24 th April 2024 | Biological E Ltd. | 11 |
| 28 th May 2024 | Cadila Pharmaceuticals Ltd. | 10 |

also focussed on the issues/challenges related to the quality of submitted ICSRs in E2B, xml format to PvPI.



NCC-PvPI, IPC team and Biological E. Ltd. representatives interactive meeting on 24th April 2024



NCC-PvPI, IPC team and Cadila Pharmaceutical Ltd. representatives interactive meeting on 28th May 2024

Workshop organized by Lovely Professional University, Punjab

Workshop on “Pharmacovigilance with a special reference to VigiFlow Software” was organized by Lovely Professional University, Jalandhar, Punjab on 29th April 2024. The objective of this workshop was to train the undergraduate & postgraduate students of pharmaceutical sciences about the monitoring and reporting of Adverse Events to the PvPI through VigiFlow software. In this workshop, Dr Jai Prakash, Officer in-Charge of PvPI, Dr R.S. Ray, Scientific Assistant and Dr Vijit Agrawal, Sr. Pharmacovigilance Associate, PvPI, IPC delivered talks on Role of PvPI in Patient Safety, Basic concept & Current PV regulations and Introduction to VigiFlow & Data Entry respectively. A total of 192 participants attended this training workshop.

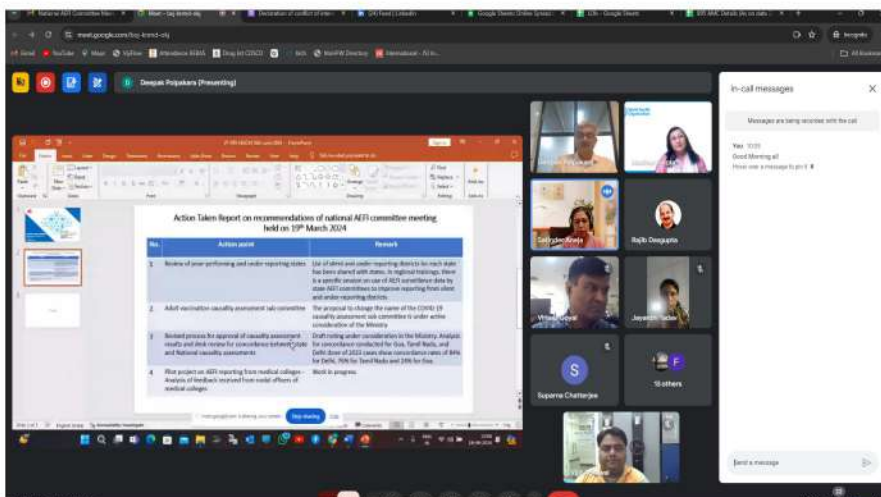


Review meeting organized by the NCVBDC, New Delhi and WHO Country office for India

The review meeting on “National Kala-azar Review and Orientation for Dossier Preparation” was organized by the National Center for Vector Borne Disease Control (NCVBDC), New Delhi and WHO Country Office for India from 2nd to 4th May 2024 at Chanakya BNR, Ranchi, Jharkhand. This meeting was to review/discuss the current status of Kala-azar programme with focus on post elimination strategies to sustain the elimination threshold levels and also to orient the state programme managers/officers for initiating documents preparation and submission of dossier. In this review meeting, Dr Jai Prakash Officer in-Charge of PvPI delivered talks on “Status of Adverse Event Reporting in Kala-Azar Programme” and Dr Vijit Agrawal, Sr. Pharmacovigilance Associate, PvPI, IPC gave live demonstration of reporting/filling of ICSRs in VigiFlow to the participants on 2nd May 2024.



National AEFI Committee meeting



The AEFI Secretariat under the chairpersonship of Dr S Aneja, Professor and Head, Dept. of Paediatrics, School of Medical Sciences and Research, Sharda University, Greater Noida organised virtual meeting on 18th June 2024. The objective of this meeting was to approve the causality assessment

classification of the AEFI cases reported following the UIP Vaccination. The PvPI official participated in this meeting virtually.

New Drugs Approved in India




The following new drugs were approved by the Central Drugs Standard Control Organization during this index period:

| S. No. | Date of issue | Name of drugs | Indications |
|--------|---------------|--|--|
| 1. | 08-05-2024 | Vonoprazan fumarate Bulk drug & Vonoprazan tablets 10mg/20 mg | <ul style="list-style-type: none"> • Treatment of Reflux Esophagitis (RE) • Treatment of Gastric Ulcer (GU) • Treatment of Duodenal Ulcer (DU) • Prevention of recurrence of Gastric Ulcer or Duodenal Ulcer during low-dose aspirin administration. • Prevention of recurrence of Gastric Ulcer or Duodenal Ulcer during NSAIDs administration. Adjunct to Helicobacter pylori eradication associated with: Gastric Ulcer, Duodenal Ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, the stomach after endoscopic resection of early-stage cancer, or Helicobacter pylori gastritis. |
| 2. | 16-05-2024 | rdESAT-6 and rCFP-10 (Cy-Tb) injection (Additional indication) | <ul style="list-style-type: none"> • For Detection of Latent-TB for population of age group 1 year and above. • For detection of Latent-TB for population below 1 year in implementation research mode under National program only.. |

REGULATORY MATTERS

| S. No. | Date of issue | Name of drugs | Indications |
|--------|---------------|---|--|
| 3. | 16-05-2024 | Selpercatinib Capsules 40 mg & 80mg | <ul style="list-style-type: none"> Adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC) Adult and paediatric patients 12 years of age and older with advanced or metastatic RET mutant medullary thyroid cancer (MTC) who require systemic therapy. Adult and paediatric patients 12 years 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) |
| 4. | 31-05-2024 | Nelarabine bulk drug & Nelarabine Injection 250mg/50ml(5mg/ml) | <ul style="list-style-type: none"> For the treatment of patients with T-cell Lymphoblastic leukemia and T-cell Lymphoblastic lymphoma in adult and paediatric patients age 1 year and older whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens |
| 5. | 31-05-2024 | Enmetazobactam bulk drug & Cefipime 2gm and Enmetazobactam 500mg Dry powder for injection | <p>Indicated for the treatment of patients 18 years of age and older for:</p> <ul style="list-style-type: none"> Complicated Urinary Tract Infection (CUTI) including acute pyelonephritis Hospital-Acquired Pneumonia (HAP), including Ventilator-Associated Pneumonia (VAP) Bacteraemia with complicated urinary tract infection or hospital-acquired pneumonia. |

Source: [Approved New Drugs \(cdsco.gov.in\)](https://cdsco.gov.in)

 Healthcare professionals, patients/consumers are advised to closely monitor the possibility of the Adverse Events associated with the use of above new drugs. If any reaction is encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form for HCPs and Medicines Side Effect Reporting Form for Consumers (<http://www.ipc.gov.in>). You can also report through PvPI Helpline No. 1800-180-3024 (Toll-Free).

Drug Safety Alerts

The NCC-PvPI, IPC issued the following drug safety alerts by uploading on the websites of PvPI, IPC and also shared with Adverse Drug Reaction Monitoring Centres through email for the sensitization of healthcare professionals, thereby strengthening the reporting of Individual Case Safety Reports (ICSRs) to PvPI. The NCC-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 | Indications | Adverse Reactions |
|--------|----------------------------|-----------------|---|---|
| 1. | 21 st May 2024 | Meropenem | For treatment of pneumonia, nosocomial pneumonia, UTI, intraabdominal infection, gynaecological infection, skin & soft tissue infection, meningitis, septicaemia & empiric treatment of presumed infection in adult patients with febrile neutropenia. | Acute Generalized Exanthematous Pustulosis (AGEP) |
| 2. | 28 th June 2024 | Acetazolamide | As an adjunct in the treatment of chronic open-angle glaucoma; secondary glaucoma; as part of pre-operative treatment of acute closure angle glaucoma. | Choroidal effusion or Choroidal detachment |
| 3. | 28 th June 2024 | Amlodipine | To reduce fatal coronary heart disease and non-fatal myocardial infarction, and to reduce the risk of stroke. To reduce the risk of coronary revascularization procedures and the need for hospitalization due to angina in patients with coronary artery diseases. | Lichenoid Keratosis |



Healthcare professionals, patients/consumers are advised to closely monitor the above mentioned ADRs associated with the use of above suspected drugs. If, such reactions are encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form for HCPs and Medicines Side Effect Reporting Form for Consumers (<http://www.ipc.gov.in>). You can also report through PvPI Helpline No. 1800-180-3024 (Toll-Free).

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Health

Latest safety alert on painkiller nimesulide brings focus back on potentially dangerous side effect

Drug standards body warns that nimesulide, a commonly used painkiller and anti-fever medicine, can cause skin rashes. However, evidence has also emerged that it can cause liver damage.

SUMI SUNANDA DUTTA | 17 April, 2024 01:58 pm IST

Representational image | Pexels

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New Delhi: The Indian Pharmacopoeia Commission (IPC) — the apex agency for setting drug standards in the country — last month issued a safety alert regarding nimesulide, a common painkiller and anti-fever medicine.

The alert warns that the drug can lead to “fixed drug eruption” — or skin rashes in specific parts of the body.

Press & Media

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Govt issues alert on Nimesulide

13 Apr 2024

On April 2024, the Indian Pharmacopoeia Commission (IPC) issued a drug safety alert regarding Nimesulide, an anti-inflammatory drug, citing potential skin rashes as an adverse effect.

Key Points

- **Nimesulide Overview:** Nimesulide, classified as a Non-steroidal anti-inflammatory drug (NSAID), is prescribed to alleviate pain, inflammation, and swelling associated with various conditions, including fever, menstrual cramps, and osteoarthritis.
- **Identifying Allergic Reactions:** Patients with known drug allergies or underlying health issues, such as kidney or liver disease, should inform their doctors.
- **Administration Guidelines:** Patients are advised to follow prescribed dosages, take the medication with food, and discontinue its use as per the doctor's instructions.
- **Contraindications:** Individuals with blood coagulation issues, children, pregnant or nursing women, and those with a history of stomach ulcers, heart failure, or liver and kidney conditions should avoid Nimesulide.
- **Monitoring and Response:** Patients should remain vigilant for any adverse reactions, particularly within the initial days of usage.
- **Historical Context:** Nimesulide faced bans in several countries, including Switzerland, Spain, and the US, due to safety concerns.
- **In India,** its usage for adults persists but is not recommended for children since 2011.

THE ECONOMIC TIMES Industry

English Edition • | 23 April, 2024, 10:33 AM IST | Today's ePaper

IPC issues alert on painkiller drug nimesulide over adverse reaction

By Teena Thacker, ET Bureau • Last Updated: Apr 12, 2024, 01:02:00 AM IST

Synopsis

Pharma standards body Indian Pharmacopoeia Commission (IPC) has issued a drug safety alert over nimesulide, saying the pill can trigger rashes on the skin (fixed drug eruption). It asked consumers and healthcare professionals to closely monitor the use of the drug and report any adverse reaction to the National Coordination Centre-Pharmacovigilance Programme of India of the IPC.

New Delhi: Next time you pop a [nimesulide](#), a commonly used [painkiller](#), be watchful.

Pharma standards body Indian Pharmacopoeia Commission (IPC) has issued a drug safety alert over nimesulide, saying the pill can trigger rashes on the skin (fixed drug eruption). It asked consumers and healthcare professionals to closely monitor the use of the drug and report any adverse reaction to the National Coordination Centre-Pharmacovigilance Programme of [India](#) of the [IPC](#).

Representational

According to the IPC, the drug is used in inflammatory conditions including joint disorders like rheumatoid arthritis, post-traumatic and post-operative painful conditions and fever, as well as in acute pain in orthopaedic, ENT and dental conditions.

Forthcoming Events

| S. No. | Date | Title | Who can participate? |
|--------|---|--|---|
| 1. | 17 th - 23 rd September, 2024 | 4 th National Pharmacovigilance Week 2024 How the 4 th NPW 2024 # tagged to create awareness | <ul style="list-style-type: none"> Healthcare Professionals Academic Medical/Pharmaceutical Institutions Adverse Drug Monitoring Centers (AMCs) Others stakeholders related to PV |
| 2. | 4 th October 2024 | Webinar on Case Narrative writing | Pharmacovigilance Associates at NCC/AMCs |
| 3. | October, 2024 | Induction-cum-Training Programme on Pharmacovigilance | <ul style="list-style-type: none"> Coordinators/Deputy Coordinators of newly-recognized AMCs Newly-recruited Pharmacovigilance Associates at AMCs & NCC-PvPI, IPC |
| 4. | 4 th - 10 th November 2024 | MedSafetyWeek 2024 | <ul style="list-style-type: none"> Healthcare Professionals Academic Medical/Pharmaceutical Institutions Adverse Drug Monitoring Centers (AMCs) Others stakeholders related to PV |
| 5. | 13 th -14 th November 2024 | Seminar on: <ul style="list-style-type: none"> Introduction to MedDRA Coding MedDRA Safety Data analysis & Standardised MedDRA Queries (SMQs) | Pharmacovigilance Associates |
| 6. | 18 th - 22 nd November 2024 | 31 st Skill Development Programme | <ul style="list-style-type: none"> Healthcare Professionals Pharmacovigilance Professionals Medical/Para-medical/Pharmacy Students Pharmacists Academicians |
| 7. | November, 2024 | Regional Training for Marketing Authorization Holders (MAHs) | <ul style="list-style-type: none"> Pharmacovigilance Professionals Pharmaceutical Industries/Marketing Authorization Holders Contract Research Organization engaged in PV |
| 8. | December, 2024 | Workshop-cum-Training Programme on Pharmacovigilance for NABH Accredited Hospitals | <ul style="list-style-type: none"> Physicians Pharmacists Nurses Medical/Paramedical students Healthcare Professionals |

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
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Website: www.ipc.gov.in

Let us join hands with PvPI to ensure patient safety