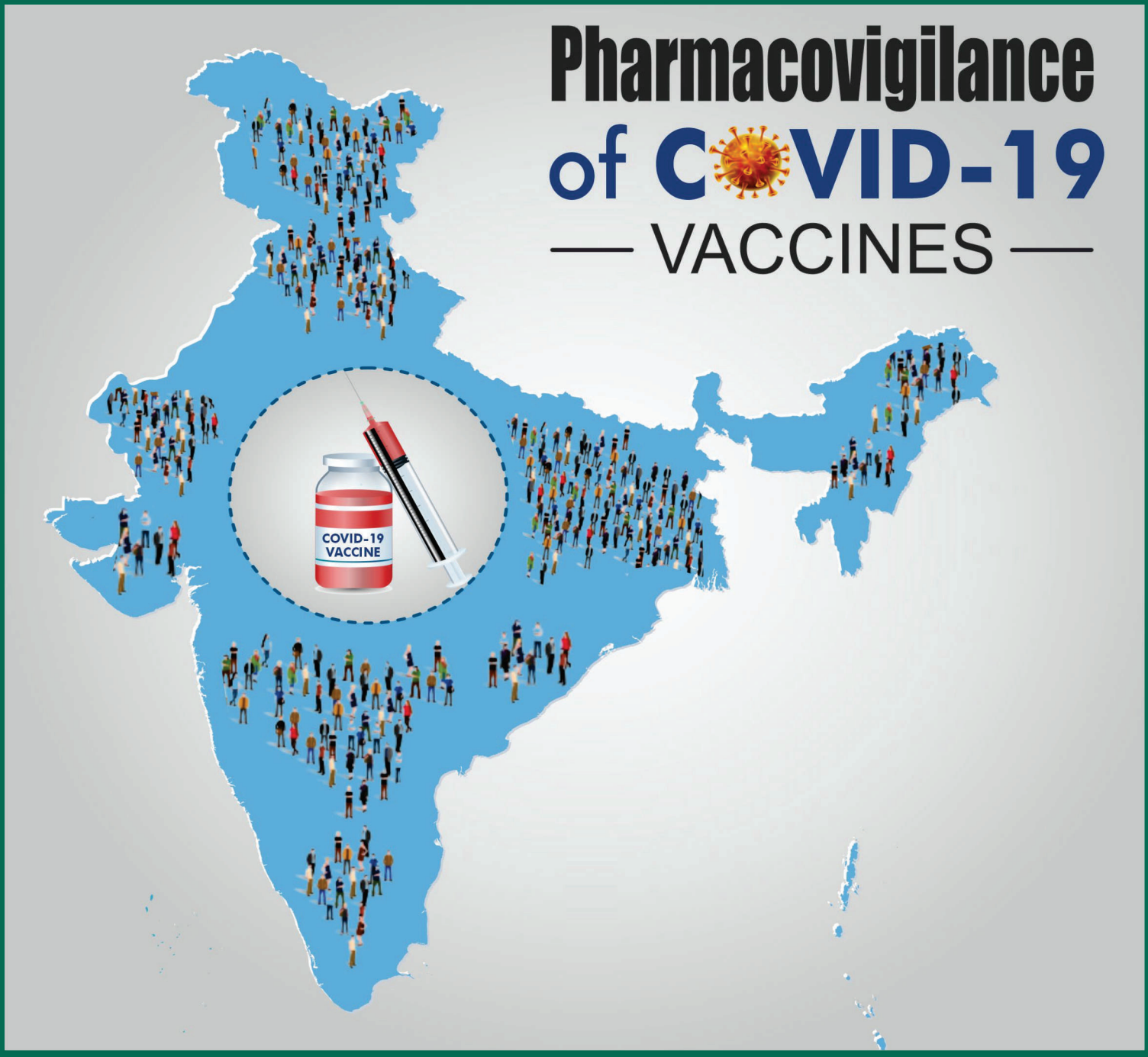
ISSN:2320-7760

Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

VOL 11 | ISSUE 34 | 2021

Pharmacovigilance of COVID-19 VACCINES



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

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Message from the Desk of
Secretary-cum-Scientific Director

Dear Readers,

It gives me immense pleasure to bring out this Year's first quarterly PvPI Newsletter. The Pharmacovigilance Programme of India (PvPI) is working dedicatedly by collecting, collating & analysing Adverse Events (AEs) reported with the use of Medical Products to promote patient safety across the Country.

In COVID-19 pandemic, the role of Pharmacovigilance Professionals became more important to monitor the safety of newly developed COVID-19 vaccines and drugs used against COVID-19. Post Marketing Surveillance will always be necessary to fill knowledge gaps left by controlled Clinical Trials. The Drugs Controller General of India gave the approval of two COVID-19 vaccines namely COVAXIN and COVISHIELD on 03rd January, 2021 for restricted use in emergency situation.

The Hon'ble Prime Minister of India, Shri Narendra Modi started National COVID-19 Vaccination Programme with the vaccination of frontline healthcare workers and subsequently for people in different age groups with co-morbidities. This posed a challenging task as well as opportunity for PvPI to take effective measures for Pharmacovigilance of COVID-19 vaccines.

NCC-PvPI, IPC has promptly taken this into account and initiated the Focussed Pharmacovigilance of COVID-19 vaccines by sensitizing Healthcare Professionals (HCPs) through Adverse Drug Reaction Monitoring Centres (AMCs) and instructed to have a close watch on AEs likely to occur with COVID-19 vaccines. NCC-PvPI had also provided training to HCPs at AMCs on collection & processing of Adverse Event Following Immunization reported with COVID-19 vaccines through virtual platform. Furthermore, NCC-PvPI Helpline No, 1800 180 3024 (Toll Free) was disseminated pan-India for the collection of AEFI with COVID-19 vaccination. During the Index Period, NCC-PvPI received a total of 3649 ICSRs associated with the COVID-19 vaccines across the Country.

As a team, we will continue to work towards patient safety and I congratulate the PvPI team & Subject Experts for their ceaseless efforts, cooperation and contribution in establishing/developing a robust Pharmacovigilance system in India.

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

Pharmacovigilance of COVID-19 Vaccines

Drug safety monitoring is a public health priority. Several therapeutic options to treat and prevent COVID-19 are being tried. Some of the drugs such as remdesivir, hydroxychloroquine, COVID-19 vaccines etc., have been used for the management of COVID-19. The Drugs Controller General (India) approved two COVID-19 vaccines namely COVAXIN and COVISHIELD on 3rd January, 2021 for restricted use in an emergency situation.

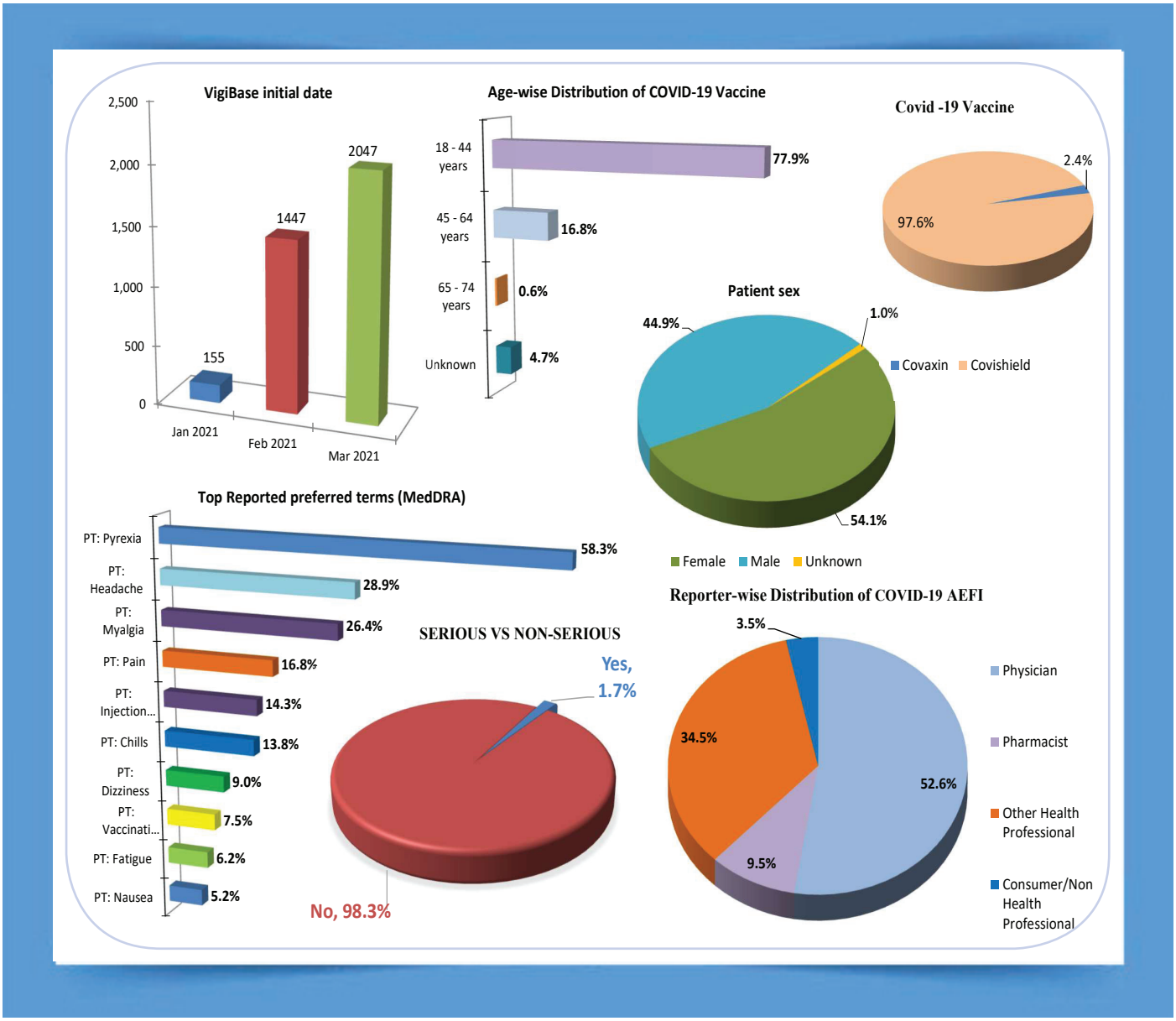
The Hon'ble Prime Minister of India, Shri Narendra Modi, started the National COVID-19 Vaccination Programme for frontline healthcare workers on 16th January, 2021. Subsequently, the vaccination of people in age groups above 60 years and 45-59 years with co-morbidities was started on 1st March, 2021. Amid COVID-19 pandemic, this posed a challenging task as well as an opportunity for the Pharmacovigilance Programme of India (PvPI) to take effective measures for the Pharmacovigilance of COVID-19 vaccines.

Keeping this in view, National Coordination Centre (NCC) - PvPI, Indian Pharmacopoeia Commission (IPC) has initiated the Focussed Pharmacovigilance of COVID-19 vaccines by sensitizing healthcare professionals through its Adverse Drug Reaction Monitoring Centres (AMCs). All concerned AMCs were instructed to have a close watch on the Adverse Events (AEs)/Adverse Drug Reactions (ADRs) likely to occur during COVID-19 vaccination and report through Toll-Free Helpline, Mobile App, Suspected ADR Reporting Form for COVID-19 drugs and Adverse Event Following Immunisation (AEFI) Case Notification Form to PvPI. NCC-PvPI Helpline No.-1800 180 3024 (Toll Free) was disseminated pan-India for the collection of AEFI of COVID-19 Vaccines.

As per the recommendation of the Core Training Panel (CTP), NCC-PvPI had trained the scientific staff of PvPI at NCC and AMCs level, on AEFI of COVID-19 vaccination. NCC-PvPI conducted the following training programmes in line with the recommendation of CTP:

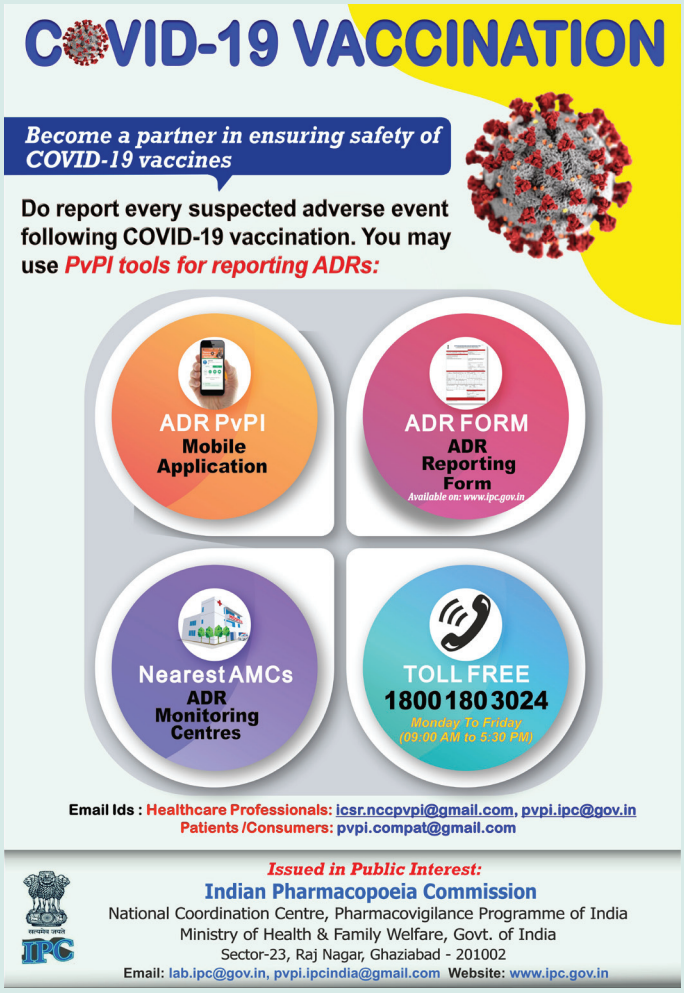
- Virtual training on "Pharmacovigilance of COVID-19 Vaccines" was organized by NCC-PvPI in association with AEFI Secretariat for Pharmacovigilance Associates and AMCs Coordinators on 7th January and 13th January, 2021, respectively. The training focused on surveillance, reporting, causality assessment of AEFI and the role of AMCs in COVID-19 vaccines pharmacovigilance.
- A virtual training was conducted on 21st and 22nd January 2021 for 'Data entry in VigiFlow', which focused on the data entry of COVID-19 ICSRs. The PV Associates were also explained about the New Tab- 'New AEFI' in the VigiFlow, specially designed to report AEs of COVID-19 vaccines.

The Adverse Events due to COVID-19 vaccines for the period January-March, 2021 were collected from various AMCs, under PvPI across the country. NCC-PvPI has submitted a total of 3649 ICSRs to VigiBase. The brief diagrammatic overview of the reported AEFI cases from COVID-19 vaccines is as follows:


VigiBase initial date
2,500
2,000
1,500
1,000
500
0
155
1447
2047
Jan 2021
Feb 2021
Mar 2021
Age-wise Distribution of COVID-19 Vaccine
18 - 44 years
77.9%
45 - 64 years
16.8%
65 - 74 years
0.6%
Unknown
4.7%
Covid -19 Vaccine
2.4%
97.6%
Patient sex
44.9%
1.0%
54.1%
Covaxin
Covishield
Female
Male
Unknown
Top Reported preferred terms (MedDRA)
PT: Pyrexia
58.3%
PT: Headache
28.9%
PT: Myalgia
26.4%
PT: Pain
16.8%
PT: Injection...
14.3%
PT: Chills
13.8%
PT: Dizziness
9.0%
PT: Vaccinati...
7.5%
PT: Fatigue
6.2%
PT: Nausea
5.2%
SERIOUS VS NON-SERIOUS
Yes, 1.7%
No, 98.3%
Reporter-wise Distribution of COVID-19 AEFI
3.5%
34.5%
52.6%
9.5%
Physician
Pharmacist
Other Health Professional
Consumer/Non Health Professional

Awareness of ADR Reporting through Posters

A poster for awareness on ADR reporting of COVID-19 Vaccines (Healthcare Professionals and Public) was designed and communicated to AMCs under PvPI.



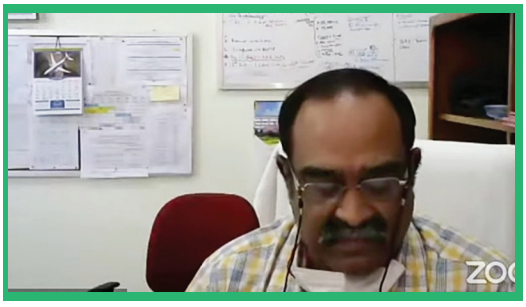
National Webinar on "Adverse Event Following Immunization (COVID-19) - Interim Report"

Amrita Institute of Medical Sciences (AIMS), Kochi along with the PvPI and Immunisation Technical Support Unit (ITSU) conducted a National Webinar on "Adverse Event Following Immunization (COVID) - Interim Report" on 11th February, 2021. This Webinar was chaired by Dr. Prem Nair, Medical Director, and Dr. (Col.) Vishal Marwaha,

Principal, AIMS, Kochi. Dr. Jai Prakash, Officer in-Charge, PvPI delivered a keynote address and emphasized on monitoring of adverse events reported due to COVID-19 vaccination.

Dr. Prem Nair

Dr. Jai Prakash



Dr. (Col.) Vishal Marwaha

Topics discussed during the webinar:

S.No.	Name of the Speaker	Topics
1.	Dr. Deepak Polpakara, Team Lead – AEFI, ITSU, Ministry of Health & Family Welfare, Government of India	Appraisal of Adverse Event Following Immunization (AEFI)
2.	Dr. Dipu TS, Associate Professor, Department of Infectious Disease, AIMS, Kochi.	Adverse Events Following COVID-19 vaccination – Interim report
3.	Dr. Aswathy S, Head & Professor, Department of Community Medicine, AIMS, Kochi.	Community perspective of Adverse Events in COVID-19 vaccines
4.	Dr. Princy Louis Palatty, Head & Professor, Department of Pharmacology, Coordinator, AIMS, Kochi.	Commonly encountered Adverse Event Following COVID vaccine Administration

Enrollment of New AMCs in 10th Phase under PvPI

NCC-PvPI received the Letter of Intent (LoI) from various organizations such as pharmacy institutions, hospitals etc., to enroll as AMCs under PvPI. The competent authority of PvPI reviewed the LoI and approved 35 new AMCs in 10th Phase. The proposed AMCs were selected on the basis of their performance in last one year in terms of quality/quantity of ADR reporting, awareness/sensitization programme conducted on Pharmacovigilance among healthcare professionals and their demography.

New AMCs enrolled in 10th Phase under PvPI across India:

States/UTs		AMCs
Andhra Pradesh	1.	All India Institute of Medical Sciences, Mangalagiri– 522503.
Assam	1.	Tezpur Medical College & Hospital, Tezpur, Sonitpur– 784010.
	2.	National Institute of Pharmaceutical Education & Research, Guwahati– 781125.
Chhattisgarh	1.	Shri Shankaracharya Institute of Medical Sciences, Bhilai– 490020.
Gujarat	1.	Zydus Medical College and Hospital, Dahod– 389151.
	2.	GMERS Medical College & Hospital, Dharpur, Patan– 384265
Jammu & Kashmir	1.	Government Medical College, Verinag Anantnag Road, Dialgam, Anantnag– 192210.
	2.	Government Medical College & Associate Hospital, Doda– 182202.
	3.	Government Medical College, Kathua– 184140.
Karnataka	1.	Shri B.V.V. Sangha's S. Nigalingappa Medical College and HSK Hospital and Research Centre, Navnagar, Bagalkot– 587102.
	2.	Bangalore Baptist Hospital (A unit of Christian Medical College, Vellore), Bellary Road, Vinayakanagar, Hebbal, Bangaluru– 560024.
	3.	Father Muller Medical College, Kankanady, Mangaluru– 575002.
	4.	Gulbarga Institute of Medical Science District Hospital Campus, Kalaburgi– 585105.
	5.	East Point College of Medical Sciences & Research Centre, Bangaluru– 560049.
	6.	Srinivas Institute of Medical Sciences & Research Centre, Mukka, Surathkal, Mangalore– 574146.
Kerala	1.	Aster, Malabar Institute of Medical Sciences Ltd., Chala East, Kannur– 670621.
	2.	Govt. Medical College, Thrissur– 680596.
	3.	P.K. Das Institute of Medical Science Vaniamkulam, Ottapalam, Palakkad– 679522.
Madhya Pradesh	1.	Government Medical College, Shahdol– 484001.
	2.	Government Autonomous Medical College, Village – Banjali, Sailana Road, Ratlam– 457001.
Maharashtra	1.	All India Institute of Medical Sciences, Mihan, Nagpur– 441108.
	2.	Government Medical College, Jalgaon– 425001.
	3.	MIMER Medical College, Talegaon Dabhade, Pune 410507.
	4.	Symbiosis Medical College for Women & Symbiosis University Hospitals and Research Centre, Lavale, Pune– 412115.
Puducherry	1.	Sri Venkateshwara Medical College Hospital & Research Centre, Ariyur, Puducherry– 605102, 605107
Punjab	1.	Chitkara College of Pharmacy, Chitkara University Chandigarh-Patiala, NH 7, 64, Tehsil, Rajpura– 140401.
	2.	All India Institute of Medical Sciences, Bathinda– 151001.
Tamil Nadu	1.	Government Thiruvarur Medical College and Hospital, Vilamal, Thiruvarur– 610004.
	2.	Govt. Tiruvannamalai Medical College & Hospital, Tiruvannamalai– 606604.
	3.	Panimalar Medical College Hospital & Research Institute, Poonamallee, Chennai– 600123.
Telangana	1.	Mamata Academy of Medical Sciences, Bachupally, Hyderabad, Telangana – 500090.
	2.	Government Medical College, Nalgonda– 508001.
Uttar Pradesh	1.	Central Drug Research Institute, Sector-10, Jankipuram Extension, Lucknow– 226021.
	2.	All India Institute of Medical Sciences, Department of Pharmacology, Gorakhpur– 273008.
	3.	Rajarshi Dashrath Autonomous State Medical College, Ayodhya– 224133.

Webinar on Pharmacovigilance: From the Reporter's Perspective

A webinar entitled "Pharmacovigilance: From Reporter's Perspective" was organized by Veer Surendra Sai Institute of Medical Science and Research, Burla on 24th January, 2021. Dr. Bhabagrahi Rath, Coordinator of this AMC welcomed the speakers & participants and keynote address was delivered by Dr Jai Prakash, Officer-in-Charge, PvPI. Ms Renuka Bhoi, Pharmacovigilance Associate was actively involved in managing this webinar under the supervision and guidance of her coordinator. A total of 72 participants attended the webinar including Faculty, Residents, Medical Students and PV Associates of various AMCs.

The experts spoke on following PV topics:

- Challenges in detecting and reporting of ADRs in paediatric population
- Challenges in detecting and reporting of ADRs in adult population
- Dermatological ADRs -Challenges in detecting and reporting
- Challenges in Pharmacovigilance & way ahead

Virtual Indian MedDRA User Group Meeting

MedDRA, India User Group Meeting is a regular annual activity of Maintenance and Support Services Organization, U.S.A., which was held virtually on 23rd March 2021. Dr. Jai Prakash, Officer-in-Charge, PvPI participated as a Panel Member to resolve the queries raised by the participants related to the use of MedDRA. Mr. Rishi Kumar, Scientific Assistant, PvPI, delivered a presentation on "MedDRA and COVID-19-PvPI Perspective".

Webinar on MedDRA Coding

MedDRA Coding is an integral part of Pharmacovigilance, and its terminology is used throughout the regulatory process, from pre-marketing to post-marketing phase, data entry, retrieval, evaluation, and presentation. NCC-PvPI, conducted a webinar on "MedDRA coding" on 22nd March, 2021. Dr Dinesh Kumar Govindraj, MedDRA Query Manager, Novartis explained the MedDRA terms selection and its different levels as per the current version of MedDRA. He also briefed about Standardised MedDRA Queries (SMQ) and Multiaxiality to 178 participants from NCC and AMCs.

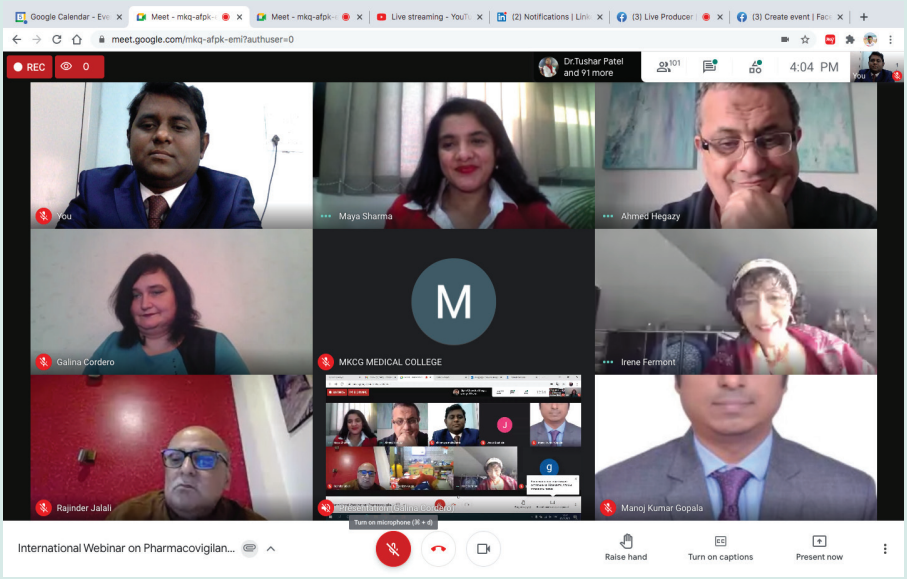
18th Signal Review Panel Meeting

PvPI had conducted virtual "18th Signal Review Panel (SRP) Meeting" under the Chairmanship of Prof. Y.K. Gupta and Co-chairmanship of Prof. Urmila Thatte on 12th March, 2021 and the recommendations of the Panel were as follows:

S.No.	Drugs	Adverse Drug Reactions	SRP Recommendations to CDSCO
1.	Tinidazole	Fixed Drug Eruptions	Signal (To be included in PIL)
2.	Tramadol	Urinary Retention	Drug Safety-related PIL change

International Webinar on "Regulatory Variations in PV: A Single Goal Towards Patient Safety"

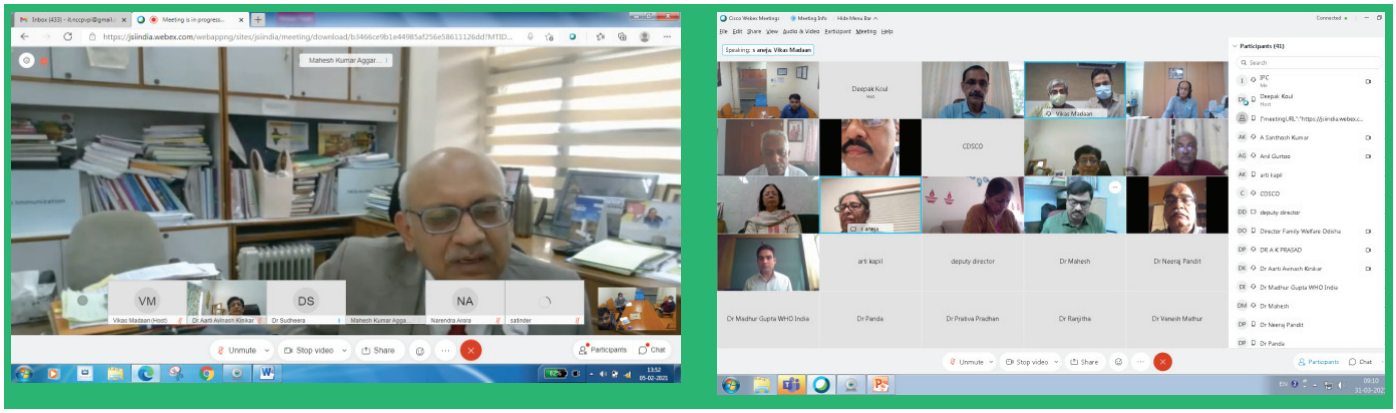
An International webinar on Pharmacovigilance entitled "Regulatory Variations in PV: A Single Goal Towards Patient Safety'' was organised by Dr. Y. Roja Ramani, Coordinator M.K.C.G. Medical College, Berhampur, Odisha on 5th February, 2021.



The experts across the globe were Dr. Jai Prakash, Dr. Maya Sharma, Dr. Manoj Swaminathan from India, Dr. Galina Cordero from Ukraine, Dr. Ahmed Hegazy from Dubai, Irene Rina Fermont from Israel, Dr. Sahid Hocine from London, Dr. Helaine Capucho from Brazil, Patricia Zuluaga Arias from Colombia and Jelena Rosic from Serbia, who shared their views and experiences on the regulatory aspects of pharmacovigilance. They also discussed their new plans and ideas in order to further strengthen the pharmacovigilance system in their respective countries. A total of 405 Indian participants and 146 foreign participants were present in this webinar across the world.

National AEFI Committee Meetings

Three virtual National AEFI committee meetings were organized by the AEFI Secretariat of ITSU- Universal Immunization Programme from January to March 2021. Overall, 182 representatives from various organizations like MoHFW, AEFI Secretariat, IPC, CDSCO, INCLEN International and WHO, Country Office-India attended these meetings. These meetings were aimed to discuss the AEFI cases, their surveillance, causality assessment and COVID-19 vaccines safety among the Indian population and in the countries where the Indian vaccines are being exported.



16th SDP on Pharmacovigilance of Medical Products

NCC-PvPI organised the "16th Skill Development Programme on Pharmacovigilance of Medical Products" in virtual mode from 15th March to 19th March, 2021. Dr. Jai Prakash, Officer-in-Charge, PvPI welcomed the participants. Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, IPC inaugurated the programme. Dr. Jai Prakash also delivered a presentation on 'Current updates of Pharmacovigilance Programme of India'. Total 17 technical sessions, covering a wide array of topics on Pharmacovigilance were conducted. A total of 105 participants belonging to diverse backgrounds including pharmaceutical professionals, physicians, academicians, coordinators & pharmacovigilance associates of AMCs, research scholars, students (pharmacy and medical) across the country attended this training programme. The objective of this training programme was to enhance Pharmacovigilance knowledge and skills of the healthcare professionals, which in turn, promote patient safety.

Training on Pharmacovigilance for NABH Accredited Hospitals

PvPI, IPC has signed a Memorandum of Understanding with the National Accreditation Board for Hospitals and Healthcare Providers (NABH) for effective implementation of Pharmacovigilance system in the country. The virtual training on Pharmacovigilance for NABH Accredited Hospitals in India was organized by NCC-PvPI, IPC in collaboration with NABH on 24th March, 2021. This training programme intended to provide a platform for the NABH-Accredited Hospitals, however few participants from Non-NABH-Accredited Hospitals also attended to understand the systems and procedures involved in ADR-reporting and relevant practices. A total of 131 participants including physicians, nurses, pharmacists, academicians and other healthcare professionals across the country, attended this programme. The following technical sessions covered the basics of Pharmacovigilance and functioning of PvPI:

1. Current Updates on PvPI
2. Importance of ADR reporting for NABH Accredited Hospitals in India
3. Monitoring & Reporting AEs/ADRs (Methodology, Forms & Formats)
4. The setting of a Pharmacovigilance system in the hospital
5. Causality Assessment in Pharmacovigilance

Trainings on Pharmacovigilance of COVID-19 Vaccines

Virtual training on "Pharmacovigilance of COVID-19 Vaccines" were organized by NCC-PvPI in association with AEFI Secretariat for the Pharmacovigilance Associates and Coordinators of AMCs under PvPI on 7th January and 13th January, 2021 respectively. A total of 354 participants attended these training programmes and were trained on the following topics with special reference to COVID-19 vaccination:

- Introduction to AEFI surveillance
- AEFI reporting, investigating under the Universal Immunization Programme
- Basics of causality assessment of AEFI
- Role of AMCs under PvPI for AEFI surveillance of COVID-19 vaccines

Induction-cum-Training Programme

NCC-PvPI organized virtual "Induction-cum-Training Programme on Pharmacovigilance" for Coordinators and Pharmacovigilance Associates of newly recognized AMCs under PvPI from 11th to 12th January, 2021. The objective of this training was to orient the newly recruited staff for collection, collation and processing of ADR data reported with the administration of drugs. A total of 62 participants attended this training programme across the country.

Other Important Trainings

Other training programmes conducted by NCC-PvPI were as follows:

S.No.	Date	Training Title & Speaker	Participants
1.	4th February, 2021	Case Narrative Writing by Dr. Anuja S. Jawale, Affiliate Safety Representative Medical Affairs, Abbott India Limited.	177
2.	21st & 22nd January, 2021	Data Entry in VigiFlow with special reference to COVID-19 AEFI cases by Mr. Rishi Kumar, Scientific Assistant, IPC.	125

Interactive meet with MAHs on ICSRs quality

NCC-PvPI organised regular interactive meetings with Marketing Authorization Holders (MAHs)/ Pharmaceutical Industries to improve the quality of ICSRs processing, causal relationship between Drug-Reaction combination and other important field parameters of ICSR. NCC- PvPI also sensitized the audience about the importance of ICSR quality score grading.

Interactive meetings conducted during the index period:

S.No.	Date	MAHs/ Pharmaceutical Industries
1.	19th March 2021	Fresenius Kabi Oncology Limited
2.	25th February 2021	Eli Lilly & Company
3.	04th February 2021	Dr. Reddy's Laboratories Limited
4.	14th January, 2021	Cipla Limited

New Drugs approved in India

The following New drugs were approved by CDSCO from January, 2021 to March, 2021

S. No.	Drugs	Indication
1.	Omidenepag isopropyl ophthalmic solution 0.002% w/v	For the treatment of glaucoma and ocular hypertension.
2.	Avanafil bulk and Avanafil tablets 50mg/100mg/200mg	For the treatment of erectile dysfunction.
• Healthcare Professionals are urged to closely monitor the safety of the above drugs • ADRs (if any) should be reported to PvPI		

Source: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzMwNg==

Drugs Safety Alerts - January to March, 2021

S. No.	Issued Date	Suspected Drugs	Indications	ADR
1.	4th January, 2021	Fexofenadine	In the treatment seasonal allergic rhinitis symptoms and chronic idiopathic urticaria.	Blurred Vision
2.		Ambroxol	Anti-tussive - Acute and chronic disease of the respiratory tract associated with abnormal bronchial secretions in particular acute attacks of chronic bronchitis, asthmatic bronchitis and bronchial asthma.	Fixed Drug Eruption
3	1st February, 2021	Cefpodoxime	Acute bronchitis, exacerbations of chronic bronchitis, bronchiolitis pneumonia, sinusitis, recurrent chronic tonsillitis, pharyngitis, acute otitis.	Drug Reaction with Eosinophilia & Systemic Symptoms (DRESS) Syndrome
4		Clarithromycin	Mild to moderately severe infections like acute exacerbation of chronic bronchitis community acquired pneumonia including infections due to chlamydia, mycoplasma spegiocella acute streptococcal pharyngitis and skin and soft tissue infections.	Burning Sensation
5	1st March, 2021	Hydroxyzine	For the management of pruritus due to allergic conditions such as chronic urticaria and atopic contact dermatoses, and in histamine -mediated pruritus.	Photosensitivity Reaction
6		Salicylic Acid	For the treatment of acne vulgaris.	Photosensitivity Reaction

Healthcare professionals (HCPs), patients/consumers were advised to closely monitor the above mentioned suspected ADRs associated with the use of the above 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://ipc.gov.in), through android mobile app and PvPI **Helpline No. 1800-180-3024 (Toll Free)**

Drug Safety Alerts: PvPI vs Other Countries

Drug	ADRs	No. of ICSRs in Global database	No. of ICSR (s) in PvPI database	Reference
Clobazam	DRESS Syndrome	27	07	WHO Pharmaceutical Newsletter No. 1, 2021, published on March, 2021.
Tramadol	Hallucination	1652	08	https://rnantnu.ca/wp-content/uploads/2021/01/EN_SSR_Tramadol_hallucinations.pdf
Torsemide (oral)	DRESS Syndrome	12	01	WHO Pharmaceutical Newsletter No. 6, 2020, published on January, 2021.

HCPs are advised to carefully monitor the above mentioned ADRs reported with the use of suspected drugs. If such ADRs encountered, it should be reported to NCC-PvPI, IPC.

PV @ GMC, Miraj, Maharashtra

Government Medical College, Miraj, Maharashtra was recognised as an AMC in 2014. The various Pharmacovigilance activities were carried out by Prof. Shraddha M. Pore, Head of Department of Pharmacology, Coordinator, Dr Shreyas R. Burute Associate Professor, Department of Pharmacology, Deputy Coordinator and Mr Amar D. Shinde, Pharmacovigilance Associate as mentioned:

- ✓ More than 1500 ICSRs processed till date.
- ✓ Regular sensitization programmes conducted with clinicians, residents, interns, nurses and other HCPs on spontaneous ADR reporting.
- ✓ Distribution of ADRs forms, news letters, pamphlets with contact details and drug alerts to the HCPs on monthly basis.
- ✓ Active participation in reporting of AEFI (During the MR vaccination drive and now for COVID- 19 vaccination).
- ✓ Display of PvPI posters at OPDs, wards and other peripheral hospitals.
- ✓ Coordination with NABH-accredited hospitals, nearby AMC in Sangli district of Maharashtra.

GMC Palakkad -Kerala in Patient Safety Services

Government Medical College (GMC) also known as Institute of Integrated Medical Science (IIMS), Palakkad, Department of Pharmacology was designated as AMC under PvPI in 2014, under the supervision and leadership of Dr. N. Sunil, Coordinator, GMC Palakkad, with the guidance and support of former Principal Dr. T.B. Culas. Dr. Akhila Sivadas is working as a Pharmacovigilance Associate at GMC, Palakkad since April 2018. Recently, AMC has actively participated in the Pharmacovigilance activities at GMC Palakkad under the support of Principal Dr. P C Ignatius and Director Dr. M. S. Padmanabhan.

Activities at the AMC

- ✓ AMC has a Pharmacovigilance Committee composed of HODs, faculties of different departments. The committee is responsible to hold periodic meetings to promote PV activities and Patient Safety Services.
- ✓ Pharmacovigilance awareness posters are put up in all OPDs, wards, and Clinical Pharmacology Department.
- ✓ Pharmacovigilance awareness posters and newsletters are being circulated to the hospitals which are designated to report ADR to our AMC as well to other peripheral hospitals.
- ✓ Circulation of PvPI newsletter, drug alerts and other information related to drug-safety among HCPs via WhatsApp groups or email on a regular basis.
- ✓ Regular meetings with committee members by adopting mandatory reporting of ADRs and obtaining feedback from departments to improve ADR-reporting.
- ✓ Maintaining ADR database or registries of all ICSR record files for easy access and retrieval in a hassle-free manner.
- ✓ Sensitization lecture for encouraging MBBS students to report ADR as part of research activities and practical exercises.

Indira Gandhi Institute of Child Health, Bengaluru excels PV

In 2014, Indira Gandhi Institute of Child Health (IGICH), Bangaluru came under the fold of PvPI as an AMC. Pharmacovigilance activities at IGICH are regularly conducted by the PV team comprising of Dr. Sanjay K.S, Director of IGICH, Dr. Basavaraja G.V, AMC-Coordinator and Mr. M. Nagendra, Pharmacovigilance Associate.

Activities at the AMC

- ✓ ICSRs were delegated to NCC on regular basis.
- ✓ PvPI posters are displayed in the OPD as well as in various hospital wards.
- ✓ Coordination for ADR reporting with NABH-accredited hospitals in neighbouring areas.
- ✓ Regular PV sensitization for clinicians via Pharmacovigilance- IGICH WhatsApp groups.
- ✓ Pharmacovigilance activities are reviewed on a monthly basis.
- ✓ Newsletters, drug alerts, and drug-safety information issued by PvPI are distributed to HCPs via email.
- ✓ The PvPI Helpline number, 1800-180-3024, is displayed in the in-patient and out-patient departments.

Dr. Shraddha Milind Pore

AMC-Coordinator, Professor & HOD Pharmacology,
GMC-Miraj, Maharashtra

PvPI-IPC, Ghaziabad is doing commendable job of increasing awareness of HCPs about ADRs and is contributing significantly in safe use of drugs in the country. As a coordinator of GMC Miraj, I feel privileged be a part of these efforts and strive sincerely and whole heartedly to add my bit along with my team towards monitoring, creating awareness and disbursing safety data to all doctors and HCPs in my area.

Dr. Sanjay. K. S.

Professor & Director,
IGICH- Bengaluru, Karnataka.

Indian Pharmacopoeia commission - PvPI plays a vital role in achieving the goal of **"protecting the safety and wellbeing of patients"**.

PvPI is the best supporting vigilance in clinical practices for the collection, monitoring, detecting, and assessment of the adverse drug reactions among patients and also prevents the ADRs and drug interactions in the healthcare system. Reporting of ADR's is one of the parameters to provide the best quality care to the patients through sensitization of the clinicians and the healthcare professionals about the "Rational use of the drugs". I congratulate and thank IPC-PvPI and the IGICH-AMC team for promoting and contributing to enhancing "Patient safety practice". I wish all the very best for their future endeavours.

Dr. Basavaraja G.V

AMC Coordinator,
IGICH-Bengaluru, Karnataka

PvPI is an important surveillance system that monitors drug safety and the rational use of medicines, producing drug-safety data for the Indian population. IGICH made every effort to improve the quality of PV performance. The technical assistance provided by PvPI-IPC as the National Coordination Centre is extremely beneficial in fulfilling PV requirements.

Dr. M S Padmanabhan

Director,
GMC (IIMS), Palakkad, Kerala

Greetings to PvPI to be a part of our institute work in monitoring the safety of drug. ADR monitoring center in our college started in 2014 is doing a great job in knowledge dissemination of drug & vaccine safety to our healthcare workers and medicos.

I congratulate the whole team of GMC, Palakkad & PvPI teams to make this program success. I also look for more active programs & CME activities in the near future.

Dr Sunil N

AMC Coordinator, HOD in charge,
GMC, Palakkad, Kerala

This youngest budding medical college in Kerala associated with PvPI from its time of inception itself i.e 2014 starting reporting ADR with surveillance in district TB centre, Palakkad got recognised as AMC at that time. From that time, we had trained our medicos, medical college clinicians, nurses, pharmacist and house surgeons in reporting ADRs. Our effort in increasing the reporting is bearing fruits now by active involvement of private hospitals not only in our Palakkad district but the whole of Malabar belt.

The working environment in COVID times were challenging but the system devised already with the help of WhatsApp group for interns, doctors and private sectors separately helped us. The AEFI for COVID-19 vaccines were also reported with a special task.

The newsletters with special reports on new drug signals were disbursed electronically from time to time to these groups. The active reporters were rewarded with certificate of recognition to improve reporting. As we are in the process of getting a new integrated unitary campus by September this year, also hoping to get the monitoring centre for MvPI, for which letter of intent is submitted . We look for a long active association with PvPI in the near future. I thank the whole PvPI team who are supporting us in all our endeavours.

Dr. Aparna Namboothiri

Assistant Professor, Pulmonary Medicine,
GMC, Palakkad, Kerala

PvPI is a boon for treating physicians as well as the patient, as anyone can report an ADR through this platform. Continuous monitoring of ADR even for medicines that we have been using for several decades is actually an eye opener. I appreciate all the activities of a very active ADR monitoring centre at our GMC, Palakkad.

PvPI invites Letter of Intent from Medical Colleges/Hospitals/Corporate Hospitals/Premier Pharmacy Institutions to enrol under PvPI

The Advantages of being an AMC are

1. Health partner for the Nation-wide ADR Reporting System.
2. Access to WHO Global safety database, VigiFlow to evaluate benefit-risk assessment of Medicines.
3. Scientific Publications/ Case Studies/Project related to PV.
4. Eligible for Financial / Manpower assistance for training/conferences/ Telephone/internet expense.
5. Reduce India's dependence on western world data for taking regulatory decision on drug safety.
6. Boost Public confidence in the use of Medicines.

NCC-PvPI, IPC invites letter of intent (LOI) to enroll under PvPI in the interest of Patient safety. The Letter of Intent is freely downloadable from www.ipc.gov.in. Interested stakeholders are requested to send the filled-in LOI and communicate it to NCC-PvPI via email (pvpi.ipc@gov.in) and the hardcopy LOI by post to Secretary-cum-Scientific Director, National Coordination Centre, Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Govt. of India, Raj Nagar, Sector-23, Ghaziabad-201 002.

For any further details please write to **pvpi.ipc@gov.in**

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

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

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

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

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

- निःशुल्क हेल्पलाइन नम्बर 1800-180-3024 (सोमवार से शुक्रवार प्रातः 9:00 बजे से सायं 5:30 बजे तक)
- मोबाइल ऐप (ADR PvPI)
- ए.डी.आर. मॉनीटरिंग सेंटर
- ए.डी.आर. रिपोर्टिंग फॉर्म

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

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

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

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

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

कोविड–19 महामारी के दौरान उपयोग होने वाली औषधियों से होने वाले दुष्प्रभाव की जानकारी कहाँ और कैसे दें

इसकी जानकारी आप फॉर्माकोविजीलेंस प्रोग्राम ऑफ इंडिया के अंतर्गत किसी भी निकटवर्ती ए०डी०आर० 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/Suggestions/ Query 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

ADR reporting Helpline (Toll Free): 1800-180-3024