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Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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PvPI - Building A Patient Safety Culture in India

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National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI),
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Newsletter CONTENTS

Message from the Desk of
Secretary-cum-Scientific Director

Dear Readers,

I am delighted to release the Pharmacovigilance Programme of India (PvPI) Newsletter Volume 12, Issue 1 for the index period from January, 2022 to March, 2022. This issue highlights the role of PvPI for the building of patient safety culture in India.

In this quarter, 29 new Adverse Drug Reaction Monitoring Centres (AMCs) have been enrolled under PvPI and total number of AMCs became 534 from 505 across the country. As on date, a total of 5.76 Lakh Individual Case Safety Reports have been reported to PvPI. The PvPI is regularly sensitizing its stakeholders about the pharmacovigilance and reporting of adverse event through awareness programmes, trainings, workshops, Skill Development Programmes, Continuing Medical Education (CME) etc. The PvPI has organized a total of 4111 training programmes and trained a total of 206989 participants in the area of pharmacovigilance.

In building patient safety culture, PvPI has taken many initiatives in the past and one of the important was the celebration of National Pharmacovigilance Week, 2021 with the objectives to create awareness amongst the public and for building a patient safety culture in India. There is a diversified pool of stakeholders for creating awareness about PvPI. Therefore, it was suggested to engage the organizations involved in public dealings to disseminate information about reporting of Adverse Events (AEs) at prominent locations.

The Marketing Authorization Holders (MAHs)/ Pharmaceutical Industries are responsible to set-up the pharmacovigilance system at their site and for monitoring the safety profile of their marketed pharmaceutical products in India. Therefore, to build-up the patient safety culture, PvPI has continuously organised regional trainings and interactive sessions with MAHs/Pharmaceutical Industries to resolve their issues & challenges about the reporting of AEs to PvPI.

The NCC-PvPI, IPC is regularly sending drug safety advisories/drug safety alerts to our AMCs and healthcare professionals for the focussed pharmacovigilance and reporting of such adverse reactions to PvPI, if encountered with the use of drugs.

At global level, the NCC-PvPI, IPC being a World Health Organization-Collaborative Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services is providing technical support in terms of organizing training, workshop & capacity building in the area of pharmacovigilance to the SEARN Countries.

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

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

PvPI - Building A Patient Safety Culture in India

The PvPI's basic objective is to create a nationwide system for patient-safety by ensuring AEs/ADRs reporting, identification of new ADRs, analysis of the benefit-risk ratio of the marketed drugs and generation of evidence-based information on the safety of drugs. All these factors help the regulatory authority in the decision-making process on the use of medicines. PvPI collects and evaluates spontaneous reports of AEs due to use of medicines, vaccines, medical devices and herbal products from all healthcare professionals, AMCs MAHs/Pharmaceutical Industries and consumers/patients. To monitor and reporting of AEs/ADRs to NCC-PvPI, Adverse Drug Reactions Monitoring Centres (AMCs) have been set-up all over India.

In order to build-up the patient safety culture in India, PvPI has created awareness and sensitized HCPs, patient/consumer, public through National and International trainings/workshops/CME etc. and also trained the workforce in the area of pharmacovigilance.

Some activities done by PvPI for developing Patient Safety Culture in India

- Healthcare Professionals have been trained in the area of Pharmacovigilance by organizing various training programmes like Skill Development Programmes, Workshops, Advanced level training programmes, Continuing Medical Education etc.
- The PvPI, IPC has initiated the celebration of “National Pharmacovigilance Week” from 16th-23rd September, 2021 and will be celebrated every year in future.
- The PvPI, IPC has organized 10 days “International 5th Asia Pacific Pharmacovigilance Training Programme.
- The PvPI, IPC has organized 10 days “International 6th Asia Pacific Pharmacovigilance Training Programme.
- The PvPI hosted annual meet of 38th WHO-Programme for International Drug Monitoring Programme for national centre of Pharmacovigilance in World.
- Focussed Pharmacovigilance for Hydroxychloroquine used as prophylactic or treatment of COVID-19, Bedaquiline used in MDRTB etc.

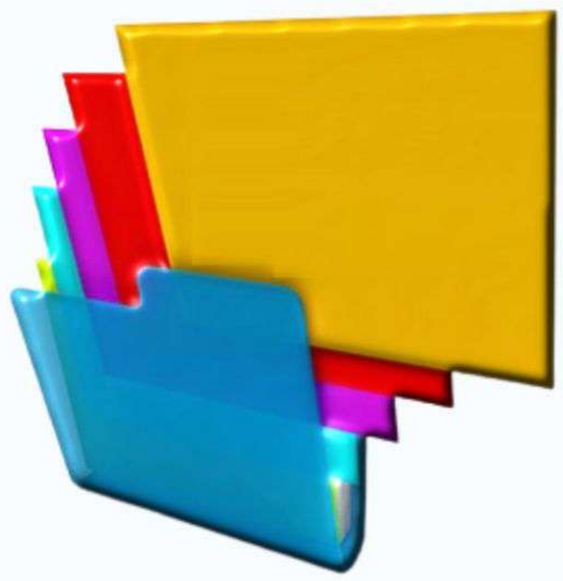
Tools Developed by PvPI

- The NCC-PvPI, IPC is in developing phase of Indigenous database-Adverse Drug Reaction Monitoring Software (ADRMS) for the processing of ICSRs.
- Android Mobile App “ADR PvPI” for consumer to report AE/ADR through mobile.

National & International Collaborations

- The PvPI has signed MOU with Public Health Programmes (PHPs) such as NTEP, NCVBDC, NACO & UIP-AEFI to capture the safety data reported with the drugs used in such programmes.
- The IPC designated as a WHO-Collaborative Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services in SEARN Countries. The PvPI, IPC is regularly sharing the drugs safety alerts, newsletter etc. with SEARN countries.

PvPI Resource Materials



- The PvPI has prepared Pharmacovigilance guidance document for MAHs/Pharmaceutical Industries and also separate guidance documents for AMCs.
- The PvPI has implemented the Quality Management System (QMS) and developed Standard Operating Procedurs (SOP) to ensure the quality of drug safety data reported in PvPI.
- The PvPI is regulary issuing its Newsletter on quarterly basis, Annual Performance Report, scientific publications, poster etc. and uploading on the webportal of PvPI, IPC to create awareness in public about the Pharmacovigilance.

Enrollment of new Adverse Drug Reaction Monitoring Centres

By enrolling of 29 new Adverse Drug Reaction Monitoring Centres (AMCs), the total number of AMCs has been increased from 505 to 534 AMCs across the Country. The list of newly enrolled AMCs is mentioned below;

S.No.	State	Name of Hospital / Medical College / Institute	Status
1.	Andhra Pradesh	Annamacharya College of Pharmacy, Boyanapalli	Government (General Hospital, Kadapa)
2.		Tirumala Multi Speciality Hospitals Pvt. Ltd, Near R.T.C. Complex, Vizianagaram-535003	Private
3.	Chhattisgarh	Shri Shankaracharya College of Pharmaceutical Sciences, SSTC Campus, Junwani, Bhilai-490020	Private
4.	Gujarat	Parul Institute of Pharmacy, Parul University, P.O Limda, Tal Waghodia, Vadodara , Gujarat-391760	Private
5.	Himachal Pradesh	All India Institute of Medical Sciences, Bilaspur, Himachal Pradesh-174001	Government
6.	Jharkhand	Sheikh Bhikhari Medical College & Hospital, Kolghatti, Hazaribag-825301	Government
7.		Raj Hospital, Mahatma Gandhi Main Road, Behind Central, Ranchi - 834001	Private
8.		Brahmananda Narayana Mutispeciality Hospital, Tamolia (Near Pardih Chowk) NH-33, Jamshedpur-831012	Private
9.	Karnataka	Nargund College of Pharmacy, Banashankari 3rd Stage, Bangalore-560085	Government
10		Sakra World Hospital, 52/ 2 & 52/ 3, Deverabeesanahalli, Varthur Hobli, Bangalore-560 103	Private
11		Sri Siddhartha Medical College and Research Center, Agalakote, BH Road, Tumakuru-572107	Private
12		Shridevi Institute of Medical Sciences and Research Hospital, Sira Road, Tumakara, Karnataka-India	Private
13	Kerala	Sree Uthradam Thirunal Academy of Medical Science's,Vattappara, Thiruvananthapuram-695028	Private

S.No.	State	Name of Hospital / Medical College / Institute	Status
14.	Rajasthan	Raj Jindal Hospital & Research Center Pvt. Ltd Bharatpur-321001	Private
15.		CKS Hospitals (A unit of CKS Medicare Pvt. Ltd.), Sikas Road, Vishwakarma Industrial Area, Jaipur-302013	Private
16.		CKRD Memorial Hospital & Research Centre, E-4, Indra Nagar, Jhunjhunu-333001	Private
17.		Dhanwantri Hospital & Research Center, 67 / 56- A New Sanganer Road, Mansarovar, Jaipur-302020	Private
18.		S. R. Kalla Memorial Gastro & General Hospital 78-79 Dhuleshwar Garden , Sardar Patel Marg C- Scheme, Jaipur-302001	Private
19.	Sikkim	Government Pharmacy College Sajong, Gangtok-737135	Government
20.	Tamil Nadu	Srinivasan Medical College & Hospital, Samayapuram ,Trichy-621112	Private
21.		Karpaga Vinayaga Institute of Medical Science & Research Centre, GST Road, Chinnakalambakkam, Maduranthgam-TK, Chengalpattu-603308	Private
22.		Government Medical College , Mullur Village, Pudukkottai - 622001	Government
23.		Swamy Vivekanandha College of Pharmacy/Vivekanandha Medical Care Hospital	Private
24.	Uttar Pradesh	Faculty of Pharmacy, Integral University , Lucknow-226026	Private
25.		Mahamana Pandit Madan Mohan Malviya Cancer Centre, Sunder Bagiya, B.H.U. Campus, Varanasi-221005	Government
26.		Autonomous State Medical College, Marehra Road, Village-Siroon, Etah-207001	Government
27.		G. S. Medical College & Hospital, NH-9, Pilkhuwa, Hapur-245304	Private
28.		Heritage Hospitals Ltd., Madhav Market , Lanka, Varanasi-221005	Private
29.	West Bengal	Peerless Hospitex Hospital and Research Center Ltd. 360, Panchasayar Road, Kolkata-700094	Private

Advisory issued by World Health Organization-Country office for India

➲ WHO on miltefosine- ocular adverse events in patients treated with miltefosine for Post-Kala-Azar Dermal Leishmaniais (PKDL)

Miltefosine is an alkylphosphocholine drug with demonstrated activity against various parasite species such as in the treatment of some forms of leishmaniaisis, an infection transmitted by certain types of sand flies. Leishmaniasis can take different forms, including cutanoeus (CL) and visceral leishmaniasis (VL).

Post-Kala-Azar Dermal Leishmaniasis(PKDL) is a sequel occurs 6 months to several years after apparent cure of VL. There have been many reports of ocular disorders originated from India, where miltefosine has been used in VL patients for 28 days and for the period of 12 weeks in PKDL. Ocular disorders include unilateral and bilateral blindness, ulcerative keratitis, leukocoria, blurred vision, ocular hyperemia, photophobia and eyepain. In some cases, symptoms get resolved after discontinuation of the treatment.

The issue was discussed by the WHO Advisory Committee on safety of Medicinal Products (ACSoMP) and groups of pharmacovigilance experts further review this safety signal. WHO is working closely with relevant stakeholders in India to further investigate this issue.

➲ WHO recommends that Healthcare Professionals:

- Take note of ocular conditions at the time of diagnosis of PKDL or other forms of leishmaniaisis requiring miltefosine treatment;
- Inform patients about the disease and potential risk of ocular infections, and advise them to immediately contact a healthcare professional of any ocular disorder occurs;
- Report ocular adverse event to national pharmacovigilance centre;
- Consider cessation of treatment with miltefosine and consult ophthalmologist for investigation and management

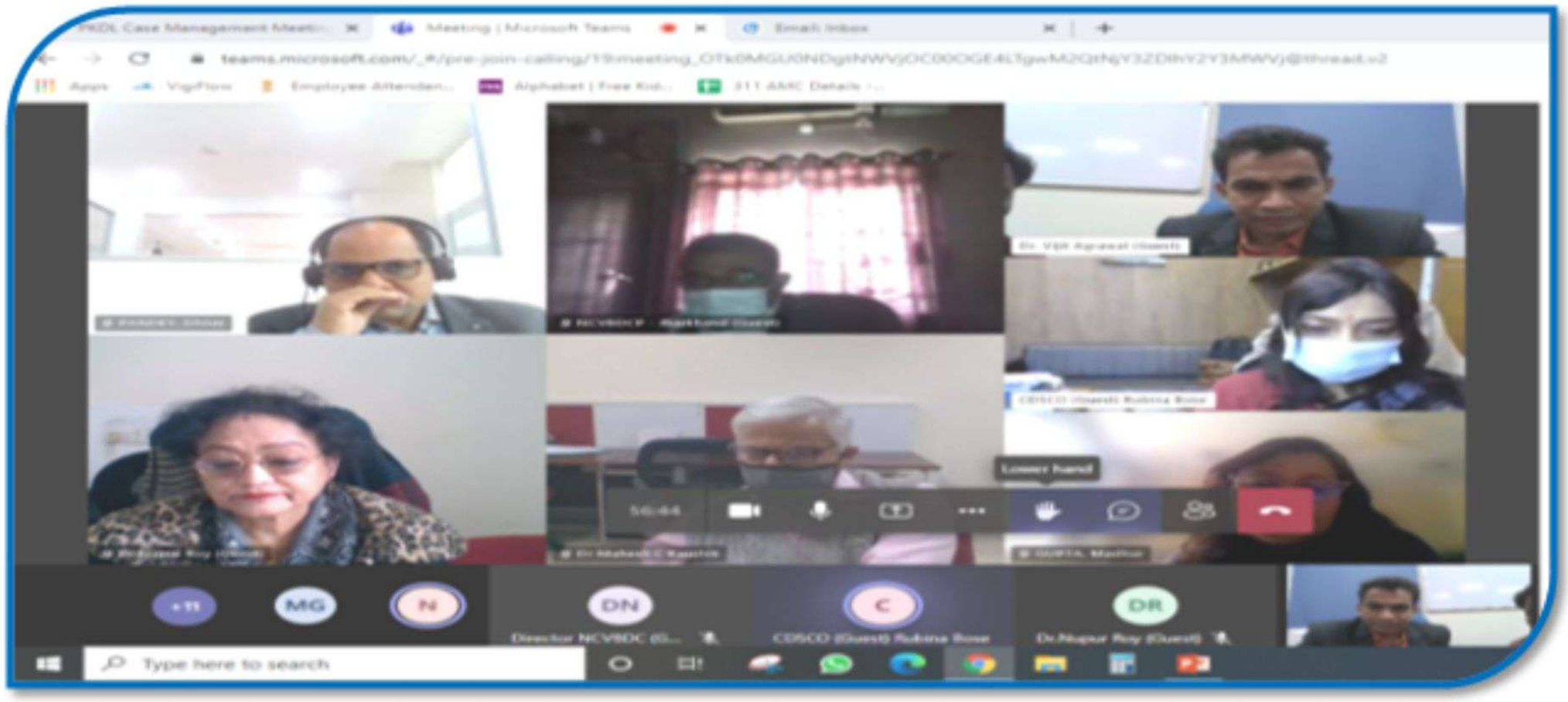
➲ Reference:

https://www.who.int/news/item/10-02-2022-statement-on-miltefosine---potential-ocular-disorders-in-patients-treated-with-miltefosine-for-post-kala-azar-dermal-leishmaniasis-(pkdl)

Meeting with National Centre for Vector Borne Disease Control (NCVBDC)

A virtual meeting on "Post Kala Azar Dermal Leishmaniasis (PKDL) case management" was organized by National Centre for NCVBDC under the Chairmanship of Director, NCVBDC on 10th January, 2022. A total of 16 participants from PvPI-IPC, WHO, NCVBDC & CARE foundation have attended this meeting. The outcomes of this meeting were as:

- The testing procedures of Miltefosine to be collected from the Marketing Authorization Holders.
- The NCC-PvPI, IPC should provide training to the Vector Borne Diseases staffs to improve ADR reporting from the field.



Meeting with NACP officials

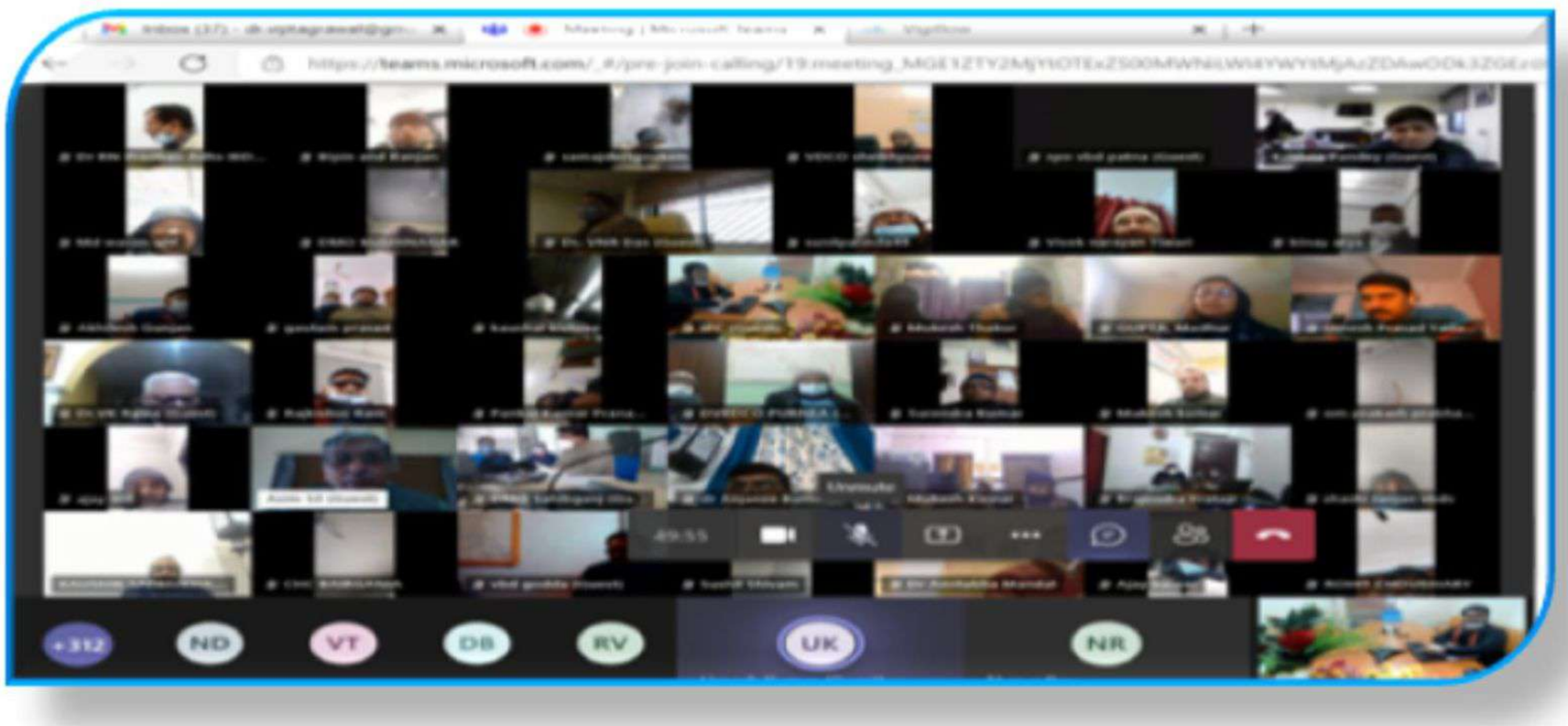
A joint meeting between PvPI-IPC & National AIDS Control Programme (NACP) was organized virtually on 14th January, 2022. A total of 12 participants from PvPI-IPC & NACP have attended this meeting. The agenda of this meeting was to discuss the various issues & challenges related to the ADR reporting from the Anti Retroviral Therapy (ART) centres in India. In this meeting, it was decided that PvPI should prepare a mutual plan to foster the ADR reporting from these centres.

Sensitization on SGLT2 inhibitors related Genital Infections

The NCC-PvPI sensitized the AMCs under the PvPI for monitoring and reporting of Adverse Reactions related to the use of SGLT2 inhibitors on February 26, 2021. 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. This 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.

The above-stated communications followed the safety announcements by Health Canada and US Food and Drug Administration (USFDA) 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.

Sensitization Programme on Post Kala-Azar Elimination Programme



- A virtual sensitization programme for case management of Post Kala-Azar Dermal Leishmaniasis was held on 18th January, 2022. A total of 312 participants attended this meeting from PvPI-IPC, WHO, NCVBDC, CARE foundation and the States, Districts, and Blocks from four Kala Azar endemic states. During the meeting, Dr. Vijit Agrawal, Sr. Pv Associate, NCC-PvPI explained about the filling and uploading of ADR format for PKDL and Kala-Azar cases.
- A virtual sensitization programme for ADR Reporting in Kala-Azar (KA) Elimination Programme was also held on 28th January, 2022. A total of 300 participants attended this training session from PvPI-IPC, WHO, NCVBDC, CARE foundation and the States, Districts, and Blocks from four Kala-Azar endemic states. During the sensitization programme, Dr.Vijit Agrawal, Sr. Pv Associate, NCC-PvPI explained about how to log in to the New VigiFlow and Data Entry in New VigiFlow.

Meeting with National Medical Commission

A joint meeting held on 25th February, 2022 between PvPI, IPC and DrVijaya Lakshmi Nag, Member of Ethics and Medical Registration Board of National Medical Commission (NMC) at her office. The agenda of this meeting was for the expansion of Pharmacovigilance Programme of India.

Meeting with Pharmacovigilance Associates posted at AMCs

A virtual meeting with Pharmacovigilance Associates posted at AMCs under PvPI was held on 11th February, 2022 to discussed the performance of their AMCs. Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, IPC has given the direction to the Pharmacovigilance Associates for increasing the reporting of AE/ADR to PvPI. In order to increase the number of AMCs under PvPI, each Pharmacovigilance Associate should also sensitize the peripheral hospitals to become an ADR Monitoring Centre under PvPI.

Guest Lecture on Quality Management System for Patient Safety

The NCC-PvPI, IPC has arranged a guest lecture of Dr. B. K Rana, CEO, Quality Accreditation Institute, Noida on "Quality Management System for Patient Safety (QMS)"on 15th February, 2022. The NCC-PvPI, IPC has Quality Management System in-place, so the objective of this guest lecture was to learn about the importance of QMS for patient safety.

Meeting with Marketing Team of HDFC Bank

Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, IPC suggested that the banks shall aware their customers about the PvPI and its activities to promote the patient safety. In this context, NCC-PvPI, IPC has organized face to face meeting with marketing team of HDFC Bank, Ghaziabad on 24th February, 2022. The PvPI has shared the resource materials with them to create awareness amongst public about the reporting of ADRs to PvPI. The HDFC marketing team requested to PvPI for the designing of a single poster for disseminating such information and shared with them.

20th Signal Review Panel Meeting

The 20th Signal Review Panel Meeting under the chairmanship of Prof. Y. K Gupta was organised by PvPI through hybrid mode on 11th March, 2022 at NCC-PvPI, IPC. The agenda of this meeting was to confirm the Signal/Prescribing Information Leaflet changes identified by PvPI. A total of 24 experts have attended the meeting. The following suspected Drug-ADR combinations were recommended to be sent to CDSCO for taking appropriate regulatory action:

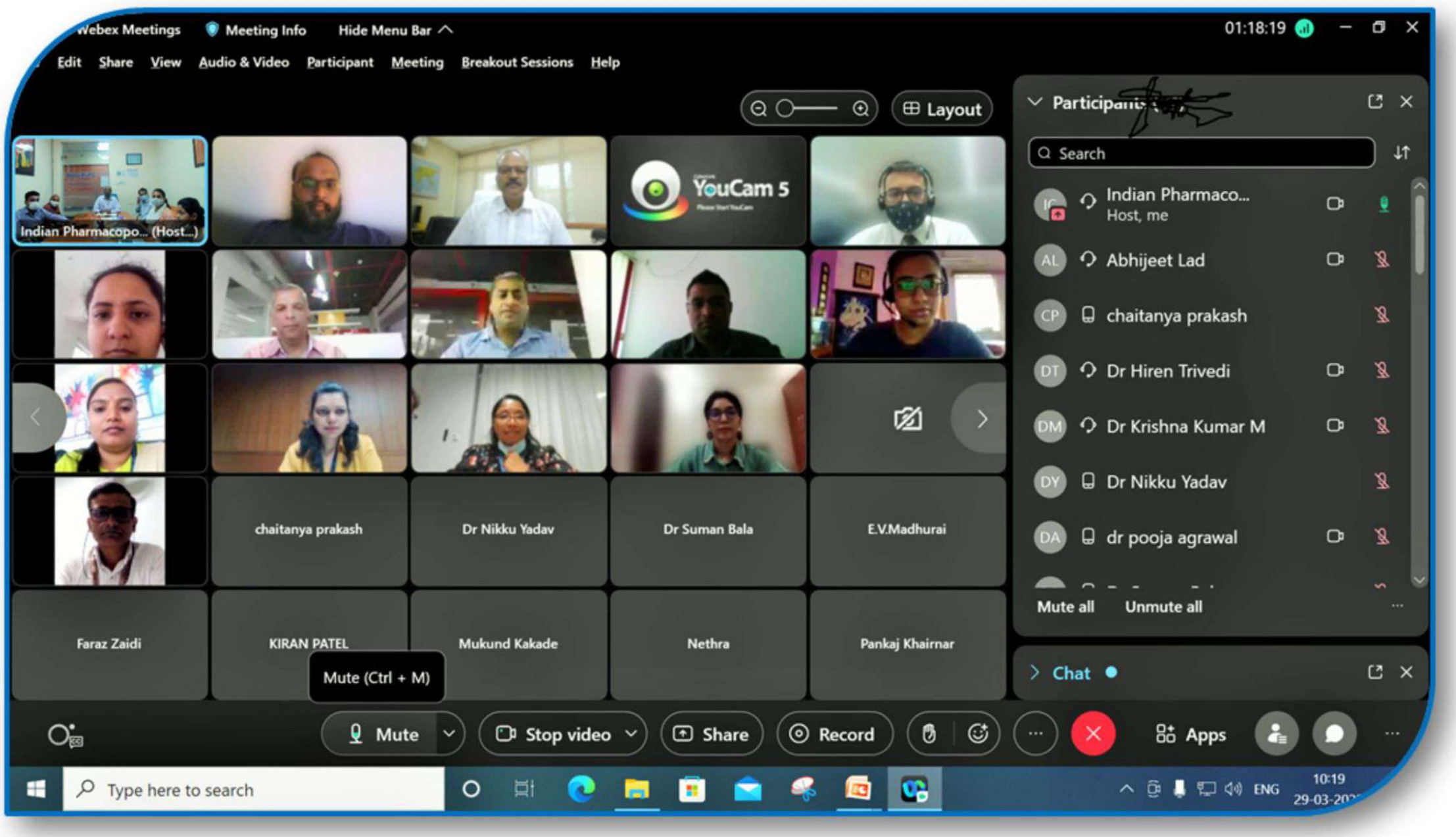
S. No.	Suspected Drugs	Adverse Drug Reactions	Recommendations of SRP
1.	Minoxidil	Folliculitis	Signal
2.	Tigecycline	Coagulopathy	PIL Changes
3.	Olanzapine	Hyponatraemia	PIL Changes
4.	Haloperidol	Cogwheel Rigidity	PIL Changes
5.	Cephalosporin Class	Fixed Drug Eruption	Signal
6	Remdesivir	Sinus Bradycardia	PIL Changes

15th Regional workshop for Marketing Authorization Holders

The NCC-PvPI, IPC has organized a virtual 15th regional workshop on “Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries - A Way Forward” for the Marketing Authorization Holders (MAHs)/Pharmaceutical industries on 29th March, 2022. A total of 35 participants have participated in this workshop. The objective of this workshop was to address the basic concepts of Pharmacovigilance & how the Pharmacovigilance system can be effectively implemented at MAHs/Pharmaceutical Industries and also focussed on the issues/challenges related to the submission of Individual Case Safety Reports (ICSRs) in E2B XML format to PvPI.

The Technical sessions of this workshop covered the following topics:

- An Overview of Pharmacovigilance Programme of India
- Establishment of Pharmacovigilance system & Good Pharmacovigilance Practices (GvP)
- Post marketing assessment of new drugs as per NDCT Rules, 2019



A virtual Interactive session with Intas Pharmaceutical Limited

The NCC-PvPI, IPC has conducted virtually interactive session with Intas Pharmaceutical Limited on 30th March, 2022 to discuss the quality related issues of ICSRs submitted by them to PvPI. The following points were discussed in the session;

- Completeness score of ICSRs submitted by Intas Pharmaceutical Limited to PvPI
- Importance of different quality parameters like drug information, adverse event, patient details etc.
- Lack of information in the ICSRs.
- The NCC-PvPI, IPC has suggested the following points to improve the quality of ICSR:
- Mandatory fields must be provided to validate the ICSR
- Adverse Event should be coded appropriately
- Information regarding start & stop date of suspected drug along with its indication, Time to Onset (TTO) & outcome of reaction etc.
- Case narrative must cover all the information filled in the ICSR
- Communication regarding generated queries after review of ICSR by PvPI must be responded within time frame to expedite the case processing.

Virtual Training on Pharmacovigilance for NABH Accredited Hospitals

The NCC-PvPI, IPC has organized one day virtual workshop-cum-training programme on 21st January, 2022 to train the NABH accredited hospitals staffs on Pharmacovigilance. The objective of this event was to provide a platform for the NABH-Accredited Hospitals to understand the systems, procedures involved in ADR-reporting and relevant practices. A total of 96 healthcare professionals from various government & private hospitals across the country have attended this training programme. In technical session, following topics were discussed;

- Current Updates on Pharmacovigilance Programme of India
- Importance of ADR reporting for
- NABH Accredited Hospitals in India
- Monitoring & Reporting AEs/ADRs (Methodology, Forms & Formats)
- Setting of a Pharmacovigilance system in a hospital
- Causality Assessment: Logics & Methods

Continuing Medical Education on Pharmacovigilance

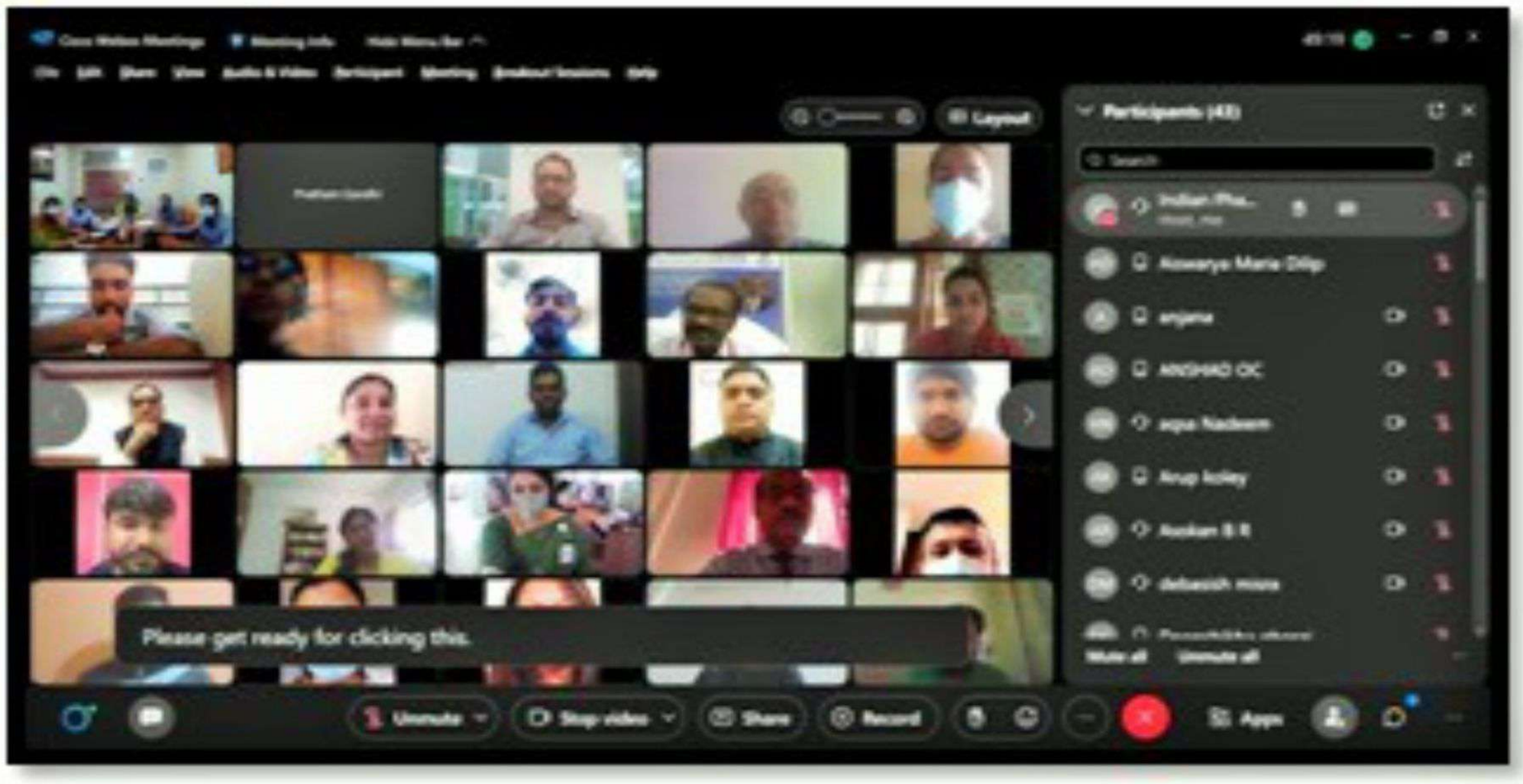
The Madras Medical College, Chennai being a Regional Training Centre of PvPI has organized one day virtual Continuing Medical Education (CME) programme on "Essentials of Pharmacovigilance towards Patient safety" on 10th February, 2022. A total of 256 healthcare professionals have participated in this training event. In technical session of this event, the following topics were discussed:

- Pharmacovigilance & Pharmacovigilance Programme of India – An overview
- Materiovigilance & Haemovigilance
- Vaccine Vigilance – AEFI
- Causality Assessment of ADRs
- Signal Detection Methods
- Signal management/Regulatory management

Advance Level Training in King Edward Memorial Hospital & Seth Gordhandas Sunderdas Medical College, Mumbai

The King Edward Memorial Hospital and Seth Gordhandas Sunderdas Medical College (KEM), Mumbai as a Regional Trainer Centre of PvPI has organized virtually one day Advanced Level Training Programme on **"The Art and Science of Benefit-Risk analysis"** on 19th February, 2022. In this training programme, Dr Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, IPC addressed on Pharmacovigilance Program of India - A Perspective from Indian Pharmacopoeia Commission. A total of 25 healthcare professionals have participated in this training programme. The objective of this training programme was to sensitized the HCPs about the Pharmacovigilance activities and reporting of ICSR to PvPI.

20th Skill Development Programme on Pharmacovigilance of Medical Products



The NCC-PvPI organized virtualy 20th Skill Development Programme on Pharmacovigilance for Medical Products from 07th to 11th March, 2022 through virtual mode. The training started with welcome address by Dr. Jai Prakash, Officer-in-Charge, PvPI and extended his warm greetings and best wishes to all the participants on behalf of IPC.

A total of 81 registered participants from Puducherry, Uttar Pradesh, Tamil Nadu, Kerala, Maharashtra, Karnataka, Telangana, Delhi, Andhra Pradesh, Odisha, West Bengal, Uttarakhand, Punjab, Bihar, Madhya Pradesh, Rajasthan, Jammu and Kashmir participated in this training programme. The participants included Academicians, Pharmacy Students, Medical Students, Industry Professionals, Physicians, Pharmacist, Pharmacovigilance Associate across the country.

During the 5 days Skill Development Programme, 19 technical sessions were conducted on various topics of Pharmacovigilance including Basics of Pharmacovigilance to in-depth signal detection method and Regulatory

intervention/outcomes in an understandable language to the participants. Prof. Y K Gupta, National Scientific Coordinator PvPI addressed all participants by his closing remarks. All participants appreciated the Skill Development Programme.

Some of other Important Trainings/Meetings/ Webinars/Workshops

A total of 220 Trainings/Meetings/Webinars/Workshops have been organized by PvPI as well as in collaboration with RTCs/AMCs during this tenure. Some of them are as follows:

S. No.	Title	Date	No. of Participants
1.	Awareness sensitization activity on **"PvPI and ADR Tollfree Number"** on field at Govt. School illage , Bhasin and Arasnara at CMMCH, Durg, Chhattisgarh	5th January, 2022	80
2.	Sensitization on preparatory measures on **identification of ADR and target setting -an integrated approach** at Government Medical Collage, Nilgiris	29th January, 2022	12
3.	Online interation on **clinical perspective** at SDSRTC, Bangaluru	30th January, 2022	73
4.	**Reporting tools of AEFI filling and ADR reporting** at srivenkateswara Medical College, Tirupati	31st January, 2022	54
5	**Signal Detection in Pharmacovigilance** at JSS Medical College & Hospital, Mysuru	18th February, 2022	60
6.	CME on **Pharmacovigilance and Medicine Safety**, AIIMS, Bhatinda	18th February, 2022	103
7.	Seminar on **Materiovigilance Reporting and sensitization** for medical students, Doctors, Healthcare Professionals at College of Medicine & JNM Hospital Nadia ,West Bengal	3rd March, 2022	11
8.	GMC/GGH-Guntur organized Sensitization program on **Safe administration of Albendazole on National De-worming day's** in Municipal High School, Sarada High School, Guntur	7th March, 2022	280
9.	Online webinar on **"Preventing ADR in women population"** for KMCH College of Pharmacy - Womens day 2022 at Karpagam Faculty of Medical Sciences & Research, Coimbatore	8th March, 2022	280
10.	JSS Medical College & Hospital organised awareness program on **Reporting of ADRs among Rural Population**	26th March, 2022	166

New Drugs Approved in India

The following new drugs were approved by CDSCO between January 2022 to March 2022:

Drug	Indication
Triamcinolone Hexacetonide injectable suspension 20 mg/ml	For intra-articular, intra-synovial or periarticular use in adults and adolescents for the symptomatic treatment of sub-acute and chronic inflammatory joint diseases including rheumatoid arthritis and Juvenile Idiopathic Arthritis (JIA), Osteoarthritis and posttraumatic arthritis, Synovitis, tendinitis, bursitis and epicondylitis.
Gimeracil bulk & Oteracil potassium bulk and Tegafur 15 mg/ 20 mg, Gimeracil 4.35 mg/ 5.8 mg and Oteracil 11.8 mg/ 15.8 mg capsules	Indicated in adults for the treatment of advanced gastric cancer when given in combination with cisplatin.
Nitric oxide nasal spray 1400 mcg/ 1600 mcg	For treatment of adult high risk patients with mild COVID-19 having risk of progression of the disease.
Vericiguat tablets 2.5 mg/ 5 mg/ 10 mg	Indicated to reduce the risk of cardiovascular death and Heart Failure (HF) hospitalization following a hospitalization for heart failure orneed for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%
Inosinepranobex bulk and Inosinepranobex 500 mg tablet	As add on therapy for treatment of mild COVID-19 patients with co-morbidities and moderate COVID-19 patients, in light of COVID 19 outbreak for restricted emergency use in the country.
Desidust at bulk and Desidust at tablets 25 mg and 50 mg	For treatment of Anemia in adult patients with chronic kidney disease (CKD) not on Dialysis and on Dialysis

Drug Safety Alerts

identified & issued by PvPI from January 2022 to March 2022

S. No.	Issuing Date	Suspected Drugs	Indication(s)	Adverse Drug Reactions
1.	18th January, 2022	Ibuprofen	For the treatment of chronic arthritic disorders and painful musculoskeletal conditions.	Fixed Drug Eruption
2.	28th February, 2022	Losartan	For the treatment of hypertension	Muscle Spasm
3.	17th March, 2022	Cephalosporin Class	Cephalosporins are beta-lactam antimicrobials used to manage a wide range of infections from Gram-positive and Gram-negative bacteria	Fixed Drug Eruption

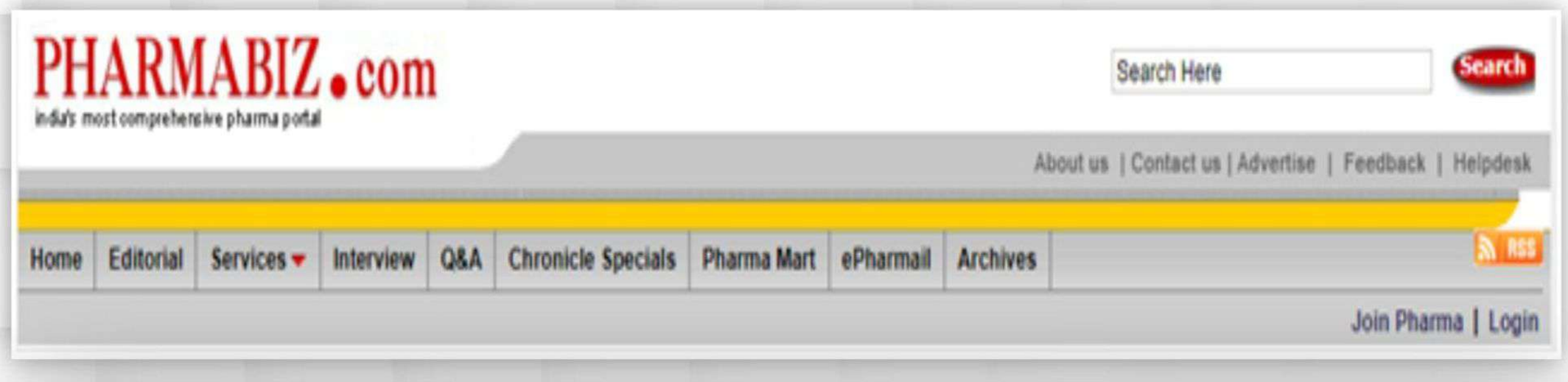
☞ **Healthcare Professionals (HCPs), patients/consumers are advised to closely monitor the above mentioned ADRs associated with the use of the above suspected drugs. If such reactions are encountered, please report to the NCC-PvPI, IPC by filling up Suspected Adverse Drug Reactions Reporting Form for 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)**

Drug Safety Alerts - Other countries vs PvPI

S. No.	Suspected Drugs	Adverse Drug Reactions (ADRs)	Total No. of ICSRs in other Countries	Total No. of ICSR(s) in PvPI data	Reference
1.	Remdesivir	Sinus Bradycardia	116	08	WHO Pharmaceuticals Newsletter No. 1, 2022
2.	Methotrexate	Muscle Spasms	594	01	
3.	Sorafenib	Tumour lysis syndrome	30	03	https://www.ema.europa.eu/en/documents/prac-recommendation/prac-recommendations-signals-adopted-7-10-february-2022-prac-meeting_en.pdf

☞ **HCPs are advised to carefully monitor the above mentioned ADRs reported with the use of suspected drugs. If such ADRs are encountered, please report to NCC-PvPI, IPC.**

PvPI in Press Media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IPC flags safety alert against nonsteroidal anti-inflammatory drug, ibuprofen

Laxmi Yadav, Mumbai

Tuesday, February 1, 2022, 08:00 Hrs [IST]

The Indian Pharmacopoeia Commission (IPC), which is the National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI), has flagged drug safety alert revealing that ibuprofen, a nonsteroidal anti-inflammatory drug (NSAID) which is used to treat pain and inflammatory diseases, is linked with adverse event known as fixed drug eruption.

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

Ibuprofen, one of the most popular over the counter medicines, is used as an analgesic, anti-inflammatory and antipyretic. It is indicated for the treatment of chronic arthritic disorders and painful musculoskeletal conditions. Unlike most other NSAIDs, ibuprofen also acts as an inhibitor of Rho kinase and is useful in recovery from spinal-cord injury.

Ibuprofen works by inhibiting the cyclooxygenase (COX) enzymes, which convert arachidonic acid to prostaglandin H2 (PGH2). PGH2, in turn, is converted by other enzymes to several other prostaglandins (which are mediators of pain, inflammation, and fever) and to thromboxane A2 (which stimulates platelet aggregation, leading to the formation of blood clots).

As per drug safety alert issued by IPC on January 18, 2022, ibuprofen is associated with fixed drug eruption, a distinctive type of cutaneous drug reaction that characteristically recurs in the same locations upon re-exposure to the offending drug.

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

IPC had earlier also flagged drug safety alerts revealing that Covid-19 drug remdesivir was linked to an adverse event known as sinus bradycardia.

Besides this, it had earlier also flagged drug safety alerts revealing that diclofenac, a NSAID, was linked to skin hyperpigmentation while dimethyl fumarate, used for relapsing-remitting multiple sclerosis, was associated with adverse drug reaction alopecia.

Cefazolin, a cephalosporin antibiotic, was linked to acute generalized exanthematous pustulosis (AGEP), according to the preliminary analysis of ADRs from the PvPI database.

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

Reference: http://www.pharmabiz.com/NewsDetails.aspx?aid=145542&sid=1

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DCGI directs state DCs to ask cos to get product licenses of 2,131 FDCs approved by Kokate Committee

Shardul Nautiyal, Mumbai
Wednesday, January 15, 2020, 08:00 Hrs [IST]

The Drugs Controller General of India (DCGI) has directed state drug controllers (DCs) to ask manufacturers to get manufacturing licenses of 2,131 new fixed dose combinations (FDCs) approved by Prof. Kokate Committee and the DCGI.

This is in continuation to the DCGI letter to state DCs dated December 12, 2018 whereby all the state DCs were requested to ask the concerned manufacturers to follow the procedure for getting manufacturing licenses as stipulated by the Central Drugs Standard Control Organization (CDSCO) (FDC Division).

As per the DCGI letter to the state DCs, in continuation to the said letter, it may be noted that apart from these 1,681 FDCs, further there are 450 more FDCs which have been declared as rational by the committee and report of the committee has been accepted by the union health ministry.

Accordingly with approval of the Union health ministry, it has been now decided to follow a specific pathway for grant of product licenses by the State DCs for these FDCs.

Manufacturers shall submit the requisite fees preferably through Bharatkosh for each FDC to CDSCO as specified under Drugs and Cosmetic (D&C) Act, 1940 and existing Rules thereunder.

The manufacturer/applicant shall submit application to the concerned DC for grant of product manufacturing license giving the details of FDC, serial number of the FDC in the list, stability studies data (6 months accelerated), test specification of the FDC alongwith method of analysis as well as label and other documents as required for grant of product license under D&C rules.

The state DC shall grant the product license of such FDCs without seeking NOC from DCGI, if other conditions of license under the D&C Rules, which need to be verified by state licensing authority (SLA) are found to have been fulfilled. The SLAs shall verify the quality of such FDCs of each applicant or manufacturer before grant of license.

DCGI further stated that every manufacturer permitted to manufacture these FDCs shall submit the periodic safety update reports (PSURs) as per new drugs and clinical trial rules - 2019 to the central licensing authority as defined in Rule 3 i.e. DCGI. Failure to submit the PSURs shall be considered as contravention of these rules.

Union health ministry had on September 16, 2014 constituted a committee under the chairmanship of Prof C K Kokate, former vice-chancellor, KLE University, Belgaum, Karnataka for examining the safety and efficacy of unapproved FDCs which were licensed by the SLAs without due approval of DCGI.

After holding a series of meetings the Kokate Committee had submitted its second assessment report to the Union health ministry on May 27, 2016 categorizing FDCs into "irrational (category 'a')", "requiring further deliberation (category 'b')", "rational (category 'c')" and "FDCs requiring generation of data (category 'd')".

Reference: http://pharmabiz.com/PrintArticle.aspx?aid=145700&sid=1

PvPI recommendations published in WHO Pharmaceutical Newsletter

World Health Organization

WHO Pharmaceuticals NEWSLETTER

2022 No. 1

Tinidazole

Risk of fixed eruption

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

Tinidazole is indicated for the treatment of intestinal amoebiasis, giardiasis, trichomoniasis and anaerobic infections.

NCC-PvPI, IPC reviewed 71 case reports of tinidazole associated fixed eruption and a strong causal relationship between them was found.

Reference:

Based on the communication from IPC, India, November 2021 *(ipc.gov.in)*

Tramadol

Risk of urinary retention

India. The NCC-PvPI, IPC has advised the CDSCO to revise the PIL for tramadol to include urinary retention as an adverse drug reaction.

Tramadol is indicated for the treatment of moderate to severe pain, diagnostic procedures and surgical pain.

NCC-PvPI, IPC reviewed seven reports of tramadol-associated urinary retention and a causal relationship between them was found.

Reference:

Based on the communication from IPC, India, November 2021 *(ipc.gov.in)*

Rajagiri Hospital – AMC, Aluva, Kerala

Rajagiri Hospital, Aluva is an ambitious undertaking of the CMI group of institutions. Our hospital is JCI & NABH accredited. To live up to our vision statement ***"To give life abundantly"*** we strive continuously to provide most advanced and holistic services to patient emphasizing patient safety in letter and spirit. The Department of Clinical Pharmacology spearheads the medication safety programme in our hospital. Moreover, we are accountable for the operations in pharmacovigilance activities. The Rajagiri hospital Aluva has been working as an ADR Monitoring Centre under PvPI since 2017. We have two pronged approach in identifying adverse drug reactions in our hospital.

Active surveillance – The clinical pharmacists interact with patients as a part of daily ward rounds and report ADRs to department of clinical pharmacology.

Passive surveillance – By continuous training and sensitization to all stake holders, we are encouraging all healthcare professionals and patients for voluntarily reporting adverse drug reactions to department of clinical pharmacology.

The causality assessment of the reported adverse reactions are carried out by our Causality Assessment Committee (CAC) having Dr. Dinu Varghese MD (Consultant & HOD, Clinical Pharmacology and AMC Coordinator), Dr. Renji Jose MD (Senior consultant, General medicine) and Dr. Eldho Mathew Paul PharmD (Senior Clinical Pharmacist & Deputy AMC coordinator).

Over the past few months, our ADR reporting trend reached new heights under the leadership of Dr Dinu Varghese MD. We are able to ensure the quality of ICSRs reported from our end by appropriate linking of safety reports and nullifying case duplication. The centre is also successful in conducting various sensitization and awareness programmes in pharmacovigilance activities to healthcare professionals. We look forward for an everlasting association with PvPI.

Chalapathi Institute of Pharmaceutical Sciences, Guntur

The Chalapathi Institute of Pharmaceutical Sciences, Guntur organised “Medication Safety Day” under PvPI, IPC on February 8, 2022. A total of 30 participants have participated in this event. The objectives of this event were as;

- To educate the usage of medication in each ward
- To observe LASA (Look alike and Sound alike)
- To keeping different drug cards
- To analyse the dose and dispensing errors
- To give better patient safety

Velammal Medical College Hospital & Research Institute, Madurai, Tamil Nadu

In Velammal Medical College Hospital and Research Institute (VMCHRI), Madurai, Pharmacovigilance Committee was formed on 27th January, 2014. The National Coordination Centre (NCC), Ghaziabad designated Velammal Medical College Hospital and Research Institute, Madurai as an AMC on 8th July, 2015. Since then we have been sending ADR reports to the NCC. Causality Assessment Committee of pharmacovigilance was framed as per IPC recommendations on 27th January, 2016.

Pharmacovigilance activities are carried out under the supervision of Dr. Raj Kishore Mahato, Coordinator and Head of the department of Pharmacology. As a part of our AMC activity, we conducted training programme, awareness and certification course on Pharmacovigilance every month to the healthcare professionals for ensuring Good Pharmacovigilance Practices (GvP) in the Country.

The National Pharmacovigilance Week (NPW) was celebrated between 17th – 23rd September, 2021. During NPW, awareness program on ADR reporting, e-poster competition, essay writing competition were organized for the students and 2nd year MBBS students have also prepared a short film on “Medication Errors” for the sensitization of HCPs.

Feedback from AMC Stakeholders

Dr Raj Kishore Mahato
AMC Coordinator
(Professor and Head of Pharmacology)
Velammal Medical College Hospital and Research Institute

Promoting safe use of medicines is a priority of Indian Pharmacopoeia Commission (IPC) that functions as the National Coordination Center (NCC) for Pharmacovigilance Programme of India (PvPI). We, Velammal Medical College Hospital and Research Institute, Madurai are pleased to have an AMC since July, 2015 and working as a multidisciplinary team. Day to day activities are managed by Ms. John Flamitha, Junior Pharmacovigilance Associate at our AMC. In the interest of patient safety and contributions to Pharmacovigilance Programme of India, we are involved in several activities like organizing awareness program on ADR reporting for public and students, CMEs, seminars etc. The NCC communicates, guides and extends full support for the smooth functioning of AMC activities as per need.

Dr. Minakshi Parikh
AMC Coordinator
(Prof. and Head Psychiatry)
BJ Medical College, New Civil Hospital
Asarwa, Ahmedabad, Gujarat

Drug safety is of overriding importance in india with it's diverse population of patients. Safe and effective management of patients is the ultimate goal of all healthcare providers. Pharmacovigilance Program of India (PvPI) has helped us to achieve our goal by boosting awareness about drugs safety and enhancing it.

13th-17th June 2022	12th-16th September 2022	17th-23rd September 2022
21st Skill Development Programme & Pharmacovigilance of Medical Products	22nd Skill Development Programme & Pharmacovigilance of Medical Products	National Pharmacovigilance Week
Last Date of Registration 7th June 2022	Last Date of Registration 6th September 2022	Last Date of Registration Not Applicable

For more information log in to https://www.ipc.gov.in/PvPI/pv_home.html

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

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, बुखार, रक्तचाप (उच्च/निम्न), सिरदर्द या अन्य कोई दुष्प्रभाव प्रतीत होता है तो ऐसी स्थिति में अपने चिकित्सक से या नजदीकी अस्पताल में जाकर चिकित्सक से परामर्श लें।

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

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

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

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

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

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

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

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

इसकी जानकारी आप फॉर्माकोविजीलेंस प्रोग्राम ऑफ़ इंडिया के अंतर्गत किसी भी निकटवर्ती ऐ॰ डी॰ आर॰ मॉनिटरिंग सेंटर पर दे सकते हैं। इस सम्बन्ध में एक विशेष फॉर्म- Suspceted 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

Indian Pharmacopoeia Commission
National Coordination Centre,
Pharmacovigilance Programme of India
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Tel.: 0120-2783400, 2783401, 2783392

For any other information/Suggestion/ Query, please contact:
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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