



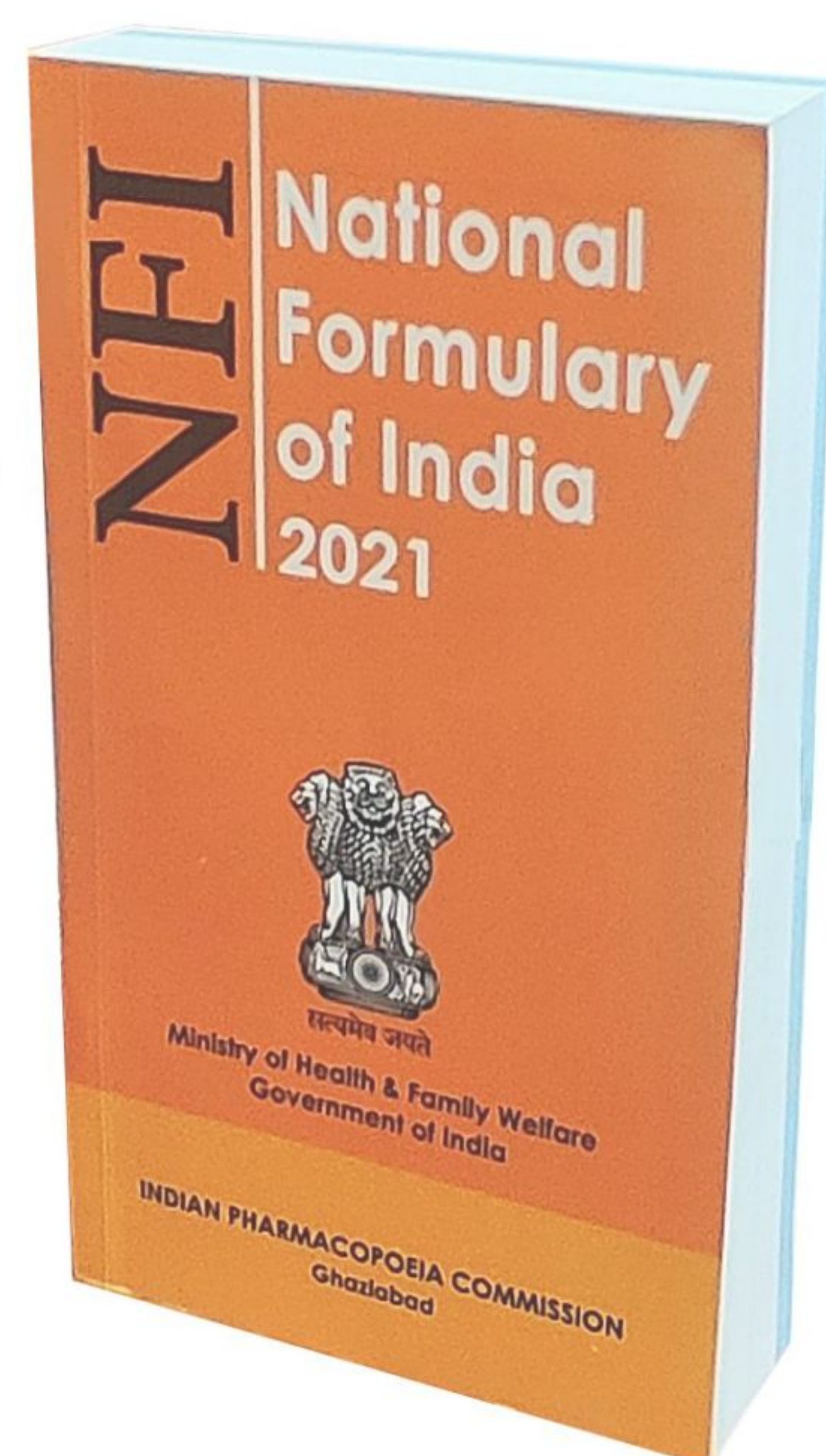
Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

VOL 11 | ISSUE 37 | 2021

National Formulary of India

for safe & rational prescribing of medicines



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

Cover Story

- 05** PvPI Achievement in 2021

Notable Events

- 07** Sixth Edition of National Formulary of India launched by Union Minister for Health and Family Welfare
- 07** #MedsafetyWeek 2021
- 08** 19th Signal Review Panel Meeting
- 08** Medsafety Week Celebration & Inauguration of Regional Training Centre (RTC), Amrita Institute of Medical Sciences
- 08** Meeting with Indian Medical Association (IMA) for PvPI expansion
- 09** Pharmacovigilance sensitization activity as part of World Antimicrobial Week
- 09** National AEFI Meeting
- 09** Awareness programme about PvPI by Healthcopeia Foundation in collaboration with National Coordination Centre Pharmacovigilance Programme of India
- 10** Meeting of NCC-PvPI and NABH officials for the Expansion of Pharmacovigilance Programme of India (PvPI)
- 10** Meeting regarding review of ocular adverse events associated with the use of Miltefosine
- 11** FDA-INO meeting
- 11** Technical Advisory Committee held under the Chairmanship of Director General Health Services (DGHS)
- 12** Pharmacovigilance Conference organized by IMT Pharmacy College, Odisha
- 12** Visit of Dr Rajeev Singh Raghuvanshi to AMC at Osmania Medical College, Hyderabad

Training and Education

- 13** 19th Skill Development Programme
- 13** Induction-cum-Training Programme

- 14** Advanced Level Training in Pharmacovigilance at BJ Medical College, Ahmedabad
- 14** Webinar on Pharmacovigilance for Marketing Authorisation Holders
- 15** Pharmacovigilance workshop organized by the World Health Organization
- 15** Advanced Level training on Pharmacovigilance by IPGMER Kolkata
- 16** Training at Amrita Institute Medical Sciences, Kochi
- 16** Webinar on Good Pharmacovigilance Practices
- 17** Other Important Trainings/Meetings/Webinars/Workshops

New Drugs

- 18** New Drugs Approved in India

Drug Safety Alerts

- 19** Drugs safety alerts identified & issued by PvPI from October 2021 to December 2021
- 20** Drugs safety alerts issued by other countries and status of ICSRs in PvPI database

Mobile Application

- 21** ADR PvPI Mobile Application

PV Field Activities

- 22** Netaji Subhash Chandra Bose Subharti Medical College (SMC), Meerut, Uttar Pradesh
- 23** Amrita Institute of Medical Sciences (AIMS), RTC & AMC, Kochi, Kerala

Stakeholders Feedback

- 24** Feedback from AMCs

Forthcoming Events

- 25** Forthcoming Events

Message from the Desk of Secretary-cum-Scientific Director



Dear Readers,

I am glad to release the Pharmacovigilance Programme of India (PvPI) Newsletter Vol. 11, Issue 37 for the index period from October to December 2021. As this is last Issue of PvPI Newsletter in the year 2021, it highlights the achievements of 2021 apart from quarterly update. As a member of WHO Programme of International Drug Monitoring, India stands 9th rank in reporting of ICSRs based on PvPI data at global level.

With the approval of 61 New AMCs in 13th Phase, the number of AMCs were increased from 444 to 505 under the PvPI. The PvPI increased the Regional Training Centres from 9 to 12 in this quarter. The newly approved Regional Training Centres are - Amrita Institute of Medical Sciences, Kochi; Maulana Azad Medical College, New Delhi and Madras Medical College, Chennai.

It is noteworthy to mention that the Hon'ble Union Minister of Health & Family Welfare, Dr. Mansukh Mandaviya released the 6th Edition of National Formulary of India (NFI) 2021 on 28th October, 2021 at Nirman Bhawan, New Delhi. The objective of this guidance document is to promote the safe,

rational and economic prescribing of medicines. The NFI-2021 interalia gives coverage to Pharmacovigilance Programme of India (PvPI) alongwith Suspected ADR Reporting Forms for proper reporting of adverse events / adverse drug reactions by the all concerned.

During this index period, in the 19th Meeting of Signal Review Panel of PvPI held on 25th October, 2021 the following two signals were confirmed :

1. Mefenemic acid associated fixed drug eruption
2. Doxycycline associated fixed drug eruption

In this quarter, PvPI conducted 19th Skill Development Programme with participation from across the country (approx. 200 participants). A total of 101 training programmes were conducted under the ambit of PvPI and 5594 personnels were trained in Pharmacovigilance. The interactive meetings with AMCs and pharmaceutical industry continued to bring the improvement in the culture of reporting and quality of ICSRs being submitted to PvPI.

As a team, we will continue to work towards patient safety and I congratulate the PvPI team, AMCs & 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

Obituary



Prof. S.K Gupta
(17-07-1942 - 22-12-2021)

Prof. S. K. Gupta passed away on 22nd December 2021 at the age of around 79 years. He was National Scientific Advisor to Pharmacovigilance Programme of India (PvPI), Former Professor and Head, Department of Pharmacology, All India Institute of Medical Science (AIIMS), New Delhi; Former Dean & Director General of Institute of Clinical Research India (ICRI) and Distinguished Professor at Delhi Institute of Pharmaceutical Sciences and Research (DPSRU), New Delhi. He had more than 40 years experience of teaching/research at the prestigious Institutes/Universities. He was a great teacher and all time available personality having strong managerial skills. Indian Pharmacopoeia Commission (IPC) has established Dr. S. K. Gupta Block for Patient Safety in his name. Prof. Gupta was attached to PvPI and used to give his valuable advice from time to time for growth and development of PvPI. He had made outstanding efforts for improving the Pharmacovigilance system in India. Under his leadership India was enrolled as a member of WHO Programme for International Drug Monitoring. He was not only an advisor to PvPI but a visionary in Pharmacovigilance. Prof. Gupta was pioneer in promoting clinical research as well in India.

PvPI expresses profound grief on the demise of Prof. Gupta. PvPI family pray the Almighty to rest his soul in peace and give strength to his family and relatives to bear this irreparable loss. He will always remain in our heart and will keep inspiring the generation for his outstanding contribution in the area of Pharmacology and Pharmacovigilance.

PvPI Achievements in 2021

First National Pharmacovigilance Week celebrated Pan India

NCC-PvPI initiated the celebration of the First National Pharmacovigilance Week Pan India from 17th to 23rd September 2021 with the theme “Pharmacovigilance: A step towards patient safety”.

New Adverse Monitoring Centres (AMCs)

Enrolled 194 new AMCs. Total number of AMCs increased from 311 to 505 across the country.

Number of ICSRs & their completeness score

A total of 69,111 ICSRs were processed from 1st January to 1st December 2021 (Source: Vigilyze). The average completeness score of ICSRs maintained at about 0.7 out of 1.

Drug Safety Alerts

PvPI had issued 18 Drug Safety Alerts.

6th #MedSafetyWeek

PvPI participated in 6th #MedSafetyWeek” organized by WHO-UMC, Sweden from 1st to 7th November 2021.

Skill Development Programmes

NCC-PvPI organized 4 Skill Development Programmes in which 645 participants were trained.

Awareness-cum-Training Programmes (NCC + AMCs)

PvPI had conducted 748 training/awareness programmes in which 58,981 participants were trained.

Release of National Formulary of India (NFI) 6th Edition 2021

Dr. Mansukh Mandaviya, Hon'ble Union Minister for Health & Family Welfare released the 6th Edition of NFI 2021 on 28th October 2021.

Interactive meetings with MAHs

To improve the quality of ICSRs, PvPI conducted 6 online-interactive sessions with representatives of MAHs/ Pharmaceutical Industries.

Meeting with Professional Associations & Health Programmes

NCC PvPI organized meetings with IMA ,PCI, NABH & NCVBDC for PvPI expansion.

Renewal of PvPI as a WHO Collaborating Centre (WHO-CC)

The NCC PvPI redesignated as WHO-CC for Pharmacovigilance in Public Health Programmes & Regulatory Services for another term of four years.

Virtual Training Session for MedDRA

NCC PvPI organized Virtual Indian MedDRA User group meeting on 22nd March 2021.
Participants = 178

Virtual Trainings on AEFI

NCC PvPI organized Virtual Trainings for the AMCs on AEFI with special reference to Covid-19 vaccination on 7th & 13th January 2021.
Participants = 354

Suspected ADR Reporting Form Version 1.4 launched

Suspected ADR Reporting Form Version 1.4 was launched during the First National Pharmacovigilance Week (17th - 23rd September 2021).

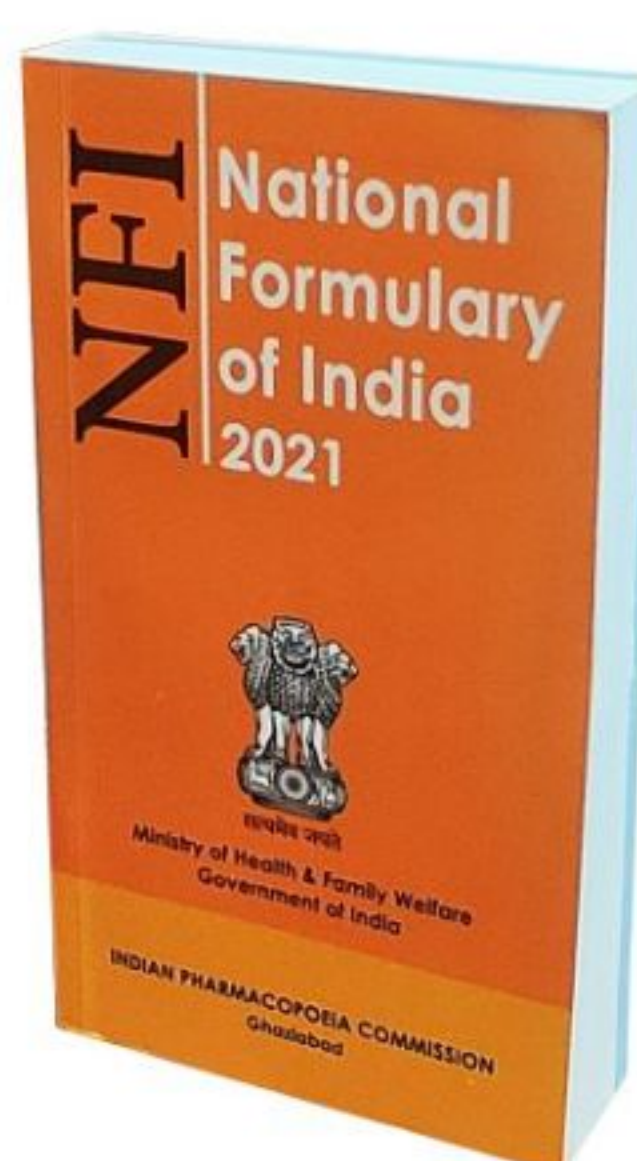
AMC Coordinators Meeting

AMC Coordinators meeting was held on 12th November 2021.

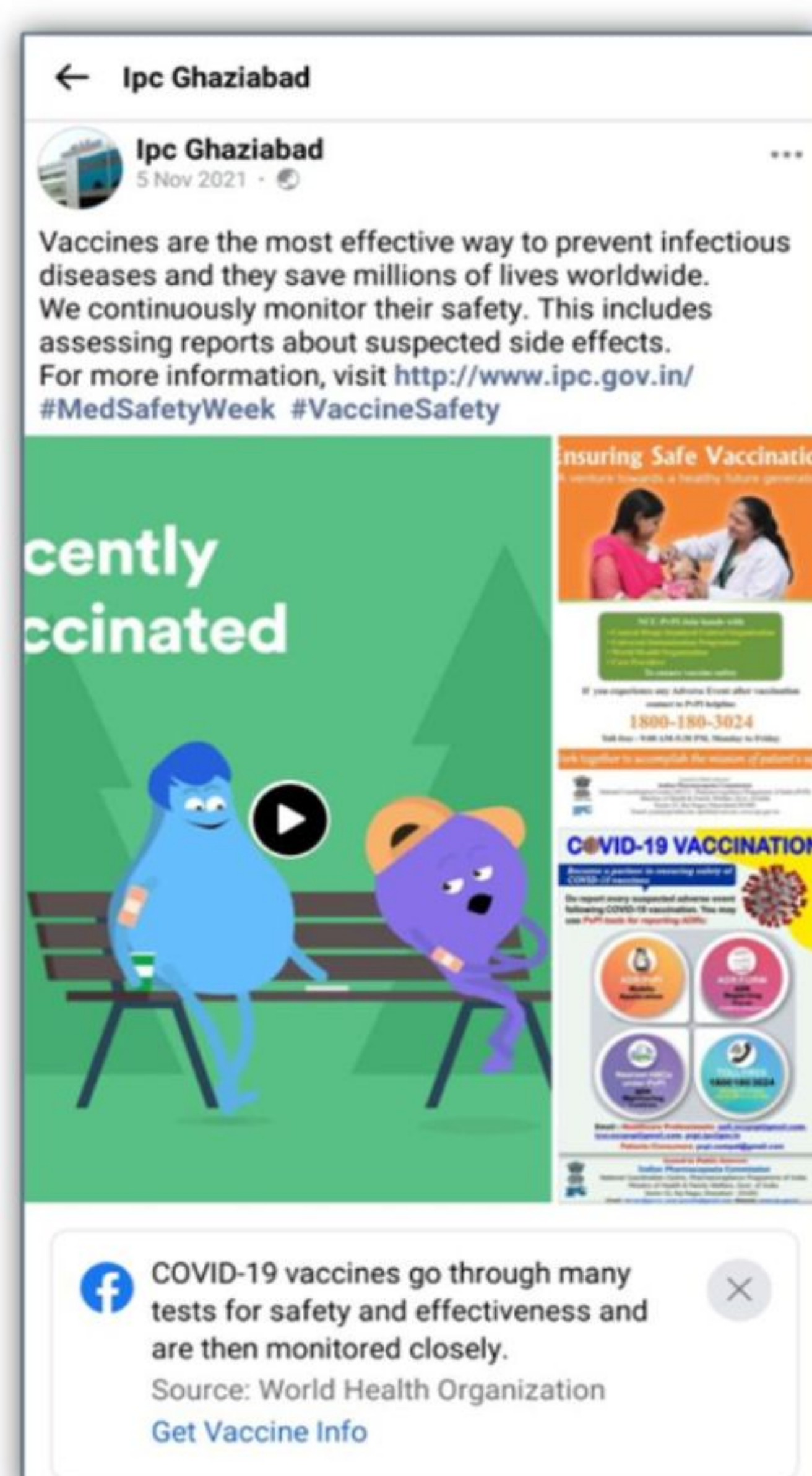
Sixth Edition of National Formulary of India launched by Union Minister for Health and Family Welfare



The Sixth edition of National Formulary of India 2021 was released by the Hon'ble Union Minister of Health & Family Welfare, Dr. Mansukh Mandaviya on 28th October 2021 at Nirman Bhavan, New Delhi. The objective of this guidance document is to promote the safe, rational and economic prescribing of medicines for



the patients. This edition is extensively revised keeping in view the current medical practices. It contains 34 therapeutic categories chapters including 591 drug monographs and 23 appendices. It also incorporates the new chapters including management of COVID-19 and value added appendices.



#MedsafetyWeek 2021

Source : Facebook, Twitter , LinkedIn

With reference to the request received from Uppsala Monitoring Centre, Sweden; the NCC PvPI participated in a week long social media campaign from 1st-7th November 2021 to promote the reporting of Adverse Events Following Immunization (AEFI).

The focus of this campaign was on the safety of vaccines. This campaign was at a crucial time when millions of people were getting vaccinated against COVID-19.



19th Signal Review Panel Meeting

The 19th Signal review meeting was organized by IPC-PvPI via hybrid mode on 25th October, 2021. The SRP confirmed following two signals :

1. Mefenamic Acid associated Fixed Drug Eruption
2. Doxycycline associated fixed drug eruption

Medsafety Week Celebration & Inauguration of Regional Training Centre (RTC), Amrita Institute of Medical Sciences

As a part of Medsafety Week, with the theme of “Effective Vaccine under Watch”, the 'Inauguration Programme of Regional Training Centre' was conducted by the Department of Pharmacology, Amrita Institute of Medical Sciences, Kochi on 8th November 2021 and a total of 58 delegates joined the programme. On behalf of IPC, Dr. Jai Prakash, Senior Principal Scientific Officer, NCC-PvPI, participated as the Chief guest in this event. The programme was presided over by the Medical director, Dr. Prem Nair along with Dr (Col) Vishal Marwaha (Principal, Amrita School of Medicine). The chief guest along with Dr. M. Ramesh (AMC & RTC Coordinator, JSS College & Hospital, Mysore) inaugurated this new Regional Training Centre at Amrita Institute of Medical Sciences.



Meeting with Indian Medical Association (IMA) for PvPI expansion

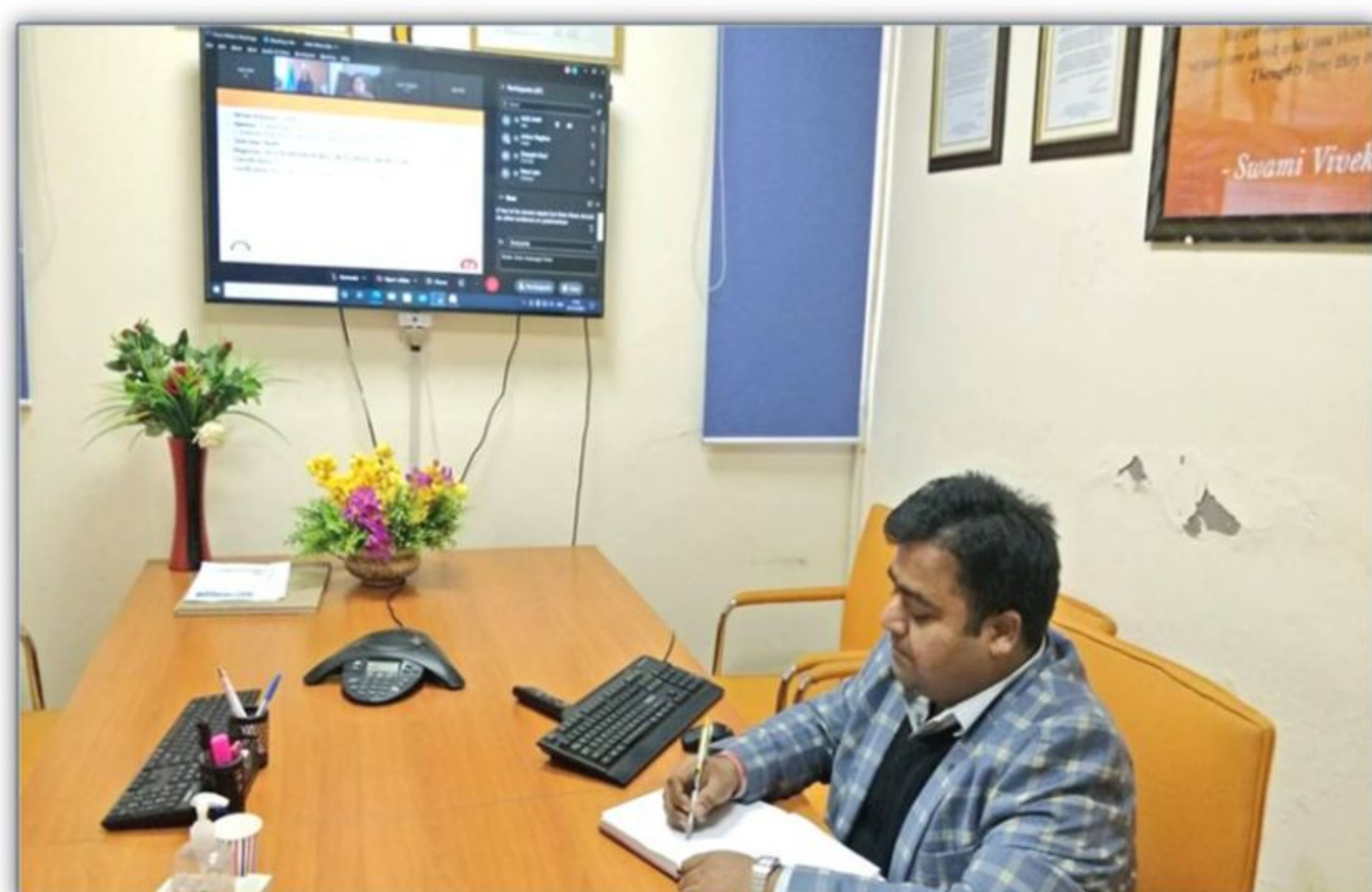
The Meeting of Pharmacovigilance Programme of India (PvPI) and Indian Medical Association (IMA) was held on 10th November 2021 via virtual mode and the meeting was to sensitize IMA Members about the PvPI activities, like the enrollment of Hospitals/



Institutions as an AMC under PvPI, the National level Symposium / Workshop on Pharmacovigilance organized by PvPI for IMA Members, etc.

Pharmacovigilance sensitization activity as part of World Antimicrobial Week

SMS Medical College, Jaipur organized a sensitization programme on Pharmacovigilance & Materiovigilance as part of "World Antimicrobial Week" on 18th-24th November 2021. It was inaugurated in the presence of Sudhir Bhandari, Principal & Controller. In the sensitization programme, awareness regarding the importance of Pharmacovigilance and ADR reporting was done for the health care professionals as well as public. Dr. Lokendra Sharma, Sr. Professor Pharmacology, Dr. Bharti Malhotra, Sr. Prof. & Head Microbiology, Dr. Rajni Sharma, Sr. Prof., Dr. Mamta Lamba, Asst. Prof., Department of Microbiology and Cycle riders group were present.



National AEFI Meeting

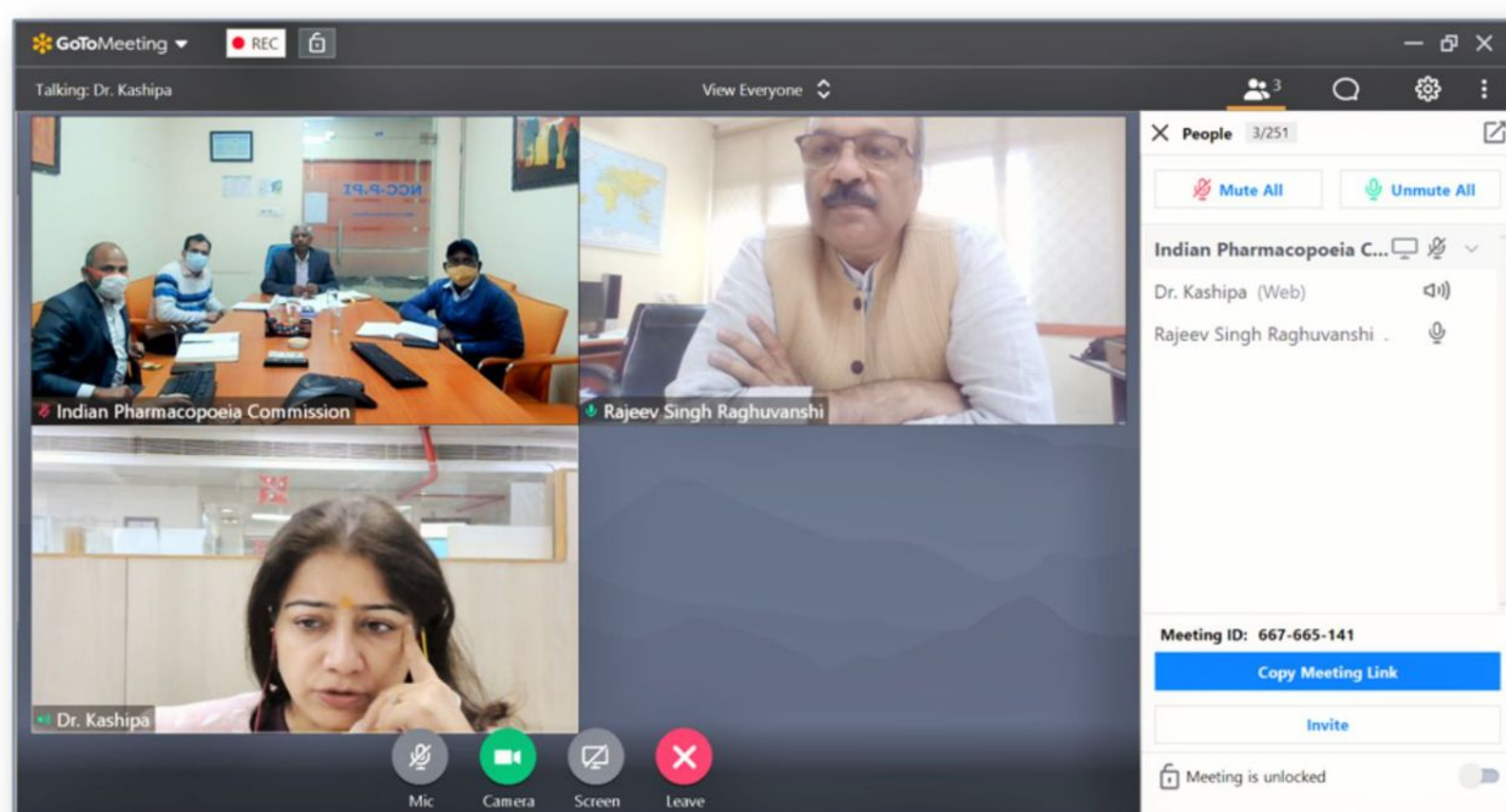
The National AEFI Committee Meeting was held on 16th & 22th November & 20th December, 2021 via virtual mode. Participants from various organizations attended this meeting and on behalf of NCC PvPI, the meeting was attended by Dr. Vijit Agarwal. This meeting was held mainly to approve the causality assessment classification of the AEFI cases reported following the COVID-19 vaccination.

Awareness programme about PvPI by Healthcopeia Foundation in collaboration with National Coordination Centre Pharmacovigilance Programme of India

A Healthcare Leadership Conclave was organized by Healthcopeia Foundation in collaboration with NCC-PvPI held on 25th November, 2021 at FICCI Federation House, New Delhi. On behalf of IPC, Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director and NCC-PvPI team participated. The theme of this event was "Better Public Health Through Pharmacovigilance" with the motive of spreading awareness about Adverse Drug Reaction Reporting system across the country.



Meeting of NCC-PvPI and NABH officials for the Expansion of Pharmacovigilance Programme of India (PvPI)



A meeting of NCC-PvPI and NABH officials for the Expansion of PvPI was held on 8th December 2021, with the objective to promote monitoring and reporting of Adverse Drug Reaction (ADR) by NABH accredited Hospitals to PvPI. On behalf of NCC-PvPI, Dr. Jai Prakash, Officer-in-Charge, welcomed the participants and appreciated the efforts of NABH for expansion of PvPI. He suggested to add the National Formulary of India in the standards of NABH

Accreditation Standards for Hospitals, as a book of reference for rational prescribing. Dr. Rajeev Singh Raghuvanshi, Director, IPC informed about the possibilities available in NABH accredited hospitals for expansion of PvPI. Dr. Kashipa represented on behalf of NABH.

Meeting regarding review of ocular adverse events associated with the use of Miltefosine

A meeting on the review of ocular adverse events associated with the use of Miltefosine held on December 8th, 2021 via virtual mode. A total of 10 participants attended this meeting from various organizations like PvPI, IPC, WHO, NCVBDC & CARE foundation. Various discussion took place regarding Miltefosine related eye complications.



FDA-INO Meeting

A FDA-INO meeting with USFDA Delegation was held at Indian Pharmacopoeia Commission on 14th December 2021. During the meeting, IPC officials interacted with the USFDA officials and updated them about PV activities on COVID-19 and other PvPI related activities.



Technical Advisory Committee held under the Chairmanship of Director General Health Services (DGHS)



A Technical Advisory Committee (TAC) meeting on reporting of ocular complications due to the use of Miltefosine in Post Kala-azar Dermal Leishmaniasis (PKDL) cases was held on 22nd December 2021 under the chairmanship of Prof. (Dr.) Sunil Kumar, Director General of Health Services MoHFW, New Delhi at Resource Center, Nirman Bhawan, New Delhi. On behalf of IPC, the meeting was attended by Dr. V. Kalaiselvan and Dr. Vijit Agarwal.

Pharmacovigilance Conference organized by IMT Pharmacy College, Odisha



A Pharmacovigilance Conference was organized by IMT Pharmacy College, Puri, Odisha with the theme “Pharmacovigilance from the student's perspective” on 24th December, 2021. During the conference, Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director was the chief guest. A total of 86 participants attended the conference.

Visit of Dr. Rajeev Singh Raghuvanshi to AMC at Osmania Medical College, Hyderabad



Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission visited the AMC at Osmania Medical College, Hyderabad to interact with Coordinators and Pharmacovigilance Associates to review the progress on the implementation of Pharmacovigilance: challenges and issues on 29th December, 2021.



19th Skill Development Programme

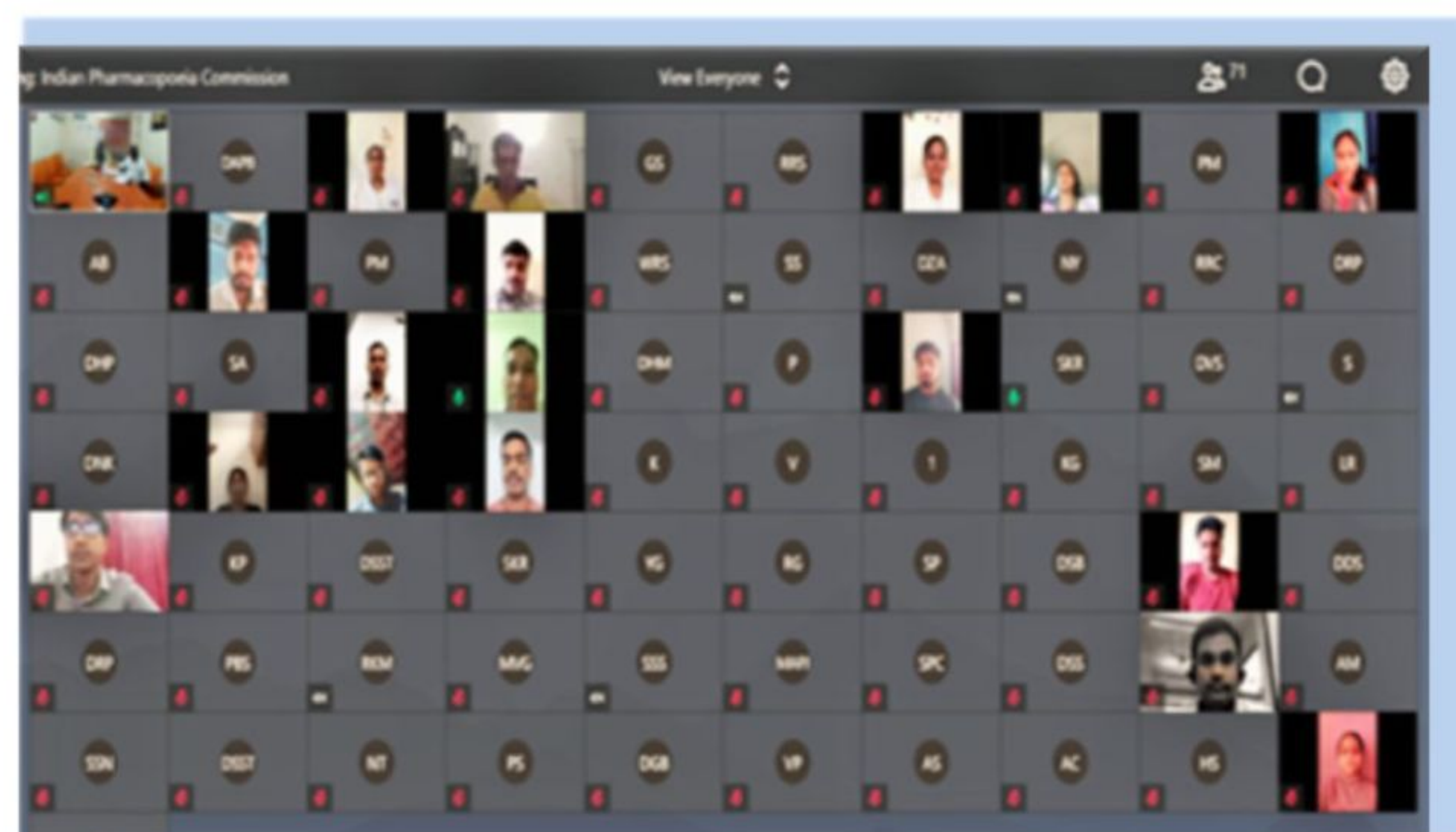
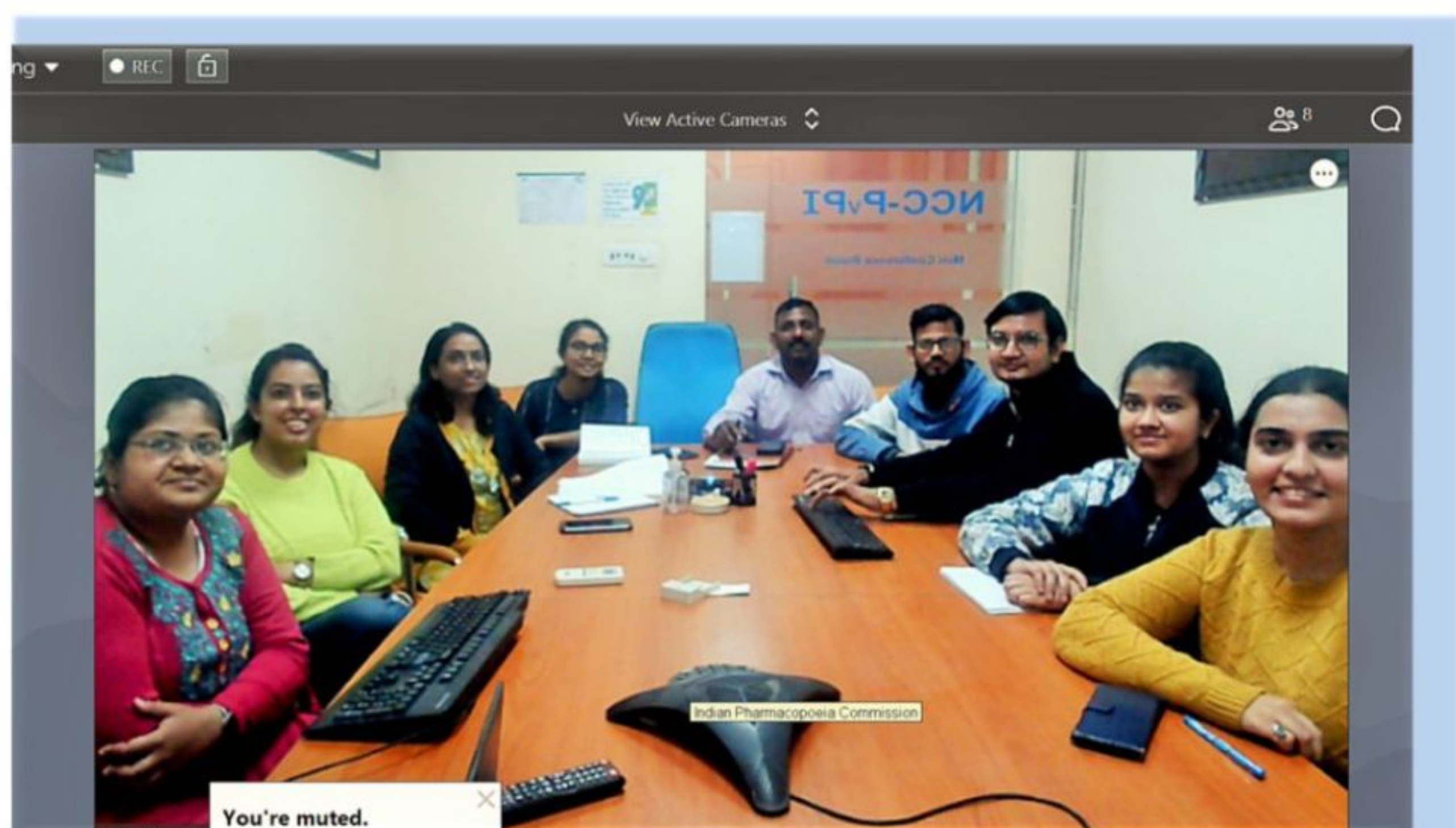
The 19th Skill Development Programme of five days was conducted by IPC from 8th November to 12th November 2021 and was attended by 189 participants. The programme was well appreciated by the participants and IPC received a positive feedback for the

same. During the 5 days of the Skill Development Programme, 16 technical sessions were conducted in the area of Pharmacovigilance including Basic Concepts of Pharmacovigilance, Signal Detection Methods, Regulatory Pharmacovigilance etc.



Induction-cum-Training Programme

A three-day Induction-cum-Training Programme on Pharmacovigilance for Coordinators, Deputy Coordinators & Pharmacovigilance Associates of newly recognized AMCs was conducted from 16th to 18th November 2021. It was attended by 106 participants from all over India. The Module of training covered the Quality Management System in Pharmacovigilance, SOPs for data entry, filling of suspected ADR reporting form and maintaining records at AMC level. The Programme was appreciated by the participants.



Advanced Level Training in Pharmacovigilance at BJ Medical College, Ahmedabad



The Byramjee Jeejeebhoy (BJ) Medical College, Ahmedabad being a Regional Training Centre (RTC) of PvPI organized an advanced level training programme in Pharmacovigilance through virtual mode on 13th October 2021. This training was organized under the leadership of Prof. Chetana Desai with assistance from her team. In this training programme Dr. Jai Prakash, Officer-in-Charge, PvPI briefed about the current scenario & way ahead of Pharmacovigilance Programme of India.



Webinar on Pharmacovigilance for Marketing Authorization Holders

NCC-PvPI had a virtual interactive meeting with Amgen Technology Private Limited representatives on 17th November 2021 regarding improving the quality of ICSRs received from them. A total of 6 participants attended the meeting. The firm agreed to the points suggested by NCC-PvPI officials for improving the quality and quantity of ICSRs to the maximum possible extent.

Pharmacovigilance workshop organized by the World Health Organization

A pharmacovigilance workshop organized by the World Health Organization together with the Uppsala Monitoring Centre on “Unmasking safety signals in an infodemic”, was held on 6th December 2021. It was organized to take stock of current methodologies in signal detection, to understand the impact of the pandemic on signal detection and to discuss new approaches, as well as to agile solutions that can serve as early warning systems and complement or enhance current signal detection practices.

Advanced Level training on Pharmacovigilance by IPGMER Kolkata

An online advanced level training on Pharmacovigilance with the theme 'Redefining Pharmacovigilance Research' was organized virtually by IPGMER Kolkata on 13th December 2021. This training was organized under the leadership of Prof. Suparna Chatterjee with assistance from her team. Dr Jai Prakash, Officer-in-Charge, PvPI delivered the keynote address during the programme. A total of 213 participants attended the training.



Training at Amrita Institute Medical Sciences, Kochi

A workshop on “Essentials of Pharmacovigilance: Basics to advanced” was conducted by RTC & AMC at Amrita Institute of Medical Sciences, Kochi, in collaboration with RTC & AMC at JSS Medical College & Hospital, Mysore under

the aegis of Pharmacovigilance Programme of India on 18th December 2021. Dr. Jai Prakash, Senior Principal Scientific Officer, PvPI-IPC, delivered the keynote address about ways to improve ADR reporting.



Webinar on Good Pharmacovigilance Practices



A webinar on “Basics of Good Pharmacovigilance Practices with reference to Module VI” was organized by NCC-PvPI on 29th December 2021 for the Pharmacovigilance Associates working under ADR monitoring centers across the country.



The session outlined the Good Pharmacovigilance Practices and emphasized the need for Pharmacovigilance and ADR reporting.

Other Important Trainings/Meetings/Webinars/Workshops

The other Pharmacovigilance training programmes organized during this tenure are as follows:

S. No.	Date	Training Title	Organizer
1.	14 th November 2021	Sensitization programme on Pharmacovigilance and ADR reporting on the occasion of "World Diabetes Day"	SMS Medical College, Jaipur
2.	2 nd December 2021	Sensitization Programme on ADR Awareness and ADR Reporting	Jawaharlal Nehru Medical College DMIMS, Sawangi
3.	3 rd December 2021	Seminar on Pharmacovigilance basics	Kamineni Institute of Medical Sciences, Nalgonda
4.	8 th December 2021	Seminar on PvPI and ADR form filling	Kamineni Institute of Medical Sciences, Nalgonda
5.	9 th December 2021 & 22 nd December 2021	Sensitization Programme on ADR Reporting & Causality Assessment	Jawaharlal Nehru Medical College DMIMS, Sawangi
6.	13 th December 2021 & 20 th December 2021	Sensitization Programme on Importance of pharmacovigilance and ADR Reporting	JNIMS Imphal, Manipur
7.	17 th December 2021	Awareness cum sensitization on Pharmacovigilance & Reporting of ADRs	Dr RKGMC, Hamirpur (H.P)
8.	24 th December 2021.	Pharmacovigilance E-Quiz on Antiretroviral drugs	Indira Gandhi Medical College and Research Institute, Puducherry

New Drugs Approved in India



The following new drugs were approved by CDSCO between October 2021 to December 2021:

Drug	Indication
Tafamidis soft gelatin capsules 61 mg	Indicated for the treatment of wild-type or hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM)
Molnupiravir bulk and Molnupiravir capsules 200mg	For treatment of adult patients with COVID-19, with SpO2 >93% and who have high risk of progression of the disease including hospitalization or death, in light of Covid-19 outbreak for restricted emergency use in the country
Selexipag bulk and Selexipag tablets...200mcg/ 400mcg/ 600mcg/ 800mcg/ 1000mcg/ 1200mcg/ 1400mcg/ 1600mcg	For the treatment of Pulmonary Arterial Hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH

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

Drug Safety Alerts




identified & issued by PvPI from October 2021 to December 2021

S. No.	Issuing Date	Suspected Drugs	Indication(s)	Adverse Drug Reaction
1.	30 th November, 2021	Diclofenac	For the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, gout, painful post-operative pain following dental surgery, migraine attack and postoperative inflammation in patients who have undergone cataract operation.	Skin hyperpigmentation
2.	28 th December, 2021	Remdesvir	Broad spectrum antiviral medication. Restricted emergency use for treatment of patients with severe COVID-19. Operative inflammation in patients who have undergone cataract operation.	Sinus Bradycardia

👉 Healthcare Professionals (HCPs), patients/consumers are 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 issued by other countries and status of ICSRs in PvPI database

S. No.	Drugs	ADR	Total No. of ICSRs in vigibase	Total No. of ICSRs in PvPI data	Reference
1.	Labetalol	Nipple Pain and Suppressed Lactation	32	01	https://www.ema.europa.eu/en/documents/prac-recommendation/new-product-information-wording-extracts-prac-recommendations-signals-adopted-25-28-october-2021_en.pdf
2.	Lenvatinib	Colitis	54	01	

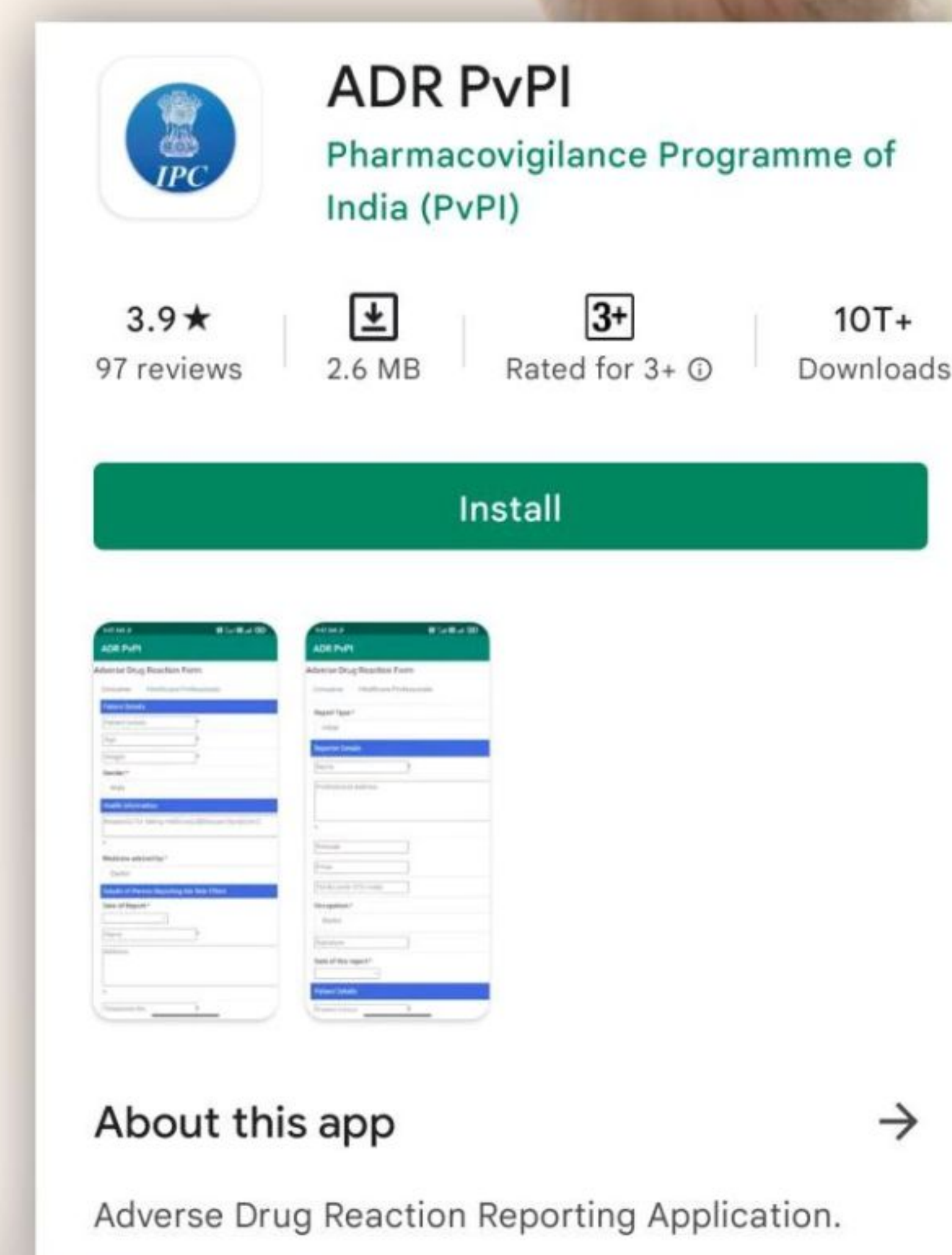
 **HCPs are advised to carefully monitor the above mentioned ADRs reported with the use of suspected drugs. If such ADRs are encountered, please report to NCC-PvPI, IPC.**



ADR PvPI Mobile Application



The “ADR PvPI” is an user-friendly Android mobile app freely downloadable from the Google Play Store. The number of reports received through this mobile app are represented below for the last quarter of this year. The users are encouraged to use it.



Number of reports received through
Mobile App





Netaji Subhash Chandra Bose Subharti Medical College (SMC), Meerut, Uttar Pradesh

Since 2014 SMC, Meerut has been working as an Adverse Drug Reaction Monitoring Centre (AMC) under PvPI. Various pharmacovigilance activities are carried out under the supervision of Dr. Surabhi Gupta, Coordinator and Head of the Department of Pharmacology, SMC, Meerut along with Dr. Jyoti Singh, Pharmacovigilance Associate. In July 2021 SMC, Meerut was also recognized as Medical Device Monitoring Centre.



This AMC continues its focus on patient safety by active ADR reporting by healthcare professionals and consumers. Centre has conducted various sensitization and awareness programmes on Pharmacovigilance for Medical, Dental, Nursing, Pharmacy and paramedical students. Distribution of PvPI posters and circulation of PvPI newsletters, drug alerts, suspected ADR reporting forms and study materials to all health care professionals was done through this centre. This centre has also maintained ADR/AEFI database of all ICSR record files for easy access and hassle free retrieval.



Amrita Institute of Medical Sciences (AIMS), RTC & AMC, Kochi, Kerala

The ADR Monitoring Centre (AMC) at Amrita Institute of Medical Sciences (AIMS), Kochi was launched in January 2014. Since then, we have been continuously sending ADR reports in a complete manner to the National Coordination Centre (NCC). We also have satellite centres such as VPS Lakeshore Hospital, EMC Hospital, Ernakulam Medical Trust Hospital, MAGJ Hospital, Apollo Hospital. Recently in August 2021, we were recognized as Regional Training Centre (RTC) for the jurisdiction of Kerala. Pharmacovigilance activities are carried out under the supervision of Dr. Princy Louis Palatty, Coordinator & Head of Dept. of Pharmacology.

AMC AIMS organized a CME on “Essentials of Pharmacovigilance: Basics To Advanced” on 18th December 2021 and conducted National level webinar on “Patient safety through Pharmacovigilance” on 18th September 2021 as part of National Pharmacovigilance Week celebration. Several animation/video making competition, E poster competition, Essay writing competition and Quiz competition were organized for Amrita students of all streams. A National level webinar on “Adverse Event Following Immunization (COVID-19) – Interim Report” was conducted on 11th February 2021.



Feedback from AMC Stakeholders

Pharmacovigilance plays an important role in the patient's safety in relation to use of medicines. It is our responsibility to monitor adverse drug reactions occurring among the Indian population. SMC, Meerut is an AMC run by Dr. Surabhi Gupta as Pharmacovigilance Coordinator since 2005. The day to day activities are managed by Dr. Jyoti Singh as Pharmacovigilance associate. Through this forum we pledge to improve patient safety through responsible Pharmacovigilance. On behalf of SMC, Meerut, we wish the entire team PvPI great success in the field of Pharmacovigilance.



Dr. Surabhi Gupta
AMC Coordinator
(Dept. of Pharmacology)
Subharti Medical College,
Meerut, Uttar Pradesh.



Dr. Lokendra Sharma
Professor
(Pharmacology & Coordinator)
ADR Monitoring Centre
(Under PvPI)
SMS Medical College,
Jaipur

The utilization of drugs are not always beneficial but may cause an ADR, which should be monitored and reported at the earliest to the regulatory authority. We, at SMS Medical College, Jaipur are pleased to have an ADR monitoring centre under PvPI since January, 2011. In the interest of patient safety and contribution towards pharmacovigilance programme several activities e.g. CMEs, workshops, seminars, guest lectures, PV awareness programme on special health days, placing of PvPI and MvPI posters, sending letters to Director, NHM, Director Medical & Health, Rajasthan and the Chief Medical & Health Officer, Jaipur District to disseminate the information on pharmacovigilance to the CHCs and PHCs, have been conducted to strengthen the practice of Pharmacovigilance in our medical college & attached hospitals as well as in the other districts near Jaipur.

The Amrita Institute of Medical Sciences, RTC & AMC, Kochi is steered by Dr Princy Louis Palatty along with an able multidisciplinary team. Patient safety can best be achieved when the mainstay of therapy being "Drugs" are "safe". The endeavour to solicit & file complete ADR forms is in itself a humongous task. The repeated sensitization, orientation & training are an ongoing venture. The targeted pharmacovigilance meets the objectives laid out. Every year it is our desire to publish a few papers related to pharmacovigilance. The NCC-PvPI is extending full support & a helping nature to resolve our problems.



Dr. Princy Louis Palatty
RTC-AMC Coordinator
Amrita Institute of Medical
Sciences,
Kochi, Kerala



**7th-11th
March 2022**

**Skill development
Programme &
Pharmacovigilance of
Medical Products**

**Last Date of Registration
2nd March 2022**

**28th
April 2022**

**Workshop cum training
programme on
Pharmacovigilance for
NABH –
accredited Hospitals**

**Last Date of Registration
25th April 2022**

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

फॉर्माकोविजीलेंस प्रोग्राम ऑफ इंडिया, स्वास्थ्य और परिवार कल्याण मंत्रालय,
भारत सरकार द्वारा जनहित में जारी

जैसा कि हम सभी जानते हैं कि दवाइयों (टैबलेट्स, कैप्सूल, 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 फॉर्माकोविजीलेंस प्रोग्राम ऑफ 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।

“फॉर्माकोविजीलेंस 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, फॉर्माकोविजीलेंस प्रोग्राम ऑफ इंडिया, में दवाइयों के प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी एकत्रित करने हेतु विभिन्न सुविधाजनक माध्यम उपलब्ध हैं, 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 दवाइयों 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 फॉर्माकोविजीलेंस 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, फॉर्माकोविजीलेंस प्रोग्राम ऑफ 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 ऑफ इंडिया के अंतर्गत किसी भी निकटवर्ती ए. डी. आर. मॉनीटरिंग सेंटर पर दे सकते हैं। इस सम्बन्ध में एक विशेष फॉर्म- Suspected Adverse Drug Reaction Reporting Form (For Drugs used in Prophylaxis/ Treatment of COVID-19) भी डिज़ाइन किया गया है, जो www.ipc.gov.in पर उपलब्ध है।



Indian Pharmacopoeia Commission
National Coordination Centre,
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare, Govt. of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392

**For any other information/Suggestion/
Query, please contact:**
Officer Incharge
Pharmacovigilance Programme of India
Email: lab.ipc@gov.in, pvpi.ipc@gov.in
Website: www.ipc.gov.in

Let us join hands with PvPI to ensure patient safety