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Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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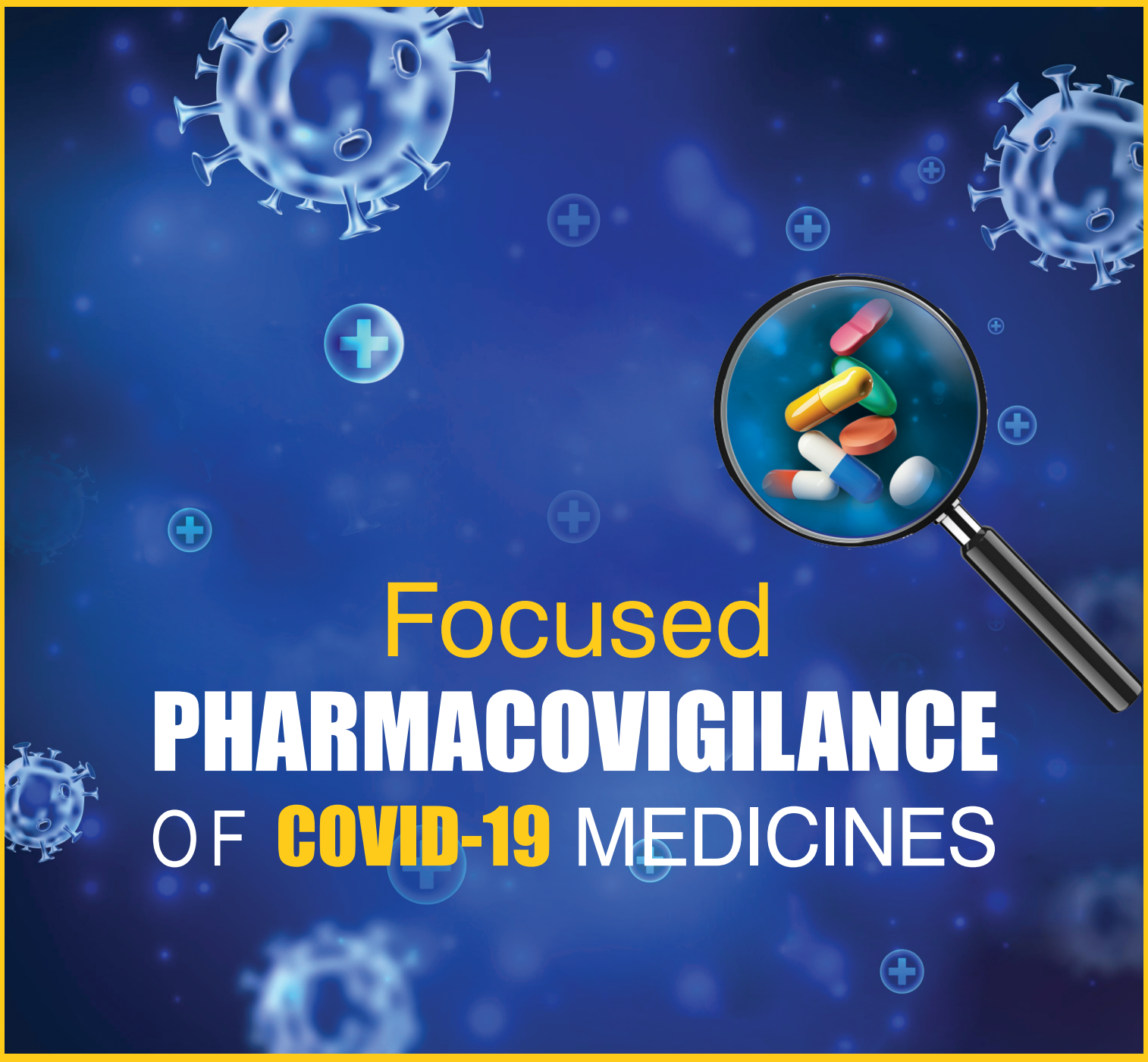

Focused PHARMACOVIGILANCE OF COVID-19 MEDICINES

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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Foreword from Secretary-cum-Scientific Director

It is a great pleasure to release the April-September 2020 Issue of the Newsletter of Pharmacovigilance Programme of India (PvPI).

The Indian Pharmacopoeia Commission (IPC) through PvPI and MvPI has been bringing under its purview as many healthcare centres and super speciality hospitals as possible to act as AMCs to cater the needs and tasks of Pharmacovigilance (PV) at the grassroots level. The efforts to strengthen and streamline the PV system across all areas of healthcare have been more intense by regularly imparting hands-on training for skill development in PV to all stakeholders to meet the challenges posed to patient safety by broad-spectrum drug use.

In the times of COVID-19, it is noteworthy to mention that PvPI has taken a call to ensure safety of medicines used for treatment/prophylaxis of COVID-19 by extending its support to the National Task Force for COVID-19 for collecting and analyzing adverse events. PvPI tools such as Toll free Helpline #1800-180-3024 (Monday to Friday 9:00AM-5:30PM) and android mobile app 'ADR PvPI' available for all stakeholders further ease the process to report the safety issues of COVID-19 drugs.

Healthcare Centres and Hospitals across the country have been urged to display PvPI helpline number on IPD/OPD slips to popularize and utilize the facility of ADR-reporting by the public at large.

PvPI is tirelessly attempting to collect adverse event reports related to COVID-19 drugs used by Healthcare Professionals or any person, to analyze safety profiles of drugs used in the prophylaxis/treatment of corona virus infection for regulatory recommendations.

I trust that the efforts put in by PvPI would ensure safety and well-being of one and all against drug-related harms of COVID-19 drugs.

I congratulate the entire PvPI team for its relentless efforts aimed at attaining a sustainable system of drug safety across the country.

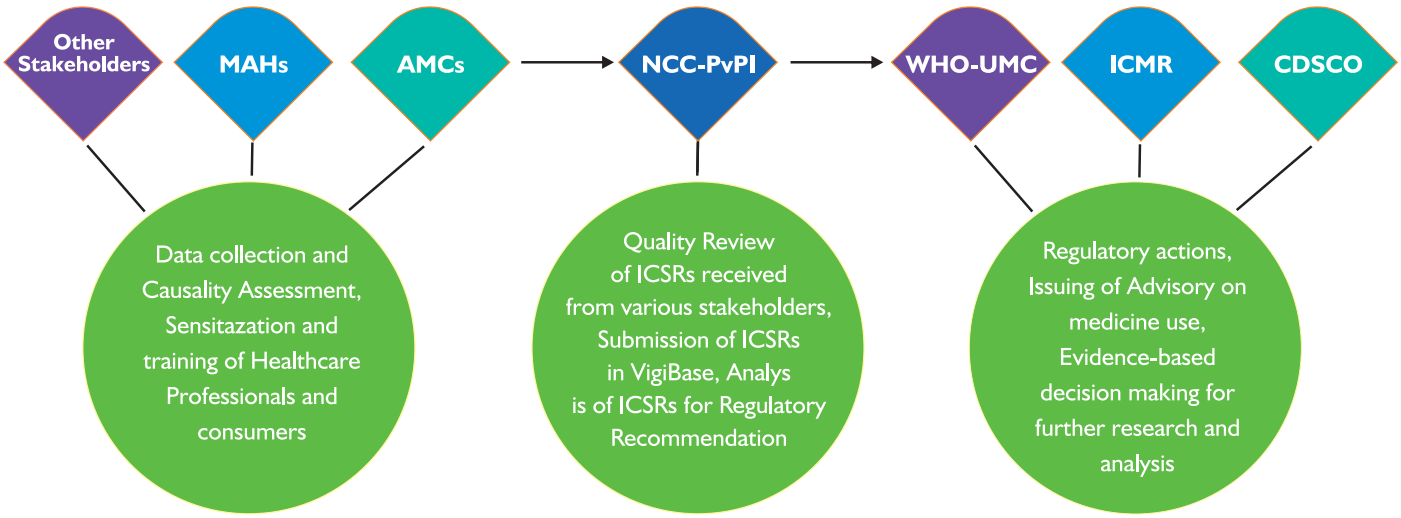
Dr. Jai Prakash
Secretary-cum-Scientific Director (I/c)
Indian Pharmacopoeia Commission,
(Ministry of Health & Family Welfare, Govt. of India)
Ghaziabad

Focused Pharmacovigilance of Drugs used in the Management of COVID-19

The ongoing COVID-19 pandemic is an emerging situation and it has made the Pharmacovigilance (PV) more important than ever before. As the medical and scientific community work diligently to find suitable treatments for COVID-19, monitoring the efficacy and safety profiles of medications constitutes a priority for PvPI and its stakeholders, especially for drugs administered to patients to treat this infection by repurposed drugs

Pharmacovigilance Programme of India (PvPI) has been streamlining its efforts towards generating the safety data of the drugs being used for prophylaxis and treatment of COVID-19. PvPI has initiated focused Pharmacovigilance of COVID-19 drugs.

PvPI occupies a vital position in disseminating the practice-based clinical information about drug safety to a wide range of stakeholders. Therefore, to streamline its efforts for continuous monitoring, PvPI dedicated training programmes for Pharmacovigilance to all the stakeholders for efficient processing, collecting and collating the Adverse Drug Reactions (ADRs) reported with the use of medicines in COVID-19, besides generating quality data. The different processes carried out in PvPI involving stakeholders are as follows:



In this context, PvPI requested all AMCs' Coordinators and Pharmacovigilance Associates to collect and report AEs/ADRs with the drugs used as prophylactic and in the management of COVID-19 across the Country.

A robust drug safety data analytical process, which has been adopted by PvPI would be beneficial in guiding safe and proper use of COVID-19 drugs.

Development of Suspected ADR Reporting Form for COVID-19 Drugs

NCC-PvPI devised a new Suspected ADR Reporting Form for the drugs used as Prophylactic and in the treatment of COVID-19 and communicated it to all ADR Monitoring Centres under Pharmacovigilance Programme of India. NCC-PvPI requested all Pharmacovigilance Associates and Healthcare Professionals to keep a vigil on the Adverse Events following the drugs used for COVID-19 and report the same to NCC-PvPI, IPC.

Revision of Advisory on Hydroxychloroquine (HCQ) use in COVID-19

After a detailed discussion on available data of in-vitro testing of HCQ for antiviral efficacy against SARS-CoV-2 and the safety profile of HCQ reported to PvPI, the National Task Force (NTF) for COVID-19 has revised the Advisory on the use of HCQ for the prophylaxis of COVID-19 infection by replacing the previous advisory dated March 23, 2020. NTF advised to consult with a physician (within their hospital/surveillance team/security organization) for any adverse event or potential drug interaction before starting the medication. NTF also emphasized that the prophylactic use of HCQ to be coupled with the Pharmacovigilance for adverse drug reactions through self-reporting using the PvPI Helpline/Mobile app. A few key features of revised advisory are as below:

- The drug is contraindicated in persons with known case of retinopathy, hypersensitivity to HCQ or 4-aminoquinoline compounds, G6PD deficiency, pre-existing cardiomyopathy and cardiac rhythm disorders.
- The drug is not recommended for prophylaxis in children under 15 years of age, in pregnancy and lactation.
- The drug has to be given under strict medical supervision with an Informed Consent.
- Rarely, the drug causes cardiovascular side effects such as cardiomyopathy and rhythm (heart rate) disorders. In such conditions, the drug needs to be discontinued. The drug can, rarely, cause visual disturbance, including blurring of vision, which is usually self-limiting and improves after discontinuation of the drug.
- Before prescribing HCQ for prophylaxis, ECG (with estimation of QT interval) may be done.
- In case of any new cardiovascular symptoms (e.g., palpitations, chest pain syncope) during the prophylaxis, an ECG should be done.
- An ECG (with estimation of QT interval) may be done in those who are already on HCQ prophylaxis before continuing it beyond 8 weeks.

Suspected ADR Reporting Form for COVID-19 Drugs

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM
(FOR DRUGS USED IN PROPHYLAXIS/TREATMENT OF COVID-19)

For VOLUNTARY reporting of ADRs by Healthcare Professionals
INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India Sector-23, Raj Nagar, Ghaziabad-201002
PvPI Helpline (Toll Free):1800-180-3024(9:00 AM to 5:30 PM,Monday-Friday)

A. PATIENT/SUBJECT INFORMATION

Patient/Subject Category:
a. Lab confirmed COVID-19 case ☐
b. Asymptomatic healthcare worker Involved in the care of suspected or confirmed COVID-19 cases ☐
c. Asymptomatic household contacts of laboratory confirmed cases ☐
d. Others (Please specify)

Reg. No. /IPD No. /OPD No. /CR No. :

AMC Report No. :

Worldwide Unique No. : To be generated by PvPI

1. Patient/Subject Initials

2. Age /Date of Birth

3.Weight (in Kg)

4.Gender: Male ☐ Female ☐ Transgender ☐

5. If female - pregnant Yes ☐ No ☐

6. Lactating Yes ☐ No ☐

9. Relevant tests/ laboratory data with dates

Test for COVID-19 :
RT PCR Test ☐ Rapid Antibody test ☐
Positive ☐ Negative ☐ Not done ☐

B. SUSPECTED ADVERSE REACTION

S.No	Reaction	Start Date	End Date	Outcome*

*Outcome may be indicated as [✓] one of the following
(a) Recovered (d) Recovering
(b) Not recovered (e) Fatal
(c) Recovered with sequelae (f) Unknown

10. Any other tests performed:
1. Chest X-Ray Yes ☐ No ☐
2. ECG Findings If any Yes ☐ No ☐
3. Biochemical Examination such as Serum Electrolytes (Na, K, Mg, Ca etc) Yes ☐ No ☐
4. Ophthalmology Exam findings, if any
5. Radiological examination
6. Other Relevant Information, if any

7. Describe Event(s)/Reaction(s) with treatment details, if any in chronological order

11. Recent Travel Information:
Recent History of International Travel:
Yes ☐ No ☐
Country Visited :
Date of Return to India :
Inter -state travel/domestic travel

12. Relevant medical/medication history:
Allergy/Hypersensitivity Reaction ☐
Chronic Alcoholism ☐
Smoking ☐
Obesity ☐
Renal Dysfunction ☐
Hepatic Dysfunction ☐
Diabetes ☐
Epilepsy/Seizures ☐
Bronchial Asthma ☐
Cardiovascular Disease ☐
Chronic Lung Disease ☐
Immunodeficiency Disorder ☐
Immunosuppressant Drug ☐
Anaemia ☐
Neurological disorder ☐
G-6-PD Deficiency ☐
Dermatological findings If any ☐
Others ☐

8. Seriousness of the reaction: No ☐ If Yes ☐(please tick appropriate box)
Death (dd/mm/yyyy) ☐
Life threatening ☐
Hospitalization/Prolongation of hospitalization ☐
Other Medically Important events ☐

13.Drug Interaction: Mention name of any interacting (with Suspected Drug) drug taken:

COVID-19 National Task Force Meet

The National Task Force for COVID-19 constituted by the Indian Council of Medical Research (ICMR), New Delhi, organized a virtual meet on May 21, 2020 to review the ongoing research and other sustainable measures to contain the impacts of COVID-19 outbreak on public health. During the meet, Dr. Jai Prakash, Secretary-cum-Scientific Director (I/c), IPC presented the **Profile of Adverse Drug Reactions due to Hydroxychloroquine (HCQ)** reported to PvPI for consideration.

Virtual meeting on ADR reporting in Kala-azar Elimination Programme

National Vector Borne Disease Control Programme (NVBDCP) and NCC-PvPI organized a virtual meeting on Adverse Drug Reactions reporting in Kala-azar Elimination Programme on 06th August, 2020. About 80 participants from NCC-PvPI, IPC, NVBDCP and VBD Officers had attended the webinar. The meeting included two technical sessions on:

(A) How to log in New VigiFlow?

(B) How to enter the ADR data in New VigiFlow?

Further, during the meeting need for ADR reporting was emphasised with the field level staff of NVBDCP and all field staff were encouraged to report ADRs. The field staff ensured that the ADRs will be reported from the field on continuous basis.

Virtual meeting on monitoring the Adverse Events of Antileprosy drugs

The Global Leprosy Programme, WHO-India and NCC-PvPI hosted a virtual meet on 7th August, 2020 to address the ADRs related to the drugs used in the National Leprosy Eradication Programme. About 9 participants from NCC-PvPI, IPC, WHO-HQ, WHO-SEARO/India etc. had attended the meeting. During the meeting, it was discussed that the Pharmacovigilance data on anti-leprotic drugs is to be shared with the Global Leprosy Programme (GLP) with the approval of the Ministry of Health and Family Welfare (MoHFW), Government of India, as they are planning to develop a technical guide to monitor the Adverse Effects and Adverse Drug Reactions caused by drugs used in the treatment of Leprosy (Hansen's disease).

Re-constitution of Signal Review Panel (SRP)

The SRP of PvPI comprises scientists and clinical experts affiliated to government and non-government academic institutions and hospitals. As and when required, experts from the pharmaceuticals industry are also invited for expert inputs on Individual Case Safety Reports (ICSRs). This panel validates and confirms the potentially identified Signals/Prescribing Information Leaflet Changes after review of ICSRs reported to PvPI. The new SRP was re-constituted under the Chairmanship of Prof. Y. K. Gupta and Co-chairmanship of Prof. Urmila Thatte in September 2020.

National Adverse Event Following Immunization (AEFI) Committee Meeting

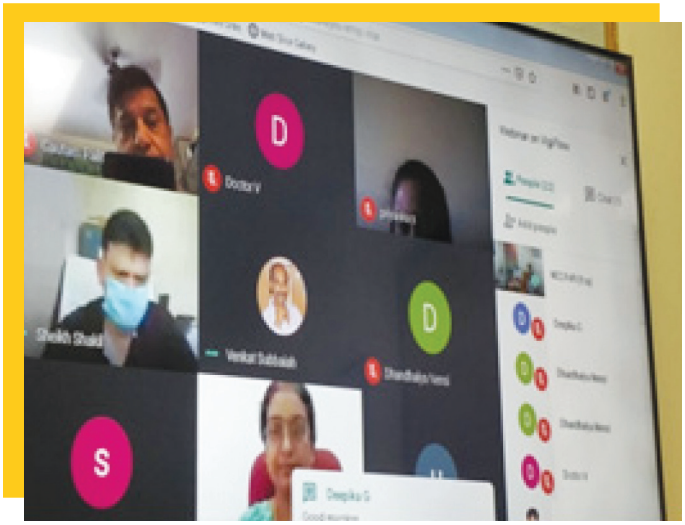
A virtual Meeting of National AEFI Committee was organized by Universal Immunization Programme (UIP) Division, AEFI Secretariat on 18th August 2020 to discuss the AEFI related cases, their surveillance and causality assessment. About 20 participants from NCC-PvPI, IPC, MoHFW, AEFI, CDSCO, WHO-Country Office for India, etc. had attended the meeting.

Focused Training for National Tuberculosis Elimination Programme (NTEP) Centres on VigiFlow

NCC-PvPI organized a focused training session (Virtual training through GoTo Meet) on Data Entry in VigiFlow for the National Tuberculosis Elimination Programme (NTEP) centres on 16th September, 2020. Dr. Jai Prakash, Officer In-charge, PvPI-IPC welcomed all the participants to this meeting and he expressed the need to enhance the quality and quantity of ADRs reporting from these centres. Dr. Vijit Agrawal, Sr. Pharmacovigilance Associate made a presentation on “the process of data entry through VigiFlow” and also gave a live demo for the same. As many as 28 participants attended the training programme and this training session helped the participants to enhance their understanding of data entry into the new version of VigiFlow.

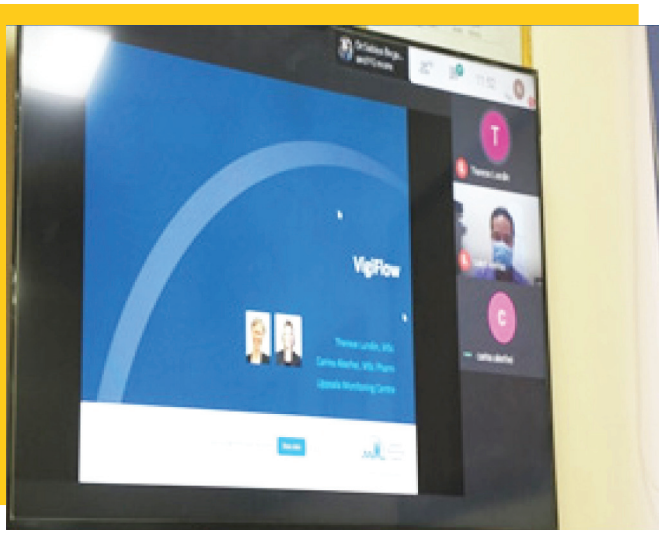
Induction-cum-Training Programme

The National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) organized one day online, Induction-cum-Training Programme for Coordinators of newly recognized Adverse Drug Reaction Monitoring Centres (AMCs) & Pharmacovigilance Associates under PvPI on 23rd Jun, 2020. A total of 54 participants including Coordinators of newly recognized AMCs & newly inducted Pharmacovigilance Associates under PvPI attended the programme. Dr. Jai Prakash, Officer In-charge, PvPI inaugurated the webinar with a welcome note and also delivered a presentation on "Pharmacovigilance Programme of India - An Overview and Current Status". Another session on "Reporting of Adverse Drug Reactions" was delivered by Mr. Rishi Kumar, Scientific Assistant, PvPI given an insight into "Suspected Adverse Drug Reaction Notification Form and New VigiFlow". At the end, participants also interacted with NCC-officials to resolve their queries regarding ADR reporting and data entry in VigiFlow.



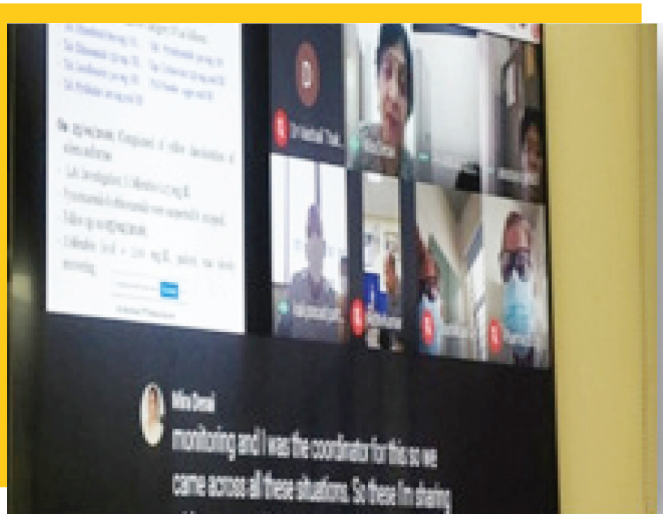
Training on VigiFlow by WHO-Uppsala Monitoring Centre (UMC)

A webinar on "VigiFlow - An Introduction, Data Entry and Current Features" was organised by NCC-PvPI in collaboration with WHO-UMC, Sweden on 25th Jun 2020. A total of 100 participants including Coordinators & Pharmacovigilance Associates had participated from AMCs across the country. The Webinar started with the opening remarks by Dr Jai Prakash, Officer-in-Charge PvPI. He extended his warm greetings and best wishes to all the participants. The speakers from UMC, Sweden, Therese Lundin & Carina Akerhei detailed the participants about the 'Updates and functioning of the New VigiFlow' with special emphasis on the case processing of Marketing Authorisation Holders. The webinar received an overwhelming response from the participants and the enthusiastic participants asked several questions, which were very well responded by the speakers.



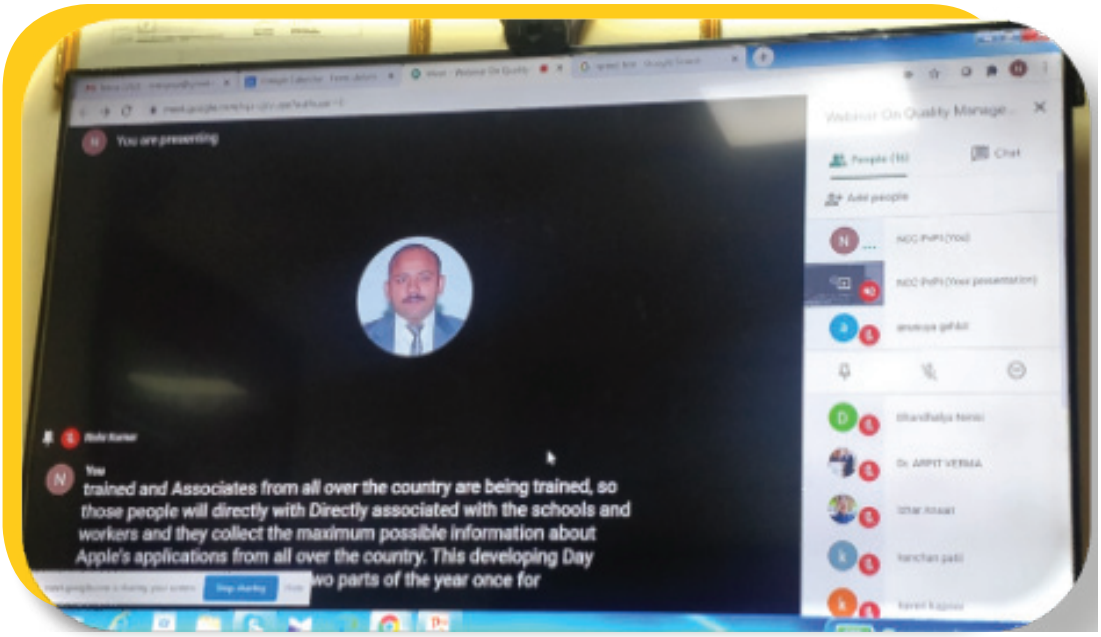
Webinar on Causality Assessment: The Logic & Methods

NCC-PvPI is continuing its effort to keep its PV Associates and Healthcare Professionals (HCPs) technically acquainted on the subject of PV as a part of Induction-cum-Training Programme. NCC-PvPI conducted an online learning session for 43 participants on 22nd July 2020. Dr Jai Prakash, Officer-in-Charge, PvPI opened the session with introductory remarks extending his warm greetings and best wishes to all the participants. Prof Mira Desai, Member-Signal Review Panel was the speaker for the session on 'Causality Assessment: The Logics & Methods'. It mainly covered causality assessment methods, its importance and practical difficulties while performing the causality assessment of ICSRs.



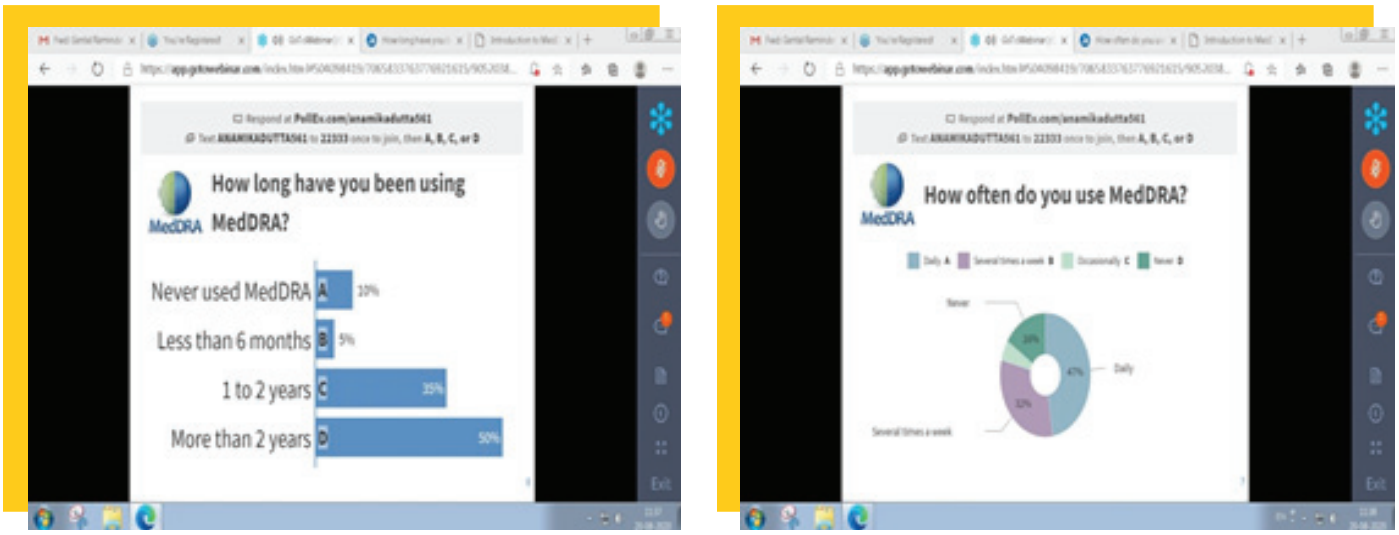
Webinar on Quality Management System

NCC-PvPI organized a webinar learning session on "Quality Management System in Pharmacovigilance' as a part of Induction-cum-training Programme on Pharmacovigilance for the Coordinators and PV Associates of AMCs under PvPI on 31st July, 2020. Total 16 Coordinators of newly recognized AMCs & newly inducted Pharmacovigilance Associates under PvPI attended the programme. Mr. Rishi Kumar, Scientific Assistant, PvPI delivered a welcome note and presentation on Quality Management System in Pharmacovigilance. The presentation covered:



Webinar on Basics of MedDRA

NCC-PvPI has organised two webinars on "What is MedDRA and how it is used?" and "MedDRA Coding Basics" for Pharmacovigilance Associates working in ADR Monitoring Centres under PvPI on 22nd August, 2020 and 26th August, 2020, respectively. The Webinars were organised in association with MedDRA, MSSO. Ms. Anamika Dutta, Medical Officer, MedDRA MSSO delivered the lecture and covered various topics in the webinar including background information about MedDRA including Scope, Structure, Term Selection, Browsing, Coding etc.. A total of 125 PV Associates and 103 HCPs had attended the training sessions. The webinars were very informative and well appreciated by the participants.



Presentation of slides during the MedDRA training Webinar

Other Important Trainings

NCC-PvPI, ADR Monitoring Centres & other PvPI Stakeholders conducted various online training programmes for the sensitization/awareness of Medical and Paramedical staff regarding PV activities across the country. The details are as follows:

S.No	Date	Training Programme	Organised By	Target Audience	No of Participants
1	25th Sep 2020	Transforming Global Health: Role of Pharmacy Professionals	NCC-PvPI & NIPER, Mohali	Pharmacy Graduates & Post Graduates	105
2	17th Sep 2020	Pharmacovigilance and Patient Safety Opportunities and Challenges during COVID-19	PGIMER-Chandigarh	Physician, Nurses, Pharmacists & Other Paramedical Staff	84
3		Health Worker Safety: A Priority for Patient Safety	MKCG Medical College and Hospital, Berhampur	Physician, Nurses, Pharmacists & Other Paramedical Staff	126
4	16th Sep 2020	Data Entry in New VigiFlow	NCC-PvPI, IPC, Ghaziabad	HCPs of NTEP Centres	35
5	2nd Sep 2020	Pharmacovigilance & patient safety: Opportunities & Challenges during COVID-19	IPGMER, Kolkata	AMC Coordinators	87
6	29th Jul 2020	Research in Pharmacovigilance in the Age of COVID-19	JSS College of Pharmacy, Mysore	Physicians, Pharmacovigilance Associates, PhD- Scholars Clinical Pharmacists & Students of Medical & Paramedical courses	280

Interactive meet with Marketing Authorization Holders (MAHs) on ICSR quality

To improve the quality of ICSRs, PvPI conducted regular interactive webinars with representatives of MAHs. During index period from April to September 2020, PvPI has conducted seven such meetings:

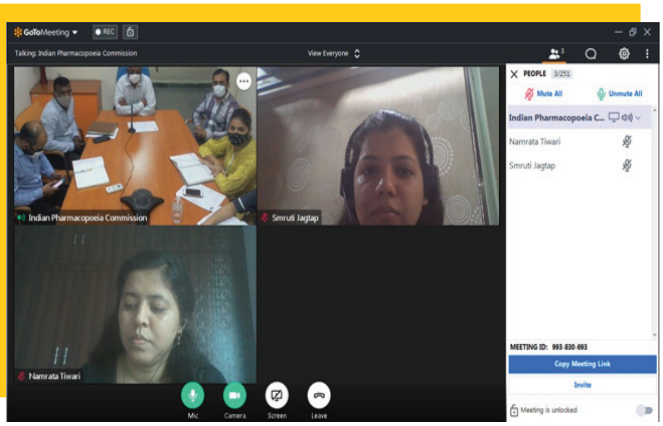
S.No	Date	Marketing Authorization Holder/ Pharmaceutical Company
1	22nd Sep 2020	Bayer Pharmaceuticals Private Limited
2	8th Sep 2020	AstraZeneca Pharma India Limited
3	24th Aug 2020	Astellas Pharma India Private Limited
4	19th Aug 2020	Allergan India Private Limited
5	27th Jul 2020	Akums Pharmaceuticals Limited
6	21th Jul 2020	Abbott India Limited
7	26th Jun 2020	Macleods Pharmaceuticals Limited

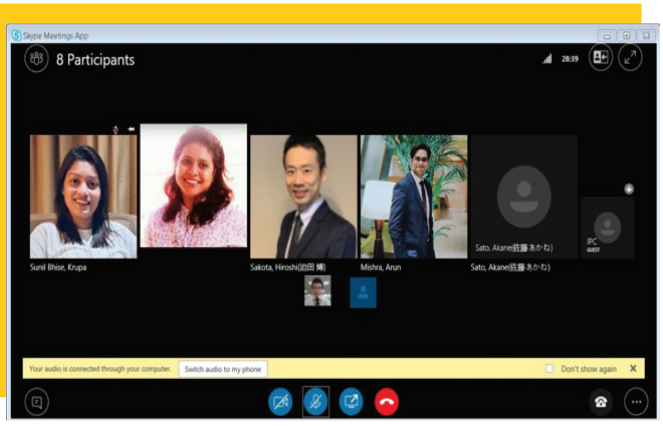
During these interactive meet, PvPI officials presented the summary of report on quality of ICSRs received from the MAHs/Pharmaceutical Industries.

- Completeness scores of ICSRs received during last year
- Lack of information in the ICSRs received
- Weightage for each field of ICSR and its impact on the overall quality score

The following points were suggested to MAHs/Pharmaceutical Industries to improve on the quality of ICSRs:

- 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.
- Narrative must cover all the information filled in the ICSR
- Communication regarding generated queries after review of ICSR must be responded within time frames to expedite the case processing.





Materiovigilance Programme of India (MvPI) Training Programmes

MvPI regularly holds training programmes of stakeholders in order to ensure effective Adverse Event reporting culture for Medical Devices. During COVID-19 pandemic, most of the training programmes were organised virtually are as follows:

S. No	Date	Training programme	Organized by	Target Audience	No. of Participants
1	25th Sep, 2020	Medical Devices: Opportunities and Challenges	Parul Institute of Pharmacy, Parul University, Vadodara, Gujarat	Physician, Nurses & Research Associates	150
2	17th-18th Sep, 2020	4th MvPI Induction-cum-Training Programme	NCC-MvPI	Coordinators & Deputy Coordinators	50
3	7th Sep, 2020.	Medical Device Rules-2017 & Materiovigilance	PGIMER, Chandigarh	Healthcare Professionals	30

New Drugs Approved in India

New drugs approved by CDSCO during April 2020- September 2020

S. No.	DRUG	INDICATION
1	Sucroferric oxyhydroxide bulk and Sucroferric oxyhydroxide chewable tablet 500mg	Phosphate binder indicated for the control of serum phosphorous levels in patients with chronic kidney disease on dialysis
2	Hydrogen peroxide 0.5% w/w wipes	Cleans, disinfects and deodorizes hard nonporous inanimate environmental surfaces
3	Centhaquine citrate bulk and Centhaquine citrate injection 1.0mg/vial	Add on resuscitative agent for hypovolemic shock
4	Hydrogen peroxide 0.5% w/w spray	Cleans, disinfects and deodorizes hard nonporous inanimate environmental surfaces
5	Remdesivir Injection 5 mg/ml and Remdesivir lyophilised powder for Injection 100 mg	For treatment of suspected or laboratory confirmed corona virus disease 2019 (COVID-19) in adults and children hospitalised with severe disease, in light of COVID-19 outbreak, for restricted emergency use in the country.
6	Lymphoseek 50mcg kit (each kit contains: Tilmanocept 50mcg, Glycine 0.1mg, Sodium ascorbate 0.1mg, Trehalose dihydrate 16mg, stannous chloride dihydrate 0.015mg, sodium hydroxide q.s, hydrochloric acid q.s, Nitrogen q.s, water for injection q.s)	Indicated for imaging and intraoperative detection of sentinel lymph nodes draining a primary tumour in adult patients with breast cancer, melanoma, or localized squamous cell carcinoma of the oral cavity. This medicinal product is for diagnostic only.
7	Favipiravir bulk and Favipiravir film coated tablet 200mg	For the treatment of patients with mild to moderate COVID-19 disease, in light of COVID 19 outbreak, for restricted emergency use in the country.
8	Remdesivir bulk drug	-
9	Propylene glycol 0.6% lubricant eye drops	Dry eye therapy for the temporary relief of burning and irritation due to dryness of the eye
10	Pretomanid bulk and Pretomanid tablets 200mg	Indicated as part of a combination regimen with Bedaquiline and Linezolid, in adults for the treatment of pulmonary extensively drug resistant (XDR), or treatment intolerant or nonresponsive multidrug resistant (MDR) tuberculosis (TB)
11	Favipiravir film coated tablet 400mg	For the treatment of patients with mild to moderate COVID-19 disease, in light of COVID 19 outbreak for restricted emergency use in the country
12	N-alkyl dimethyl benzyl ammonium chloride 0.105% w/w spray	Cleans, disinfects, deodorizes hard, nonporous inanimate environmental surfaces

13	Defetilide bulk and Dofetilide capsules 125mcg, 250mcg, 500mcg	Maintenance of Normal Sinus Rhythm (Delay in AF/AFl Recurrence) Dofetilide is indicated for the maintenance of normal sinus rhythm (delay in time to recurrence of atrial fibrillation/ atrial flutter [AF/AFl]) in patients with atrial fibrillation/atrial flutter of greater than one week
14	Octyl decyl dimethyl ammonium chloride 6.670% spray	Cleans, disinfects, deodorizes hard, nonporous inanimate environmental surfaces
15	Carbetocin bulk and Carbetocin injection 100 mcg/ml	Prevention of postpartum haemorrhage due to uterine atony

- HCPs are urged to closely monitor the safety of the above new drugs
- ADRs (if any) should be reported to PvPI

For more information, please refer following link:

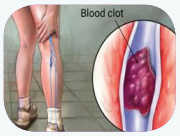
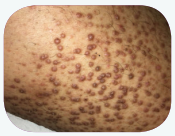
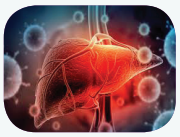
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjYwMA==

Drugs Safety Alerts issued during April 2020-September 2020

S. No.	Date	Suspected Drugs	Indication	ADRs
1	04th Sep, 2020	Fluvoxamine	Fluvoxamine is a Selective Serotonin Reuptake Inhibitor (SSRI) indicated for the treatment of Obsessive Compulsive Disorder and Depression.	Intracranial/ Pulmonary Hypertension
2	31st Aug, 2020	Pramipexole	Pramipexole is indicated for the treatment of sign and symptoms of idiopathic Parkinsons disease.	Photosensitivity Reaction
3	7th Jul 2020	SGLT-2 Inhibitors	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 Diabetes Mellitus.	Genital Pruritus
4		Fluconazole	For the treatment of systemic candidiasis, mucosal candidiasis, prevention of fungal infections in patients with malignancy.	Symmetrical Drug-Related Intertriginous And Flexural Exanthema (SDRIFE)
5	1st Jun 2020	Hydroxychloro-quine Sulphate	Off Label drug use as Prophylactic & Treatment of COVID-19 disease	Mouth Ulceration

Healthcare Professionals, Patients/Consumers are advised to closely monitor the above mentioned ADRs associated with the use of above suspected drugs. If such reactions are encountered, please report to the NCC-PvPI, IPC by filling up Suspected Adverse Drug Reactions Reporting Form for HCPs/Medicines Side Effect Reporting Form for Consumer (download from http://www.ipc.gov.in), through Android Mobile App (ADR PvPI) and PvPI Helpline No. **Helpline No. 1800-180-3024.**

Drug Safety Alerts issued by other countries and status of ICSR in PvPI database

Name of Drug	ADRs	No. of ICSRs in Global database	No. of ICSR in PvPI da-tabase	Reference
Tofacitinib (Xeljanz)	Risk of Embolism Venous/ serious and fatal infections 	06	01	Drug safety update, MHRA 18 March 2020 (https://www.gov.uk/drug-safety- update/tofacitinib-xeljanz-new-measures-to-minimise-risk-of-venous-thromboembolism-and-of-serious-and-fatal-infections)
Insulin human	Risk of cutaneous amyloidosis 	05	01	Drug safety update, MHRA18 March 2020. (https://www.gov.uk/drug-safety-update/insulins-all-types-risk-of-cutaneous-amyloidosis-at-injection-site)
Pirfenidone (Esbriet)	Risk of serious liver injury 	08	04	Product Safety Alerts, HSA, 14 September 2018 (http://www.hsa.gov.sg).

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

Safety concerns with SGLT2 Inhibitors

The Sodium Glucose Co-transporter-2 (SGLT2) inhibitors are second-line drugs used for the management of Type-II Diabetes Mellitus. SGLT2 inhibitors are a new class of Anti-diabetic agents; hence the safety profile of these agents is under the constant surveillance of Pharmacovigilance Programme of India. There are safety reports available from other regulatory agencies on the use SGLT2 inhibitors. The following table provides a compilation of ADRs associated with SGLT2 inhibitors:

S. No.	Drug	Adverse Drug Reaction	Regulatory Au-thority	Source
1	SGLT2 Inhibitors	Risk of Toe amputation	European Medicines Agency (EMA)	https://www.ema.europa.eu/en/news/sglt2-inhibitors-information-potential-risk-toe-amputation-be-included-prescribing-information
			United States Food & Drug Administration (USFDA)	https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-confirms-increased-risk-leg-and-foot-amputations-diabetes-medicine
2.		Diabetic ketoacidosis	Health Canada	https://www.hsa.gov.sg/announcements/safety-alert/interim-update-on-risk-of-serious-ketoacidosis-associated-with-sodium-glucose-cotransporter-2-(SGLT2)-inhibitors
3.		Fournier's gangrene	Medical and Healthcare products Regulatory Agency (MHRA, UK)	Medical and Healthcare products Regulatory Agency. SGLT2 inhibi-tors: reports of Fournier's gan-grene. Drug Safety Update 2019;12(7):3
			United States Food & Drug Administration (USFDA)	https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/sodium-glucose-cotransporter-2-SGLT2-inhibitors

Boost to PV @ RNTMCH, Udaipur

RNTMCH was recognized as an ADR monitoring centre under PvPI in August 2014 and conducted various awareness/sensitization programmes on regular basis for their Medical & Paramedical staff including students to enhance the PV activities.

The various PV activities were carried out by Dr. Meena Atray, Coordinator with the involvement of Dr. Apurva Agrawal, Deputy Coordinator and Mr. Jeewan Lal Menaria, PV Associate in RNTMCH.

PV @ Sriram Chandra Bhanja Medical College and Hospital (SCBMCH), Cuttack

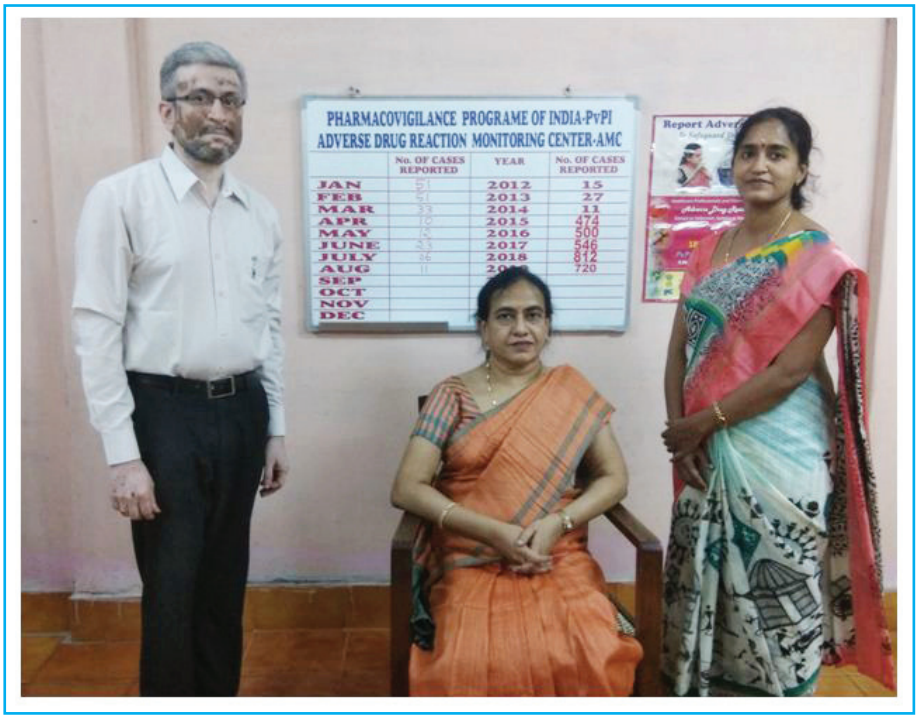
SCBMCH was recognised in Year 2011 as an ADR monitoring centre under PvPI.

The PV activities were managed from time to time by the Coordinators namely Prof. Srikanta Mohanty, Dr. Kali Prasad Pattnaik, Prof. Sabita Mohapatra, Dr. Priti Das and Mr. Swayam Sourav Sahoo, PV Associate.

PV @ Madurai Medical College (MMC), Madurai

MMC was recognised in Year 2014 as an ADR monitoring centre under PvPI.

MMC is actively participating in PV activities under the supervision of Dr. Malarsivaraman, Director, Department of Pharmacology, Dr M Malathi, Coordinator and Mr. T Thirumalai Nambi as Senior Pharmacovigilance Associate.



Dr. Lakhan Poswal

Principal and Controller,

RNT Medical College and associated hospitals, Udaipur

Pharmaceuticals are essential for disease management but no drug is absolutely safe. Inclusion of limited number of patients and exclusion of vulnerable group of population in clinical trials, aggressive marketing strategies by pharmaceutical companies and over the counter availability of drugs demand need of a monitoring system to promote safe and rational use of drugs. PvPI occupies a prime role in meeting the challenges and creating our own database. Our ADR monitoring centre and HCPs are working together in effective implementation of the program. I appreciate the entire team of ADR monitoring centre for their active involvement and contribution in improving health safety.

Dr. Meena Atray

Sr. Professor and Head of Department of Pharmacology

Coordinator, ADR Monitoring Centre, RNT Medical College, Udaipur

The main goal of drug utilization is effectiveness and safety but the safety is relative. Adverse drug reactions are one of the major cause of morbidity and mortality, constitute significant economic burden on the patient and government and most of the ADRs are preventable. PvPI recommends reporting of ADR of drugs, herbal preparations, ayurvedic and complementary medicines, blood and blood products, biologicals, medical devices and vaccines to safeguard the health of Indian population and ensuring benefits overweighs risk of medicine use. RNT Medical College was recognised as ADR monitoring centre under PvPI in August 2014. To promote awareness and to sensitize HCPs, several activities including continuous training of faculty, staff nurses and PG/UG students have been conducted. I want to thank our Principal and Controller, Dr. Lakhan Poswal for encouraging and providing all requirements in time and all HCPs for their active participation and contribution in fulfilling the objectives PvPI.

Dr. Lalit Kumar Regar

Additional Principal, RNT Medical College, Udaipur

PvPI, a robust and stable program, purpose of which is to collate, process and analyze data and use the inferences to recommend regulatory interventions to CDSCO and communicate risks to healthcare professionals and the public. ADR reporting is the most effective step towards ensuring health safety. Our institutional pharmacovigilance team is doing excellent work to aware clinician & nursing staff to report adverse drug reactions and ensure drug safety

Dr. Madhubala Chauhan

Superintendent Pannadhay Mahila Chikitsalay,

RNT Medical College Udaipur Rajasthan

Pharmacovigilance programme of India is wonderful and appreciable programme for health-care providers and consumers. It ensures safety of patients during drug use. It makes the doctors and patients more aware and updated about adverse drug reactions. My best wishes for success of programme. I congratulate programme coordinator Dr Meena Atray, Sr.Professor and Head of Department of Pharmacology and Deputy Coordinator Dr Apoorva Agrawal, Associate Professor Pharmacology, RNT Medical College Udaipur, Rajasthan

Dr. Neera Samar

Sr. Professor, Department of Medicine,

MB hospital, Udaipur Rajasthan

In today's scenario, the extensive production of newer drugs necessitates robust surveillance and vigilance programmes to ensure drug safety. Pharmacovigilance Programme of India (PvPI) has done admirable work in updating and educating healthcare providers regarding rational drug use. ADR monitoring has enabled us to make more informed choice of drug leading to improved patient outcomes. Also I would like to appreciate my colleagues and fellow members of ADR monitoring team at RNTMC, Udaipur, Dr. Meena Atray and Dr. Apurva Sharma, for their contribution.

Dr. Sharad Mehta

Associate Professor, Department of Dermatology

Member, Pharmacovigilance Committee

RNT Medical College Udaipur (Rajasthan)

PvPI is a very important and relevant national programme which is need of the hour, and all healthcare professionals need to actively participate in this programme for improvement in drug safety. Constant encouragement and support by the ADR monitoring centre of RNT Medical College has inspired us to report all possible adverse events we come across in our Dermatology Department. Looking forward to working with PvPI and ADR Monitoring Centre of Institute for availability of better and safe drugs.

Dr. R Selvakumar

Director Institute of Anaesthesiology

Madurai Medical College, Madurai

The usefulness of a drug vigilance system which aims to have a surveillance over the quality of drugs being used in public health care system like ours is immense. When we procure drugs in bulk quantity as in our health system, it's our duty to keep a check over the quality of drugs also. The Pharmacovigilance of Madurai Medical College is exactly doing that in our Hospital. In our institute of Anaesthesiology, once we encountered adverse reactions for Bupivacaine and we have reported the same to the Pharmacovilance Committee and they made all arrangements for quality check and safeguard the wellbeing of patients. I recommend a random analysis of all the essential drugs being used in our public health care system can be done by the Pharmacovigilance committee to standardize the quality of the drugs in future.

Dr. M Natarajan

H.O.D & Professor, Department of General Medicine

Madurai Medical College, Madurai.

Pharmacovigilance has become an important tool for identifying non-descriptive adverse drug reactions in medicine. The existence and availability of such forum should reach the access of all health care providers. The Pharmacovigilance Programme of India taking all the necessary steps to reach all the level of health care providers.

Dr. M Vijay Anand

Associate Professor, Department of Dermatology

Madurai Medical College, Madurai.

Adverse reactions to the drugs are a major challenge in modern medicine and these reactions may affect skin and internal organs. Cutaneous adverse drug reactions are most frequent form of adverse drug reactions they may vary in severity from mild to severe life-threatening reactions. As more and more drugs come in to market, we witness a lot of unusual form of cutaneous adverse drug reactions. Identifying and documenting these reactions will help in studying the incidence and also the likelihood of association with certain drugs. At Madurai Medical College the Pharmacovigilance committee is doing an excellent job in coordinating with all departments and documenting and reporting the adverse reactions.

Dr. Malarsivaraman

Director & H.O.D, Department of Pharmacology

Madurai Medical College, Madurai

AMC's under PvPI plays a pivotal role in monitoring, reporting of ADR and thereby preventing the patient sufferings from drugs and their quality related ill effects. We have reported as many as 3000 ICSR's to the national database since, our inception as AMC under NCC-PvPI, in 2014. Our Clinicians contributed in a great way to report unlisted ADR's and they played a vital part in signal detection. We have also taken many preventive actions to withdraw the complained products after proper assessment by the Causality Assessment Committee. We have been given the status of Medical device Monitoring Centre since July 2020 and continue to contribute to our level best for all the patient safety measures of NCC-PvPI.

Dr. M Malathi

Coordinator, Institute of Pharmacology

Madurai Medical College, Madurai.

The Pharmacovigilance activities in Madurai Medical College is carried out since January 2014. In recent times we have involved undergraduate (MBBS and B.Pharm) Postgraduate (MD Pharmacology) students to inculcate the Pharmacovigilance culture among students. This has kindled the interest of the students to involve in many short-term research projects. Materiovigilance is another milestone and our team are eager to improve our activities and efforts are being made consistently in the right direction to achieve the goal.

Dr. P Jothi Sundaram

Professor, Department of Obstetrics and Gynaecology

Madurai Medical College, Madurai

Pharmacovigilance is an upcoming field of medicine which includes drug safety, quality check and notification of adverse reaction to concerned authority. In GRH, Pharmacovigilance Committee of Madurai Medical College plays a key role in detection, assessment and prevention of adverse drug reaction. In OBG department, when we are dealing with two lives, Pharmacovigilance helped us in preventing maternal morbidity and mortality.

Dr. Priti Das

Deputy Coordinator, Associate Professor, Department of Pharmacology

SCB Medical College, Cuttack, Odisha.

India being a heavily populated country, has enormous genetic variability and multiple methods are being adopted for healthcare management. SCB MCH, Cuttack being the premier healthcare institute in the state and eastern India is doing a tremendous job at fulfilling healthcare needs. Ensuring that the benefits of medications are outweighing the risk is the need of the hour. AMC at Department of Pharmacology is putting untiring efforts in creating awareness among clinicians and encouraging them to report all ADRs. We are working with vigor and zeal for active participation and regular follow up. PvPI has a pivotal role in upholding patient safety in public health. At AMC in Pharmacology Department, SCB MCH we extend complete cooperation and wish PvPI a long way and all the success for future endeavors.

Dr. Dipak Ranjan Das

Assistant Professor, Department of Cardiology,

SCB Medical College, Cuttack, Odisha.

Human beings can't completely eliminate disease from the earth. So drugs will always be required for some ailments or the other. Hence drugs safety monitoring by Pharmacovigilance Programme of India (PvPI) will always be a crucial part of our medical practice. The ADR Monitoring Centre in SCB Medical College, Cuttack is providing yeoman service in this regard be increasing awareness among clinicians, reporting SAEs and contributing towards better patient care ultimately. The scope of work of this unit is sure to increase in days ahead as more number of patients are likely to be treated with more number of drugs.

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।

सत्यमेव जयते
IPC

Indian Pharmacopoeia Commission
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Pharmacovigilance Programme of India
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Sector-23, Raj Nagar, Ghaziabad- 201002
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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