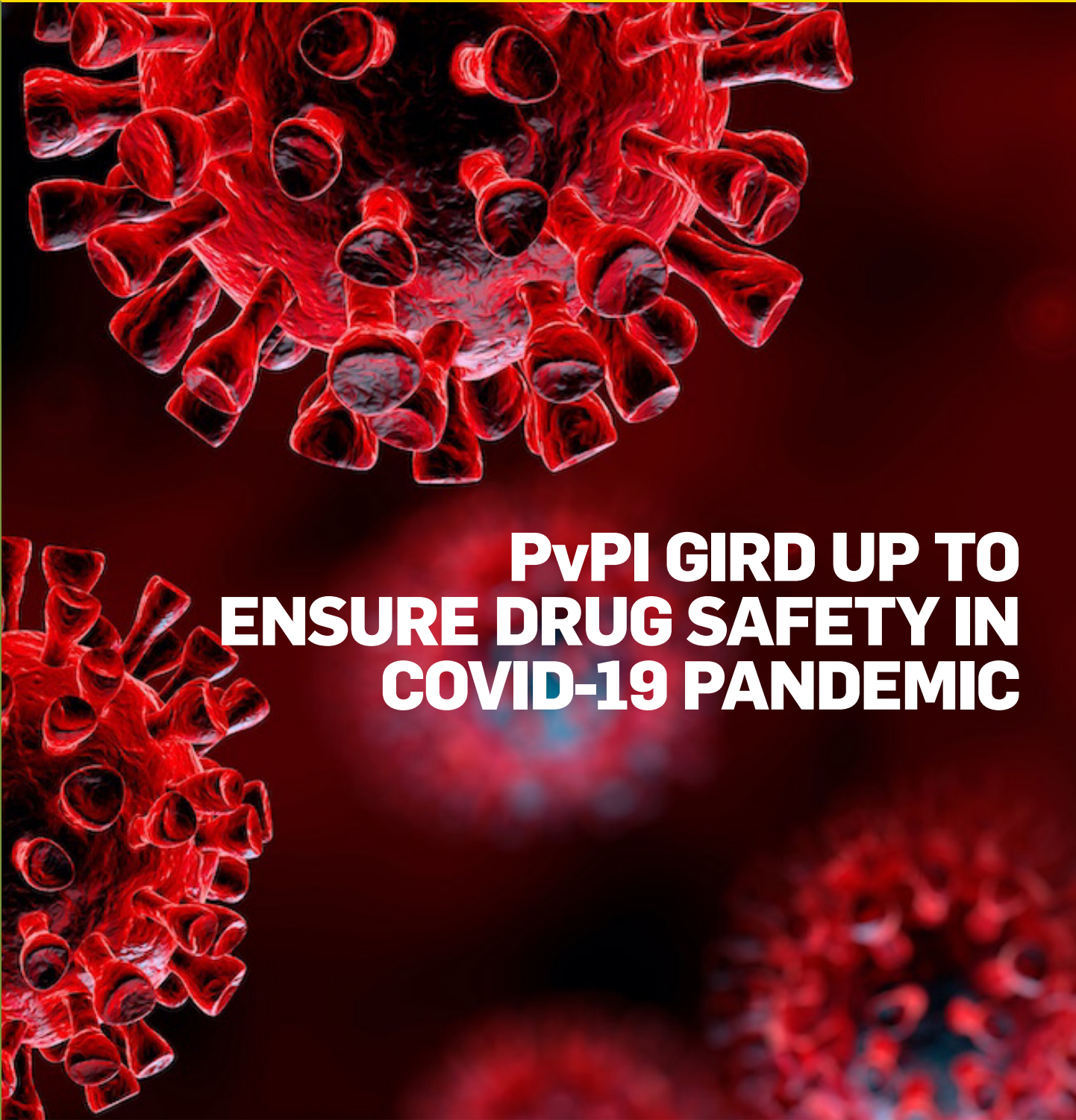




# Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

VOL 9 -10 | ISSUE 29-30 | 2019-20

A large, detailed microscopic image of a virus, likely SARS-CoV-2, is the background for the main title. It shows a spherical particle with a textured surface and numerous red, cup-shaped structures (spikes) protruding from it. The background is a dark, reddish-brown color.

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This is a matter of proud and appreciation that Pharmacovigilance Programme of India (PvPI) is bringing out its newsletter on regular basis to delineate its achievements and activities.

The journey of PvPI so far has created a platform to ensure the safety of medicines in Indian population, provided a base to take regulatory decisions on the basis of the safety profile of drugs and ultimately helping healthcare professionals to practice evidence-based medicines.

I am happy to note that PvPI has enrolled forty one (41), new ADR Monitoring Centre (AMCs) in its sphere of activities which will surely strength PvPI activities across the length and breadth of the country.

During the challenging times in COVID-19 pandemic, PvPI stood strong and took prominent actions for reporting of Adverse Drug Reactions (ADRs) on account of emergency use of different medicines in prophylaxis & treatment of corona-virus infection. PvPI tools such as Toll free Helpline #1800-180-3024 (Monday to Friday 9:00AM-5:30PM) and android mobile app 'ADR PvPI' made available for all stakeholders to report the safety issues of medicines.

PvPI staff is expeditiously analyzing the safety profile of medicines used for the prophylaxis and the treatment of corona-

virus infection and recommendations in terms of PIL update and drug safety alerts are regularly shared with Central Drugs Standards Control Organization (CDSCO).

This is also important to note that online training activities for all stakeholders have already initiated and the task force at National Coordination Centre (NCC) is striving hard for arranging online trainings and workshops for MAHs, NABH-accredited hospitals and other stakeholders to ensure capacity building in Pharmacovigilance.

I extend my heartfelt gratitude to all the members of PvPI at NCC and AMCs for their significant efforts, inputs and commitment. I am sure that with cooperation of all, we would also be able to pursue the excellence in strengthening the PvPI in future.

**Prof. Y. K. Gupta**  
National Scientific Coordinator  
Pharmacovigilance Programme of India

# Foreword from Secretary-cum-Scientific Director



Greetings to Readers,

With great pride, enthusiasm and a sense of responsibility, I wish to reach out to all the readers of the Pharmacovigilance Programme of India (PvPI) Newsletter. The National Coordination Centre-PvPI is committed for discharging its assigned responsibilities in the fascinating field of Pharmacovigilance across India and beyond. The continually changing scientific scenario in the field of Pharmacopoeial Sciences and Pharmacovigilance has gained impetus in recent years, which has prompted healthcare professionals and patients to be more vigilant towards the quality and safer use of medicines. We have been facing challenging times during the past few months on account of COVID-19 pandemic. As the medical and scientific fraternity work tirelessly to find suitable treatments for COVID-19, the concerted efforts of PvPI to promote drug safety and ultimately patient safety are vital for the success of public health initiatives in India.

The journey of PvPI has been remarkable during the last one decade as there has been a phase-wise expansion of PvPI. The continuous support of all 311 AMCs is vital for the success and effectiveness of the Pharmacovigilance Programme of India. The National Coordination Centre (NCC)-PvPI took lead in responding to the emerging challenges of medicine safety during the COVID-19 pandemic and rolled out the newly devised suspected ADR reporting form for the drugs used in the treatment and prophylaxis of COVID-19 infection.

The National Task Force for COVID-19, constituted by the Indian Council of Medical Research, New Delhi considered the PvPI data, while revising the advisory on the use of Hydroxychloroquine (HCQ), as prophylaxis for COVID-19 infection. PvPI has been continuously working towards establishing a robust drug safety monitoring and reporting mechanism. Communication tools such as Suspected ADR reporting form for Healthcare professionals, Medicines side effect reporting form for consumers, Suspected ADR reporting form for the drugs used in the treatment/Prophylaxis of COVID-19, Tollfree Helpline #1800-180-3024 (Monday to Friday 9:00 AM-5:30 PM) and Android Mobile App 'ADR PvPI' are facilitating the reporting of Adverse Drug Reactions to PvPI.

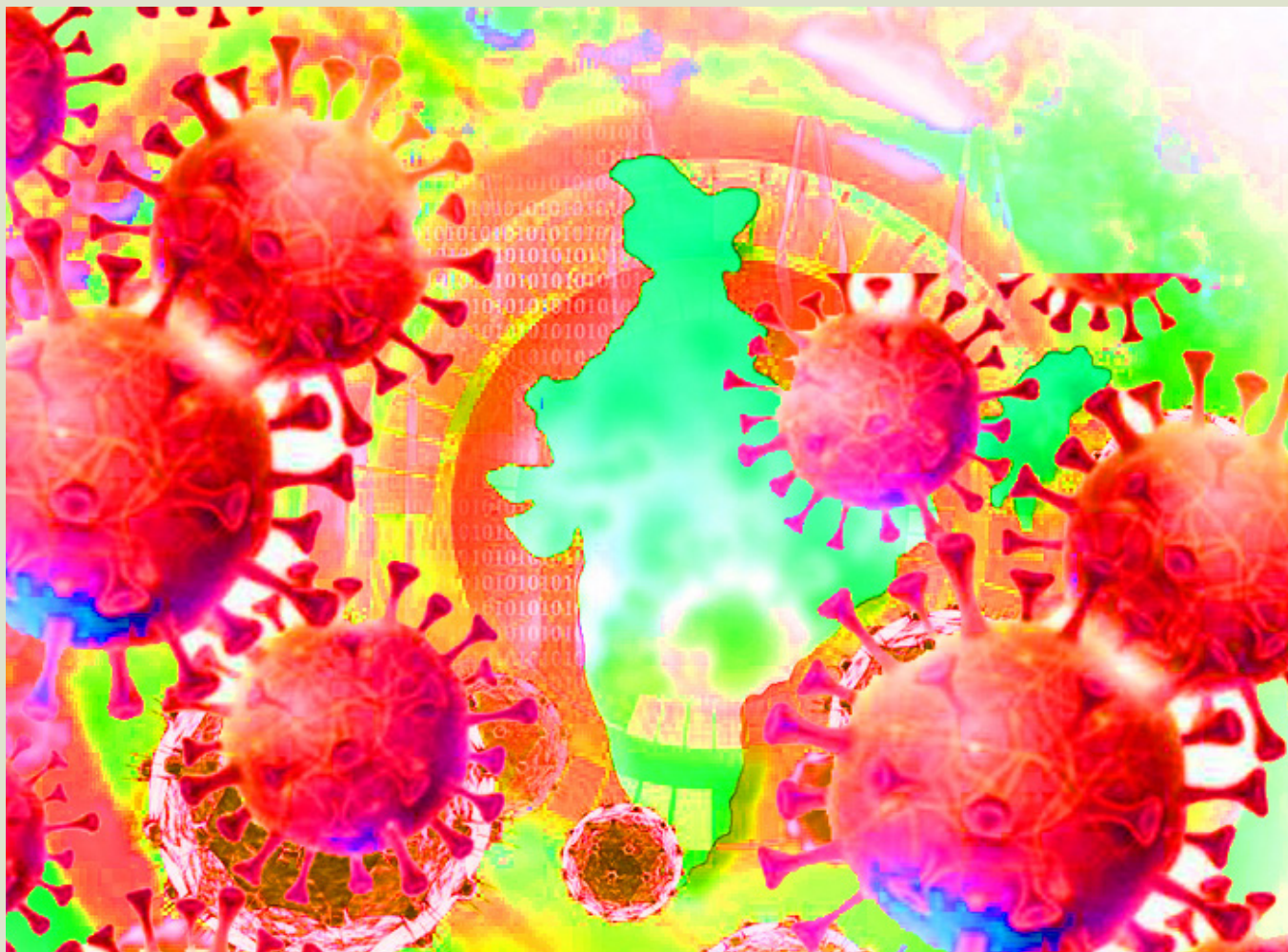
We are confident that the overall administrative and financial support of the Ministry of Health and Family Welfare, untiring efforts of the PvPI staff, AMC personnel, Industry stakeholders, Multidisciplinary experts, will continue providing the credible data to rely upon and to boost the public confidence in the safety of medicines. We welcome stakeholders' feedback to take improvement measures in this area to ensure the safety and well-being of one and all. We look forward to our journey together towards the safe use of medicines.

With Kind Regards

**Dr. Jai Prakash**

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





# PvPI ensures medicine safety during COVID 19 Pandemic

**T**he pandemic Coronavirus Disease-19 (COVID-19), has transformed our lives and led to a complete paradigm shift in Pharmacovigilance (PV) worldwide. New therapeutic information for the treatment of COVID-19 and considerable COVID-19 drug interactions are emerging as clinical and PV data arrive daily. Previous experience in the treatment of coronavirus, such as SARS-COV and MERS-COV, provided clinicians with a reference point for dealing with the novel coronavirus, however, new data on drug safety is piled up every day.

For sufficient information about the efficacy and Adverse Drug Reactions (ADRs) of treatments

used against COVID-19, all adverse events must be collected, recorded and reported as quickly as possible. As the medical and scientific community work tirelessly to find suitable treatments for COVID-19, it is our duty at Pharmacovigilance Programme of India (PvPI) to generate safety data of the medicines used for treatment/prophylaxis of COVID-19.

From the very initiation of COVID-19 pandemic in India, PvPI started its series of actions towards safeguarding public health through its nationwide network of 311 ADR Monitoring Centres (AMCs). This network soon started collecting ADRs reported due to the use of any medicines for treatment/prophylaxis of COVID-19 further, these reports are



Dear Colleagues,

Warm Greetings from National Coordination Centre, Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission!!

As you are aware that the nation is passing through the COVID-19 pandemic, NCC-PvPI requests all healthcare professionals to closely monitor the adverse drug reactions (ADRs) with special emphasis on the drugs used in the treatment and Prophylaxis of COVID-19 to enhance patient safety. The National Task Force for COVID-19 constituted by Indian Council of Medical Research (ICMR) has taken into consideration of the data generated from Pharmacovigilance Programme of India (PvPI) of an adverse event/adverse drug reaction due to the prophylactic use of Hydroxychloroquine.

Therefore, in order to ensure the effective implementation of Pharmacovigilance system in the country, you are hereby requested to sensitize all healthcare professionals including Physicians, Nurses, Pharmacists and consumers as per the advisory issued by ICMR to monitor and report Adverse drug Reactions, if any through self reporting by using PvPI-ADR Mobile App, Toll free 1800 180 3024 and ADR reporting forms to National Coordination Centre, PvPI (NCC-PvPI, IPC) in the larger interest of Indian population.

Thanks and regards,

Technical Secretariat  
National Coordination Centre-  
Pharmacovigilance Programme of India (NCC-PvPI),  
WHO Collaborating Centre for Pharmacovigilance in  
Public Health Programmes and Regulatory Services,  
Indian Pharmacopoeia Commission  
Sector-23 Raj Nagar Ghaziabad-201002, U.P.

being analyzed at National Coordination Centre (NCC) – PvPI, IPC.

The National Task Force to fight against COVID-19 pandemic at Indian Council of Medical Research (ICMR), New Delhi, directed healthcare professionals (HCPs) to report all ADRs related to use of Hydroxychloroquine (HCQ) to PvPI using its helpline #1800-180-3024 or mobile app 'ADR PvPI'. Hence, shouldering this responsibility, PvPI tools are actively engaged to support the data generation on safe use of HCQ in COVID-19.

As a part of Comprehensive Pharmacovigilance Strategy, the PvPI with the help of experts has come

out with a newly designed ADR Reporting form. This form will help in reporting ADRs arising from the drugs used in the prophylaxis and the treatment of COVID-19 to ensure medication safety and is made available across all AMCs of PvPI in the country. PvPI has shared this form with the National Task Force for COVID-19 for the distribution among all HCPs involved in the care of coronavirus infected patients. This ADR form is available on the IPC website. (<http://www.ipc.gov.in/news-highlights/752-adr-reporting-form-for-drugs-used-in-covid-19.html>).

In its continued efforts towards ensuring safe use of drugs for COVID-19, all the AMC Coordinators and Pharmacovigilance Associates posted at the respective AMCs under the ambit of PvPI are being sensitized regularly to keep a close watch on the ADRs which may occur due to drugs used during COVID-19. Data generated in terms of Individual Case Safety Reports (ICSRs) from AMCs are further analyzed regularly at the NCC-PvPI and the information gathered shared with the regulatory authority (CDSCO) and the National Task Force for COVID-19.

Monitoring the safety of medicines is an obvious objective of PvPI. Multiple therapeutic options including re-purposed drugs are being tried in the treatment of coronavirus infections. PvPI reiterates its commitment towards ensuring medicine safety in public interest and urges all the healthcare professionals and the consumers to report any possible ADRs related to drugs used in COVID-19 by using active PvPI tools.

**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**

1. 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) : \_\_\_\_\_

2. Age/Date of Birth : \_\_\_\_\_

3. Weight (in Kg) : \_\_\_\_\_

4. Gender : Male ☐ Female ☐  
Transgender ☐ Yes ☐ No ☐

5. If female pregnant : Yes ☐ No ☐

6. Lactating : Yes ☐ No ☐

7. 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 : Yes ☐ No ☐  
5. Radiological examination : Yes ☐ No ☐  
6. Other Relevant information, if any : \_\_\_\_\_

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

**B. SUSPECTED ADVERSE REACTION**

S.No.	Reaction	Start Date	End Date	Outcome*

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

9. Describe Event(s)/Reaction(s) with treatment details, if any in chronological order : \_\_\_\_\_

10. 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-I/PD Deficiency ☐  
Dermatological findings, if any ☐  
Others ☐

11. Drug Interactions : Mention name of any interacting (with Suspected Drug) drug taken : \_\_\_\_\_

12. 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 ☐

# 6<sup>th</sup> Asia-Pacific PV Training Course @ IPC

To address the unique challenges for implementing Pharmacovigilance practices in countries of the Asia-Pacific region, The Indian Pharmacopoeia Commission (IPC), NCC-PvPI, Ministry of Health & Family Welfare, Government of India has organized “6<sup>th</sup> Asia-Pacific Pharmacovigilance (PV) Training Course” from 24<sup>th</sup> February to 6<sup>th</sup> March, 2020 at Ghaziabad. Fourteen participants, from 6 countries including Bangladesh, India, Nigeria, Philippines, Yemen and Zimbabwe attended the training programme. The objective of

this training course was to further develop effective and sustainable Pharmacovigilance practices for member-countries of the WHO Programme for International Drug Monitoring (WHO-PIDM). During this course 31 technical sessions, 5 workshops and 4 hands-on sessions were conducted. The speakers for these sessions included the experts from Uppsala Monitoring Centre (UMC)-Sweden, MHRA-UK, ISO-P-UK, CDC-South Africa, MoHFW-India, MedDRA, MSSO-India, CDSCO-India, CDDEP-India, NIB-India, PvPI, IPC-India, Pharma Industries and Academia.





# World Conference on access to Medical Products

**T**he Ministry of Health & Family Welfare (MoHFW), Government of India and WHO organized the “2019 World Conference on Access to Medical Products -- Achieving the Sustainable Development Goals (SDGs 2030)”, in New Delhi from November 19–21, 2019. The three-day conference was attended by Dr Jai Prakash, Secretary-cum Scientific Director (I/c), IPC. Embarking on WHO’s 13th Global Programme of Work (GPW13) for strategic direction in Sustainable Development Agenda 2030 for Health, the conference stressed that access to

effective, safe, quality-assured and affordable medical products (medicines, vaccines, diagnostics, devices) was the key to attaining Universal Health Coverage (UHC). India’s contribution to providing access to medical products worldwide, is well recognized. Being a major hub for manufacturing medical products, including generics, India has excelled in R&D for affordable products with supportive technology platforms, network of clinical sites and testing facilities, and health technology innovation for meeting critical global health needs.

# National AEFI meeting

**A** National AEFI meeting was held at AEFI Secretariat, New Delhi on December 20, 2019 to assess the progress made by AEFI during the year 2019. With inaugural remarks by Dr Satinder Aneja Chairperson, National AEFI Committee and Dr Madhur Gupta, Technical Officer, WHO-India, discussed 3S Project’s progress and also presented a report

on Rotavirus vaccine in India. AEFI Secretariat official Dr Nidhi gave a brief analysis of AEFI cases reported in the MR campaign. An emergent need for continuous training to DIOs and paediatricians was recommended by the chairperson for increasing AEFI reporting. Various Android apps are also being developed which help the paediatricians report AEFI cases.

# Symposium on Lymphatic Filariasis eradication

**A** National symposium on Lymphatic Filariasis was jointly organized by National Vector-Borne Disease Control Programme (NVBDCP), WHO, Bill and Melinda Gates Foundation, Global Health Strategies, Clinton Health Access initiative, PCI and PATH at Pravasi Bhartiya Kendra on October 30, 2019.

Dr Harsh Vardhan, Union Health Minister, Government of India, addressed NVBDCP stakeholders such as ICMR, Media, PvPI-IPC, WHO, PCI, etc., on key issues related to Lymphatic Filariasis.

## TOPICS ADDRESSED:

- An overview on Epidemiology of Lymphatic Filariasis in India, and Mass Drug Administration (MDA) of IDA i.e. Ivermectin, Diethylcarbamazine and Albendazole
- Scaling up IDA to accelerate Lymphatic Filariasis Elimination in India
- Roadmap for 2020–30 to eliminate neglected tropical disease (NTD) by creation, collaboration and integration and progress of Global Programme to Eliminate Lymphatic Filariasis (GPELF)
- Enhancing post-MDA surveillance to verify elimination

# PV awareness workshop at HIMSR, New Delhi

**H**amdard Institute of Medical Sciences and Research (HIMSR), Jamia Hamdard, New Delhi organized a workshop in collaboration with PvPI, IPC on November 21, 2019, at HIMSR, New Delhi.

The workshop was attended, among others, by HIMSR faculty, B.Pharm, M.Pharm, MBBS students, resident doctors and research scholars.

IPC officials Dr V Kalaiselvan, Principal Scientific Officer, Dr Shashi Bhushan, Senior Scientific Officer and Dr R S Ray, Scientific Assistant attended the workshop.

The keynote address at the Workshop-cum-Awareness programme was delivered by Dr G N

Qazi, Director General (HIMSR), Jamia Hamdard. Dr Kalaiselvan, deliberated on the Materiovigilance Programme of India. Dr Shashi Bhushan, dwelt upon the “Pharmacovigilance Programme of India”, highlighting the achievements of IPC, NCC-PvPI in promoting patient safety and also sensitized the audience to the regular Skill Development Programme sessions at IPC. Other speakers included Prof Arunabha Ray, Coordinator, HIMSR and Prof Kavita Gulati, Coordinator, VPCI. Dr Shoma Mukherjee, Assistant Professor and Ms Kajal Kiran Sharma, Pharmacovigilance Associate conducted the hands-on-training for the participants.



## AEFI Partners' meet

**A**n Adverse Event Following Immunization (AEFI) Pharmacovigilance Partners' meeting was held at Nirman Bhawan, MoHFW, New Delhi on November 4, 2019. The day-long meeting was attended by National AEFI committee members and experts from WHO-India office, CDSCO and AEFI Secretariat. Dr Vijit Agrawal, Senior PV Associate, represented IPC at the meeting.

### SALIENT FEATURES

➤ Dr M K Aggarwal, Deputy Commissioner-

Universal Immunisation Programme (DC-UIP) sought an update from all stakeholders following last Pharmacovigilance Partner's meeting

- Progress of IDP and SAFE-VAC discussed
- AEFI surveillance update
- QMS update by AEFI Secretariat
- PvPI be included in trainings conducted by AEFI Secretariat, and vice versa, urged PvPI official
- Discussion on further training for AEFI surveillance
- Dr M K Aggarwal asked CDSCO to create a process for collating AEFI data from all stakeholders for signal detection



# Vaccine Safety workshop at WHO-India

**W**orkshop on 'Literature Search and Synthesis on Vaccine Safety' was organised by WHO-India at, New Delhi on November 25-26, 2019. Dr Shashi Bhushan, Senior Scientific Officer, Dr R S Ray, Scientific Assistant and Dr Vijit Agrawal, Sr. PV Associate represented NCC-PvPI, IPC, Ghaziabad at the workshop.

The objective of the two-day workshop was to enhance the understanding of all stakeholders on Literature Search and Synthesis on Vaccine Safety. Representatives from CDSCO, PvPI, AEFI Secretariat attended the workshop and the following topics were discussed by the experts:

- Why it is important to do literature search and how to do it

- Sources of vaccine safety literature information
- Databases available for literature search
- Critical appraisal of manuscript and framework for synthesis of data
- Group exercises for all above-mentioned topics

## BENEFITS AND OUTCOME:

- Knowledge on how to start a literature search and how to raise a research question. What are the key elements for good research and selection of literature?
- Use of referencing software to minimize efforts and maximize work efficiency – e.g Zotero, End Note, etc.

# CDSCO and PvPI- Internal Review Meeting

**T**he Meeting on “Policy, Capacity building, Strengthening & Implementation of Pharmacovigilance” amongst officials of CDSCO and PvPI meeting was held on 20th January 2020 at Mini Conference Room, CDSCO HQ, New Delhi. The meeting was attended by Mrs Rubina Bose, DDC(I), West Zone, CDSCO (DCG(I)-Nominee); Dr Shashi Bhushan, Senior Scientific Officer, IPC, Dr R S Ray, Scientific Assistant, Mr Rishi Kumar, Scientific Assistant, Ms. Swati Thapliyal, PV Associate and Mr Deepak Malik, IT Associate.

## OUTCOME OF MEETING

- Website related issues such as sharing of PvPI update link with the CDSCO, IT Official for timely updating CDSCO/IPC website and shifting of old notifications to Archive-section of IPC Website was discussed.
- Zonal Office communication – Need for support from Officials of CDSCO at zonal offices on the Training/Awareness programmes conducted by PvPI.

- To the issue regarding the WHO- Country office and NCC-PvPI communication gap, Mrs Rubina Bose requested PvPI to convey this in person to DCG(I).
- Guidance Document for Marketing Authorization Holder (MAH)- Need for updation of current version of Guidance Document for MAH in consultation with CDSCO.
- PvPI/CDSCO opined not to endorse Pharmacovigilance Module of Life Science Sector Skill Development Council (LSSSDC) and to convene a meeting in this regard with DCG(I), CDSCO.



# 16<sup>th</sup> Signal Review Panel meet at NCC-PvPI

IPC-PvPI organized the 16th Signal Review Panel (SRP) meeting at IPC, Ghaziabad on December 27, 2019. SRP chairperson Prof Urmila Thatte welcomed the Panel and appreciated the efforts of Dr Jai Prakash, Senior Principal Scientific Officer, IPC, and his team for the overall growth of PvPI. At the

meeting the PvPI team presented 12 Drug-ADR combinations which were identified on the basis of Individual Case Safety Reports (ICSRs) received at PvPI. The members, after the discussion on each combination, recommended the following outcome to be communicated to the CDSCO.

S. No	Drug	Adverse Drug Reaction	Recommendations to CDSCO
1.	Oseltamivir	Sinus Bradycardia/Bradycardia	Signal
2.	Alfuzosin	Palpitation	To include in PIL
3.	Benidipine	Photosensitivity reaction	To include in PIL
4.	Pentoxifylline	Palpitation	To include in PIL
5.	Piperacillin+Tazobactam	Acute Generalised Exanthematous Pustulosis (AGEP)	To include in PIL
6.	Tinidazole	Skin Hyperpigmentation	To include in PIL
7.	Terlipressin	Atrial Fibrillation	Drug Safety Alert
8.	Olanzapine	Hyponatraemia	Drug Safety Alert
9.	Piperacillin+Tazobactam	Blurred vision	Drug Safety Alert
10.	Fluconazole	Mouth ulceration	Drug Safety Alert

## Interactive session with Industry Partners

NCC-PvPI, regularly conducts interactive sessions with MAHs to update them on the collation, analysis and quality scoring procedures for individual ICSRs, followed at PvPI. As the completeness score of ICSRs is one of the main criteria of quantitatively assessing the power of individual

ICSR for contributing towards potential regulatory recommendations, hence the interactive meeting with MAHs on the quality of ICSRs submitted by them serves the purpose of improving the overall quality of PvPI data submitted to Vigibase. The table below provides details of such meetings conducted during the index period:

S. No.	Meeting	Venue & Date	No. of Participants
1.	Interactive meeting on improving the quality of ICSRs received from Glenmark Pharmaceuticals Limited	NCC-PvPI, IPC, Ghaziabad December 06, 2019	7
2.	Interactive meeting on improving the quality of ICSRs received from Sun Pharma Pharmaceuticals Limited	NCC-PvPI, IPC, Ghaziabad January 23, 2020	11
3.	Interactive meeting on improving the quality of ICSRs received from GSK Pharmaceuticals	NCC-PvPI, IPC, Ghaziabad January 28, 2020	11

### RECOMMENDATIONS:

The following points were suggested to improve the quality of ICSRs:

- Provide information mainly Time to onset, Patient information, Outcome and Indication
- Provide complete information in the narrative section
- Provide Causality Assessment in WHO-UMC scale
- All four sections of ICSRs – identifiable reporter, identifiable patient, suspected drug and suspected adverse reaction – need to be completed during ICSR processing to consider the case valid





# Skill Development Programmes at NCC-PvPI

PvPI organized its serial Skill Development Programme (SDP) on “Basics and Regulatory Aspects of Pharmacovigilance” at IPC, Ghaziabad.

During the year, three such programmes were conducted. The details of these training programmes are provided in the table below:

S. No.	Date	Training Programme	Place	No. of Participants
1.	July 15-19, 2019	12 <sup>th</sup> Skill Development Programme on Pharmacovigilance for Medical Product	NCC-PvPI, IPC, Ghaziabad	18
2.	September 23-27, 2019	13 <sup>th</sup> Skill Development Programme on Pharmacovigilance for Medical Product	NCC-PvPI, IPC, Ghaziabad	51
3.	December 9-13, 2019	14 <sup>th</sup> Skill Development Programme on Pharmacovigilance for Medical Product	NCC-PvPI, IPC, Ghaziabad	28



## TRAINING & EDUCATION



### OUTCOMES

- Participants acquired basic knowledge in Pharmacovigilance
- Acquired skills to deliver Good Pharmacovigilance Practices at par with international standards
- Visited AMC-NDDTC hospital, Ghaziabad, gaining insight into work culture at AMC and ADR reporting
- Participants were given hands-on training on different modes of ADR-reporting





# ALT-cum-Coordinators' meet at AIIMS Bhopal

AIIMS Bhopal organized an Advance Level Training on Pharmacovigilance-cum-Coordinators meeting for the states of Madhya Pradesh and Chhattisgarh on November 8, 2019. Nearly 50 participants including nine Coordinators/Deputy Coordinators and five Pharmacovigilance Associates of ADR Monitoring Centres in Madhya Pradesh and Chhattisgarh attended the programme. Dr Sarman Singh, Director, AIIMS-Bhopal inaugurated the programme. He highlighted the importance of Pharmacovigilance for patient safety. Dr Balakrishnan, HOD, Dept of Pharmacology, AIIMS-Bhopal made the opening remarks.

## MOOT ISSUES:

Topic of Presentation	Speakers
Pharmacovigilance and RNTCP	Dr S P Dhaneria, Professor and Head, Pharmacology and Dean Academics, AIIMS-Raipur
Haemovigilance: How to report an adverse event after a blood transfusion	Dr Manisha Shrivastava, Medical Superintendent and Head of Transfusion Medicine, AIIMS-Bhopal
Adverse Drug Reactions due to Drug Interactions	Dr Nitin Gaikwad, Additional Professor, Pharmacology, AIIMS-Raipur
Genovigilance	Dr S Balakrishnan, Professor and Head of Pharmacology, AIIMS-Bhopal
Brief Reports of RTC, AIIMS-Bhopal	Ms Deepa Chaudhary and Ms Anamika Choure, PvAs, AIIMS-Bhopal
Open Discussion	Demo of New VigiFlow

The programme concluded with the vote of thanks by Coordinator, Dr Ratinder Jhaj, AIIMS-Bhopal.

# MedDRA training at NCC-PvPI

With an objective of understanding the coding process using MedDRA terminologies, NCC-PvPI, IPC organized a MedDRA training at IPC, Ghaziabad on November 14-15, 2019. At the two-day training programme, Dr Anamika Dutta, Instructor at MedDRA-Maintenance and Support Services Organization (MSSO), provided training to all Pharmacovigilance Associates and IPC-PvPI officials. MedDRA is a clinically-validated international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry. The terminology is used through the entire regulatory process, from pre-marketing to post-marketing, and for data entry, retrieval, evaluation, and presentation. MedDRA was developed under the auspices of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). This training facilitated participants to gain knowledge on the exchange of clinical information



through standardized mechanisms developed by MedDRA.

## TOPICS DELIVERED:

- MedDRA an important tool for product evaluation, monitoring, communication, electronic records' exchange and oversight
- Coding (data entry), retrieval and analysis of clinical information on human medical products, including pharmaceuticals, biologics, etc

# PV workshop for the Pharma industry

**R**egional Workshop on “Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries — A Way Forward” is a featured training programme which is regularly organized by PvPI for updating

the Marketing Authorization Holders (MAHs) on the process of reporting ADRs to PvPI and regulatory perspective of PV in India. During Oct 2019 to Mar 2020 two such workshops were organized:

Date	Training Programme	Venue	Number of Participants
January 10, 2020	13 <sup>th</sup> Regional workshop on Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries - A Way Forward" for MAHs	Sri Aurobindo Institute of Medical Sciences (SAIMS), Indore	32
November 29, 2019	12 <sup>th</sup> Regional workshop on Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries - A Way Forward" for MAHs	Central Drug Testing Laboratory (CDTL), Mumbai	33

## TOPICS DELIVERED:

- Pharmacovigilance Regulations in Drugs and Cosmetics Rules 1945, Schedule Y and M Guidelines and New Drugs and Clinical Trials Rules
- Introduction to ADR-reporting forms and overview

- of Causality Assessment Scale, An Overview of Pharmacovigilance Programme of India
- Introduction to E2B XML Format for ADR/AE reporting to PvPI and Good Pharmacovigilance Practices (GVPs) and Risk Minimization Measures (RMM)

# ALT-cum-Coordination's meet at PGI, Chandigarh

**A**n Advance Level Training on Pharmacovigilance-cum-Coordination's meeting was organized by PGIMER, Chandigarh on December 1, 2019.

The training programme was primarily aimed at making PV Associates understand the current and advance updates in the field of Pharmacovigilance and also acquaint them with ways of using the new version of VigiFlow effectively.

Following topics were deliberated upon by speakers during the workshop:

- Current update on PvPI programme and way forward – Dr Bikash Medhi

- Drugs in Real World – Dr Rajan Mittal
- Pharmacovigilance for Vaccines – Dr Sapan Kumar B
- Challenges in New VigiFlow – Dr Vijit Agrawal.
- SAE Reporting, Causality Assessment, Clinical Trial Rules and Materiovigilance, etc were also discussed

## BENEFITS AND OUTCOME:

- PV Associates' doubts and queries on use of New VigiFlow – such as how to send the report to NCC, how to add the follow-up, how to use search-filters and how to access the report – were well addressed
- Participants also learned coding with MedDRA

# Approved New Drugs in India

New drugs approved by CDSCO during July- September 2019

S. No	DRUG	INDICATION
1.	<b>Acalabrutinib 100 mg capsules</b>	For treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy
2.	<b>Abemaciclib 50 mg, 100 mg, 150 mg and 200 mg film-coated tablets</b>	(i) Abemaciclib is indicated for treatment of women with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist. (ii) As monotherapy for treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting
3.	<b>Ripasudil hydrochloride hydrate bulk drug and Ripasudil Eye drops 0.4% w/v</b>	To treat glaucoma and ocular hypertension when other medicines for glaucoma have insufficient effect or cannot be used
4.	<b>Diperoxochloric acid concentrate and Diperoxochloric acid topical solution</b>	Indicated for wound healing in diabetic neuropathic ulcers of skin and subcutaneous tissues reduction
5.	<b>Endoxifen citrate bulk and Endoxifen tablets 8 mg</b>	For acute treatment of manic episodes with or without mixed features of Bipolar I disorder
6.	<b>Azelnidipine bulk and Azelnidipine tablets 16 mg</b>	For treatment of Stage II Hypertension
7.	<b>Genopep bulk and Genopep 0.05% w/w cream</b>	Indicated for treatment of burn wound, antimicrobial therapy, scar prevention/reduction
8.	<b>Alalevonadifloxacin mesylate bulk and Levonadifloxacin tablets 500mg</b>	Indicated in adults ( $\geq 18$ years of age) for treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI), including diabetic foot infections and concurrent bacteraemia caused by susceptible isolates of the following: Gram-positive organisms:- <i>Staphylococcus aureus</i> (methicillin-resistant, methicillin-susceptible, quinolone-resistant, quinolone-susceptible isolates), <i>Streptococcus pyogenes</i> , <i>Enterococcus faecalis</i> , <i>Streptococcus dysgalactiae</i> ssp. <i>dysgalactiae</i> , <i>Streptococcus agalactiae</i> .
9.	<b>Midodrine hydrochloride bulk drug</b>	For the treatment of symptomatic orthostatic hypotension (as indication)



10.	<b>Lorlatinib film-coated tablets 25 mg and 100 mg</b>	For treatment of ALK fusion gene-positive unresectable advanced and/or recurrent non-small cell lung cancer with resistance or intolerance to ALK tyrosine kinase inhibitor(s)
11.	<b>Levonadifloxacin L-arginine tetrahydrate bulk and Levonadifloxacin injection 800 mg/100 ml</b>	Indicated in adults (≥ 18 years of age) for treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI), including diabetic foot infections and concurrent bacteraemia caused by susceptible isolates of the following: Gram-positive organisms:- <i>Staphylococcus aureus</i> (methicillin-resistant, methicillin-susceptible, quinolone-resistant, quinolone-susceptible isolates), <i>Streptococcus pyogenes</i> , <i>Enterococcus faecalis</i> , <i>Streptococcus dysgalactiae</i> ssp. <i>dysgalactiae</i> , <i>Streptococcus agalactiae</i> .
<ul style="list-style-type: none"> <li>Healthcare professionals are urged to closely monitor the safety of these drugs.</li> <li>ADRs, if any, to be reported to PvPI.</li> </ul>		

Source: on [https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=NDk2NA==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDk2NA==)

# Safety Concerns with the use of 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 Antidiabetic 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 including Toe Amputation, Diabetic Ketoacidosis and Fournier's Gangrene. The Central Drugs Standard Control Organization (CDSCO) vide

its letter 12-74/13-DC dated March 25, 2019 has also issued a warning letter on the precautionous use of SGLT2 Inhibitors following the safety alert issued by EMA, USFDA, Health Canada and MHRA-UK. PvPI, IPC has also sensitized all stakeholders vide official letter to all AMCs dated July 15, 2019.

All stakeholders including HCPs and public at large are hereby sensitized and informed to report all the suspected adverse events with the use of SGLT2 Inhibitors by using PvPI Toll free Helpline #1800-180-3024, "ADR PvPI" Mobile App and ADR reporting forms.

## Drug Safety Alerts for October 2019- March 2020

Preliminary analysis of Suspected and Unexpected Serious Adverse Reactions (SUSARs) from the PvPI database revealed that the following drugs are associated with the risks as given below:

**Suspected Drug:** Cetirizine

**Indication:** For the treatment of allergic rhinitis and chronic urticaria

**ADR:** Acute Generalized Exanthematous Pustulosis

**Suspected Drug: Clozapine**

**Indication:** Indicated in the management of Schizophrenic patients

**ADRs:** Neural Tube Defects

**Suspected Drug: Cetirizine**

**Indication:** For the treatment of allergic rhinitis and chronic urticaria

**ADRs:** Hiccups

**Suspected Drug: Cilostazole**

**Indication:** For the treatment of stable intermittent claudication, acting or cramping in legs that occurs with walking

**ADRs:** Tinnitus

**Suspected Drug: Levamisole**

**Indication:** Indicated in the treatment and control of mature and developing immature infections of haemonchus, ostertagia, trichostrongylus, cooperia, nematodinus, bunostomum, oesophagostomum and dictyocaulus and all forms of liver fluke infection

**ADRs:** Stevens Johnson Syndrome

**Suspected Drug: Cephalosporin**

**Indication:** Indicated in the treatment of serious infections due to susceptible organisms –respiratory tract infections, urinary tract infections, skin biliary tract infections, septicemia, meningitis, infections due to susceptible organisms and in the treatment of infections due to penicillin-resistant strains of staphylococci

**ADRs:** Acute Generalized Exanthematous Pustulosis

**Suspected Drug: Disulfiram**

**Indication:** Indicated as an adjuvant in the treatment of carefully selected and co-operative patients with drinking problems

**ADRs:** Skin Hyperpigmentation

**Suspected Drug: Fluconazole**

**Indication:** Indicated for the treatment of systemic candidiasis, mucosal candidiasis, prevention of fungal infections in patients with malignancy

**ADRs:** Mouth Ulceration

**Suspected Drug: Piperacillin+Tazobactam**

**Indication:** Indicated in the treatment of LRTI/UTI/Intra abdominal infections, skin and skin structure infections, bacterial septicemic polymicrobial infections

**ADRs:** Blurred Vision

**Suspected Drug: Olanzapine**

**Indication:** Indicated for the treatment of Schizophrenia

**ADRs:** Hyponatremia

**Suspected Drug: Terlipressin**

**Indication:** Indicated in the treatment of bleeding oesophageal varices

**ADRs:** Atrial Fibrillation

Healthcare professionals, patients/consumers are advised to closely monitor the possibility of above-mentioned adverse events while prescribing/consuming above-quoted suspected drugs and report to the NCC-PvPI either by filling up suspected adverse drug reactions reporting form/medicine side-effect reporting form for consumer (<http://ipc.gov.in>) via PvPI tollfree **Helpline #1800-180-3024**



# PV @RGCID, Bangalore

**S**DS Tuberculosis and Rajiv Gandhi Institute of Chest Diseases (SDS RGCID), Bangalore, is a 470-bed teaching institute comprising two departments — Department of Pulmonary Medicine and Department of Thoracic Surgery. The institute has been functioning as an AMC since 2013 under the aegis of Director & Coordinator Dr C Nagaraja, Deputy Coordinator Dr Akshatha J S and Pharmacovigilance Associate Dr Dharini B.

### AMC ACTIVITY:

- More than 1,900 ICSRs processed till date
- Successfully conducted four CME-cum-workshops on Pharmacovigilance
- Regular sensitization programmes conducted with clinicians, PGs, nurses and other HCPs on spontaneous ADR reporting
- Display of PvPI posters at OPD and wards
- Coordinating with NABH-accredited hospitals in Karnataka for ADR reporting
- Active screening of tubercular patients through laboratory investigations

- Dedicated trainings for pharmacy and nursing students in nearby colleges
- Collaborating with more than 14 RNTCP centres in Bangalore to collect spontaneous ADR reporting







## PV at ANIIMS, Port Blair

The first medical college of the islands, Andaman & Nicobar Islands Institute of Medical Sciences (ANIIMS), Port Blair, was approved as an Adverse Drug Reaction Monitoring Centre (AMC) under PvPI in July 2015, and has been identifying and reporting ADRs occurring in patients admitted to the institute. The medical college is attached to Govind Ballabh Pant (GB Pant) Hospital with an in-patient capacity of around 400 patients. Dr Mangesh Bankar, Associate Professor, Department of Pharmacology, ANIIMS, has been actively serving as AMC Coordinator with Dr Nimisha Elezebeth Zachariah deputed by PvPI, IPC, Ghaziabad as Patient Safety Pharmacovigilance Associate since August 2019. The Pharmacovigilance activities have been taking place under the guidance of Dr C Dinesh M Naidu, HOD, Department of Pharmacology, ANIIMS.

### AMC ACTIVITY:

- Contact details of AMC personnel put up in the wards, OPDs and casualty, enabling healthcare providers to inform AMC personnel about an ADR



- WhatsApp group “ADR REPORTING” comprising HCPs of the institute for spontaneous reporting of ADRs
- ADR reporting boxes with a “quick form” placed at casualty, wards and OPDs since October 5, 2019
- Regular sensitisation-cum-training programme on PV for HCPs and common public
- Causality Assessment Committee (CAC) holds regular meetings and remains vigilant towards data compiling and documentation
- Pharmacovigilance Committee meets once in every three months with a focused approach on strengthening the ongoing National Pharmacovigilance Programme.

# Boost to PV@ NEIGRIHMS, Shillong

**N**orth Eastern Indira Gandhi Regional Institute of Health and Medical Sciences (NEIGRIHMS), Shillong is a super speciality teaching and referral institute with state-of-the-art infrastructure. It is a postgraduate tertiary care medical institute -- the first in northeast India established in 1987 by the Ministry of Health and Family Welfare, Government of India. The hospital has 531 beds with a user-and-eco-friendly patient-care system. NEIGRIHMS was recognized as an Adverse Drug Reaction Monitoring Centre (AMC) under PvPI in 2014. The core PV team comprises Dr Dhriti Kumar Brahma, Associate Professor & Coordinator In-charge, Prof (Dr) Chayna Sarkar, Professor & Head, Department of Pharmacology, Dr Bhupen Barman, Associate Professor, Department of General Medicine, Dr Julie B Wahlang, Assistant Professor, Department of Pharmacology, and Dr Melambha Surong as Patient Safety PV-Associate appointed by NCC-PvPI.

## AMC ACTIVITY:

- The only AMC in Meghalaya, NEIGRIHMS shoulders the responsibility of raising PV awareness among all hospitals and the allied staff of the region



- Regular around-the-ward participation for inculcation of GVPs at NEIGRIHMS and other peripheral hospitals
- Dissemination of resource material provided by PvPI among all stakeholders
- Ensuring continuous availability of ADR-reporting forms and PV pamphlets at all wards and OPDs
- Regular sensitization programmes for HCPs to encourage reporting of suspected ADRs and obtaining feedback from departments to improve ADR-reporting
- Sensitization lectures for encouraging MBBS students, interns, PG students, nurses, pharmacists to report suspected ADRs as part of research activity and practical exercise
- Circulation of drug alerts and other info related to drug-safety among HCPs
- Installation of drop boxes at prominent places for ease of collecting ADRs
- Access to ADR Alert Cards for averting any noxious/unintended reaction



## Dr C NAGARAJA

**Director & Coordinator, SDS Tuberculosis and Rajiv Gandhi Institute of Chest Diseases, Bangalore**

Pharmacovigilance also known as drug safety plays an important role in patient care and safety in relation to use of medicines and all medical and paramedical interventions. Pharmacovigilance Programme of India (PvPI) has helped our doctors by raising awareness about new drug effects. I appreciate PvPI for enhancing patient-safety activities by periodic intimation of drug alerts and wish the entire PvPI team success in its future endeavors.



## Dr AKSHATHA JS

**Prof Department of Pulmonary Medicine, Deputy AMC Coordinator, SDS Tuberculosis and Rajiv Gandhi Institute of Chest Diseases, Bangalore**

The ultimate goal of all healthcare providers is safe management of patients. PvPI has established itself as a key surveillance system in this regard. Monitoring adverse reactions of drugs post-marketing helps identify newer drug reactions. Regular intimation of alert signals by the PvPI ensures patient safety as a continuous process. However, there is need for sensitizing HCPs to the pharmacovigilance system early in practice by including PV in the UG curriculum. I feel privileged to be an integral part of our institute's pharmacovigilance team which, I believe, is doing a commendable job.



## Dr UMA BUGGI

**Senior Physician, SDS Tuberculosis and Rajiv Gandhi Institute of Chest Diseases, Bangalore**

As a senior physician I feel privileged to be part of AMC-PvPI at our 470-bed teaching hospital. Assessing, monitoring and collating ADRs help patient-safety by curbing iatrogenesis and medication errors. I whole-heartedly appreciate PvPI for their various patient-friendly initiatives, extend support and wish success to Pharmacovigilance at our AMC.



## Dr SOMOSHEKAR M

**Senior Medical Officer, Nodal DRTB Centre-Bangalore City, SDS Tuberculosis and Rajiv Gandhi Institute of Chest Diseases, Bangalore**

NCC-PvPI is well organized with a safety monitoring system for medical products consumed by each individual and reporting by everyone helps early detection and monitoring of ADRs. PvPI, since its inception in 2010, has helped reduce the morbidity and mortality associated with indiscriminate use of medicines in day-to-day practice. PvPI Guidance Document for the safe use of medicines and reporting ADRs has progressively improved the healthcare of Indian populace by and large.



## Dr SATYA RANJAN PATRA

**HOD, Department of Surgery, & Member, Pharmacovigilance Committee, ANIIMS, Port Blair, Andaman & Nicobar Islands**

"Pharmacovigilance plays an important role in patient safety as it is particularly concerned with adverse drug reactions. For a successful Pharmacovigilance programme, a complex and vital relationship has to exist between a wide range of partners involving all healthcare professionals, paramedical staff, patients and consumers. The Department of Pharmacology, ANIIMS, has been actively involved in ADR data collection by both active and passive means, and reporting them. Pharmacovigilance Committee's motto is: no adverse effect should go unreported. It periodically interacts with the faculty and residents to create and reinforce awareness about reporting adverse drug reactions. We at ANIIMS are indebted to the medical and paramedical staff of the institute and GB Pant Hospital for their positive response in reporting ADRs."





## STAKEHOLDERS' FEEDBACK



**Dr MANGESH BANKAR**

**AMC Coordinator and Associate Professor, Department of Pharmacology, ANIIMS, Port Blair, Andaman & Nicobar Islands**

"Pharmacovigilance Programme of India is responsible for the safety of medication among the population. It is a privilege to be part of such a programme that works to generate medication safety worldwide. Our AMC has been actively contributing to the PvPI database since July 2015. I appreciate the efforts of all HCPs who have been working hard to raise awareness about this programme at our AMC. We are also grateful to all healthcare and paramedical staff for their active participation and contribution to bolstering Pharmacovigilance."

**Dr SHIPRA GUPTA**

**Senior Resident, Department of Ophthalmology, ANIIMS, Port Blair, Andaman & Nicobar Islands**

"PvPI has helped raise awareness among working clinicians for judiciously using drugs, keeping in mind the concomitant adverse reactions. Pharmacovigilance is much needed in today's scenario when medicine has turned to be a powerful tool to increase life expectancy. Pharmacovigilance Associate and other AMC personnel have brought about an increase in the rate of ADR-reporting and made the whole programme a great success."



**Dr D K BRAHMA**

**Associate Professor, Pharmacology & Coordinator, AMC-NEIGRIHMS, Shillong**

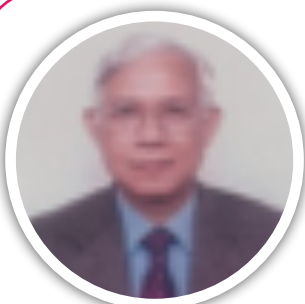
"Considering the importance of monitoring the Adverse Drug Reaction, PV activities were commenced at our Institute after the department of Pharmacology was set up in 2009. The recognition of the institute as an ADR Monitoring Centre (AMC) by PvPI in 2014 has enhanced the pace of PV activities at the institute. At present, this AMC has been functioning with alacrity and is committed to achieve the ultimate goals of PV."

**Prof (Dr) D M THAPPA**

**Director, NEIGRIHMS**

"NEIGRIHMS is an autonomous medical institute under the Ministry of Health and Family Welfare, Government of India, with 531 beds providing tertiary and super-speciality healthcare services to all the people of Northeastern states of India. It has been a recognized Adverse Drug Reaction Monitoring Centre (AMC) since 2014 as declared by the Pharmacovigilance Programme of India (PvPI). The Centre is regularly sending individual case safety reports (ICSRs) from NEIGRIHMS to the PvPI. AMC-NEIGRIHMS has been putting in the best efforts for enriching the quality of Pharmacovigilance performance. Many Adverse Drug Reactions (ADRs) are reported only during post-marketing surveillance and this may even decide the fate of the drug in quest. A number of drugs have been discontinued for reasons that the risk associated with their use outweighs the corresponding benefits. This, indeed, underlines the importance of Pharmacovigilance in healthcare."

I appreciate the key role of AMC-NEIGRIHMS for its contribution to PvPI. I wish them all the best in their future endeavors towards generation of patient safety data."



**Prof (Dr) A C PHUKAN**

**Dean, NEIGRIHMS**

"Drug Safety is one of the most important components of patient safety in medical practice. The primary objective of any physician or healthcare professional towards the management of a disease is always patient safety where Pharmacovigilance plays a major role. NEIGRIHMS, Shillong is one of the 270 Adverse Drug Reaction Monitoring Centres (AMCs) in India and has been extending support to patient safety mechanism through Pharmacovigilance. This centre regularly monitors and reports to the NCC-Pharmacovigilance Programme of India (PvPI). Healthcare professionals' sensitization to the reporting of suspected Adverse Drug Reactions (ADRs) and its impact upon patient safety are being regularly conducted at the Institute. I appreciate AMC-NEIGRIHMS for its significant contribution to Pharmacovigilance."

**Prof (Dr) CHAYNA SARKAR**

**Professor & Head, Pharmacology, NEIGRIHMS**

"Not all hazards can be known before a drug is marketed. The birth of Pharmacovigilance came from the disaster caused by thalidomide in 1961. The ultimate goal of ADR monitoring is to ensure that the benefits of use of medicines outweigh the risks and thus safeguard the health of population. Furthermore, it promotes and fosters systematic and rational drug use besides boosting to a high degree confidence for safety. Now, Pharmacovigilance is an integral part of healthcare delivery system. All healthcare stakeholders of NEIGRIHMS, Shillong have a crucial role to play in safety of medicine by regular monitoring and reporting of ADRs to PvPI."



**Dr NOOR TOPNO**

**Medical Superintendent, NEIGRIHMS, Shillong**

"Avoidable errors in medical practice leading to increased cost of hospitalization, and even loss of life, are a major concern for hospitals. Adverse drug reactions comprise by far the most common iatrogenic 'illness', complicating nearly 10% of all therapeutic prescriptions. Some adverse drug reactions are often reported by serendipity only after the drug has been marketed and, therefore, present a management challenge. Better approaches must be devised for detection, reporting and managing ADRs. Pharmacovigilance through ADR reporting under the aegis of NCC-PvPI is a vital step in this direction. ADR reporting is a chain of events where each stakeholder has an important role to play and this chain is as strong as its weakest link. Let's join hands to strengthen the noble cause of NCC-PvPI through ADR reporting in our own institutions."



**Dr BHUPEN BARMAN**

**Associate Professor, General Medicine, NEIGRIHMS & Member, Causality Assessment Committee (CAC), AMC-NEIGRIHMS**

"Pharmacovigilance Programme of India (PvPI) has been doing a great job and has changed the way we look at PV from a systematic perspective. At NEIGRIHMS, under the guidance of Adverse Drug Monitoring Centre (AMC), Department of Pharmacology has been constantly monitoring the ADRs. It helps us in formulating case study reports, safety data processes, adverse drug reports and regulatory documents."



**Dr BHASKAR BORGHAIN**

**Professor & Head, Orthopedics, NEIGRIHMS**

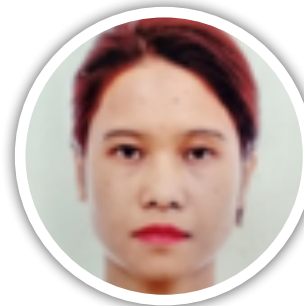
"Pharmacovigilance Programme of India (PvPI) will go a long way in restoring patient's faith, accountability and continued learning for all stakeholders of medical sciences. Drug safety is of paramount importance in India with its diverse genetic pool of patients."



**Dr ROSINA KSOO**

**Assistant Professor, Pediatrics, NEIGRIHMS**

"The Adverse Drug Reaction Monitoring (AMC) under the Pharmacovigilance Programme of India (PvPI) at NEIGRIHMS is worth appreciation. Patient safety is of paramount importance in our day-to-day practice; and adverse drug reaction monitoring is an essential step to ensuring a safe outcome of any drug prescribed to our patients. A relentless and continuous reporting of all adverse drug reactions will go a long way in raising awareness and sensitization of all doctors & paramedical staff to Pharmacovigilance while ensuring rational drug use at our medical college and in our state."



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

## फॉर्माकोविजिलेंस 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 फॉर्माकोविजिलेंस 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।

“फॉर्माकोविजिलेंस 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 फॉर्माकोविजिलेंस प्रोग्राम ऑफ़ इंडिया, में दवाईयों के प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी एकत्रित करने हेतु विभिन्न सुवधाजनक 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](http://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 स्वास्थ्यकर्म 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 फॉर्माकोविजिलेंस 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 फॉर्माकोविजिलेंस 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।



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*Let us join hands with PvPI to ensure patient safety*  
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