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Vears of Successful Journey of PvPI

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Pharmacovigilance Programme of India (PvPI)



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Message

भारत सरकार स्वास्थ्य एवं परिवार कल्याण मंत्रालय निर्माण भवन, नई दिल्ली - 110011 Government of India Ministry of Health & Family Welfare Nirman Bhavan, New Delhi-110011



Dear Readers,

I am glad to note that Indian Pharmacopoeia Commission (IPC) has completed 10 years as the National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) on 14th April 2021. PvPI is one of the important programmes of the Ministry of Health and Family Welfare, Government of India to monitor the safety of pharmaceutical products across the country. The programme has undergone tremendous expansion in a phased manner since its recasting on 15th April 2011. A nationwide network has been set up with Healthcare Professionals (HCPs) and the current outreach of PvPI is 346 Adverse Drug Reaction Monitoring Centres (AMCs) across the country. The scope of the programme not only covers the safety of medicines, but also the safety of medical devices, blood and blood related products used for transfusion through the Materiovigilance Programme of India (MvPI) and Haemovigilance Programme of India (HvPI) respectively under the umbrella of PvPI.

The PvPI has quality management system and standard procedures in place. There is a robust system of collecting, collating and analyzing the adverse events of pharmaceutical products and recommending regulatory measures. On the international map, the current ranking of PvPI is 9th among Member Countries under WHO-Programme of International Drug Monitoring in terms of Individual Case Safety Reports (ICSRs) submitted to WHO-Global database (VigiBase).

The inputs from PvPI help the Central Drugs Standard Control Organization take appropriate regulatory actions. The NCC-PvPI also trains the HCPs in the area of Pharmacovigilance through the Skill Developments Programmes and other training programmes.

Providing accessible and responsive health care services is the highest priority of the Government of India and efforts will continue to be made to in this direction.

I urge the HCPs and the public at large to report the Adverse Events on account of the use of pharmaceutical products, medical devices, blood & its related products to the nearest **ADR** Monitoring

I congratulate the Staff of PvPI, MvPI and HvPI for their untiring efforts, and the subject experts for their valuable inputs from time to time for the success of the programmes. I am sure that with your commitment and dedicated efforts, the programme will attain a new heights and achieve its goals successfully.

Wishing you all the best

(Mandeep K. Bhandari)

A Decade of Successful Journey of PvPI - Highlights

PvPI was initiated by Government of India on 14th July, 2010 with the All India Institute of Medical Sciences (AIIMS), New Delhi as National Coordination Centre for monitoring Adverse Drug Reactions (ADRs) in the country. To ensure implementation of this programme in a more effective way, it was decided by the Ministry of Health & Family Welfare to recast this programme and shift the National Coordination Centre from AIIMS, New Delhi to the Indian Pharmacopoeia Commission, Ghaziabad.

The vision of the Programme is to improve patient safety and welfare of Indian population by monitoring safety of medicines, thereby reducing the risk associated with their use. The PvPI strived hard to achieve its mission to safeguard the health of Indian population by ensuring that the benefit of medicines outweighs the risks associated with their use. Since the recasting & shifting of the programme, it has taken a momentum and highlights of a decade journey of PvPI are mentioned below:

ICSRs Contribution

501946 ICSRs -9^{th} largest reporter of ICSRs to WHO-Global database (VigiBase)

Signals/PIL changes/Drug Safety Alerts issued by PvPI

- Signals identified 7
- PIL changes recommended 50
- Drug Safety Alerts 121
- Order issued by CDSCO for regulatory

Training Programmes organised by

- Skill Development Programme 142686 HCPs trained in PV
- 5th Asia Pacific PV training Programme 30 participants from 14 countries
- 6th Asia Pacific PV training Programme 14 participants from 6 countries
- 38th WHO-PIDM Annual Meet >150 participants from over 57 countries

National Regulatory Authority (NRA) assessment of PV

Successfully met WHO International Standards as per Global Bench Marking Tools in Pharmacovigilance and declared as functional with Maturity Level 4 out of 5

PvPI Resource Materials

- Information Brochure of PvPI
- PV Guidance document for MAHs
- · Guidance document for Spontaneous ADR reporting
- Quality Manual & SOPs for PvPI
- Newsletters, Annual Performance Reports, Scientific Publications, PvPI Directory & Posters etc.
- IPC Website www.ipc.gov.in

PvPI Expansion

Current outreach in States/UTs

- PvPI 346 AMCs
- MvPI Launched on 6th July 2015: Enrolled 74 MDMCs
- HvPI Launched on 10th Dec 2012; Enrolled 1150 Blood Banks

Tools developed by PvPI

- Indigenous Database ADRMS software in testing phase
- Mobile App ADR PvPI Android Mobile App for consumer
- PvPI Toll Free 18001803024
- AE Reporting tool developed
- o Reporting form for HCPs & Consumers in vernacular languages
- Developed dedicated form for COVID-19 drugs

National & International Collaborations

- PvPI has signed MoU with PHPs (NTEP. NVBDCP, NACO & UIP-AEFI)
- IPC designated as WHO-CC for PV in PHPs & regulatory services

Focussed Pharmacovigilance

- Active Surveillance of Bedaquilline
- Hydroxychloroquine in COVID-19
- COVID-19 vaccines
- 3S Smart Safety Surveillance of Rotavirus Vaccine





CME at AIIMS Mangalagiri, Andhra Pradesh

All India Institute of Medical Sciences(AIIMS) Mangalagiri, Andhra Pradesh had successfully conducted the first Continuing Medical Education (CME) on "Awareness and Sensitization on Pharmacovigilance and ADR Reporting" on 10th April 2021. The doctors and nursing officers across different specialties of the institute attended this CME. During this event, a poster competition on the theme "Adverse Drug Reactions: Detection, Assessment, and Prevention" was also organized and 29 participates were provided hands-on exercise for filling of ADR form (Version 1.3) on a hypothetical case scenario. A significant improvement was noticed in the knowledge of delegates regarding the importance of Pharmacovigilance and ADR reporting. The feedback was obtained from the participants.

Sensitization Programme on ADR and it's Reporting at AFMC, Pune

Armed Forces Medical College (AFMC), Pune, has conducted two hours sensitization programme on adverse drug reactions and its reporting on 10th June 2021. A total of 40 participants have participated in this sensitization programme and covered the session on ADR terminologies and the importance of ADR during COVID-19



pandemic. In addition to this, a hands-on-training exercise was conducted for pharmacists to make an actual complete understanding of filling suspected ADR reporting forms.

State Level CME on Pharmacovigilance

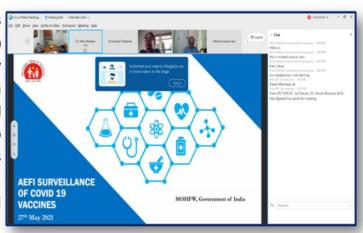
A virtual training programme on 'ADR Reporting: Physician as a key stakeholder' was organized by Maharaja Krushna Chandra Gajapati Medical College and Hospital (MKCG MCH), Berhampur, Odisha, in collaboration with NCC-PvPI, IPC, Ghaziabad on 13th May 2021. It was attended by 73 participants across the State of Odisha. During the training programme, Dr Jai Prakash, Officer-in-Charge, PvPI presented a keynote on "PvPI strategies during COVID-19 pandemic.

Sensitization cum Awareness Activity about Pharmacovigilance Programme of India

Sagar Institute of Research & Technology - Pharmacy, Bhopal organized AICTE sponsored Online Short Term Training Programme (STTP) on "Interplay between Health Wellbeing, Environment and Community Pharmacy" from 26th April 2021 to 01st May 2021. In this sensitization programme, Dr. Vijit Agrawal, Sr. Pharmacovigilance Associate delivered a talk on "Overview of Pharmacovigilance, Pharmacovigilance Programme of India and reporting of Adverse Drug Reactions" on 27th April 2021.

National AEFI Meeting

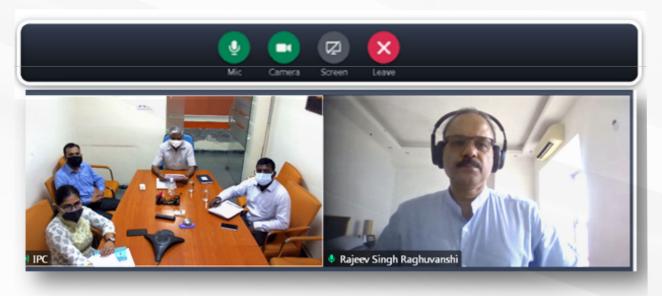
Three virtual National Adverse Events Following Immunization (AEFI) committee meetings were organized by the AEFI Secretariat of Immunization Technical Support Unit (ITSU) - Universal Immunization Programme from April to June 2021. A total of 113 representatives from various organizations like MoHFW, AEFI Secretariat, IPC, CDSCO, INCLEN International and WHO - Country Office



for India have attended these meetings. The agenda of these meetings was to discuss the AEFI cases, their surveillance, causality assessment and COVID-19 vaccines safety in the Indian population.

17th Skill Development Programme

NCC-PvPI, IPC has organized virtually 17th Skill Development Programme on "Pharmacovigilance for Medical Products" from 21st to 25th June, 2021 to train & develop skilled human resources in the field of Pharmacovigilance. The webinar started with a welcome address by Dr. Jai Prakash, Officer-in-Charge, PvPI, followed by Keynote address by Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, IPC. A total of 152 participants from Gujarat, Uttar Pradesh, Maharashtra, Karnataka, Kerala, Tamil Nadu, Andhra Pradesh, Assam, Kashmir and Tripura etc., participated in this training programme. The participants included professionals from Pharmaceutical Industries, Physicians, Academicians, Coordinators & Pharmacovigilance Associates of ADR Monitoring Centres, Research Scholars, Students (Pharmacy and Medical) across the country.



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

Induction-cum-Training Programme

NCC-PvPI organized virtual "Induction-cum-training Programme on Pharmacovigilance" On 27th & 28th April 2021 for newly inducted Pharmacovigilance Associates (PvAs) and Coordinators of AMCs under PvPI to make them aware of their role, responsibilities and functioning. The webinar was well appreciated by the coordinators and PvAs.

Webinar on Pharmacovigilance for Marketing **Authorisation Holders**



NCC-PvPI organized a webinar on "How to develop a positive culture of Adverse Event Reporting by Pharmaceutical Industries/Marketing Authorization Holders?" on 29th April 2021. A total of 62 participants attended the webinar including an international speaker from UMC, Sweden.

NCC-PvPI organised a virtual interactive meeting with PV officials of Emcure Pharmaceuticals Ltd. India for improving the quality of ICSRs on 24th June 2021. NCC-PvPI sensitized them about the importance of ICSRs Grading and its impact on the quality reporting of ICSRs. NCC-PvPI, also suggested establishing a causal relationship between the Drug-Reaction combination and other important field parameters of ICSR should be collected from a reporter by representatives of Marketing Authorization Holder (MAH).



Interactive meet with MAHs/ Pharmaceutical Industries on ICSRs quality

New Drugs Approved in India

The following new drugs were approved by CDSCO between April 2021 to June 2021:

S. No. Drug(s)		Indication(s)	
1.	Ozenoxacin bulk and Ozenoxacin cream 1% w/w	Indicated for the topical treatment of impetigo due to <i>Staphylococcus</i> aureus or <i>Streptococcus</i> pyogenes in adult and pediatric patients 2 months of age and older As an adjunct therapy only in moderate to severe COVID-19 patients	
2.	2-Deoxy-D-Glucose bulk and 2-Deoxy-D-Glucose 2.34g & 5.85g sachet		
3.	Capmatinib 150mg and 200mg film-coated tablets	Capmatinib is a kinase inhibitor indicated for the treatment of an adult patient with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping	
4.	Rucaparib camsylate bulk and Rucaparib tablets 200mg/250mg/300mg	 For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are incomplete or partial response to platinum-based chemotherapy. For the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)- associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA. Prostate cancer For the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic) associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy 	

Drug Safety Alerts

	S. No.	Drug(s)	Indication(s)			
	5.	TrientineTetrahydrochloride bulk and Trientine Tetrahydrochloride capsules 333 mg (Each capsule contains Trientine tetrahydrochloride 333 mg equivalent to Trientine 167mg base)	For the treatment of Wilson's disease (hepatolenticular degeneration in patients intolerant to Penicillamine. It should be used who continued treatment with Penicillamine is no longer possible becaut of intolerable or life-endangering side effects			
	6.	Vigabatrin bulk and Vigabatrin powder for oral solution 500mg	 For the treatment of Refractory Complex Partial Seizures as adjunctive therapy patients 2 years of age and older who have responded inadequate to several alternative treatments; Vigabatrin for Oral Solution, US 500 mg is not indicated as a first-line agent. Infantile Spasms - monotherapy in infants 1 month to 2 years of age for whom the potential benefits outwein the potential risk of vision loss. 			
	7.	Cangrelor tetra sodium bulk and Cangrelor for injection 50mg/vial	Indicated as an adjunct to percutaneous coronary intervention (PCI) to reduce the risk of per procedural myocardial infarction (MI), repeat coronary revascularization, and stent thrombosis (ST) in patients who have not been treated with a P2Y12 platelet inhibitor and are not being given a glycoprotein IIb/IIIa inhibitor.			
	8.	Rifapentine bulk and FDC of Isoniazid and Rifapentine (300mg/300mg)	Indicated for the treatment of latent tuberculosis, caused by Mycobacterium tuberculosis (For use in NTEP only)			
Healthcare Professionals are urged to closely monitor the safety of the above Drugs ADRs (if any) should be reported to PvPI						

 $\textbf{Source:} https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file$ _division.jsp?num_id=NzM4MA==

Drugs Safety Alerts - April 2021 to June 2021

S. No.	Issuing Date	Suspected Drugs	Indication(s)	Adverse Drug Reactions
1.		Baclofen	For the symptomatic treatment of neuronal spasticity due to multiple sclerosis, spinal cord, pathology & injury	Encephalopathy
2.		Rosuvastatin &Ticagrelor Interaction	Rosuvastatin: Risk reduction of MI stroke and arterial revascularisation procedure in patients without clinically evident CHD but with multiple risk factors.	Rhabdomyolysis
	28 th June 2021		Ticagrelor: For the prevention of thrombotic events (cardiovascular death, Myocardial Infarction and stroke) in patients with Acute Coronary Syndromes (ACS) unstable angina, non-ST Elevation Myocardial Infarction (STEMI) including patients managed medically and those who are managed with Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Grafting (CABG)	
3.		Clobazam	Acute and chronic anxiety states and as an adjunctive therapy in patients with refractory epilepsy.	Drug reaction with eosinophilia and systemic symptoms (DRESS) Syndrome
4.	05 th April 2021	Zinc (Acetate/Oxide/ Sulphate/ Gluconate)	In the treatment of acute diarrhoea in children as an adjunct to oral rehydration.	Diarrhoea

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

Drugs Safety Alerts - PvPI vs Other Countries

Drugs	ADRs	No. of ICSRs in Global database	No. of ICSRs in PvPI database	References
Diuretics including Acetazolamide	Risk of eye disorders	44	06	
Ifosfamide (Solution)	Potential risk of Encephalop athy	968	03	WHO Pharmaceuticals Newsletter 2021, No. 2, published on May, 2021.
Sofosbuvir	Stevens- Johnson Syndrome	06	04	

 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 NCC-PvPI, IPC.

Institute of Postgraduate Medical Education & Research (IPGMER), Kolkata, West Bengal

IPGMER, Kolkata, West Bengal was recognised as an AMC under PvPI in 2011. This AMC is also the Regional Training Centre of PvPI in the eastern regional of India. The various Pharmacovigilance activities were carried out under supervision of Dr. Suparna Chatterjee Coordinator and Head of the Department of Pharmacology, IPGMER along with Ms Manjari Bhattacharya, Pharmacovigilance Associate. It continues its focus on patient safety by:



- Active ADR reporting to identify signals.
- Conducting various training, awareness and skill development programs like ALTs, seminars, outreach programs at peripheral hospitals, etc. to facilitate knowledge acquisition and skill building among residents, other doctors, nurses, and paramedical staff.
- Sensitizing and awareness on Pharmacovigilance for nursing, paramedical and medical undergraduate students.
- Focused pharmacovigilance activity as the situation demands including reporting of adverse events of COVID-19 vaccines.



Institute of Medical Sciences, Banaras Hindu University (IMS-BHU), Varanasi, Uttar Pradesh



IMS BHU, Varanasi, Uttar Pradesh was recognised as an AMC under PvPI in 2011. The various Pharmacovigilance activities were carried out under supervision of Dr. Amit Kumar Singh, AMC Coordinator, Department of Pharmacology, IMS-BHU. Mr. Awadhesh Kumar Yadav, Pharmacovigilance Associate assisted in pharmacovigilance activities as mentioned below.

- AMC PV Committee discussed ways to improve awareness on Pharmacovigilance among HCPs through continuous awareness programme.
- Build trust among HCPs in ADR reporting by organizing PV training, seminars, lectures for doctors, nurses, pharmacists and other medical students at centre & nearby hospitals.



- Distributions of PvPI flex boards and posters to various departments of hospital & nearby hospitals.
- Circulation of PvPI Newsletter, Drug Alerts, Suspected ADR Reporting Forms and PV related matter to all HCPs.
- PvPI toll-free number has been printed on OPD slips.
- Coordination with the Deworming Programme, CDSCO and AEFI official regarding training, seminars and ADRs reporting.
- Maintaining ADR/AEFI database or registries of all ICSR record files for easy access and hassle-free retrieval.

Maharaja Krushna Chandra Gajapati Medical College & Hospital, Berhampur, Odisha

M.K.C.G Medical College & Hospital, Berhampur, Odisha was enrolled as an ADR Monitoring Centre under PvPI in July, 2011. Pharmacovigilance activities of AMC have been carried out effectively under the Stewardship of Coordinators Dr. Y. Roja Ramani with the enthusiastic support of Dr. Chinmaya Mahapatra, PvA. This centre has constituted a Causality Assessment Committee and Pharmacovigilance Committee and sensitizing HCPs for ADR reporting regularly.



Activities and Achievements

- M.K.C.G Medical College & Hospital, has reported 2078 ADRs in VigiFlow, organized two International webinars, a State Level CME, and other sensitization programmes on Pharmacovigilance.
- Dissemination of PvPI awareness flyers, posters and pamphlets in OPDs, IPD wards, Emergency wards and ICUs.
- The AMC contributed towards the collection of ADRs related to Albendazole on National Deworming Day.
- Drug alert cards were issued to the persons getting vaccinated with COVID-19 Vaccine at the vaccination centres for prompt reporting of any adverse event following vaccination.

Feedback from AMC Stakholders

Prof. Suparna Chatterjee

AMC-Coordinator IPGMER, Kolkata, West Bengal

IPGMER is the East Zone Regional Centre for Training and Technical Support steered by Prof. Suparna Chatterjee as Pharmacovigilance Coordinator and Prof. Avijit Hazra as Deputy Coordinator since 2011. She is also serving as a member of the Signal Review Panel of PvPI. The day-to-day activities are managed by Ms. Manjari Bhattacharjee as Pharmacovigilance Associate. Both Coordinator and Deputy Coordinator are passionate about pharmacovigilance and the role it can play in the improvement of patient outcome. Through this forum, we renew our pledge to further the noble goal of patient safety through responsible pharmacovigilance.

> Dr. Amit Singh AMC-Coordinator & Professor (Department of Pharmacology) IMS BHU Varanasi, U.P.

Pharmacovigilance plays an important role in the patient's safety in relation to use of medicines. It is responsible for the monitoring of adverse drug reactions occurring among the Indian population. It helps in creating awareness among

clinicians for the appropriate use of medicines and proved to be a powerful tool for reporting adverse drug reactions. PvPI also promotes sensitization for the reporting of suspected adverse drug reactions among health care workers at various levels. Continuous reporting of all such adverse drug reactions will ensure rational use of medicines. I appreciate the key role of AMC, IMS BHU for its significant contribution to the Pharmacovigilance Programme of India and thankful to all participating health care workers in this programme. I wish them all the best in their future endeavours towards the generation of patient safety data.

Dr. Y. Roja Ramani

AMC-Coordinator, (Department of Pharmacology) M.K.C.G Medical College & Hospital, Berhampur, Odisha

AMC, M.K.C.G Medical College & Hospital, Berhampur has been actively involved in the Pharmacovigilance activities in collaboration with National Coordination Centre, PvPI since January 2011. Becoming an established and effective AMC is a process that needs time, vision, dedication, expertise and continuity. Various CME's and training programmes at our AMC have contributed towards the goal of the Pharmacovigilance Programme of India. Constant encouragement and timely feedback to every stakeholder involved has played a pivotal role in this process. State, national and international level online training programmes/webinars for the sensitization/ awareness of medical and paramedical staff regarding PV activities were conducted for its smooth functioning, AMC, M.K.C.G Medical College & Hospital appreciates the unconditional support of NCC in becoming vigilant towards the COVID-19 drugs and vaccines associated ADRs. We hope the robust drug safety data analytical process adopted by PvPI will ensure effective Adverse Event Reporting culture among the stakeholders in the coming years.

Feedback from MAH Stakholders

Dr. Ankit Patil Country Safety Lead Pfizer India, Drug Safety Unit (DSU)

PvPI is playing a pivotal role in establishing and developing a robust Pharmacovigilance system in India. The team has put in sincere efforts in implementing various initiatives for skill development, awareness, training, and providing a platform for new talent in Pharmacovigilance. All these are helping to build capacity and capabilities in Pharmacovigilance.

I extend my best wishes to the entire PvPI team; well done!

Dr. Raghunath Dhule Pharmacovigilance Officer In-Charge Allergan an Abbvie Company

It is highly commendable the way PvPI has strengthened the Pharmacovigilance system in India. Since its inception, PvPI has constantly strived hard to create lot of awareness about drug safety in the pharmaceuticals industry, HCPs and the common public alike with the single goal of patient's safety. The same philosophy is applied within Allergan (An AbbVie Company) to ensure our drugs are safe and effective. We are contributing to PvPI by sending adverse events and sensitizing our company employees to report adverse events in a timely manner. On behalf of Allergan (An AbbVie company), we wish the entire team PvPI great success in all their endeavours.

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

फॉर्माकोविजीलैंस प्रोग्राम ऑफ़ इंडिया, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार दवारा 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 (ए स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार ने एक विशेष कदम उठाया एवं इस कदम के अंतर्गत फॉर्माकोविजीलेंस प्रोग्राम ऑफ़ इंडिया को नवीकृत किया, जिसका राष्ट्रीय समन्वय केंद्र, भारतीय भेषज संहिता आयोग, राजनगर, गाजियाबाद, उत्तर प्रदेश में स्थित है। इस समन्वय केंद्र का मुख्य कार्य दवाओं से होने वाले प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी ए.डी.आर मॉनीटिरिंग सेंटर के द्वारा एकत्रित करके उसका ऑकलन 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 प्रतिकृत प्रभाव/दुष्प्रभाव जैसे कि त्वचा संबंधित परेशानी, डायरिया, जी मिचलाना, उल्टी, बुखार, रक्तचाप (उच्च/निम्न), सिरदर्द या अन्य कोई दुष्प्रभाव प्रतीत होता है तो ऐसी स्थिति में अपने चिकित्सक से या नजदीकी अस्पताल में जाकर चिकित्सक से परामर्श लें।

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

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

- ए.डी.आर. मॉनीटरिंग सेंटरए.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 फॉर्माकोविजीलेंस विषय पर वर्ष भर कौशल विकास कार्यक्रम का आयोजन किया जाता है। इस कार्यक्रम की पूर्ण जानकारी भारतीय भेषज संहिता आयोग की वेबसाइट पर उपजल्हा है।

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

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

इसकी जानकारी आप फॉर्माकोविजीलेंस प्रोग्राम ऑफ़ इंडिया के अंतर्गत किसी भी निकटवर्ती ऐ डी आर मॉनिटरिंग सेंटर पर दे सकते हैं। इस सम्बन्ध में एक विशेष फॉर्म- Suspceted Adverse Drug Reaction Reporting Form (For Drugs used in Prophylaxis/ Treatment of COVID-19) भी डिज़ाइन किया गया है, जो <u>www.ipc.gov.in</u> पर उपलब्ध है।



Indian Pharmacopoeia Commission

National Coordination Centre, Pharmacovigilance Programme of India Ministry of Health & Family Welfare, Govt. of India Sector-23, Raj Nagar, Ghaziabad-201002 Tel.: 0120-2783400, 2783401, 2783392 For any other Information/Suggestion/ Query contact

Officer Incharge

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Let us join hands with PvPI to ensure patient safety

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