सत्यमेव जयते

IPC

Pharmacovigilance Programme of India

Information Profile

A step towards patient safety

Published by:

National Coordination Centre for PvPI

INDIAN PHARMACOPOEIA COMMISSION

Ministry of Health and Family Welfare, Government of India

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Introdcution

Pharmacovigilance Programme of India is Government of India's flagship drug safety monitoring programme, which collects, collates and analyses drug-related adverse events and send recommendations to CDSCO for taking appropriate regulatory actions.

Adverse Drug Reaction (ADR) is one of the leading causes of morbidity and mortality worldwide. The consequences of ADRs burden the healthcare system with increased cost of therapy and prolongation of hospitalization. In developing countries, the cost of management of adverse reactions in the general population is very high and under-recognized. It is, therefore, imperative to evaluate the safety of medicines through Pharmacovigilance system.

Evolution of Pharmacovigilance in India

In early 1980 attempts were made in India towards ADR monitoring. The Drugs Controller General of India established five Centres in 1982 for nationwide monitoring of ADRs. An estimated 58000, ADR case reports were collected in a multi-institute study conducted by ICMR in 1987. However, the project did not continue. In 1998, India joined World Health Organization (WHO) International Drug Monitoring Programme. At that time, National Coordination Center for Pharmacovigilance was the Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi.

The Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, Govt. of India launched the National Pharmacovigilance Programme (NPP) in November, 2004 considering the importance and benefits of pharmacovigilance in patient safety. NPP mainly aimed at promoting ADR reporting culture by healthcare professionals. A large number of ADR reports collected by NPP had generated a pool of ADR data. However, the programme did not meet the expectation and was temporarily suspended in 2009.

Mission, Vision & Objectives of PvPI

Pharmacovigilance Programme of India (PvPI) was operationalized in July, 2010 by Ministry of Health & Family Welfare (MoHFW), Government od India (GoI) with a mission to reduce the risks associated with the use of medicines in Indian population. The AIIMS, New Delhi was established as National Coordinating Centre for PvPI. Later on, Ministry of Health and Family Welfare, Government of India recasted PvPI on 15th April, 2011 and shifted the National Coordination Centre from All India Institute of Medical Sciences (AIIMS), New Delhi to IPC, Ghaziabad and is continuing.

Mission

To safeguard the health of Indian population by ensuring that the benefits of use of medicine outweigh the risks associated with its use.

Vision

To improve patient safety and welfare of Indian population by monitoring safety of medicines, thereby reducing the risk associated with their use.

Objectives

- Create a Nation-wide system for patient-safety by ensuring drug-safety
- Identify and confirm the signals from the reported cases
- Analyse the benefit-risk ratio of marketed medications
- Generate evidence-based information on safety of medicines
- Support regulatory agencies in the decision-making process on use of medications
- Communicate safety information on use of medicines to various stakeholders for preventing/minimizing the risk
- Collaborate with other National Centres for exchange of information and data management

- Provide training and technical support to other National Pharmacovigilance Centres across the globe
- To organize and sensitize the stakeholders for celebration of National Pharmacovigilance Week from 17th September- 23rd September every year
- Promote rational use of medicines
- Emerge as a National Centre of Excellence for Pharmacovigilance activities.

Core committees at NCC-PvPI

Following committees are constituted at NCC-PvPI to ensure smooth and effective functioning of the programme:

Steering Committee

It is the chief administrative and monitoring body of NCC-PvPI, which guides and supervises the functioning of programme.

Working Group

All technical issues related to the establishment and implementation of the programme, including providing technical inputs, are handled by the Working Group, which reports to the CDSCO for regulatory interventions.

Quality Review Panel

Quality Review Panel is responsible for quality, causality assessment and completeness of ICSRs. The panel also makes recommendations to the PvPI Working Group after data analysis and devises formats and guidance documents for follow-up action.

Signal Review Panel

The Signal Review Panel (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 pharmaceutical industries are also invited for

taking expert inputs, to collate and analyse information from ICSRs. This panel assesses the results of identified computerized Signals from ICSRs to validate and confirm. It looks into biostatistical methods for analysis and creates standardized post-analytical reports that help in understanding the information derived from ADRs. It also decides upon actionable indicators.

Core Training Panel

The Core Training Panel (CTP) of PvPI guides in the identification of training needs, organizing National and International training programmes, designing training modules and helps to conduct the training for healthcare professionals and other stakeholders throughout the year. It also identifies trainers for zone-wise training centres. The CTP interacts with National and International agencies for participation and implementation of training programmes in Pharmacovigilance. The Core Training Panel is assisted by the internal training team of PvPI. PvPI can also constitute any sub-committee as and when required.

Current Scenario

NCC-PvPI collects, collates and evaluates spontaneous reports of ADRs due to use of medicines, vaccines, medical devices & herbal products from all healthcare professionals and consumers/patients. To monitor ADRs, ADR Monitoring Centers (AMCs) have been set up all over India, which send reports to NCC- PvPI located at IPC, Ghaziabad. NCC-PvPI was started with 22 AMCs in the initial phase and currently has 1075 ADR monitoring centers (Medical colleges, district and corporate hospitals) across the country.

Keeping in view the progress made by and contribution of PvPI for drug safety, World Health Organization (WHO) on July 18, 2017 recognized IPC-PvPI as a WHO-Collaborating Centre for Pharmacovigilance in Public Health Programs and Regulatory Services.

This is a matter of pride and honor to India this being first of its kind, putting it on the world map. Pharmacovigilance Programme of India (PvPI) has successfully completed two consecutive tenures as a WHO Collaborating Centre. In recognition of its continued contributions, PvPI has been redesignated as a WHO Collaborating Centre for a third term.

Expansion of PvPI

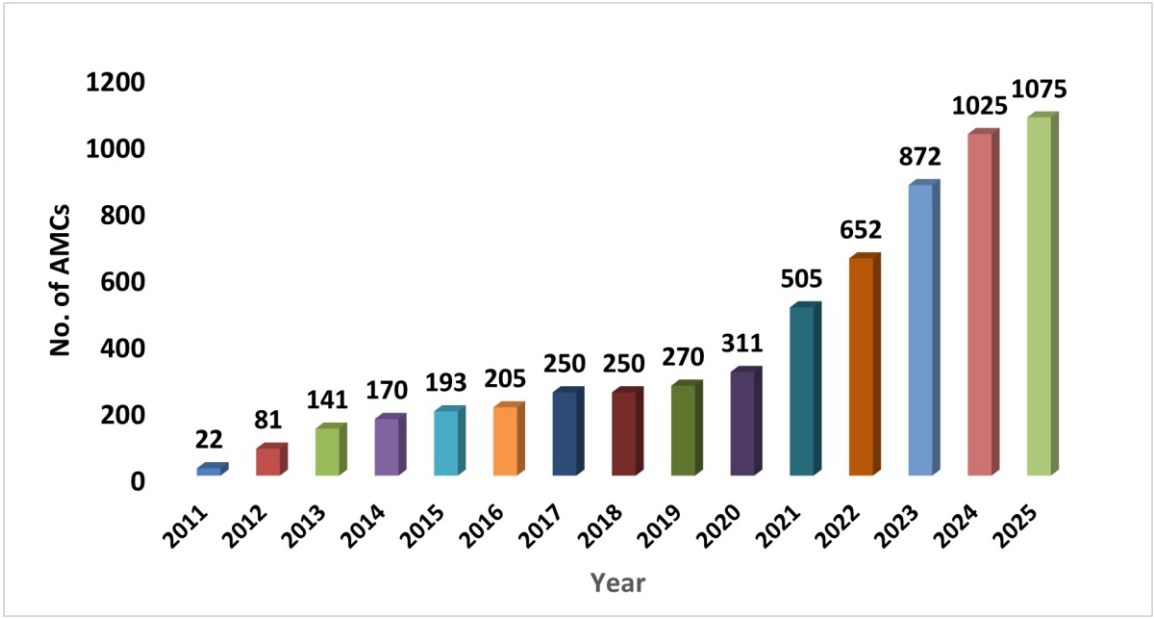

Figure - 1. Expansion of PvPI

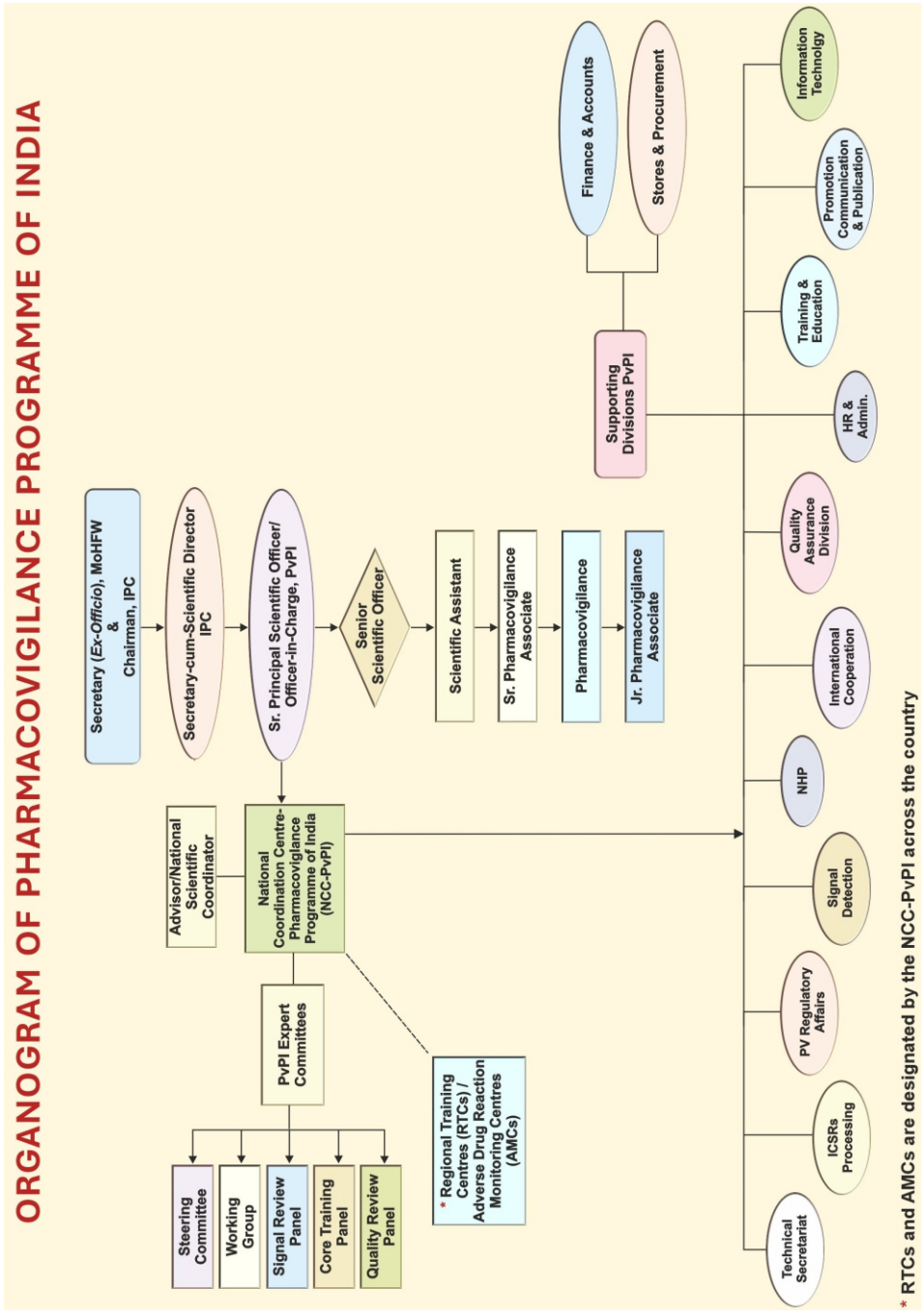

Figure - 2. Organogram of Pharmacovigilance Programme of India

Reporting of AEs

Who can Report ?

- Consumer/Patients
- Physicians
- Pharmacists
- ADR Monitoring Centres (AMCs)
- Pharmaceutical Industries/MAHs
- Others

Why to Report ?

- To ensure the safety of patients taking medicines.
- To reduce the risks associated with the use of medicines (economic burden, quality of life).
- To help regulatory authority make vital policy decision regarding safe use of medicines.

What to Report ?

All types of suspected ADRs:

- Known or unknown
- Serious or non-serious
- Frequent or rare

ADRs by:

- Medicines
- Medical Devices
- Biologicals including Vaccines, Blood & Blood Products

Medication Errors:

- Product dispensing/monitoring/prescribing/selection/storage error/issues.
- Accidental exposure to product.
- Inappropriate use of medical products.
- Product transcribing errors and communication issues.

Off-label Use:

- Use of medicines for an unapproved indication, age group, dosage or route of administration.

Misuse/Overdose/Abuse:

- Use of a medication (for a medical purpose) other than as directed or as indicated; taking medicine more/more often or for a longer period.
- Ingestion/application of medicine in quantities much greater than recommended.
- Nonmedical use of a substance for psychic effect, dependence, or a suicide attempt or gesture, recreational use of substances for any reason.

Lack of Efficacy and other product quality-related issues

- No/Lack of drug effect.
- Drug ineffective for approved/unapproved indication.
- Delayed or incomplete drug effect.
- Ineffective drug dosing regimen.
- Drug effect faster/less than expected.

Channels for reporting AEs/ADRs

Suspected ADR Reporting Form for Healthcare Professionals (HCPs) (Version 1.4)

The Suspected ADR reporting Form is specifically designed for healthcare professionals to capture detailed information about an AE/ADR. This form is available on IPC (www.ipc.gov.in) or CDSCO (www.cdsco.gov.in) website.

Medicines Side-Effect Reporting Form (For Consumers)

Consumers/patients may also make use of Medicines Side-effect Reporting Form for reporting any suspected AE/ADR to PvPI. This form is available in 10 Indian languages: Hindi, Bengali, Gujarati, Kannada, Malayalam, Marathi, Assamese, Oriya, Tamil and Telugu.

Suspected ADR Reporting Form (For drugs used in Prophylaxis/ Treatment of COVID-19)

The Suspected ADR Reporting Form is designed for healthcare professionals during pandemic to capture detailed information about an AE/ADR related to the drugs used in Prophylaxis/ Treatment of COVID-19. This form is available on IPC (www.ipc.gov.in).

Personal Protective Equipment (PPE) Adverse Event Reporting Form

In view of COVID-19 Pandemic, NCC-MvPI has specially designed a PPE Adverse Event Reporting Form, which primarily aims to collect the adverse events associated with the use of PPEs used for medical purposes.

Medical Device Adverse Event Reporting Form (For Consumers)

Consumers/patients may also make use of suspected medical device adverse event reporting form for reporting any suspected AE to MvPI. This form is available in Hindi and English languages.

Medical Device Adverse Event Reporting Form (For HCPs and MAHs)

Healthcare professionals including registered medical practitioners, professionals from allied health sciences, biomedical engineers and license holders including manufacturers and importers can use this form for reporting any suspected medical device-linked adverse event to MvPI-IPC. This form is available in Hindi and English languages.

Other important ADR Reporting Forms

Healthcare Professionals and other stakeholders can also report AEs/ADRs using specific forms designed purposely for reporting AE/ADR associated with Medicines used in Kala-azar treatment-Adverse Drug Reaction Form for Kala-Azar treatment, serious cases related to vaccine use - Serious AEFI Case Notification Form.

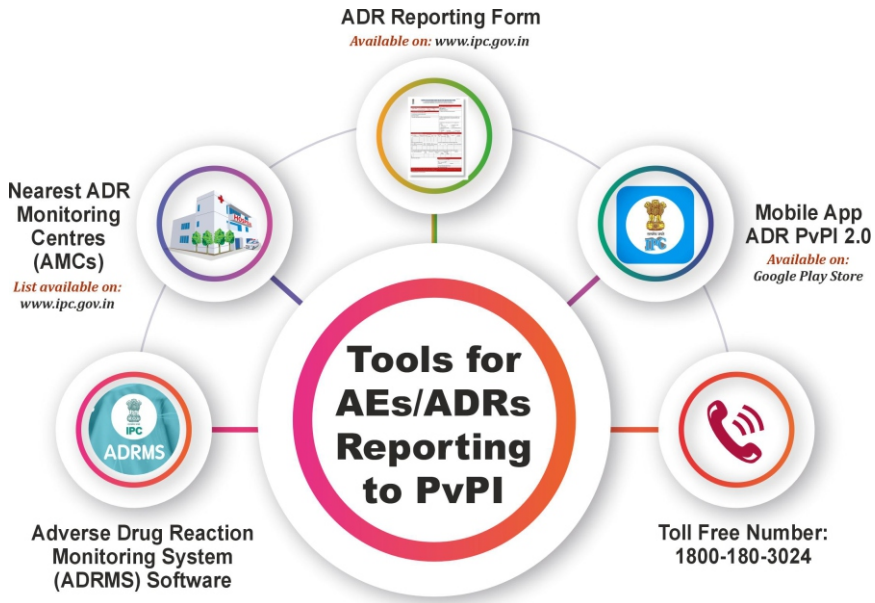

Figure - 3. AEs/ADRs Reporting Tools

Global Status of Indian ICSRs

The Pharmacovigilance Programme of India is responsible for the collection, assessment, detection and communication of risks associated with the use of medical products in Indian Population. The ICSRs collected by AMCs, MAHs, Healthcare Professionals, Patients/Consumers through different channels reported to NCC-PvPI, IPC.

8th Largest Reporter of ICSRs

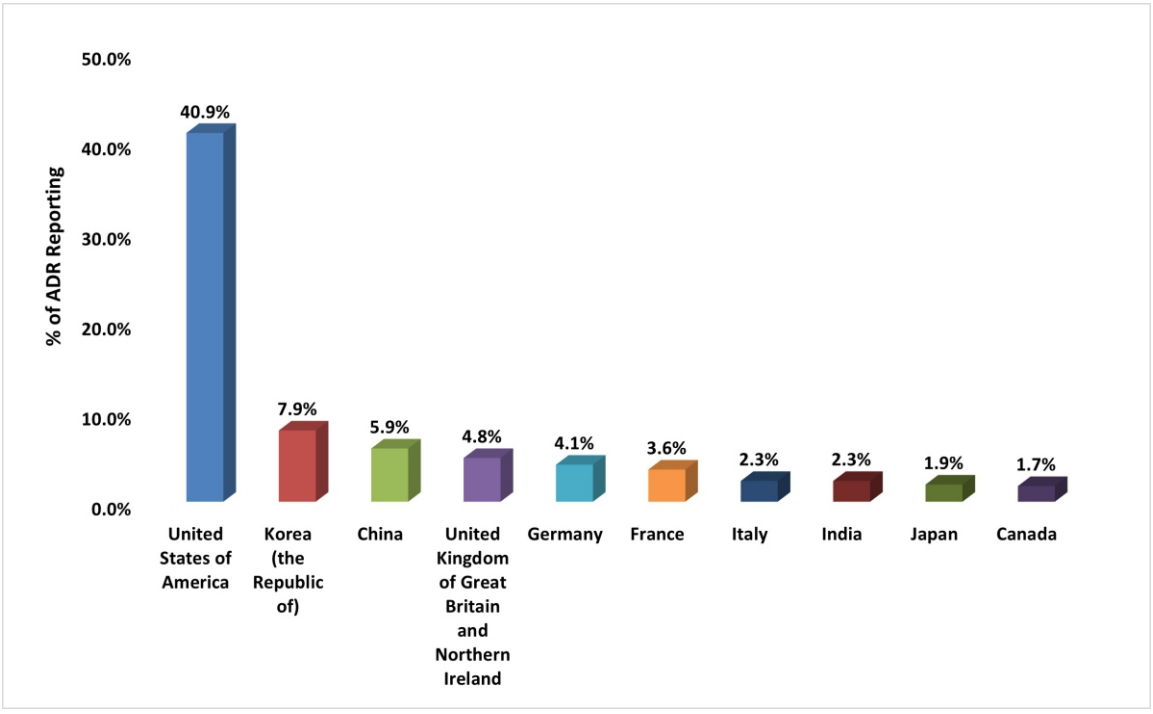

Figure - 4. Global Status of Indian ICSRs

Quality of ICSRs

The VigiGrade™ completeness score is a WHO system to measure the quality of the information provided on ICSRs. The graph represents the average completeness score of ICSRs submitted from India (Blue line) as compared to submitted ICSRs by all the other countries (Green dotted line). The average completeness score for the last financial year accounts for about 0.80 out of 1.

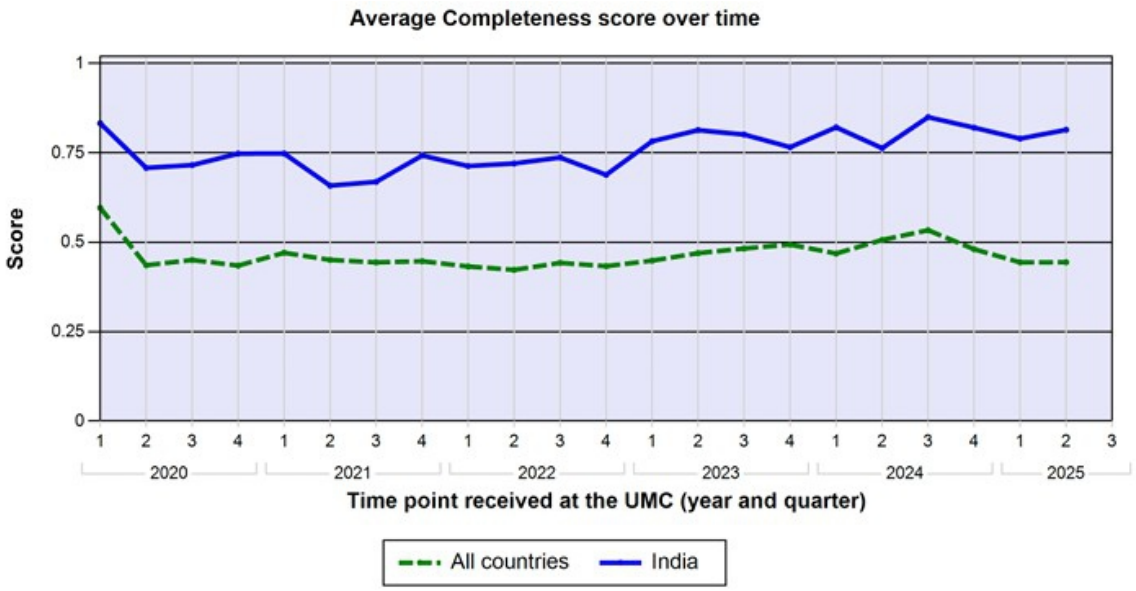

Figure - 5. Graphical representation of VigiGradeTM Completeness score of quality of ICSRs submitted by PvPI to UMC database

PvPI Recommendations to CDSCO

Drug Safety Alerts	Updating Package Inserts	Signals
182	66	16

Signals Identified by PvPI till date

S. No.	Suspected Drug	Adverse Drug Reaction
1.	Cefixime	Acute Generalized Exanthematosus Pustulosis
2.	Itraconazole	Acute Generalized Exanthematosus Pustulosis
3.	Furosemide	Dermatitis Lichenoid
4.	Lithium Carbonate	Drug Reaction with Eosinophilia & Systemic Symptoms Syndrome
5.	Fluconazole	Hyperpigmentation
6.	Oseltamivir	Sinus Bradycardia/ Bradycardia
7.	Tinidazole	Fixed Eruption
8.	Mefenamic Acid	Fixed Drug Eruption
9.	Doxyycline	Fixed Drug Eruption
10.	Minoxidil	Folliculitis
11.	Cephalosporins	Fixed Drug Eruption
12.	Paracetamol	Fixed Drug Eruption
13.	Aceclofenac	Fixed Drug Eruption
14.	Ibuprofen	Fixed Drug Eruption
15.	Oral Itraconazole	Symmetrical Drug Related- Intertriginous and Flexural Exanthema
16.	Gliclazide	Erythema Multiforme

PvPI Collaboration with PHPs

PvPl has collaborated with several national health programmes and research institutions in order to develop safety database of medicines in India:

National Collaborations

S. No.	Year	Health Programme/ Institution
1.	2013-2014	Revised National Tuberculosis Control Programme (RNTCP)-Pharmacovigilance of Anti-tubercular drugs. AEFI Secretariat (UIP)-Pharmacovigilance of Vaccines.
2.	2014-2015	National AIDS Control Organization (NACO)-Pharmacovigilance of Anti-Retroviral Drugs.
3.	2015-2016	Cohort Event Monitoring of Anti-TB Drug- Active Surveillance of Bedaquiline at 6 AMCs under PVPI.
4.	2016-2017	Indian Medical Association (IMA) - Sensitization and training of Clinicians on PV.
5.	2023	National Accredited Board of Hospitals (NABH), Quality Council of India-Implementation of ADR - reporting by all NABH Accredited hospitals
6.	2023	NIPER (National Institute of Pharmaceutical Education and Research), Guwahati

International Collaborations

S. No.	Year	Organization
1.	2017	World Health Organazation-South-East Asia Regional Office (WHO-SEARO). WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes & Regulatory services. PvPI has successfully completed two consecutive tenures as a WHO Collaborating Centre. In recognition of its continued contributions, PvPI has been redesignated as a WHO Collaborating Centre for a third term.

Training, Skill Development Programmes and Sensitization Programmes

The PvPI organizes trainings for stakeholders in the area of Pharmacovigilance. NCC-PvPI has recognized 12 Regional Training Centres (RTCs) to impart training in pharmacovigilance and to cater the needs of PV trainees and adapting Good Pharmacovigilance Practices.

Capacity Building in PvPI

The details of training programmes conducted during the index period are as follows:

1. Trainings organised by the NCC-PvPI, IPC

- Skill Development Programme (SDP) on Pharmacovigilance.
- Induction-cum-Training Programme for newly recruited PV Associates and newly appointed AMC Coordinators.
- Regional Training Programme for MAHs
- Interactive meetings conducted for MAHs.
- Pharmacovigilance training for National Accreditation Board for Hospitals & Healthcare providers (NABH) accredited hospitals.
- Hand holding meetings for AMCs
- Refresher training for Pharmacovigilance associates

2. Trainings organised by the RTCs & AMCs

- Advanced Level Trainings (ALT) Programmes
- Sensitization and awareness programmes for reporting AEs.

3. Celebration of National Pharmacovigilance Week

4. International webinar organised by NCC-PvPI for SEARN Countries and WHO Member States.

5. Other Training Programmes on Pharmacovigilance

National Pharmacovigilance Week

The National Coordination Centre - Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) has initiated organizing National Pharmacovigilance Week (NPW) from 17th to 23rd September, 2021 onwards and also sensitizing the stakeholders including AMCs, Pharma industries, Academic institutions across the country. The National Pharmacovigilance Week is celebrated every year throughout the country from 17th to 23rd September in the interest of patient safety.

The objective of NPW is to focus on PV activities aimed at creating awareness amongst the public, healthcare professionals, pharmaceutical industries and healthcare authorities about the reporting of adverse drug reactions and encourage them for carrying out the activities related to Pharmacovigilance among general public.

Launching of the Adverse Drug Reaction Monitoring System (ADRMS) Online Portal

To advance the vision of Hon'ble Prime Minster Shri Narendra Modi's Digital India, The Adverse Drug Reaction Monitoring System (ADRMS) Online Portal was launched by the Hon'ble Minister of Health & Family Welfare and Minister of Chemicals and Fertilizers, Shri J.P. Nadda during the 1st Policy Makers Forum meeting at Dr. Ambedkar International Centre in New Delhi on August 19, 2024. The event was attended by senior officials from the Ministry of External Affairs, Department of Pharmaceuticals, Central Drugs Standard Control Organization, and the Indian Pharmacopoeia Commission.

The ADRMS software, developed by the Pharmacovigilance Programme of India (PvPI), is India's first comprehensive medical product safety database tailored to the need of the Indian population. It will facilitate the reporting of adverse events related to medicines, vaccines and medical devices by the stakeholders.

WHO NRA Re-benchmarking for Vaccines in India

For WHO NRA Re-benchmarking for Vaccines in India, an assessment was done from 16th to 20th September, 2024. A team of WHO assessors visited NCC-PvPI, IPC, Ghaziabad on 18th September 2024 to assess the Vigilance Function.

The WHO team reviewed the relevant documents and interviewed the PvPI staff for the purpose of assessment of Vigilance function, as per the WHO Global Benchmarking Tool. As of 4th October 2024, India's regulatory system has successfully achieved overall maturity level 3, following the implementation of all critical recommendations and submission of corrective and preventive actions for any identified gaps during the benchmarking.

This success is a cumulative of intensive effort by the Ministry of Health and Family Welfare, Government of India, including CDSCO, in collaboration with WHO, to implement a roadmap to strengthen capacity for regulation of vaccines.

Communication & Resource Materials of PvPI

Communication is essential for achieving the objectives of Pharmacovigilance in terms of promoting the rational, safe & effective use of medicine, preventing harm from adverse reactions and contributing to the protection of public health. The PvPI communicates drug safety information/resource materials to the CDSCO and other stakeholders through different mechanism such as emails, press release, social media and website of IPC etc. For more information, please visit the website www.ipc.gov.in .

The communication division of NCC-PvPI, IPC communicates with stakeholders to make aware about the activities carried out in PvPI across the country. The modes of communication by NCC-PvPI, IPC are as follows:

- PvPI Newsletters
- Annual Performance Report of PvPI
- Awareness Posters & Pamphlets
- PV Guidance document for MAHs of Pharmaceutical Products (Version 2.0)
- Quality Manual
- Guidance document for spontaneous reporting of ADRs
- Handbook of PvPI
- PV Comic

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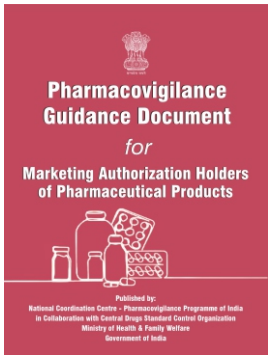
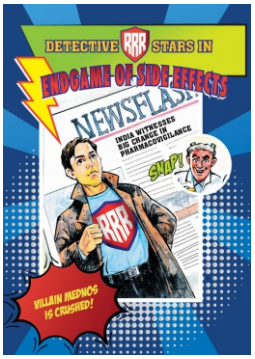


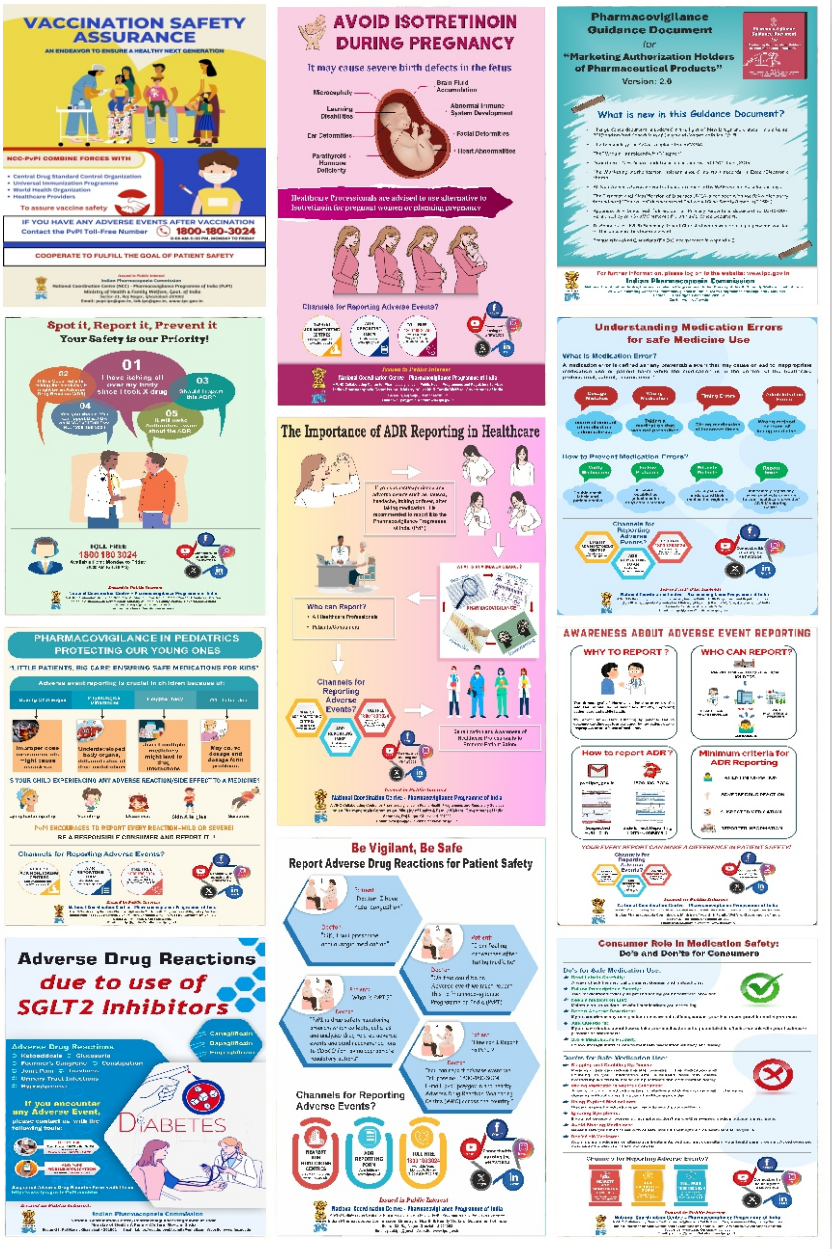
PV Guidance document
for MAHs

Quality Manual
Pharmacovigilance
Programme of India



Pharmacovigilance
Comic

Public Outreach through Awareness Posters



PvPI in Social Media

Version 1.4

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

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)

Initial Case ❑ | Follow-up Case ❑

FOR AMC / NCC USE ONLY

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

AMC Report No. :

Worldwide Unique No. :

A. PATIENT INFORMATION *

1. Patient Initials:

2. Age or date of birth:

3. Gender: M ❑ F ❑ Other ❑

4. Weight (in Kg.)

B. SUSPECTED ADVERSE REACTION *

5. Event / Reaction start date (dd/mm/yyyy)

6. Event / Reaction stop date (dd/mm/yyyy)

7. Describe Event/Reaction management with details , if any

12. Relevant investigations with dates :

13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)

14. Seriousness of the reaction : No❑ if Yes ❑ (*please tick anyone*)

❑Death (dd/mm/yyyy) ❑Congenital-anomaly

❑Life threatening ❑Disability

❑Hospitalization-Initial/Prolonged ❑Other Medically important

15. Outcome:

❑Recovered ❑Recovering ❑Not Recovered

❑Fatal ❑Recovered with sequelae ❑Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	8. Name (Brand/ Generic)	Manufacturer (if known)	Batch No. / Lot No.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates		Indication	Causality Assessment
								Date Started	Date Stopped		
i											
ii											
iii											
iv#											

9. Action taken after reaction (*please tick*)

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown
i						
ii						
iii						
iv						

10. Reaction reappeared after reintroduction of suspected medication (*please tick*)

Yes	No	Effect unknown	Dose (if re-introduced)

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates		Indication
					Date Started	Date Stopped	
i							
ii							
iii#							

Additional Information :

D. REPORTER DETAILS *

16. Name & Address : _____

_____

Pin : _____ Email : _____

Contact No- : _____

Occupation : _____Signature : _____

17. Date of this report (dd/mm/yyyy) :

Signature and Name of Receiving Personnel :

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

Use separate page for more information

* Mandatory Fields for suspected ADR Reporting Form

ADVICE ABOUT REPORTING

A. What to report?

All adverse events should be reported

Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines & Herbal Products.

Report every serious adverse drug reactions. A reaction is serious when the patient outcome is :

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability (significant, persistent or permanent)
- Congenital anomaly
- Report intervention to prevent permanent impairment or damage

NOTE : Serious/Adverse Event following immunization can also be reported in Serious AEFI case Notification Form available on http://www.ipc.gov.in

B. Who can report?

All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurse etc.) can report adverse drug reactions

C. Where to report?

Duly filled in Suspected Adverse Drug Reaction Reporting Form can be sent to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC) for PvPI.

Call on Helpline (Toll Free) 1800 180 3024 to report ADRs or directly mail this filled form to pvpi.ipc@gov.in

A list of nationwide AMCs is available at : http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D.What happens to the submitted information?

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC-PvPI through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The Signal Review Panel of PvPI reviews the data and suggests any interventions that may be required.

E. Mandatory fields for suspected ADR Reporting Form (*)

Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) & reporter information.

For Adverse Drug Reaction Reporting Tools

- **E-mail : pvpi.ipc@gov.in**
- **PvPI Helpline (Toll Free) : 1800 180 3024** (9:00 AM to 5:30 PM, Monday-Friday)
- **ADR Mobile App : "ADRPvPI"**

Version 1.0
संस्करण 1.0

MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

औषधि दुष्प्रभाव सूचना फॉर्म (उपभोक्ताओं के लिए)

Indian Pharmacopoeia Commission, National Coordination Centre- Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Government of India.

भारतीय भेषज संहिता आयोग, राष्ट्रीय समन्वय केंद्र – भारतीय फार्माकोविजिलेंस कार्यक्रम,
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार।

1.Patient Details/ रोगी का विवरण

Patient Initials/ रोगी के आद्याक्षर::	Gender/ लिंग (√): Male/ पुरूष ☐ Female/ स्त्री ☐ Other/ अन्य ☐	Age (Year or Month)/ आयु (वर्ष या माह) :

2. Health Information/ स्वास्थ्य संबंधी जानकारी

a. Reason(s) for taking medicine(s)(Disease/Symptoms)/ दवा(दवाएं) लेने का कारण (रोग/लक्षण):

b. Medicines Advised by/ दवाई की सलाह देने वाला (√): Doctor/ डॉक्टर ☐ Pharmacist/ फॉर्मासिस्ट ☐ Friends/Relatives/ मित्र/रिश्तेदार ☐
Self (Past disease experienced/No past disease experienced)/ स्वयं (पूर्व बीमारी का अनुभव/पूर्व बीमारी का कोई अनुभव नहीं) ☐

3. Details of Person Reporting the Side Effect/ दुष्प्रभाव की सूचना देने वाले व्यक्ति का विवरण

Name (Optional)/ नाम (वैकल्पिक):

Address/ पता:

Telephone No/ टेलीफोन नं:	Email/ ईमेल:

4. Details of Medicine Taking/Taken/ ली जा रही है / ली जा चुकी दवाई का विवरण

Name of Medicines/ दवाइयों के नाम	Quantity of Medicines taken (e.g. 250 mg, Two times a day)/ ली गई दवाई की मात्रा (उदाहरण के लिए 250 मिग्रा, एक दिन में दो बार)	Expiry Date of Medicines/ दवा के निष्क्रिय होने की तिथि	Date of Start of Medicines/ दवाइयां आरंभ करने की तिथि	Date of Stop of Medicines/ दवाइयां रोकने की तिथि dd/mm/yy

Dosage form/खुराक का स्वरूप (√) : Tablet/ गोली (टेबलेट) ☐ Capsule/ कैप्सूल ☐ Injection/ इंजेक्शन ☐ Oral Liquids/ मौखिक तरल ☐ If Others (Please Specify.....)/यदि अन्य (कृपया निर्दिष्ट करें.....)

5. About the Side Effect/ दुष्प्रभाव के बारे में

When did the side effect start?/ दुष्प्रभाव की शुरूआत कब हुई थी? dd/mm/yy ☐ Side Effect is still Continuing (Yes/No)/
When did the side effect stop?/ दुष्प्रभाव कब समाप्त हुआ था? dd/mm/yy ☐ क्या दुष्प्रभाव जारी हैं (हां/नहीं):☐

6.How bad was the Side Effect? (Please √ the boxes that Apply)/ दुष्प्रभाव कितने हानिकारक थे? (कृपया जो लागू हो, उस पर √ का निशान लगाएं)

☐ Did not affect daily activities/ दैनिक गतिविधियां प्रभावित नहीं हुई थी	☐ Affect daily activities/ दैनिक गतिविधियां प्रभावित हुई
☐ Admitted to hospital/ अस्पताल ले जाना पड़ा	☐ Death/ मृत्यु
☐ Others/ अन्य	

7.Describe the Side Effect (What did you do to manage the side effect?)/ दुष्प्रभाव की व्याख्या करें (आपने दुष्प्रभावों से छुटकारा प्राप्त करने के लिए क्या किया)?

This reporting is voluntary, has no legal implication and aims to improve patient safety. Your active participation is valuable. The information provided in this form will be forwarded to ADR Monitoring Centre for follow-up. You are requested to cooperate with the programme officials when they contact you for more details. Please do report even if you do not have all the information.

यह रिपोर्टिंग स्वैच्छिक है, कोई कानूनी निहितार्थ नहीं है और इसका लक्ष्य मरीज की सुरक्षा में सुधार करना है। आपकी सक्रिय भागीदारी मूल्यवान है। इस फॉर्म में दी गई जानकारी की अनुवर्ती कार्रवाई हेतु एडीआर निगरानी केंद्र को भेजा जाएगा। आपसे अनुरोध है कि आप कार्यक्रम के अधिकारियों का सहयोग करें जब वे अधिक जानकारी प्राप्त करने के लिए आपसे संपर्क करें। कृपया पूर्ण जानकारी न होने पर भी सूचित करें।

Please turn the page to read the instructions
निर्देशों को पढ़ने के लिए कृपया पेज पलटें

Send your report by mail or Fax to/ मेल या फैक्स के द्वारा अपनी रिपोर्ट निम्न पते पर भेजें

Pharmacovigilance Programme of India
National Coordination Centre,
Indian Pharmacopoeia Commission,
Ministry of Health & Family Welfare, Govt. of India
Sector-23,Rajnagar,Ghaziabad-201002.Uttar Pradesh
Tel.:0120-2783400, 2783401, 2783392
FAX: 0120-2783311
Email: pvpi.compat@gmail.com
For more information visit us at *www.ipc.gov.in*

Call us on Helpline/ हेल्पलाइन पर हमें फोन करें

1800-180-3024 **(Toll Free/ (टोल फ्री))**

(9:00 AM to 5:30 PM, weekdays/ प्रात: 9:00 बजे 5:30 बजे तक, प्रत्येक कार्यदिवस पर)

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public.
गोपनीयता: रोगी की पहचान को पूर्णत: गुप्त और सुरक्षित रखा जाएगा है। कार्यक्रम के स्टाफ से उम्मीद की जाती है कि स्टाफ का कोई भी व्यक्ति सार्वजनिक अनुरोध पर रिपोर्ट देने वाले की पहचान का खुलासा नहीं करेगा।

Instructions to Complete the Reporting Form
सूचना फॉर्म को पूरा करने के लिए निर्देश

Section 1 - Patient Details

- ✓ In patient Initial, write first letter of the name and first letter of the surname (e.g. Pradeep Sharma-PS).
- ✓ Provide personal information (Gender, Age).

Section -2 Health Information

- ✓ Provide reason(s) for taking medicines and medicines advised by (Doctor, Pharmacists, Friends/ Relatives and Self).

Section 3 - Details of Person Reporting the Side Effect

- ✓ Provide the name (optional), address; telephone no. and email are necessary to assess the report.

Section 4 - Details of the Medicines Taking/Taken

- ✓ Give all details about the Medicines (Name of Medicines, Quantity of Medicines taken, Expiry Date, start and stop date of Medicines) that have caused side effect.
- ✓ Please provide Dosage form (Tablets, Capsule, injections, Oral liquid) and if others please specify.

Section 5 - About the Side Effect

- ✓ Provide side effect start and stop dates and also specify whether the side effect is still continuing.

Section 6 - How bad was the Side Effect

- ✓ Please tick marks the appropriate boxes that apply.

Section 7- Describe the Side Effect

- ✓ Please describe the details of side effect and what treatment was taken to manage the side effect.

निर्देश 1 – रोगी का विवरण

- ✓ रोगी के आद्याक्षर में, नाम का पहला अक्षर लिखें और उपनाम का प्रथम अक्षर लिखें (जैसे प्रदीप शर्मा–प्रश)।
- ✓ व्यक्तिगत जानकारी (लिंग, आयु) प्रदान करें।

निर्देश –2 स्वास्थ्य संबंधी जानकारी

- ✓ दवा लेने के कारण और परामर्शदाता का नाम दें (डॉक्टर, फार्मासिस्ट, मित्र/रिश्तेदार और स्वयं)।

निर्देश 3 – दुष्प्रभाव की रिपोर्ट करने वाले व्यक्ति का विवरण दें

- ✓ रिपोर्ट के मूल्यांकन हेतु नाम (वैकल्पिक), पता, टेलीफोन नं और ई–मेल उपलब्ध कराएं।

निर्देश 4 – ली जा रही है / ली जा चुकी दवाइयों का विवरण

- ✓ उन दवाइयों (दवाइयों का नाम, ली गई दवाइयां, निष्क्रिय होने की तिथि, दवाइयां शुरू करने एवं रोकने की तिथि) का विवरण दें जिनके कारण आपको दुष्प्रभाव हुआ है।
- ✓ खुराक का स्वरूप (गोली (टेबलेट), कैप्सूल, इंजेक्शन, मौखिक तरल (पीने वाली दवा) और यदि कोई अन्य हो तो निर्दिष्ट करें।

निर्देश 5 – दुष्प्रभाव के प्रभाव के बारे में

- ✓ दुष्प्रभाव आरंभ और समाप्त होने की तिथि बताएं और यह भी निर्दिष्ट करें कि क्या दुष्प्रभाव अभी भी जारी हैं।

निर्देश 6 – दुष्प्रभाव कितने हानिकारक थे?

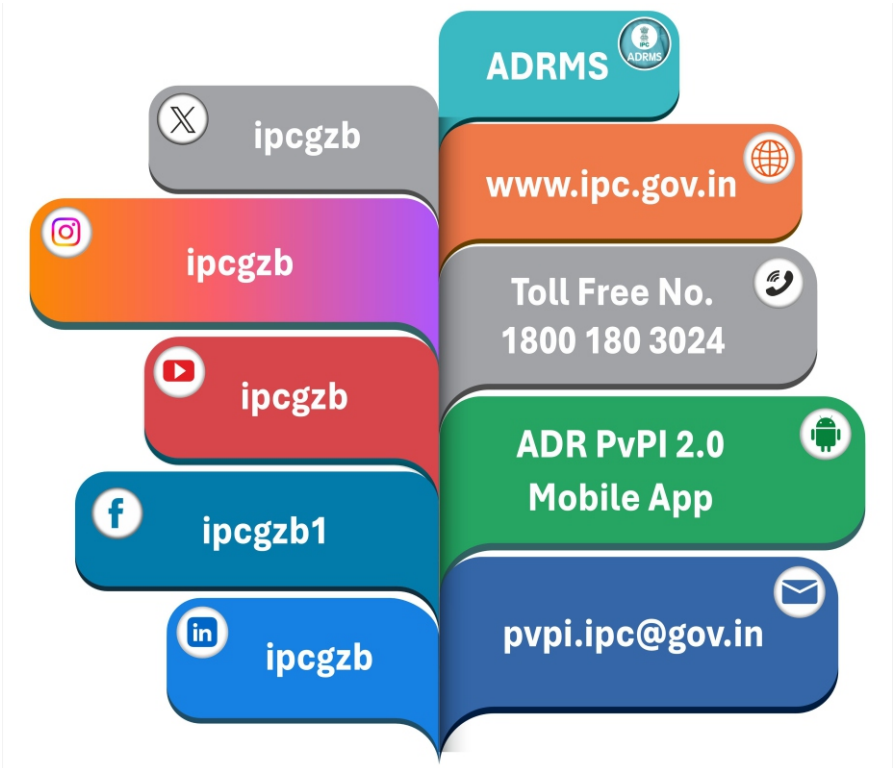
- ✓ कृपया उचित डब्बे पर निशान लगाएं।

निर्देश 7– दुष्प्रभाव की व्याख्या करें

- ✓ कृपया दुष्प्रभाव का विवरण और उस दुष्प्रभाव से छुटकारा पाने के लिए क्या उपचार किया गया, विवेचना करें।

इस फॉर्म को पूरा करने के लिए अपना समय देने हेतु आपका धन्यवाद।

Let us join hands with PvPI to ensure patient safety



NCC-PvPI Team

सत्यमेव जयते

IPC

National Coordination Centre- Pharmacovigilance Programme of India

WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services

INDIAN PHARMACOPOEIA COMMISSION

Ministry of Health and Family Welfare, Government of India

Sector - 23, Raj Nagar, Ghaziabad - 201002

Email: pvpi.ipc@gov.in Tel.: 0120-2783400, 2783401, 2783392

Website: www.ipc.gov.in