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Overview on Pharmacovigilance: Ensuring Medication Safety

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Review Article

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Abstract

Pharmacovigilance plays a pivotal role in ensuring drug safety by monitoring and evaluating the effects of medications before and after their market launch. In India, a rapidly expanding pharmaceutical industry coupled with a diverse patient population and growing drug consumption necessitates robust pharmacovigilance measures. This abstract highlights the need for pharmacovigilance in India, emphasizing factors such as the expansion of the pharmaceutical sector, diverse patient demographics, increased drug consumption, limited awareness and reporting, regulatory compliance, globalization of clinical trials, and emerging safety concerns. The Pharmacovigilance Programme of India (PvPI) serves as a cornerstone for patient safety, focusing on data collection, signal detection, capacity building, and regulatory collaboration. Reporting adverse drug reactions (ADRs) to PvPI is crucial, and various reporting methods, including online reporting, Vigiflow software, ADR reporting forms, direct communication, telephone reporting, and email, are discussed. Additionally, advice on what to report, who can report, where to report, and the handling of submitted information is provided to encourage effective ADR reporting. Overall, pharmacovigilance in India is essential for ensuring the safe and effective use of pharmaceutical products, protecting public health, and minimizing risks associated with medications.

Keywords: Pharmacovigilance; Drug Safety; India; Pharmaceutical Industry; Patient Population; Adverse Drug Reactions (ADRs); Pharmacovigilance Programme of India (PvPI); Drug Consumption; Regulatory Compliance; Clinical Trials; Safety Concerns; ADR Reporting; Data Collection; Signal Detection; Patient Safety

Introduction

Pharmacovigilance, the systematic monitoring and evaluation of drugs' effects pre- and post-market release, is fundamental to ensuring medication safety and efficacy. This process involves the detection and prevention of adverse drug reactions (ADRs) through comprehensive data collection from healthcare providers, patients, and pharmaceutical companies. With the pharmaceutical industry rapidly expanding globally, including in India, the importance of robust pharmacovigilance measures cannot be overstated. The Indian pharmaceutical sector has witnessed significant growth in recent years, emerging as a major player in the global generic drugs market [1]. This expansion has led to an increased influx of medications into the market, necessitating vigilant monitoring to safeguard public health.

Furthermore, India's diverse population, characterized by variations in genetics, lifestyles, and healthcare practices among different regions and communities, underscores the need for tailored pharmacovigilance strategies [2]. Such diversity can result in differential drug responses and ADRs,

emphasizing the importance of proactive surveillance to address varying safety concerns effectively. Additionally, the escalating consumption of pharmaceutical drugs in India due to population growth, urbanization, and improved healthcare access heightens the urgency for robust pharmacovigilance systems [3]. Despite these imperatives, challenges such as limited awareness among healthcare professionals and underreporting of ADRs persist in India [4].

In response to these challenges, regulatory agencies such as the Central Drugs Standard Control Organization (CDSCO) have mandated pharmacovigilance activities to ensure drug safety and regulatory compliance [5]. The Pharmacovigilance Programme of India (PvPI), launched in 2010, serves as a pivotal initiative to enhance patient safety and monitor the safety of pharmaceutical products nationwide [6]. Through a patient-centric approach, PvPI facilitates data collection, signal detection, capacity building, and regulatory collaboration to promote medication safety.

What is Pharmacovigilance?

Pharmacovigilance is the process of monitoring and evaluating the effects of drugs both before and after their launch into the market [7]. It involves assessing the quality of drugs and detecting and preventing any adverse effects that may arise. This comprehensive approach to drug safety encompasses gathering information from various sources, including healthcare providers, pharmaceutical companies, and patients, to better understand the risks and benefits associated with specific medications.

The development of new drugs involves significant investments of time and resources by pharmaceutical companies, including extensive clinical trials to ensure safety and efficacy before market approval. With the advancement of information technology (IT), pharmacovigilance has evolved to incorporate IT systems for enhanced safety signal detection and management.

Regulators now require proactive surveillance programs throughout a drug's lifecycle, including comprehensive risk management plans and ongoing signal detection and analysis. This shift in approach highlights the importance of not only reporting adverse events but also actively monitoring safety concerns throughout a product's lifespan.

Pharmacovigilance plays a crucial role in evaluating drug safety post-marketing, informing regulatory decisions, and ensuring the ongoing safety of both new and existing medications. It encompasses various activities, including spontaneous reporting of adverse events, systematic epidemiological studies, and the identification and evaluation of safety signals.

Safety signals, which indicate a potential concern about the safety of a drug, can arise from various sources, including post-marketing data and pre-clinical studies. Pharmacovigilance also addresses a range of other issues related to drug safety, such as substandard medicines, medication errors, lack of efficacy reports, and misuse or abuse of medications.

Need for Pharmacovigilance in India

Rapidly Expanding Pharmaceutical Industry: India's pharmaceutical sector has experienced substantial growth in recent years, becoming one of the largest producers of generic drugs globally [8]. This expansion has led to an increase in the number of drugs entering the market, highlighting the necessity for robust pharmacovigilance measures to ensure their safety and efficacy.

Diverse Patient Population: India's population is incredibly diverse, with variations in genetics, lifestyles, and healthcare practices among different regions and communities [9]. This diversity can result in differential drug responses and adverse reactions, underscoring the importance of pharmacovigilance to monitor and address such variations effectively.

Growing Drug Consumption: The consumption of pharmaceutical drugs in India has been steadily rising due to factors such as population growth, urbanization, and increased access to healthcare services [6,9]. With more people using medications, there is a heightened need for pharmacovigilance to detect and mitigate any adverse effects that may arise.

Limited Awareness and Reporting: Despite the importance of pharmacovigilance, there remains a lack of awareness among healthcare professionals, regulators, and the general public in India [8]. This lack of awareness often leads to underreporting of adverse drug reactions, hindering the timely identification of potential safety concerns.

Regulatory Compliance: Regulatory agencies such as the Central Drugs Standard Control Organization (CDSCO) have mandated pharmacovigilance activities to ensure drug safety and regulatory compliance [8]. Pharmaceutical companies operating in India must establish pharmacovigilance systems to adhere to these regulations and maintain the safety of their products.

Globalization of Clinical Trials: India has become an attractive destination for clinical trials due to its large and diverse patient population, as well as lower research and development costs [9]. However, the globalization of clinical trials also brings the need for rigorous pharmacovigilance

practices to safeguard the well-being of trial participants and ensure the ethical conduct of research.

Emerging Safety Concerns: The introduction of new drugs and therapies poses potential safety risks, including adverse drug reactions and medication errors [8]. Pharmacovigilance plays a crucial role in identifying and addressing these safety concerns, thereby enhancing patient safety and public health.

Role of Pharmacovigilance in Medicines Regulation

The role of pharmacovigilance in medicines regulation in India is pivotal for ensuring the safety, efficacy, and quality of pharmaceutical products. Pharmacovigilance encompasses systematic monitoring, detection, assessment, and reporting of adverse events associated with medicines a detailed exploration of its role.

Monitoring and Reporting Adverse Events: Pharmacovigilance involves the systematic monitoring, detection, assessment, and reporting of adverse events associated with medicines [10]. This includes collecting data on adverse drug reactions (ADRs) from healthcare professionals, patients, and pharmaceutical companies.

Risk Assessment and Management: Pharmacovigilance plays a pivotal role in assessing the risks associated with the use of medicines and implementing measures to manage these risks effectively [11]. This involves evaluating the benefit-risk profile of medicines and taking regulatory actions when necessary, such as updating product labels or issuing safety alerts.

Regulatory Compliance: Pharmacovigilance is integral to regulatory compliance in India's medicines regulation framework [12]. Regulatory authorities such as the Central Drugs Standard Control Organization (CDSCO) require pharmaceutical companies to establish pharmacovigilance systems and adhere to reporting obligations outlined in pharmacovigilance guidelines.

Post-Marketing Surveillance: Pharmacovigilance extends beyond pre-market clinical trials to encompass post-marketing surveillance of medicines [10]. This involves monitoring the safety of medicines after they have been approved and marketed to detect any previously unidentified adverse effects or safety concerns.

Signal Detection and Analysis: Pharmacovigilance activities include the identification and analysis of safety signals, which are indications of potential safety issues associated with medicines [11]. This involves analyzing pharmacovigilance data to detect patterns or trends that may suggest previously unrecognized risks.

Public Health Protection: Pharmacovigilance ultimately serves to protect public health by ensuring the safe use of medicines and minimizing the risks of adverse drug reactions and other medication-related problems [12]. By promptly identifying and addressing safety concerns, pharmacovigilance contributes to improving patient safety and healthcare outcomes.

Pharmacovigilance Programme of India (PvPI)

The Pharmacovigilance Programme of India (PvPI) is a comprehensive initiative aimed at enhancing patient safety and monitoring the safety of pharmaceutical products in India. PvPI, role in patient safety [13] are:

Establishment and Structure: The PvPI was launched in 2010 under the aegis of the Ministry of Health and Family Welfare, Government of India. It operates under the guidance of the Indian Pharmacopoeia Commission (IPC) and encompasses a nationwide network of Adverse Drug Reaction Monitoring Centers (AMCs).

Patient-Centric Approach: At the core of the PvPI is a patient-centric approach aimed at safeguarding the health and well-being of individuals who use pharmaceutical products. By actively monitoring adverse drug reactions (ADRs) and other medication-related issues, the PvPI strives to prevent harm and enhance patient safety throughout the healthcare system.

Data Collection and Reporting: The PvPI facilitates the collection, collation, and analysis of ADR reports from various sources, including healthcare professionals, consumers, and pharmaceutical companies. These reports are submitted to the CDSCO through the Pharmacovigilance Program of India (PvPI) website or Vigiflow software.

Signal Detection and Analysis: A key aspect of the PvPI is the detection and analysis of safety signals associated with pharmaceutical products. By systematically analyzing pharmacovigilance data, the PvPI identifies potential safety concerns, emerging trends, and patterns of adverse reactions, enabling timely intervention and risk mitigation strategies.

Capacity Building and Awareness: The PvPI conducts capacity building initiatives, training programs, and awareness campaigns to educate healthcare professionals, pharmacists, and consumers about pharmacovigilance principles, reporting procedures, and the importance of medication safety. These efforts aim to enhance reporting rates, promote proactive surveillance, and foster a culture of patient

Regulatory Support and Collaboration: The PvPI

collaborates closely with regulatory authorities, healthcare institutions, pharmaceutical companies, and other stakeholders to strengthen pharmacovigilance activities and support evidence-based decision-making. By providing regulatory support and sharing pharmacovigilance data, the PvPI contributes to informed regulatory actions and policy formulation to protect public health

Work flow of Adverse Drug Reaction report in PvPI

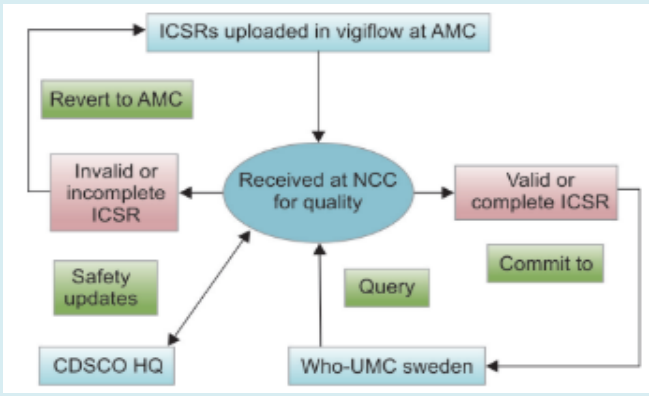


Figure 1: Work flow of ICSR at regional, national, and international levels.

ICSRs- Individual Case Safety Reports.
AMC- Adverse Drug Reaction Monitoring Centre.
NCC- National Coordinating Centre (NCC) (at IPC, Ghaziabad).

Aims of Pharmacovigilance Program of India (PvPI)

It is due to pharmacovigilance program in India [14] that the regulatory agencies, media, and consumers have become more aware about the benefits and risks associated with the use of medicines. The various aims of PvPI are:

- To monitor ADRs in the Indian population
- To create awareness among HCPs about the importance of ADR reporting in India
- To generate evidence-based data/recommendations on the safe use of drugs
- To support the CDSCO in formulating safety-related regulatory decisions of medicines
- To identify and analyze new signal from the reported cases
- To communicate the safety information on use of drugs to various stakeholders to minimize the risk
- To create a national center of excellence at par with global drug safety monitoring standards
- To monitor benefit–risk profile of drugs and communicate information to all key stakeholders
- To collaborate with other national centers for the exchange of information on adverse drug reports
- To promote rational use of medicine.

The Pharmacovigilance Programme of India (PvPI) is a cornerstone of patient safety in India, encompassing data collection, signal detection, capacity building, and regulatory collaboration to ensure the safe and effective use of pharmaceutical products.

How Reporting adverse drug reactions (ADRs)

Reporting adverse drug reactions (ADRs) to the Pharmacovigilance Programme of India (PvPI) is a crucial step in ensuring medication safety [15].

Online Reporting: A convenient way to report ADRs to the PvPI is through the online reporting portal available on the Pharmacovigilance Program of India (PvPI) website [16]. The online reporting form allows healthcare professionals, consumers, and pharmaceutical companies to submit ADR reports electronically.

Vigiflow Software: Healthcare facilities and pharmacovigilance centers can use Vigiflow software, a dedicated tool provided by the PvPI, to collect, collate, and submit ADR reports [17]. Vigiflow facilitates systematic data entry and ensures standardized reporting formats for consistency and accuracy.

ADR Reporting Forms: Pharmacovigilance centers, healthcare institutions, and pharmacies may have physical ADR reporting forms available for healthcare professionals and consumers to fill out [18]. These forms capture essential information about the ADR, including details about the patient, the suspected medication, and the adverse event experienced.

Direct Communication: Healthcare professionals can report ADRs directly to designate [19]. These centers serve as focal points for ADR reporting and facilitate the collection and analysis of pharmacovigilance data

Telephone Reporting: In some cases, healthcare professionals or consumers may prefer to report ADRs via telephone (toll free no 1800-180-3024) or email [20]. Contact information for pharmacovigilance centers or national coordinating centers can be obtained from the PvPI website or other official sources for direct communication and reporting.

Advice About Reporting [21]

What to report?

- Report 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
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products etc.

Note: Adverse Event Following Immunization can also be reported in Serious AEFI case Notification Form available on http://www.ipc.gov.in).

Who can Report?

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

Where to Report?

- Duly filled inSuspected 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.

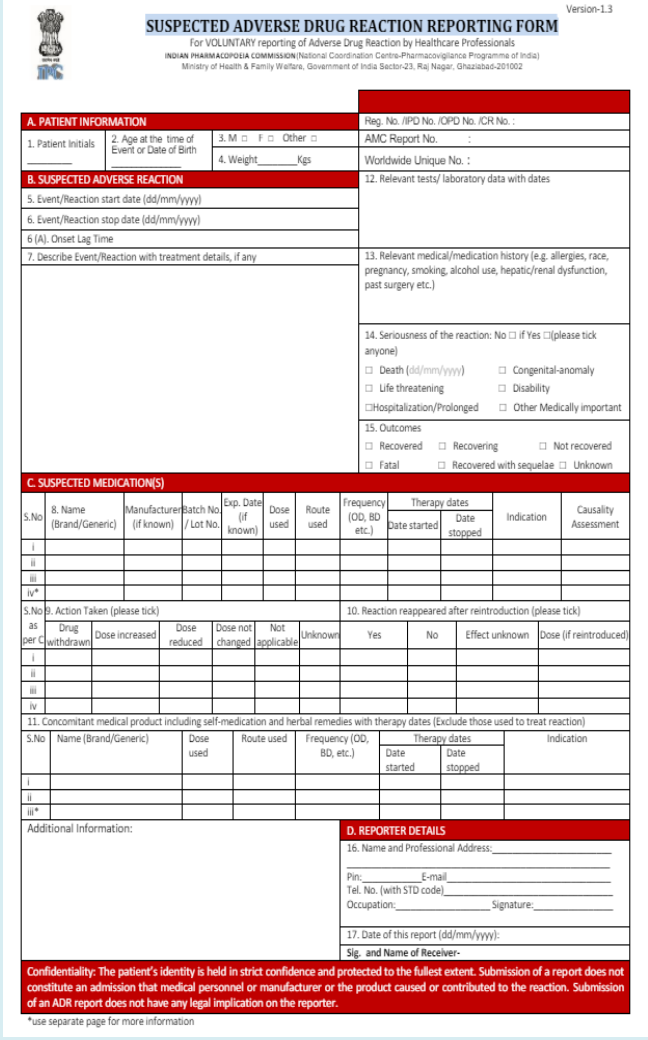
What Happens to the Submitted Information?

- 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 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 to review the data and suggest any interventions that may be required.

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) and reporter information.

ADR Reporting Forms



Version-1.3

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reaction 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

A. PATIENT INFORMATION

1. Patient Initials _____ | 2. Age at the time of Event or Date of Birth _____ | 3. M ☐ F ☐ Other ☐ | 4. Weight_____Kgs

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

AMC Report No. :

Worldwide Unique No. :

B. SUSPECTED ADVERSE REACTION

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

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

6 (A). Onset Lag Time

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

12. Relevant tests/ laboratory data with dates

13. Relevant medical/medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction, past surgery etc.)

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

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

☐ Life threatening ☐ Disability

☐Hospitalization/Prolonged ☐ Other Medically important

15. Outcomes

☐ 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.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
i											
ii											
iii											
iv*											

S.No as per C	9. Action Taken (please tick): Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Reaction reappeared after reintroduction (please tick): Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										

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 used	Route used	Frequency (OD, BD, etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication
i							
ii							
iii*							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address:_____

Pin:_____E-mail_____

Tel. No. (with STD code)_____

Occupation:_____Signature:_____

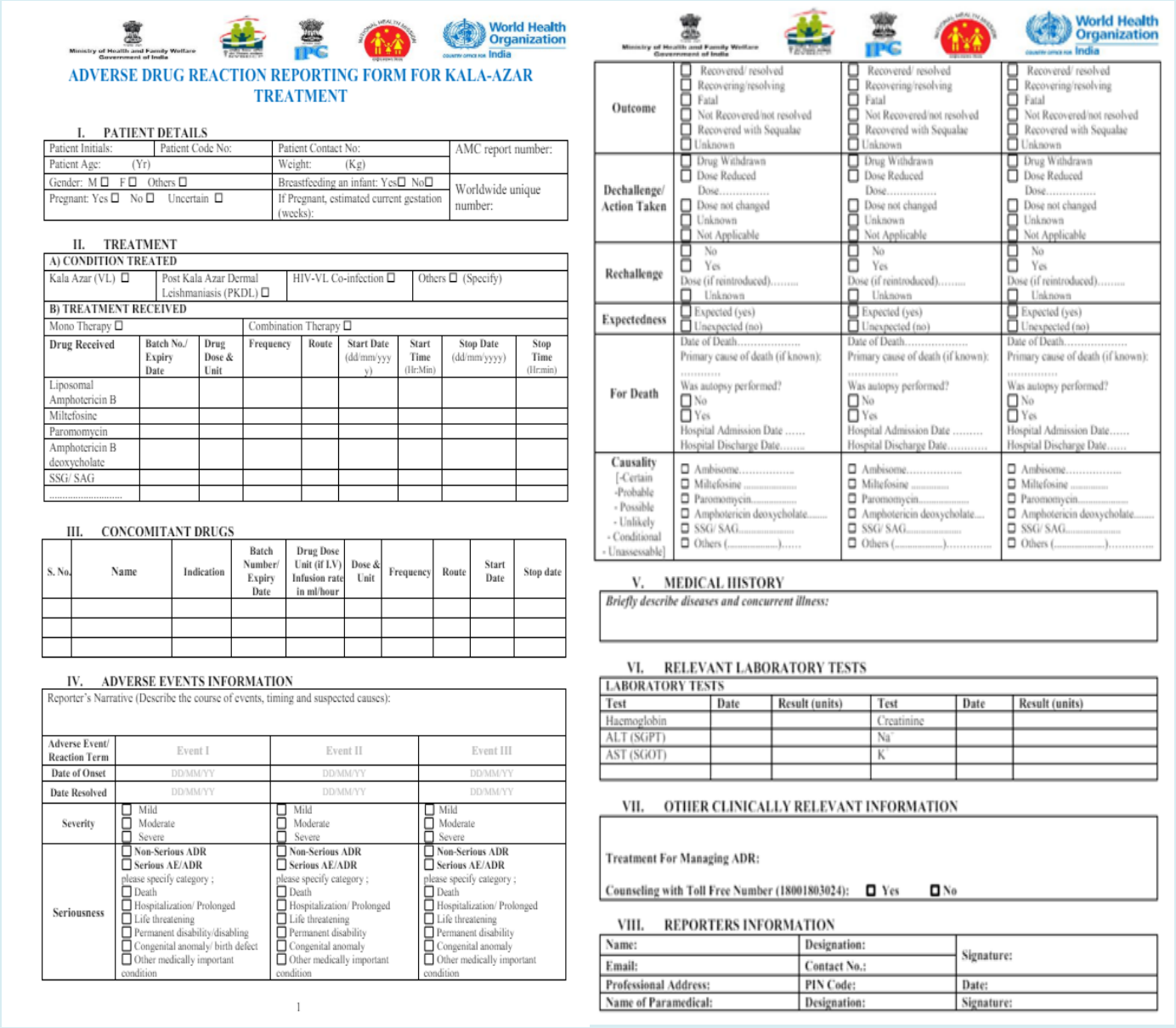
17. Date of this report (dd/mm/yyyy):

Sig. and Name of Receiver-

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

Figure 2: Suspected ADRs reporting form (for HCPs-Health Care Professionals).



ADVERSE DRUG REACTION REPORTING FORM FOR KALA-AZAR TREATMENT

I. PATIENT DETAILS

Patient Initials:	Patient Code No:	Patient Contact No:	AMC report number:
Patient Age: (Yr)		Weight: (Kg)	
Gender: M ☐ F ☐ Others ☐		Breastfeeding an infant: Yes☐ No☐	Worldwide unique number:
Pregnant: Yes ☐ No ☐ Uncertain ☐		If Pregnant, estimated current gestation (weeks):	

II. TREATMENT

A) CONDITION TREATED

Kala Azar (VL) ☐	Post Kala Azar Dermal Leishmaniasis (PKDL) ☐	HIV-VL Co-infection ☐	Others ☐ (Specify)

B) TREATMENT RECEIVED

Mono Therapy ☐ Combination Therapy ☐

Drug Received	Batch No./ Expiry Date	Drug Dose & Unit	Frequency	Route	Start Date (dd/mm/yyyy)	Start Time (Hr:Min)	Stop Date (dd/mm/yyyy)	Stop Time (Hr:min)
Liposomal Amphotericin B								
Miltefosine								
Paromomycin								
Amphotericin B deoxycholate								
SSG/ SAG								
.....								

III. CONCOMITANT DRUGS

S. No.	Name	Indication	Batch Number/ Expiry Date	Drug Dose Unit (if I.V) Infusion rate in ml/hour	Dose & Unit	Frequency	Route	Start Date	Stop date

IV. ADVERSE EVENTS INFORMATION

Reporter's Narrative (Describe the course of events, timing and suspected causes):

Adverse Event/ Reaction Term	Event I	Event II	Event III
Date of Onset	DD/MM/YY	DD/MM/YY	DD/MM/YY
Date Resolved	DD/MM/YY	DD/MM/YY	DD/MM/YY
Severity	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Seriousness	☐ Non-Serious ADR ☐ Serious AE/ADR please specify category ; ☐ Death ☐ Hospitalization/ Prolonged ☐ Life threatening ☐ Permanent disability/disabling ☐ Congenital anomaly/ birth defect ☐ Other medically important condition	☐ Non-Serious ADR ☐ Serious AE/ADR please specify category ; ☐ Death ☐ Hospitalization/ Prolonged ☐ Life threatening ☐ Permanent disability ☐ Congenital anomaly ☐ Other medically important condition	☐ Non-Serious ADR ☐ Serious AE/ADR please specify category ; ☐ Death ☐ Hospitalization/ Prolonged ☐ Life threatening ☐ Permanent disability ☐ Congenital anomaly ☐ Other medically important condition

1

Outcome	☐ Recovered/ resolved ☐ Recovering/resolving ☐ Fatal ☐ Not Recovered/not resolved ☐ Recovered with Sequalae ☐ Unknown	☐ Recovered/ resolved ☐ Recovering/resolving ☐ Fatal ☐ Not Recovered/not resolved ☐ Recovered with Sequalae ☐ Unknown	☐ Recovered/ resolved ☐ Recovering/resolving ☐ Fatal ☐ Not Recovered/not resolved ☐ Recovered with Sequalae ☐ Unknown
Dechallenge/ Action Taken	☐ Drug Withdrawn ☐ Dose Reduced Dose..... ☐ Dose not changed ☐ Unknown ☐ Not Applicable	☐ Drug Withdrawn ☐ Dose Reduced Dose..... ☐ Dose not changed ☐ Unknown ☐ Not Applicable	☐ Drug Withdrawn ☐ Dose Reduced Dose..... ☐ Dose not changed ☐ Unknown ☐ Not Applicable
Rechallenge	☐ No ☐ Yes Dose (if reintroduced)..... ☐ Unknown	☐ No ☐ Yes Dose (if reintroduced)..... ☐ Unknown	☐ No ☐ Yes Dose (if reintroduced)..... ☐ Unknown
Expectedness	☐ Expected (yes) ☐ Unexpected (no)	☐ Expected (yes) ☐ Unexpected (no)	☐ Expected (yes) ☐ Unexpected (no)
For Death	Date of Death..... Primary cause of death (if known): ..... Was autopsy performed? ☐ No ☐ Yes Hospital Admission Date ..... Hospital Discharge Date.....	Date of Death..... Primary cause of death (if known): ..... Was autopsy performed? ☐ No ☐ Yes Hospital Admission Date ..... Hospital Discharge Date.....	Date of Death..... Primary cause of death (if known): ..... Was autopsy performed? ☐ No ☐ Yes Hospital Admission Date..... Hospital Discharge Date.....
Causality [-Certain -Probable - Possible - Unlikely - Conditional - Unassessable]	☐ Ambisome..... ☐ Miltefosine ..... ☐ Paromomycin..... ☐ Amphotericin deoxycholate..... ☐ SSG/ SAG..... ☐ Others (.....).....	☐ Ambisome..... ☐ Miltefosine ..... ☐ Paromomycin..... ☐ Amphotericin deoxycholate..... ☐ SSG/ SAG..... ☐ Others (.....).....	☐ Ambisome..... ☐ Miltefosine ..... ☐ Paromomycin..... ☐ Amphotericin deoxycholate..... ☐ SSG/ SAG..... ☐ Others (.....).....

V. MEDICAL HISTORY

Briefly describe diseases and concurrent illness:

VI. RELEVANT LABORATORY TESTS

LABORATORY TESTS					
Test	Date	Result (units)	Test	Date	Result (units)
Haemoglobin			Creatinine		
ALT (SGPT)			Na^+		
AST (SGOT)			K^+		

VII. OTHER CLINICALLY RELEVANT INFORMATION

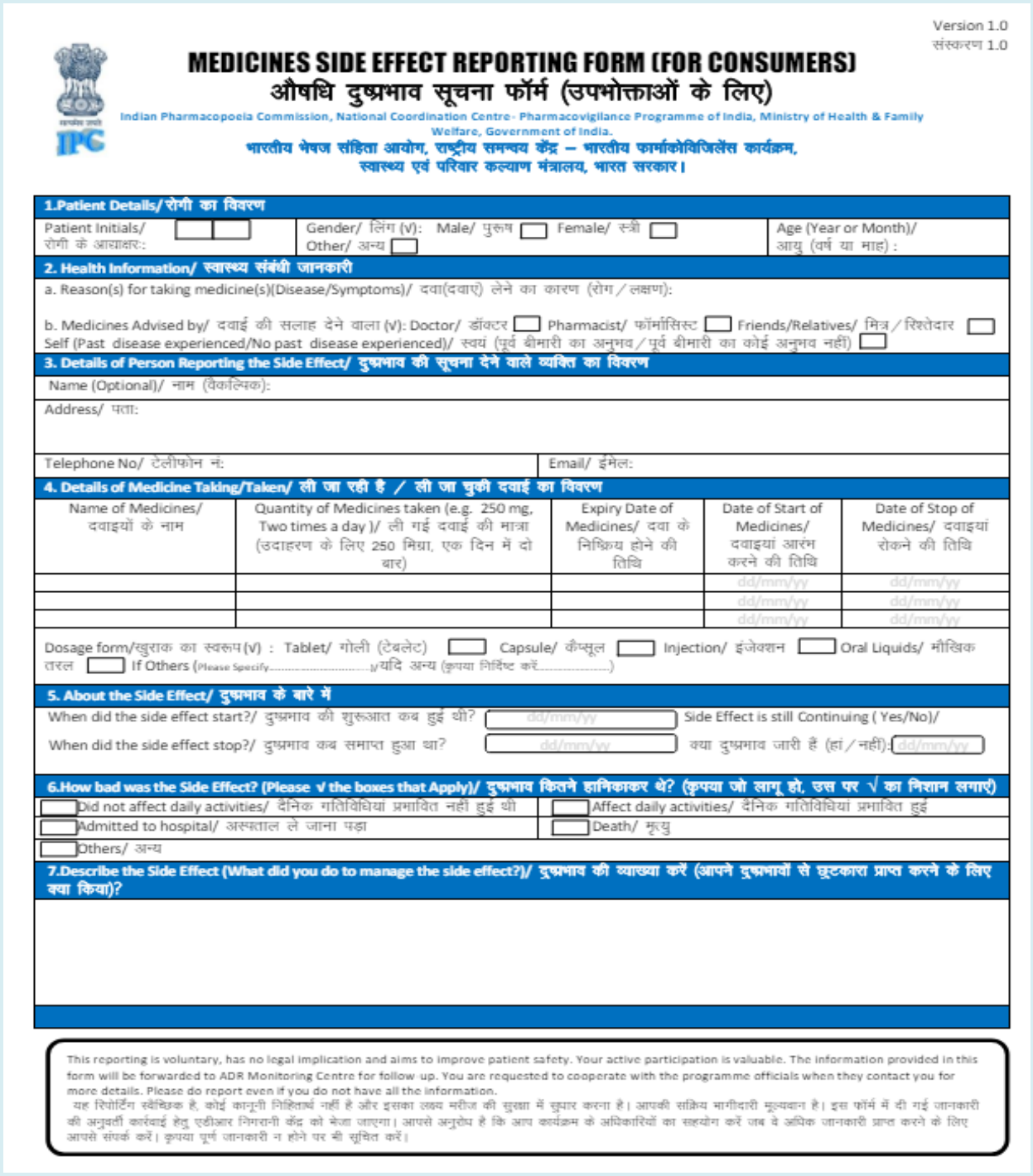
Treatment For Managing ADR:

Counseling with Toll Free Number (18001803024): ☐ Yes ☐ No

VIII. REPORTERS INFORMATION

Name:	Designation:	Signature:
Email:	Contact No.:	
Professional Address:	PIN Code:	Date:
Name of Paramedical:	Designation:	Signature:

Figure 3: ADR Reporting Form for Kala Azar.



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/ पुरुष ☐ 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	dd/mm/yy
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	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): dd/mm/yy

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।

Figure 4: (Reporting form in Hindi) Medicines side effect reporting form also available in 7 Vernacular Languages for patients (Hindi, Assamese, Bengali, Gujrati, Kannada, Malayalam, Marathi, Oriya, Tamil and Telugu) ref. PvPI website.

Conclusion

It can be concluded that Pharmacovigilance is an important tool in ensuring patient safety as by reporting the ADRs, the patient morbidity and mortality can be reduced. This also enhances the knowledge of prescribers about drug-related events, and thus appropriate modification in the treatment can be done to benefit the patients.

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