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Pharmacovigilance Programme of India: A Review

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Pharmacovigilance Programme of India: A Review

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I. Introduction

According to World Health Organisation (WHO), Pharmacovigilance (PV) as the pharmacological science and activities relating to the monitoring, detection, assessment, understanding, and prevention of adverse drug reactions (ADRs), or any long-term and short-term medicine-related problems (Figure 1&2). Variety of ADRs associated with medication prompted the event of the science of PV [1-4]. This prompted WHO for a systematic study of ADR of medicine, that is that the starting of PV. Thenceforth variety of ADRs was detected, a number of that square measure shows in (Table 1). ADR is taken into account to be the 6th leading reason behind death. India, with a current population of 1.27 billion, is that the 4th largest producers of prescription drugs within the world with quite 6000 licensed makers and over 60000 branded formulations within the market. In the United States of America, ADRs contribute 3-7% of hospital admissions. In England, 1% chronicles of the entire hospital admissions were due to ADRs throughout the year 1999-2008. ADRs square measure common in the Australian healthcare system additionally and that they contribute to a 1% of hospital admissions [5,6]. The percentage of hospital admissions due to ADRs in bound countries is 100% or additional. Drug attributed deaths square measure calculable to be 0.19% altogether medical inpatients. About 0.40% of ADRs known were directly joined to high costs. ADRs not solely increase the mortality and morbidity; however, additionally multiply the health care value [7]. The PV effort within India is coordinated bythe Indian Pharmacopoeia Commission (IPC) and conducted by the Central Drugs Standard Control Organization (CDSCO). The most responsibility of the IPC is to keep up and develop the PV database consisting of all suspected ADR to medicines observed. IPC is functioning as a National Coordination Centre (NCC) for the Pharmacovigilance Programme of India (PvPI). NCC is working underneath the direction of a committee that recommends procedures and guidelines for regulatory interventions [8].The main responsibility of NCC is to watch all the ADR of medicines being observed within the Indian population and to develop and maintain its PV information. The aim of the commission that acts just like the NCC for PvPI is for the safety of the patient, and the population with relevancy use of the drug. The Commission has become operational from 1st January 2009 an associate autonomous body, absolutely supported by the central government with specific fund allocations under the administrative control of the Ministry of Health and Family Welfare [9]. The Secretary, Ministry of Health and Family Welfare, is the Chairperson and therefore the Chairman-Scientific Body is that the Co-Chairman of the Commission. The Secretary-cum Scientific Director is that the Chief Scientific and Executive officer of the Commission. The CDSCO, Directorate General of Health Services underneath the aegis of Ministry of Health & Family Welfare, Government of India unitedly with IPC, Ghaziabad is initiating a nation-wide PV program for shielding the health of the patients by reassuring drug safety. The program shall be coordinated by the IPC, as an NCC. The center can operate underneath the superintendence of a steering committee. The PvPI was initiated by the government of India on 14th July 2010 with the All India Institute of Medical Sciences (AIIMS), New Delhi as the NCC for monitoring ADRs in the country for safe-guarding public health. Within the year 2010, 22 ADR monitoring center, as well as AIIMS, came upon underneath this program [10-13]. To confirm the implementation of this program in an exceedingly method, the NCC was shifted from the AIIMS to the IPC, Ghaziabad, Uttar Pradesh on 15th April 2011 (Figure 3).

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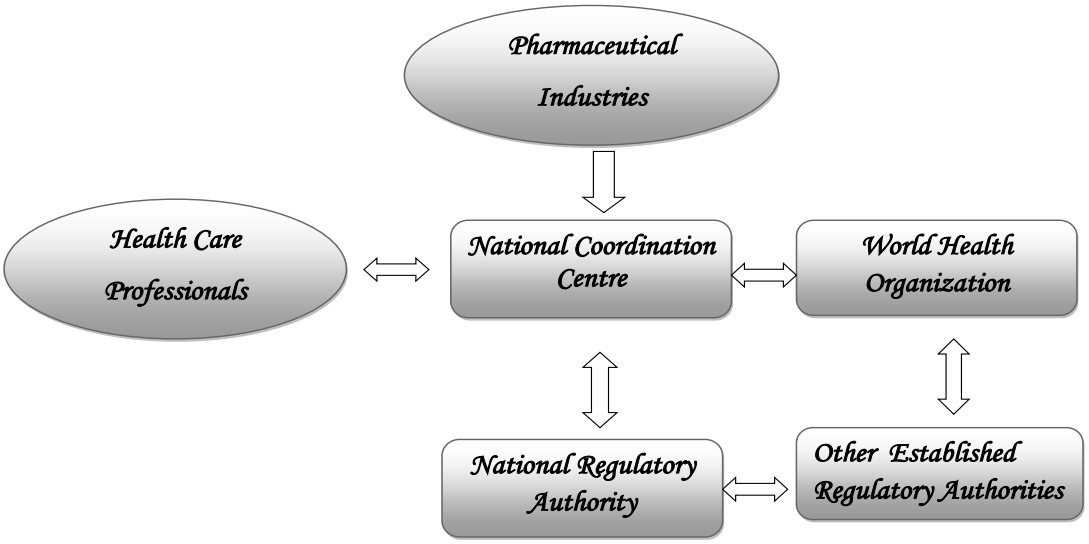

Figure 1: Diagrammatic representation of the Pharmacovigilance

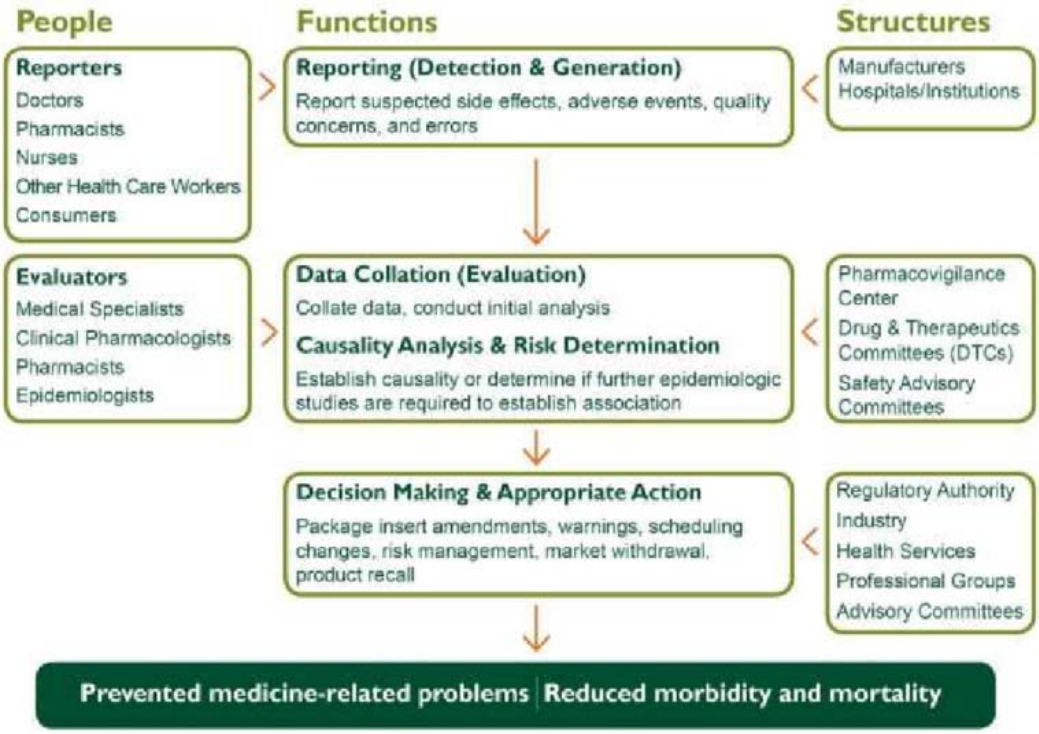

Figure 2: Pharmacovigilance framework

Table 1: Nine examples of serious & unexpected ADR cause to drugs [14]

Sr. No.	Drug	Year	Serious & unexpected adverse event
1	Chloroform (Anaesthetic)	1848	Episode of ventricular fibrillation & death
2	Sulphanilamide (Elixir)	1937	Death
3	Thalidomide	1961	Amelia, phocomelia &dysmelia
4	Clioquinol	1970	Subacute nephropathy
5	Practolol	1975	Sclerosing peritonitis
6	Benoxaprofen	1982	Nephrotoxicity&cholestatic jaundice
7	Terfenadine	1997	Torsade de pointes
8	Rofecoxib	2004	Cardiovascular effects
9	Veralipride	2007	Anxiety, depression & movement disorders

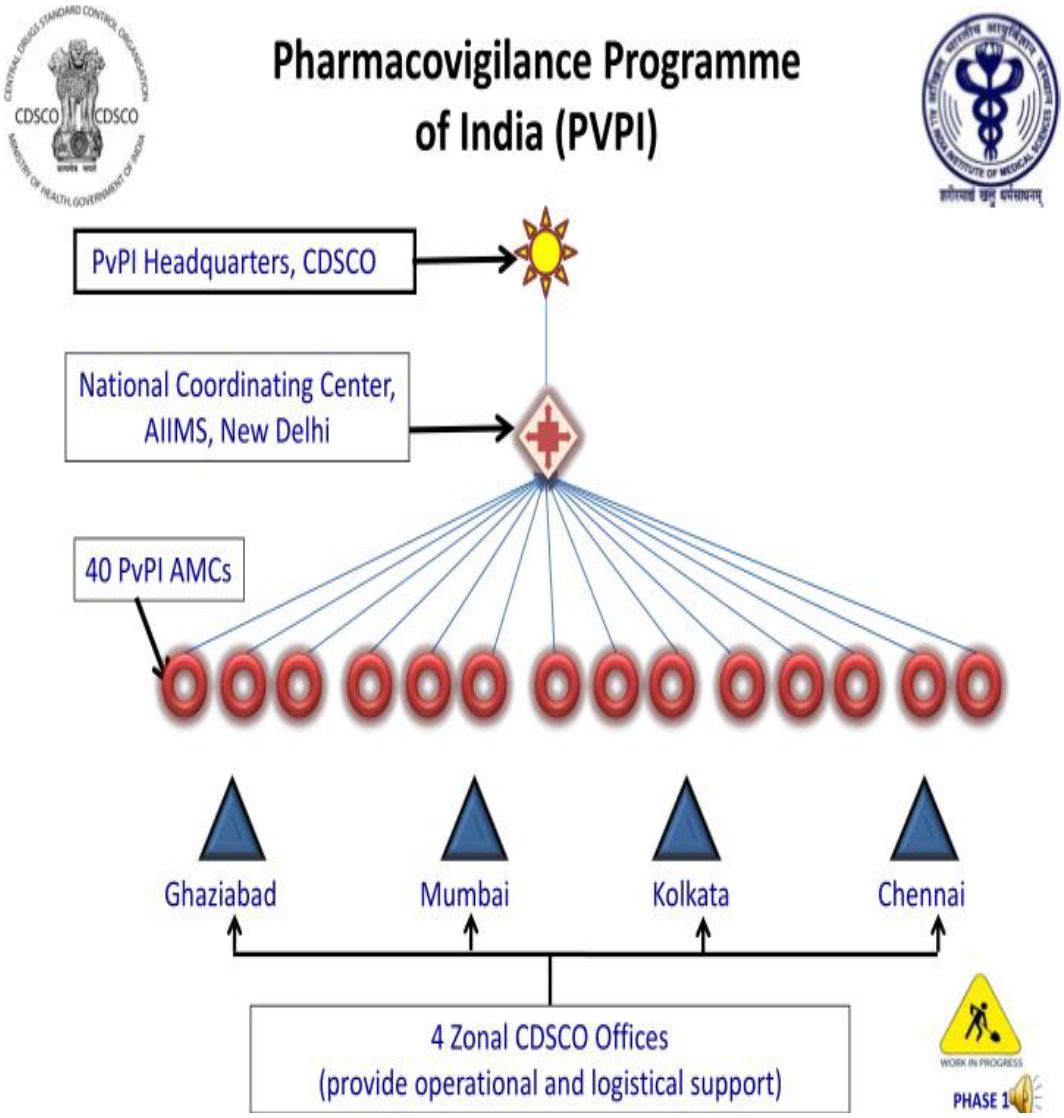

Figure 3: Pharmacovigilance Programme of India

II. History of the Pharmacovigilance Programme in India

The concept of PV is not new, because the time of Charak Samhita in 700 BC had cautioned that properly understood however improperly administered drug is Vagueness poison and Vagbhatta- a physician represented adverse events, reason, delayed ADRs to Ayurvedic Drugs' around 500 AD. After that, many reports of ADRs from India area unit found within the history of modern medicine, but there was no systematic effort of ADR monitoring since the primary try was created in 1989 [15,16].

III. Scope of the Pharmacovigilance Programme of India

Before registration and selling of drugs within the country, its safety and efficaciousness expertise area unit primarily based totally on the employment of the drugs in clinical trials. These trials in the notice common ADR. Some vital reactions, like those, that take a protracted time to develop, or those, that occur seldom, might not be detected in clinical trials. Additionally, the controlled conditions beneath that medicines area unit utilized in clinical trials don't essentially replicate the method they will be utilized in observe. For a drug to be thought-about safe, its expected advantages ought to be more than any associated risks of harmful reactions. So, to achieve a comprehensive safety profile of drugs, a continuous post-marketing monitoring system, i.e. PV is crucial. To monitor the security of drugs, information from several sources is employed for PV [17]. These embrace spontaneous ADRs coverage mechanism; medical literature published worldwide; action taken by regulative authorities in alternative countries. Since there exist substantial social and economic consequences of ADRs and therefore the positive benefit/cost magnitude relation of implementing applicable risk management -there may be a have to be

compelled to interact health care professionals and therefore the public at massive, during a well-structured program to make synergies for watching ADRs within the country. The PvPI aims is to collate data, method and analyze it and use the inferences to advocate regulative interventions, besides human action risks to health care professionals and therefore, the public [18].

IV. Management of the Pharmacovigilance Programme of India

This is headed by the Secretary cum scientific Director: Dr. Gyanendra Nath Singh, who is working with the help of Advisor and National Scientific Coordinator supported by the several committees like- Steering Committee, Working Group, Quality Review Panel, Core Training Panel, etc. involving experts from all over the country.Current Status of NCC-PvPI Presently the PvPI program has more than 200 Adverse Drug Monitoring Centres (AMCs) involving all states and Union Territories through-out India[19].

V. Reporting of Adverse Drug Reactions

Suspected ADR reporting forms for health care professionals (Figure 4) and consumers (Figure 5) a unit available on the website of IPC to report ADR. To get rid of barrier in ADR reporting, the consumer reporting form is available in 10 vernacular languages (Hindi, Tamil, Telugu, Kannada, Bengali, Gujarati, Assamese, Marathi, Oriya, and Malayalam). ADRs will be conjointly reportable via PvPI helpline number (18001803024) on week days from 9:00 am to 5:30 pm. The mobile Android application for ADR reporting has conjointly been created available to the general public [20].

Version-1.2

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions 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

FOR AMC/NCC USE ONLY

AMC Report No. :

Report Type ☐ Initial ☐ Follow up

Worldwide Unique No. :

A. PATIENT INFORMATION

1. Patient Initials _____

2. Age at time of Event or Date of Birth _____

3. M ☐ F ☐ Other ☐

4. Weight_____Kgs

12. Relevant tests/ laboratory data with dates

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)

6. Date of recovery (dd/mm/yyyy)

7. Describe reaction or problem

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

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

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Required intervention to Prevent permanent impairment/damage
☐ Hospitalization/Prolonged
☐ Disability ☐ Other (specify)

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		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
iv											

S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	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		Indication
					Date started	Date stopped	
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):

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. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

Figure 4: Suspected ADR reporting form for Healthcare professionals

Version 1.0

MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

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

1.Patient Details

Patient Initials: ☐☐	Gender (√): Male ☐ Female ☐ Other ☐	Age (Year or Month) :

2. Health Information

a. Reason(s) for taking medicine(s)(Disease/Symptoms):

b. Medicines Advised by (√): Doctor ☐ Pharmacist ☐ Friends/Relatives ☐ Self (Past disease experienced/No past disease experienced) ☐

3. Details of Person Reporting the Side Effect

Name (Optional):

Address:

Telephone No:	Email:

4. Details of Medicine Taking/Taken

Name of Medicines	Quantity of Medicines taken (e.g. 250 mg, Two times a day)	Expiry Date of Medicines	Date of Start of Medicines	Date of Stop of Medicines
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy

Dosage form (√) : Tablet ☐ Capsule ☐ Injection ☐ Oral Liquids ☐ If Others (Please Specify.....)

5. About the Side Effect

When did the side effect start? dd/mm/yy Side Effect is still Continuing (Yes/No): ☐

When did the side effect stop? dd/mm/yy

6.How bad was the Side Effect? (Please √ the boxes that Apply)

☐ Did not affect daily activities	☐ Affect daily activities
☐ Admitted to hospital	☐ Death
☐ Others	

7.Describe the Side Effect (What did you do to manage the side effect?)

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.

Figure 5: ADRs reporting form for consumers

VI. World Health Organization-Uppsala Monitoring Centre & India

The WHO Program for International Drug Monitoring provides a forum for WHO member states that has India to collaborate within the monitoring of drug safety. At intervals the Program, individual case reports of suspected ADRs are collected and keep in an exceedingly common information, presently containing over 3.7 million case reports. Since 1978, the Uppsala Monitoring Centre (UMC) in Sweden has dispensed the Program. The UMC is accountable for the gathering of knowledge concerning ADRs from around the world, particularly from countries that are members of the WHO together with India. Member countries send their reports to the UMC wherever they are processed, evaluated, and entered into the WHO International information. When there are several reports of adverse reactions to a particular drug, this process may lead to the detection of a signal- an alert about a possible hazard communicated to member countries. This happens solely once elaborated analysis and expert review. These ADR reports are assessed regionally and will cause the action at intervals in the country. Through membership of the WHO International Drug Monitoring Program, a rustic will recognize if similar reports are being created elsewhere. India is a country with a large patient pool and healthcare professionals, yet ADR reporting is in its infancy (Table 2) [21-23].

Table 2: Responsibilities & functions of the stakeholders in the program

Centre	Role
ADR monitoring centre	Collection of ADR reports, perform follow up with the complainant to check completeness as per standard operating procedure (SOPs), data entry into Vigiflow, reporting to PvPI-NCC through Vigiflow with the source data (original) attached with each ADR caseTraining/ sensitization/ feedback to physicians through newsletters circulated by the PvPI-NCC.
PvPI AMC other than medical colleges [Corporate hospitals, autonomous institutes, Pharmaceutical industry and public health Programmers]	Collection of ADR reports, perform follow up with the complainant to check, completeness as per SOPs, report the data to CDSCO- Headquarter (HQ).
Pharmacovigilance programme of India, National coordinating centre, Indian pharmacopoeia commission(Ghaziabad)	Preparation of SOPs, guidance documents & training manuals, data collation, Cross-check completeness, Causality Assessment etc as per SOPs, conduct Training workshops of all enrolled centres, publication of medicines safety newsletter, reporting to CDSCO-HQ, Analysis of the Performance measurement system, Periodic safety update report, Adverse event following immunization data received from CDSCO-HQ.
Zonal/Sub-zonal CDSCO Offices	Provide procurement, financial and administrative support to ADR monitoring centres, report to CDSCO-HQ.
Central drugs standard control organization-Headquarter (New Delhi)	Take appropriate regulatory decision & actions on the basis of recommendations of PvPI NCC at IPC, propagation of medicine safety related decisions to stakeholders, collaboration with WHO-UMC, provide for budgetary provisions &administrative support to run PvPI.

VII. Aim of the Pharmacovigilance Programme of India

Pharmacovigilance has specific aims as follows:

1. Improve patient care and safety in about the use of medicines and all medical and paramedical interventions.
2. Improve public health and safety in about the use of medicines.
3. Contribute to the assessment of benefit, harm, effectiveness, and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use.
4. Promote understanding, education, and clinical training in PV and its effective communication to the public[24].

VIII. Objectives of the Pharmaco-vigilance Programme of India

1. To create a nation-wide system for patient safety reporting.
2. To identify and analyze the new signal ADR from the reported cases.
3. To analyze the benefit-risk ratio of marketed medications.

4. To generate the evidence-based information on the safety of medicines.
5. To support regulatory agencies in the decision-making process on the use of medications.
6. To communicate the safety information on the use of medicines to various stakeholders to minimize the risk.
7. To emerge as a national center of excellence for PV activities.
8. To collaborate with other national centers for the exchange of information and data management.
9. To provide training and consultancy support to other national PV centers located across the globe[25,26].

IX. Conclusion

The adverse drug reaction observation and reporting programs or pharmacovigilance program of India is aiming to identify the risks related to the utilization of the drugs. The current analysis has disclosed opportunities or interventions particularly or avertible adverse events, which arecan to facilitate in promoting safer drug use, data to the health care professionals. Improve the standard of patient care and educate to extend awareness. Therefore, currently, this point has returned to aware the general public too for the reporting the adverse drug reaction to the nearest hospital or ADR monitoring center or the health care professionals. They will directly report the adverse drug reaction through the government. Toll-free number 18001803024, adverse drug reaction application, email, and alternative methodology like social media.

Acknowledgement

None

Conflict of Interest

The Authors declare that there is no conflict of interest.

Abbreviations: WHO: World health organization, CDSCO: Central drugs standard control organization, PvPI: Pharmacovigilance programme of India, NCC: National coordinating centre, AIIMS: All India institute of medical sciences, IPC: Indian pharmacopoeia commission, PV: Pharmacovigilance, ADR: Adverse drug reaction, AMC: ADR monitoring centre, UMC: Uppsala monitoring centre.

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