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Pharmacovigilance Program of India (PvPI) 2010 - A Review Article

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ABSTRACT:
Drug safety, or pharmacovigilance, according to WHO is the term for the pharmacological science that deals with the gathering, identification, evaluation, tracking, and avoidance of unfavorable consequences associated with pharmaceutical goods. In order to protect the health of the Indian populace, the Pharmacovigilance Program of India (PvPI) was launched in 2010 and its purpose is to make sure that the advantages of using medication outweigh any potential risks. A clinical trial with strict pharmacovigilance monitoring in a population of different race and ethnicity is necessary, even if the medicine has previously received approval in another nation. This review paper offers a succinct synopsis of the development, operation, difficulties of the existing state of affairs, and prospects for pharmacovigilance in India.

KEYWORDS: Pharmacovigilance, Pharmacovigilance program of India, Adverse Drug Reaction, Public health.

Ⅰ. INTRODUCTION:

One of the biggest drug-using populations in the world is found in India. It is estimated that between 60,000 and 80,000 medication brands are illogically given and misused in India. Both regulatory shortcomings and a lack of pharmaceutical safety practices may be to blame for this. The occurrence of adverse drug reactions (ADRs) is largely caused by misuse and improper prescription. The last few years have seen an unparalleled expansion of the clinical research sector globally. Drugs and other medical items are flooding the market as a result of advancements in a wide range of scientific and technological, chemistry, and physiology sectors, as well as improved production methods and logistics. (1) The advancements in the world have not failed to reflect in India. India has become a highly sought-after destination for pharmaceutical businesses worldwide, owing to its swift modernization and adoption of the open market policy. With a present valuation of over INR 90,000 crore, the pharmaceutical business in India is predicted to develop at a rate of 12-14% per year, significantly higher than the current national average of 7-8%. (2) PV's main objectives are to quantify previously reported adverse drug reactions (ADRs), find unreported ADRs, assess how well medications work in practical settings, and lower the death and morbidity rates linked to ADRs (3). The Government of India launched the Pharmacovigilance program to solve these problems. Pharmacovigilance programs in India are designed to inform the public and healthcare professionals about potential dangers, but they also gather, compile, and evaluate data in order to draw conclusions and suggest regulatory actions. (4)

Ⅱ. WHY PHARMACOVIGILANCE IS REQUIRED?

Drugs are designed to prolong life, not end it. In many cases, disease-related death cannot be prevented. However, it's unacceptable when a medication causes death. ADRs rank in the top 10 causes of death in the US, and they are thought to be responsible for 5700 fatalities annually in the UK. Hospitalizations for drug-related incidents account for about 10% of hospitalizations in certain nations (5)(6).

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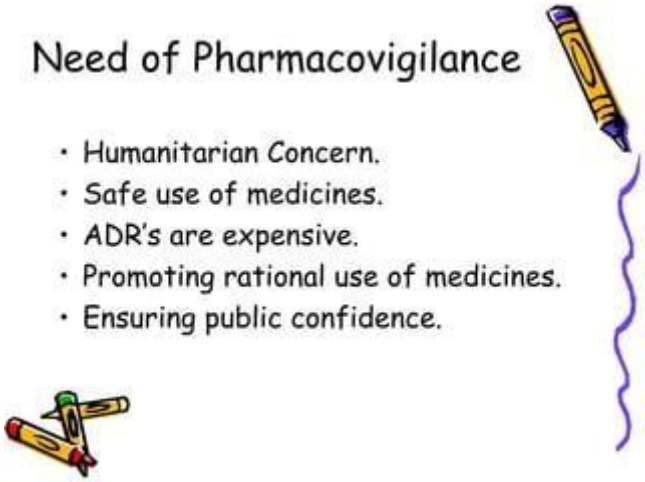
Figure 1. Need of Pharmacovigilance



Ⅲ. TERMS RELATED TO PHARMACOVIGILANCE AND THEIR DEFINITIONS: -

a) Adverse Event: An adverse event is any unfavorable medical incident that might arise when taking medication, even if it has nothing to do with the drug's usage. (7)

b) Adverse drug reaction: An adverse drug reaction (ADR) is any unpleasant, unexpected, and undesirable side effect of a medication that happens at a dosage that is administered to humans for therapeutic purposes, prophylaxis, diagnostic, or alteration of physiological function. (8)

c) Post Market surveillance: After a pharmaceutical drug or device is brought onto the market, post-marketing surveillance, or PMS, is the process of keeping an eye on its safety. (9)

d) Clinical trials: They are a type of research study used in medicine and drug development to produce safety and efficacy data, or more precisely, data regarding adverse drug reactions and side (12) The programme was also intended to be implemented in four phases: beginning (2010–2011); expansion and consolidation (2011–2012); expansion and maintenance (2012–2013); expansion and optimization (2013–2014); and excellence (2014– 2015).

Furthermore, the program has three expert panels (quality review, signal review, and core training panels) that provide technical guidance to the regulatory, as well as a steering committee and working group that provide technical input to the regulatory:

effects of other treatments, for various health interventions (such as medications, diagnostics, devices, and therapy protocols. (10)

e) Safety signals: A safety signal is an excessive number of adverse events compared to what is expected to be connected to the use of a product. These signals can originate from pre-clinical data, post-marketing data, and events connected to other products in the same pharmacological class, among other sources. (11)

Ⅳ. PHARMACOVIGILANCE PROGRAM IN INDIA [PVPI]

As the National Coordination Center for the Pharmacovigilance, the All India Institute of Medical Sciences (AIIMS), New Delhi was chosen. In order to maintain public health, the Indian government launched the Programme of India (PvPI) on July 14, 2010. In 2010, 22 ADR monitoring centers were constructed by this program, including AIIMS in New Delhi.

(1) The Quality Review Panel assesses the correctness and completeness of ICSRs, makes recommendations to the PvPI working group based on data analysis, and develops forms and instructions for subsequent actions.

(2) The Signal Review Panel provides biostatistical methodology for analysis and actionable indicators, discovers and evaluates signals from the ICSRs submitted to NCC, and recommends to CDSCO the required regulatory measures.

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(3) The Core Training Panel collaborates with international organizations on the implementation of pharmacovigilance training programs, as well as identifies trainers, training needs, and training materials. (13)

MISSION: To protect the Indian population's health by ensuring that the benefits of using medicine outweigh the risks connected with its usage. (14)

PERSPECTIVE: To promote patient safety and welfare in the Indian population by monitoring drug safety and, as a result, lowering the risk associated with medication usage. (14)

Table 1. The Development of India's Pharmacovigilance Programme.

Year	Event
1747 :	First reported clinical trials by James Lind, proving the effectiveness of lemon juice in preventing scurvy.
1937 :	Death of 107 children due to sulfanilamide toxicity.
1950 :	Apalstic anemia reported due to chloramphenicol
1961 :	Global disaster due to thalidomide toxicity
1963 :	16th World Health Assembly recognize to rapid action on ADR's
1968 :	WHO pilot research project for international drug monitoring
1996 :	Clinical trials of global standards started in India
1997 :	India joined WHO Adverse Drug Reaction Monitoring Program
1998 :	Pharmacovigilance initiated in India
2002 :	67th National Pharmacovigilance Center established in India.
2004-05 :	National Pharmacovigilance Program launched in India
2005 :	Conduct of structured clinical trials in India
2009-10 :	PVPI initiated

V. ORGANISATION OF PVPI:

To extend PvPI's reach to rural areas during business hours, a toll-free helpline (1800 180 3024) day. The ADR reporter's information is provided to the local monitoring centers to allow for any follow-up. In May 2015, PvPI and NSCB Medical College, Jabalpur collaborated to produce an Android mobile application for reporting ADRs. (15)

An enhanced version of the application featuring source document and image attachment features. with SMS feedback capability has been implemented. A live person answers the helpline; missed calls are returned the next NCC developed XML creation and auto-filling of report details in October 2017. PvPI is also on Twitter (@IPCNCCPvPI), Facebook (Ncc PvPI Ipc), WhatsApp (7042343309), and LinkedIn (NCC PvPI). (16)

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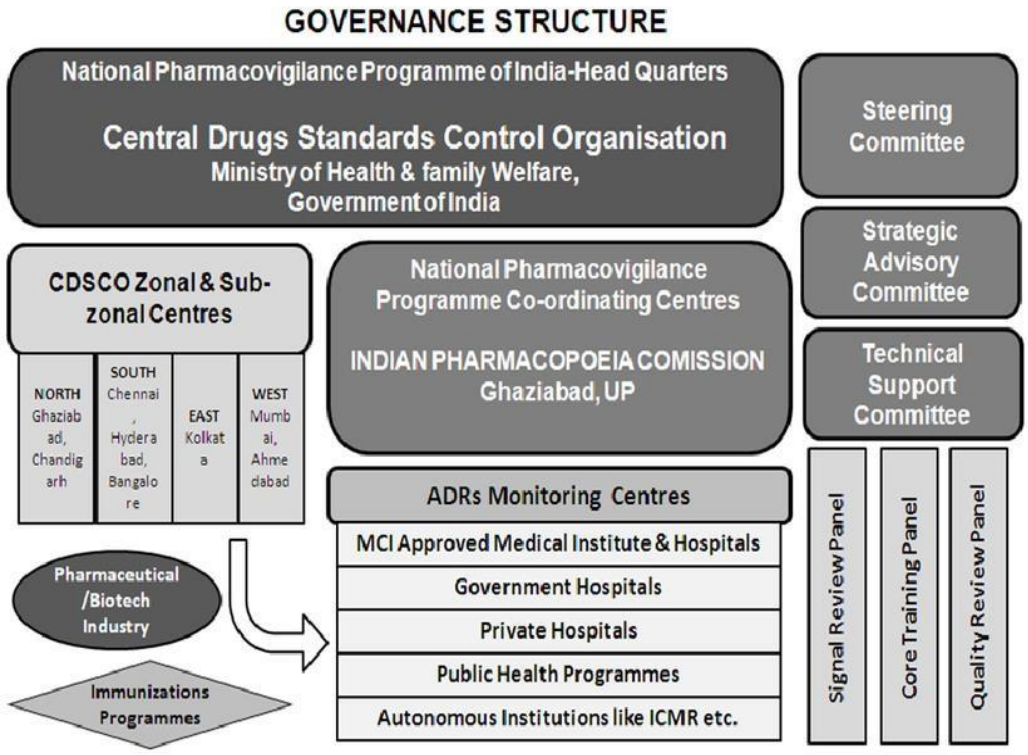
Figure no. 2 Governance structure of pharmacovigilance program of India (16)



VI. CURRENT SITUATION: Various organizations and government agencies throughout the world have datasets large enough to conduct data mining activities on adverse occurrences related to pharmaceutical products. The United States Food and drugs Administration (USFDA) database has over 100,000 adverse medication reactions, whereas the WHO safety database is substantially larger. The increased knowledge of Pharmacovigilance processes among Indian health care practitioners has resulted in a rise in the volume of data in Indian databases. Thus, with the addition of more data and the sharing and comparison with international databases such as the USFDA, WHO, and Uppsala Monitoring Center (UMC), CDSCO will be able to make decisions based on its own data obtained from the Indian population, thereby making a significant contribution in the field of pharmacovigilance worldwide. (17)

The various medical colleges would serve as peripheral ADR monitoring centers, collecting and maintaining ADR reports, carrying out follow-ups as needed in accordance with standard operating procedures, entering and maintaining data in the prescribed database software (Vigiflow), and reporting to the National Coordinating Center. (17)

Reporting of ADR:

Suspected ADR reporting forms for health care providers and consumers are accessible on the IPC website to report ADR. The consumer reporting form is accessible in ten vernacular languages (Hindi, Tamil, Telugu, Kannada, Bengali, Gujarati, Assamese, Marathi, Oriya, and Malayalam). ADRs will also be reportable via the PvPI helpline number (18001803024) from 9:00 a.m. to 5:30 p.m. on weekdays. In addition, a mobile Android application for ADR reporting has been developed and made available to the general public.

What to be reported?

PvPI promotes the reporting of all suspected ADRs, whether they are known or unknown, significant or nonserious, frequent or rare, and regardless of an established causal association between the drug and the reaction. ADRs can be reported in connection with the use of allopathic drugs, vaccines,

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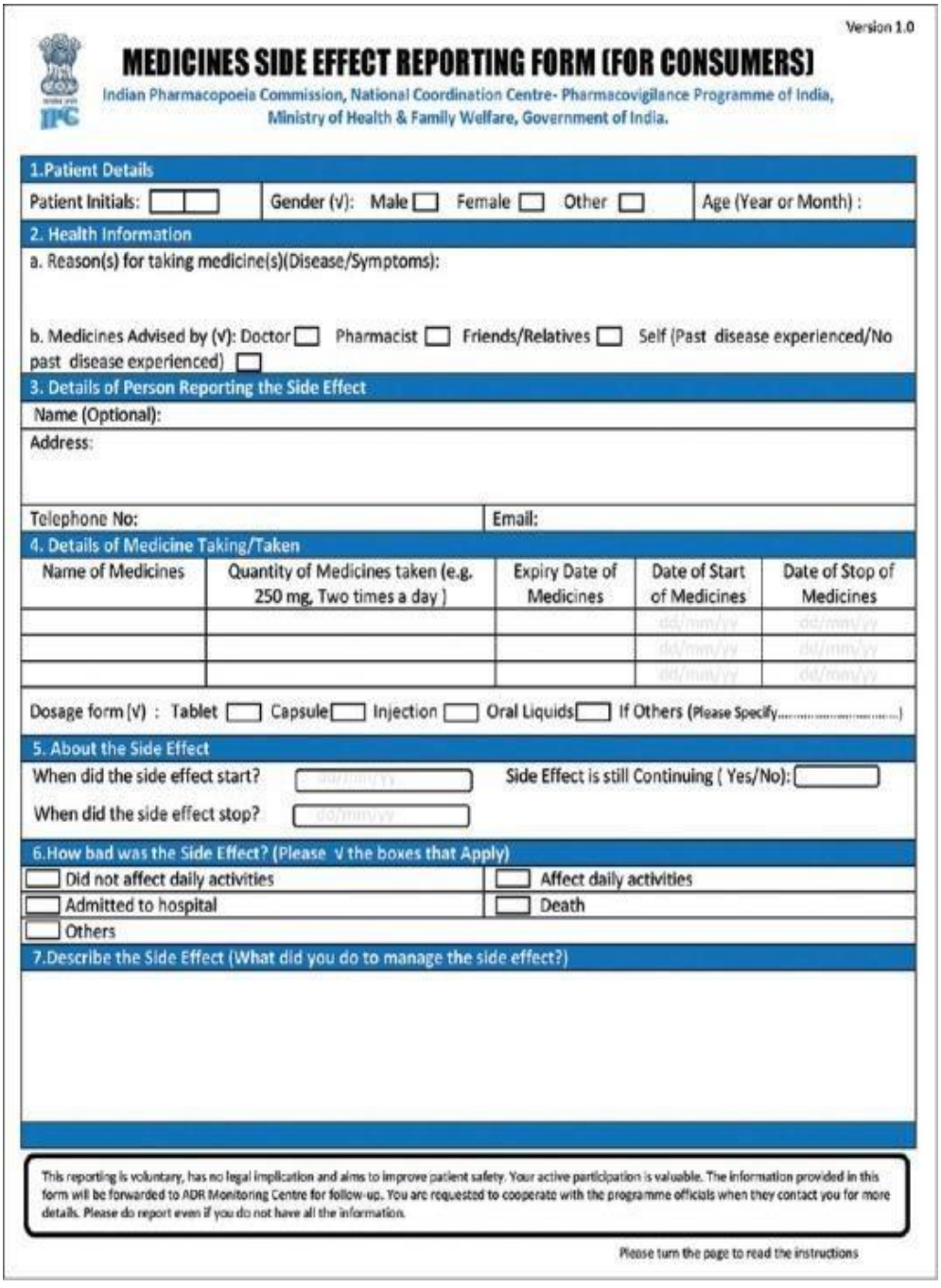
traditional medicines, medical equipment, contrast media, and other products.

Where to File a Report?

ADRs can be reported to NCC or AMCs by all healthcare professionals (clinicians, dentists, pharmacists, nurses) and patients/consumers. Individual case safety reports for pharmaceutical products can also be sent to NCC by pharmaceutical companies.

Figure no. 3 Medicines side effect reporting form (for consumers)



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.

Please turn the page to read the instructions

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Figure no. 4 Suspected adverse drug reaction reporting form

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
www.ipc.nic.in

FOR AMC/NCC USE ONLY
AMC Report No. :
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

B. SUSPECTED ADVERSE REACTION
5. Date of reaction started (dd/mm/yyyy)
6. Date of recovery (dd/mm/yyyy)
7. Describe reaction or problem

12. Relevant tests/ laboratory data with dates
13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)
14. Seriousness of the reaction (Yes ☐ No ☐)
☐ 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
								Date started	Date stopped	
i										
ii										
iii										
iv										

S.No as per C	9. Action Taken						10. Reaction reappeared after reintroduction			
	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)

D. REPORTER DETAILS
16. Name and Professional Address:_____
_____
Pin:_____E-mail_____
Tel. No. (with STD code)_____
Occupation:_____ Signature:_____

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

Additional Information:

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.**

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Ⅷ. PROGRAM ROADMAP FOR PVPI:

PvPI has now entered the excellence phase and is attempting to serve the Indian populace through private-public partnerships and collaboration with foreign regulatory authorities. The initiative's present goal is to deliver considerably safer public health through the use of technology and techniques such as data mining.

Figure no. 5 Program Roadmap (PvPI)
Adapted from Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission, 2013.

Ⅸ FUTURE ASPECTS OF PVPI:

An effective pharmacovigilance system is required for medication safety. It will benefit everyone, including healthcare professionals, regulatory bodies, pharmaceutical businesses, and consumers. It assists pharmaceutical companies in continuously monitoring their goods for risks, developing and implementing effective threat management plans, and keeping their products alive in difficult circumstances. (18) (19) The following proposals have the following capability:

1. Creating and sustaining a strong pharmacovigilance framework.
2. Requiring the dissemination of pharmacovigilance announcements and the presentation of pharmacovigilance investigations without recommendations on a regular basis
3. Credible conversations with different work groups.
4. The (DCGI) Drug Controller General Of India office is bolstered with ready clinical and logical pharmacovigilance assessors.
5. Developing a globally recognized individual country-specific hostile event notification structure.
6. Creating a clinical pre- and post-display information base for SAEs/SUSARs and ADRs to accept all understanding information from multiple partners and recognize signals.
7. Pharmacovigilance education and training for medical students, pharmacists, and nurses.

The PV may be involved in certain risk factors that result in the incidence of specific ADRs. PV will eventually need to focus on using patients as a source of information alongside more traditional groups such as health professionals. Currently, the DCGI must fast improve PV in order to incorporate Good Pharmacovigilance Practice (GPP) into the cycles and strategies to help assure administrative

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consistency and increase clinical preliminary security and post advertising observation. A well-functioning PV framework is needed if drugs are to be utilized safely. It will help medical practitioners, administrative specialists, pharmaceutical businesses, and patients. It helps pharmaceutical businesses ensure the safety of their products. Post marketing PV is currently a difficult and time-consuming procedure for regulatory authorities. (20) (21)

X. INTERNATIONAL COLLABORATIONS:

In its pharmacovigilance initiatives, PvPI interacts with a number of international organizations and agencies. The primary partnership is with the organizations listed below. (22)

1. World Health Organization (WHO)

2. Uppsala Monitoring Center (UMC), Sweden. The International Drug Monitoring Program of the WHO is built on the premise of data exchange among member countries. The initiative currently has more than 100 countries participating. The WHO Collaborating Center for International Drug Monitoring is known as UMC. The UMC is in charge of gathering, analyzing, and communicating information from member countries.

3. The Council for International Organizations of Medical Sciences (CIOMS) The CIOMS is an internationally oriented think tank that provides recommendations on drug safety concerns. CIOMS is a WHO subsidiary, and its reports are utilized by the WHO to develop policies. (23)

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