

# Pharmacovigilance Programme of India (PvPI)

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# Introduction

Pharmacovigilance is a system to monitor the safety and effectiveness of medicines and other pharmaceutical products.

*As per WHO:*

Pharmacovigilance as “science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems”.

## **Background**

1989 - ADR monitoring system for India proposed (12 regional centres)

1997 - India joined WHO-ADR monitoring programme (3 centres: AIIMS, KEM, JLN)

2004 – 2008 - National Pharmacovigilance Programme

**2010 – Pharmacovigilance Programme of India**

▶ Initiated with AIIMS, New Delhi as **National Coordination Centre (NCCC)** for monitoring ADRs in the country **July 2010**, shifted to Indian Pharmacopoeia Commission (IPC), Ghaziabad on **15<sup>th</sup> April 2011**

▶ **Vision:**

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

▶ **Mission:**

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

# PERFORMANCE & EFFECTIVENESS OF THE PHARMACOVIGILANCE SYSTEM

Who can Report	What to Report	Whom to Report
Healthcare professionals (clinician, dentist pharmacist ,nurses and others) can report suspected adverse drug reaction. Pharmaceutical companies can also send ICSRs specific for their product to NCC.	All types of suspected ADRs-irrespective of whether they are known or unknown, serious and non-serious, frequent or rare. Although pharmacovigilance is primarily concerned with pharmaceutical medicines, adverse reactions associated with drugs used in traditional medicine (e.g. herbal remedies) should also be considered.	Use the 'Suspected Adverse Drug Reaction Reporting Form' which is available on the official website of IPC ( <a href="http://www.ipc.gov.in">www.ipc.gov.in</a> ) as well as CDSCO ( <a href="http://www.cdsc.nic.in">www.cdsc.nic.in</a> ) to report any ADR. A reporter who is not a part of AMC can submit the ICSR to the nearest AMC or directly to the NCC.

## Scope and Objectives

- \* To create a nation-wide system for patient safety reporting
- \* To identify and analyze new signal from the reported cases
- \* To analyze the benefit - risk ratio of marketed medications
- \* To support regulatory agencies in the decision-making process on use of medications
- \* To communicate the safety information on use of medicines to various stakeholders to minimize the risk
- \* To provide training and consultancy support to other national pharmacovigilance centers across globe
- \* To promote rational use of medicine

# Short Term Goals

- ▶ To develop and implement pharmaco-vigilance system in India
- ▶ To enroll, initially, all MCI approved medical colleges in the program covering north, south, east and west of India
- ▶ To encourage healthcare professionals in reporting of adverse reaction to drugs, vaccines, medical devices and biological products
- ▶ Collection of case reports and data

## Long Term Goal

- ▶ To expand the pharmacovigilance programme to all hospitals (govt. & private) and centres of public health programs located across India
- ▶ To develop and implement electronic reporting system (e-reporting)
- ▶ To develop reporting culture amongst healthcare professionals
- ▶ To make ADR reporting mandatory for healthcare professionals



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graph TD; A((Pv Methods in PvPI)) --- B((Spontaneous Reporting)); A --- C((Targeted Spontaneous Reporting)); A --- D((Cohort Event Monitoring)); B --- C; C --- D; D --- B;
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**Spontaneous Reporting**

**Pv  
Methods in  
PvPI**

**Targeted  
Spontaneous  
Reporting**

**Cohort Event  
Monitoring**

# 1. Spontaneous Reporting

A spontaneous report is an unsolicited communication by healthcare professionals or consumers to a company, regulatory authority or other organisation (e.g., WHO, CDSCO etc) that describes one or more adverse drug reactions in a patient who was given one or more medicinal products and that does not derive from a study or any organised data collection scheme

## Spontaneous reporting system under PvPI

Electronic reporting: Electronic transmission of ICSRs from ADR Monitoring Centers to National Coordination Centre through VigiFlow (WHO Global Safety Database).

Voluntary reporting: Submission of ICSRs to the National Coordination Centre by Pharmaceutical companies or health care professionals.

Peripheral reporting: Submission of ICSRs by hospitals, healthcare clinics, health care professionals, patient to the nearest ADR Monitoring Centre.

# Spontaneous Reporting



Pros	Cons
Covers the whole population	Inherent under-reporting
Includes all marketed medicines	Captures only suspected ADRs
Continual monitoring throughout life cycle of medicine	Reporting bias e.g. Seriousness, severity New medicine Publicity of specific ADR
Detects signals of new, rare or serious ADRs	Denominator unknown
Most commonly used method	Difficult to detect - delayed ADRs &

## 2. Targeted Spontaneous Reporting

Objective:

To learn more about the ADR profile of specific medicine(s) in your population

Or

To estimate the incidence of a known ADR to a specific medicine in your population

### **3. Cohort Event Monitoring**

Objective: A prospective, longitudinal, observational, cohort study of adverse events associated with one or more monitored medicines.

It is related to class of medicine that has previously caused ADRs

Potentially significant adverse event observed during post-marketing surveillance

## Cohort event monitoring

Pros	Cons
Early detection of signals of unsuspected ADRs	More labor intensive than SR or TSR
Denominator information allows incidence rates of ADRs to be calculated	More costly Much data collected most of which represents 'Background noise'
Assessment of risk; identification of risk factor; between drug comparisons	Training required
Death record	LTFU may be substantial and needs to be actively managed

# Comparing the Pv methods

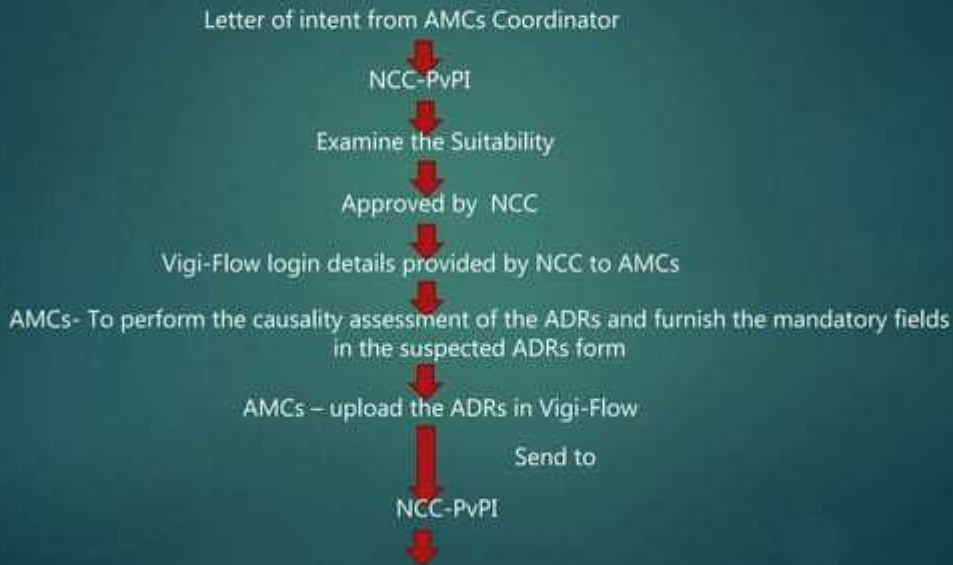
Method	Medicines	Population	Reports
Spontaneous Reporting	All medicines	All exposed individuals but denominator unknown	All ADRs
Targeted Spontaneous Reporting	Specific medicines	All exposed individuals but denominator known	Specific ADRs
Cohort Event Monitoring	Specific medicines	Defined cohort	All AEs



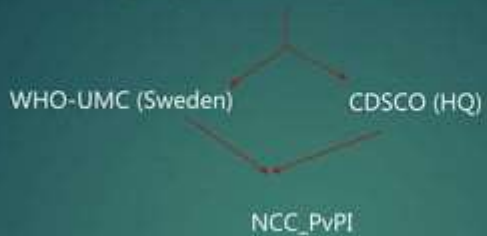
# Organization Committees under NCC

- ▶ **Steering Committee**
- ▶ **PvPI Working Group**
- ▶ **Quality Review Panel**
- ▶ **Signal Review Panel**
- ▶ **Core training panel**

# NCC Working Module




## Quality assessment by NCC-PvPI



# Responsibilities of Stakeholder

## ▶ Personnel at AMC

- Collection of ADR reports
- Perform follow up with the complainant to check completeness as per SOPs
- Data entry into Vigiflow
- Reporting to PvPI National Coordinating Centre (PvPI NCC) through Vigiflow with the source data (original) attached with each ADR case
- Training/ sensitization/ feedback to physicians through newsletters circulated by the PvPI NCC



## ➤ Personnel at NCC

- Preparation of SOPs, guidance documents & training manuals
- Data collation, Cross-check completeness, Causality Assessment etc as per SOPs
- Conduct Training workshops of all enrolled centers
- Publication of Medicines Safety Newsletter
- Reporting to CDSCO Headquarters
- Analysis of the PMS, PSUR, AEFI data received from CDSCO HQ

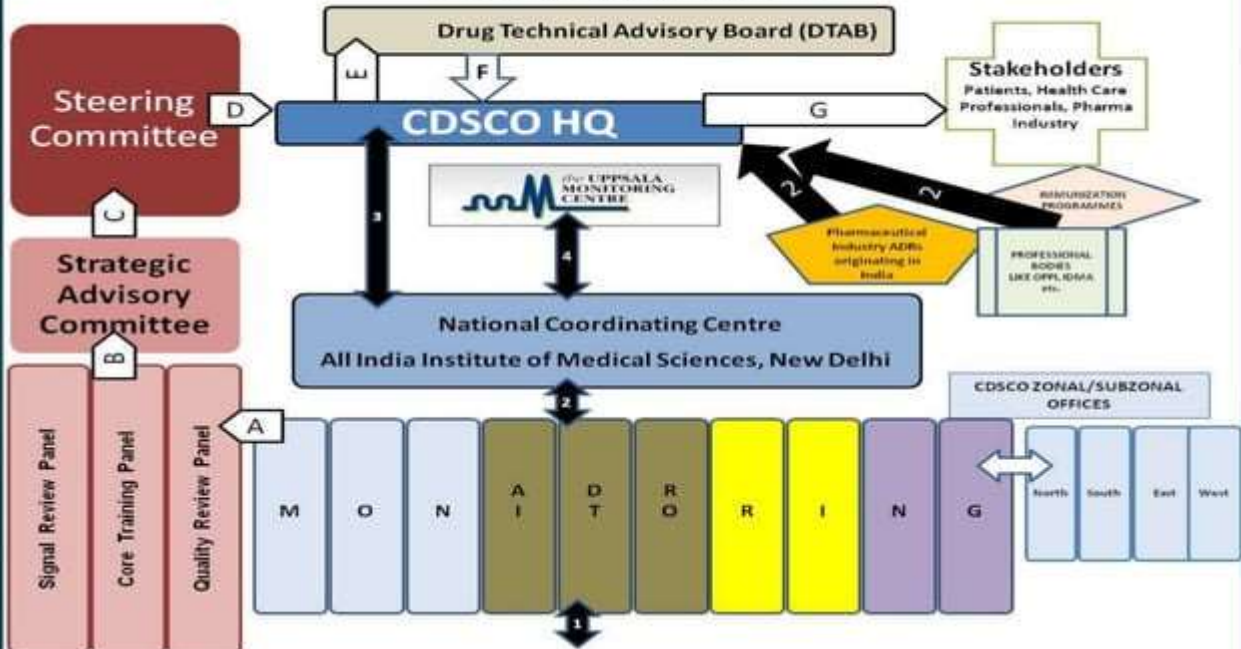
## ➤ Personnel at Zonal/ Sub-zonal CDSCO

- Provide procurement, financial and administrative support to ADR monitoring centers
- Report to CDSCO HQ

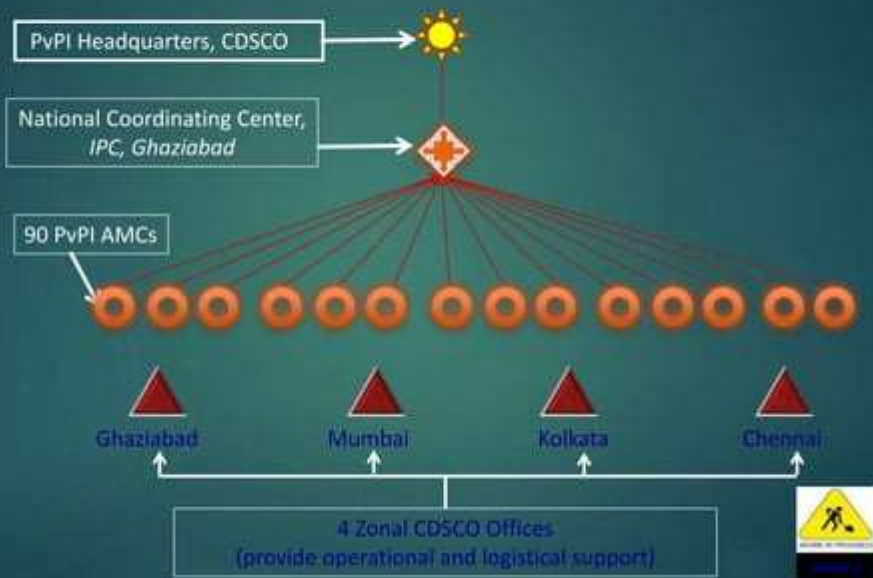
## ➤ Personnel at CDSCO HQ

- Take appropriate regulatory decision & actions on the basis of recommendations of PvPI NCC at IPC Ghaziabad.
- Propagation of medicine safety related decisions to stakeholders
- Collaboration with WHO-Uppsala Monitoring Center - Sweden
- Provide for budgetary provisions & administrative support to run PvPI

# COMMUNICATION CHANNELS



# Pharmacovigilance Programme of India (PVPI)





# Phases or Road Map of PvPI

- ▶ Initiation phase (2010-2011)
- ▶ Expansion and consolidation phase (2011-2012)
- ▶ Expansion and maintenance phase (2012-2013)
- ▶ Expansion and optimization (2013-2014)
- ▶ Excellence phase (2014-2015)

**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, Mayapuri, New Delhi-110029Report Type  Initial  Follow-up**A. PATIENT INFORMATION**

1. Patient Initials	2. Age at time of Event or Date of Birth	3. M <input type="checkbox"/> F <input type="checkbox"/> Other <input type="checkbox"/>
		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:

**FOR AMC/NCC USE ONLY**

AMC Report No. \_\_\_\_\_

Reg. No./SPD No./CPD No./DR No.

Worldwide Unique No. ( )

11. Relevant test(s)/laboratory data with dates:

13. Relevant medical/medication history (e.g. allergies, co-morbidities, pregnancy, smoking, alcohol use, recent/ongoing infections etc.):

14. Seriousness of the reaction: No  If Yes  (please tick any/all) Death ( ) Congenital anomaly Life threatening Required intervention to prevent permanent impairment/damage Hospitalization/Physiologic Other (specify) Disability

15. Outcomes

 Recovering Not recovered Fatal Recovered with sequelae  Unknown**C. SUSPECTED MEDICATION(S)**

S. No	Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (QID, BID, etc.)	Therapy dates		Indications	Causality Assessment
								Date started	Date stopped		
1											
2											
3											
4											

5. No. of Action Taken (please tick)

Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Other (specify)
----------------	----------------	--------------	------------------	----------------	-----------------

1					
2					
3					
4					

16. Reaction improved after withdrawal (please tick)

Yes No Effect unknown 

Dose (if continued) \_\_\_\_\_

17. Concurrent and 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 (QID, BID, etc.)	Therapy dates		Indications
					Date started	Date stopped	
1							
2							
3							
4							

Additional Information:

**D. REPORTER DETAILS**

18. Name and Professional Address:

Name: \_\_\_\_\_ E-mail: \_\_\_\_\_

Tel. No. (with STD code): \_\_\_\_\_

Occupation: \_\_\_\_\_ Signature: \_\_\_\_\_

19. 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 professional or manufacturer or the product caused or contributed to the reaction.

## VIGIFLOW

Vigiflow is an Individual Case Safety Report (ICSR) management system developed and hosted by Uppsala monitoring centre (UMC).

### **How to access Vigiflow**

Web address: **<https://adr.who-umc.org>**

Log in is done with a personal user name and password from the secure web-page

The minimum information you have to enter on a spontaneous report for it to be considered 'complete' by VigiFlow is the following six mandatory fields:

- 1) Report title
- 2) Patient initial
- 3) Patient age (either date of birth, age at time of onset or age group)
- 4) Onset date of reaction (year only)
- 5) Reaction term
- 6) Drug name

# Patient Information

2013-12623 - Gastric ulcer haemorrhagic-Aspirin

## Patient characteristics

date of birth

(dd mm cyy)

age at time of onset

age group

patient initials

body weight (kg)

body height (cm)

sex

- male  
 unknown

Patient sex should be marked here

Initial letter of patient name

additional patient info.

expand

# REPORT INFORMATION

## Report information - standard case

report Id

date first received

16 07 2013

(dd mm cyy)

report title



type of report

spontaneous

serious

yes  no [clear](#) ?

reason for seriousness

- |  |  |
|--|--|
| <input type="checkbox"/> death                     | <input type="checkbox"/> life-threatening ?                  |
| <input type="checkbox"/> hospitalization/prolonged | <input type="checkbox"/> disabling                           |
| <input type="checkbox"/> congenital-anomaly        | <input type="checkbox"/> other medically important condition |

country of occurrence

India

country of primary source

India

does this case fulfill local criteria for an expedited report

yes  no [clear](#)

additional documents held by sender  yes  no [clear](#)

was the case medically confirmed  yes  no [clear](#) ?

# Information on sender

## Information on sender



### type of sender

- pharmaceutical company     health professional
- regulatory authority     regional pharmacovigilance center
- other

[clear](#)

### date first received at sender

(dd mm ccyy)

### Other case identifiers in previous transmissions

### worldwide unique number


authority report number



company report number

# Information on Primary Source

**Information on primary source(s)**



<b>given name</b> <input type="text"/>	<b>family name</b> <input type="text"/>
<b>institution</b> <input type="text"/>	<b>department</b> <input type="text"/>
<b>street address</b> <input type="text"/>	<b>state</b> <input type="text"/>
<b>postal code</b> <input type="text"/>	<b>city</b> <input type="text"/>
<b>telephone</b> <input type="text"/>	<b>fax</b> <input type="text"/>
<b>e-mail</b> <input type="text"/>	
<b>country of reporter</b> India <input type="button" value="v"/>	
<b>reporter qualification</b>	
<input type="radio"/> physician	<input type="radio"/> pharmacist <input type="button" value="clear"/>
<input type="radio"/> lawyer	<input type="radio"/> other health professional
<input type="radio"/> consumer or other non-health professional	
<b>literature reference</b> <input type="text"/>	

After adding information click here



# Death related information

**Death related information**

death date  
[ ] [ ] [ ]  
(dd mm yyyy)

death cause  
[ ] code [ ] search term [ ]

was an autopsy performed  yes  no  unknown

comments  
[ ]

Any comment related to death can be included here

# Result of test and procedure

2013-12623 - Gastric ulcer haemorrhagic - Aspirin

**Results of tests and procedures**

results of tests and procedures - free text

To add detail of test

The free text field for tests and procedures is a common field for all

add new [ ]

check entries [ ] next [ ]

# Relevant medical history

## Relevant medical history

relevant medical history - free text



# Relevant Past Drug Therapy

## Relevant past drug therapy

## Therapy

### Therapy:

drug name



start date

(dd mm cyy)

end date

(dd mm cyy)

indication

code

reaction

# SAVE REPORT

## Welcome to VigilFlow

You have an unsaved report from last session! This might be due to a last session by timeout or any other reason. The reason might also be that you choosed to exit without first saving the report that you were working with!

would you like to retrieve the unsaved report?

retrieve

skip


If you click on *retrieve*, the unsaved version of the report will open and can be saved by clicking the save option. If you do not want to retrieve the report, you can click on *skip* and the **list of reports** page will open.

## Save report

### Report comments

comment  
(shown together with  
the report in the  
report list)

Comments on the case (optional) can be written.

Information in green note is found  (the comment icon) in the list report. Comment is included on *internal PDF printouts* of the report.

Note that the comment will be deleted when the report is committed and cannot be restored.

Generate report Id by checking the box. An Id will be generated automatically if the report is sent to another centre or committed

Generate report Id  
(this means that the report will be entered into the system and that you will not be able to delete it)

save

Click the save button. A message saying 'The report was successfully saved'

# VigiFlow Demo Chart

Login with User Id and password

Quick start

1

2

3

4

## REPORT INFO PAGE

- a) Report information section
- b) Information on sender
- c) Information on Primary source

## PATIENT PAGE

- a) Patient Characteristics
- b) Death related information

## TEST AND PROCEDURES PAGE

- a) Result from test and procedure
- b) test

Free Text Information

Structured Information

## RELEVANT MEDICAL HISTORY PAGE

Free text information

Structured Information

5

**RELEVANT PAST  
DRUG THERAPY**

1

6

**REACTION PAGE**

- a) Reactions/ Events- Free text
- b) Relatedness of Drugs to reactions

2

3

4

5

7

**DRUG PAGE**

- a) Suspected Drugs
- b) Concomitant drug

6

7

**The CAUSALITY  
ASSESSMENT**

**Save Report**

**Send to NCC**

**Quality Review at NCC**

**Submit Report to UMC**

THANK

YOU