## CONTENT : -



# Pharmacovigilance in India :-

### ✖ Introduction :-

- ✖ Pharmacovigilance is a system to monitor the safety and effective 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 centers) .
- ✖ 1998 – India joined WHO- ADR monitoring programmed ( 3 centre's : AIIMS, KEM (King Edward Memorial ), , AMU ( Aligarh Muslim University )
- ✖ 2004 – 2008 – National Pharmacovigilance Programmed .
- ✖ ( * 2 Zonal , * 5 Regional , * 24 Peripheral , * Overseen by CDSCO )
- ✖ 2010 – Pharmacovigilance Programmed of India .

### ✖ Mission of Pharmacovigilance program in India :-

- ✖ Initiated with AIIMS, New Delhi as National Coordination Centre (NCC) for monitoring ADRs in the country July 2010, shifted to India Pharmacopoeia Commission (IPC) , Ghaziabad on 15th April 2011 .

## ✖ Vision :-

- ✖ To improve patient safety and welfare of India population by monitoring the drug safety reducing the risk associated with use of medicines.

## ✖ Mission :-

- ✖ Safeguard the health of the Indian population by ensuring that the benefits of use medicine outweigh the risk associate with its use .

## National Pharmacovigilance program (NPP) :-

- ✖ The National Pharmacovigilance Program (NNP) officially inaugurated by the Central Health Minister at New Delhi.

## Objective of Pharmacovigilance Programmed of India :-

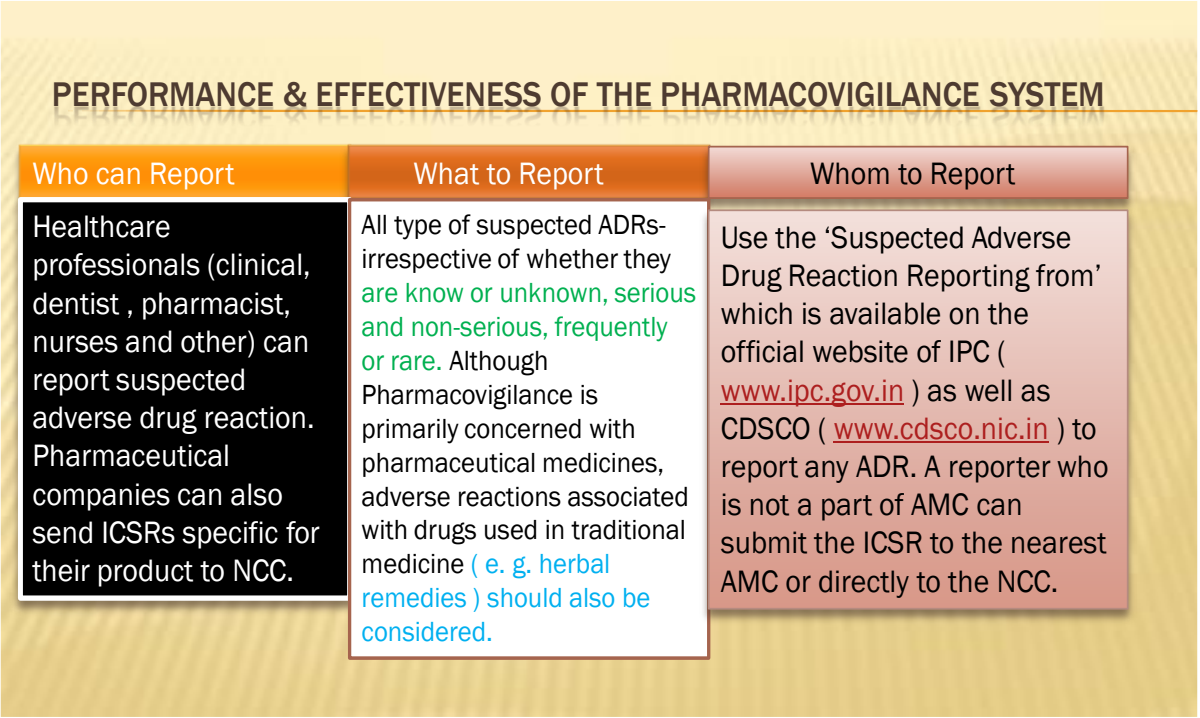
- ✖ To create a nation system for patient safety reporting.
- ✖ To identify and analyse the new signal ADR from the reported cases.
- ✖ To generate the evidence- based information on safety of medicines.
- ✖ To support regulatory agencies in the decision- making process on use of medicines.
- ✖ To communicate the safety information on use of medicine to various stakeholders to minimize to the risk.
- ✖ To provide training and consultancy to other national Pharmacovigilance centers locates across globe.
- ✖ To collaborate with other national centre's for the exchange of information and data management.

## 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 report and data.

## Long term goal:-

- ✖ To expand the Pharmacovigilance programme to all hospitals ( govt. & private ) and centers 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.




## Organization committees under NCC :-

- ❖ Steering Committee
- ❖ Working Group
- ❖ Quality Review Panel
- ❖ Core Training Panel
- ❖ Signal Review Panel

## NCC working module :-

- ✖ Letter of intent AMCs Coordinator

- NCC - PvPI
- Examine the Suitability
- Approved by NCC
- Vigi- Flow login provided by NCC to AMCs
- AMCs- To perform the causality of the ADRs and furnish the mandatory field in the suspected ADRs form
- AMCs- upload the ADR in Vigi- Flow send to
- NCC – PvPI

## Responsibilities of stakeholder :-

- **Personnel at AMC :-**
- Collection of ADR reports
- Perform follow up the complainant to check completeness as per SOPs.
- Reporting to PvPI National Coordinating Centre.
- Training/ sensitization / feedback / to physicians through newsletters circulated by the PvPI NCC.

## Personnel at NCC :-

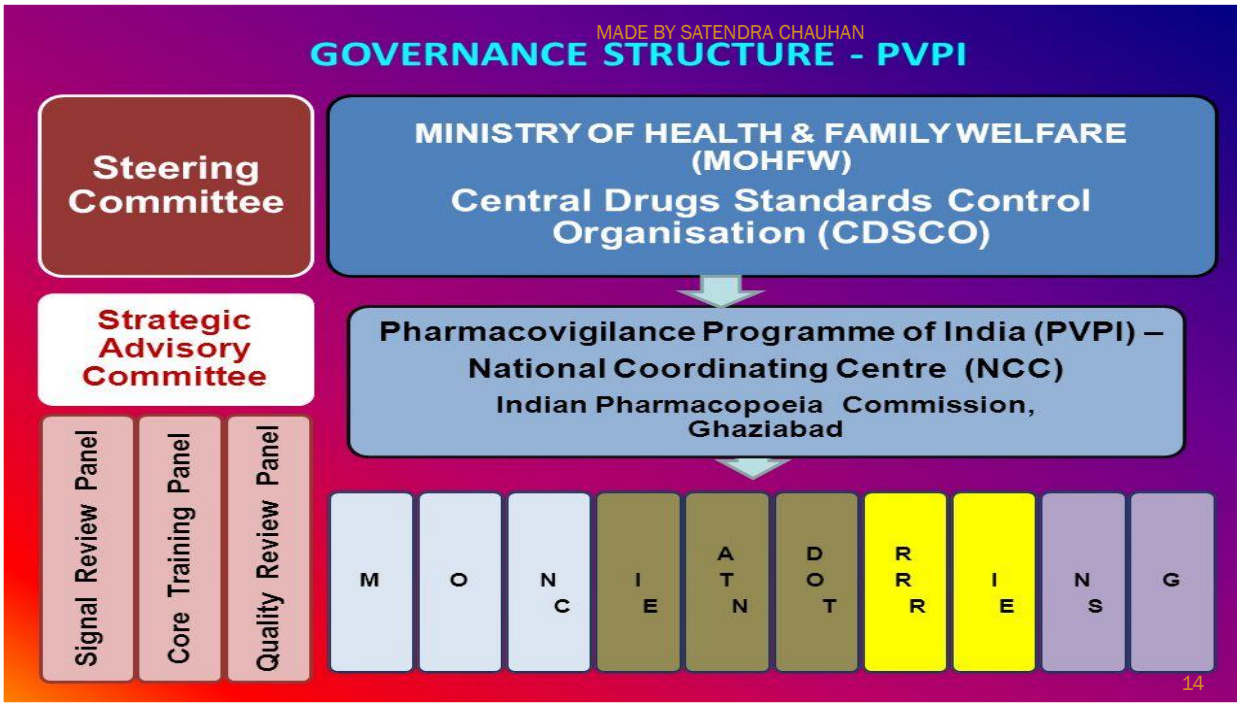
- Preparation of SOPs, guidance documents & training manuals.
- Data collation, Cross- cheek completeness , Causality Assessment etc as per SOPs.
- Conduct Training workshops of all enrolled centers
- Publication of Medicines Safety Newsletter.
- Reporting to CDSCO Headquarters.
- Analysis of the PMS,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

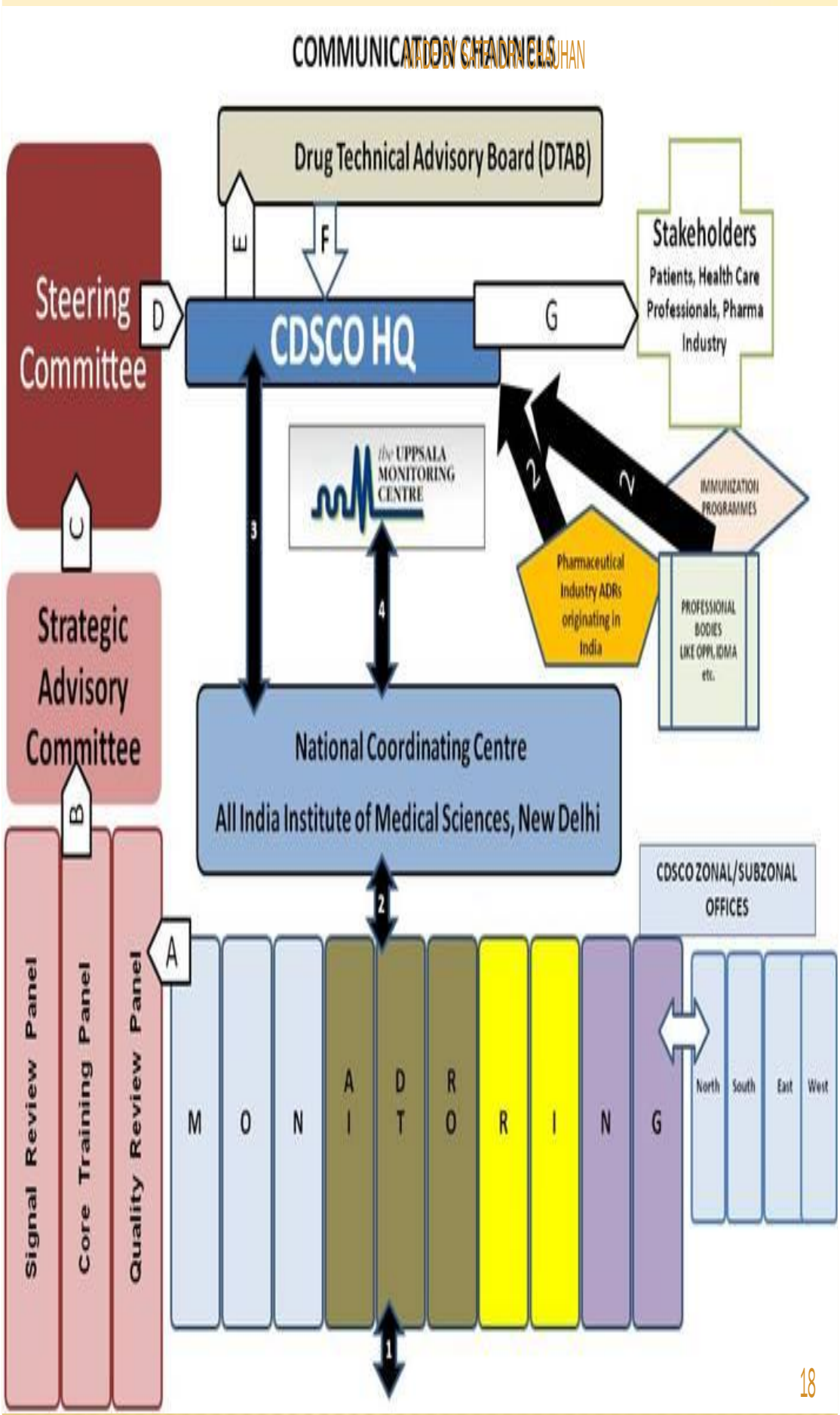
## ✖ Personnel at CDSCO HQ : -

- ✖ Take appropriate regulatory decision & action on the basis of recommendation of PvPI NCC at IPC Ghaziabad.
- ✖ Propagation of medicine safety related decision to stakeholders.
- ✖ Collaboration with WHO- Uppsala Monitoring Centre – Sweden.
- ✖ Provide for budgetary provisions & administrative support to run PvPI.




## Phase 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 ).

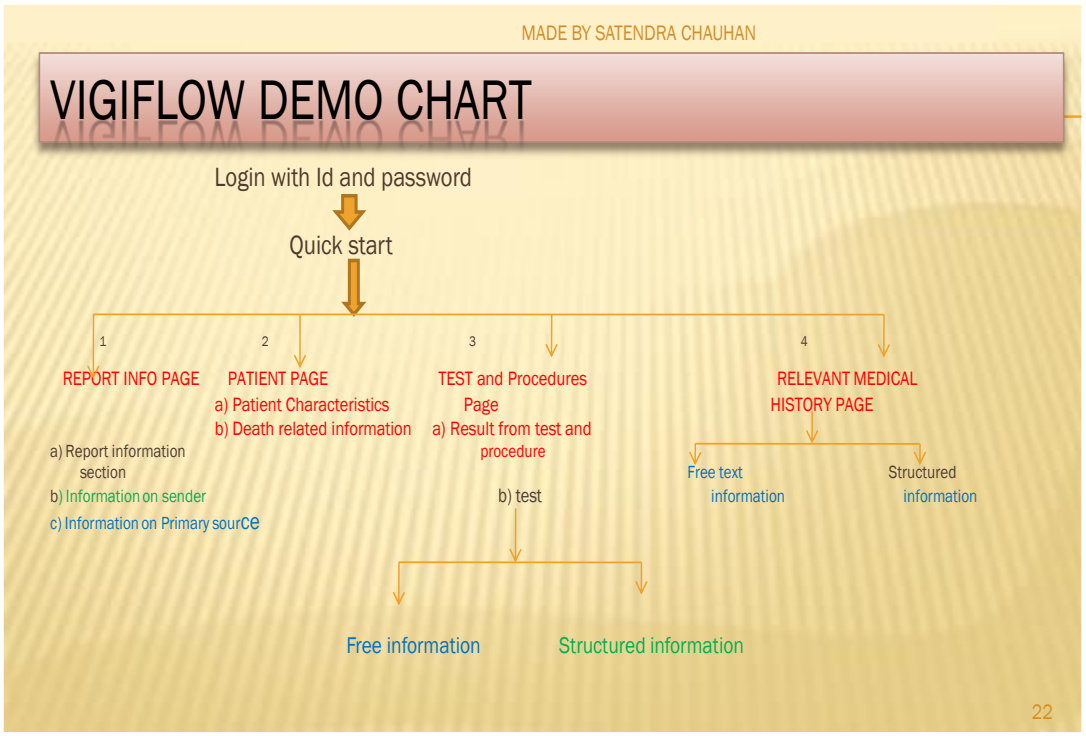

COMMUNICATION CHANNELS
Drug Technical Advisory Board (DTAB)
Steering Committee
CDSCO HQ
Stakeholders
Patients, Health Care Professionals, Pharma Industry
the UPPSALA MONITORING CENTRE
IMMUNIZATION PROGRAMMES
Pharmaceutical Industry ADRs originating in India
PROFESSIONAL BODIES LIKE OPPI, IDMA etc.
Strategic Advisory Committee
National Coordinating Centre
All India Institute of Medical Sciences, New Delhi
CDSCO ZONAL/SUBZONAL OFFICES
Signal Review Panel
Core Training Panel
Quality Review Panel
MONITORING
North
South
East
West
A
B
C
D
E
F
G
1
2
3
4
5
6

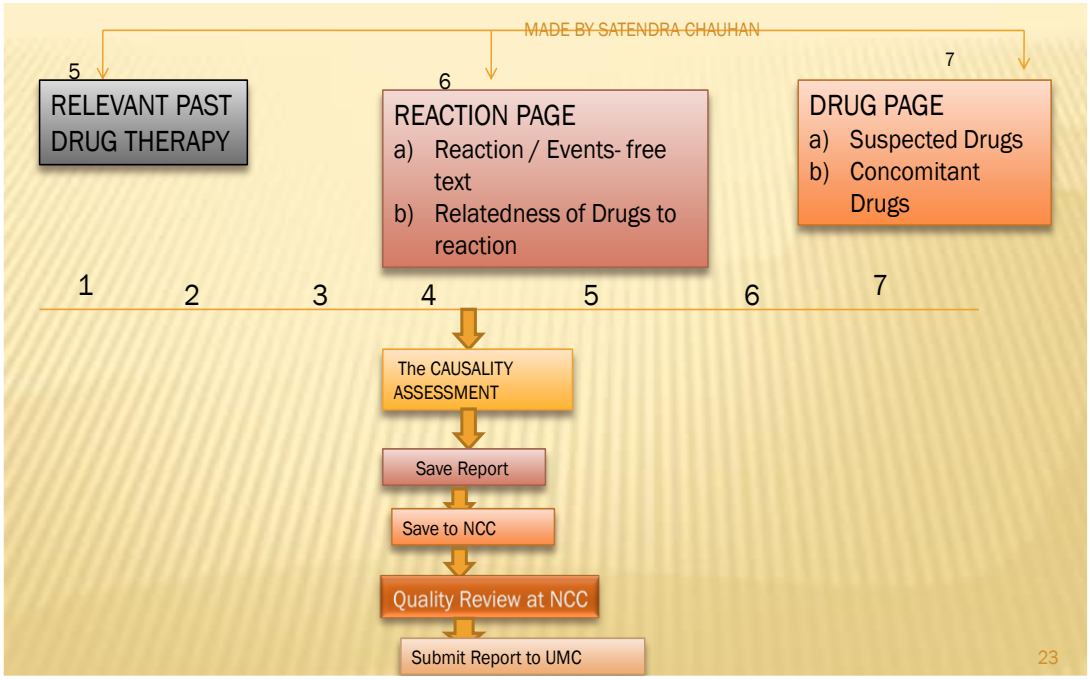
# Vigiflow:-

- 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 tile
- 2). Patient initial

3). Patient age (either DOB, age at time of onset or age group)

- 4). Onset date
- 5). Reaction term 6).
- Drug name
- Vigiflow demo chart :-
-


MADE BY SATENDRA CHAUHAN
VIGIFLOW DEMO CHART
Login with Id and password
Quick start
1
REPORT INFO PAGE
a) Report information section
b) Information on sender
c) Information on Primary source
2
PATIENT PAGE
a) Patient Characteristics
b) Death related information
3
TEST and Procedures Page
a) Result from test and procedure
b) test
Free information
Structured information
4
RELEVANT MEDICAL HISTORY PAGE
Free text information
Structured information
22


MADE BY SATENDRA CHAUHAN
5
RELEVANT PAST DRUG THERAPY
6
REACTION PAGE
a) Reaction / Events- free text
b) Relatedness of Drugs to reaction
7
DRUG PAGE
a) Suspected Drugs
b) Concomitant Drugs
1 2 3 4 5 6 7
The CAUSALITY ASSESSMENT
Save Report
Save to NCC
Quality Review at NCC
Submit Report to UMC
23

THANK YOU !

# CHHATRAPATI SHAHUJI MAHARAJ UNIVERSITY, KANPUR

## SCHOOL OF PHARMACEUTICAL SCIENCES

## ASSIGNMENT -2

**On Topic- Industry and National Programmed related to Pharmacovigilance**


**Subject.Clinical Research & Pharmacovigilance (MPL-204T)**

**Submitted to:-**
Dr. Mamta Tiwari
Associate professor
School of pharmaceutical sciences, CSJM University, Kanpur

**Submitted by:-**
Satendra Chauhan
M.Pharma (pharmacology) 1st sem.
Enrollment NO. - CSJMU22000020758

# CONTENT : -

- Introduction
- Pharmacovigilance in India
- Scope and Objectives
- National Related programmers (NRP)
- Why Pharmacovigilance
- Methods in Pharmacovigilance
- Spontaneous reporting
- Mission
- Vision

MADE BY @ SATENDRA CHAUAHN 2

Introduction :-

- **Pharmaco - Vigilance**

❖ Pharmakon = Medicine

❖ Vigilance = To keep watch

❖ Alter of watchfulness

❖ In respect of danger ; care ; caution

❖ **Introduction :-**

❖ Pharmacovigilance is a system to monitor the safety and effective 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”.

Why Pharmacovigilance

- Incomplete information collected during the pre- marketing phase of drug.
- ADRs are leading cause of morbidity and mortality in both developing and developed world.
- 4$^{th}$ leading cause of death in USA.

- 30 – 70 % of all ADRs are Preventable .

They increase cost of patient care and loss of patient confidence in health care system.

Methods in Pharmacovigilance ….

- Passive surveillance
- Spontaneous reporting
- Case series Study
- Stimulated reporting
- Active surveillance
- Comparative observational studies
- Cross sectional , case control and cohort studies
- Targeted clinical investigations
- Descriptive studies.

Spontaneous reporting :-

- Health care professional describes his/ her own observation of a suspected ADR with marketed drug.
- USA - Med watch program

  UK - yellow card system

## Impact of yellow card scheme :-

| Year | Medicine | Adverse reaction |
|---|---|---|
| 2014 | Voriconazole | Liver and photo toxicity, squamous cell carcinoma |
| 2014 | TNF alpha inhibitor | Risk of TB |
| 2013 | Risperidone and paliperidone | Intraoperative floppy iris syndrome during cataract surgery |
| 2012 | Statins | Hyperglycemia and diabetes |
| 2011 | Citalopram and escitilopram | QT interval prolongation |
| 2009 | Finasteride | Potential risk male breast cancer |
| 2003 | Aspirin | Reyes syndrome in children's under 16 years |

MADE BY @ SATENDRA CHAUAHN 8

Why do need Pharmacovigilance In India ?

- India is a vast country with a population of over 1 – 2 billion with
- Vast ethnic variability
- Different disease prevalence patterns
- Practice of different system of medicines
- Different socioeconomic status .

Pharmacovigilance in India :-

- Background :-
- 1989 – ADR monitoring system for India proposed ( 12 regional centers) .
- 19987 – India joined WHO- ADR monitoring programmed ( 3 centre's : AIIMS, KEM (King Edward Memorial ), , AMU ( Aligarh Muslim University )
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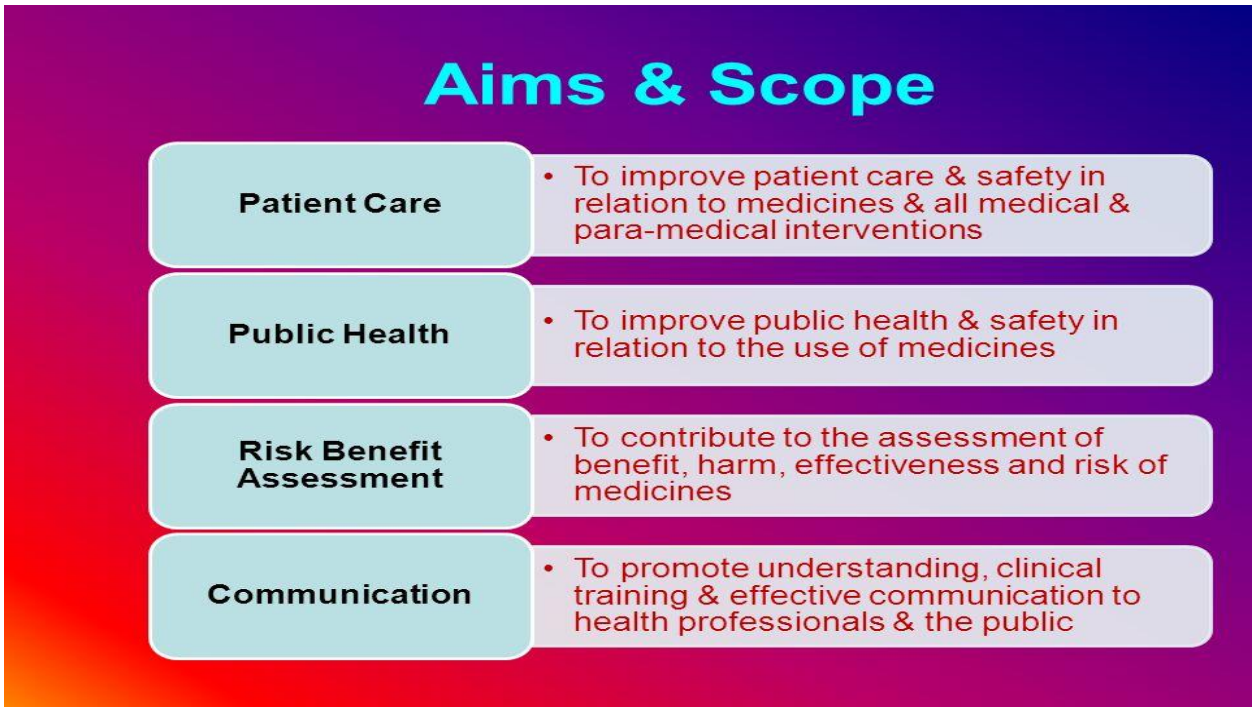



National Pharmacovigilance program (NPP) :-

- The National Pharmacovigilance Program (NNP) officially inaugurated by the Central Health Minister at New Delhi
- **Established in 1968, the WHO Programme for International Drug Monitoring (PIDM)** provides a global platform for Member States to exchange safety and regulatory information on all medicines and vaccines.

National Pharmacovigilance program (NPP) :-

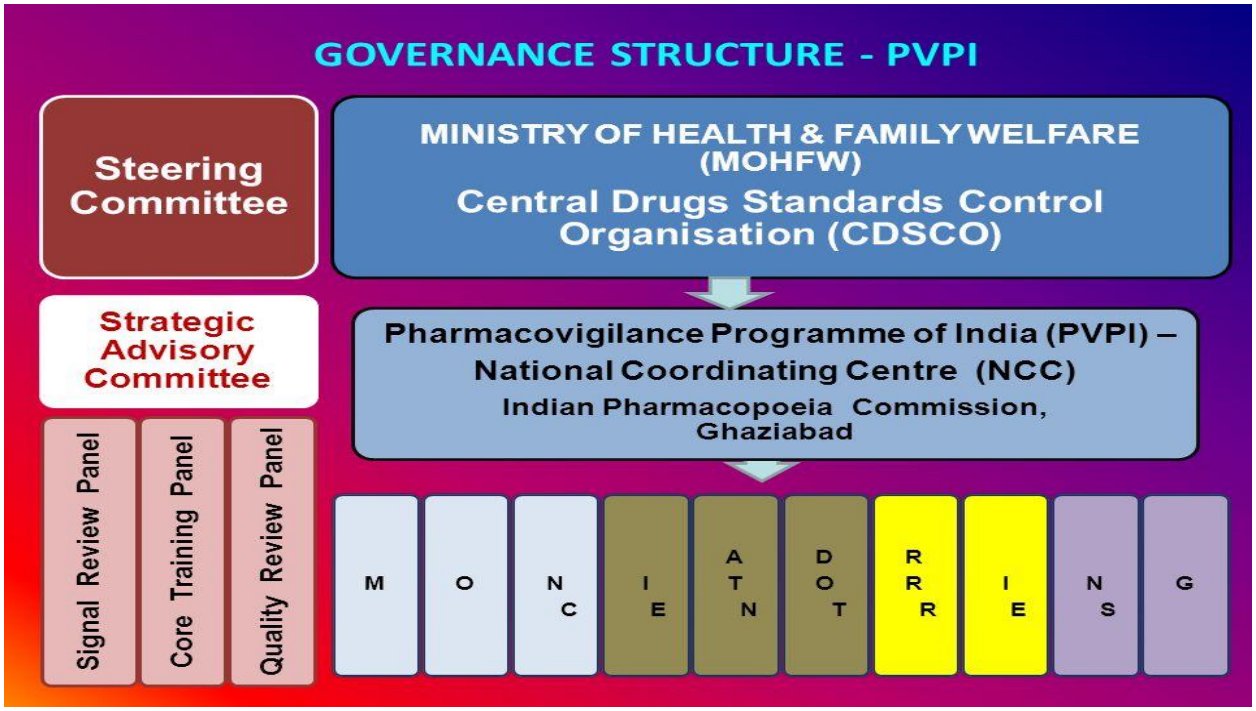
- **Pharmacovigilance is the science of monitoring and assessing the safety, efficacy, and quality of drugs through pre-marketing clinical trials and post-marketing surveillance**. Its main objective is to detect adverse effects that may arise from using various pharmaceutical products.

The Uppsala Monitoring Centre (UMC, WHO), Sweden is maintaining the international database of adverse drug reaction (ADR) reports received from several National Centre's. In September 2005, the database had 3.5 million adverse drug reaction reports and 78 countries were participating in this programme. Vigibase online (web based) system is used for submission of ADR reports.

**Who to Report ?**

- Use the 'Suspected Adverse Drug Reaction Reporting from' which is available on the official website of IPC ( www.ipc.gov.in ) as well as CDSCO ( www.cdsco.nic.in ) 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.




National Coordinating Center :-

- Preparation of SOPs, guidance documents & training manuals
- Cross check completeness, causality assessment as per SOPs.
- Reporting to CDSCO headquarters
- Conduct training workshop of all enrolled centers.
- Publications of medicine safety neswletters.

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 & action on the basis of recommendation of PvPI NCC at IPC Ghaziabad.
- Propagation of medicine safety related decision to stakeholders.

- Collaboration with WHO- Uppsala Monitoring Centre – Sweden.
- Provide for budgetary provisions & administrative support to run PvPI

Which is the National Pharmacovigilance Centre?

- All India Institute of Ayurveda, New Delhi is the National Pharmacovigilance Co-ordination Centre (NPvCC) for implementation of the Pharmacovigilance program for ASU & H Drugs.

Regional Centers Under PvPI :-

- These regional centers are recognized as regional Resource Center.
- Eastern Region : IPGMER , Kolkata
- Western Region : KEM Hospital , Mumbai
- Northern Region : PGIMER- Chandigarh
- Southern Region : JSS Hospital , Mysore.

What is the importance of Pharmacovigilance for industry?

- The Pharmacovigilance team in WHO aims to **assure the safety of medicines and vaccines by ensuring reliable and timely exchange of information on safety issues**, promoting Pharmacovigilance activities throughout the Organization and encouraging participation in the WHO Programme for International Drug Monitoring.

What is the scope of Pharmacovigilance in pharmaceutical industry :-

- **Pharmacovigilance involves activities related to understanding assessment, detection and prevention of adverse effects or any other drug-related problems**
- The aims of Pharmacovigilance within the industry are essentially the same as those of regulatory agencies; that is to protect patients from unnecessary harm **by identifying previously unrecognized drug hazards, elucidating pre-disposing factors, refuting false safety signals and quantifying risk in relation to benefit**.
- Although the perspectives of companies and the regulatory agencies may be different they now work more and more closely together and share information.

# 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 ☐ Other (specify)
☐ Disability

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 |
|---|---|---|---|---|---|---|---|---|---|---|
| i | | | | | | | | | | |
| ii | | | | | | | | | | |
| iii | | | | | | | | | | |
| iv | | | | | | | | | | |

| S.No as per C | 9. Action Taken: Drug withdrawn | Dose increased | Dose reduced | Dose not changed | Not applicable | Unknown | 10. Reaction reappeared after reintroduction: 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 confidence 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.**