

# All India Institute of Medical Sciences Rajkot



## Clinical Pharmacology & Therapeutics e – Bulletin “Panacea”

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# Contents

Topics	Page Number
• Core Area- Pharmacovigilance	1
• Drug Alert	6
• New Drug release and Recent Advances	7
• Quiz	8

# Pharmacovigilance

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine/vaccine-related problem.

Pharmacovigilance also includes monitoring adverse drug reactions (ADR) by

- Vaccines,
- Blood products
- Biological
- Medical devices
- Herbals
- Traditional and complementary medicines

## Need of pharmacovigilance



### (1) Medical Disasters related to drugs:

1. 107 paediatric deaths by *sulphanilamide elixir*
2. Death by *chloroform anaesthesia*
3. Seal limb babies (Phocomelia) by  
a. *thalidomide*



### (2) Drugs/vaccines are tested in the clinical trials

- In a small number of selected individuals
- Limited period of assessment

### (3) Certain ADRs emerge when drugs are exposed to

- Heterogenous population (paediatric, geriatric, pregnant, lactating mothers)
- With concurrent diseases or drugs
- Used for a longer period of time



## Adverse Drug Reaction (ADR)

“A response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function.”

Impact of ADRs on health care system:

- 10-25% incidence of ADR in a clinical setting
- 1.3 million emergency department visits/year
- 350,000 patients need to be hospitalized for treatment of ADRs/year





# Pharmacovigilance program of India (PvPI)



Pharmacovigilance Program of India (PvPI) was launched by the MoHFW, the Government of India in 2010

The National Coordinating Centre (NCC) of PvPI is at Indian Pharmacopoeia Commission (IPC), Ghaziabad.

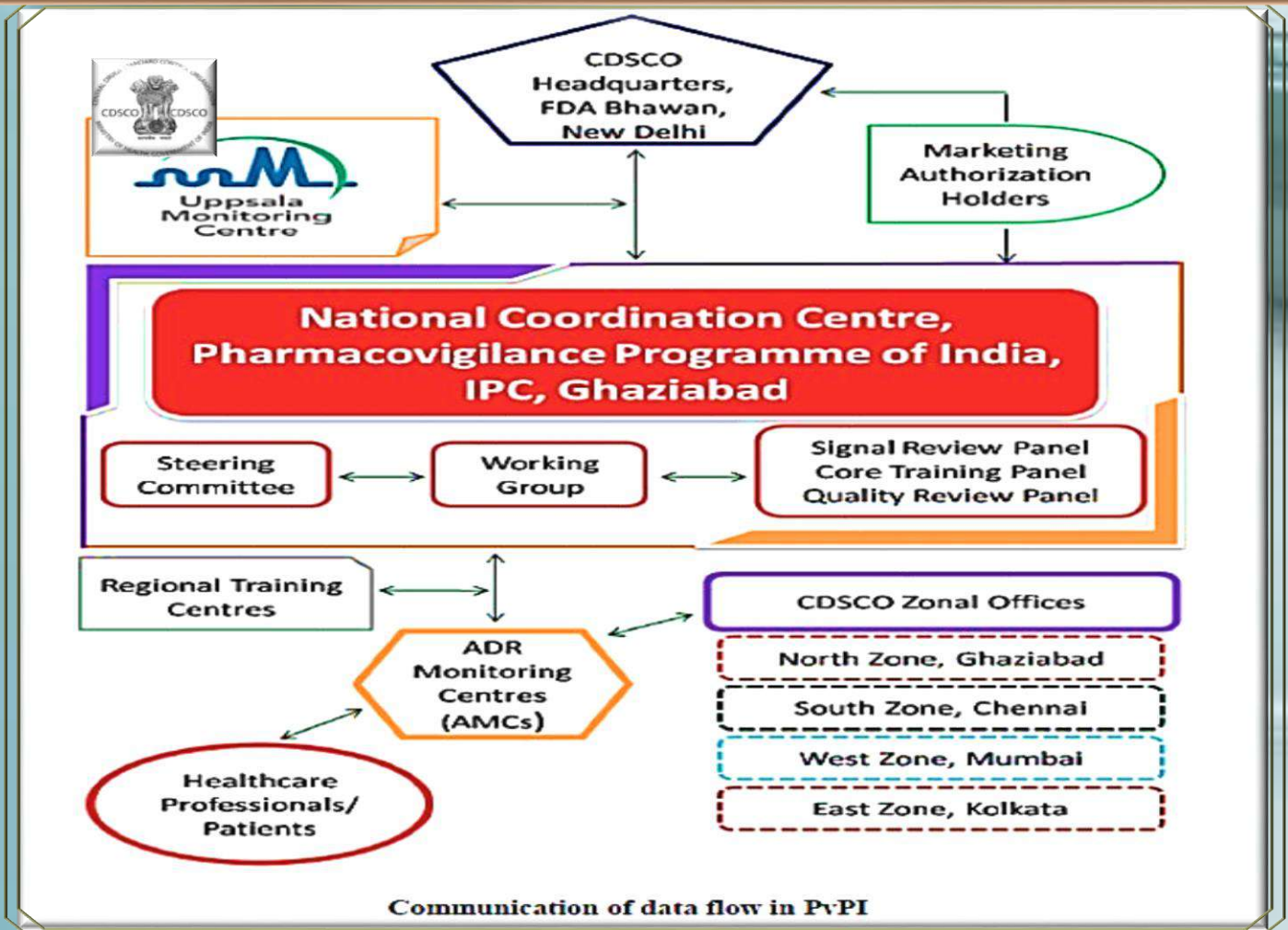
NCC: Helps in capacity building for

- Monitoring
- Surveillance
- Collaboration with national health programs
- Co-ordinate with CDSCO and international centre of pharmacovigilance (UMC)



- International Centre of PV
- Situated at Sweden- collaborate with WHO
- Support access for operation of pharmacovigilance system to member countries

## Communication network of PvPI



**PvPI is integrated with Vaccination, RNTCP, NACO, Medical Devices and Blood products**

**AEFI:** Adverse events following immunization (AEFI)

**HvPI:** Haemovigilance (ADR of Blood or blood product )

**PvPI -RNTCP:** (ADR of Antitubercular drugs)

**PvPI - NACO:** (ADR of ARV drugs)

**MvPI:** Materiovigilance: (ADR associated with medical devices)

Individual Case Safety Reports (ICSR) collected by AMC (Adverse drug reaction Monitoring Center) and communicated to NCC-IPC during 2020-21

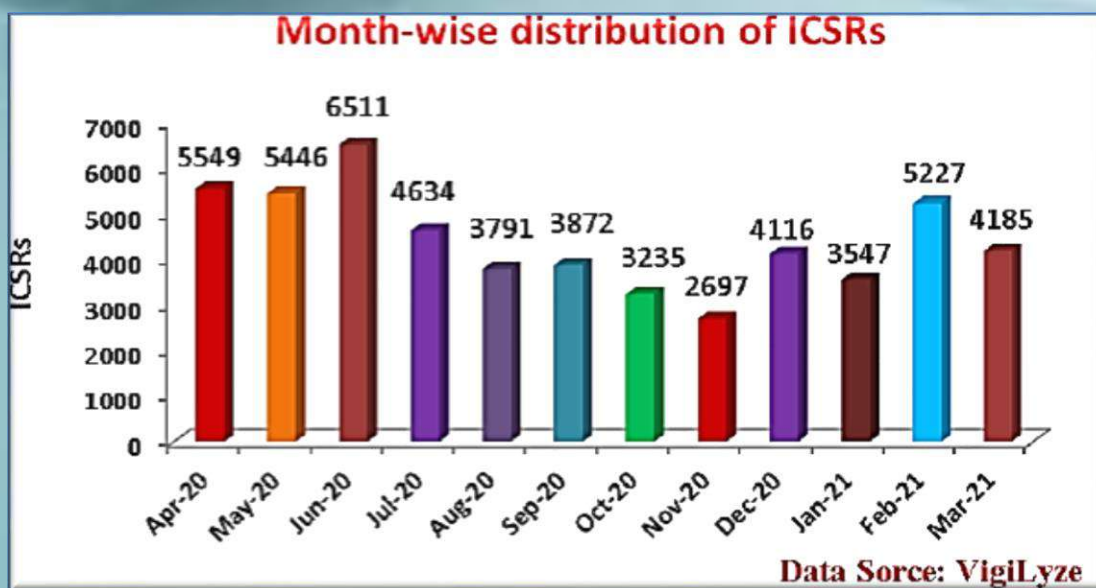


Figure: Pharmacovigilance programme of India, performance Report 2020-2021, IPC

## How to report ADR?

## Who, Where and What to report about ADR?

### Who can report ADR?



### Where to report ADR?



### What to report?

All the types of ADR associated to drug, vaccine, medical device whether...

- Known/ Unknown
- Serious/Nonserious
- Frequent/ Rare
- Should be reported to AMC/ NCC- IPC

**Essential information needs to report about ADR:**

- Patients' information
- Suspected ADR
- Suspected medications
- Reporter's information



**Reported Information remains**



- 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

**No legal action can be taken against reporting doctor**

### Take Home Message



*Let's join hands for safe use of medicine and better patient care*

**Do reporting of ADR and communicate to the Department of Pharmacology AIIMS, Rajkot**

### **ADR reporting form**

**[https://www.ipc.gov.in/images/ADR\\_Reporting\\_Form\\_1.4.pdf](https://www.ipc.gov.in/images/ADR_Reporting_Form_1.4.pdf)**

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# Drug Alert

Drug safety alert issued by CDSCO (2021-22)

<b>Drug</b>	<b>Adverse Drug Reaction</b>	<b>Date</b>
Cephalosporin	Fixed drug eruption	17 <sup>th</sup> March, 2022
Losartan	Muscle spasm	28 <sup>th</sup> February, 2022
Ibuprofen	Fixed drug eruption	18 <sup>th</sup> January, 2022
Dimethyl Fumarate	Alopecia	30 <sup>th</sup> September, 2021
Cefazoline	Acute generalized exanthematous pustulosis	30 <sup>th</sup> September, 2021
Hydroxyzine	Photosensitivity reaction	1 <sup>st</sup> March 2021



## New Drug Releases and Recent Advances

### MARALIXIBAT CHLORIDE

- Reversible inhibitor of the ileal bile acid transporter (IBAT) and decreases the reabsorption of bile acids (primarily the salt forms) from the terminal ileum.
- Indicated for the treatment of **cholestatic pruritus in patients with Alagille syndrome (ALGS)** 1 year of age and older.

### MITAPIVAT SULFATE

- Pyruvate kinase activator that acts by allosterically binding to the pyruvate kinase tetramer and increases pyruvate kinase activity.
- The RBC form of pyruvate kinase (PK-R) is mutated in PK deficiency, which leads to reduced ATP, shortened RBC lifespan, and **chronic hemolysis**. (due to altered PK-R)

### PACRITINIB

- Oral kinase inhibitor(JAK2>JAK3 and TYK2) modulating the hematopoiesis and immune function
- Treatment of adults with intermediate or high-risk primary or secondary (post- polycythemia vera or post-essential thrombocythemia) **myelofibrosis** with a platelet count below  $50 \times 10^9 /L$

### DARIDOREXANT HYDROCHLORIDE

- Orexin receptor antagonists (OX1R and OX2R)
- Treatment of adult patients with **insomnia** characterized by difficulties with sleep onset and/or sleep maintenance.

# Quiz



## Buzz your brain..... Who am I ???



Identify the ADR and causative drug.....



1. A 40-year-old male patient presented with the changes in the nail bed as shown in image after taking treatment. The likely drug would be.....
- a. Furosemide
  - b. Thiazide
  - c. Sulfonamide
  - d. Atropine

2. Changes in the eye were observed in a female patient who presented to the ophthalmology outpatient department after taking a prolonged drug therapy. Culprit drug would be?

- a. Atenolol
- b. Mefloquine
- c. Vigabatrin
- d. Artesunate

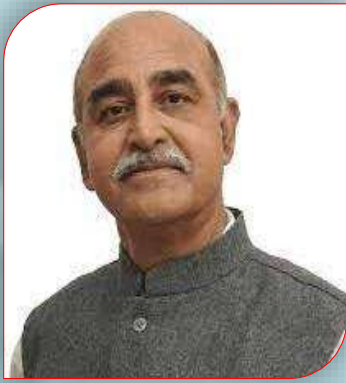


3. A patient presented with the skin reaction shown in the figure after taking a drug. Identify the culprit drug....

- a. Omeprazole
- b. Tetracycline
- c. Salbutamol
- d. Sumatriptan

Answers:

- 1) Nail bed changes – Thiazide
- 2) Central serous retinopathy – Vigabatrin
- 3) Toxic Epidermal necrolysis - Tetracycline



### Message from Executive Director.....

"I heartily congratulate the department of pharmacology for bringing this informative newsletter on clinical pharmacology and therapeutics. My best wishes to the entire team....."

Dr. (Col) CDS Katoch, Executive Director, AIIMS, Rajkot.

## Team Pharmacology



This is an effort to bring forward important information on Clinical Pharmacology and Therapeutic advances. This initiative will definitely be useful for medical practitioners and all readers for effective, safe and rational use of medicines. We hope you enjoy reading this e-bulletin!

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