Reporting of Adverse Drug Reactions (ADRs)

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POINTS OF DISCUSSION

- ***What is ADRs***
- ***What is Pharmacovigilance.***
- ***Pharmacovigilance Programme of India (PvPI).***
- ***How to report ADRs.***

Adverse Drug reaction (ADR)

According to WHO (1972): A response to a drug which is noxious and unintended, and which occurs at doses normally used for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function.

Classification of ADRs.

- ***Minor ADRs*: No therapy, antidote or prolongation of hospitalization is required.**
- ***Moderate ADRs*: Requires change in drug therapy, specific treatment or prolongs hospital stay by at least 1 day.**
- ***Severe ADRs*: Potentially life threatening, causes permanent damage or requires intensive medical treatment.**
- ***Lethal*: Directly or indirectly contributes to death of the patient.**

SIDE EFFECTS:

Unwanted but often unavoidable, **pharmacodynamic effects** that occur at therapeutic doses. Predicted from the pharmacological profile of a drug

E.g.

Based on therapeutic effect: Atropine (preanaesthetic): dryness of mouth.

Based on a different action: Promethazine (anti-allergic): sedation.

What is Pharmacovigilance ?

- Pharmakon (Greek) = Medicinal Substances
- Vigilia (Latin) = To keep watch

WHO Definition

- The science & activities relating to the detection, assessment, understanding & prevention of adverse effects or any other drug related problems

Pharmacovigilance Programme of India (PvPI)

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

Vision

To improve patient safety and welfare of Indian population by monitoring the drug safety.

Mission

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

Objectives

- To create a national-wide system for patient safety reporting
- To identify and analyze new signal from the report cases
- To analyze the benefit-risk ratio of marketed medications
- To generate evidence based information on safety of medicines
- To support regulatory agency in the decision-making process on use of medications
- To promote rational use of medicine

ADVERSE DRUG REACTION MONITORING CENTRE (AMC)

All MCI approved teaching hospitals (Government and Non government) established as AMCs under the PvPI.

Total number of AMCs in India till now is **346.**

Regional centers **4.**

REGIONAL CENTERS UNDER PvPI:

Eastern Region: IPGMER, Kolkata
Western Region: KEM Hospital, Mumbai
Northern Region: PGIMER, Chandigarh
Southern Region: JSS Hospital, Mysore

Scope.....

Continuous monitoring of ADR.

Re-assessing and updating benefit/risk profile through periodic safety update reviews (PSUR).

Develop risk evaluation & mitigation strategies by adding information in the prescribing leaflet

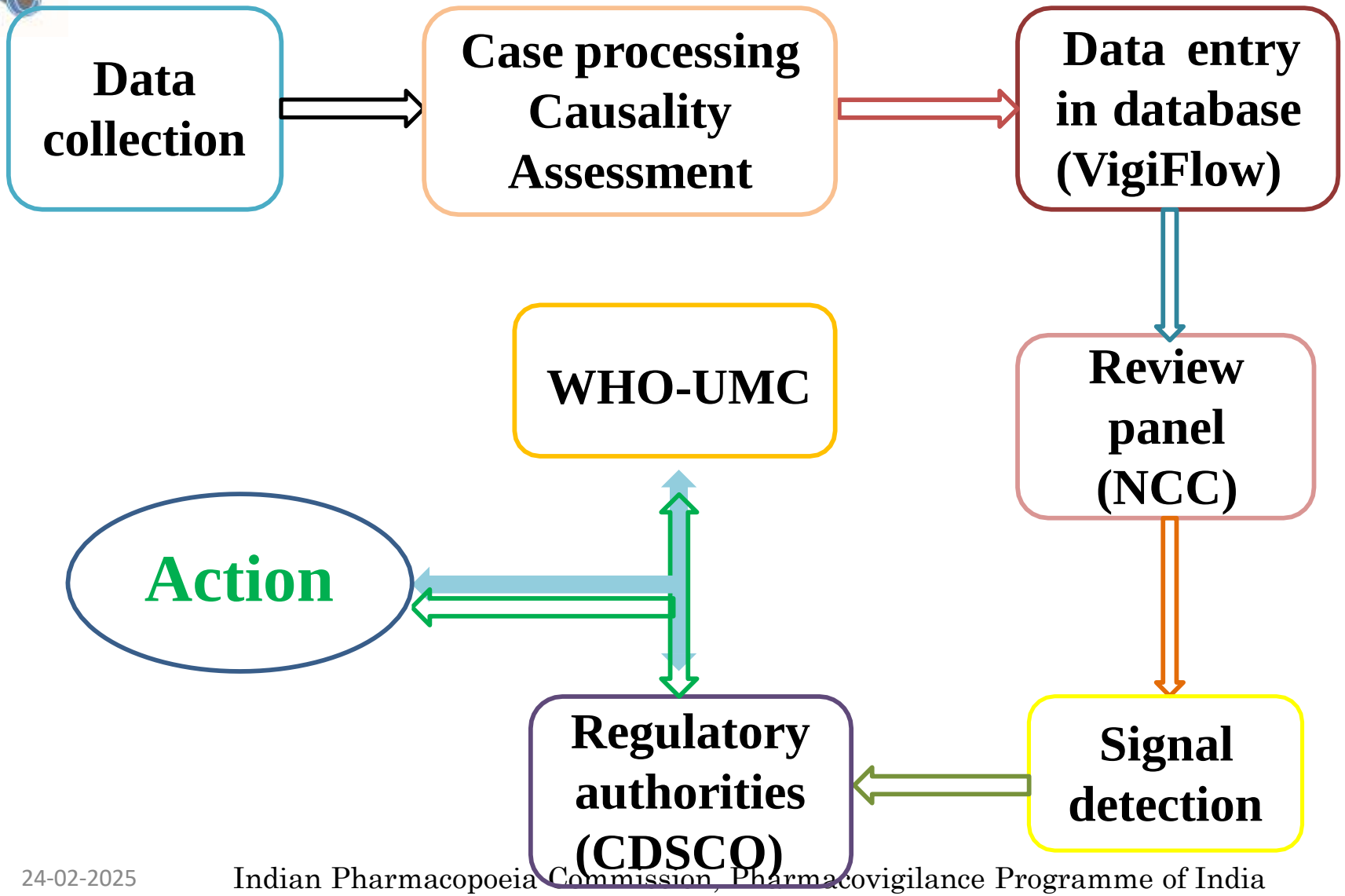
- ❑ Black box warning
- ✓ Restriction of use in categories of patients
- ❖ Withdrawal of drugs

Monitoring safety of:

- **Drugs-** Pharmacovigilance
- **Blood and blood products-** Haemovigilance
- **Medical Devices-** Materiovigilance
- **AEFI**—Adverse event following immunisation

Prevent and minimize antimicrobial resistance

Pharmacovigilance Work flow



Version 1.4

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of ADRs 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

PvPI Helpline (Toll Free) :1800-180-3024 (9:00 AM to 5:30 PM, Monday-Friday)

Initial Case ☐ Follow-up Case ☐

A. PATIENT INFORMATION *

1. Patient Initials:
2. Age or date of birth:
3. Gender: M ☐ F ☐ Other ☐
4. Weight (in Kg.)

B. SUSPECTED ADVERSE REACTION *

5. Event / Reaction start date (dd/mm/yyyy)
6. Event / Reaction stop date (dd/mm/yyyy)
7. Describe Event/Reaction management with details , if any

FOR AMC / NCC USE ONLY

Reg. No. / IPD No. / OPD No. / CR No. :
AMC Report No. :
Worldwide Unique No. :

12. Relevant investigations with dates :

13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)

14. Seriousness of the reaction : No ☐ If Yes ☐ (please tick anyone)
☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Disability
☐ Hospitalization-Initial/Prolonged ☐ Other Medically Important

15. Outcome:
☐ 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.	Expiry Date (If known)	Dose	Route	Frequency	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication	Causality Assessment
i											
ii											
iii											
iv#											

9. Action taken after reaction (please tick)

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown
i						
ii						
iii						
iv						

10. Reaction reappeared after reintroduction of suspected medication (please tick)

Yes	No	Effect unknown	Dose (If re-introduced)

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	Route	Frequency (OD, BD, etc.)	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication
i							
ii							
iii#							

Additional Information :

D. REPORTER DETAILS *

16. Name & Address : _____
_____
Pin : _____ Email : _____
Contact No- : _____
Occupation : _____ Signature : _____

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

Signature and Name of Receiving Personnel :

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

Use separate page for more information

* Mandatory fields for suspected ADR Reporting Form

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i											
ii											
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iv#											

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					Date Started	Date Stopped	
i							

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_____

Pin : _____ Email : _____

Contact No- : _____

Occupation : _____ Signature : _____

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\# Use separate page for more information

* Mandatory Fields for suspected ADR Reporting Form

ADR reporting

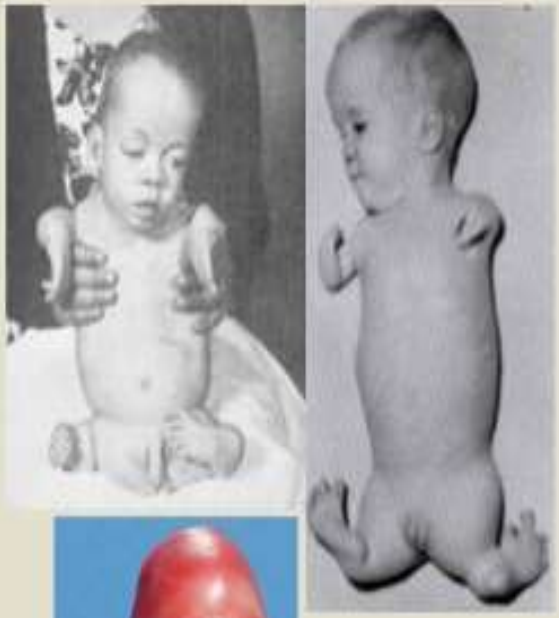
- Why?
- Who?
- What?
- How?
- Whom?

Why ADR reporting

- Leading causes of death in many countries.
- 5% of all hospital admissions in India
- Significant economic burden on the patient.

Importance of Pharmacovigilance

•Thalidomide tragedy (1961-62): The greatest of all drug disasters. Thalidomide had been introduced and welcomed as a safe and effective hypnotic and antiemetic. It rapidly became popular for the treatment of nausea and vomiting in early pregnancy.

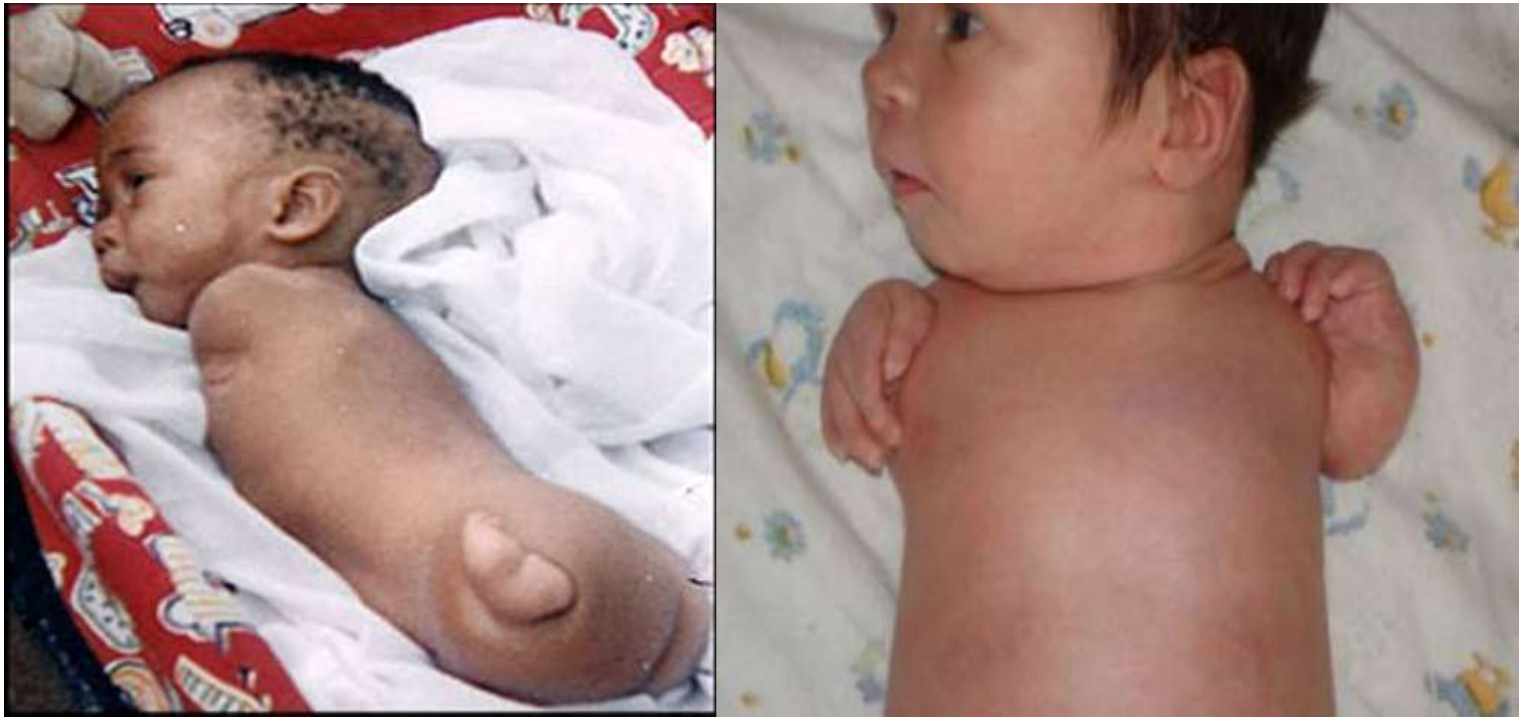


•Tragically the drug proved to be a potent human teratogen that caused major birth defects in an estimated 10,000 children

•Phocomelia was a characteristic feature

Thalidomide Disaster

Thalidomide 4,000 - 10, 000 cases of phocomelia (congenital limb defects) used as antiemetic (morning sickness) in pregnant females (1957-1961)



This lead to withdrawal of the drug from the market

Reporting of Adverse Drug reactions:

Who can report?

- Patients, patients relatives or patient's caretakers.
- Health care professionals (physicians, dentists, pharmacists, radiographers, nurses and any other health care professionals.
- Manufacturers.
- Authorities

What to report

1.All ADR of prescription & non prescription medicinal products

2.All suspected ADRs regardless of product information provided by company

3. Unexpected reaction, regardless of nature or severity

4.A serious reaction whether expected or not

5. Suspected ADR of drug-drug, drug-food & drug-food supplements interaction

6. ADR occurring from overdose or medication errors.

7. Suspected pharmaceutical defects.

Scope of pharmacovigilance has been widened to include :

- Herbals
- Traditional & complementary medicines
- Blood products
- Biologicals
- Medical devices
- Vaccines

Various reporting systems:

- WHO international system
- US FDA " MedWatch"
- UK ' Yellow card' system
- National Pharmacovigilance system: India

How to report?

- Suspected ADR reporting forms for **healthcare professionals.**
- Suspected ADR reporting forms for **consumers.**
- Consumers directly can report to NCC-PvPI through Helpline no

  18001803024

  9920174172---Kims satara

- Through ADR reporting **mobile application** available in Google play store


80%
4:49 PM
"Adverse Drug
Reaction Reporting
Application"
ADR PvPI
Pharmacovigilance Programme of In..
3+
UNINSTALL
OPEN
500
Downloads
4.4
20
Medical
Similar
Adverse Drug Reaction Reporting
Application.
WHAT'S NEW
Improvements for reliability and speed

Whom to report

- Adverse drug reaction monitoring centre(AMC)
- National co-ordination center(NCC)
- Pvpi.ipcindia@gmail.com
- **The submitted ADR report does not have any legal implication on the reporters**

Benefits of ADR reporting

- Early Detection of Adverse Events
- Improved Patient Safety
- Identification of Rare Adverse Events
- Evaluation of Risk-Benefit Profile
- Regulatory Decision Making
- Contribution to Medical Knowledge
- Enhanced Drug Development Process
- Increased Transparency and Public Trust
- Global Collaboration and Information Sharing

- Priyanka nilesh patil a 25 yr old female pt of wt 70 kg was given IVFEROX 1 gm iv on 23rd march 2023 for anaemia.
- After starting inj. Pt.immediately started breathlessness &tightness in chest. Physician stopped transfusion.
- After 15-20 min pt. Became fine.
- Manufacturer—glenmark
- Batch—BIV-23006A
- Exp—4/2025

DRUG SAFETY ALERTS 2020-21

SR NO	SUSPECTED DRUG	INDICATION	ADVERSE REACTION
01	Fexofenadine	In the treatment of relief of symptoms associated with seasonal allergic rhinitis and chronic idiopathic urticaria	Blurred Vision
02	Ambroxol	Anti-tussive - Acute and chronic disease of the respiratory tract.	Fixed Drug Eruption
03	Cefpodoxime	Acute bronchitis, exacerbations of chronic bronchitis, bronchiolitis pneumonia.	Drug Reaction with Eosinophilia Systemic Symptoms (DRESS) Syndrome
04	Clarithromycin	Mild to moderately severe infections like acute exacerbation of chronic bronchitis community acquired pneumonia.	Burning Sensation
05	Omeprazole	Antacid	Dysuria

DRUG SAFETY ALERTS 2020-21

SR NO	SUSPECTED DRUG	INDICATION	ADVERSE REACTION
06	Hydroxyzine	For the management of pruritus due to allergic conditions such as chronic urticaria and atopic contact dermatoses, and in histamine - mediated pruritus.	Photosensitivity Reaction
07	Salicylic Acid	For the treatment of acne vulgaris.	Photosensitivity Reaction
08	Zinc (Acetate/Oxide/Sulphate/Gluconate)	In treatment of acute diarrhoea in children as an adjunct to oral rehydration.	Diarrhoea
09	Pramipexole (Dopamine antagonist)	Idiopathic Parkinsons disease	Photosensitivity Reaction
10	**Hydroxychloroquine Sulphate**	**Off Label drug use as Prophylactic & Treatment of COVID-19 disease**	**Mouth ulceration**

PvPI Recommendation to NRA and CDSCO

SR NO	SUSPECTED DRUG	ADRs	PvPI Actions
01	Carbamazepine	Stevens Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)	For Drug Safety Label Change – Patient may be screened for HLAB*1502 prior to initiating the Carbamazepine treatment
02	Piperacillin and Tazobactam	Hypokalaemia, Bronchospasm	To include in PIL
03	Rota-Virus Vaccine	Intussusception	To include in PIL
04	Rabies Vaccine	Erythema Multiforme	To include in PIL
05	Azithromycin	Acute Generalised Exanthematosus Pustulosis (AGEP)	To include in PIL

PvPI Recommendation to NRA and CDSCO

SR NO	SUSPECTED DRUG	ADRs	PvPI Actions
05	Sodium Valproate	Gum Hyperplasia	To include in PIL
06	Fluconazole	Hyperpigmentation	Signal
07	Diclofenac	Nicolau Syndrome	To include in PIL
08	Amlodipine	Alopecia/ Gingival Hypertrophy	To include in PIL
09	Glibenclamide	Palpitation	To include in PIL
10	Oseltamivir	Sinus Bradycardia/Brady cardia	Signal
11	Quetiapine	Urinary Incontinence	To include in PIL

Dying from a disease is sometimes unavoidable; but dying from a medicine is unacceptable.