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PHARMACOVIGILANCE

Introduction to Pharmacovigilance

- Pharmakon ⟶ In greek ⟶ Drug/Medicinal Substance.
- Vigilia ⟶ In latin ⟶ To keep watch.

Defination → As Per WHO, Pharmacovigilance has been defined as "The Science and Activities relating to the detection, Assessment, understanding and Prevention of Adverse effects or any other drug-related Problem to medicine". (Particularly long term and short term Adrs)

OR

Drug Discovery ++++ Post market surveillance

- As Per the European Commission(EU), "The Science and Process to monitor the Safety of Medicinal drugs and take Action for Increasing the benefits and Reducing Risk of Medicines."

Information Recieved from:
- Health care Providers
- Pharma companies
- Direct Patient

Morbidity ↑sc
Mortility ↓sc

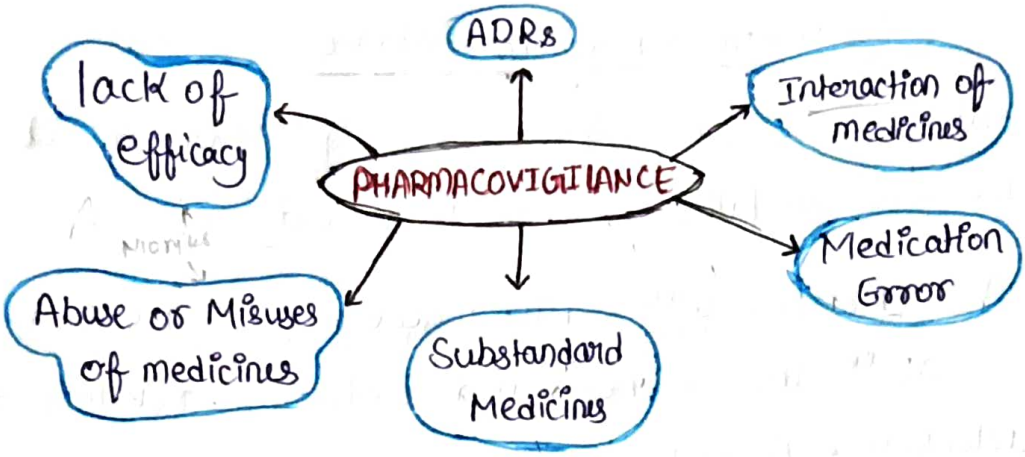
Objects

1. To Improve Patient care and Safety.
2. To Improve Public health and Safety.
3. To Provide medicines and all medicinal and Paramedical Service Safe.
4. To assess, benefit, Risk and effectiveness of medicine.
5. To Promote education and clinical training.
6. To Promote Rational and Safe use of medicines.

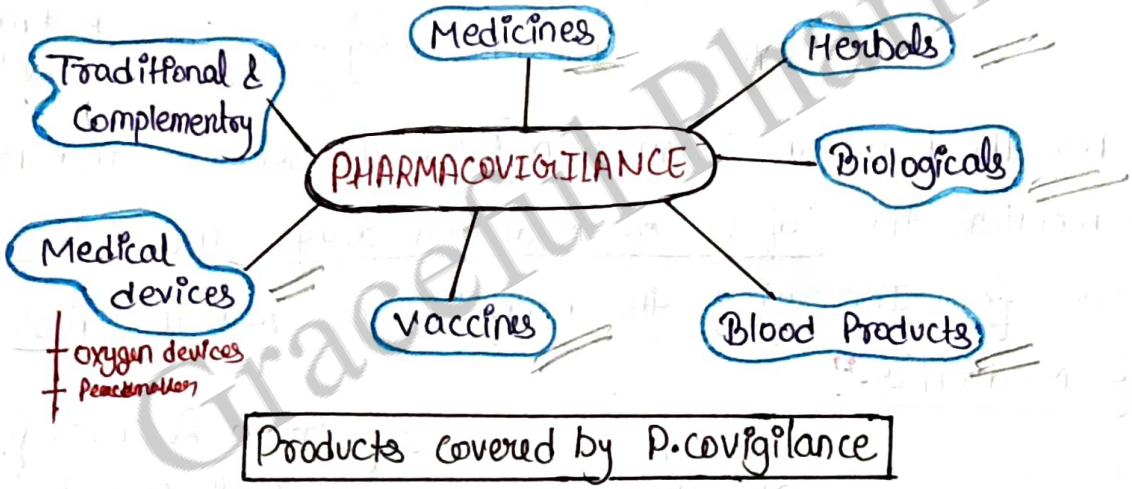
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Scope of Pharmacovigilance :-

PVPI regulated by IPC



In Recent years the scope of P.covigilance has covers not only the conventional medicines, but beyond these -



Products covered by P.covigilance

AIM :-

- To Improve Patient care and Safety.
- To Improve Public health and Safety.
- To Promote education and clinical training.
- To Promote Rational and Safe use of medicines
- To contribute to the assessment of benefit, Harm, effectiveness and Risk of medicines.

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History and Development of P.covigilance

History of PV → During 20th century, they were some Serio Adverse events associated with the Medical Products and drugs that resulted in Pressure on Governmer businesses to Produce legalization and guidance, as well as the evolution of the Regulatory bodies to Protect the Safety of Patients.

:— Chloroform Anesthetic —: (first)

- About 169 Years Ago in 1848 (29 Jan.), A young girl (Hannah Green from the North England died after receiving Chloroform Anesthetic before removal of Infected toenail.
- How ever, Sir James Simpson found that Chloroform was a Powerful and Safer anaesthesia.
- The death of Hannah still remained unknown but the reason being Investigated for her death was found to be Pulmonary aspiration or lethal Arrhythmia.

:—Sulfanilamide Elixir Tragedy —:

- Sulfanilamide elixer was a Raspberry flavor syrup Prepared by mixing Sulphanilamide and Diethylene glycol (DEG 70%). Solvent given to the children.
- In 1937, More than 100 children died after Its consumptic The Reason was the toxic Solvent DIETHYLENE GLYCOL.
- After 1937 Tragedy, Required Safety testing of New drug before their market approval. and that NDA Incorporat Safety data in Simple word. & Introduced the Possibility of Conducting factory Inspection

:— Thalidomide Tragedy —:

- The Idea of Pharmacovigilance took shape mainly after 1961, after the thalidomide tragedy was reported.
- Thalidomide marketed in 1956 in western Germany. was mainly used as a hypnotic/sedative drug and later used in order to manage nausea and morning sickness in Pregnant women.
- The drug was tested in about 300 Patients with out any Prior toxicity studies.
- However, the babies born to these pregnant mother Suffered from major congential Malformation of limbs – PHOCOMELIA (Seal like limbs).
- first Reports of birth defects – 1959.
- 13 reports of birth defects – 1961
- 10000 Infants affected by PHOCOMECIA.

(1) Adr (effect): Any undesirable & unwanted effect of drug administ

(2) Adrs Reaction: Any Response, which is Noxious & unintended, which occurs at doses Normally used in humans

Ex: Proplyaxis, for Diagnosis

(3) Adverse Event: Any untoward (unexpected) medical occurance
- that may Present during treatment with P. Product.
- Does not nessasily have Causual relationship with treatment (No need to have a caused relationship)

Development of Pharmacovigilance

1848 - Hannah's death caused by chloroform.

1937 - USA with the solvent diethyl glycol.

1938 - Federal food, D & C Act was establishment and the Public health system was renovated.

1961 - MC. Bride's letter about the tragedy of thalidomide.

1964 - The Yellow card start by UK Government.

The Yellow card scheme is the main ADR Reporting scheme in U.K. It Recieves more than 20,000 Reports of Possible Side-effects each year.

1965 - European legislation was developed [EC Directive 65165]

1968 - WHO program for International drug Monitoring was Instituted.

1978 - WHO center moved from Geneva to Uppsala

1986 - ADR Monitoring System for India was proposed (12 Regional centers).

1997 - India Joined - ADR Monitoring Programme (3 - centers, AIIMS, KEM HOSPITAL, JLN)

2010 - The P.covigilance Programme of India was Implemented. [finally start in India (PVPI)]

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Importance of Safety Monitoring of Medicine

- An Adverse drug reaction could be any unintended Reaction in Patient's body which occurs as a Result of Administration of drug. 30% death in world
- Drug Safety monitoring (DSM) is a Risk Mitigation Exercise in which the ADRs caused by therapeutic drugs, biologicals or devices can explore or Prevented or Minimized.
- DSM is an essential element for the effective use of medicines and for High quality medical care.

Also Include Pharmacovigilance Portion

Pre-clinical Animal Experiments

↓

Animal Experiments for Acute toxicity, Organ damage, dose dependence, metabolism, kinetics, carcinogenicity, Mutagenicity/Teratogenicity

If Positive

Clinical Studies

↓

PHASE-I

20-50 healthy volunteers to collect Preliminary data

↓

PHASE-II

150-350 Subjects with disease - to determine Safety and dosage Recommendations

↓

PHASE-III

250-4000 more varied Patient grp - to determine short-term Safety and

Spontaneous Reporting

↓

PHASE-IV

Post-approval Studies

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Example of Serious Adverse Reactions

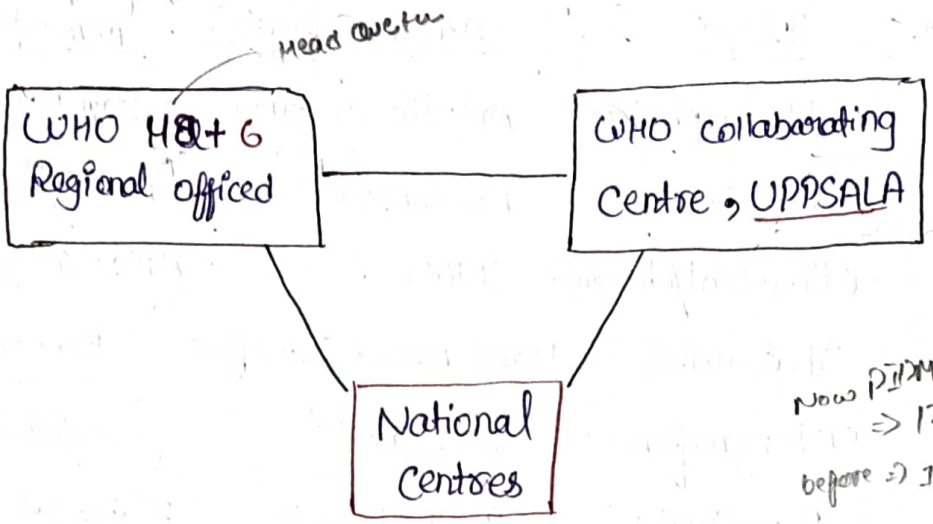
Year	Doug	Adverse effects	Remarks
1950	chloramphenicol	Aplastic anaemia	Still being used
1961	Thalidomide	Phocomelia	National disaster
1970	Clioquinol/Chloroquinine	SMON	After 30 years of use
2012	Sibutramines	Heart Related Side-effect	Banned
1982	Ticrynafen	Hepatatis	withdrawn
1990	Itretinate	Birth defects	High risk of birth defects

Objectives

- Identify unknown Side-effects
- ensure Patient safety.
- Prevent ADRs
- enhance Public health
- Some drugs

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WHO International drug Monitoring Programme



—: The WHO Programme for International drug monitoring Programme (WHO PIDM) is an International collabration of medicines - related Safety Problems.

—: with more than 170 full members and associate members in the Programme in 2022, It covers about 99% of the world's Population.

—: WHO Promote the Pharmacovigilance at country level Initially.

—: The WHO PIDM members consisted of 10 countries, As of March 2022, 151 members have Joined the WHO PIDM.

—: WHO PIDM members Submit the Report of adverse effect associated with medical Product, known as Individual case safety Reports to the Global database. (Regulate)

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WHO Programme Include three Part

1. Uppsala monitoring centre (Sweden)
2. WHO Headquaters (Geneva)
3. National Pharmacovigilance centre from the members Countries.

- WHO PIDM members submit report of Adverse effect associated with Medicinal Products, known as Individual case Safety Reports to the global database Vigibase.

Vigibase → It is the unique WHO global database of report.

↳ **Advisory Committee on Safety of Medical Product (ACSoMP)**

→ The ACSoMP shall Provide advice on P.Covigilance Policy and Issues related to the Safety and Effectiveness of Medicinal Product.

→ WHO Collabrating centre for International drug monitoring (Uppsala Monitoring centre)

→ To the member State of WHO.

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↳ Pharmacovigilance in WHO HQ:-

- Exchange of Information
- Policies, Guidelines,
- Country Support
- Collaboration
- Resource mobilisation.

(1) Exchange of Information →

- National Information officers
- Publication (WHO Pharm. Newsletter, Drug Alerts)
- International conference of drug Regulatory Authorities (ICDRA)

CDSCO

(2) Policies, Guidelines →

- Importance of Pharmacovigilance (2002).
- Safety Monitoring of herbal medicines (2004).
- P.covigilance in Public Health.
- ACSOMP

(3) Country Support :-

- Training courses on P.covigilance (Regional training courses).
- Address specific / Stated Needs; Ebola, ARVs, Antimalarials.
- Annual meeting of Pharmacovigilance centers.

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④ Collaboration :-
- Malaria
- HIV/AIDS
- Vaccines

⑤ Resource Mobilisation :-
- Grates foundations
- European commission
- Global fund
- Others
- Human resources : PVSA.

WHO COLLABORATING CENTRE —: THE UPPSALA MONITORING CENTRE

→ Established as a foundation 1978.
→ UPPSALA Monitoring centre Present in Sweden.
→ It operated by WHO.
→ 124 Countries Jointed to this Programm.
→ International administrative board.
→ WHO Headquarter's Responsible for Policy.
→ Self financing.

ADR

—: functions :-

→ Collect Information of ADR.
Analyze Information of ADR.

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Pharmacovigilance Programm of India (PvPI)

→ It is a Nation-wide Pharmacovigilance Programme.

→ Pharmacovigilance Programme of India (PvPI) was launched in 14-July, 2010. (Most Imp.)

→ India Joined WHO PIDM in 1998.

→ PvPI are managed by IPC (Indian Pharmacopoeia Commiss

→ IPC is an Autonomous Institution of Ministry of Health and family welfare (MHfW), Govt. of India.

→ And working / functioning as National coordination (NCC) Centre for Pharmacovigilance Programm of India.

→ 2010 with AIIMS as NCC for Monitoring ADRs.

—: NCC Responsibilities :—

-∘ Preparing SOPs, Guidance document and training Manual

-∘ ~~Enrol~~ Enrolment of New ADR Monitoring centres (AMCs).

-∘ Reviewing and analysing Individual case Report (ICRs).

-∘ Publisher the PvPI News letter.

-∘ Reporting all concerned Issues to CDSCO HQ.

-∘ Monitor all the ADR (Adverse Reaction) of medicines being observed in Indian Population.

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History of PvPI/Background

- 1986 -: ADR Monitoring System for India start (12-Regional centre)
- 1998 -: India Joined WHO-ADR Monitoring Programme.
  (3-centres: AIIMS, KEM, JLN)
- 2004-2008 -: National Pharmacovigilance Programme (NPP)
  -: NPP officially Inaugurated (Opening) by the central Health Minister at New delhi.
  -: The MHFW is Initated (By one) the NPP coordinated by the CDSCO.
- July 2010 -: The PvPI launched with AIIMS, New delhi as National coordination centre (NCC) for Monitoring ADRs in the country.

Most IMP

- Dr. Surinder Singh, former DCGI (India)
- Relaunching PvPI in India, 14-July/2010.
- He is also Responsible for National Haemovigilance Programm in 2012.

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