Pharmacovigilance – A wake up for
althcare professionals and the publ

Prepared By: Mr. Sagar D. Kadam
Asst.Professor & Admin. Officer

HSBPVT's GOI College of Pharmacy, Kashti.
Tal. Shrigonda, Dist. Ahmednagar.
State: Maharashtra

Pharmacovigilance

WHO defined as 'the pharmacological science and activities relating to th detection, assessment, understanding and prevention of adverse effects o any other drug-related problem'.

An umbrella term used to describe the processes for monitoring an evaluating ADRs is a key component of effective drug regulation systems clinical practice and public health programs.

Adverse reaction as a response to a medicine used in humans or animals which is noxious and unintended, including lack of efficacy, and whic occurs at any dosage and can also result from overdose, misuse or abuse of medicine.

Pharmacovigilance is the study of the safety of marketed drugs examine under the practical conditions of clinical use in large communities

Drug safety and risk

The challenge of maximizing drug safety and maintaining public confidence has become increasingly complex.

Pharmaceutical and biotechnology companies must not only monitor, also proactively assess and manage drug risk throughout a produc lifecycle, from development to post market.

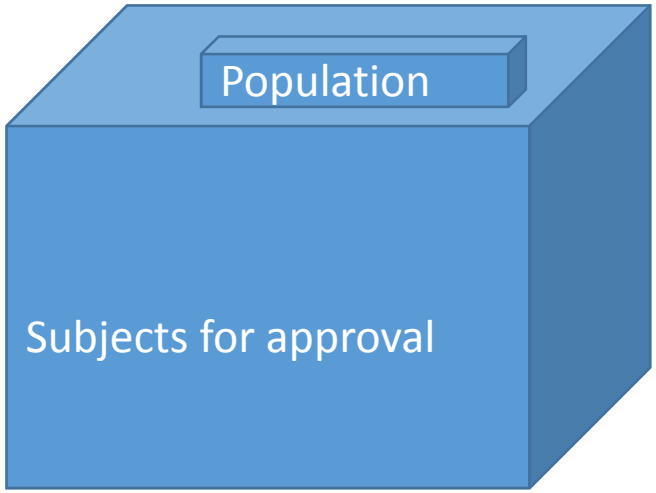


Pharmacovigilance rational

roval Data-
ed-Limited # Pts-
ata not mature

- Post Approval Data
- -Real life ; uncontrolled
- -Off label use -Generic

-Solicited Safety Data
-Unsolicited Safety Da



Pharmacovigilance important?

Drugs appear to be safe and well-tolerated, but the safety in the 'real world' is unclear

- Chronically/repeatedly use of drugs
- Use with other drugs

Safety in vulnerable groups is unknown

- Pregnant women & breast feeding mother, elderly, young children

Significant harm to a few patients, rumours and myths

- can destroy the credibility, adherence to and success of a treatment.

Pharmacovigilance important?

Pharmacovigilance provide evidence

- medicine-related problems : treatment failure, counterfeit/poor quality medicines, drug interactions, incorrect use.

Generate evidence that will inspire public confidence and trust.

Pharmacovigilance systems is strongly recommended

- Is system of reporting exists?
- capacity for monitoring?

Pharmacovigilance –Major Aims

Early detection of unknown safety problems

Detection of increases in frequency

Identification of risk factors

Quantifying risks

Preventing patients from being affected unnecessarily

Pharmacovigilance Partnership



- Safety of medicines is supported by doctors, pharmacists, nurses and other health professionals in the country.

- Studies conducted in developed countries have consistently shown that approximately 5% of hospitalised patients are admitted into hospital as a result of an ADR.

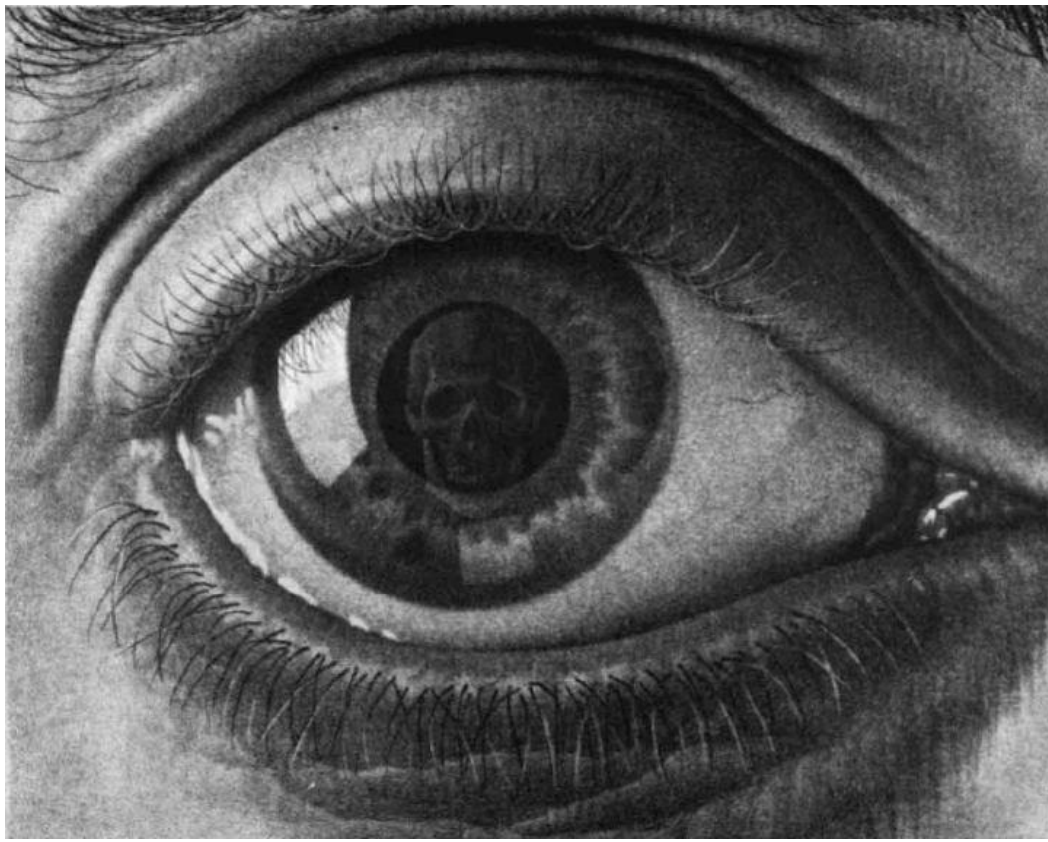
- The information obtained from your reported reactions promotes the safe use of medicines on a local and national level.

- Therefore it is the responsibility of the manufacturer as well as the Drug Regulatory Authority to monitor the performance of these medicines once they are marketed.

Pharmacovigilance Promotes:

Systematic & rational use

Boost confidence for safety



Evolution of Pharmacovigilance…

USA



Diethylenglycol(DEG)



Mistakenly used to solubilize sulphanilamide



107 died

Process in Pharmacovigilance



- **C**ollect and record of AEs / ADRs
- **C**ausality assessment and analysis of ADRs
- **C**ollate and code in database
- **C**ompute risk-benefit and suggest regulatory action
- **C**ommunicate for safe use of drugs among stakeholders

Drugs recently banned in India

- Rosiglitazone
- Sibutramine
- Rimonabant
- Nimesulide (Under 12 years)
- Cisapride
- Phenylpropanolamine
- Gatifloxacin and
- Tegaserod

Additional benefits of ADR monitoring…

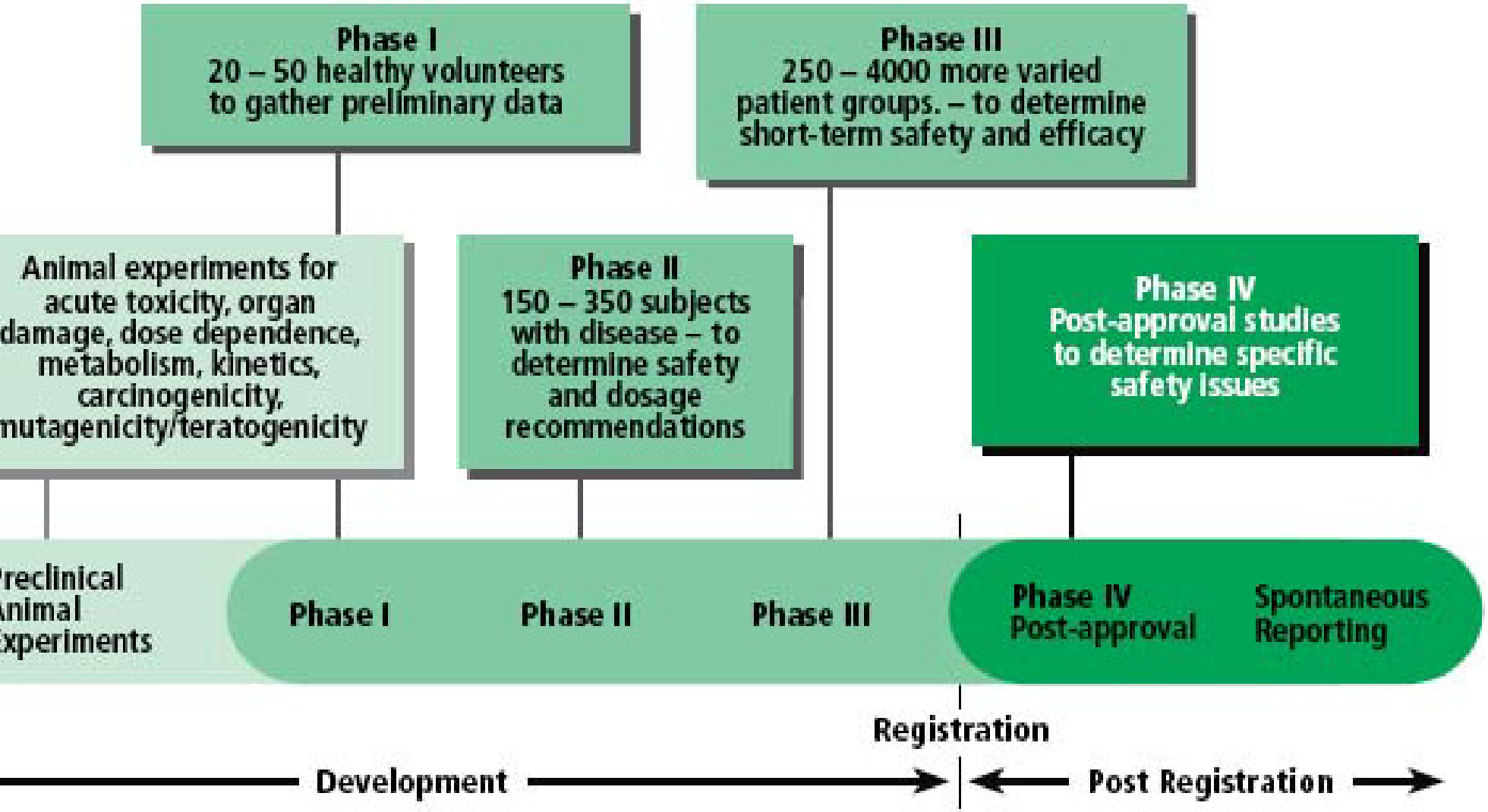
DRUG	ADVERSE EFFECT	USES
Aspirin	GI Bleed	Antiplatelet activity
Minoxidil	Hypertrichosis	Treatment of Alopecia
Sildenafil	Marked penile erections	Erectile Dysfunction
Lithium	Leukocytosis	Leukopenia during cancertreatment
Cannabinoids	Increased appetite	Anorexia and weight

Role of Pharma Company Globally

- Investment in R&D of new compounds
  Commitment to bring new drug to market to enhance patients' health and quality of life
- Strict governance to conduct clinical trials and product development activities
- Conduct relations with patients and healthcare professionals in accordance with ethical and legal principles

Ref: Adams CP, BrantnerVV (2010). Spending on New Drug Development. '*Health Econ. 19: 130–141 (2010)*

harmacovigilance practice in Industry
linical development of medicines



Pharmacovigilance during clinical researc

Adverse events during clinical studies

Submit to regulatory authorities within specified time frame

Notify all investigators and ethics committees

Safety review by independent Drug Safety Monitoring Boards

- Provide annual reports

❑Summary and analysis of all the serious adverse events

❑New safety findings from animal studies

❑Evaluations of benefit and risk

When Product is Marketed

afety reporting is an obligation for companies in Marketing Phase

clude:

- Phase IV Studies (Post authorization studies)
  - Clinical trials (intervene disease management)
  - Pharmacoepidemiological studies (non-interventional or observational

isk Management Plan

eriodic Safety Updates Report (PSUR)

pontaneous Reports

Risk Management Planning (RMP)

RMP : a strategic safety program designed to decrease product risk

Three main elements

- Safety reports in pre-clinical and clinical phases
- Pharmacovigilance Plan -company must indicate how to resolve the uncertainties (e.g., extra studies)
- Risk minimization plan –how the company propose to reduce the severity or frequency of known adverse reactions (e.g., special communication programmes, or educational exercises, registration programmes for patients or pharmacists)

Indicate timelines for those plans

Periodic Safety Update Reports (PSUR)

verview of the safety of the product, including all Adverse Drug Repor

ummary of the worldwide registration and usage status

ctions taken about safety issues

regulatory requirement for authorized medicine

enerated every 6 months for the first 2 years of launch,then annually fo
ears

Spontaneous Reporting

Spontaneous reporting

- Reporting by HCPs (Health Care Professionals)
- Any serious adverse reactions : Legal obligations on the company to report within a specified time frame to the regulatory authority
- Non-serious reactions: included in periodic safety update reports
- Entered on the data base of company and regulatory body

Literature screening on weekly basis

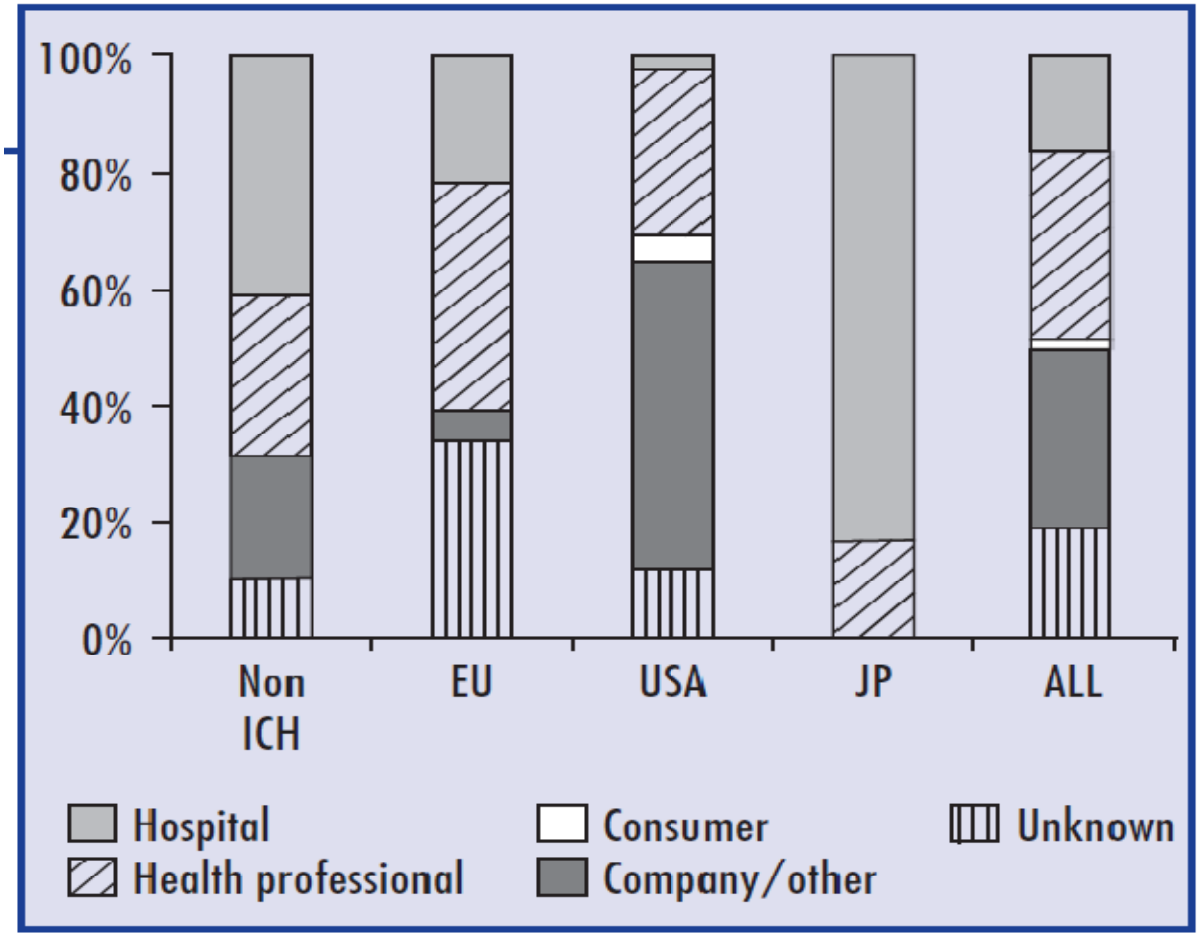
Pharmacovigilance Team at the Company

Each R&D international company has a dedicated Clinical Safety tean for:

- ✓Overseeing the above plans
- ✓Signal detection from ADR reporting
- ✓Perform trend analysis

Local Office of R&D company has dedicated regulatory/medica affairs expert for looking after the local pharmacovigilance plans an coordinating with the global team

Sources of Report at WHO-UMC (Uppsala Monitoring Centre,Sweden)



Source: Drug Information Journal, *Vol. 42, pp. 409–419, 2008*

Number of Medicinal Products

Medicinal Product Records in WHO-DD, March 1, 2006, for the Top 15 Countries

Country	Medicinal Product Records	Product Names	Combination of Ingredients
United States	72,700	9,100	3,800
Puerto Rico	51,900	3,600	1,600
India	40,800	14,500	2,100
Germany	37,400	10,700	5,200
Japan	36,500	15,600	3,600
China	29,000	4,100	1,500
Taiwan, Province of China	24,100	7,700	1,700
UK	24,100	7,400	3,300
Thailand	23,700	7,600	1,600
Pakistan	21,000	6,400	1,300
Russian Federation	20,500	3,800	1,600
Republic of Korea	20,500	7,800	1,800
Netherlands	20,100	3,400	1,900
Brazil	17,100	5,500	1,600
Indonesia	17,000	5,500	1,800

The second and third columns are unique product names and unique combinations of ingredients.

Source: Drug Information Journal, *Vol. 42, pp. 409–419, 2008*

Improving Pharmacovigilance

Increase the awareness of healthcare professionals and the public on th understanding of importance of pharmacovigilance

Develop and promote an effective channel for ADR reporting, such a online reporting system

All the parties involved in pharmacovigilance reporting are coordinate under a platform from BPOM

A centralized database for safety reports to facilitate systematic follow u and detailed analyses

Improve communication among stakeholders in the reporting of advers events such as, the regulator, the health care providers, and manufacturer fo pharmacovigilance

Good Pharmacovigilance Practice (GVP

- Modules
- Pharmacovigilance system and its quality system
- Pharmacovigilance master file
- Pharmacovigilance inspection
- Pharmacovigilance audit
- Risk management system
- Management and reporting of ADR medicinal product
- Periodic safety update report (PSUR)
- Post-authorisation safety studies
- Additional monitoring
- Safety communication

ne ADRs are unavoidable and cannot be prevented hence
d Pharmacovigilance Practice (GVP) should be followed.

ultimate goal of this activity is to improve the safe and rational
of medicines, thereby improving patient care and public health.

s increase in the awareness of importance of Pharmacovigilance
ealthcare professionals and the public is needed.


THANK
YOU