WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.084
Volume 10, Issue 1, 466-471. Review Article ISSN 2277– 7105

INTRODUCTION TO PHARMACOVIGILANCE

Kalyani Dhamal*, Omkar Bhalekar, Phadke Pragati, Gadade Aarti and Durgude Vishakha

LSDP College of Pharmacy, Mandavgan Pharata, Tal-Shirur, Dist-Pune, Maharashtra 412211.

Article Received on
01 Nov 2020,

Revised on 21 Nov. 2020,
Accepted on 11 Dec. 2020

DOI: 10.20959/wjpr20211-19443

***Corresponding Author**
Kalyani Dhamal
LSDP College of Pharmacy, Mandavgan Pharata, Tal-Shirur, Dist-Pune, Maharashtra 412211.

ABSTRACT

Pharmacovigilance (drug safety) is pharmacological science deals with study of collection, detection, assessment, monitoring, prevention of adverse effect of pharmaceutical product. Generally PV focus on to increase the benefit by reducing the side effects. Any drug or pharmaceutical dosage form related adverse effects from patients to pharmacovigilance provided via healthcare providers/profession. Every company needed a Qualified Person For Pharmacovigilance (QPPV) for to ensure that company meets own legal obligation for monitoring product safety on market. The history of pharmacovigilance was started 170 years ago, 29Jan 1848. In England a little baby (Hannah Greener) was died taking chloroform as anesthetic before removal of infected toenail. The origin of pharmacovigilance in India goes back to 1986, but nothing but happen until 1997. In 2005 WHO sponsored the national pharmacovigilance programmed for INDIA, Central Drug Standard Control Organization (CDSCO), New Delhi. Current status of PV in India accepted as a continuous process for to improve safety of medicines including pharmaceutical companies, regulatory authorities, healthcare profession, and patients.

KEYWORLD- Pharmacovigilance, CDSCO, QPPV, healthcare profession.

INTRODUCTION

Pharmacovigilance is defined as by “European Commission”, Process and science of monitoring safety of medicine and taking the steps to reduce risks associated and increase benefits associated with it. Pharmacovigilance is derived from Greek word pharmakon (drug), vigilare (to keep watch). Pharmacovigilance (PV) also known drug safety, is heart of clinical research. Safety of clinical trial and post marketing pharmacovigilance are important

part of product lifecycle. Once the drug launched in market without any safety report, it is less effective and harmful. Every drug associated with adverse effect, serious adverse effect, suspected unexpected serious adverse effect. The serious adverse effects causes patients death, birth defect, life threatening effect, hospitalization, congenital anomaly, significant disability. The role of pharmacovigilance in day to day life is to determine which adverse events cross the line of drugs efficacy. The process of PV start when any patients complaint he/she got some adverse effects while taking our company product. Reporter can anyone of below-: Doctors, medical staff, medical representative, pharmacovigilance executive, medical advisory team, patients or patients relative.

History of pharmacovigilance in india

From the ancient time of ayurveda pharmacovigilance very well known to people. In 700BC Charak Samhita give idea improper use of drug is like a poison. In 500AD, Vagbhatta a physician describe adverse effects, contraindication, delay ADR to ayurvedic drugs. Several cases of adverse effects found in India, but no systematic effort of ADR. In 1986, ADR monitoring system consist of 12 centers with each center has 50million population. In 2005, National pharmacovigilance programmed launched in India. later it renamed as Pharmacovigilance programme of India (PVPI) in 2010. New Delhi as national coordination center for monitoring adverse drug reaction. For more safeguard implementation of programme, national coordination center was shifted from All India Institute for medical science (ALLMS), New Delhi to Indian pharmacopoeia commission, Ghaziabad on 15 April 2011. pharmacovigilance in India organised by Indian pharmacopeia commission and conducted by Central drug standard control organization(CDSCO).

Scope and Objective of pharmacovigilance

1. To create national wide system for patient safety monitoring.
2. To analyze benefit ratio of marketed formulations.
3. To identify and analyze new signal from reported cases.
4. To generate information regarding to safety of medicines.
5. To support regulatory agency in decision making related to medicines.
6. To provide national training and regulatory support to other national pharmacovigilance programme centers.

The various country with their pharmacovigilance regulatory authorities are below

Country	Regulatory authority
India	Central drug standard control Organization (CDSCO)
USA	Food and drug administration (FDA)
UK	Medicines and healthcare product regulatory agency (MHRA)
Australia	Therapeutic goods administration (TGA)
Canada	Health canada
Europe	European medicines agency (MPA)
Italy	Italian pharmaceutical agency
China	State food and drug administration
Sweden	Medical product agency (MPA
Pakistan	Drug control organization ministry of health
Thailand	Ministry of public health
Japan	Ministry of health labour and welfare (MHLW)
South Africa	Medicines control council
Shrilanka	SPC ministry of health
Brazil	Agencia national de vigiloncia Sanitaria (ANVISA)
Germany	Federal institute for drugs and medical devices
Malaysia	National pharmaceutical control bureau, ministry of health
Switzerland	Swiss agency for therapeutic products
Uganda	Uganda national council for science and Technology (UNCST)
Sweden	Medical product agency (MPA)

The various terminology used in pharmacovigilance

1. Active substance

Any substance or mixture of substance intended to be used in manufactured of medicinal product.

2. Adverse event

Any unfavorable /unintended sign, symptoms associated with use of medicinal product.

3. Adverse drug reaction

A drug response which is noxious and unintended when used in patients diagnosis and treatment or for modification of physiological function.

4. Audit

A clearly documented verifiable evidence used to access implementation and appropriateness, operation of pharmaceutical system.

5. Audit finding

Evaluation of collected audit evidence against audit criteria.

6. Causality

A method of finding relationship between drug exposed and reported adverse drug reaction.

7. Clinical trial

Type of research which studies new tests and treatment and evaluates their effects on human health outcomes.

8. Company core data sheet

A document prepared by marketing authorization holder containing safety information, material, dosing, pharmacology and other information of marketed product.

9. Complete clinical trial

Final report of clinical trial is available.

10. Consumer

A person may or may not be actual consumer of health care, but all the member pf general public are consumer.

11. Development international birth date

Date of first approved for conducting an international clinical trial in any country.

12. Direct healthcare professional communication

An important information is delivered directly to individual healthcare profession by marketing authorization holder to inform them need to take certain action in relation to medical product.

13. Drug

A medicine or substance which show physiological effect when ingested or introduced in body.

14. Drug interaction

A change in action of drug when administered with food, beverage or any other supplement.

15. Excipient

An inactive substance that act as medium or vehicle for drug or active substance.

16. Generic drug

A pharmaceutical drug that contain same chemical substance as a drug that originally protected by chemical patent.

17. Good manufacturing practices

A system that ensure products are produced and controlled by there quality standard.

18. Good pharmacovigilance practices

A set of measure that drawn up to facilitate the performance of pharmacovigilance in European union.

19. Healthcare profession.

A medically qualified person such as doctors, pharmacist, dentist, nurses, other specified local regulation.

20. Immunity

Ability of organism to resist a particular infection by action of particular toxins.

21. Individual case safety report

An adverse event report for individual patients and source of data in pharmacovigilance .

22. Meddra coding

A terminology for coding all medical information obtained during all phases of development and marketing.

23. Medical device

24. Any device intended to use for medical purpose.

25. Medication error

Any unintentional error in, dispensing, prescribing, administration of medical product.

26. Off label use.

Any situation where drug used only for medical purpose not for marketing authorization.

27. Overdose

Any drug or substance ingested more than recommended.

28. Risk benefit analysis

Analysis that quantify risk and benefits.

29. Serious adverse event

Any untoward medical occurrence that causes patients death ,is life threatening require patients hospitalization.

30. Signal management in pharmacovigilance

A set of activities give idea about any new risk associated with particular drug

31. Unexpected adverse drug reaction

Adverse drug reaction whose nature, severity, specificity ,outcome not concern with particular drug.

32. Validated signal

A signal validation process that verify available documentation contain sufficient evidence that demonstrating existence of new aspect of association and analysis of further signal.

DISCUSSION

Pharmacovigilance is also known drug safety, both are function as gathering and reporting adverse drug reaction. So its important to check the safety and efficacy of every drug before launched to market. PV is important part of clinical research.

CONCLUSION

Pharmacovigilance is based on qualitative and quantitative study of spontaneous adverse drug reaction report, followed by clinical assessment with regard to no impact on overall safety profile of drug.

ACKNOWLEDGMENT

More thanks to my all teachers and friends for their huge support and also thanks to google to.

REFERENCES

1. Kumar A: past, present, future of pharmacovigilance in India, systematic review in pharmacy, 2011; 2: 1.
2. The Erice declaration: on communicating drug safety information, 1998; 7: 191.
3. www.google.com.
4. WHO pharmacovigilance defination, 2002.
5. Aronson JK, Louis lewin -meylers predecessor edi-1, side effects of drug annual, 2004; 27.
6. Code of federal regulations, title revised as April, 2019; 21: 312-32.
7. Hamburg MA, innovation, regulation and FDA N Engl J med, 2010; 363(25): 2228-32.
8. What introductory guide, medDRA version, 2017; 201.
9. M. Aylin aricl, ayse gelal, yucel demiral, yesim tuncok, Indian journal of pharmacology, august, 2015; 47(4): 436-9.
10. Pushpraj p Gawai, introduction and evaluation of pharmacovigilance for beginners, Int J Sci Rep, 2020; 6(10).
11. www.wikipedia.org.