WWW.IJRPR.COM

International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

Risk Management of Pharmocovigilance

Ms.Vrushali Kakade [1] , Ms.Nandini Hotkar [2] , Dr. Vijaysinh Sable [3] ,Dr.Rani Mhetre [4]

(Author [1] , Guide [2] , Principal [3] , Vice- Principal [4])

ABSTRACT -

Risk management in pharmacovigilance is an important method for guaranteeing the safety and efficacy of pharmaceutical products throughout their lifecycle. It entails the systematic identification, assessment, mitigation, and communication of the dangers associated with drug use. Risk Management Plans (RMPs) are essential to this procedure because they outline safety standards, pharmacovigilance activities, and risk reduction initiatives. Signal identification, causality assessment, benefit-risk evaluation, and risk minimization methods are all essential components. Continuous monitoring, regular re-evaluation, and adherence to regulatory criteria are required to maintain an ideal benefit-risk profile, which protects the public from potential side effects while optimizing pharmacological therapeutic advantages. Risk management in pharmacovigilance is critical to assuring drug safety and efficacy. It includes detecting, assessing, and reducing associated risks. This process is governed by Risk Management Plans (RMPs), which comprise safety standards, pharmacovigilance tactics, and risk-reduction initiatives. Continuous monitoring, signal identification, and benefit-risk assessments are all necessary components. The goal is to balance a drug's benefits against its possible hazards, guaranteeing patient safety through constant monitoring and regulatory compliance. Key word: Adverse Drug Reaction, Pharmacovigilanc Risk Factors, and Pharmacovigilance Objective

Introduction -

Pharmacovigilance(PV) began in 1961, when Dr. W. McBride linked thalidomide to deadly malformations. The World Health Organization launched the "Programme for International Drug Monitoring" in 1968 with the goal of centralizing worldwide adverse drug reaction data and identifying early PV signs. PV, which was coined in the mid-1970s, refers to actions that focus on analyzing the risks associated with pharmacological therapy and recognizing probable adverse effects. Pharmacovigilance (PV) is the systematic process of acquiring, monitoring, investigating, evaluating, and interpreting data from healthcare practitioners and patients about the harmful effects of various medical goods. This comprises drugs, biological and blood products, herbs, vaccinations, medical devices, and traditional treatments. The major purpose is to detect potential dangers linked with these items, in order to uncover new information and protect patients from injury. Pharmaceutical and biotechnology businesses face a difficulty in keeping public trust while assuring drug safety in today's complicated landscape. (The basic goal of post-marketing pharmacovigilance is to detect signs of probable adverse drug reactions (ADRs) as soon as feasible.

Objective -

To determine whether data mining in a pharmacovigilance database can be used to uncover known and potentially novel risk factors for ADRs in pharmacovigilance practice. The study used bleeding events caused by DOACs as a test model. Pharmacovigilance strives to demonstrate pharmacological efficacy by long-term monitoring, assuring public health and safety, promoting safe and cost-efficient drug usage, supporting pharmacovigilance education, and enabling effective communication. The goals also include delivering information to consumers, practitioners, and regulators, as well as developing mechanisms for collecting and analyzing reports from patients and physicians. Improve patient well-being and safety when administering drugs and performing any medical or paramedical treatments. Drug effectiveness research include determining how well a drug works, beginning with laboratory testing and progressing to pharmacy distribution and long-term adverse effect monitoring. This comprehensive study covers everything from original development to years of post- market observation. Pharmacovigilance is the monitoring and reporting of severe or notable side effects caused by medications. Enhance the public's well-being and safety when using pharmaceuticals. Evaluate the benefits, drawbacks, efficacy, and hazards of medications to encourage their safe, logical, and efficient use, with a focus on cost effectiveness.

Role of Management of Pharmacovigilance -

Pharmacogenomics(PGx) blends classic pharmaceutical sciences like biochemistry with detailed insights into genes, proteins, and specific genetic variations (SNPs). It focuses on understanding how genetic differences impact how individuals respond to drugs, connecting gene expression or SNPs with a drug's effectiveness or potential side effects. The goal of PGx is to create informed approaches for tailoring drug therapy based on a patient's genetic makeup, aiming to maximize effectiveness while minimizing adverse reactions. These methods aim to bring about "personalized medicine,"

tailoring drugs and combinations based on an individual's specific genetic traits. Pharmacogenetics (PG) evolved from studying rare, often coincidental extreme reactions observed in people—either due to inherited conditions or unusual responses to drugs or environmental factors. Research in PG (Pharmacogenomics) and PGx (Pharmacogenetics) continues to evolve, with ongoing refinement and exploration in both areas Each approach represents an iterative process, suggesting that there are continuous cycles of investigation and enhancement. Within these processes, there exists ample space for identifying opportunities to improve and optimize the translation of findings into practical applications. Pharmacovigilance plays a crucial role in promptly detecting and assessing risks associated with drugs. Before widespread approval for post-marketing surveillance, medications undergo testing on a limited population. Pharmacovigilance involves identifying, quantifying, and documenting drug-related issues, contributing to minimizing risks in healthcare systems. It also enhances understanding of factors and mechanisms behind drug related injuries. To effectively carry out the different responsibilities within pharmacovigilance, collaboration and input from various influential stakeholders in society are essential

History of Pharmacovigilance in India -

In 1986, a formal adverse drug reaction (ADR) monitoring system of 12 regional centers servicing a 50 million-person population was planned for India, marking the beginning of pharmacovigilance in that country. But nothing noteworthy happened until 1997, ten years later, when India became a member of the Uppsala, Sweden-based World Health Organization's (WHO) Adverse Drug Reaction Monitoring Programme. Due to its failure, the World Bank-funded and WHO-sponsored National Pharmacovigilance Program for India was launched on January 1, 2005 (Garlapati and Nagandla 2015). The National Pharmacovigilance Advisory Committee, based at the Central Drugs Standard Control Organization (CDSCO) in New Delhi, was tasked with overseeing the National Pharmacovigilance Program, which was established in January 2005.Information was to be gathered nationwide and sent to the Committee and the Uppsala monitoring center in Sweden by two zonal centers: the South-West zonal center (housed in the Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai) and the North-East zonal center (housed in the Department of Pharmacology, AIIMS, New Delhi). Two regional centers would report to the New Delhi center, and three would report to the Mumbai center. Reports from numerous peripheral centers would be sent to each regional center. There are 26 peripheral centers at the moment. There are three main goals for the program. Preda (2013).

Aim of Pharmacovigilance

The primary goals of pharmacovigilance have been outlined for human drugs (Stephens, 2000) , and these can be easily adapted for veterinary pharmaceuticals:

1.Detection and measurement of previously unknown adverse medication responses.

2.Identification of patient subgroups at higher risk of adverse medication reactions, such as those based on species, breed, age, gender, physiological status, and underlying disease.

3.Continuous monitoring of a product's safety in each species for which it is approved, to ensure that the risks and benefits are appropriate. This should include expanding monitoring to new
indications and species.

4.Comparing the adverse reaction profile to other drugs in the same therapeutic class, both within and between species.

5.Detection of inappropriate prescription and administration; for the latter, administration by certain groups, such as farmers or the general public, may require monitoring.

6.Additional research into a drug or product's toxicological, pharmacological, or microbiological qualities in order to better understand, if possible, the causes driving adverse drug responses.

7.Detection of drug interactions. This is especially crucial for new pharmaceuticals that are provided alongside current goods or even other new drugs.

8.Provide adequate information on adverse drug reactions and drug-drug interactions to
veterinarians and others involved in animal therapy, such as farmers and other animal owners.

9.The adverse impact of veterinary medical products on the environment and its organisms.

10.A violation of the authorized residue limits for veterinary medicines in animal-derived foods such as meat, milk, and honey.

11.Legislation and rules that control pharmacovigilance requirements (Elhassan, 2015).

Adverse Drug Reaction -

When a person takes a standard dose of medication, there is a potential that the drugs can cause harm to the patient, which is known as an adverse reaction. An adverse drug reaction (ADR) differs from a side effect. Assessing ADRs is very important in pharmacovigilance.

1.Unlisted/unexpected Adverse Drug Reaction

An adverse reaction is an unexpected or severe response to a medicine that does not correspond to the information supplied during clinical trials. It highlights differences between the actual nature or strength of the drug's effects and the information known at the time the trials were done. Creating an investigator's brochure for an unapproved medicine entails summarizing important information about its safety and efficacy. Make careful to incorporate preclinical and clinical data, study objectives, and possible dangers. Consult the regulatory guidelines and work with specialists to deliver technical information in a clear and concise manner.

2.Listed/Expected Adverse Drug Reaction

Adverse medicine Reactions (ADRs), including the nature, intensity, and specificity of the medicine, have already been documented or translated into accessible language.

Classification of ADR

Pharmaceutical Classification

Type A (Augmented)

The most common type of adverse drug reaction (ADR), accounting for up to 80%, is foreseeable due to pharmacological causes. Examples include hypoglycemia caused by insulin or oral hypoglycemics, hypotension caused by beta-blockers, and NSAID-induced stomach ulcers. These ADRs are dose-dependent, which means they become more severe as the dosage increases. Most of these reactions can be avoided by progressively introducing low doses. Adverse Drug Reactions (ADRs) such as aplastic anaemia from halothane, hepatitis from chloramphenicol, and neuroleptic malignant syndrome from certain anaesthetics and antipsychotics may not be expected based on established pharmacological principles. These responses occur regardless of the dose provided.

Type C (Continuous drug use) ADR, or Adverse Drug Reaction, can occur after taking medication for an extended period of time. This type of ADR may be irreversible and unexpected, such as dementia caused by anticholinergic drugs

Type C (Chronic)

Characteristics: Refers to long-term drug use and may be dose-related. These responses usually occur after lengthy treatment.

Examples: Long-term corticosteroid use can lead to osteoporosis.

Type D (delayed)

ADR, or Adverse Drug Reaction, refers to side effects that appear after therapy has finished, such as ophthalmopathy from chloroquine or pulmonary/peritoneal fibrosis from thioridazine. One example is corneal opacities that develop after thioridazine treatment.

Type E (end of dosage)

Adverse Drug Reactions (ADRs) sometimes involve withdrawal symptoms, particularly with depressant medicines like alcohol or benzodiazepines, resulting in complications such as seizures

Need for pharmacovigilance activities

Pharmacovigilance studies of medications on the market (Phase IV studies) provide critical

information. Phases I–III are conducted in a limited number of individuals (a few hundred), usually under favorable conditions, i.e. in the hospital, under close supervision, over a short period of time, with few concomitant medications, and with few high-risk individuals (e.g. children, older individuals, pregnant women, or patients with renal or hepatic failure). Marketed medications are utilized in a much broader spectrum of patients and settings, potentially leading to the appearance of hitherto unknown ADRs. Rare ADRs (occurring in 1/1000 people) are unlikely to be detected in pre-marketing trials. If the unrecognized ADR is serious, it might have disastrous effects. A medication from a commonly used pharmacological class may be used in up to 100,000 people in the first month, resulting in an uncommon (1/1000) but serious adverse reaction in 100 patients. There is no clinical trial design or evaluation procedure that can eliminate the potential of significant adverse drug reactions happening after marketing. As a result, pharmacovigilance studies are necessary to identify and quantify ADRs in order to avoid future occurrences . In conclusion, clinical trials are ideally adapted to validating clinical benefits but have limited utility for detecting ADRs

Discussion -

Pharmacovigilance (PV) is the science and practice of detecting, assessing, analyzing, and preventing adverse effects or other drug-related problems. Risk management in pharmacovigilance is critical because it ensures that a drug's benefits outweigh its dangers across its entire lifecycle. The following discussion covers many aspects of risk management in pharmacovigilance:

1. Risk Identification

Pre-Market: Risk detection starts early in the medication development process, largely with clinical trials. These trials give preliminary data on adverse drug reactions (ADRs), which are critical to evaluating the medicine's possible hazards. Post-Market: Once a drug is on the market, risk identification continues through spontaneous reporting systems, literature reviews, and studies designed to monitor drug safety in real-world settings .

Conclusion -

Any company's longevity and success depend on its capacity to effectively manage risk. By methodically identifying potential risks, evaluating their impact, and putting effective risk mitigation strategies into place, organizations can safeguard their operations, assets, and reputation. The process helps to maximize potential possibilities that may arise from risk management in addition to preventing or minimizing losses. The organization's resilience and adaptability to changes in its internal and external surroundings are guaranteed by the ongoing monitoring and improvement of the risk management process. In the end, proactive risk management promotes long-term growth and the accomplishment of strategic objectives.

REFERENCE -

1. Pharmacovigilance: Present status and future perspectives Dr. Alka Sawarkar, Dr. RK Sharma, Dr. Vidhi Gautam, Dr. K Shramankar and Dr. Neelam Dinodia

2. Opportunities and challenges of pharmacovigilance in special populations: a narrative review of the literature Yanping Li, Yuanlin Wu, Tingting Jiang, Haiyan Xing, Jing Xu, Chen Li, Rui Ni, Ni Zhang, Guiyuan Xiang, Li Li, Ziwei Li, Lanlan Gan and Yao Liu

3. Pharmacovigilance for evaluating adverse drug reactions: value, organization, and methods Jean-Louis Montastruca,b,, Agnès Sommeta,b, Isabelle Lacroixa,b, Pascale Oliviera,b ,Geneviève Durrieua,b, Christine Damase-Michela,b, Maryse Lapeyre Mestrea,b, Haleh Bagheria,b

4. Uses of pharmacovigilance databases: An overview Kévin Bihana,∗, Bénédicte Lebrun Vignes a ,Christian Funck-Brentano b, Joe-Elie Salemb

5. Identification of risk factors for adverse drug reactions in a pharmacovigilance database Sofia Attelind 1,2 | Niclas Eriksson1,3 | Anders Sundström2 |Mia Wadelius1 | Pär Hallberg1

6. 6.Pharmacovigilance: An Overview Author links open overlay panel Paul Beninger MD, MBA

7. 7.Signal Management in Pharmacovigilance: A Review of Activities and Case Studies Author links open overlay panel Paul Beninger MD, MBA

8. 8.Pharmacovigilance: methods, recent developments and future perspectives Review Article Published: 04 June 2008 Volume 64, pages 743–752, (2008) Cite this article

9. 9.Risk Management for the 21st Century: Current Status and Future Needs Leading Article
Open access Published: 09 February 2021 Volume 44, pages 409–419, (2021) Cite this article

10. 10.Pharmacovigilance for evaluating adverse drug reactions: value, organization, and methods Author links open overlay panel Jean-Louis Montastruc a b, Agnès Sommet a b, Isabelle Lacroix a b, Pascale Olivier a b, Geneviève Durrieu a b ,Christine Damase-Michel a b, Maryse LapeyreMestre a b, Haleh Bagheri a b

11. 11.Pharmacovigilance, risks and adverse effects of self-medication Author links open overlay panel Jean-Louis Montastruc a b, Emmanuelle Bondon-Guitton a , Delphine Abadie a, Isabelle Lacroix a, Aurélia Berreni a, Grégory Pugnet c, Geneviève Durrieu a,Laurent Sailler c , Jean-Paul Giroud b , Christine Damase-Michel a , François Montastruc a