INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

Mini Review

A Review Article on Pharmacovigilance

Siratul Nisha*, Rijwan Ahmad

JBIT College of Pharmacy, Dehradun, Uttrakhand, India 248197

ARTICLE INFO

Published: 2 Jan 2026
Keywords:
Pharmacovigilance, Drug safety, Adverse Drug Reactions (ADRs), Patient safety, Medicine safety
DOI:
10.5281/zenodo.18131156

ABSTRACT

The World Health Organization defines pharmacovigilance as the knowledge and actions involved in identifying, assessing, and Understanding and preventing adverse responses to drugs is crucial for ensuring patient safety. It ensures patients receive safe drugs. Pharmacovigilance refers to drug safety. Pharmacovigilance aims to improve patient care, public health, and medication safety, as well as identify potential consequences. India's pharmacovigilance is raising awareness of adverse drug reactions (ADRs), and this assessment offers recommendations for addressing present challenges. This contributes significantly to safe drug delivery for patients. To increase our understanding of adverse medication responses, we might report them spontaneously, monitor them closely, and search databases. The review aims to address many elements of pharmacovigilance, including recent methodological innovations.

INTRODUCTION

Pharmacovigilance focuses on detecting, assessing, understanding, and preventing harmful consequences. Any other drug-related issues. The World Health Organization defines pharmacovigilance as the science of detecting, assessing, understanding, and preventing drug-related problems, including both long-term and short-term adverse effects.[1] Pharmacovigilance is a key component of the healthcare system that assesses, monitors, and identifies interactions between medications. Drug use and its effects on humans. Pharmaceutical and biotechnology fields aim to cure, prevent, reduce, or treat diseases. However, there are hazards, such as adverse drug reactions (ADR), which can cause misery to patients. ADR monitoring is crucial for ensuring pharmaceutical safety. [2] Pharmacovigilance focuses on adverse drug reactions (ADRs), which are harmful reactions to medications. Unintended consequences, such as lack of efficacy, may arise when employed for sickness prevention, analysis, or treatment, or to alter physiological function. [3] Pharmacovigilance involves gathering, monitoring, analyzing, and interpreting data from healthcare experts. We monitor patients for adverse effects of pharmaceuticals, blood and

***Corresponding Author:** Siratul Nisha
Address: *JBIT College of Pharmacy, Dehradun, Uttrakhand, India 248197*
Email : siratulnisha4@gmail.com

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

biological products, herbals, sera, vaccinations, medical gadgets, and traditional/complementary therapies to identify potential dangers and prevent harm. [4] Pharmacovigilance prioritizes adverse drug reactions (ADRs), which refer to any unwanted and undesirable effects of a medicine. Lack of efficacy in preventing, diagnosing, or treating illness or modifying physiological function. [3]PV system disparities in poor nations are driven by local contextual factors including healthcare spending and disease categories. Prevalence and Political Climate. [14] PV aids medicine manufacturers in patient engagement efforts. Communicating the risk-benefit profile of drug goods to patients improves their understanding and builds trust in the business.

PURPOSE:-

Pharmacovigilance is a relatively recent discipline in the pharmaceutical industry. Over the past 20 years, photovoltaics has expanded to include several disciplines in R&D businesses. The medical community is becoming more aware and interested in photovoltaics as technology advances. This article covers the background and functionality of photovoltaics.

OBJECTIVES:-

- The goal is to enhance patient care and safety when using medications.
- To enhance public health and safety, medicines.
- Assessing the benefits and risks of medicines, while supporting safe and effective use.
- Promote education, clinical training, and effective communication about pharmacovigilance among healthcare workers and the public.

ROLE OF PHARMACOVIGILANCE :-

Pharmacovigilance focuses on adverse drug reactions (ADRs). Continuous monitoring of pharmacological effects, adverse effects, and contraindications. To optimize benefits and minimize dangers, it's important to consider potential bad effects that may cause significant morbidity or even death. Drug regulatory agencies are responsible for establishing a Pharmacovigilance system to monitor adverse drug reactions (ADRs) throughout the product's life cycle, from development to completion.

HISTORY OF PHARMACOVIGILANCE IN INDIA :-

Pharmacovigilance in India began in 1986. A formal monitoring system for Adverse Drug Reactions (ADR) was launched with 12 regional collaborators. Each center serves a population of 50 million. However, no significant growth was achieved. In 1997, India participated in the World Health Organization's (WHO) Adverse Drug Reaction (ADR) program in Uppsala, Sweden, but failed. After 2005, the WHO-supported and World Bank-funded National Pharmacovigilance Programme (NPPV) of India became operating. [5,6,7]

PHARMACOVIGILANCE PROCESS :-

Simply it is a drug safety monitoring process. Pharmacovigilance is one of the most important departments in the Pharmaceutical industry. Before Jumping into the process, let’s look at some facts! The pharmacovigilance department, (called be Safety Team) collaboratively works with different verticals.[18]

ADVERSE DRUG REACTIONS :-

The World Health Organization defines an adverse drug reaction as any unwanted and harmful response to a medicine. Doses commonly used in

humans for illness prevention, diagnosis, and treatment, as well as modifying physiological functions.[8] Adverse reactions may arise from use of the product within or outside the marketing authorisation or from occupational exposure.[9] Adverse drug reactions are considered as one among the leading causes of morbidity and mortality. Pharmacovigilance is the field concerned with the study of ADR.[10]

MONITORING OF ADRS :-

ADR monitoring is tracking the negative effects of a medicine over time. Pharmacovigilance plays a Impersonation is essential for monitoring ADRs.[11] Pharmaceutical regulators must screen drugs in the market and report any possible bad effects. Reactions are identified. ADRs can occur from using different goods, including pharmaceuticals, herbal medications, cosmetics, medical equipment, and biologicals. Introducing this monitoring procedure ensures patients obtain safe and effective medicines. Failure to disclose adverse events can lead to negative consequences while using restorative products. Effective ADR monitoring methods can limit the adverse effects of medicinal drugs.

BENEFITS OF ADR MONITORING :-

- An ADR monitoring and reporting program can provide the following benefits.
- It caters information about quality and safety of pharmaceutical products.
- It initiates risk-management plans.
- It prevents the predictable adverse effects and helps in measuring ADR adherence.
- It educates the healthcare team, including patients, pharmacists, and nurses, about adverse medication reactions and raises awareness about them. The primary goal of ADR monitoring is to expose the quality and frequency of ADRs and to identify the risk factors that can trigger the adverse reactions.[10]

NEED FOR PHARMACOVIGILANCE:-

Reason 1 :-Humanitarian concern - Insufficient evidence of safety from clinical trials Animal experiments Phase 1-3 studies prior to marketing authorization.

Reason 2:-Medicines are supposed to save lives Dying from a disease is sometimes unavoidable; dying from a medicine is unacceptable.

Reason 3:-ADR-related cost to the country exceeds the cost of the medications themselves.

Reason 4:-Promoting rational use of medicines and adherence.

Reason 5:-Ensuring public confidence.

Reason 6:-Ethics, to know of something that is harmful to another person who does not know, and not telling, is unethical.

"ROLE OF PHARMACOVIGILANCE" IN MEDICINES REGULATION"

Strong regulatory frameworks support national medicine safety standards and public trust.To Be effective. Drug regulatory bodies should focus on more than just approving new medications. They should also oversee the safety of clinical trials, complementary and traditional treatments, vaccines, and biological products.

- Establish communication links amongst all groups involved in drug safety.
- Ensure efficient and ethical operations, especially during disasters.

To fulfill their individual goals of pharmacovigilance initiatives and Authorities in charge of drug regulation must be mutually

encouraging. Inonesense, pharmacovigilance Programs must keep close ties with the authority in charge of drug regulation to guarantee that the latter are thoroughly informed on daily safety concerns. clinical practice, whether these concerns are pertinent Regarding upcoming regulatory measures or to worries that appear in the public domain. Conversely, Regulators must comprehend the specialized Given the crucial part pharmacovigilance plays in guaranteeing the ongoing safety of medicines goods. [16]

NATIONAL PROGRAMME OF PHARMACOVIGILANCE :-

Experience with a product's safety and effectiveness prior to marketing is restricted to its use in clinical trials, which are not representative of practice. situations because they are constrained by the number of patients, the length of the experiment, and the extremely regulated environment in which clinical trials are carried out. The pre-marketing conditions under which patients are researched may not accurately represent how the medication will be used in hospitals or in general practice after it is put on the market. Information regarding drug interactions, chronic toxicity, use in specific populations (such as children, pregnant women, and the elderly), and uncommon but dangerous adverse drug reactions is sometimes lacking or insufficient. It's possible that some negative drug reactions won't be discovered until a significant number of patients have taken the medication.[13]

PHARMACOVIGILANCE IN INDIA :-

In India, the idea of monitoring adverse drug reactions (ADRs) did not exist until much later. throughout the nation. PV is not new in India, despite being in its early stages. It wasn't until 1986 that a few doctors, mostly from academic institutions, demanded that more focus be placed on the possible negative effects of prescription drugs and the sensible prescription of medications.This led to the formation of the first ADR monitoring program consisting of 12 regional centers, each covering a population of 50 million, but was unsuccessful.[19] Nothing much happened until a decade later when India joined the WHO Adverse Drug Reaction Monitoring Programme based in Uppsala, Sweden in 1997. Three centers or ADR monitoring were identified, mainly based in the teaching hospitals: A National Pharmacovigilance Center located in the Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi and two WHO special centers in Mumbai (KEM Hospital) and Aligarh (JLN Hospital, Aligarh). These facilities were required to notify India's drug regulating body of any adverse drug reactions. These centers' primary responsibility was to keep an eye on adverse drug reactions (ADRs) to medications sold in India. However, they were inoperable due to a lack of government funding and a failure to alert prescribers about the need to report adverse drug reactions (ADRs) and the purposes of these monitoring centers. After this attempt failed, the World Bank-funded and WHO-sponsored National Pharmacovigilance Program (NPVP) for India was created on January 1, 2005. [20]

CLINICAL TRIALS IN INDIA :-

India has been a desirable location for clinical trials for international pharmaceutical companies due to its clinical research space and Opportunities are really appealing. The following are some benefits that India offers for clinical trials:

- High degree of compliance to international guidelines such as the International Conference
- on Harmonisation (ICH) / WHO Good Clinical Practice (ICH-GCP) and the

regulations lay down by the US Food and Drug Administration.

- Availability of well qualified, English speaking research professionals including physicians.
- Ongoing support and cooperation from the government.
- Lower cost compared to the west [21].
- Increasing prevalence of illnesses common to both developed and developing countries.
- Availability of good infrastructure. Changes in Patent Laws since January 2005.

According to a recent Federation of Indian Chambers of Commerce and Industry (FICCI) research, scientific viability, medical Some of the growth factors that have contributed to the recent transformation of Indian clinical research include infrastructure, clinical trial experience, regulations, commercialization possibilities, and cost competitiveness.[22]

CONCLUSION :-

Globally, pharmacovigilance is a component of healthcare systems. The WHO oversees pharmacovigilance activities and offers technical assistance with ADR reporting. Although pharmacovigilance systems are well-established in many nations, the true rate of adverse drug reactions (ADRs) is far higher than reported. Both the quality of reports and the underreporting of ADRs are significant issues. The safe use of medications, patient safety, and ultimately preserving public health are the fundamental goals of pharmacovigilance. National regulators and international organizations should encourage the public and medical professionals to report more adverse drug reactions in order to accomplish this goal.

REFERENCES

1. World Health Organization. The importance of pharmacovigilance – safety monitoring of medicinal products. World Health Organization, Geneva, 2002.
2. Dhara R Sanghavi, Priti P Dhande, Vijaya A Pandit. Perception of Pharmacovigilance among doctors in a tertiary care hospital: influence of an interventional lecture. Int J Risk Saf Med. 2013; 25(4): 197-204.
3. Shuka SS, Gidwani Bina, Pandey R, Rao SP, Singh V and Vyas Amber, "Importance of Pharmacovigilance in Indian Pharmaceutical Industry", Asian Journal of Research in Pharmaceutical Science, 2, 2012, 04-08.
4. Sanvidhan G Suke, Prabhat Kosta and Harsh Negi. Role of Pharmacovigilance in India : An overview, online J Health Inform-2015,7(2):e223.
5. Jadhav Sudhakar and Chakraborthy Guno, "Pharmacovigilance in India: Need of Hour", Journal of Advances in Pharmacy and Healthcare Research (JAPHR), 1, 2011, 01-03.
6. Muraraiah Sushma, Rajarathna Kavitha, Sreedhar Divyasree, Basavalingu Deepashri and Jayanthi C.R. "A questionnaire study to assess the knowledge, attitude and practice of Pharmacovigilance in a paediatric tertiary care centre", Journal of Chemical and Pharmaceutical Research, 2011, 416-422.
7. S Amarnath, S Jaikumar, S Basalingappa, M Thulasimani and S Ramaswamy, "Pharmacovigilance for Health Care Professional Students", Research Journal of Pharmaceutical, Biological and Chemical Sciences (RJPBCS), 4, January-March 2013, 1204-1217.
8. WHO (1972) International drug monitoring: the role of national centres. Technical report series WHO 1972, no 498.

9. Moore N (2001). The role of clinical pharmacologist in management of ADRs. Drug safety, 211(1): 1-7.
10. WHO, Pharmacovigilance: ensuring the safe use of medicines, Geneva: WHO 2004.
11. WHO, Safety of medicines: A guide to decting and reporting adverse drug reactions,Geneva: WHO, 2002.
12. Vaidya, S.S., Bpharm, J.J.G., Heaton, P.C. and Steinbuch, M., 2010. Overview and comparison of postmarketing drug safety surveillance in selected developing and well-developed countries. Drug Information Journal, 44(5), pp.519-533.
13. du Plessis, D., Sake, J.K., Halling, K., Morgan, J., Georgieva, A. and Bertelsen, N., 2017. Patien centricity and pharmaceutical companies: is it feasible?. Therapeutic innovation & regulatory science, 51(4), pp.460-467.
14. Radecka, A., Loughlin, L., Foy, M., de FerrazGuimaraes, M.V., Sarinic, V.M., Di Giusti, M.D., Lesicar, M., Straus, S., Montero, D., Pallos, J. and Ivanovic, J., 2018. Enhancin pharmacovigilance capabilities in the EU regulatory network: the SCOPE joint action. Drug safety, 41, pp.1285-1302.
15. Edwards, I.R. and Aronson, J.K., 2000. Adverse drug reactions: definitions, diagnosis, and management. The lancet, 356(9237), pp.1255-1259.
16. https://globalpharmacovigilance.com/pharmacovigilance-process/
17. Kulkarni, R.D., 1986. Reporting systems for rare side effects of non-narcotic analgesics in India. Problems and opportunities. Medical toxicology, 1, pp.110-113.
18. Moride, Y., Haramburu, F., Requejo, A.A. and Begaud, B., 1997. Under-reporting of adverse drug reactions in general practice. British journal of clinical pharmacology, 43(2), pp.177-181.
19. Butlen-Ducuing, F., Rivière, F., Aarum, S. and Llinares-Garcia, J., 2010. European Medicines Agency support mechanisms fostering orphan drug development. Drug News &Perspectives, 23(1).
20. Giezen, T.J., Mantel-Teeuwisse, A.K. Straus, S.M., Egberts, T.C., Blackburn, S., Persson, I. and Leufkens, H.G., 2009. Evaluation of post-authorization safety studies in the first cohort of EU risk management plans at time of regulatory approval. Drug Safety, 32, pp.1175-1187

HOW TO CITE: Siratul Nisha, Rijwan Ahmad, A Review Article on Pharmacovigilance, Int. J. of Pharm. Sci., 2026, Vol 4, Issue 1, 134-139. https://doi.org/10.5281/zenodo.18131156