IJTI | INTERNATIONAL JOURNAL OF THERAPEUTIC INNOVATION

Review article

A review on Pharmacovigilance and drug safety post-marketing surveillance

Lokesh Gavatiya, Shweta Gogate*, Rita Mourya, Somesh Kumar Saxena, Bharti Patel

SAM College of Pharmacy, SAM Global University, Raisen, Madhya Pradesh, India

Corresponding author: Shweta Gogate, ✉ gogateshweta@yahoo.com, **Orcid Id**: https://orcid.org/ 0009-0008-1170-3453

Received - 27-02-2025**, Revised** - 28-03-2025, **Accepted** - 15-04-2025 **(DD-MM-YYYY)**

Refer this article

Lokesh Gavatiya, Shweta Gogate, Rita Mourya, Somesh Kumar Saxena, Bharti Patel, A review on Pharmacovigilance and drug safety post-marketing surveillance. March-April 2025, V3 – I2, Pages - 35 – 38. Doi: https://doi.org/10.55522/ijti.v3i2.0112.

ABSTRACT

Drug students play an important role in ensuring drug safety by monitoring unwanted drug reactions (ADRs) and other drug problems once drugs enter the market. This review examines the importance of subsequent market surveillance (PMS) for the identification, evaluation and prevention of side effects that may not be recognized by side effects. Various pharmacy systems, regulatory framework conditions, and reporting mechanisms used around the world are being discussed, highlighting their impact on public health and drug safety. Issues related to reporting, data management and regulatory harmonization can also be examined. This check concludes with recommendations to improve drug students' practices to improve patient safety and optimize the effectiveness of the drug in a real environment.

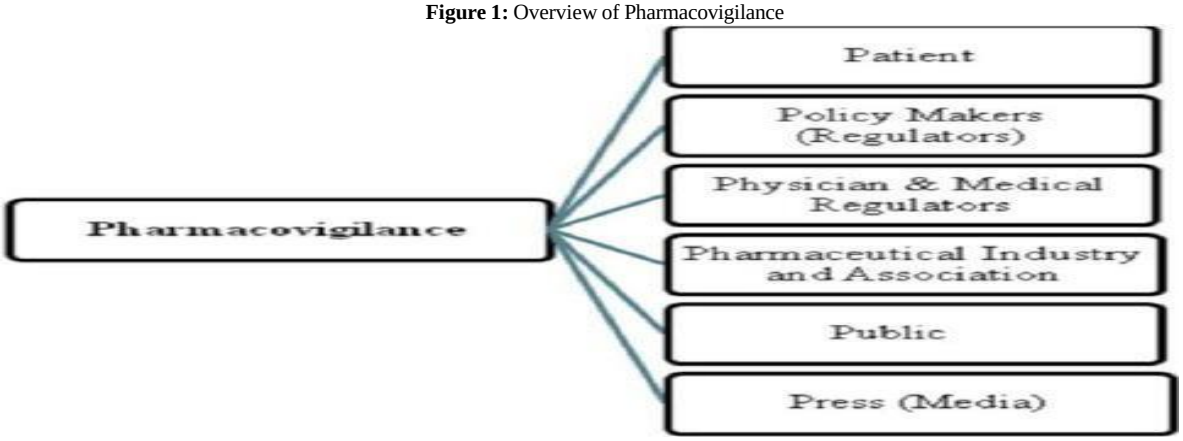
Keywords: Pharmacovigilance, Drug Safety, Post-Marketing Surveillance, Adverse Drug Reactions (ADRs), Risk Management, Regulatory Frameworks, Drug Monitoring, Public Health, Spontaneous Reporting, Signal Detection.

INTRODUCTION

Pharmacobiliance is defined as science and activity in ter ms of recognition, evaluation, understanding, and prevention of sid e effects or other possible drug-related issues, particularly long-term and short term side effects of a drug. Systematic pharmacy is important to co nstruct reliable information on the safety of all categories of drugs for the development of appropriate guidelines for safe and effective use. Essentially, it involves identifying and evaluating security sig nals [1].

Pharmacovilance has become increasingly important over the past decade, and this is related to absolute amounts of unnecessary drug responses (ADRs), and some hospitalizations involve ADRs with significant social costs. Avoidable ADR percentages range from 35% to 50%, with implicit rejection implied in social welfare houses. 3 Therefore, it was a strong need to monitor the effectiveness of drug products after introduction into the market. H. After monitoring after marketing. Pharmacy science practices were created after the well-known thalidomide tragedy of the 1960s, leading to the development of the first voluntary reporting system from ADRS [2].

Figure 1: Overview of Pharmacovigilance



Aims of Pharmacovigilance

Pharmacovilance is the science of monitoring, assessing, assessing, assessing and evaluating information from healthcare service providers, pharmaceutical companies and patients, and is negatively affected by drugs, biological, herbal and traditional drugs. For drug students, the quality of the drug and detection and prevention of adverse effects of drug products using the following goals are monitored and evaluated. To identify new information about drug-related hazards [3].

NACH Market Surveillance (PMS) refers to the systematic and continuous monitoring of a drug as soon as it is approved and brought to the market. This includes collection, analysis, and interpretation of data relating to the security and effectiveness of a drug in a real-world setting. In contrast to pre-market clinical research that provides valuable knowledge during the drug development stage, post-marketing monitoring is an ongoing process aimed at recognizing, assessing and preventing side effects or other drug-related issues that may occur after a product has been reached. The PMS acts as a careful legal guardian, examining the performance of the drug in a variety of patient populations and the announcement of potential risks or benefits that may not be recognized during prior market assessments [4].

Overview of Pharmacovigilance

Role of Regulatory Agencies

World Health Organization

Health is the complete, mental and social happiness with health, not merely lack of illness or frailty, but its complete physical, mental and social happiness. The World Health Organization (WHO) is a specialized UN body related to international public health. Es Wurde Am7. April 1948, Mit Hauptsitz, Genf, Schweiz, Gegründet. The world is in the world. The WHO logo was chosen in 1948 by the first World Health Assembly. The logo consists of a UN symbol overcome by staff members with snakes wrapped around it. The line with the snake has long been a symbol of the medical and medical profession [5].

History

The first global health organization. The second half of the 19th saw the Sver Cholera Epidemia. During this time, many international sanitary confectionery was held in Europe, combining politics and practice with regard to quarantine and disease control. The League of Nations established the Health Organization in 1920 [6].

Central Drugs Standard Control Organization (CDSCO)

CDSCO is the National Regulatory Authority (NRA) of India. He works under the Ministry of Health Ministry's Department of Health Services (DGHS). Government of India. CDSCO is the central drug regulatory authority regarding the performance of functions assigned to the central government in accordance with the Act on the Drug and Cosmetics Act. The CDSCO Center is located in Neu-Delhi. CDSCO and state supervisors are responsible for granting blood and blood products, intravenous fluids, vaccines and serum licensing. The Indian General Controller (DCGI) is responsible for the regulation of medicines and medical devices within CDSCO. The Drug Technical Advisory Committee (DTAT) and the Drug Consultation Committee (DCC) are advised by the DCGI. Medical Device Licenses and Classification are functions of the Central Licensing Authority (CLAA). We are also responsible for determining and enforcing security standards, conducting surveillance according to the market, warning issues, and recalls of medicines for unnecessary events [7].

United States Food and Drug Administration (USFDA)

The Food and Drug Administration (FDA) is an agency of the U.S. Department of Health and Human Services. It consists of six product centers, one research center and two offices. The Centre for Drug Assessment and Research (CDER) will make safe and effective medicines available to improve people's health. Laws modernizing food and drugs say the USFDA has four roles.

1. To improve health by reviewing research and new products approval.
2. To assure that foods and drugs are safe and properly labeled.
3. To work with other countries to decrease the burden of regulation.
4. To cooperate with scientific experts and consumers to properly implement these obligations.

The Food and Drug Director appointed by the President leads the FDA. The FDA was approved by the US Congress to enforce the FD&C Act during federal period. The FDA is headquartered in Illegal White Oak, Maryland. There are also 223 branches and 13 laboratory in 50 states [8].

European Medicines Agency (EMA)

EMA is the European Union (EU) agency that evaluates and monitors healing products. Prior to 2004 it was known as the European Agency for the assessment of Medical Products or European Medication Assessment Agency (EMEA). The EMA was established in 1995 with indirect subsidies from member states to harmonize EU and pharmaceutical industry funding with the drug work of existing state regulators. The EMA is a decentralized London organization before its withdrawal from the EU from the UK. I moved to Amsterdam in March 2019. The EU is currently the source of about a third of the new drugs brought to international markets each year [9].

Medicines and Healthcare products Regulatory Agency (MHRA)

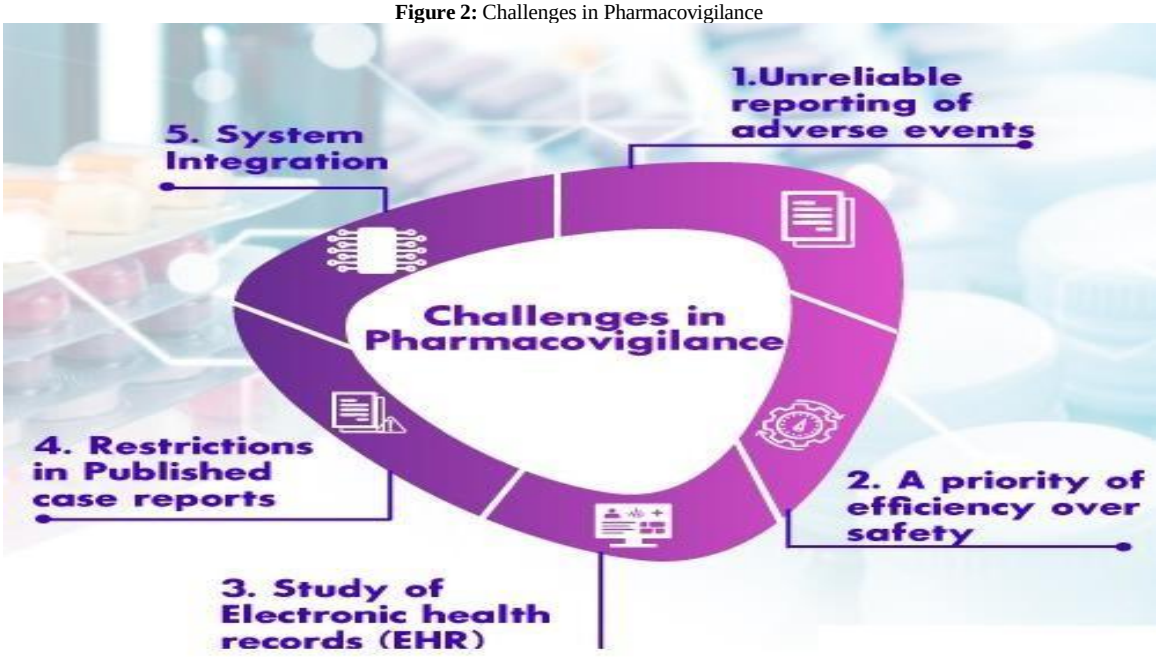
The Medicine and Healthcare Product Regulatory Authority (MHRA) is the UK's Ministry of Health and Social Affairs executive body responsible for the fact that medicines and medical devices are functional and safe. MHRA was founded in 2003 through the merger of a pharmaceutical management agency (MCA) and a medical agency (MDA). In April 2013, it merged with the National Institute of Biological Standards and Control (NIBSC) and was renamed. This allowed MHRA identity to be used only for regulatory centres within the group. The agency employs more than

1,200 people in York, London and Hertfordshire, South Mium. The MHRA is divided into three main centers: MHRA Regulation (Normal and Pharmaceutical and Medical Device Industry) Clinical Practice Research Data Link (CPRD) and NIBSC.

Artificial intelligence in PV

Artificial intelligence (AI) is increasingly being used in Pharmacovilance (PV). Using Medline to search for "artificial intelligence" and "pharmacy" we can see that the realm of artificial intelligence is expanding very rapidly with drug presence or AIPV. AIPV spins are further required as AI, machine learning (ML), deep learning (DL), data mining and cognitive computing are nested and overlapping [8]. The first use of AI in PV is to create new epidemiological concepts based on the recognition of the distinction between the terms "biosimilar" and "generic." By creating data that is useful for effectiveness and security, AI can help close the currently existing gaps in the PV ecosystem. Artificial intelligence is the use of machine learning to solve problems in the future by introducing learning technology into a system and using historical data. AI increases the success rate of clinical research and helps in randomizing patients. Diabetes, cancer and diabetic retinopathy are the three most important global health issues where artificial intelligence has shown promising results related to the identification, avoidance, reduction and treatment of these diseases. Individual individual security reports (ICSRs) are the main types of data used in PVs. These are suspected records of unfavourable events collected in various routes and substantial databases and observed continuously to identify warning signs. Electronic Health Records (EHRS), published literature, patient registration, patient support programs, chatbot interactions, and even direct patient communication via social media are some of the various sources of ICSR. The amount of ICSRS can rise every year, but 90% of unwanted events (AEs) are not detected. Therefore, technology is needed to maintain adverse events. Making decisions in complex environments is supported by artificial intelligence. Proposals from AI in the health care system include asthma expectations, persecution of insulin levels through smartphone apps, identification of osteoporosis risk groups, eye for anticoagulant compliance, and treatment of tuberculosis. In the past, forms of security reports for individual cases have been collected, packaged and sent to regulators around the world. This process required more time and work. The thalidomide disaster of 1961 required disclosure of side effects from medication. However, it took Australian obstetricians and German doctors two years to find the causal relationship between drug side effects and hocomeria. As a result, the WHO has established guidelines and initiatives to stop this type of disaster. This requires a central, objective software system with data on the drug safety profile [10].

Figure 2: Challenges in Pharmacovigilance



ADR is one of the leading causes of death. In most cases, these dangerous events can be avoided. Despite the fact that more side effects occur in patients over 60 years of age, the likelihood of suffering ADR increases to age 50. Patients admitted to the hospital's medical department found that ORRS stayed in-person in 3.8% of hospitalizations, but 57% of these ADRs were not recognized by lawyers at the time of approval. A recent study on reasons for staying in children's hospitals (children under 19 years of age) showed that 2.09% of all stays in children's hospitals are caused by ADR, and 39% are life-threatening [11].

Future Prospects

A robust pharmacy system that can record new ADR A and regulatory measures needed to protect public health. There was little emphasis in the decision-making process on generating information that could help health professionals and patients. This information gathering and communication is an important goal for drug students. Information regarding the safety of active monitoring of medicinal products is required. When developing new methods

for active monitoring after stamping, one must consider how important it is to gather information. While spontaneous reports are useful equipment when generating signals, the relatively small number of reports received for a particular connection do not help identify patient characteristics and risk factors.

Pharmacological methods should also be able to describe which patients are at risk for ADR. As a source of information, the pharmacovigilance approach coordinates with increased patient participation in drug safety. At this time, DCGIs need to act promptly to improve the presence of drugs in order to improve compliance in modulatory research and to monitor clinical research, integrate excellent pharmacy viewing practices (GPPs) into processes and procedures. When using medications carefully, a functioning pharmacy system is essential. This is advantageous for health professionals, regulators, pharmaceutical companies and consumer members. It helps pharmaceutical companies monitor drugs at risk. After Pharmacovilance's marketing, there is now a challenging and boring process not only for the entire sector but also for the regulators [10].

CONCLUSION

India is the fourth largest drug producer of medicines and is now an important hub for clinical research worldwide. With the introduction of new drugs, our country's robust drug presence system is one hour to protect our population from the potential damage and adverse effects of some new drug molecules. Pharmacovigilance plays a key role in managing the challenges of ever-growing local communities and the effectiveness of pharmaceuticals. However, the Indian pharmacy system is still not well developed. Despite the recent implementation of a properly structured pharmacy program in India, in accordance with CDSCO goals and recommendations, desirable success remains a great dream. In India, we ensure the availability of safe medicines for the public.

REFERENCES

1. Tripathi KD, 2003. Essentials of Medical Pharmacolog. Jaypee Brothers Medical Publishers (P) Ltd. Pages 202-203.
2. Foley DJ, Wallace RB, Fulton MM, 2005. Polypharmacy in the elderly: A literature review, J Am Acad Nurse Pract. 7, Pages 123-132. Doi: https://doi.org/10.3109/13814780009069956.
3. Muhammad Afsana, G Naga Malleshwari, 2023. Post-Marketing Surveillance and Drug Safety Monitoring: Ensuring Patient Well-Being. 7 (6), Page 387
4. R Swetha Sri, Ch Mounika, Dr K.Bhavya Sri, 2020. A Review on Pharamaceutical Regulatory Agencies of India, USA And Europe. International Journal for Research Trends and Innovation. 5(3), Pages 2456-3315. Doi: https://ijrti.org/papers/IJRTI2003024.
5. Hauben M, Hartford CG, 2021. Artificial intelligence in pharmacovigilance: scoping points to consider. Clinical therapeutics. 43(2), Pages 372-9. Doi: https://doi.org/10.1016/j.clinthera.2020.12.014.
6. Wani P, Shelke A, Marwadi M, 2022. Role of artificial intelligence in pharmacovigilance: a concise review. Journal of Pharmaceutical Negative Results. 29, Pages 6149-56. Doi: 10.1007/s40290-022-00441-z.
7. Grady C, 2005. Payment of clinical research subjects. J Clin Invest. 115, Pages 1681-1687.
8. International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. Development Safety Update Report E2F. 2010.
9. Food and Drug Administration. Code of Federal Regulations Title 21. Sec. 312.33 IND Annual Reports. 2010.
10. European Commission. Detailed Guidance on the Collection, Verification and Presentation of Adverse Reaction Reports Arising from Clinical Trials on Medicinal Products for Human Use. 2006.