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"Unveiling the Hidden Dangers: The Critical Role of Pharmacovigilance in Detecting and Preventing Adverse Drug Reactions"

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ABSTRACT :

Adverse drug reactions (ADRs) represent a significant public health concern, manifesting as unanticipated, harmful side effects that can severely impact patient well-being, increase mortality rates, and burden healthcare systems with extended hospital stays and additional costs. Research indicates that ADRs account for 3-7% of hospital admissions and are a leading cause of death, highlighting the critical need for effective pharmacovigilance (PV). Pharmacovigilance encompasses the detection, assessment, understanding, and prevention of adverse effects related to pharmaceutical products, ensuring their safety from pre-market testing through post-market surveillance.The emergence of new medications without extensive safety evaluations and the shift towards over-the-counter availability pose increasing risks for ADRs. High-profile drug withdrawals, such as cerivastatin, underscore the necessity for robust PV systems. Major pharmaceutical companies now prioritize early signal detection and comprehensive risk management throughout a product's lifecycle, integrating PV into clinical research and regulatory compliance.Veterinary pharmacovigilance also plays a crucial role in monitoring adverse effects in animals, ensuring the safe use of veterinary medicines and protecting public health by evaluating drug residues in animal-derived foods. Historical events, such as the thalidomide disaster, have shaped the regulatory landscape, prompting the establishment of stringent safety protocols and the global WHO Programme for International Drug Monitoring.India's PV program has evolved significantly, reflecting its status as a major pharmaceutical manufacturer and clinical trial hub. Recent initiatives aim to enhance PV infrastructure, training, and awareness among healthcare professionals, leveraging advancements in information technology for better data collection and analysis.Future PV systems must focus on proactive risk management and effective dissemination of safety information to healthcare providers and patients, ensuring that new ADRs are promptly identified and mitigated to safeguard public health. Continuous improvement in PV practices is essential to meet the challenges posed by the dynamic nature of pharmaceuticals and biological therapies.

Keywords: Pharmacovigilance, Adverse Drug Reactions (ADRs), Clinical Trials, Risk Assessment, Patient Safety, National Pharmacovigilance Program.

Introduction :

An adverse drug reaction is any unanticipated, undesirable, or harmful side effect brought on by taking a medication. Many research carried out globally have indicated that adverse drug reactions (ADRs) considerably reduce life quality raise mortality, lengthen hospital stays, and number of hospitalizations. According to a seminal study by Lazarova in 1998, adverse drug reactions (ADRs) account for 3-7% of hospital admissions and rank between the fourth and sixth leading cause of death in the United States. 15 out of every 1000 patients admitted may die as a result of adverse drug reactions (ADRs), of which more than half are missed by the doctors at the time of admission [1]. The financial burden of adverse drug reactions (ADRs) on the healthcare system is also enormous. As more new medications are approved for sale without first undergoing extensive safety testing by regulatory bodies, and as prescription only medications (POM) are replaced with over-the-counter (OTC) medications so that patients can use them more frequently for self-medication, the public is at risk of developing adverse drug reactions (ADRs)[2]. The study of pharmacovigilance focuses on both the short- and long-term negative effects of medications, as well as adverse drug reactions, detection, assessment, comprehension, and prevention. Clinical research requires pharmacovigilance because of the recent, well-publicized drug withdrawals of medications like cerivastatin. Concerns about pharmacovigilance have recently been brought up by the pharmaceutical industry and government agencies due to the withdrawal of several well-known medications, including ceretitin . Major pharmaceutical companies have now adopted the early detection of signals from both clinical trials and post-marketing surveillance studies in order to identify the risks associated with the medicinal product and effectively manage the risks by implementing strong risk management plans throughout the product's life cycle. The field of pharmacovigilance is a dynamic field that has gained new depth with the introduction of signal detection and risk management. However, further development is necessary to maximize the sector's usefulness and contribution to public health. It is crucial to comprehend the significance of pharmacovigilance and how it affects the product's life cycle. This will make it possible to include best practices in pharmacovigilance into the processes and procedures to help guarantee regulatory compliance and improve the safety of clinical trials and post-marketing surveillance. Gildeeva (2016) [3]. The gathering and evaluation of data, especially post-marketing monitoring of the unfavorable effects of

veterinary medications, is known as veterinary pharmacovigilance. A negative and unintentional reaction that happens at levels typically employed in animals for disease prophylaxis, diagnosis, treatment, or alteration of physiological function is referred to as an adverse effect or reaction to a veterinary product. Pharmacovigilance is currently acknowledged as a crucial element in the safe and effective use of veterinary medications as a result of the advancement of knowledge and technology in the veterinary field. Ensuring the safety of veterinary medicines once they are approved and being used in the market is the goal of a strong pharmacy surveillance system. Saygi (2016) [4].

It is crucial to promptly detect any negative effects associated with medications, and the information gathered from the study needs to be evaluated to lower the risk of using the product in the future[5]. Pharmacovigilance (PV) was first published in the Lancet in December 1961. The Australian physician W. McBride was the one who initially suspected a link between thalidomide, a medication used during pregnancy that was used as an antiemetic and sedative in pregnant women, and serious fetal deformities (phocomelia). The "Programme for International Drug Monitoring" was a pilot project launched by the World Health Organization (WHO) in 1968 with the goal of centralizing global data on adverse drug reactions (ADRs). Specifically, the primary goal of the "World Health Organization (WHO) Programme" was to locate Pharmacovigilance (PV) signals as soon as feasibl [6]. A French group of toxicologists and pharmacologists coined the word "pharmacovigilance" (PV) in the middle of the 1970s to describe the actions that support the evaluation of the risks of side effects that may be connected to drug therapy. PV is the scientific study of gathering, observing, investigating, evaluating, and researching data from medical professionals and patients about the side effects of drugs, blood products, herbal remedies, medical devices, biological products, vaccinations, and complementary and traditional medicine in order to find new information about product hazards and shield patients from harm. Pharmaceutical and biotechnology companies have an increasingly complex task in maximizing drug safety and upholding public confidence. They need to not only monitor drug risk throughout a product's lifecycle, from development to post-market, but also proactively estimate and manage [7]. Drug reactions that are unpleasant and unexpected that happen at levels typically used for prophylaxis, diagnosis, or treatment of disease, or for altering physiological function, are of special relevance to pharmacovigilance (PV).

To optimize benefits and reduce dangers, it is imperative to continuously monitor pharmacological effects, side effects, contraindications, and overtly adverse effects that could result in a significant degree of morbidity, and in some circumstances, even mortality. Before a drug is marketed and prescribed to large populations both inside and outside of the country, care and caution should be exercised in the pre-clinical and clinical testing stages to ensure complete safety. Less common side effects and adverse drug reactions (ADRs) are frequently unknown at the time a drug enters the market because clinical trials typically comprise several thousand people at most [8]. Pharmacovigilance (PV) after marketing use techniques like data mining and case report analysis to determine the connections between medications and adverse drug reactions (ADRs). It is the duty of the drug regulatory agencies to maintain a functioning pharmacovigilance (PV) system to track adverse drug reactions (ADRs) both during the course of a drug's development and later on in its commercialization. In the practice of drug safety monitoring, a wide range of partners are involved, including the government, business, academia, medical and pharmaceutical associations, health care facilities, hospitals, poison information centers, patients, consumers, and the media. These relationships are intricate and crucial. If PV is to grow and succeed in the future, then sustained cooperation and dedication are essential [9].

There was no significant need to create a robust PV system to identify adverse drug reactions (ADRs) of marketed pharmaceuticals because very few new drugs were discovered in India and very few new drugs were introduced for the first time in India in the past. The medicine's safety parameters were evaluated and remedial measures, such its withdrawal or outright ban, were implemented by the firms and regulatory bodies based on their experience from markets where the drug was in use for several years prior to its release in India[10]. India must now refrain from copying copyrighted items and marketing them without a license from the original inventor company, as a new patent regime known as Trade-Related Intellectual Property Rights and Services (TRIPS) has evolved in the country's biotechnology and pharmaceutical industries. Recognizing the demands of the new regime, the top Indian businesses have already committed significant resources to the search and development of novel medications required for the Indian and global markets. It is hoped that research and development by Indian biotech and pharmaceutical businesses will result in novel pharmaceuticals based on clinical and pre-clinical data that is mostly generated in India.In these situations, the Indian regulatory bodies are unable to rely on the expertise of foreign markets to evaluate the frequency and significance of an appropriately constructed Pharmacovigilance (PV) system in India. Given that Indian companies are capable of creating and distributing novel drugs through in-house research, it is imperative that this seminar provides an overview of the goals and approaches employed in Pharmacovigilance, along with a critical analysis of the state of the field in India, obstacles to be addressed, and opportunities for growth in the context of India. When a product is first introduced in India, Pharmacovigilance (PV) standards are put in place to monitor adverse drug reactions (ADRs)[11].

Fig. 1 Key goals of Pharmacovigilance

2. Origin of Pharmacovigilance

Only after an occurrence that took place in 1937 did a new breakthrough occur in this field. Approximately 105 children and 71 adults were discovered dead in that year as a result of syrup ingestion. Included diethyl glycerol and sulphonamide, in which the latter was implicated. Diethyl glycerol was added as a solvent and sulphonamide was decreased as syrup starting in 1932 to treat streptococcal infections. Sulfanilamide, also known as Prontosil, was first introduced as a syrup in 1932 and contains diethyleneglycol as a solvent. It is used to treat streptococcal infections. Its safety was not assessed prior to launch, despite taste and odor tests. Due to this catastrophe, the Food Drug and Cosmetic Act was approved by the US Congress in 1938, requiring producers of pharmaceutical products to provide scientific proof of the products' safety before allowing them to be sold [12].

The thalidomide disaster marks a turning point in the history of pharmacovigilance. When thalidomide was first available in 1957, it was frequently recommended as a purportedly safe remedy for nausea and morning sickness. About 300 people underwent testing, and none of them experienced any toxicity. It was quickly connected to a congenital condition called phocomelia, which resulted in serious birth abnormalities in the offspring of pregnant women who used this medication. It was stopped in 1962 following reports of multiple phocomelia cases (Hama, 2015) [13]. The Kefauver-Harris amendment, which mandates scientific proof of safety and efficacy prior to drug testing in humans, was approved in the same year. In 1968, the World Health Organization launched the Programmed for International Drug Monitoring to consolidate the data already available on adverse drug reactions (ADRs). The network, which began as a pilot initiative in ten nations with established national reporting systems for ADRs, has subsequently grown dramatically as other nations throughout the world have developed. The chronological sequences that follow are designated as fallows[14].

1937: The Sulfanilamide Disaster, in which the dissolution of sulphonamide in diethylene glycol caused over 100 individuals to pass away from renal failure. 1938: The FDA mandated preclinical toxicology and pre-marketing clinical evaluations.
1950: Chloramphenicol usage resulted in aplastic anemia. The FDA launched a hospital-based medication monitoring program in 1960.
1961: The tragedy of thalidomide.
Rapid Action on ADR was identified as important in 1963 by the 16th World Health Assembly[15].

3.Requirement for Pharmacovigilance

1. 1.It could be necessary to keep an eye on a drug's effects both during clinical trials and once it hits the market.
2. Unfavorable outcomes may even occur throughout clinical trials and following its market debut
3. Keep an eye on medication quality.
4. Recognize the health hazards associated with administering specific medications.
5. Avoid hurting people.
6. Examine how effective medications are[16-18].

4. Pharmacovigilance's purpose

The primary objectives of pharmacovigilance for human medications have been established [19], and they are easily transferable to veterinary medications:

1. The identification and measurement of adverse medication reactions that were previously unidentified.
2. The identification of patient subgroups based on factors such as species, breed, age, gender, physiological status, and underlying disease that put them at an increased risk of experiencing adverse medication reactions.
3. Ongoing safety monitoring to make sure that the risks and benefits of a product are still deemed appropriate for each species for which it is approved. This ought to involve expanding monitoring to encompass new species and signals.
4. Examining the adverse reaction profile within and between species as well as in comparison to other products in the same therapeutic class.
5. The identification of improper prescriptions and their administration; in the case of the latter, supervision of the public's or farmers' administration may be necessary.
6. Additional research into the toxicological, pharmacological, or microbiological characteristics of a medication or product in an effort to comprehend, if feasible, the mechanisms driving adverse drug reactions.
7. Drug-drug interaction detection. This is especially crucial for newly developed medications that are given in combination with already-marketed goods or even other novel medications.
8. Giving veterinarians and other healthcare professionals who treat animals, such as farmers, other animal owners, and veterinarians, the proper information about drug interactions and adverse drug response data.
9. Adverse effects of veterinary pharmaceuticals on the environment and surrounding organisms.
10. The use of veterinary medications with permissible residue limits in animal-derived foods like meat, milk, and honey.
11. Rules and laws pertaining to the necessity of pharmacovigilance [20].

5. Veterinary Pharmacovigilance's Significance

When a new medication is introduced without first undergoing extensive safety testing, it may not be able to be marketed as therapeutically safe and effective and may even have detrimental or fatal side effects. A few decades ago, prolonged drug usage was the basis for evaluating a medicine's safety in India. However, this method was unreliable and did not guarantee total safety. Several Indian companies and research funding authorities began investing in individual drug development and the introduction of fresh products in light of this fact[21]. New information on a product's risk-benefit profile is often generated after it is produced, and this knowledge can be either favorable or negative. To protect the public's health, a thorough analysis or evaluation of recently created data using the Pharmacovigilance system is required. Measuring side effects is crucial to minimizing risks and optimizing benefits because they can lead to morbidity or mortality. The pharmaceutical business and regulatory bodies are rigorous as a result of a recent, well-publicized medicine withdrawal [22]. India ranked fourth in the world for pharmaceutical manufacture by concentrating on medication safety, or pharmacovigilance. more than two distinct prescription or over-the-counter medications at once, as these may interfere and cause discomfort. Therefore, the pharmacovigilance system needs to be improved in order to prevent this scenario and shield patients from any potential harm brought on by new or existing drugs. The staff responsible for pharmacovigilance monitors adverse drug reactions (ADRs) and precisely analyzes them, sharing the data with relevant parties to guarantee responsible drug use. Meeting the issues posed by the growing strength and variety of pharmacological and biological therapies, including vaccines, which inevitably contain a sometimes unanticipated risk of harm, has become imperative[23].

6. Pharmacovigilance's purview

Since the WHO technical report in 1972, the field of pharmacovigilance (PV) has grown significantly and is still a lively clinical and scientific field. It possesses proven necessary to face the challenges posed by the growing variety and potency of biological and pharmacological medications, including vaccinations, which inevitably involve a sometimes unanticipated risk of harm. On the other hand, there is a lower chance of injury when medications are used by people who understand and take responsibility for their use as well as by knowledgeable medical professionals. It is crucial that side effects and toxicity are examined and adequately conveyed to a knowledgeable audience when they manifest, especially if they were previously undiscovered in relation to the medication [24]. Pharmacovigilance (PV) has previously played this role, but additional work is needed to fully integrate the discipline into public policy and clinical practice. In order to comply with regulatory requirements, pharmaceutical companies operating in India are required to do certain tasks, including gathering and promptly reporting any major adverse drug effects (ADRs). An organizational structure and a range of stakeholders are common components of a PV study scenario . This is the function of pharmacovigilance, which has already seen significant advancements. However, more is needed to incorporate the subject into public policy and clinical practice. In order to comply with regulatory requirements for Pharmacovigilance for its marketed medicines, pharmaceutical companies operating in India are required to perform certain tasks, including the gathering and prompt reporting of serious adverse drug reactions (ADRs). An example of a standard setup for pharmacovigilance research, with participants at different levels [25].

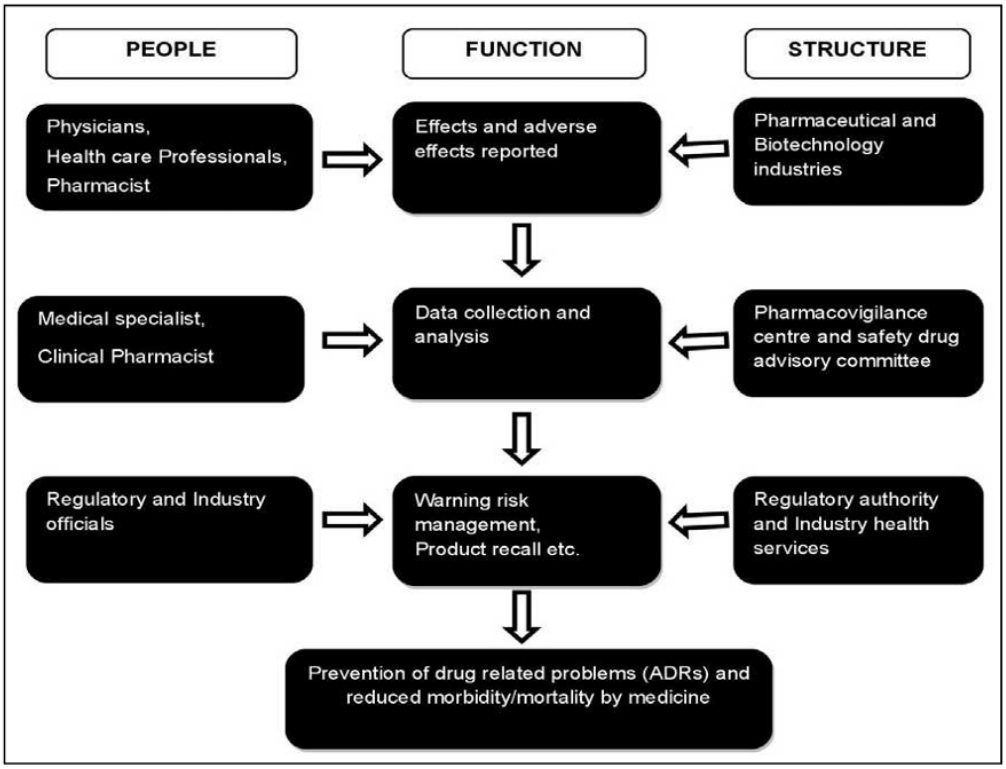

Fig.2 Function of pharmacovigilance

7. India's Pharmacovigilance History

Pharmacovigilance began in India in 1986 with the establishment of the formal adverse drug reaction (ADR) monitoring system, which was made up of 12 regional centers that each had a population under its purview. For India, a proposal of 50 million was made. But not much happened until 1997, when India became a part of the WHO's adverse drug reaction monitoring programme, which is headquartered in Uppsala, Sweden. That was ten years later. After this failed attempt, the World Bank-funded National Pharmacovigilance Program for India, sponsored by the WHO, began operations on January 1, 2005 [26]. The National Pharmacovigilance was to be in charge of the National Pharmacovigilance Program, which was founded in January 2005. committee with its headquarters located in New Delhi, at the Central Drug Standard Control Organization (CDSCO). Information from all over the nation was to be gathered by two zonal centers and sent to the Committee and the Uppsala monitoring center in Sweden. The South-West zonal center was housed in the Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai, and the North-East zonal center was located in the Department of Pharmacology, AIIMS, New Delhi. There would be two regional centers reporting to the New Delhi center and three to the Mumbai center. A number of peripheral centers would report to each regional center in turn. There are 26 peripheral centers at the moment. Three main goals make up the program [27]. Fostering a reporting culture is the short-term goal; including a large number of healthcare professionals in the system in information dissemination is the intermediate goal. The program's long-term goal is to serve as a benchmark for worldwide drug monitoring.

8. Current Scenario of Pharmacovigilance

India is a large country with over 60,000 branded pharmaceutical products and over 6,000 licensed medication manufacturers. formulas. In addition to being the world's fourth-largest manufacturer of pharmaceuticals, India is becoming a centre for clinical trials. To safeguard the Indian populace from any potential harm that some of the new pharmaceuticals may cause, the pharmacovigilance system must be greatly improved since many new drugs are being brought into the nation [28]. Previously, drug companies and regulatory bodies in India relied on long-term drug use in Western markets for their safety evaluations, and the government did not really need to set up a robust pharmacovigilance system of its own. However, the time it takes for a medicine to become available in India after it is approved has significantly shortened in recent years, making the crucial longer-term safety data unavailable. Furthermore, drug companies based in India have expanded their ability to research and develop new drugs on their own, which has increased the significance of creating sufficient internal pharmacovigilance standards to identify adverse drug events [29]. Inspections of all pharmaceutical companies in India The Summary of Pharmacovigilance System document that each pharmaceutical company operates should be kept up to date and submitted to the DCGI. This document will be the foundation for all subsequent Pharmacovigilance inspections. To inform them of the plans being made by the Drug Control General of India (DCGI) to enhance and create a strong system in pharmacovigilance, a high-level discussion with a range of stakeholders, including the Ministry of Health and Family Welfare (MHW), Indian Council of Medical Research (ICMR), Medical Council of India (MCI), Pharmacy Council, Nursing Council, Dental Council, Pharmaceutical Companies, Consumer Associations, Nongovernmental Organizations

(NGOs), and Patient Groups, should be started. bolster the DCGI office by adding qualified medical and scientific pharmacovigilance assessors. It is recommended that officials operating in the DCGI's pharmaceuticalvigilance department as well as in the peripheral, regional, and zonal centers receive comprehensive training covering all facets of the field. Training should be arranged twice a year as part of this continuing activity. establishing a single adverse event reporting form that may be utilized by everyone in the nation. Not only should the National Pharmacovigilance Centers use a single, national adverse event reporting form, but all registered hospitals—private and public—as well as teaching hospitals, Drug Information Centers, and pharmacies across the nation should as well. Additionally, all primary healthcare centers (PHCs) in rural areas as well as all active general practitioners and physicians should have access to it. establishing a post-marketing and clinical trial database. From the date of the clinical trial's initial registration in India, ADRs for signal detection and full access to all pertinent data from multiple stakeholders should be made accessible to the DCGI and the other stakeholders. The overall benefit-risk profile of the product and the unified standards of reporting trials guidelines should be complied with by this data. The current schedule for safety reporting should be followed, along with specifics about all adverse events (AEs) and adverse drug effects (ADRs) for each study arm. A thorough account of cases involving previously unreported AEs, ADRs, and the reasons behind study withdrawals should also be provided. For medications that are already on the market, the type and frequency of all adverse events—both serious and non-serious—should be reported in periodic safety update reports (PSURs) and added to the summary of product characteristics (SPCs). Record all new drug indications by keeping a uniform database for each pharmaceutical business. The regulatory bodies and pharmaceutical companies should keep a record of all new drug indications within the database. It is necessary to monitor all new issues closely. Under these conditions, pharmaceutical companies ought to schedule meetings with the DCGI to discuss their risk management plan (RMP) for the safety concerns at hand and explain how they would implement practical measures to reduce the education and training of nurses, doctors, and pharmacists in the field of pharmacovigilance [30].

There are numerous clinical research-focused courses offered by different organizations, but as of right now, the nation does not provide any pharmacovigilance-related courses. To ensure that doctors receive the right theoretical and practical training, the MCI and other stakeholders should include a pharmacovigilance syllabus in the pharmacology and medicine curricula. In a similar vein, pharmacovigilance training should be provided to nurses and pharmacists so that they can identify adverse drug reactions (ADRs) and cultivate a culture of reporting ADRs going forward. an awareness campaign and a training schedule that covers every facet of pharmacovigilance through both in-person and remote learning. These are intended to raise awareness among patients, medical professionals, pharmacists, and chemist-druggist trades, as well as research and development (R&D)-based pharmaceutical companies, especially those engaged in new drug research. The agencies will then look into the reports and promptly take corrective action. Advances in information technology (IT) have created new opportunities for national and international collaborations that can improve post-marketing surveillance programs and increase drug safety when working with pharmacovigilance organizations to enhance drug safety. One instance of an international partnership to create a standardized post-marketing surveillance database is the Uppsala Monitoring Center (UMC). The sharing of adverse reaction data between national drug monitoring centers in 80 countries serves as the foundation for the system. Through the internet, the data is sent, saved, and retrieved quickly and securely [31]. All together, the UMC database has about four million records with a substantial amount of data fields. With the assistance of skilled private companies, a database akin to this may be constructed for the DCGI using safety information obtained from clinical trials and post-marketing surveillance. A core group of experts representing multinational corporations (MNCs), Indian pharmaceutical businesses, and regulatory authority professionals will need to be assembled in order to establish a network of pharmacovigilance and pharmacopeidemiologists in India (DCGI). collaborating with the IT industry to develop a strong pharmacovigilance system for India.The developed software tools can be utilized for data collecting and analysis, trend analysis of drug use in different disease areas, medication errors, compliance, and drug interactions that result in adverse drug reactions (ADRs) [32].

9. India's Pharmacovigilance Program

A formal 12-center adverse drug reaction monitoring system was developed in 1986, however there was no development with a focus on the activity of pharmacovigilance. India took part in the WHO's adverse drug reaction monitoring program, which was based in Uppsala, Sweden, in 1997. The level of engagement needed to support pharmacovigilance activities was insufficient. As a result, the Government of India launched the Pharmacovigilance Program for India (PvPI) on July 14, 2010. The All India Institutes of Medical Sciences (AIIMS), located in New Delhi, was chosen as the National Coordinating Center (NCC) for PvPI in order to validate the safety of products and protect public health. In 2010, a number of adverse medication reaction monitoring centers were founded. On April 15, 2011, the NCC was moved from AIIMS, New Delhi to IPC and Ghaziabad in order to ensure the program operated smoothly and effectively. AMCs, or adverse drug reaction monitoring centers, were permitted for use in a limited number of qualified medical colleges, hospitals, and clinics. These AMCs gather, analyze, and submit the Individual Case Safety Reports (ICSRs) to the appropriate regulatory body. Under PvPI, 250 AMCs—both government and non-government—had been founded as of January 2017[33].

For the purpose of reporting spontaneous adverse medication reactions, about 20 Anti-Retroviral Therapy (ART) and 17 Revised National Tuberculosis Program (RNTCP) centers were constructed. An approved individual is the technical associate from Banaras Hindu University's Medical Sciences department who collects ICSRs, follows up on them, and enters them into the Vigi-Flow software's online database. All community health centers (CHCs) and primary health care centers (PHCs) provide reports to the regional center regarding adverse drug reactions. The natural medicines were thought to be risk-free and free of negative medication reactions. However, the foundational text of ayurveda, "Charka Samheta," shows that improper compounding and dispensing of herbal medications can also result in adverse drug reactions (ADR).Therefore, in accordance with WHO recommendations [34], it was crucial to include ADR data for AYUSH medications in order to submit PV for Ayurveda, Siddha, and Unani (ASU).

10.Future Prospects

As the likelihood of new ADRs growing, PV systems with the ability to identify them and take appropriate regulatory action will be necessary to safeguard public health. Not much focus has been placed on producing information that helps with decision-making for patients or healthcare providers. PV's collection and dissemination of this data is one of its main objectives. It is imperative to obtain information regarding the safety of drug active surveillance. When creating new techniques for active post-marketing surveillance, it's critical to remember that every serious reported occurrence requires comprehensive and reliable data collection. While spontaneous reporting can be helpful in creating signals, it is less helpful in determining patient features and risk factors due to the comparatively small number of reports collected for a given connection. PV techniques also need to be able to identify the patients who are most likely to experience an adverse drug reaction (ADR). The PV approach would be a reliable source of information given the increasing patient involvement in medication safety [35]. The PV may be useful in determining specific risk factors for the development of particular ADRs. PV will need to shift its focus in the future from conventional groups like health professionals to patients as a source of information. The DCGI should move swiftly right now to increase PV in order to include Good Pharmacovigilance Practice (GPP) into the processes and procedures in order to help guarantee regulatory compliance and improve post-marketing surveillance and clinical trial safety. For medication to be utilized cautiously, a functioning PV system is necessary. It will help consumers, pharmaceutical businesses, regulatory agencies, and healthcare professionals. It aids pharmaceutical corporations in risk-monitoring their products. PV post-marketing is now an industry-wide and regulatory agency process that is difficult and time-consuming [36].

The PV's objective is to gather data, work documentation, and expertise online, with a focus on emerging and critical safety issues. Although they are currently also routinely screened for, non-serious events are less important than serious events when comparing changes in health. However, GlaxoSmithKline has developed a potent new approach to Pharmacovigilance (PV) by fusing traditional, case-based PV methods with data visualization and disproportionality tools. These technologies are part of a system structure that makes it easier to organize knowledge, track safety issues, and conduct in-stream reviews. PV will progress thanks to the procedures and this incredibly inventive equipment, which will increase productivity and offer new analytical possibilities. Pharmaceutical companies may use a similar strategy for quick ADR analysis and detection. Improved communication and transparency would support consumer reporting, which is a step in the right direction toward getting more consumers involved in PV[37].

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Conclusion :

Adverse drug reactions (ADRs) remain a significant global health concern, impacting patient safety, healthcare costs, and clinical outcomes. The historical data and contemporary studies underscore the critical need for robust pharmacovigilance (PV) systems. ADRs not only contribute to increased hospital admissions and mortality rates but also impose substantial financial burdens on healthcare systems.Pharmacovigilance has evolved considerably since its inception, especially after pivotal events like the thalidomide tragedy, which highlighted the dire consequences of inadequate drug safety monitoring. The development and implementation of PV practices have become essential in mitigating the risks associated with both human and veterinary medications. The pharmaceutical industry's adoption of early signal detection and risk management strategies has further enhanced the effectiveness of PV.In India, the establishment and subsequent advancements of the Pharmacovigilance Program for India (PvPI) demonstrate a significant commitment to improving drug safety. The expansion of adverse drug reaction monitoring centers and integration of AYUSH medicines into PV systems reflect a comprehensive approach to safeguarding public health. However, the future of pharmacovigilance demands continuous improvement. Enhanced collaboration between regulatory agencies, pharmaceutical companies, healthcare professionals, and IT sectors is crucial for developing sophisticated data collection and analysis tools. Training healthcare providers in PV practices and raising public awareness about ADR reporting are essential steps in creating a proactive drug safety culture.To maximize the benefits and minimize the risks of drug therapies, ongoing efforts in pharmacovigilance must focus on integrating best practices into clinical and regulatory frameworks. This will ensure the timely detection and management of ADRs, ultimately leading to safer medication use and improved patient outcomes globally. The commitment to pharmacovigilance is not just a regulatory obligation but a moral imperative to protect public health and enhance the quality of healthcare.

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