

Pharmacovigilance: Need for Indian Pharma Industry

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ABSTRACT :-

Pharmacovigilance is an integral part of clinical trials. Pharmacovigilance "is defined as the pharmacological science concerned with the identification, assessment, understanding and prevention of side effects, particularly long-term and short-term adverse drug reactions." This is about what exactly pharmacovigilance is. What we know about the benefits, risks, challenges and future of pharmacovigilance in Indian medicine. Here the focus is on the objectives and role of pharmacovigilance in regulating medicines and their partners.

Prevention and control is actually medical and scientific knowledge that concerns both error control, evaluation, better understanding and preventive measures such as side effects, a much longer concept, but also short term side effects such as medication. Rather, the goal of prevention and control is to increase the security of surveillance and also to identify any advertising messages received that may have been underestimated following the transformation of medical practices. Prevention and Control actually played an important role in the prudent use of the drug and also provided information on the side effects experienced by patients. In fact, Indian pharmaceutical technology ranks third in the world in terms of volume, but also seventeenth in terms of valuation. The country has also become a center for medical research and drug development, as well as advances in innovation, discovery and design. And production of a wide range of environmentally harmful particles, active ingredients and medicines. National Pharma Technology includes a comprehensive and standardized Quality management system, such as the enhanced, to ensure safe evaluation. This helps explain the need for this pharmaceutical technology, the basic principles between prevention and control, and the current state of the drug economy in the country.

Keywords:- Safety, efficacy, ADRs, industry, pharmacovigilance, adverse event, drug development, Monitoring, Indian Pharma industry.

I. INTRODUCTION:-

Pharmacovigilance has been defined as the process of identifying and responding to drug safety issues and has grown considerably as a discipline over the past 10 to 15 years. An educational survey in 1994 revealed that more than 320 people currently worked in company pharmacovigilance functions in the UK alone. Pharmaceutical companies are international, hence the number of staff working in this field within the industry, particularly in other European countries and the USA, is far greater. A major pharmaceutical company such as Astra has over 100 permanent, experienced staff in pharmacovigilance within its research and development organisation in Sweden and the UK and a similar number in local operating companies worldwide. This development has been driven by an increased recognition of the role of pharmacovigilance, the investigation and marketing of a wider range of diverse medicinal products and more stringent and detailed regulatory requirements. The number of individual reports of possible adverse drug reactions (ADRs) can be considerable, for key marketed products often more than 1000 case reports a year are received worldwide from health care professionals and other sources.(1)

What is pharmacovigilance(PV):-

Pharmacovigilance – also known as drug safety – is a broad term that describes the collection, analysis, monitoring and prevention of adverse effects in drugs and therapies. It is a completely scientific and process-driven area within pharma.(2)

STEPS IN PHARMACOVIGILANCE PROGRAMME :-

1. Determination of pharmacological risk of drug
2. Clinical studies
3. Pharmaceutical epidemiological study
4. Case reporting
5. Case series development
6. Case series analysis
7. Use of data mining to identify product-event combinations
8. Spontaneous reporting (3)

Partners in Pharmacovigilance :-

- Government
 - Pharmaceutical industry
 - Hospitals and universities
 - Medical and pharmaceutical associations
 - Drug information centers
 - Health workers
 - Patients
 - Consumers
 - Media
- World Health Organization (4)

Aims of Pharmacovigilance:-

1. Improve patient care and safety
2. Improve public health and safety
3. Contribute to the assessment of benefits and harms Effectiveness and risks of medicines
4. Promote clinical education and training
- 5 .Promote effective communication with the public
6. Promote the rational and safe use of medicines(8)

IMPORTANCE OF PHARMACOVIGILANCE:-

When a pharmaceutical drug is introduced in the market there are still a lot of things that are unknown about the safety of the new drugs. These medicines are used by various patients for different diseases. These people might be using several other drugs and must be following different traditions and diets which may adversely affect the impact of medicine in them. Also the different brands of same medicine might differ in the manner of their production and ingredients. Additionally, adverse drug reactions might also occur when drugs are taken along with traditional and herbal medicines that have also to be monitored through pharmacovigilance. In some cases, adverse drug reaction of certain medicines might occur only in one country's or region's citizens. To prevent all undue physical, mental and financial suffering by

patients, pharmacovigilance proves to be an important monitoring system for the safety of medicines in a country with the support of doctors, pharmacists, nurses and other health professionals of the country.

The Importance of Pharmacovigilance are as follows:-

1. Safety monitoring of medicinal products
2. Drug monitoring
3. Pharmaceutical preparations – adverse effects
4. Adverse drug reaction reporting
5. Product surveillance, Post marketing
6. Legislation(3)

Objectives of pharmacovigilance :-

Improving patient care and safety associated with the use of medicines and all medical procedures

- Improving public health and safety associated with the use of medicines;
- Identify problems related to medication use and communicate results in a timely manner.
- Participate in the assessment of the benefit-risk ratio, effectiveness and risk of drugs to prevent harm and maximize benefit.
- Encourage the safety, more rational and effective (including economically more advantageous) use of medicines
- Promote understanding, education and training in pharmacovigilance and its effective communication to the public.(5)

ROLES OF PHARMACOVIGILANCE:-

Pharmacovigilance has been widely accepted to Possess a significant role in early observation of The risk associated with the drug. All the Medicines are tested on a concerned small ratio Of population before it is approved for post-Marketing surveillance. The pharmacovigilance Has been known to possess various roles like, Identification, quantification and documentation Of drug-related problems; contribution towards Reducing the risk of drug-related problems in Healthcare systems; and enhancement of Knowledge and understanding of factors and Mechanisms which are responsible for drug-Related injuries. [6] However, in order to fulfill Various roles of pharmacovigilance, the Interactions and influence of many stakeholders In society with decision-making powers has been Required, which include, politicians at national, Regional and local levels; healthcare Administrators; drug regulatory authorities; Pharmaceutical companies; healthcare

Professionals like physicians, dentists, Pharmacists and nurses; academic institutions; Media representatives; health insurance Companies; lawyers; and patient group.(7)



Key goals of pharmacovigilance(9):-

ACTIVITIES IN PHARMACOVIGILANCE OPERATIONS:-

- Case Registry
- Triage
- Registry
- Enrollment
- Processing
- Data Entering
- Coding
- Labelling

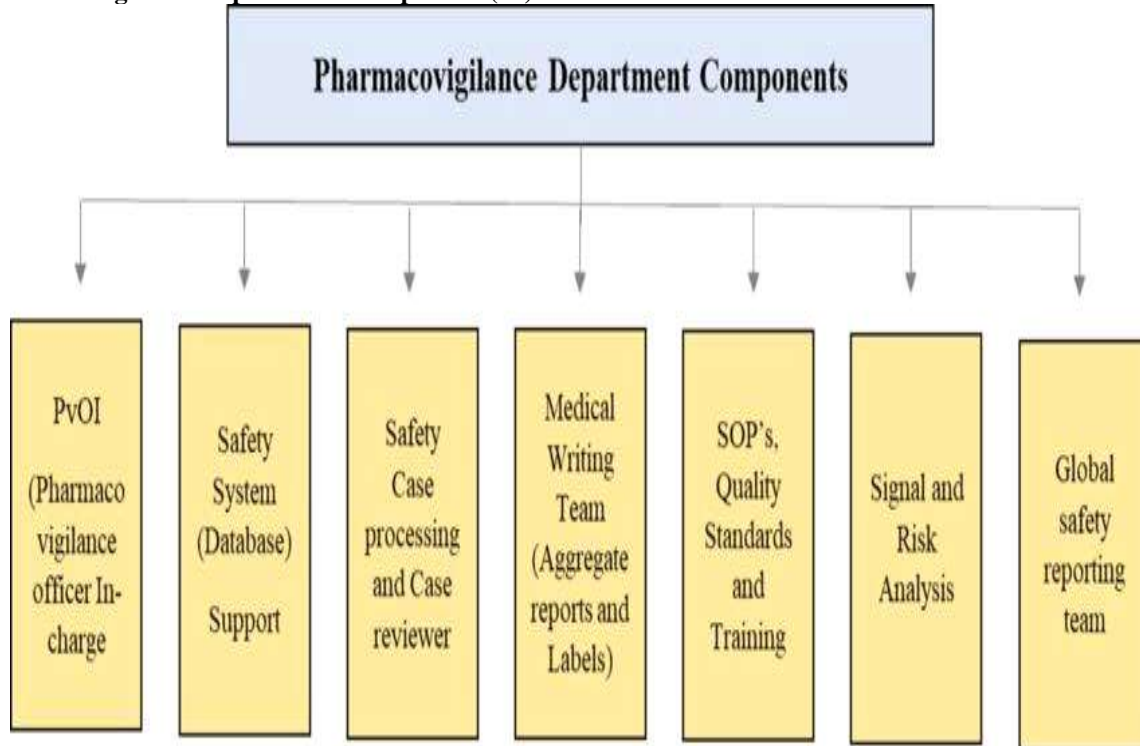
Medical Review:

- Serious Case Medical Review
- Non Serious Listing Review
- Aggregate Report Review

Aggregate Reports:

- Analysis And Creation of IND/NDA Reports
- Analysis And Creation of Pader Report
- Analysis And Creation of Psur & Bridge Reports(10)

Pharmacovigilance Department Components(11)



Pharmacovigilance Programme of India (PvPI):-

Central Drug Standards Control Organization (CDSCO), Directorate General of Health Services, Ministry of Health and Health Services, Family Welfare, Government of India, in collaboration with Pharmacopoeia Commission of India, Ghaziabad, launches national pharmacovigilance program to protect patients' health by promising drug safety. The program is coordinated by the Indian Pharmacopoeia Commission, Ghaziabad, as the National Coordination Center (NCC). The Center operates under the supervision of a steering committee. The Pharmacovigilance Program of India (PvPI) was launched on July 14, 2010 by the Government of India in collaboration with the All India Institute of Medical Sciences (AIIMS), New Delhi, as a national coordination center for drug surveillance. (ADR) in the country. Of the country to protect public health. In 2010, 22 adverse reaction monitoring centers were set up under this program, including AIIMS in New Delhi. To ensure more effective implementation of this program, the National Coordination Center was transferred from All India Institute of Medical Sciences (AIIMS), New Delhi to Indian Pharmacopoeia Commission, Ghaziabad, Uttar on April 15, 2011. Pradesh.

Before registration and marketing of the drug in the country. Experiences regarding the safety and effectiveness of a drug are based primarily on their use in clinical studies. These tests are primarily used to detect common side effects. Some important reactions, such as those that take time to develop or occur infrequently, may not be detected in clinical trials. Furthermore, the controlled conditions under which drugs are used in clinical trials do not necessarily reflect how they are used in practice. For a drug to be considered safe, its foreseeable benefits must outweigh the associated risk of harmful reactions. Therefore, to obtain a complete safety profile of a drug, a

A system of continuous post-market surveillance, i.e. H. pharmacovigilance is essential. Pharmacovigilance uses information from many sources to monitor the safety of medicines. These include the spontaneous signaling mechanism (ADR); medical literature published worldwide, actions by regulatory authorities in other countries, etc. At the same time, adverse drug reactions have significant social and economic consequences and the application of appropriate risk management has a positive cost-effectiveness ratio (it is necessary to involve medical professionals and the general public in a well-organized program to create

synergies). Monitoring of adverse effects). Drug reactions in the country). The goal of PvPI is to collect, process and analyze data and use the results to recommend regulatory interventions and communicate risks to healthcare professionals and the public.

Mission:- Safeguard the health of the Indian population by Ensuring that the benefits of use of medicine outweigh the Risks associated with its use.

Vision:- To improve patient safety and welfare in Indian Population by monitoring the drug safety and thereby Reducing the risk associated with use of medicines.

Objectives:-

- To create a nation-wide system for patient safety Reporting
- To identify and analyze the new signal (ADR) from The reported cases
- To analyses the benefit – risk ratio of marketed Medications
- To generate the evidence based information on Safety of medicines
- To support regulatory agencies in the decision-Making process on use of medications(12)

NEED OF PHARMACOVIGILANCE :-

It is widely accepted that clinical drug development is a complex and time-consuming process. Once a drug is brought to market, it leaves the safe scientific environment of clinical trials and becomes available for free consumption to the general public. At this time, the safety and effectiveness of most medications are only tested in the short term on a limited number of carefully selected people. It is therefore necessary to introduce pharmacovigilance, in particular to ensure the early detection of new adverse reactions or subgroups of patients with exceptional susceptibility; and take measures to manage these risks. In addition, it is important that new and medically evolving treatments are monitored once they come to market to determine their effectiveness and safety in practice. In addition, more information is generally needed on use in specific population groups such as children, pregnant women and the elderly, as well as on the effectiveness and safety of chronic use in combination with other drugs. Subsequently, numerous adverse events, drug interactions, and risk factors were reported during the years of drug introduction (13).

KEY TASKS AND RESPONSIBILITIES OF PHARMACOVIGILANCE :-

- Organize, manage and maintain a highly compliant Pharmacovigilance (PV) system for Emmaus Medical.
- Maintain awareness and ensure adherence to established and updated local and global processes and Guidelines as well as national and international regulations and guidelines for pharmacovigilance.
- Ensure PV business continuity and after hours availability.
- Lead and coordinate internal and external PV audits and inspections.
- Monitor PV system performance and compliance of partners and distributors.
- Maintain expertise in country as well as worldwide regulations and guidelines and promote increased Awareness of the legislative and regulatory environment in the country.
- Accountable for all strategic PV activities for MEA.
- Active contribution to the activities relevant to the pharmacovigilance system to ensure monitoring of the Safety profile of Emmaus Medical products and to meet regulatory requirements.
- Act as the responsible contact person in the region, internally and externally, for safety-related aspects And PV.
- Ensure internal regulatory/PV processes and procedures are well documented and support compliant Regulatory/PV activities.
- Perform other duties as assigned.(14)

Main objective of pharmacovigilance :-

Adverse Drug Reactions:

The main objective of the Pharmacovigilance is mainly related with the reporting of the ADRs. As per the definition of the WHO ADR is defined as a response to medicine in humans or Animals, which is unintended and noxious including the lack of efficacy that occurs at any Dosage and can also be due to misuse, overdose and abuse. Adverse event (AE) is any Undesirable experience associated with the use of the medicinal product in human (kc, Tragulpiankit, Gorsanan, & Edwards, 2013). Per the literature review ADR and AEs are Common problems due to the pharmacotherapy and which are main reason for the congenital Anomaly, morbidity and mortality around the world. In some countries ADRs are categorized as A top ten for the leading causes of the mortality. Per the research studies conducted at various Parts of the world containing 41900 patients and identified that approximately

6.7% of all the Hospitalization were due to ADRs (Mehta, M Dheda, & Steel, 2014). Below are the statistics From the countries were AEs accounted for hospitalization (Mehta, M Dheda, & Steel, 2014)

- 3.2 % in France
- 6.7% in the USA
- 12% in Sweden
- 6.5% in the UK

The studies conducted by Metha (2014) showed for managing ADRs it causing significant Burden on the Health care. Per the literature review, some countries are spending 15% of their Budget to manage drug related issues. So, due to ADRs pose more burden on the health care System as they lead to prolonged hospital stays and increase cost of the treatment.

ADR reporting:

The success of the Pharmacovigilance depends upon the suspected ADR reporting process. The ADR reporting process can be done by two methods

- Voluntary
- Spontaneous reporting

Spontaneous reporting is considered as the most common method and the keystone for Any Pharmacovigilance system (European, 2014).The two reporting system are considered as the essential components of the drug safety Surveillance system and are the most effective methods of collecting ADRs especially in case of The new and serious ADRs. This type of reporting lies within in the HCPs identify and report suspected ADRs to the respective health authorities or the pharmaceutical companies that own Marketing authorization for the product.Though the process is considered as vital role for the reporting but under reporting is the most Outcome for the spontaneous reporting system (European, 2014). The underreporting system Will impact majorly on the safety profile of the product which delays in identifying the ADRs And can increase risks of drugs related morbidity and mortality rate. Overall, under reporting of The ADRs is common and significant problem for developing effective drug safety surveillance Programs for products. (15)

Pharmacovigilance in Healthcare Education:-

Social insurance experts have little cognizance of Pharmacovigilance and ADR revealing and just couple Of instructive associations effect sly affected this Mindfulness.

Future human services suppliers ought To along these lines obtain a sufficient arrangement of Pharmacovigilance capabilities to normally recommend, Circulate and screen drugs. Anticipating, diagnosing, Overseeing and detailing ADRs are a critical piece of Normal and safe recommending and are acclimatized Into various strides of the WHO-six-advance Guide To Good Prescribing.¹⁹ Various examinations have Communicated worry about the absence of medicinal Services proficient skills in pharmacovigilance.^{20,21}This absence of undergrad instruction and preparing In pharmacovigilance is predictable with the low Dimension of information, abilities and activities seen In doctors as well as in rehearsing pharmacists, dental Practitioners and medical attendants.²²⁻²⁴ Newness to Pharmacovigilance, a low dimension of ADR-detailing Abilities, an absence of learning joined with negative Demeanors like obliviousness, fear legitimate risk and Absence of significance are believed to be identified with The current deficient reaction to numerous ADRs.²⁵⁻²⁸A few mediations (actualizing conventions, instructive Workshops, or continued messaging or phone calls) Have been executed trying to enhance the fitness of Social insurance experts,²⁹⁻³² yet these intercessions are Exorbitant or neglect to deliver clinically applicable and Long-haul impacts. (16)

Pharmacovigilance as specialty in the Pharmaceutical industry:-

The PV as a discipline is now well established in The biopharmaceutical industry. The majority of Biopharmaceutical companies have either well-Managed in-house PV department or partially/Completely outsource such activities to a third Party such as CRO or BPO. Achieving the required Quality outcome during the conduct of PV activities By an organization is intrinsically related to the Availability of a sufficient number of competent And appropriately qualified and trained personnel. The majority of workflow and capacity planning is Dependent on qualified and trained human resources Due to the fact that the safety data requires thorough Assessment in the context of clinical practice and Pharmacotherapy. This helps to draw a meaningful Conclusion out and then submit this data in a pre-Defined format for the purpose of regulatory Reporting. Also, regulatory guidelines, including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines require that the personnel involved In clinical

research and PV activities are qualified by Education training, and experience to perform his or Her respective task(s). Because many of the clinical Research and PV operations are regularly subjected To audits and inspections, it is expected that the PV Activities are conducted with integrity, high quality And compliance to meet the regulatory standards.

Growth of pharmacovigilance business:-

The PV market has seen an exponential growth in Terms of volume and revenue over the last 6-7 years. The growth is accompanied by increased outsourcing Of PV operations to CROs and BPOs, which are now Representing half of the overall market share in Drug safety. A recent industry report forecasts that The PV market will exceed USD 8 billion by 2024 With Asia Pacific alone anticipated exceeding USD 2.4 billion by the same year. Major players in the Market are innovator and generic pharmaceutical Companies, CROs, BPOs, and Knowledge Processing Organizations (KPOs). India, being the hub for many Of these companies, the PV market is expected to Reach USD 668 million by 2024. Increasing number Of clinical studies following recent regulatory Reforms along with the low operating cost of the Region can be attributed to this growth in India.(17)

Jobs in pharmacovigilance :-

There are a number of job roles that sit within drug safety, each with varying tasks and levels of responsibility. Exact duties will depend on whether you are working within the pre-approval or post-approval stages of pharmacovigilance, and the type of company you are employed by. Some roles you might want to consider include:

PV Associate – a more entry level role that involves providing support in all administrative aspects of safety information, including capturing adverse event information and entering data from trials

PV Support – usually responsible for supporting the collection and tracking of PV requirements as well as interacting with vendors to support the handover of PV activities

PV Manager – generally performs the role of project manager, provides advice on PV strategy and coordinates regulatory documents for products

PV Specialist / Scientist– involves assessing and processing incoming safety data from multiple

sources, entering data and providing information to marketing partners/third-party partners

Clinical Scientist – a medical and healthcare professional who supports other clinical staff in their work with patients. Their work is very broad and can include laboratory and testing work, research and management.

Clinical Research Associate – plans, prepares and carries out clinical trials in order to test new or existing drugs and assess their safety and benefits of use.

Clinical Data Manager – responsible for ensuring that statistical information and results from clinical trials are recorded and reported accurately, both during and after they are complete. (18)

The future of pharmacovigilance :-

The pharmacovigilance field is constantly evolving and adapting to changes in the healthcare landscape. The future of pharmacovigilance will continue to be driven by advances in technology, changes in the regulatory environment, and the increasingly global nature of drug development and drug use.

Technology will continue to play a major role in shaping the future of pharmacovigilance. The rise of big data and real-world data will provide new opportunities for more effective and efficient monitoring of drug safety. New analytical methods, such as machine learning, will allow for a more sophisticated analysis of data. And mobile health technologies will enable patients and healthcare providers to report adverse events more easily and quickly.

The regulatory environment Is also likely to change in the coming years. The European Union's new Clinical Trials Regulation, which is set to go into effect in 2020, will have a major impact on clinical trial conduct and data sharing. In addition, the FDA is considering new regulations that would require sponsors to submit electronic medical records for certain drugs undergoing post marketing studies. These changes could have a significant impact on the Future of Pharmacovigilance.

Finally, the globalization of drug development and use will continue to present challenges for pharmacovigilance. As more drugs are developed and used internationally, it becomes increasingly difficult to track safety information across borders. This challenge is compounded by the fact that, oftentimes, different countries have different regulations regarding adverse event reporting.(19)

Challenges and Future Directions in Pharmacovigilance in Clinical Trials:

Despite advances in pharmacovigilance, several challenges remain to be addressed. Additionally, several possible future directions could further improve the effectiveness of pharmacovigilance in clinical trials. Here are some of the key challenges and future directions for

Challenges:

Global harmonization and standardization: Global harmonization and standardization of Pharmacovigilance practices remains a challenge. Differences in regulations, reporting requirements, data collection methods And data collection between countries can lead to inconsistencies and hinder effective data sharing and analysis .

Ethical considerations and participant rights: Ensuring the ethics of behavior and protecting the rights of participants Are ongoing challenges. When collecting, analyzing, and reporting safety data, it is important to maintain confidentiality, informed consent, and participant confidentiality. Balancing the need for Data transparency and subscriber privacy can be difficult.

Future Directions:

Real-time monitoring and proactive pharmacovigilance: Technological advances can enable real-time monitoring of safety data, enabling proactive identification and management of safety signals. Continuous monitoring of patient data, integration of wearable devices, and use of real-world evidence can improve safety monitoring in clinical trials.

Integration of artificial intelligence and machine learning: Further integration of artificial intelligence (AI) and machine learning (ML) techniques can support automatic adverse event detection, signal identification and risk prediction. Artificial intelligence algorithms can analyze large data sets, detect patterns and generate safety alerts in real-time, improving the efficiency and accuracy of pharmacovigilance processes.(20)

II. CONCLUSION:-

The Indian pharmaceutical industry is the third largest industry next to number Overall, but thanks to concepts like pricing it is also the 13th. Mainly the real economy itself is controlled , even branded generics Which account for almost 70-80% of both sectors . It has has also proven to be a

center for both clinical trials and drug discovery processes. And through these visits new drug suppliers, equipment and organizations involved in the synthesis are regularly added. Therefore, a typical quality management system is required to both monitor the harmful effects of substances and ensure the health of the consumer. Despite all the efforts outside Cisco, an organization such as a global quality management system in the country faces many difficulties that need to be overcome, from successful implementation, prevention and control to the lack of knowledge on the part of many pharmacies, care. Staff, patients and professionals struggling with absenteeism, for example when reporting side effects. The two hours would be used to begin training the medical professional itself, a pharmacologist. However, medical professionals have begun to promote the use of these comprehensive investigation platforms, which have confirmed some phenomena in humans. Conventional norms such as prevention and control across the country, motivated by large-scale prevention and control processes that are both contrived and causal, would therefore certainly serve their purpose in ensuring the safety of people, including sick people. And the creation of a global framework, for example for the safety of Medicines that are monitored.

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