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A Review on Pharmacovigilance

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ABSTRACT

Pharmacovigilance (PV) plays a key role in the healthcare system by assessing, monitoring and detecting drug interactions and adverse drug reactions in humans. Medicines are intended to cure, prevent or treat disease. However, there are also risks, especially adverse drug reactions (ADRs) that can cause serious harm to patients. Therefore, for safe drugs, adverse reactions should be monitored throughout the life cycle of each drug, during drug development (e.g. pre-market, including early stages of drug design, clinical trial phase and post-marketing surveillance). Pharmacovigilance is the science and activities concerned with the detection, assessment, understanding and prevention of adverse effects or any other drug/vaccine related issues.

Thepresent review presents in brief about the relevance, need, role, partners and program of pharmacovigilance.

KEYWORD :- Pharmacovigilance

I. INTRODUCTION

PV is the science of collecting, monitoring, researching, evaluating and evaluating information from health care providers and patients about the adverse effects of drugs, products biologics, blood products, herbal remedies, vaccines, medical devices, traditional and complementary medicine. intended to identify new hazard information associated with the product and to prevent harm to patients.The primary goal of pharmacovigilance is to provide patients with certainty about their medicines. Because relatively few patients are selected in clinical trials, results regarding the safety and efficacy of drugs are limited, drugs are approved for use, and drugs are tested for a limited period. After approval, it can be used for many patients for a long time. As this drug is being used by more people, certain side effects may occur. This raises drug safety issues. Therefore, it is important to continuously monitor the safety of all medicines. Pharmacovigilance, therefore, plays an important role in monitoring the safety and efficacy of medicines. Drug safety and Pharmacovigilance remains a dynamic clinical and scientific discipline. According to WHO, Pharmacovigilance (PV) as the pharmacological science and activities relating to the monitoring, detection, assessment, understanding and prevention of adverse drug reaction or any long term and short term medicines related problem. Pharmacovigilance is highly regulated in major regions of the world where medicines are developed.While major advancements of displine of pharmacovigilance have taken place in the western countries not much has been achieved in India. There is an immense need to understand the importance of pharmacovigilance and how it impacts the life cycle of the product. This will enable integration of good pharmacovigilance practice in the process and procedures to help ensure regulatory compliance and enhance clinical trials safety and post marketing surveillance.

HISTORY OF PHARMACOVIGILANCE IN INDIA

Pharmacovigilance in India has a history that parallels the global development of the field. Here's a brief overview:

Early Initiatives: India's pharmacovigilance efforts began in the 1980s with the establishment of the Adverse Drug Reaction Monitoring Centre (AMC) in Mumbai, which later became the Pharmacovigilance Programme of India (PvPI). These early initiatives focused on collecting and analyzing data on adverse drug reactions (ADRs) in India.

National Pharmacovigilance Programme: In 2004, the Ministry of Health and Family Welfare launched the National Pharmacovigilance Programme for monitoring ADRs in India. This program aimed to improve drug safety monitoring and reporting across the country.

Pharmacovigilance Regulations: India introduced pharmacovigilance regulations in 2010, making it mandatory for pharmaceutical companies to report serious adverse events to the regulatory authorities. This was a significant step towards strengthening pharmacovigilance practices in the country.

Pharmacovigilance Cell: In 2013, the Central Drugs Standard Control Organization (CDSCO) established a Pharmacovigilance Cell to

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oversee and coordinate pharmacovigilance activities in India. This cell plays a key role in monitoring and evaluating ADR reports from various sources.

Global Harmonization: India has also been actively involved in global harmonization efforts in pharmacovigilance. It is a member of the International Council for Harmonisation (ICH) and has adopted ICH guidelines to align its pharmacovigilance practices with international standards.

Current Status: Today, India has a well-established pharmacovigilance system with a network of ADR monitoring centers across the country. The PvPI plays a central role in coordinating these efforts and ensuring the safety of pharmaceutical products in India.

• Medicines and Cosmetics Act and its rules 1945: The establishment of pharmacovigilance rooms in the pharmaceutical industry is mandatory.

• National Health Policy: Drug Monitoring, including prescription audits, including antibiotic use, Ministry of Health and Ministry of Health; Family Welfare, Government of India.

WHAT IS PHARMACOVIGILANCE

There is a want to display the consequences of medication earlier than and after it‟s efficaciously examined and released within side the market. Pharmacovigilance includes tracking and assessing the first-class of medication , detection and stopping of any destructive consequences of medication . Pharmacovigilance includes comparing statistics furnished via way of means of fitness care providers, pharmaceutical organizations and sufferers with the intention to apprehend the dangers and blessings worried with a specific drug. Pharmaceutical organizations spend tens of thousands and thousands of greenbacks and a drastically long term in growing new drugs.

They once more spend a whole lot of cash in accomplishing medical trials earlier than the medicine are approved and released withinside the market. It is identified that records technology (IT) has entered and converted the arena of fitness care and medical medicinal drug wherein the paintings of medical doctors and the care of sufferers continue with better quality, performance and decrease costs. It is likewise no secret that IT has merged in to medical protection exercise and sparks the advent of worldwide pharmacovigilance structures for protection sign detection.

Regulators are demanding proactive surveillance programs that include comprehensive risk management plans and signal detection /analysis throughout a clinical products‟ life cycle.

- This addresses what exactly is pharmacovigilance?
- What do we know of its benefits and risks?
- What challenges are out there preventing its wide spread usage?
- And what does the future hold for pharmacovigilance in worldwide medicine?

These sports are beneathneath keen on the intention of figuring out destructive activities and understanding, to the quantity possible, their nature, frequency, and capacity danger factor. Pharmacovigilance in precept includes the identity and assessment of protection signals. Safety sign seek advice from a situation approximately an extra of destructive activities as compared to what could be anticipated to be related to merchandise use. Signals can arise from post marketing data and other sources, such as pre clinical data and events associated with other products in the same pharmacological class. Pharmacovigilance is particularly concerned with adverse drug reactions. Many other issues are also relevant to pharmacovigilance science are substandard medicines, medication errors, lack of efficacy reports, use of medicines for indications that are not approved and for which there is inadequate scientific basis, case reports of acute and chronic poisoning, assessment of drug related mortality, abuse and misuse of medicines, adverse interactions of medicines with chemicals, other medicines and food.

AIMS OF PHARMACOVIGILANCE

Detecting Previously Unrecognized Adverse Effects: Pharmacovigilance helps in identifying new or rare adverse effects of medicines that may not have been evident during clinical trials.Assessing the Risks and Benefits of Medicines: It aims to continuously evaluate the risks and benefits of medicines to ensure that the benefits outweigh the risks.Preventing Harmful Effects of Medicines: Pharmacovigilance helps in identifying and preventing harmful effects of medicines, thereby improving patient safety.Promoting Rational and Safe Use of Medicines: It aims to promote the rational and safe use of medicines by providing information on their

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risks and benefits to healthcare professionals and patients.Contributing to the Evaluation of Medicinal Products: Pharmacovigilance data contributes to the overall evaluation of medicinal products by regulatory authorities, which helps in making informed decisions about their approval, withdrawal, or restrictions.Improving Patient Care and Public Health: By ensuring the safe use of medicines, pharmacovigilance contributes to improving patient care and public health outcomes.

1. To Increase public protection from the new drugs
2. To contribute to assessment of benefit efficiency and risk of medicines.
3. Endorse healthy communication to the community.
4. To promote rational and safe use of medicines.
5. Efficacy of drug and their monitoring about adverse effects of drugs.
6. Pharmacovigilance keeps way of any drastic effects of medicines. Improve public health and safeties in relation to the use of promote understanding, education and clinical training in pharmacovigilance.More information is generally needed about use in specific population groups, notably Children, pregnant women and the elderly, and about the efficacy and safety of chronic use, especially in combination with other medicines. Experience has shown that many adverse effects, interactions (i.e. with foods or other medicines) and risk factors come to light only during the years after the release of a medicine.

NEED OF PHARMACOVIGILANCE

It is widely accepted that clinical development of medicines is a complex process which require huge amount of time for its completion. Once a drug is marketed, it leaves the secure and protected scientific environment of clinical trials and is free for consumption by the general public. At this point, most medicines will only have been tested for short-term safety and efficacy on a limited number of carefully selected individuals. Hence, need of pharmacovigilance arises which include, securing the early detection of new adverse reactions or patients subgroups of exceptional sensitivity; and introducing certain measures in order to manage such risks. Moreover, it is essential that new and medically Still evolving treatments are monitored for their effectiveness and safety under real-life conditions after being marketed. Furthermore, more information is generally needed about use in specific population groups like children, pregnant women and the elderly, about the efficacy and safety of chronic use in combination with other drugs. Numbers of adverse Effects, drug-interactions and risk factors have been reported later in the years of drug release.

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.

OBJECTIVE OF PHARMACOVIGILANCE

Improvement of affected person care and protection in relation to using drug treatments with scientific and paramedical interventions stays to be an essential parameter. The essential goals of Pharmacovigilance contain showing the efficacy of medication with the aid of using tracking their unfavourable effect Profile for decades from the lab to the Pharmacy; monitoring any drastic results of medication enhancing public fitness and protection in relation to using drug treatments ; encouraging the safe, rational and cost- powerful use of medication ; selling understanding, training and clinical education in pharmacovigilance; and powerful communique to the regularly occurring public. In addition, imparting records to consumers, practitioners and regulators at the powerful use of medication along with designing packages and tactics for gathering and reading reports from sufferers and clinicians finish to the goals of pharmacovigilance studies.

1. To create a nation-wide system for patient safety reporting.
2. To identify and analyse the new signal (ADR) from the reported cases.
3. To generate the evidence-based information on safety of medicines.
4. To analyse the benefit-risk ratio of marketed medications.
5. To support regulatory agencies in the decision-making process on use of medications.

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6. To communicate the safety information on use of medicines to various stakeholders to minimise the Risk.
7. To emerge as a national centre of excellence for pharmacovigilance activities.
8. To provide training and consultancy support to other national pharmacovigilance.
9. To collaborate with other national centres for the exchange of information and data management

ROLE OF PHARMACOVIGILANCE

Pharmacovigilance has been extensively widely wide-spread to own a oversize position in early commentary of The hazard related to the drug. All the drug treatments are examined on a worried small ratio of populace earlier than it's miles authorised for post-advertising and marketing surveillance. The pharmacovigilance has been recognised to own diverse roles like, identification, quantification and documentation of drug- associated issues; contribution towards lowering the hazard of drug- associated issues in healthcare systems; and enhancement of understanding and expertise of things and mechanisms that are accountable for drug-associated injuries. However, so one can fulfill diverse roles of pharmacovigilance, the interactions and affect of many stakeholders in society with decision-making powers has been Required, which include, politicians at national, local and neighborhood levels; healthcare administrators; drug regulatory authorities; pharmaceutical companies; healthcare specialists like physicians, dentists, pharmacists and nurses; educational institutions; media representatives; fitness insurance Companies; lawyers; and affected person group.

"Role of pharmacovigilance" in medicines regulation"

Robust regulatory arrangements provide the foundation for a national method of medicine safety, and for public confidence in medicines. To be effective the remit of drug regulatory authorities needs to go further than the approval of new medicines, to encompass a wider range of issues relating to the safety of medicines, namely:

- Clinical trials;
- The safety of complementary and traditional medicines, vaccines and biological medicines;
- The development of lines of communication between all parties which have an interest in Medicine safety, ensuring that they are able to function efficiently and ethically,

Particularly at times of crisis.

PURPOSE OF PHARMACOVIGILANCE

Pharmacovigilance has developed and will continue to develop in response to the special needs.
The concerns of Pharmacovigilance include the following:

• Herbals
• Traditional and complementary medicines
• Blood products and biologicals
• Medical devices
• Vaccines

Other issues of relevance to the science includes substandard medicines, medication errors, inadequate

Efficacy reports, use of medicines for indications that are not approved and for which there is inadequate scientific basis, case reports of acute and chronic poisoning, adverse interactions of medicines with chemicals, other medicines and food.

PARTNERS IN PHARMACOVIGILANCE

A complex and vital relationship exists between wide ranges of partners in the practice of drug safety monitoring. Sustained collaboration and commitment are vital if future challenges in pharmacovigilance are to be met in order to develop and flourish.

• Government
• Industry
• Hospital and academia
• Poison information centers
• Health professionals
• Patients
• Consumers
• Media
• WHO

PHARMACOVIGILANCE PROGRAMME

The country wide pharmacovigilance appliance performs a critical position in growing public consciousness of drug Protection. However, minimal necessities for a practical country wide pharmacovigilance gadget are required which encompass a country wide Pharmacovigilance centre with certain staff, solid simple funding, clean mandates, nicely defined systems and roles and taking part with the WHO programme for worldwide drug Monitoring; the lifestyles of a country wide Spontaneous reporting gadget with a

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country wide person case protection report (ICSR) form; a country wide database or gadget for collating and handling adverse drug response reports; a country wide pharmacovigilance advisory committee capable of offer technical help on causality assessment, hazard assessment, hazard management, Case investigation; and a clean verbal exchange method for recurring verbal exchange and crises verbal exchange .

- Assessing the risks and benefits of medicines in order to determine what action, if any, is necessary to improve their safe use.
- Providing information to users to optimise safe and effective use of medicines.
- Monitoring the impact of any action taken.

INDIA'S CURRENT PV PROGRAM

India's current PV program recognizes the need to revive NPVP and the framework for the new current program was developed in a brainstorming workshop jointly organized by the Department of Pharmacology, AIIMS and CDSCO at the end of of 2009. The program, now renamed Pharmacovigilance Initiative of India (PVPI), was launched by the Government of India on July 14, 2010, with AIIMS New Delhi acting as the National Coordinating Center (NCC) for monitoring adverse reactions in thecountry to protect public health. In 2010, 22 ADR monitoring centres, including AIIMS in New Delhi, were created under this project. To ensure more efficient implementation of the program, the NCC was transferred from AIIMS, New Delhi to Indian Pharmacopoeia Commission (IPC), Ghaziabad, Uttar Pradesh on 15 April 2011.Generate independent drug safety data that meets Global drug safety monitoring standards. The latest PVPI AMC report was prepared by VigiFlow's ADR service. In May 2014, the CNC received a total of 3,537 individual case safety reports (ICSRs) and 1,948 post-vaccination adverse events (AESIs) from AMCs. Seven centers received Access to VigiFlow from UMC in Sweden. Of the 97 AMCs that operate Vigiflow, 82 have filed traffic complaints via VigiFlow.PGIMER in Chandigarh recorded the highest number of adverse reaction reports (311 in May 2014), followed by MMC in Chennai with 225. JSS, Mysore 216 reports; 184 reports from UCMS-GTBH, Delhi; 167 LHMC Reports, New Delhi. The report has been assessed by the NCC (qualitative and medical).

II. CONCLUSION:-

Pharmacovigilance looks at all available information to assess the safety profile of a drug. Pharmacovigilance should also take the benefit of the drug in account. Pharmacovigilance required for systematically identifying and correlating drugs and side effects and taking corrective actions.Moreover, providing the regulators with the necessary information to amend the recommendations on the use of the Medicines; improving communication between the health professionals and the public; and educating the health professionals to understand the effectiveness and risk of medicines theyPrescribe, is the need of the moment.

Table 1: Common Drug Interactions

Class of Drugs	Effects
Tetracycline	Poor absorbtion of tetracyclines
Amino glycoside	Hearing problem, kidney problem
Anti diabetic	Lower blood sugar
Warfarin	Increased risk of bleeding
Phenytoin	CNS and Respiratory depression
Barbiturates	Muscle weakness,Reduced consciousness, coma
Lithium	Hypothermia
Alprazalon, Diazepam	CNS depression, sedation
Warfarin	Haemorrhage
Methotrexate	Bone marrow suppression
Benzodiazepines	Sedation and Respiratory suppression
Ethanol	Additive CNS effect, Death
Predmisone	Edema
Theophyllines	Insomnia, seizures, restlessness
Miconazole	Severe hypoglycaemia

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