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A review Article on: Pharmacovigilance

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ABSTRACT:-
Pharmacovigilance, defined by the World Health Organization as "the science and set of activities related to the identification, assessment, understanding and prevention of adverse reactions or other problems associated with medicines", plays an important role in ensuring the safety of medicines for Patients. It plays a key role in providing safe medicines to patients. Pharmacovigilance generally describes drug safety . The goals of pharmacovigilance include improving patient care and drug safety, improving public health and drug safety, and identifying drug-related complications. . Currently, pharmacovigilance in India is increasing awareness of adverse drug reactions (ADRs), and this review provides insights into implementation to address current issues. It makes a crucial contribution to ensuring that patients receive safe medication. Our knowledge of adverse drug reactions can be improved in several ways, including spontaneous reporting, intensive monitoring, and database searching. The main objective of the review is to uncover various aspects of pharmacovigilance , including new methodological developments.

I. INTRODUCTION :-

Pharmacovigilance is the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problems. According to the World Health Organization, "Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problem, particularly long term and short term adverse effects of medicines.[1]Pharmacovigilance is one of the pillars of the healthcare system through assessment, monitoring and discovery of interaction among drugs and effect of drugs in human beings. Fields of medicines like pharmaceutical and biotechnology are map out to cure, prevent, mitigate or treat diseases; although there are risks in particular Adverse Drug Reaction (ADR) can cause distress to patients. Thus, ADRs monitoring is having vital importance for safety of a medication.[2]Pharmacovigilance greatly focuses on adverse drug reactions (ADRs) which are defined as any reaction to a drug which is harmful and unintended including lack of efficacy used for the prophylaxis, analysis or therapy of illness or for the modification of physiological function.[3] Pharmacovigilance is the science gathering, monitoring, exploring, assessing and evaluating information from healthcare professionals and patients on adverse effects of the medications, blood and biological products, herbals, sera, vaccines, medical devices, traditional and complementary medicines with a view to spot new information about hazards associated with medications and preventing harm to patients.[4] Pharmacovigilance greatly focuses on adverse drug reactions (ADRs) which are defined as any reaction to a drug which is harmful and unintended including lack of efficacy used for the prophylaxis, analysis or therapy of illness or for the modification of physiological function.[3]

PV systems' differences in developing countries are influenced by local contextual factors such as healthcare expenditure, disease types and prevalence, and political climate.[14] PV also plays a role in helping drug manufacturing firms in carrying out patient outreach through communicating with patients about drug products' risk–benefit profile thus making them better informed and building their trust in the industry.[15] Such assessment can help define the elements of a sustainable PV strategy and areas for improvements as the basis to plan for improved public health and safety of medicines.[16]

An ADR may be defined as "an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or

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specific treatment, or alteration of the dosage regimen, or withdrawal of the product"[17]

Purpose:

Pharmacovigilance (PV) is a relatively new discipline in the pharmaceutical industry. After rapid development over the last two decades, photovoltaics now encompasses many other disciplines in research and development companies. With its development, the medical community's awareness and interest in the role of photovoltaics has increased. This article provides an overview of the background and functionality of photovoltaics.

Objectives:

➢ To improve patient care and safety associated with the use of medicines.

➢ To improve public health and safety of medicines.

➢ To identify complications associated with the use of drugs and conveying it a suitable manner.

➢ To evaluate advantage efficacy and risk of medicines as well as promoting safe, rational and more effective use of medicines.

➢ To encourage education understanding and clinical training in Pharmacovigilance along with its effective communication to the healthcare workers and public.

Role of Pharmacovigilance :-

Pharmacovigilance is specifically concerned with ADRs. Incessant monitoring of effects of drug, side effects, contraindication and outright adverse effects which could result in a drastic degree of morbidity and in some cases even mortality are essential to maximize benefits and reduce risks. The drug regulatory agencies hence

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the responsibility of having a well-established Pharmacovigilance system for monitoring ADRs during the life time of marketed product from drug development phase and to finished product.

History of Pharmacovigilance in India :-

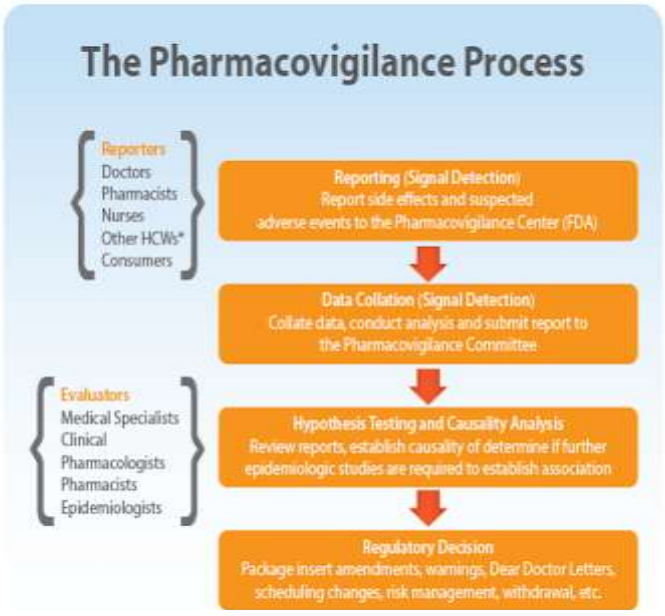
Pharmacovigilance in India started from 1986. A formal Adverse Drug Reactions (ADR) monitoring system was initiated with 12 regional centres, each covering a population of 50 million. However, no noteworthy growth was made. Afterward in 1997, India joined the World Health Organization (WHO) and Adverse Drug Reaction (ADR) scrutinizing program based at2 Uppsala, Sweden but got fail. Hence, after 2005 WHO supported and World Bank – funded National Pharmacovigilance Programme (NPPV) of India was made operational.[5,6,7]

History (1):

Year	Events
1747	First reported clinical trials by James Lind, proving the effectiveness of lemon juice in preventing scurvy
1937	Death of 107 children due to sulfanilamide toxicity
1950	Aplastic anemia reported due to chloramphenicol
1961	Global disaster due to thalidomide toxicity
1963	16th World Health Assembly recognize important to rapid action on ADR
1968	WHO pilot research project for international drug monitoring
1996	Clinical trials of global standards started in India India joined WHO Adverse Drug Reaction Monitoring programme
1998	Pharmacovigilance initiated in India
2002	67th National Pharmacovigilance Center established in India
2004	National Pharmacovigilance Program launched in India
2005	Conduct of structured clinical trials in India
2009-2010	PVPI Initiated

Pharmacovigilance Process :-

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



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Adverse Drug Reactions :-

As per World health Organization adverse drug reaction is defined as "any response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function"[8]. Adverse reactions may arise from use of the product within or outside the marketing authorisation or from occupational exposure.[9] Adverse drug reactions are considered as one among the leading causes of morbidity and mortality. Pharmacovigilance is the field concerned with the study of ADR.[10]

Monitoring of ADRs :-

ADR monitoring is the practice of continuously monitoring the undesirable effects caused using any drug. Pharmacovigilance plays an imperative impersonation in monitoring ADRs.[11]

It is inherent for pharmaceutical regulators to screen their pharmaceutical products in the market and record if any suspected adverse reactions are identified. ADRs can occur by use of various pharmaceutical products, herbal drugs, cosmetics, medical devices, biological etc. Introducing this monitoring procedure intends at warranting that patients to receive safe and beneficial medicinal products.{Karch and Lasanga 1997}. If any of the adverse events are not stated, it may result in noxious and serious effects of remedial products. Thus properly conducting ADR monitoring programs will help to reduce the harmful effects of therapeutic products.

Benefits of ADR monitoring

An ADR monitoring and reporting program can furnish following benefits:

1. It caters information about quality and safety of pharmaceutical products.
2. It initiates risk-management plans.
3. It prevents the predictable adverse effects and helps in measuring ADR adherence.
4. It instructs health care team i.e., patients, pharmacists and nurses about adverse drug effects and creates awareness regarding ADRs. The main objective of ADR monitoring is to disclose the quality and frequency of ADRs and to identify the risk factors that can cause the adverse reactions.[10]

NEED FOR PHARMACOVIGILANCE :-

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

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

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

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

Reason 5:-Ensuring public confidence.

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

"Role of pharmacovigilance" in medicines regulation"

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
- 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

In order to achieve their respective objectives pharmacovigilance programmesand drug regulatory authorities must be mutually supporting. On the one hand, pharmacovigilance programmes need to maintain strong links with the drug regulatory authorities to ensure that the latter are well briefed on safety issues in everyday clinical practice, whether these issues are relevant to future regulatory action or to concerns that emerge in the public domain. On the other, regulators need to understand the specialized and pivotal role that pharmacovigilance plays in ensuring the ongoing safety of medicinal products.[12]

National Programme of Pharmacovigilance :-

Before a product is marketed, experience of its safety and efficacy is limited to its use in clinical trials, which are not reflective of practice conditions as they are limited by the patient numbers and duration of trial as well as by the highly controlled conditions in which Clinical

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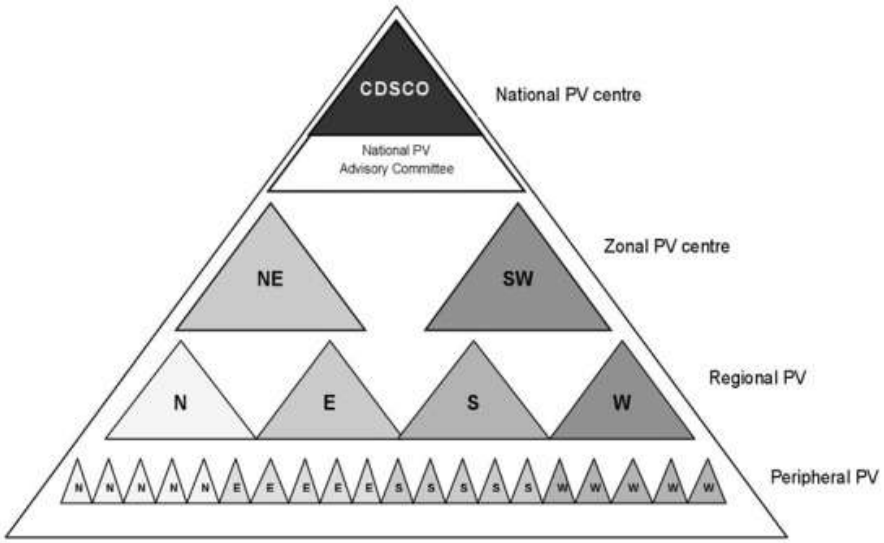
Trials are conducted. The conditions under which patients are studied during the pre-marketing phase do not necessarily reflect the way the medicine will be used in the hospital or in general practice once it is marketed. Information about rare but serious adverse drug reactions, chronic toxicity, use in special groups (e.g. pregnant women, children, elderly) and drug interactions is often incomplete or not available. Certain adverse drug reactions may not be detected until a very large number of people have received the medicine.[13]

PV In India :-

In India, consideration for the surveillance of ADRs developed relatively late, as traditionally there was no concept of surveillance of medicines in the country. Even though PV is still in its infancy, it is not new to India. It was not until 1986 when a few physicians, mainly from academic institutions, called for greater attention to be devoted to the potential adverse effects of prescription medicines and rational prescribing of medicines. This led to the formation of the first ADR monitoring program consisting of 12 regional centers, each covering a population of 50 million, but was unsuccessful.[19] Nothing much happened until a decade later when India joined the WHO Adverse Drug Reaction Monitoring Programme based in Uppsala, Sweden in 1997. Three centers for ADR monitoring were identified, mainly based in the teaching hospitals: A National Pharmacovigilance Center located in the Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi and two WHO special centers in Mumbai (KEM Hospital) and Aligarh (JLN Hospital, Aligarh). These centers were to report ADRs to the drug regulatory authority of India. The major role of these centers was to monitor ADRs to medicines marketed in India. However, they were non-functional as information about the need to report ADRs and about the functions of these monitoring centers never reached the prescribers and there was lack of funding from the government. This attempt was unsuccessful, and hence, again from 1 January 2005, the WHO-sponsored and World Bank-funded National Pharmacovigilance Program (NPVP) for India was formulated[20] NPVP structure is shown in figure.



National Pharmacovigilance Programme Zones in India

Clinical Trials In India :-

Global pharmaceutical companies have found India to be a preferred destination for clinical trials because India's clinical research space and opportunities are very attractive Some of the advantages for clinical trials that India has as are as follows:

- High degree of compliance to international guidelines such as the International Conference on Harmonisation (ICH) / WHO Good Clinical Practice (ICH-GCP) and the regulations lay down by the US Food and Drug Administration.

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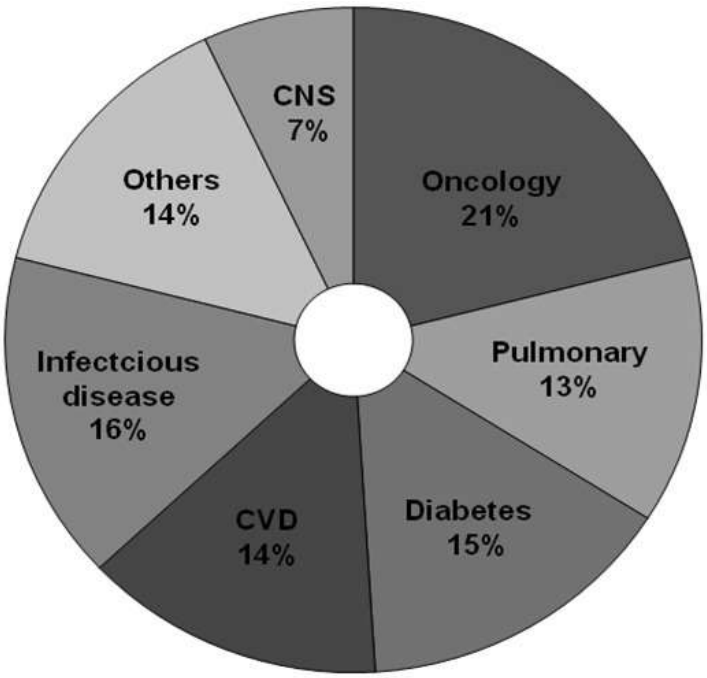
- Availability of well qualified, English speaking research professionals including physicians.
- Ongoing support and cooperation from the government.
- Lower cost compared to the west [21]
- Increasing prevalence of illnesses common to both developed and developing countries.
- Availability of good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

As per a recent report from Federation of Indian Chambers of Commerce and Industry (FICCI), scientific feasibility, medical infrastructure, clinical trial experience, regulations, commercialization potential and cost competitiveness are some of the growth drivers responsible for the metamorphosis of Indian clinical research in the recent past.[22]



II. CONCLUSION :-

Pharmacovigilance is a part of healthcare systems worldwide. The WHO leads pharmacovigilance operations and provides technical support in reporting ADRs. Many countries have well-built pharmacovigilance systems, but actual incidence of ADRs is much higher than what is reported. Underreporting of ADRs is a major problem as well as the quality of reports. The basic objective of pharmacovigilance is the safe use of drugs, patient safety, and, ultimately, safeguarding public health. To achieve this goal, national regulators and international organizations should empower healthcare professionals and the public to report more ADRs.

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