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DRUG SAFETY MONITORING BY PHARMACOVIGILANCE OF INDIA

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ABSTRACT

Now a day's usage of medicine has been increasing day-by-day and pharmaceutical companies are developing new drug products and humans are taking more and effective drugs as well as investigational drugs for health improvement. Safety and efficacy are the 2 major predominant considerations about any drug. In each and every phase of products, life cycle pharmacovigilance plays a critical role. Thus, the significance of pharmacovigilance is developing and it has become a very important and inseparable part of clinical research.

KEYWORDS: Pharmacovigilance, Adverse Drug Reaction, Post Marketing Surveillance.

INTRODUCTION

Pharmacovigilance majorly known as drug safety is the main integral part of clinical research. Throughout the product life cycle in clinical trials, safety and post-marketing pharmacovigilance plays a critical role.[1-3] The word pharmacovigilance is derived from two words one *Parmakon* originated from a Greek word which means "drug" and another *vigilare* derived from a Latin word which means to keep awake or to keep watch." Pharmacovigilance is defined as the pharmacological science relating to the detection, understanding, assessment and prevention of adverse effects, particularly long-term and short-term adverse effects of medicines, and other drug-related problems".[4-8]

AIMS OF PHARMACOVIGILANCE

1. To improve the patient care & safety
2. To contribute to the assessment of benefit, harm, and effectiveness of the medicine
3. To Identify previously unrecognized adverse effects of the drugs
4. To Promote the rational & safe use of medicine
5. To Promote education & clinical training
6. To Identify patient-related risk factors of ADR such as dose, age, gender
7. Any response to a drug which is unintended occurs at particular doses
8. To diagnose or therapy of disease, or for the modification, of physiological function.

Pharmacovigilance helps in removal of approved and licensed products from the market because of clinical toxicity, which is caused by adverse drug reactions in the body. Below is a short note on adverse drug reactions.[10-19]

Adverse Drug Reactions: ADR is a response to the drug, which alters the normal physiological function of the body. The factors which cause ADR includes mainly poly drug therapy, age, and gender.

There are mainly two 2 of ADRs. They are:

TYPE A: These are the common, predictable, dose-dependent, and are seldom fatal.

TYPE B: These are uncommon, unpredictable, dose-independent which involve relatively high rates of serious morbidity.[20-26]

A high index of ADRs is to be successfully diagnosed by clinicians, as it is the high level of awareness about the drugs being used. Pharmacovigilance, unify all the information in all aspects of the benefit-risk ratio of drugs in a population.[27-28] Events that occur when a particular drug is administered are recorded in the patient's notes by drug monitoring, then the adverse reaction of the drug and the activity of the drug being monitored. These studies aim to detect ADR of drugs.

Reporting of ADRs after marketing must be actively encouraged and it involves all those concerned health care professionals including doctors, pharmacists, nurses,

pharmaceutical companies and patients as well. To develop and enhance this program, a culture of learning on pharmacovigilance for health care students must be started and basic knowledge must be provided in their early professional carrier. This method can help the healthcare professionals to understand and also create awareness by giving adequate information to patients at their initial phase of treatment about the potential benefits and risks of the therapy. In the process of development of a new pharmaceutical drug, there are many stages they are preclinical trails, then clinical trials which include four phases including post-marketing surveillance. In the clinical trials, the first three-phase helps in the determination of safety, efficacy and side effects of the developed drug product respectively, whereas in case of fourth phase post-marketing surveillance the post-marketing studies are carried out for determining the safety of patients. Thus, the fourth phase helps in uplifting the knowledge of pharmacovigilance.

POST-MARKETING SURVEILLANCE

Pharmaceutical drug or medical device is monitored during the clinical trial and also often after it has been released into the market. Since drugs are approved based on the clinical trials which involve a relatively small number of people who do not have any other medical complication, post-marketing surveillance plays an important role to know the ADRs of drugs after they have released into the market.

1. Spontaneous ADR Reporting: It is necessary to report ADRs to Pharmacovigilance department by doctors, health care professionals and others in the provided forms where they can notify the suspected ADRs they have addressed. These forms are greatly available in the healthcare centers to encourage the reporting, it helps in spontaneous reporting for all the drugs and it is an affordable method of detecting rare ADRs. This spontaneous reporting helps to identify many unexpected ADRs, drug-related problems and it also helps in the withdrawal of many marketed drugs with the information being provided which guide the safer use of the product. ADR's which occurred by particular drugs should be analyzed and reported quickly. Pharmaceutical manufacturers have to communicate with the doctors at the clinical level regarding the ADRs for

- Changing Medication formula if necessary
- Implementing new prescribing procedures
- Implementing new dispensing procedures
- Educating the professional staff
- Educating Patients

2. Prescription Event Monitoring: It involves health professionals submitting all the clinical events reported by the patient to the prescribed new drug. This method mainly focuses on studying the safety of new medications that are used by general practitioners in this method. By this method, patients being prescribed by drugs are monitored.

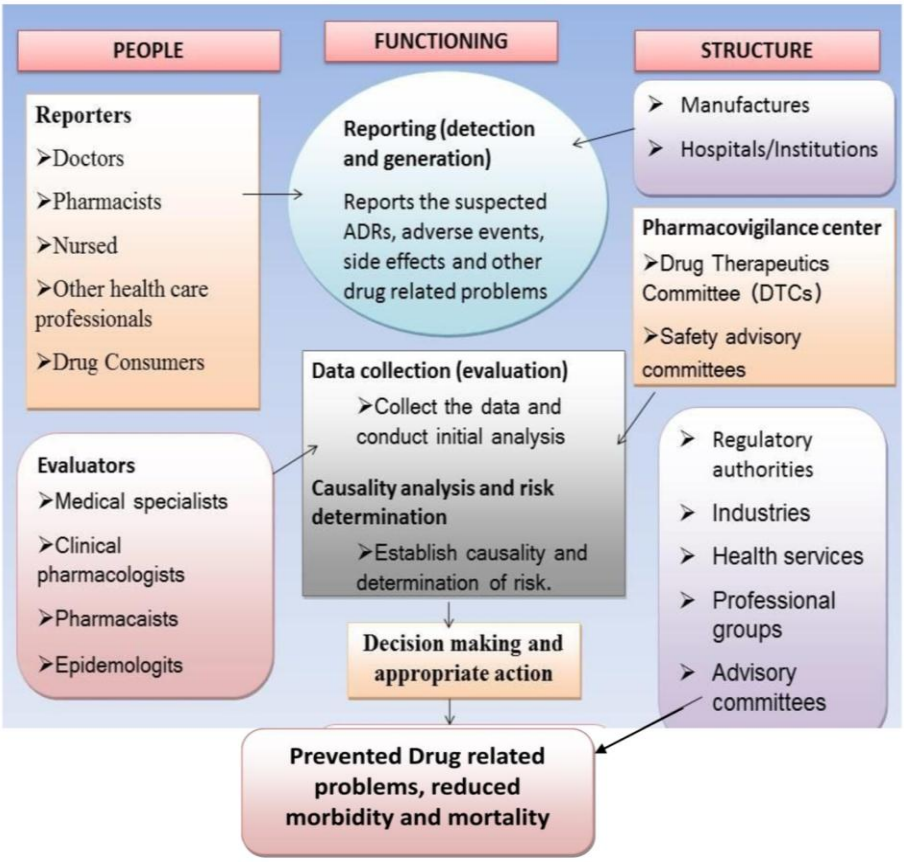

Figure 1: The Pharmacovigilance Framework.

3. Electronic Health Records: It is a collection of health information which is stored on a computer. About one person linked by a person identifier represents the basis for healthcare Information system development.

4. Patient Registers: To bring together patient records, patient registers are maintained. It is time-consuming and less expensive.

PHARMACOVIGILANCE PROGRAMME OF INDIA (PVPI): PvPi officially started on 23rd November 2004 at New Delhi, under the control of CDSCO (Central Drug Standard Control Organization) and Directorate general of health services, Indian pharmacopeia commission (Ghaziabad). The program is conducting by the NCC (National Coordinating Centre) to ensure that the benefits of the use of medicine against the harmful risks.

Objectives of PVPI

- To monitor ADRs
- To create awareness among healthcare professionals about ADRs
- To monitor the benefit-risk profile of medicines and
- To support the CDSCO

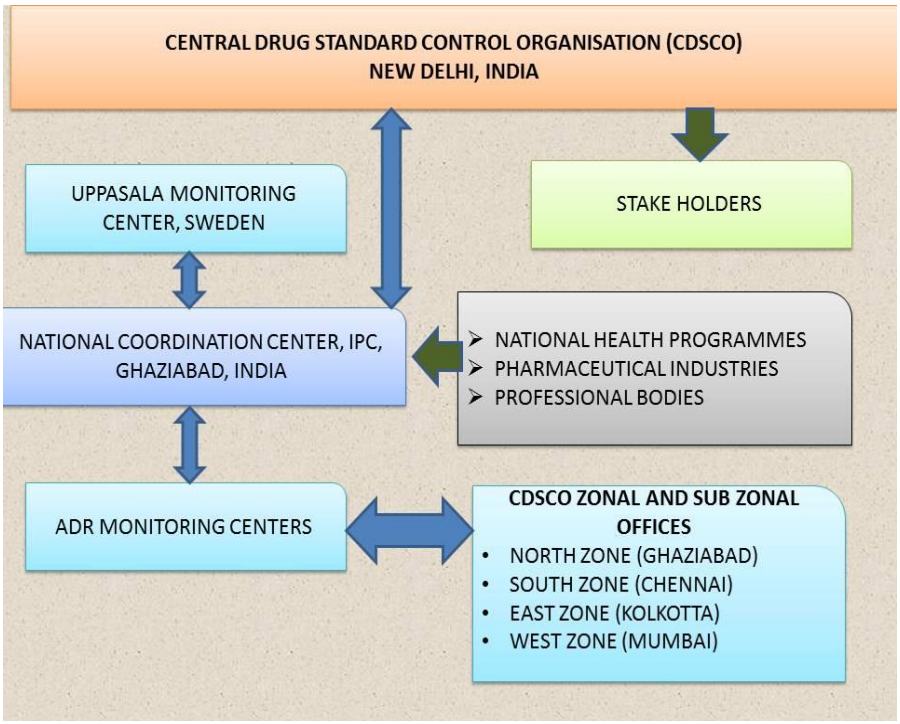

Figure 2: Pharmacovigilance Programme of India (Pvpi) Organization.

CONCLUSION

Pharmacovigilance gives information on assessment of the safety profile of a drug, the success of pharmacovigilance is largely dependent on the participation of professionals of healthcare countrywide to report ADRs/AEs. Current progress in Pharmacovigilance is marked by an increase in the use of databases to make the process more proactive and well organized. It must need everyone's individual interest to develop safe and effective rational medicines environment.

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