Chapter 12
Pharmacovigilance

Medicines and vaccines have transformed the prevention and treatment of diseases. In addition to their benefits, medicinal products may also have side effects, some of which may be undesirable and / or unexpected. Pharmacovigilance is an allied field of Pharmacy that comprises of research, detection, monitoring and analysis of the pharmaceuticals or drugs. It is concerned with drug safety and deals with preventive measures for adverse effects of any medicine/vaccine.It has significant role in medical science or health care sector as it monitors and identifies interactions amongst pharmaceuticals and their effects in human. All medicines and vaccines undergo rigorous testing for safety and efficacy through clinical trials before they are authorized for use. However, the clinical trial process involves studying these products in a relatively small number of selected individuals for a short period of time. Certain side effects may only emerge once these products have been used by a heterogenous population, including people with other concurrent diseases, and over a long period of time

Pharmacovigilance aims to identifying new information about hazards as related to medication. Pharmacovigilance promotes the systematic, rational use and assures the confidence for the safety of drugs. It improves Patient care and safety, Public health and safety.Pharmacovigilance conducting advanced drug monitoring study based Adverse drug reactions, adverse events report of new drugs include:

1. Medication errors and irrational use of medicines
2. Herbal, traditional and complimentary medicines
3. Substandard medicines and counterfeit medicines
4. Blood products, biologicals, medical devices and vaccines ADR

Pharmacovigilance main aim is to give clear information regarding drug safety and its Risk or benefits of drugs to the patients. Patients are main end users of medicine. Patient information leaflet relating to medicine to be provided to the patient to increase the advantages of the

medication and to reduce the risk associated with them. It is essential for Risk Minimization by making an early detection and preventing the progression of the adverse effects.

Pharmacovigilance professionals have to monitor, assess, detect and prevent the adverse effects of medicines. A number of institutions have developed adverse reaction and medication error surveillance systems in their centers. In the last decade or so, ADR monitoring was recognized as an essential quality assurance activity with most accreditation agencies such as national Accreditation Board for Hospitals, Joint Commission on Accreditation for Hospitals Organization, and Medical Council of India insisting upon its establishment.
There are few specific scopes for pharmacovigilance professionals:

- To improve patient care and safety in relation to the use of medicines and all medical and paramedical intervention
- To improve public health and safety in relation to the use of medicines
- To contribute to the assessment of benefit, harm, effectiveness, and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use and
- To promote understanding, education, and clinical training of pharmacovigilance and its effective communication to the public.

Overview of Pharmacovigilance

Pharmacovigilance is required through the entire life cycle of a drug – starting at the preclinical development stage and going right through to continue monitoring of drugs once they hit the market. Pharmacovigilance plays a critical in every phase of the study, and most importantly, in the post-marketing phase. Once the product enters the market, the intake of an investigational product cannot be controlled by the sponsor. However, it is very important for the sponsor to monitor and assess data on its safety aspects. This can be done by a robust pharmacovigilance strategy that is technology-driven and harmonizes with the medicine and regulatory aspects as well. The basic elements of a pharmacovigilance strategy are strong standard operating procedures, accurate case study report capturing, updated safety database, speedy signal detection, expedited reporting to regulatory authorities, and lastly, risk management.

It can be broken down into three main sub-specialisms:

Surveillance: Surveillance is geared towards risk management and signal detection. Roles in this specialism focus analysis of drug safety information gathered from other professionals.

Operations: Operations focus on collecting and recording information during preclinical development, early clinical trials, and gathering real-world evidence (RWE) of adverse events reported by medical professionals and patients. Operations may also create standard operating procedures (SOPs), individual case study reports, and regulatory reports.

Systems: Systems is concerned with the development of robust systems to store and manage data relating to pharmacovigilance. It involves keeping abreast of changing regulations and guidance in the pharmacovigilance industry and ensuring compliance at all levels of an organization.

Pharmacovigilance approve the 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 receipt, processing and reporting of adverse event reports;
- Following-up with reporters to obtain further details about a case report;
- Providing an information service to healthcare professionals and patients on product safety; and
- Providing safety expertise to internal cross-functional colleagues.