Chapter-11

Pharmacovigilance

Pharmacovigilance

- **Definition, aim and scope**
- **Overview of Pharmacovigilance**

Pharmacovigilance:

- Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.
- All medicines and vaccines undergo rigorous testing for safety and efficacy through clinical trials before they are authorized for use.

Or

- Pharmacovigilance is defined as 'the activities involved in the detection, assessment, understanding, and prevention of adverse effects or any other drug related problems…'
- All drugs have the capacity to cause adverse effects and no drug is completely safe.

Aim:

- The primary aim of pharmacovigilance is to detect ADRs, which are any harmful or unintended effects associated with the use of medicines. The timely detection of ADRs can help to prevent serious harm to patients.
- The aim of pharmacovigilance is to minimize the risks associated with the use of medicines. This can involve changing the way a medicine is used or making changes to the product labeling or packaging.
- Pharmacovigilance aims to promote public health by ensuring that medicines are used safely and effectively.

Scope:

- Pharmacovigilance involves activities related to understanding assessment, detection and prevention of adverse effects or any other drug-related problems Pharmacovigilance is a continuous process accepted for safety evaluation accompanied by steps to improve safe usage of medicines.
- Pharmacovigilance is a science important to reverse most of the adverse effects by modifying the dose or omitting the offending drug.

- Pharmacovigilance knowledge on safety of drugs is obtained from clinical usage practiced daily involving patients, health professionals, regulatory authorities and pharmaceutical companies.
- Pharmacovigilance in companies is characterised in monitoring safety of the drug post launch.
- The implementation and incorporation of pharmacovigilance is growing slowly and steadily in the Indian healthcare system along with increasing awareness among patients and health professionals.
- Indian companies are increasing efforts and investment in research and development to enhance the capacity of developing and marketing new drugs that meet pharmacovigilance requirement of Indian regulatory authorities.
- The purpose of pharmacovigilance in India is to recommend regulatory interventions, communicate risks to healthcare professionals and public obtained by data collected, collated and analyzed; improve patient care and safety; contribute in assessing benefit, effectiveness and risk of medicines; promote education and clinical training on safe and rational use of medicines.

Overview of Pharmacovigilance:

The overall objective as per the National Pharmacovigilance Programme will be:

- To monitor safety of the drugs and provide structured inputs for appropriate regulatory interventions
- To create awareness about ADR monitoring in India

Regional centres will be the secondary pharmacovigilance centres under the National Pharmacovigilance Programme.

To carry out the functions as envisaged in the “Protocol for the National Pharmacovigilance Programme” a Coordinator will have to be designated who will be in-charge of the pharmacovigilance activities at the designated regional centre.

By accepting to participate in the National Pharmacovigilance Programme all centres explicitly agree that all pharmacovigilance activities at their institutions shall be performed in strict consonance with the National Pharmacovigilance Programme appended here (Coordinators of the centres and heads of the institutions are advised to carefully go through the Protocol prior to joining the programme).