Pharmacovigilance:

Background: Before the year 1968 there were no specific monitoring system for identification or prevention of ADR. First initiative to monitor ADR was after thalidomide tragedy. Thalidomide with antiemetic and sedative property was very popular among pregnant women for treatment of morning sickness. After consumption of thalidomide, many pregnant women delivered babies with congenital anomaly called as Phocomelia.
WHO realized need to monitor ADR after this serious adverse event. Soon later International ADR collaborating centre was established in Sweden (Upsala monitoring centre) in 1968.

Definition: As per WHO guidelines, pharmacovigilance is defined as branch of pharmacology that is concerned with detection, assessment, understanding and prevention of adverse drug reactions.

Why need for Pharmacovigilance?: When new drugs are being developed it is really difficult to recognize adverse effects due to limited number of participants and controlled atmosphere of the clinical trials. But when same drug enters into the market after getting authorized permission; various new adverse effects will be identified. This could be due to larger exposure of population to the drug. There is increase in treatment cost due to ADR & sometimes patient may die due to severe ADR.

Pharmacovigilance Programme of India (PVPI): In India, under CDSCO (Central Drug Standard Control Organization) National Pharmacovigilance Programme of India was established with an aim to aware medical and paramedical fraternity about importance of reporting of ADR. National coordinating centre is at Allahabad which is linked to all over India.
Various ADR monitoring centres (AMC) has been set up all over the India to collect the data through Medical Colleges, Government & Private hospitals and Medical universities. The data collected by different AMC is transported electronically through vigiflow to NCC for analysis & further evaluation. Data collected at NCC will be studied, evaluated and appropriate initiatives will be taken for prevention of ADR. Recently haemovigilance & biovigilance have been included in PVPI.

Causality & Severity assessment: With the help of standard scales like Naranjo scale, WHO scale drug reactions are assessed for its causal relation with the untoward event. The ADR will be classified as definite, possible, probable or doubtful after causality assessment.

Role of healthcare professionals: in order prevent ADR and support in collecting ADR data base all healthcare professional shall contribute by voluntary ADR reporting. As a most important component of healthcare system, a healthcare professional also shall sensitize other medical as well as paramedical staff to report ADR.