K.K. Wagh Institute of Pharmacy

PHARMACOVIGILENCE

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DEFINITION:

- WHO defined pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems

AIMS OF PHARMACOVIGILANCE:

- 1. Early detection of unknown adverse reactions and interactions.
- 2. Detection of increases in frequency of adverse reactions.
- 3. Identification of risk factors and possible mechanisms underlying adverse reactions.
- 4. Estimation of quantitative aspects of benefit/risk analysis and dissemination of information needed to improve drug prescribing and regulation.
- 5. Provide information to healthcare professionals and patients to optimize safe and effective use of medicines.

Scope of Pharmacovigilance

- **1) In Herbal Medicine:** The safety and efficacy of herbal medicines has become the key concern to both general public and national health authorites. However, use of herbal plants in the traditional and ancient medicine system continues to expand rapidly all over the world.

- **2) In Disease Control Public Health Programmes:** The major concern today in countries having no such safety monitoring or regulatory system (pharmacovigilance)) or in remote areas having few or no health care surveillance or infrastructure is monitoring the safety of medicines or therapeutic drugs.
- for example, for the treatment of tropical diseases such as leishmaniasis, malaria and schistosomiasis, and for the treatment of tuberculosis and HIV/AIDS.
- Pharmacovigilance must be priority for every country with a public health disease control programme.

- **5) Ecopharmacovigilance:** Adverse drug reactions related to drugs within the ecosystem with all consequences in human beings and other organisms in environment are included in the ecopharmacovigilance. examples includes:
- 1) Patient excretion of drugs or its metabolites through sewage system
- 11) Hospital or self-disposal of unused expired or unwanted drugs through flushing or trash
- 111) Direct release of drugs and its byproducts from the manufacturing units into the waste water system iv) Terrestrial deposition leading from solid waste landfills and sludge application to lands v Rapid breakdown of acetylsalicylic acid which leads to their deposition in the lands
- vi) Clofibric acid, active metabolite of clofibrate detected in drinking water
- vii) Fluoroquinolone, a fat soluble and stable drug gets absorbed to sludge particles through sewage treatment process.

- **4) Blood Bank:** In blood banks, pharmacovigilance also plays an important role as it keeps a record of all the donors donating blood, their health safety data, etc. for example, if a person has suffered from dengue fever in the past donates blood and any type of adverse reaction is observed in patient receiving the same blood, then the pharmacovigilance team keeps a record of the adverse drug reaction occurred due to the donated blood.

- **5) Immunisation and Vaccination:** Pharmacovigilance plays a crucial role in vaccination. for example, polio vaccine initially being given as polio drops, but recently the manufacturers changed the dosage form to inject able, therefore after vaccination of polio injections the site of inject has to be kept on check for any kind of inflammation, thrombosis, or other skin reactions.
- **6) In Dermatology:** In order to keep a check on any type of skin reactions or adverse events related to Skin diseases, pharmacovigilance plays an important role in the area of dermatology.

Importance of Pharmacovigilance:

Pharmacovigilance in India:

- India is the most populated country having 37 (28 + 9) states and union territories Its healthcare sector has more than the 15,000 hospitals and more than 5 lacs doctors. India is the fourth largest country in the world in producing the pharmaceutical products.
- Large number of patients with epilepsy are consuming new or old anti-epilentie drugs but hardly or no any major problem have been recognised/reported. It could be the result of lack of pharmacoepidemiological studies but it is very much related to absence of an effective and efficient.

- **Pharmacovigilance system:**
- The various firms and enterprises utilizes the pharmacovigilance studies data in other countries before the introduction of drug in Indian market. Hence, Indian obligations under Trade Related Intellectual Property Rights and Services (TRIPS), made it compulsory that the country can no longer copy patented products and market them without license from the innovator company during the post 2005 period. Naturally Indian government has to invest more money on the discovery and drug development.

- Pharmacovigilance is the scientific study of collecting, storing, analysing, monitoring, researching, assessing and evaluating information from healthcare providers, patients and the public on the adverse effects of medications.
- It is the process of identifying and responding to the issues of the drug safety. India has the asset of a large number of medicines, just like its population.
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- Originally the National Pharmacovigilance center was established at AlIMS, New Delhi, which organized many seminars, workshops in the area of pharmacovigilance. But still the pharmacovigilance is in the stage of infancy in India.
- The National Pharmacovigilance Program (NPP) was initiated in 2004 under the guidance of the Central Drugs Standard Control Organization (CDSCO) with the objective of developing a sustainable ADR monitoring program.
- The program was inaugurated by Dr. Ambumani Ramadoss, Health Minister of India on 23 November 2004 at New Delhi.

- The program was sponsored by WHO and funded by World Bank. Now the NPP is based at CDSCO, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, Nirman Bhavan, New Delhi.
- **The NPP (National Pharmacovigilance Program) constitutes:**
- **(a) Administrative body:** It consists of steering committee, Technical support committee and strategic advisory committee. The functions of these committees are:
- Co-ordination of comprehensive National Program.
- Operational supervision of CDSCO.
- Recommend procedure and guidelines for Regulators Interventions.

- **(b) National Pharmacovigilance Centers:** Initially twenty six peripheral centers, five regional centers and two zonal centers were established.
- The peripheral centers records the Adverse Events (AE) and send to the Regional centers.
- The regional centers scrutinize the data received from the peripheral centers and submit it to zonal centers.
- The zonal centers will analyse the data and submit it to National Pharmacovigilance Center.
- The Zonal Center will also provide training and general support to coordinate the functioning of the Regional center.

- **(c) ADR monitoring centers:** The various ADR monitoring centers include:
- MCI approved medical colleges.
- Private hospitals and health centers
- Autonomous institutions

The functions of these ADR monitoring centers are:

- Monitoring spontaneous report
- Monitoring Benefit/Risk of medicine
- Post-marketing surveillance of medicine.

Importance of Safety Monitoring of Medicine:


THANK YOU