Pharmacovigilance –National and International scenario

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Safety and efficacy are the two major concerns about any drug. While the efficacy of a drug can be detected with relative ease, the same cannot be said about safety because the adverse effect of a drug may be uncommon but very serious and many patients may be affected or subjected to a potential risk before the relationship with the drug is established.

India- Strength

- More than half a million qualified Doctors and15,000 hospitals having bed strength of 6,24,000.
- The fourth largest producer of pharmaceuticals in the world.
- An important Clinical trial hub in the world.
- Many new drugs are being introduced in our country.

Therefore, there is a need for a vibrant pharmacovigilance system in the country to protect the population from the potential harm that may be caused by some of these new drugs.

- The National Pharmacovigilance Programme initiated by Central Drugs Standard Control Organization (CDSCO).
- Started in 23 November, 2004.
- Largely based on the recommendations made in the WHO document titled "Safety Monitoring of Medicinal Products – Guidelines for Setting up and Running a Pharmacovigilance Centre".

Aims of Pharmacovigilance program

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

- The Programme aims to foster the culture of ADE notification in its first year of operation and subsequently aims to generate broad based ADR data on the Indian population and share the information with global health-care community through WHO-UMC
- The purpose of the programme is to collate data, analyze it and use the inferences to recommend informed regulatory interventions, besides communicating risks to healthcare professionals and the public.

Salient Features

- 26 peripheral centers, 5 Regional Centers, 2 Zonal Centers
- The Peripheral centers will record the Adverse Events (AE) and send to the Regional Centers.
- They in turn collate and scrutinize the data received from the Peripheral Centers and submit to the Zonal Centers.
- The Zonal Centers will analyze the data and submit consolidated information to the National Pharmacovigilance Centre.
- The Zonal Centre will also provide training, general support and coordinate the functioning of the Regional Centers.

THE NATIONAL PHARMACOVIGILANCE CENTRE AT CDSCO

- Monitor the adverse drug reactions of medicines . This will include the collation, review and evaluation of all spontaneous ADR reports received by the unit on a nation-wide basis. This information will then be keyed into the ADR database for use in aggregate analysis.
- Review Periodic Safety Update Reports (PSURs) submitted by pharmaceutical companies. Pharmaceutical companies are required to submit the PSURs of all new chemicals drugs. PSURs shall be expected to be submitted every 6 monthly for the first 2 years of marketing in India, and annually for the subsequent 2 years.
- Maintain contacts with international regulatory bodies working in pharmacovigilance and exchange information on drug safety.
- Assess the regulatory information relating to safety in order to determine what action, if necessary, needs to be taken to improve safe use.
- Provide information to end-users through adverse drug reaction news, bulletins, drug alerts and seminars.

Mile stones

- **Short-term objectives:** To foster a culture of notification
- **Medium-term objectives:** To engage several healthcare professionals and NGOs in the drug monitoring and information dissemination processes.
- **Long-term objectives:** To achieve such operational efficiencies that would make Indian National Pharmacovigilance Programme a benchmark for global drug monitoring endeavors.

Pharmacovigilance in AYUSH

- National Center at IPGT&R Jamnagar.
  - ADR related to drugs of herbal, mineral, metallic, animal and other origin in ASU.
  - First consultative meeting -29-30 Aug. 2008
- 8 Regional Centers, 30 peripheral centers.
  - Identification
  - Training
  - Implementation