**PHARMACOVIGILIANCE OF HERBAL & TRADITIONAL SYSTEM**

Pharmacovigilance is an important & integral part of clinical research. Pharmacovigilance is defined as a the pharmacological sciences relating to detection , assessment ,understanding & prevention of adverse effects particularly long term & short term adverse effects of medicine . Pharmacovigilance is the process of monitoring the safety of medicines.

All over the world Pharmacovigilance of herbal medicines observed and act in case of drug toxicity to drugs or medicines in the market. various agencies in different countries work in Pharmacovigilance. Now a day we have communication facilities they remove and control harmful effect & adverse effect. WHO ,USFDA,FDA ,European medicines agency developed Pharmacovigilance laws 29, 35, 36.FDA launched a national electronic system named “ Sentinel Initiative ” in may 2008 to observed the safety of FDA regulated products including health care product, vaccines, herbal medicines.

**The important purpose of Pharmacovigilance programme are:**

* To patient care
* To provide medicines & all medical and paramedical services staff.
* To improve public health services.
* To support understanding, educating & clinical training in Pharmacovigilance
* To asses benefit ,risk & effectiveness of medicines.
* To support effective communication to health care professionals & the public.

There are various methods to identify the problem related to use of medicines. The prescription events monitoring & careful review of adverse drug reaction in hospitalization patients & patients discharge from the hospital covered under the active Pharmacovigilance.

Passive Pharmacovigilance depends mainly on spontaneous reporting. During clinical practice the heath care professionals are supposed to report the adverse reaction to Pharmacovigilance.

**The major and well known limitation of spontaneous reporting are :**

Under reporting

Lack of information

Biased reporting

With all these limitation this methods still used throughout the word because it has relevance on suspicion of ADRs sent by clinicians & substituent analysis of the reports by physicians ,clinical pharmacologist ,practicing pharmacist.

Plants and plants parts are used for their aroma, neutraceuticals & medicinal purpose. Now a days, online purchases in the form tablet ,powder, dried parts of plant, extract of plant are also available. for medicinal or therapeutics purpose and dietary supplements people have used a variety of herbs and their part of herbs in daily lifestyle.

According to WHO has recommend moving towards traditional medicinal convention that primarily including herbs or plants & mineral products. Theses advise have influence most developing countries to explore traditional practices.

.The WHO launched the 13th General Program of Work (GPW13) to ensure healthy lives and promote well-being for all age groups with the help of traditional and complementary medicine.

**The system of managing a healthy lifestyle & the treatment**

The traditional system of medicine (TSM) includes Ayurveda, Siddha, Homeopathy,Unani, Yoga, and Naturopathy. Ayurveda has been practiced worldwide.

**Traditional system follow**

 **Traditional system of**

 **medicines**

 **Ayurveda**

 **Siddha**

**Naturopathy**

 **Yoga**

 **Homeopathy**

 **Unani**

Natural products are used in ayurveda & it is an ancient system of healthy lifestyle in India BY following natural ways.

**Food medicines involvement**

Food used as medicines. Various flavoring agents from plants are used in Indian kitchen. Some examples like Zingiber officinale ehich is added to impart flavor to food, they also used as pharmacological activity like antioxidant, cardiac tonic, gastrointestinal disorders . Black paper are also used in Antiinflammatory activity & diabetic risk.

**Natural remedies for the treatment of contagious & non contagious disease**

Saponin is also used for the treatment of cancer. Tulsi also used for the treatment of cough. Nigella sativa control the warfarin metabolism and they can potential food drug interaction.

**Manufacturing of herbal medicines**

Herbal medicines prepared by nature based substance. Natural compound beneficial for therapeutic purposes. For the examples of different plant like turmeric used for the treatment of antiseptic, Aloevera used for the treatment of nephrotoxicity.

**Scope of Pharmacovigilance**

Interaction of medicines

Adverse drug reaction reaction

Lack of efficacy

Medication error

Substandard medicines

Pharmacovigilance

Abuse misuse of medicines

Pharmacovigilance covers not only the conventional medicines but beyond these. These include herbal medicine other complementary product, biological product, vaccines,& possible medical devices.

**Product covered by Pharmacovigilance**

MEDICINES

Traditional & complementary

Herbals

Biological

Blood product

Medical devices

 Vaccines

**What is to be standardized?**

 Undesirable effect.

Medication error.

Case study

Drug mishandling

Adverse dug reaction

**Pharmacovigilance system**

With the purpose of developing a set of indicators to monitor or evaluate Pharmacovigilance system it is essential to understand its operation. As on date the spontaneous reporting system is considered as the basic of global Pharmacovigilance. For the purpose the systematic collection analysis of the report of suspected ADRs are required

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**Information may be include in the report**

Any adverse drug reaction associated with the use of traditional & natural medicines & any other factors affecting the safety of product ,product safety should be mention in the report.

Following information may be include:

**Patient data:**

Information of patient /costumer with appropriate personal needs to be provided in order to avoid copy & to facilitate follow-up patient Age, gender, patient history patient other risk factors like allergy, drug abuse.

**Product information :** information of herbal & traditional product may be include brand name ,composition of drug , label claim, dose, part of plant used ,proper methods manufactured by, marketed by batch no. date of manufacturing & expiry. Caution may be include , storage condition.

**Adverse drug reaction:** patient history is the important of control drug –drug,food drug interaction. **Information** related suspected product.

Reporter information: All the data of patient to be confidential. They used only for data verification & complication condition.

**Pharmacovigilance centre do after receiving the report**

All health care professional doctors, Pharmacist,Chemist, nurse ,clinical officer ,pharmaceutical assistant ,traditional medicine practitioner & other health care provider provide the data & send to TFDA.

Adverse reports may be faxed in case of perceived urgency.

After detecting signal, PV centre has to inform the concerned National Regulatory Authority (NRA) to take appropriate regulatory action including risk management and communication such as withdrawing products from the market, adding warnings, amending labeling or packaging, restricting prescribing criteria or use as per the evidences received.

**Communication network of Pharmacovigilance (PV)**

MASS MEDIA

CONSUMERS/PATIENTS

NATIONAL REGULATORY AUTHORITY

 OTHER

**NATIONAL PHARMACOVIGILANCES CENTRE**

MANUFACTUR

 **What are the challenges to do Pharmacovigilances misleading medicinal products?**

Complexity of herbal product:

* + Improper Clinical trial data : lots of herbal and traditional medicine products is not always available. So very difficult to maintain the safety & efficacy of herbal product.
* Phytoconstituents complexicity : Herbal and traditional medicine are several chemical constituents they produced complexicity.
* Various factors like environment, cultivation storage condition, processing time can be affected their variability. All makes it difficult to determine pharmacological action & this types ingredient causes a safety and efficacy of product.
* Quality control & quality assurance of rational pharmaceutical products ,herbal and traditional medicines are manufactured from material of herbal & commercial sources ,result in uncertain condition. Quality of product may be affected.
* Less of Technical expertise and facilities may be create problem.

**Differences in product regulation:** all country classified drug with health claim.

**Information** like product name part should be include in product.

**Botanical nomenclature** the nomenclature of crude plant may be include. In many words the name in Latin, vernacular name.

**Safety monitoring** safety monitoring are the important point for reduce the ADRs.

**How can Pharmacovigilance for herbal and traditional medicine be improved?**

* Networking should cover health facilities (traditional medicine practitioners), manufacturer, drug store (pharmacists) and consumer.
* Harmonize regulations for herbal/traditional medicine products among Member States.
* Proactive Pharmacovigilance through the product life cycle is the way forward and the future direction for drug safety. For instance, the regulatory system should have a mechanism to collect safety data before marketing approval and after marketing. !
* TRM practitioners should participate in causality assessment process and they should be trained on causality assessment. ! PV should be integrated into curriculum of medical education.
* PV should be integrated into good pharmacy practices (GPP) in community pharmacy.
* Use of modern technology and its development through IT facilities and mobile application tools should be encouraged.
* The exact scientific name of the plant, the plant part used and the name of the manufacturer should be included in the ADR report on herbal medicines.
* Regular training programmers for strengthening national capacity in monitoring the safety of traditional medicine products and for promoting awareness should be encouraged.
* It would be better to start early with the professional training of health-care students to create a culture of reporting ADRs.
* National quality specification and standard for herbal materials (selection, sampling, testing of plant material, stability studies), GMP, labeling, and licensing schemes for manufacturing, imports and marketing should be mandatory.

**List of unapproved medicines list**

* + Kerela tablets, manufacture by shriji herbal products ,India
	+ Churna (Maha sudarshan powder) manufactured by zandu pharmaceuticals, Mumbai India.
	+ Tablets sudarshan manufactured by zandu pharmaceuticals, Mumbai India.