

Herbal medicine use and the Emerging concern for ADR monitoring

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Introduction:

- ▶ Nearly 80% of population use Herbal medication in one or the other form in their lives.
- ▶ Herbal medicines have promising potential with respect to the efficacy is considered.
- ▶ But the major problem is that, majority of them remain untested!!!! And at times are poorly monitored or not monitored at all.
- ▶ Knowledge of their potential adverse effects very limited.

Herbal Medicine Includes??

- ▶ **Herbs:** include crude plant material, such as leaves, flowers, fruit, seeds, wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered.
- ▶ **Herbal materials:** Include, in addition to herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs
- ▶ **Herbal preparations:** These form the basis for finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials.
- ▶ **Herbal products:** Consist of herbal preparations made from one or more herbs. If more than one herb is used, the term “mixture herbal product” can also be used. Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients.

Factors Which Plays a Role in Increased Use of Herbal Products:

(I) Efficacy or effectiveness of plant medicines.

(II) **Preference of consumers for natural therapies.**



(III) Dissatisfaction with orthodox pharmaceuticals.

(IV) Erroneous belief about herbal medicines.

(V) High cost and side effects of most modern drugs.

(VI) Improvements in the quality, efficacy, and safety of herbal medicines.

(VII) Patients' belief that their physicians have **not properly identified the problem.**



(VIII) Self-medication.

- Uncomfortable about discussing their medical problems with the Physicians.
- Fear of possible misdiagnosis and
- Lack of time to see a physician.



(IX) The marketing strategies and efforts by various manufacturers of herbal medicines and their sales representatives have seriously projected these products into greater limelight.



(X) Various advertisements in the mass media have significantly increased consumers' awareness.

BUT???????

- ▶ There is *popular misconception* that natural means safe and
- ▶ Remedies of natural origin are *harmless* and are devoid of *adverse drug reactions (ADR's)*.



Regulatory Authority:

- ▶ Like conventional medicines, licensed herbal medicines hold a product license based on safety, quality, and efficacy.
- ▶ Compulsory that they are accompanied by comprehensive information such as
 1. Indications,
 2. Precautions,
 3. How to use the product,
 4. Side effects,
 5. How to store the product and
 6. Regulatory information, for safe use.

Challenges Faced By Regulatory Authority:

- ▶ **Regulatory status** of a particular herbal product may **differ in different countries**.
- ▶ Many of these products are **classified** as **foods or dietary supplements** in some countries. **Quality tests** and production standards tend to be **less rigorous or controlled**.
- ▶ Traditional health practitioners may **not** be **certified or licensed**.
- ▶ Herbal Meds **enter directly** into the **non-prescription medicines category** rather than by reclassification from the prescription medicines category.

Quality Assurance and Control:

- ▶ **Quality assurance** and control measures should be in place in every country where **herbal medicines** are **regulated**.
- ▶ **Weak regulation** and quality control may result in a **high incidence** of **adverse reactions**.

For appropriate use!!!

Providers of Health Care Medicine:

- ▶ A variety of health-care professionals serve as qualified providers of herbal medicines, according to each country's national health-care delivery system and legislative framework.
- ▶ Prescriptions are not required to obtain herbal medicines since these are categorized as non-prescription medicines.

Actions to be taken:

All providers of herbal medicines should play a role in monitoring the safety of non-prescription herbal medicines.

Lack of Proper Knowledge of Herbal Medicines:

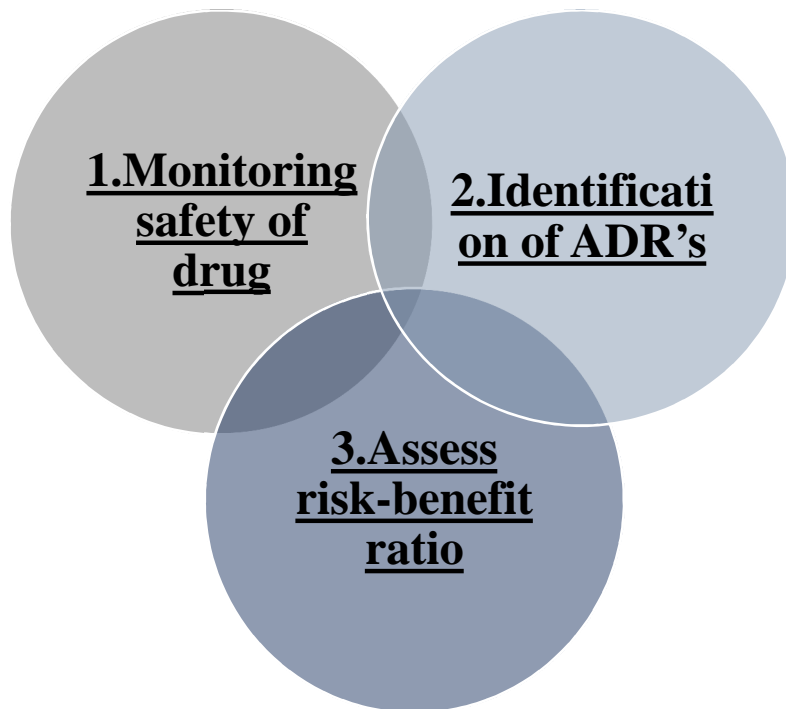
- ▶ Providers of medicines may have **little training** in and **understanding** of how herbal medicines affect the health of their patients.
- ▶ Health professionals who work in **poisons centres** and **health information services** also need to be **informed about herbal medicines**.

- ▶ The **concomitant use** of traditional medicines with other medicines, which is now quite frequent, is quite outside the traditional context and has become a particular **safety concern**.

Actions to be taken:

The education of health-care professionals, providers of herbal medicines and patients/consumers is vital for the prevention of potentially serious risks from misuse of herbal medicines.

Pharmacovigilance of Herbal Drugs:



Herbal medicines exhibit particular challenges because they are available from a wide range of outlets typically where there is no health care professional available, most purchases are in a conventional OTC environment.

Methods in Pharmacovigilance:

1. Passive surveillance and
2. Active surveillance.

Pharmacovigilance is therefore, one of the important post-marketing safety tools in ensuring the safety of pharmaceuticals and related health products.

Safety Monitoring of Herbal Medicines:

Most common sources of information on adverse events and reactions to medicines are

1. Clinical trials and
2. Spontaneous reports (voluntary, unsolicited communications on marketed medicinal products).

If adequate coverage of herbal medicines is to be achieved, national reporting schemes should be developed to include

1. All providers of herbal medicines (both prescribers and dispensers) and
2. Providers of traditional and alternative medicine according to national circumstances.

Conclusion:

- ▶ **Herbal medicines:** Available as Over the Counter drugs (OTC) and are approved without prior post marketing safety monitoring.
- ▶ **Consumer reports:** The reports from the consumers about any adverse reactions should be accepted as an important source of information.
- ▶ **Standardization:** Standardization of methods and quality control data on safety and efficacy are required for understanding the use of herbal medicines.
- ▶ Even though there is a promising potential with the efficacy of herbal medicine, there should be a need of **Pharmacovigilance activities** among health care professionals to monitor the **safety and ADR reporting**.

References:

1. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems. World Health Organization, Geneva, 2004.
2. Dubey SK, Anand A, Gupta A. Pharmacovigilance of Herbal Drugs: A New Perspective. International Journal for Pharmaceutical Research Scholars. 2014.1(3).
3. Ekor M. The Growing Use of Herbal Medicines: Issues Relating To Adverse Reactions and Challenges in Monitoring Safety. Frontiers in Pharmacology. January 2014.



Thank You