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A REVIEW ON SURVEILLANCE OF HERBAL MEDICINES

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ABSTRACT

Herbal medicines are the oldest form of healthcare known to mankind. Herbal medicines, sometimes referred to as Herbalism or Botanical medicine is any manufactured medicine obtained exclusively from plants (aerial & non-aerial parts, juice, resin & oil) either in the crude state or as a pharmaceutical preparation. WHO's policy on herbal medicines acknowledges their important role for the health of a large number of people. WHO promote the safe and effective use of herbal medicines and encourages their integration. Clinical trials with herbal drugs are feasible; a survey of the specialized literature reveals that few well-controlled double-blind (placebo-controlled) trials have been carried out with herbal medicines. Plants contain several hundred constituents and some of them are present at very low concentrations. In spite of the modern chemical analytical procedures available, only rarely do phytochemical investigations succeed in isolating and characterizing all secondary metabolites present in the plant extract. During the past decades, public interest in natural therapies, namely herbal medicine, has increased dramatically not only in developing countries but mainly in industrialized countries. Herbal plants play a vital role for the development of new drugs. During 1950-1970 approximately 100 plants based new drugs were introduced in the USA drug market. There is a growing interest in herbal drugs, and as an example of this, the consumption of medicinal plants has doubled in the last ten years in Western Europe. The turnover of herbal medicines in India as over the counter products, ethical and classical formulations and have remedies of Ayurveda, Unani and Siddha systems of medicine is about $1 billion with a meagre export of $ 80 million. 80% of the exports to developed countries are of crude drugs and not finished formulations leading to low revenue for the country.

Key words: Herbal medicines, Safety, Efficacy, WHO Policy.

INTRODUCTION

Herbal medicines are the oldest form of healthcare known to mankind. Herbal medicines, sometimes referred to as Herbalism or Botanical medicine is any manufactured medicine obtained exclusively from plants (aerial& non-aerial parts, juice, resin & oil) either in the crude state or as a pharmaceutical preparation(Rates, 2001).Medicinal plants play a key role in the human health care. About 80% of the world population believes on the use of traditional medicines which is predominantly based on plant materials.

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The traditional medicine refers to a broad range of ancient natural health care practices including folk / tribal practices as well as Ayurveda, Siddha, and Unani **(**Subramoniam, 1993). India is an involved with a rich wealth of medicinal plants. One of the earliest treaties on Indian Medicine, the Charak Samhita (1000 BC) records the use of over 340 drugs of plant origin.

In India there are about 45000 plant species of about 7300 plant species are used in traditional health care system. 90% of the medicinal plants come from natural habitats which are said to be in great demand. Medicinal plants, herbs, spices & herbalremedies are known to Indian System remedies are known to Indian System of Medicine since long times (Trivedi, 2009).According to the WHO definition, herbal drugs contain as active ingredients plant parts or plant materials in the crude or processed state plus

certain excipients, i.e., solvents, diluents or preservatives. Usually, the active principles responsible for their pharmacological action are unknown. One basic characteristic of phytotherapeutic agents is the fact that they normally do not possess an immediate or strong pharmacological action. For this reason, phytotherapeutic agents are not used for emergency treatment. (Akerele, 1993; Bulletin of the World Health Organization 1993,1998)

WHO'S POLICY ON HERBAL MEDICINES:

WHO's policy on herbal medicines acknowledges their important role for the health of a large number of people. WHO promote the safe and effective use of herbal medicines and encourages their integration.

OBJECTIVES:

WHO's policy may be summarized as follow:

Review the current status of the appropriate use of herbal medicine in the region.

Present and discuss various issues and models for the appropriate use of herbal preparation.

Develop draft guidelines for the appropriate use of herbal medicine. (Anonymous, 2003).

EFFICACY AND SAFETY OF HERBAL DRUGS:

The WHO estimates that 65%-80% of the world's population use traditional medicines as their primary form of health care. The use of herbal medicine, the dominant form of medical treatment in developing countries, has been increasing in developed countries in recent years. Assessment of safety and efficacy of these medicines is an important issue for the health profession. Herbal medicines, in which plants (dried or in extract form) are used as therapeutic substances, are one of a number of practices encompassed by the term "complementary and alternative medicine" (CAM).

SAFETY:

Any assessment of safetyof herbal medicines must be based on unambiguous identification and characterization of the constituents. A literature search must be performed. This should include the general literature such as handbook specific to the individual form of therapy, modern handbook on phytotherapy, phytochemistry, pharmacognosy, article in scientific journals, official monograph etc. The search should not only focus on the specific herbal medicinal preparation, but should include different parts of the plant. A drug is defined as being safe if it causes no known or potential harm of users. There are three categories of safety.

Category1: safety established by use over long time.
Category2: safety under specific condition of use
Category3: herbal medicine of uncertain safety.

EFFICACY:

The preliminary assessments of efficacy can be obtained through the result of in vitro testing and experiments on animals, authorities licensing new medicines for public use require evidences of their effect of human being. Only carefully planned clinical trials that clearly minimize experimental bias are able to satisfy these requirements (Mukherjee, 2005).

NEW DEVELOPMENTS IN HERBALS:

There has been a controversial discussion about herbal medicines sold outside pharmacies if they claim other than therapeutic indication. This legislation leads to fantastic indication claim as for ex. Blood purifier, to fortify heart or nerves or heart nutrition so it is difficult to find scientific evidence of efficacy for such products. So the corresponding products have to be labelled as traditionally used based on different criteria as:

- To tontify and to fortify.
- For amelioration of subjective health conditions.
- To support organ functions.
- For prophylaxis.
- As mildly active drug.
- Herbal medicines with indication proved by new controlled clinical trials.
- Those with indication proved at least by long term traditional use which is supported by experimental data.
- Herbal medicines with documented traditional use but without further assessment of efficacy requiring a special labelling on the package of the finished drug (Mukherjee, 2005).

CLINICAL TRIALS OF HERBAL DRUGS:

Clinical trials with herbal drugs are feasible; a survey of the specialized literature reveals that few well-controlled double-blind (placebo-controlled) trials have been carried out with herbal medicines. Recent meta-analysis of reviews published in important medical journals, such as the Annals of Internal Medicine, the Journal of the American Medical Association (JAMA), the British Medical Journal, the Lancet, and the British Journal of Clinical Pharmacology, among others, confirms this assumption. Several factors might contribute to the explanation of such discrepancies, for example:

- lack of standardization and quality control of the herbal drugs used in clinical trials,
- use of different dosages of herbal medicines,
- inadequate randomization in most studies, and patients not properly selected,
- numbers of patients in most trials insufficient for the attainment of statistical significance,
- difficulties in establishing appropriate placebos because of the tastes, aromas, etc,
- wide variations in the duration of treatments using herbal medicines,

As a function of such difficulties, few herbal drugs have been studied adequately and well-controlled double-blind clinical trials to prove their safety and efficacy have been lacking. However, a large number of clinical trials have been performed with some herbal drugs, including the extract of *Ginkgo biloba* (used for the treatment of CNS and cardiovascular disorders). (Kanowski *et al.*, 1997).

STANDARDIZATION AND QUALITY OF HERBAL DRUGS:

Plants contain several hundred constituents and some of them are present at very low concentrations. In spite of the modern chemical analytical procedures available, only rarely do phytochemical investigations succeed in isolating and characterizing all secondary metabolites present in the plant extract. Apart from this, plant constituents vary considerably depending on several factors that impair the quality control of phytotherapeutic agents. Quality control and standardization of herbal medicines involve several steps. However, the source and quality of raw materials play a pivotal role in guaranteeing the quality and stability of herbal preparations. Other factors such as the use of fresh plants, temperature, light exposure, water availability, nutrients, period and time of collection, method of collecting, drying, packing, storage and transportation of raw material, age and part of the plant collected, etc., can greatly affect the quality and consequently the therapeutic value of herbal medicines. Some plant constituents are heat labile and the plants containing them need to be dried at low temperatures. Also, other active principles are destroyed by enzymatic processes that continue for long periods of time after plant collection. This explains why frequently the composition of herbal based drugs is quite variable. Thus, proper standardization and quality control of raw material and the herbal preparations themselves should be permanently carried out. In the cases where the active principles are unknown, marker substance should be established for analytical purposes. However, in most cases these markers have never been tested to see whether they really account for the therapeutic action reported for the herbal drugs. (Blumenthal 1999 a; Lazarowych and Pekos, 1998).

MARKETED POTENTIAL OF HERBAL DRUGS:

During the past decades, public interest in natural therapies, namely herbal medicine, has increased dramatically not only in developing countries but mainly in industrialized countries. This has increased the international trade in herbal medicine enormously and has attracted most of the pharmaceutical companies, including the multinationals. Until a few years ago, only small companies had interest in the marketing of herbal medicines. Currently, most large multinational companies are interested in commercializing herbal drugs. It is estimated that the European market alone reached about $7 billion in 1997. The German market corresponds to about 50% of the European market, about $3.5 billion which represents about $42.90 per capita. This market is followed by France, $1.8 billion; Italy, $700 million; the United Kingdom, $400 million; Spain, $300 million; the Netherlands, about $100 million. European herbal medicines are distributed under 6 basic therapeutic categories: cardiovascular, 27.0%; respiratory, 15.3%; digestive, 14.4%; tonic, 14.4%; hypnotic/sedative, 9.3%; topical, 7.4%; others, 12.0%.[12-13]

MODERN MEDICINES FROM HIGHER MEDICINAL PLANTS:

Herbal plants play a vital role for the development of new drugs. During 1950-1970 approximately 100 plants based new drugs were introduced in the USA drug market including deserpine, reseinnamine, reserpine, vinblastin and vincristine which are derived from higher plants. From 1971 to 1990 new drugs such as ectoposide, E-guggulsterone, teniposide, nabilone, plaunotol, Z-guggulsterone, lectinan, artemisinin and ginkgolides appeared all over the world. 2% of drugs were introduced from 1991-1995 including paclitaxel, toptecan, gomishin, irinotecan etc. Plant based drugs provide outstanding contribution to modern therapeutics; for example: serpentine isolated from the root of Indian plant *Rauwolfiasepentina* in 1953, was a revolutionary event in the treatment of hypertension and lowering of blood pressure. Vinblastin isolated from the *Catharanthus rosesus* is used for treatment of Hodgkins, choriocarcinoma, non-hodgkinslymphosarcoma, small cell lung and breast cancer (Farnsworth and Blowster, 1967). Indian indigenous tree of *Nothapodytes nimmoniana* (*Mappiafoetida*) are mostly used in Japan for the treatment of cervical cancer. Plany derived drugs are used to cure mental illness, skin disease, tuberculosis, diabetes, jaundice, hyper tension and cancer. Medicinal plants play an important role in the development of potent therapeutic agents. More than 64 plants have been found to possess antibacterial properties; and more than 24 plants have been found ti possess antidiabetic properties (Perumal S and Ignacimuthu ,1998).

REGULATORY ASPECTS AND APPROVAL OF HERBAL DRUGS:

The legal process of regulation and legislation of herbal medicines changes from country to country. The reason for this involves mainly cultural aspects and also the fact that herbal medicines are rarely studied scientifically. Thus, few herbal preparations have been tested for safety and efficacy. The WHO has published guidelines in order to define basic criteria for evaluating the quality, safety, and efficacy of herbal medicines aimed at assisting national regulatory authorities, scientific organizations and manufacturers in this particular area[4]. Several regulatory models for herbal medicines currently

exist, including prescription drugs, over-the-counter drugs, traditional medicines and dietary supplements. Thus, the need to establish global and/or regional regulatory mechanisms for regulating herbal drugs seems obvious (Bulletin of the World Health Organization, 1993; Eskinazi *et al*., 1999; Foster and Tyler, 1998).

HERBAL MEDICINE SCENARIO IN INDIA:

The turnover of herbal medicines in India as over the counter products, ethical and classical formulations and have remedies of Ayurveda, Unani and Siddha systems of medicine is about $1 billion with a meagre export of $ 80 million. 80% of the exports to developed countries are of crude drugs and not finished formulations leading to low revenue for the country. The list of medicinal plants exported from India are Aconitum species (root), *Acorus calamus* (rhizome), *Adatoda vasica* (whole plant), *Berberis aristata* (root), *Cassia augustifolia* (leaf and pod), *Colchicum luteum* (rhizome and seed), *Hedychium spicatum* (rhizome), *Heradeum candicans* (rhizome), *Juglans regia* (husk), *Juniperus communis* (fruit), *Juniperus macropoda* (fruit), *Picrorhiza kurrooa* (root), *Plantago ovata* (seed and husk), *Podophyllum emodi* (rhizome), *Pinica granatum* (flower, root and bark), *Rauwolfia serpentina* (root), *Rheum emodi* (rhizome), *Saussurea lappa* (rhizome), *Swertia chirayita* (whole plant), *Valerianajatamansi* (rhizome), *Zingiber officinale* (rhizome). Five of these, i.e. *Glycerrhiza glabra*, *Commiphora mukul*, *Plantago ovata*, Aloe barbadensis and Azardicaindica are used in modern medicine. Others are used in 52 to 141 herbal formulations and Triphala (*Terminalia chebula*, *Terminalia belerica* and *Embelica officinalis*) along is used in 219 formulation. (Anonymous, 1996).

FUTURE SCENARIO OF HERBAL DRUGS:

There is a growing interest in herbal drugs, and as an example of this, the consumption of medicinal plants has doubled in the last ten years in Western Europe. Use of medicinal plants is expected to raise globally, due to increasing trend towards self-medication, reduction in costs of subsidized health care, various international and national organizations improving the status of herbal medicine industry and renewed interest of companies in isolating useful compounds from the plants.

It implies increasing pressure on wild plant resources and, therefore, the need for serious conservation efforts including development of cultivation techniques has never been greater. Serious over-exploitation of many medicinal plants such as Rauwolfia, Dioscorea, Swertiachirata, Valeriana, Orchis and Harpagophytumprocumbens has already occurred (Hamberger *et al.*, 1991).This traditional role of international organization and universities is one that has considerable potential for expansion, so far as medicinal plants are concerned. There are some aspects of particular relevance for the rational utilization of medicinal plants and other natural products. Significant progress over the next few years will depend on the imagination and determination, which can be brought to bear on the subject (Wagner and Fransworth, 1990). Modern instrumentation and biological assay methods provide the possibility of developing suitable quality control criteria for herbal drugs. The structural determination of novel plant constituents can be performed with minimal delay by using a combination of sophisticated spectroscopic (UV, FT-IR, 1H-NMR, 13C-NMR, Mass spectroscopy) and X-ray crystallographic techniques. High-throughput automated bioassays are widely available, so that a detailed biological profile can be obtained easily on just a few milligrams of a natural product. Thus, there is every indication that the direct utility and promise of plants for the improvement of human health will continue well into the 21st century (Kinghornand Balandrin, 1993).

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CONFLICT OF INTEREST:

The authors declare that they have no conflict of interest.

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