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Herbal Medicine Scenario in India and European Countries

Parul Agarwal^{1*}, Amreen Fatima¹ and Prem Prakash Singh¹

1. Institute of Pharmacy, Bundelkhand University Jhansi, U.P, India.
[E-mail: agarwal.parul@gmail.com]

Herbal medicines are the synthesis of therapeutic experiences of generations of practising physicians of indigenous systems of medicine for over hundreds of years while nutraceuticals are nutritionally or medicinally enhanced foods with health benefits of recent origin and marketed in developed countries. Herbal medicines are also in great demand in the developed world for primary health care because of their efficacy, safety and lesser side effects. They also offer therapeutics for age-related disorders like memory loss, osteoporosis, immune disorders, etc. for which no modern medicine is available. WHO too has not systematically evaluated traditional medicines despite the fact that it is used for primary health care by about 80% of the world population. However, in 1991 WHO developed guidelines for the assessment of herbal medicine. Suggestions for herbal medicine standardization are outlined. The scenario and perceptions of herbal medicine are discussed.

Keyword: Herbal medicine, India, European countries.

1. Introduction

Early humans recognized their dependence on nature for a healthy life and since that time humanity has depended on the diversity of plant resources for food, clothing, shelter, and medicine to cure myriads of ailments. Led by instinct, taste, and experience, primitive men and women treated illness by using plants, animal parts, and minerals that were not part of their usual diet. Primitive people learned by trial and error to distinguish useful plants with beneficial effects from those that were toxic or inactive, and also which combinations or processing methods had to be used to gain consistent and optimal results. Even in ancient cultures, tribal people methodically collected information on herbs and developed well-defined herbal pharmacopoeias. Physical evidence of the use of herbal remedies some sixty thousand years ago has been found in a burial site of a Neanderthal man uncovered in 1960 in a cave in northern Iraq ^[2].

1.1 Herbal Medicine

The World Health Organization (WHO) has recently defined traditional medicine (including herbal drugs) as comprising therapeutic practices that have been in existence, often for hundreds of years, before the development and spread of modern medicine and are still in use today. Or say, traditional medicine is the synthesis of therapeutic experience of generations of practising physicians of indigenous systems of medicine³.

1.2 Herbal Medicine Market

As per available records, the herbal medicine market in 1991 in the countries of the European Union was about \$ 6 billion (may be over \$ 20 billion now), with Germany accounting for \$ 3 billion, France \$ 1.6 billion and Italy \$ 0.6 billion. The Indian herbal drug market is about \$ one billion and the export of herbal crude extracts is about \$ 80 million (Table 1). The 10 best-selling herbal medicines in developed countries¹ are given in Table 2. The sales of these drugs

account for almost 50% of the herbal medicine market³.

1.3 Herbal Medicine Scenario in India

The turnover of herbal medicines in India as over-the-counter products, ethical and classical formulations and home remedies of Ayurveda, Unani and Siddha systems of medicine is about \$ 1 billion with a meagre export of about \$ 80 million. Psyllium seeds and husk, castor oil and opium extract alone account for 60% of the exports. Three of the 10 most widely selling herbal medicines in developed countries, namely preparation of *Allium sativum*, *Aloe barbadensis* and *Panax* species are available in India.

Table 1: Market size of herbal medicines³

Country	Drug sales in US \$ (billion)
Europe(1991)	
Germany	3.0
France	1.6
Italy	0.6
Others	0.8
Europe(1996)	10.0
USA(1996)	4.0
India(1996)	1.0
Other countries	5.0

India is one of the 12 mega biodiversity centres having over 45,000 plant species. Its diversity is unmatched due to the presence of 16 different agroclimatic zones, 10 vegetative zones and 15 biotic provinces. The country has 15,000–18,000 flowering plants, 23,000 fungi, 2500 algae, 1600 lichens, 1800 bryophytes and 30 million micro-organisms⁴. Tables 2 and 3 give the names of medicinal plants exported and imported in India, respectively

Table 2: Medicinal plants being exported from India⁴

Botanical Name	Part of the Plant
<i>Zingiber officinale</i>	Rhizome
<i>Rauvolfia serpentina</i>	Root
<i>Swertia chirayita</i>	Whole plant
<i>Cassia angustifolia</i>	Leaf & pod
<i>Acorus calamus</i>	Rhizome
<i>Adhatoda vasica</i>	Whole plant
<i>Aconitum</i> species	Root
<i>Picrorhiza kurroa</i>	Root
<i>Colchicum luteum</i>	Rhizome & Seed
<i>Rheum emodi</i>	Rhizome

1.4 Herbal Medicine Standardization

In indigenous/traditional systems of medicine, the drugs are primarily dispensed as water decoction or ethanolic extract. Fresh plant parts, juice or crude powder are a rarity rather than a rule. Thus medicinal plant parts should be authentic and free from harmful materials like pesticides, heavy metals, microbial or radioactive contamination, etc. The medicinal plant is subjected to a single solvent extraction once or repeatedly, or water decoction or as described in ancient texts. The extract should then be checked for indicated biological activity in an experimental animal model(s). The bioactive extract should be standardized on the basis of active principle or major compound(s) along with fingerprints. The next important step is stabilization of the bioactive extract with a minimum shelf-life of over a year. The stabilized bioactive extract should undergo regulatory or limited safety studies in animals. Determination of the probable mode of action will explain the therapeutic profile.

Table 3: Medicinal plants being imported in India⁴

Botanical Name	Native Name
<i>Cuscuta epithymum</i>	Aftimum vilaiyti
<i>Glycyrrhiza glabra</i>	Mulethi
<i>Lavandula stoechas</i>	Ustukhuddus
<i>Smilax china</i>	Chobehini
<i>Smilax ornata</i>	Ushba

1.5 Role of Whom in Herbal Medicine

Since 1978 when WHO officially recognized the potential of herbal medicine and traditional health practitioners in extending primary health care to underserved populations herbal medicine has been more widely used not only in developing countries but also in developed countries. In accordance with requests from member states, a series of resolutions concerning policy, objectives & activities on herbal medicine have been issued by the world health assembly [5].

1.6 The Role of Herbal Medicines in Traditional Healing

The pharmacological treatment of disease began long ago with the use of herbs. Methods of folk healing throughout the world commonly used herbs as part of their tradition. Some of these traditions are briefly described below, providing some examples of the array of important healing practices around the world that used herbs for this purpose⁶.

1.6.1 Traditional Chinese medicine:

Traditional Chinese medicine has been used by Chinese people from ancient times. Although animal and mineral materials have been used, the primary source of remedies is botanical. Of the more than 12000 items used by traditional healers, about 500 are in common use [7].

1.6.2 Japanese traditional medicine:

Many herbal remedies found their way from China into the Japanese systems of traditional

healing. Herbs native to Japan were classified in the first pharmacopoeia of Japanese traditional medicine in the ninth century^[8].

1.7 Introduction of traditional herbal medicines into Europe, the USA and other developed countries

The desire to capture the wisdom of traditional healing systems has led to a resurgence of interest in herbal medicines, particularly in Europe and North America, where herbal products have been incorporated into so-called 'alternative', 'complementary', 'holistic' or 'integrative' medical systems^[9].

One problem is that ingredients once used for symptomatic management in traditional healing are now used in developed countries as part of health promotion or disease prevention strategies; thus, acute treatment has been replaced by chronic exposure (e.g., herbal products used for weight loss)^[10].

3. Use of Traditional Herbal Medicines in Developed Countries

3.1 Origin, type and botanical data:

Plants and their secondary metabolite constituents have a long history of use in modern 'western' medicine and in certain systems of traditional medicine, and are the sources of important drugs such as atropine, codeine, digoxin, morphine, quinine and vincristine. Use of herbal medicines in developed countries has expanded sharply in the latter half of the twentieth century.

3.2 Medicinal applications, beneficial effects and active components:

In some cases, the active principles of plant-derived products have been isolated and characterized, and their mechanisms of action are understood (e.g., ephedrine alkaloids in some species of *Ephedra*). For many, however, including virtually all of the most common products in the marketplace, such information is incomplete or unavailable. This is in large part due to the complexity of herbal and botanical preparations; they are not pure compounds.

4. Awareness, Control, Regulation & Legislation on Use

4.1 The European Union:

The importance of herbal medicinal products varies from one country to another. These products are not a homogeneous group. In general, they are either fully licensed medicinal products with efficacy proven by clinical studies or by references to published scientific literature (in accordance with Article 4.8 a (ii) of Council Directive 65/65/EEC) or are available as products with a more or less simplified proof of efficacy according to their national use^[11].

4.1.1 Definition of herbal medicinal products:

According to Council Directive 65/65/EEC, which has been implemented in national law in all Member States, medicinal products require prior marketing approval before gaining access to the market. In almost all Member States, herbal medicinal products are considered as medicinal products, and are, in principle, subject to the general regulations for medicines as laid down in the various national medicine laws^[11].

4.1.2 Classification of herbal products:

Generally, herbal products are classified as medicinal products if they claim therapeutic or prophylactic indication, and are not considered as medicinal products when they do not make these claims. Products not classified as medicinal in most cases belong to the food or cosmetic areas, although they sometimes contain plants which have pharmacological properties. For example, senna pods (from *Cassia* plants, used as laxatives) (see General Remarks and monograph on *Rubia tinctorum*, *Morinda officinalis* and anthraquinones in this volume) can be marketed as food in Belgium

4.1.3 Individual supply:

Herbal medicinal products (like other medicinal products) are made up and/or supplied to individual patients following a one-to-one consultation between patient and practitioner. A specific situation exists in the United Kingdom, where a practitioner, according to Section 12 of

the Medicines Act 1968, may supply products to a customer without a licence^[12].

4.1.4 Good manufacturing practices and quality control:

All Member States apply the manufacturing requirements of Council Directive 75/319/EEC to herbal medicinal products. Starting materials for herbal medicinal products are in principle controlled in accordance with the European Pharmacopoeia in all Member States. Good manufacturing practice inspections are carried out in nearly all Member States^[13].

4.2 Individual countries:

4.2.1 France:

Traditional use of approximately 200 herbal drugs or preparations derived from these drugs has been recognized for minor indications. As of 1997, local medicinal plants were on the A list of the French Pharmacopoeia which groups the 454 herbs which benefit/risk ratio is considered as positive when traditionally used. ¹³have reviewed the surveillance or pharmacovigilance of herbal medicines in France. Between 1 and 15 October 1996, the authors observed 15 publications or publicities in 23 magazines widely available in France; these publications/ publicities offered for sale by mail a number of medicinal plants found or not found on the list of 34 'approved' plants ^[14].

4.2.2 Germany:

Summarized the legal requirements for the use of phytopharmaceutical drugs in the Federal Republic of Germany. The legal status for herbal remedies was defined by the Medicines Act of 24 August 1976 ^[15,16].

4.2.3 United Kingdom:

A number of papers have discussed the situation regarding herbal medicines in the United Kingdom recommended that herbal products be licensed as special products 'medicines'; he estimated that unlicensed preparations accounted for over 80% of herbal sales. Many medicine-like products on the British herbal market remain unregistered for two reasons: acceptable data on

efficacy, safety and quality may not be available, and the licensing fee is high [17].

4.2.4 Canada:

The Canadian Food and Drug Act and findings of an Expert Advisory Committee on Herbs and Botanical Preparations were consulted by to provide an overview of the issues regarding regulation of herbal products in Canada. Herbal products not registered as drugs in Canada are sold as foods and are thus exempt from the drug review process that evaluates product efficacy and safety. An Expert Advisory Committee on Herbs and Botanical Preparations was formed in 1984 to advise the Health Protection Branch (HPB). HPB published lists of hazardous herbal products in 1987, 1989, 1992 and 1993. The last publication elicited a large response from consumers and the herbal industry. As of 1995, the list was still under review.[18]

4.2.5 Japan:

Japanese traditional medicine, as used in Japanese society for more than a thousand years, may be divided into folk medicine and Chinese medicine (or Kampo medicine). Kampo medicine is so popular that the per capita consumption of herbal medicine in Japan seems to be the highest in the world. One hundred and forty-six Kampo drugs are registered as drugs by the Ministry of Health and Welfare (MHW) and are included in coverage under the National Health Insurance [19].

5. Discussion

Herbal medicines are being used by about 80% of the world population primarily in the developing countries for primary health care. They have stood the test of time for their safety, efficacy, cultural acceptability and lesser side effects. The chemical constituents present in them are a part of the physiological functions of living flora and hence they are believed to have better compatibility with the human body. Ancient literature also mentions herbal medicines for age-related diseases namely memory loss, osteoporosis, diabetic wounds, immune and liver disorders, etc. for which no modern medicine or only palliative therapy is available.

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