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Alternative and Traditional Medicines Systems in Pakistan: History, Regulation, Trends, Usefulness, Challenges, Prospects and Limitations

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1. Introduction

The Islamic Republic of Pakistan, with an area of 796095 Km² is the sixth largest country of the world and has population of 160 million. Of these 43.2% are less than 15 years, 53.4% from 15-64 and 3.4% 65 plus, with a per capita income of US$ 492. 33 percent of the population lives in the urban areas and 67.0% lives in the rural areas. Its population growth rate is 2.06% (NIPS, 2003).

Over the last few decades, there has been a considerable interest worldwide in Traditional medicine/Complementary and Alternative Medicine (TCAM) particularly in herbal products. The World Health Organization also advocates the important role of alternative and traditional medicines in preventive, promotive and curative health, especially in developing countries and encourages member states to support traditional medicines to and plan for, formulation of policies with appropriate regulations (WHO, 2001).

Major categories of Traditional/Complementary and alternative medicines (TCAM) in vogue in the developing and developed countries are categorized as: whole body systems (Ayurveda, homeopathy, Unani, and Traditional Chinese Medicine); mind–body medicine (meditation, prayer, mental healing); biologically based therapies (use of natural substances, such as herbs, foods, vitamins, dietary supplements, herbal products); manipulative and body-based practices (massage); and energy medicine (Reiki) (Shaikh *et al.,* 2009). In Pakistan traditional medicines have been a strong part of our cultural heritage and playing a significant role in providing health care to a large part of the population. However, there has been lack of concerted efforts for proper utilization of traditional medicines in the health care system. Primarily three categories i.e. Tibb-e-Unani, Ayurveda and Homoeopathy are in vogue whereas Chinese Traditional System, Reiki, Acupuncture and aromatherapy has been introduced in certain parts of the country in the last few years (Malik *et al.,* 2006).

The Government of Pakistan in the last two decades for providing a comprehensive, universal and equitable health care to all Pakistani nationals in line with WHO's goal i.e. " Health for all by 2000" has declared its official policy on TRM as part of National Health Policy. This goal cannot be achieved without utilizing the Traditional and/Complementary and alternative medicines (TCAM) (WHO, 1978). The National Policy of Health, 1997 suggested developing a new curriculum, prerequisite for admissions in Tibba/Homoeopathic Colleges has been changed from Matric (Grade 10) to FSc (Pre-medical i.e. Grade 12) for which the colleges needs affiliation with universities, enactment of a law to cover manufacturing of traditional medicines, strengthening the roles of National Council for Tibb and Homoeopathy and supporting research and development. The policy suggested regulation of traditional medicines practice and education, establishment of pharmaceutical laboratory at federal level and conducting training courses for the collection of medicinal plants. The National Health Policy of 2001 also suggested amendments of Unani, Ayurvedic and Homoeopathic (UAH) Act, 1965 to incorporate degree and post graduate level courses (NHP, 97, 2001) which have now been implemented.

1.1 Tibb-e-Unani

According to basic principles of Tibb-e-Unani (Greco-Arab) body is made up of the four basic elements, which are "earth", "air", "water" and "fire" with different "temperaments" i.e. cold, hot, wet and dry. The body organs get their nourishment through four "humors" i.e. Blood, Phlegm, Yellow Bile and Black Bile. Concept of health in Tibb-e-Unani is a state of body in which there is equilibrium in the "humors" and functions of the body are normal in accordance with its own temperament and the environment. When the equilibrium of the "humors" is disturbed and the functions of body are abnormal, that state is called disease. It takes a holistic approach towards prevention of diseases, cure and promotion of health and relies on drugs made from medicinal plants, herbs, minerals, metallic and animal origin for the treatment of diseases.

Unani system of medicine has its origin in Greece. It is believed to have been established by the great physician and philosopher- Hippocrates (460-377 BC). The Arabian scholars and physicians under the patronage of Islamic rulers of many Arabian countries have played great role in the development of this system. Many disciplines like chemistry, pharmaceutical procedures like distillation, sublimation, calcinations and fermentation were developed and refined by them. The most influential historical figure in this golden era of Unani medicine was Avicenna (980-1037 A.D). His most important medical work was "The cannons of medicine" Al-Qunoon. The present form of Unani medicines greatly owes to him. His book Al-qanoon or (The canon of medicine) was an internationally acclaimed book on medicine, which was taught in European countries till the 17th century. Many physician of Arab descent in Spain have also contributed to the development of the system. Some of the important names are-Abul Qasim Zohravi (Abulcasus 946 – 1036 AD) and he is the author of the famous book on surgery "Al Tasreef"-(http://www.indianmedicine.nac.in).

The Arabs were instrumental in introducing Unani medicine in sub-continent in around 1350 AD. The first known Hakim (Physician) was Zia Mohd Masood Rasheed Zangi. Some of the renowned physicians who were instrumental in development of the system are-Akbar Mohd Akbar Arzani (around 1721 AD)- the author of the books- Qarabadin Qadri and Tibb-e- Akbar; Hakim M. Shareef Khan (1725-1807)- a renowned physician well-known

for his book Ilaj ul Amraz. Hakim Ajmal Khan (1864-1927) a great name among the 20th Century Unani physicians. He was a multifaceted personality besides being a physician he was a scientist, politician and a freedom fighter. He was instrumental in the establishment of Unani and Ayurvedic College at Karol Bagh, Delhi. He was a keen researcher and has supervised many studies on Rauwolfia serpentina- the source plant for many well-known alkaloids like reserpine, Ajamaloon etc. Another great contributor is Hakim Kabeeruddin (1894-1976) and had translated 88 Unani books of Arabic and Persian languages into Urdu. The first institution of Unani medicine was established in 1872 as Oriental College at Lahore in the undivided India. Thereafter many institutions came into existence. Practically, Unani medicine is innovative in that it has accepted the challenges like professional practice-patient relations, forms of intervention and disease conceptualization itself. Unani medicine has maintained its popularity in a number of South Asian countries and it account for more than 30% of the total medicinal consumption (Jabin, 2011, Ravishankar and Shukla, 2007, Siddiqui, 2004).

1.2 Homeopathy

Homoeopathy means treating diseases with remedies, prescribed in minute doses, which are capable of producing symptoms similar to the disease when taken by healthy people. It is based on the natural law of healing-" Similia Similibus Curantur " which means " likes are cured by likes". Dr. Samuel Hahnemann (1755-1843) gave it a scientific basis in the early 19th century. Homoeopathic system of medicine was introduced to this part of the subcontinent a little over a century ago and has blended well with the traditional concepts. It has gained tremendous popularity in Islamic Republic of Pakistan. The City of Lahore in Pakistan has the privilege of being the first city of undivided India, where Homoeopathy was introduced by Dr. J. M. Honigberger, a German Physician. The first homoeopathic college of the Punjab was opened in Lahore in early 1920. It was started by an American Missionary, Dr. Freeburn and Maj. Dr. Sadiq Ali. This institution, the Central Homoeopathic Medical College, produced many eminent homoeopaths of Subcontinent. (*www.nchpakistan.com*)

2. Regulation of traditional/complementary and alternative medicines

Traditional/Complementary medicines practiced in Pakistan are regulated under Unani, Ayurvedic and Homoeopathic (UAH) Act of 1965 which has been amended to recognize the degrees Course. The practitioners of these systems have to be registered by their respective councils i.e. National Council for Tibb (NCT) and National Council for Homoeopathy (NCH).

National Council for Tibb (NCT): It is responsible for developing curriculum, education and examination of Tibb-e-Unani and Ayurvedic system of medicine and for registration of Tabibs who have passed the examination. Out of total 22 council members 14 are elected through a process of postal ballot and remaining are nominations from the federal and provincial government, term of members is 5 years. The council members elect the president from amongst themselves. There are approx. 45,799 Hakims / Tabibs and 537 Vaids registered with NCT and about 28 recognized Tibbia colleges (Malik *et al.*, 2005). There are two Universities who are imparting five years BEMS degree along with M. Phil and PhD degrees.

National Council for Homoeopathy (NCH): Like NCT, National Council for Homoeopathy is responsible for developing curriculum, education, examination of Homoeopathic system of medicine and registration of homoeopathic doctors. The council members are elected through the same process as with National Council for Tibb. There are about 118,000 homeopaths registered with NCH and 135 recognized Homeopathic colleges in Pakistan (Malik *et al.,* 2005). There are three Universities who are imparting five years BHMS degree along with M. Phil and PhD degrees.

The bill to regulate the manufacture, storage, import and export of Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal and Non-allopathic medicines 2010 has been prepared in consultation with the stakeholders of the TRM Sector and is with National Assembly of Pakistan for final enactation very soon. Till today manufacturing is not regulated by any Government body. However manufacturers are self regulating by adopting cGMP (current good manufacturing practices) to ensure safety and quality of their products. The abuse of allopathic medicines by the practitioners or manufacturers is being trialled under Drugs Act of 1976.

3. Trends in use of traditional/complementary and alternative medicines

Traditional/Complementary and Alternative medicines have been practiced in many countries for centuries, including parts of the world where biomedical healthcare is readily available. According to one estimate, around 75-90% of the developing world's population and about half of the industrialized world's population still depend on the complementary and alternative systems of medicine (Robinson and Zhang, 2011). The studies showed that 42% of Americans, 52% of Australians, and between 20% and 65% of Europeans use some form of CAM (Zollman and Vicker, 1999, Maclennan *et al.,* 2004, Ernst, 2000). Estimates of CAM use in Western countries range from about one third to half of the general population (Menniti-ippoliti *et al.,* 2002, Gianelli *et al.,* 2004). In Italy, the proportion has almost doubled during the last decade (14) although it still remains far below the estimates reported in many European countries and the United States. The analysis of data collected in 1999–2000 among the general population by the Italian National Institute for Statistics showed that in Tuscany, 13.6% of adults had made use of CAM in the previous year (Maclennan *et al.,* 1996). In African and other developing countries, up to 80% of the population depends on CAM, including herbal remedies, for health maintenance and therapeutic management of disease (WHO, 2001). The persuasive appeal of CAM is premised on the fundamental assumptions and principles by which the system operates. These include the presumption that CAM modalities are ''natural,'' provide the user with a connection to life-supporting forces (vitalism), have a ''scientific basis,'' and promote ''spirituality'' as well (Kaptchuk and Eisenberg, 1998). In Pakistan, alternative system of medicines has been considered to be the first line of treatment in rural areas where 80% of the country's population lives.

The overall trend in Pakistan shows that 51.7% chose Traditional and complementary and alternative medicine (TCAM) while 48.3% chose biomedicine. Of those who chose CAM, 20% also used biomedicine as well; 16% homeopathy, 12.4% Unani medicine, 2.1% mind–body medicine (faith healing), 0.9% biologically based practices (home remedies, diet and nutrition) 0.05% energy medicine (Reiki), 0.05% Traditional Chinese Medicine, and 0.02% aromatherapy. About half of the studied population used TCAM. The population estimates of use of TCAM are within the range reported elsewhere. It reflects an increasing popularity

of CAM in Pakistan as well. Combined use of biomedicine with TCAM was common and often patients did not reveal the use of TCAM to the biomedicine practitioners (Shaikh *et al.,* 2009).

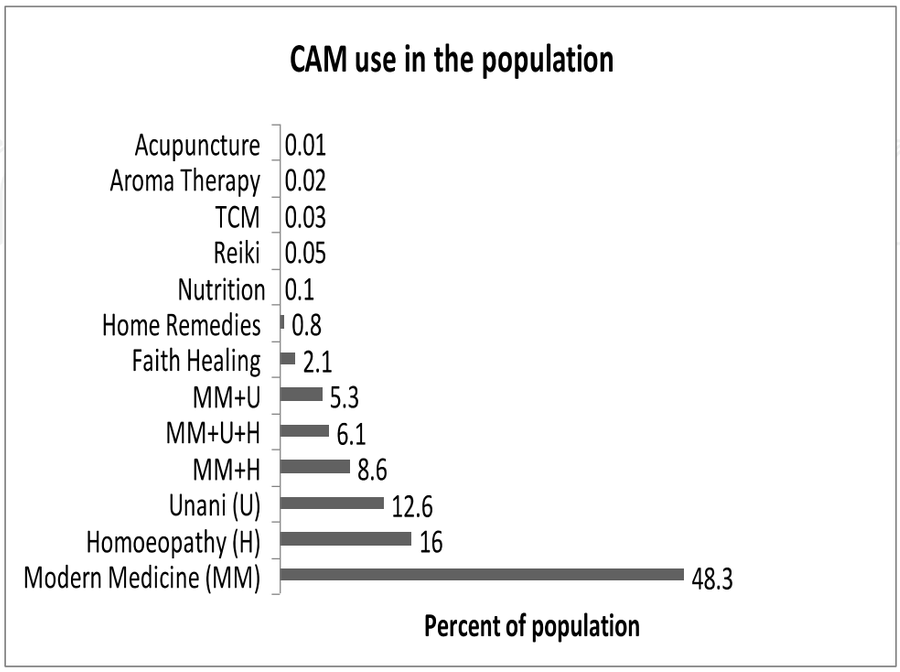

Fig. 1. Source: Shaikh *et al.,* 2009

4. Research and development in traditional/complementary and alternative medicines sector

Pakistan has not been able to develop a coordinated institutional infrastructure and human resource to add value to the medicinal plants resources for its sustainable use of floral wealth. Major research activities on medicinal plant research in Pakistan are on the documenting level. The research is being conducted mainly in universities and that too as ethno-botanical listing of resources. Recently the work on various medicinal plants were carried out in various institutes to establish their antimicrobial, antiplatelet and acetyl-cholinesterase, inhibitory constituents, inflammatory, analgesic, gut modulatory, anti-diarroeal effects and constipation effects (Malik *et al.,* 2010, 2011, Ghayur *et al.,* 2011, Ahmad and Gilani, 2011, Khan *et al.,* 2011, Bashir *et al.,* 2011, Mahmood *et al.,* 2011).

Some of the institutions involved in research of various aspects of medical plants are as follows;

Taxonomy, collection, herbarium

i. Pakistan Forest Institute, Peshawar
ii. National Agriculture and Research Council, Islamabad.
iii. Quaid-i-Azam University, Islamabad.
iv. Pakistan Museum of Natural History, Islamabad.
v. National Institute of Health, Islamabad.

vi. Herbarium, University of Karachi, Karachi.
vii. Hamdard University, Bait-ul-Hikmah, Karachi
viii. Botany Department of Various Universities of Pakistan

Phyto-chemistry

i. International Center for Chemical Research, Institute of Chemistry, University of Karachi;
ii. Pakistan Council for Scientific and Industrial Laboratories, Peshawar
iii. Chemistry and Pharmacology Departments of various Universities of Pakistan

Pharmacology

i. National Institute of Health, Islamabad.
ii. HEJ Research Institute, University of Karachi, Karachi
iii. The Aga Khan Medical University, Karachi.
iv. Hamdard University, Karachi.
v. University of Agriculture, Faisalabad.
vi. University of Veterinary and Animal Sciences, Lahore.
vii. University of Agriculture, Peshawar.
viii. Pharmacology and Pharmacognosy Departments of various Universities of Pakistan.
ix. Al-Majeed College of Eastern Medicines, Hamdard University, Karachi

Ethno-Botany Data Base

i. Pakistan Forest Institute, Peshawar, KPK
ii. Botany Departments of various Universities of Pakistan
iii. Hamdard University, Karachi

Standardization, Quality Control and Safety Assurance

i. National Institute of Health, Islamabad.
ii. Hamdard University, Karachi
iii. Pharmacognosy Department, University of Karachi, Karachi.
iv. HEJ Research Institute, University of Karachi, Karachi.

Medicinal Plants Cultivation, Tissue Culture

i. Hamdard University Karachi.
ii. National Institute of Health, Islamabad.
iii. Qarshi Industries, Hattar.
iv. University of Malakand, KPK.
v. PMNH, Islamabad.
vi. Hamdard Laboratories, Karachi.
vii. PARC, Islamabad
viii. NARC, Islamabad

Propagation

i. University of Malakand, KPK
ii. NARC, Islamabad.
iii. NIBGE, Faisalabad.

iv. NIAB, Faisalabad.
v. PCSIR laboratories, Karachi

Conservation

i. Forest Department, Peshawar, KPK.
ii. MACP, Pakistan
iii. WWF, Pakistan
iv. IUCN, Pakistan
v. SDC/IC, Pakistan
vi. AKRSP, Pakistan
vii. Palas Conservation and Development Project (PCDP) Kohistan, KPK, Pakistan

5. Intellectual property rights and protection of indigenous knowledge

Intellectual property (IP) has been considered a fundamental human right for all people since the adoption of the Universal Declaration of Human Rights (UDHR) in 1948. Article 27 of the Declaration states that everyone has the right "to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." Since 1948, many international human rights instruments and documents have reinforced the importance of IP as a human right. The importance of TCAM in developing countries cannot be overemphasized, as indigenous people cannot survive or exercise their fundamental human rights as distinct nations, societies and people without the ability to conserve, revive, develop and teach the wisdom they have inherited from their ancestors.

Natural resources are open to exploitation from within and outside the country. Thus commercial activities may lead to problems of access to medicine, loss of biodiversity, extinction of the endangered species and destruction of natural habitats and resources. If TRM are patented and fall into private ownership, people would be deprived of the only accessible and affordable source of medicine needed to protect health. Already patenting of some of the material indigenous to this subcontinent has been patented in the West endangering accessibility to this lifesaving material to the native population. The Trade Related Intellectual Property Rights (TRIPS) agreement does not adequately safeguard against such misuse of indigenous resources of the country in a foreign country. This is thus a critical issue for developing country where a large population still relies heavily on the TCAM. Unjustified patent protection can result in affordability problem for the people mainly due to higher prices which obviously would be the outcome. In various WHO workshops participants have urged countries to investigate all available ways and means of protecting such knowledge and TCAM products from abuse. Documentation, national legislation and bilateral agreements are some of the safeguards. However, collection, compilation for documentation of traditional knowledge and products and their wide publication is the most effective way of preventing their misuse by not allowing their patents for not having fulfilled the patentability criteria.

Thus under the implications of WTO/TRIPS protection of indigenous knowledge of traditional medicines is extremely vital for Pakistan in order to ensure continued availability of traditional medicine resources at affordable cost. Pakistan's patent ordinance does not allow patenting of plant materials, but this may not be enough to address the threat from

outside. There is still lack of awareness in government and public sector about TRIPS Agreement and its implications. Stake holder's needs to be educated about mechanisms for patenting their products and awareness about protection of indigenous knowledge. Hussain and Malik (2006, 2009, and 2010) from time to time have proposed various strategies in order to obtain following objectives;

- Protection of indigenous knowledge and medicinal plant resources in Pakistan.
- Continued availability of cost effective traditional medicine products and services.
- Awareness about Trade Related Intellectual Property Rights (TRIPS) Agreement and Patent Laws in all concerned.

6. Medicinal plants: Sustainable cultivation, collection and use

Pakistan has an area of 80,943 km2, lies between 60° 55′ to 75° 30′ E longitude and 23° 45′ to 36° 50′ N latitude and an altitude ranging from 0 to 8611 m. Therefore, has a variety of climatic zones and a unique biodiversity. It has about 6,000 species of higher plants. It has been reported that 600 to 700 species are used for medicinal purposes. It has also been estimated that 70% of the total species are uni-regional and about 30% are bi-or pluri-regional (Shinwari, 2010). The country has four phyto-geographical regions:

i. Irano-Turanian (45% of species)
ii. Sino-Himalayan (10%)
iii. Saharo-Sindian (9.5%)
iv. Indian element (6%).

Despite the Saharo-Sindian Region being the biggest area, the diversity of species confined to this area is lowest for any phyto-geographical region (Ali and Qaiser, 1986). The local communities of different regions of Pakistan have centuries old knowledge about traditional uses of the plants occurring in their areas. This indigenous knowledge of plants has been transferred from generation to generation. These plants are used to treat almost any kind of disease from headache to Stomachic to cut and wound (Bhardwaj and Gakhar, 2005). Some of the important plants are commercially harvested for extraction of various types of active ingredients. Though different systems of Unani, Ayurvedic (Eastern medicines) are largely based on the medicinal properties of plants, yet the precious wealth of indigenous knowledge is in danger of being lost. The use of traditional knowledge also reflects the values embedded in the traditions upheld by elders, especially with regard to medicine. Medicinal plants practitioners know that respecting Plants is often essential to the efficacy of medicines, which should not be seen as 'miracle' cures based on chemical compounds, but due to curative energy that draws its medicinal qualities founded on a relationship between the plants and the people (Juden, 2003). There are few educational institutes where they are studying practical implications of medicinal plants. Major reason of use of plants as medicines is that medicinal plants contain synergistic and/or side-effects neutralizing combinations (Gilani and Atta-ur-Rahman, 2005). There is also a concern about the harmful effects of synthetic chemicals; hence, trends are changing towards natural products. Besides the research based activities, the medicinal plants from the wild resources are also exploited for commercial purposes which lead to the endangerment of species in their respective habitats. Though these medicinal plants are also important sources of income for poor people as well as for herbal dealers, and exporters but still no cultivation practices for these medicinal plants are observed in Pakistan.

6.1 Major issues pertaining to medicinal plants cultivation and conservation

The major issues that the medicinal plants face in Pakistan, besides the prospects of cultivation and conservation are as follows;

i. Increased global demand of herbal medicines and current status

Globally, there is a rising trend to shift resources from allopathic to traditional healthcare systems. The global market estimates to surge US$ 5 trillion by 2050. Twelve percent of Pakistani flora is used in medicines and more than 300 medicinal plants are traded. Ten leading Dawakhanas (Herbal manufacturers) of Pakistan annually consume more than 2 million kg of 200 medicinal plants in 1990s while its consumption increased multifold in the last two decades. According to an estimate, 22 species of medicinal plants worth Rs.14.733 million were traded in 1990 while in 2002, this value rose to more than Rs.122 million, an eight-and-a-half times increase. In 1990, 95 species were consumed worth Rs. 36 million while in 2002, medicinal plants worth Rs. 218 million were consumed: a six-fold increase (Shinwari *et al.,* 2002). Shinwari *et al.* (2006) published a "pictorial guide of medicinal plants of Pakistan" enlisting more than 500 species of flowering plants, being used as medicine. It has also been reported that nearly 37% (266 species) of the total of 709 endangered species are endemic to Pakistan. Endemic species may also be explored for ethnobotanical, pharmacological and pharmaceutical activities (Shinwari, 2010).

Hence there is a global need to cultivate and conserve medicinal plants. In Russia 50,000 tons of medicinal plants are used annually of which, 50% are cultivated. In Lucknow (India) medicinal plants worth Rs.90 million are grown annually. European Union (EU) uses 3,000 kg of Glycerrhiza each year for which 400 tons plant roots are needed. In China, in the year 2000, the total output value of the pharmaceutical industry was 233 billion yuan (28 billion US$). By the year 2010, the share of traditional Chinese medicine in the international market of herbal medicine was projected to improve to 15% from the existing 3%. Unfortunately in Pakistan not enough emphasis has been given to the cultivation of medicinal plants (Shinwari, 2010). Recently, the Government of Pakistan through Ministry of Food Agriculture and Livestock (MINFAL) has started a project entitled as "Production of Medicinal Herbs in Collaboration with Private Sectors" (PMHPS) in July 2006 to promote the cultivation of medicinal herbs and spices plants as crop in Pakistan. The project has focused the production of medicinal herbs on commercial scale through research based technology package oriented to World Health Organization (WHO) guideline of good agriculture, collection and processing practices (Aslam, 2008).

ii. Causes of threats to existence of medicinal plants in Pakistan

The hotspots of medicinal plants in Pakistan are spread over 13 Natural Regions from alpine pastures to mangrove forest. More than 10% of the flora is endangered (Shinwari *et al.,* 2000, 2002). Reasons of endangerment includes population pressure, poverty and poor quality of the natural resource-base, breakdown of social institutions, lack of land use plans and lack of enforcement of existing rules in whatever form these are. In addition rapid infrastructural development (roads, building construction), deforestation, spread of irrigation system, pollution and to top it all, the destructive activities of the colossal influx of the Afghan refugees also contribute in threatening the medicinal plants

Over-harvesting of medicinal plants for commercial purposes and chemical analysis has also threatened their abundance, and even occurrence. Human pressure has also caused fragmentation of populations (Gilani *et al.,* 2009).

iii. Policy issues in relation to promoting large scale cultivation and conservation

Almost all the medicinal plants in Pakistan are collected from the wild. Local collectors are unaware of the best collection procedures. Medicinal plants from the sites of collection to the national and international markets pass through various middlemen. Consequently, the prices of the crude drugs increase more than 100% along the trade chain. The rapid loss of floristic and cultural diversity, and the state of absolute material poverty of 30% of people in Pakistan, makes it urgent that we should find solutions to their problems and to take active roles in making decisions about the management of natural resources and about the legal status of their traditions and knowledge.

The sustainable supply of good quality medicinal plants can only be made possible through proper collection, conservation and cultivation. The following strategies have been proposed to achieve the objectives such as to carry out mapping regarding availability of medicinal plant growth in wild for their sustainable supply, improve the quality of the source materials, this in turn would improve the quality, safety and efficacy of subsequent finished traditional medicines, encourage and support the cultivation of quality medicinal plants on commercial scale for their continued availability, promote environmental protection and conservation of medicinal plants, introducing guidelines on Good Agricultural and Field Collection Practices for medicinal plants and to promote organic agriculture for the promotion of healthy living.

7. Challenges faced by system: Global viz-a-viz Pakistan

The last few decades have seen certain national and international policies for preserving and promoting traditional medicine sector but the progress of their implementation has been rather sluggish. Furthermore, these policies fail to redress a number of concerns related to traditional medicines such as education, safety, efficacy, quality, rational use, availability, preservation and development of such health care, sustainable use of natural resources and assuring equity in transactions at various levels and so on (WHO, 2002, Bodeker *et al.,* 2007). The traditional medicines sector not only in Pakistan but also globally is confronted with challenges like recognition, uniform quality standard, education standards, evidence based research, safety and efficacy, rational use, herbal and drug interactions, inadequate understanding of socio-cultural context of their practice and usage, protection of intellectual property rights of knowledge holders, assuring sustainable natural resource use, regulation and capacity building of non-formal practitioners, developing appropriate methodologies for evaluation, resolving conflicts with mainstream medicine.

1. Recognition

It is necessary that Traditional Medicines (TRM) are recognized, respected and endorsed by governments for full actualization of their potential. The World Health Organization has defined three types of health systems to describe the degree to which TCAM is an officially recognized element of healthcare: the Integrative system, the inclusive system and the tolerant system (WHO, 2002).

Integration is currently being practiced in China, the Koreas, Viet Nam and supported by Australia (Cohen, 2004). China, India, Canada, Nigeria, Mali and UK among others, provide Governmental support to strengthen training; research and the use of TRM in their national healthcare strategies (Patwardhan *et al.,* 2005, 2006). Similar practices are also observed in

other parts of the world, including the EU and the Americas. The WHO Global Atlas of TM/CAM remains an excellent information and reference resource

2. Education standards

It is becoming important to educate medical students and registered medical practitioners about TCAM therapies (Brooks, 2004). Two important dimensions have been identified in traditional medicines education. The first one is to ensure that the knowledge, qualifications and training of traditional medicines practitioners are adequate. Secondly, there should be good understanding between traditional medicines practitioners and that of conventional or biomedicine practitioners. In many developing countries informal, experiential learning by apprenticing with physicians continues to be the major trend. All of them have their own attendant issues. Little attention has been paid by allopathic students when it is integrated into their curriculum, a university level formal education for traditional medicines makes it difficult to transfer many of the experience based aspects of tradition in an institutional milieu. For example pulse diagnosis or the understanding of vital points or certain non physical methods of treatments are seldom taught today. Recently, the Traditional Medicines, Department of Health System Governance and Service Delivery, World Health Organization (WHO, 2010), Geneva, Switzerland has developed Benchmarks for training in Unani Medicines, Ayurveda, Nuad Thai, Traditional Chinese Medicines, Naturopathy and Tuina.

3. Safety, efficacy and quality standards of traditional medicines

The uniformity in the composition of the active constituents of the medicinal plants is not possible owing to different collection places of origin along with time of collection, process of storage, drying etc. It reflects inconsistent quality of the pharmacologically active secondary metabolites that is not desired. Hence efficacy of traditional medicines is a concern as sufficient scientific data is not available to support its use worldwide (WHO, 2002). There are two aspects of safety evaluations: Firstly, to ensure right quality of material and right processes; secondly to ascertain that there is no contamination, adulteration or spiking. There are reports that steroids, heavy metals and other allopathic ingredients are found in herbal preparation (Keane, 1999, Saper *et al.,* 2004). Such studies are wrongly used to limit the use of TCAM. In fact, such a QC failure should not create a bias against TCAM. Various reasons are attributed to these, such as malpractice, lack of documentation, non-appropriate policies and lack of standardized research methodologies. It is argued that modern medicine emphasizes on a scientific approach, while traditional medicine have developed rather differently with much influence by the culture and historical context in which they first evolved. Their principles, concepts and practice are quite different from those of Western biomedicine (Shankar *et al.* 2006). They generally tend to focus on a holistic approach to life, equilibrium between mind and body and environment and to adopt a preventive approach (WHO, 2002) thus making it difficult to develop appropriate methodologies without harming these unique features. Furthermore, issues such as chemical complexity of multiple plant based formulations are also challenges for developing a suitable methodology for research.

There is a general perception and understanding that herbal medicines are safe. However reports of toxicity in traditional medicines have been a matter of grave concern. Effective quality control and regulation are certainly needed without limiting public access to these

preparations or resorting to restrictive trade practice, at the same time ensuring public interest (Patwardhan, 2005). Standardization of several aspects such as nomenclature of medicinal plants and other resources, their collection practices, semi processes and final processing, packaging, preservation, storage, product life, labeling and modes of distribution including clinical application are needed to ensure quality, safety and efficacy of traditional medicines.

4. Rational prescribing and use

Information, education and communication are three major pillars of rational use. Qualification and licensing of providers, proper use of products of assured quality, good communication between traditional medicines providers, allopathic practitioners as well as patients and provision of scientific information and guidance for public are some of the key challenges in assuring rational use (WHO, 2002).

5. Herbal and drug interactions

Herbal Medicines are readily available in the market from health food stores without prescriptions and are widely used in Pakistan and all over the world. According to recent survey the majority of people who use herbal medicines do not inform their physicians about their consumption that can cause abnormal test results and confusion in proper diagnosis. Drug herb interactions can results in unexpected concentration of therapeutic drug. Several herbal products interfere with immunoassays used for monitoring the concentrations of therapeutic drugs. Herbal medicines can also cause undesired effects. Therefore, the common belief that anything natural is safe is not correct. Contrary to popular belief that "natural are safe", herbal medicines can cause significant toxic effects, drug interaction and even morbidity or mortality (Pamer, 2005). Some of the reported drug-herbal medicines interactions are as follows;

a. Ginseng and Warfarin may decrease effectiveness
b. Ginseng and Thenelzine produce toxic symptoms e.g. headache insomnia and irritability,
c. St. John's Wort and Paroxetine hydrochloride produce Lethargy, Nausea
d. St. John's Wort and Theophylline lower concentration and efficacy
e. St. John's Wort and Indinavir lower concentration and may cause treatment failure in HIV patients.
f. Ginkgo Biloba and Aspirin produce Bleeding, can inhibit PAF
g. Ginkgo Biloba and Warfarin can cause hemorrhage
h. Ginkgo-Biioba and Thiazide: Hypertension.
i. Kava and Alprazolam Addictive effects with CNS depressants.
j. Alcohol, Garlic and Warfarin can increase effectiveness of Warfarin

6. Access and cost effectiveness

In developing countries over 50% of deaths are attributed to five infectious diseases. Common communicable diseases are widely prevalent in areas where access to modern drugs is non-existent or limited (WHO, 2002). In the developing countries traditional medicines continues to be comparatively cost effective and accessible though it is feared that a technology intensive production process would make traditional medicines unaffordable.

For the health sector to improve, measures such as improving physical and economic access, preventive strategies, wellness management, promotion of best and essential practices in both communicable and chronic diseases, increased cooperation between various medical systems, sustainable natural resource use, protection of traditional medicines and knowledge, and equitable transactions are vital.

7. Evidence based medicines (EBM) or scientific evidence

The Scientific Evidence or Evidence Based Medicines (EBM) has emerged as an important dimension in modern medical care. The modernist attitude towards traditional knowledge has been as 'either modernize or disappear'. In a context where the mightiest comes to be identified with the best reason (Couze and Featherstone 2006), traditional medicine is in a challenging process of proving itself through a completely different epistemology. However public preferences are moving in a direction where science is not the starting point for health decision making (Terasawa, 2004, Janska, 2005). It is feared that imposition of EBM, research on selected aspects of traditional medicines through randomized controlled studies, and the absorption of successful practices as evidence based 'modern' medicine would result in medical absorption and finally resulting in an erosion of 'alternate' approaches to health.

8. Ecological obligation

The significance of this concern becomes evident in connection with the discussion of article 8(j) of the Convention on Biological Diversity 1992, where it is implied that medicinal plants, blood samples from indigenous people and research conducted by foreigners into indigenous ways of life, supported by indigenous possessors of traditional knowledge, have led to patentable discoveries of benefit solely to those foreign researchers, with no economic return to indigenous people themselves. The traditional medical knowledge of indigenous peoples throughout the world played an important role in identifying biological resources worthy of commercial exploitation. Knowledge about the way in which local people have used plants has always been important to collectors. Unfortunately, no international system has yet successfully designed and implemented a mechanism that provides for an effective legal protection to traditional knowledge holders' rights at the international level (UNESCO/WIPO, 1999, Burgland, 2005).

9. Value addition

The herbal materials are usually supplied in unprocessed form to the dealers. However, if the plants are processed into a consumer usable form, the value added product would fetch higher income as compared to the raw material.

10. Intercultural approach

In the promotion of traditional and complementary and alternative medicines in the contemporary context it is essential to have an intercultural approach. As mentioned earlier traditional medical knowledge in various countries have evolved within socio-cultural and historical context and their epistemic framework, principles, concepts and practice are quite different from those of modern science (WHO, 2002, Shankar *et al.*, 2007). While there is a contemporary value in applying modern science and technology tools for creating objective and verifiable standards for traditional knowledge products and concepts. Currently the approach to creating standards is one-sided, because it does not adequately consult the

available qualitative TCAM standards and parameters. Furthermore, most therapies in traditional medicines involve both drug as well as non-drug interventions (Shankar *et al.*, 2007) making it complex to develop appropriate methodology.

Some additional challenges faced by Traditional Medicines System in Pakistan are as under;

- Market Demand is unknown
- Absence of regulatory environment and framework i.e., Traditional medicines Act, Policy, Strategy, Action Plan, Dwindling resources, R&D Facilities, Infrastructure and allocation of appropriate financial resources

8. Prospects and limitations of the system

8.1 Prospects

There has been significant paradigm shift at the policy level in terms of Traditional and Alternative medicines regulation in Pakistan. The Government has in place a number of organizations and initiatives aimed at strengthening the infrastructure and coordinating various aspects of the sector, supplemented by non-government organizations (NGOs) and private sector cooperation and initiatives. However, political will, stronger coordination of the sector at the national level under a long term strategic action plan has become imperative. Approximately 40539 registered Unani and 118,000 homoeopathic medical practitioners are practicing both in the public and private sector in urban and rural areas. About 360 tibb dispensaries and clinics provide free medication to the public under the control of the health departments of provincial governments (Shaikh *et al.,* 2009).

People have been consulting traditional healers for ages and they will keep on doing so for various reasons. The solution lies only in bringing these traditional medicines healers into the mainstream health infrastructure by providing them with proper training, facilities and back-up for referral. The regulatory authorities and policy makers have to play a crucial role in this scenario, in terms of recognition of traditional medicines and their role, financing and appreciating training and research in this field. The inclusion of some courses in line with WHO Guidelines, 2010 about various Traditional/ Complementary medicines into the medical curriculum of pharmacy and allopathic medical schools may be considered. A positive interaction between all stakeholders of health care providers, academicians, policy makers and researchers has to be initiated to work for a common goal to improve the health of the people. It is important to note that as the global use of healing practices outside conventional medicine is on the rise, ignorance about these practices by physicians and scientists risks broadening the communication gap between the public and the profession that serves them (Wetzel *et al.,* 1998, Chez and Jonas, 1997). The National Institute of Health, Islamabad, Pakistan has conducted many workshops in order to harmonize modern and Traditional medicines Sector in the region (Hussain and Malik, 2010).

The integration of the two systems at least in terms of evidence-based information sharing is necessary. It would also be worthwhile to emphasize that regular systematic review of traditional medicines therapies are imperative in the process of recognizing the traditional medicines sector. In order to achieve ambitious and gigantic targets in Millennium Development Goals, gross improvements in quality and efficacy of medical care would require strengthening and integration of public health programs (World Bank, 2004).

Evidence based traditional medicines should be accessible and cost-effective for the people at primary health care level of developing countries and, more importantly, the outcomes of the treatments could be very efficacious (Cooper, 2004). Moreover, financial allocation and distribution on the basis of research and evidence would be another important change to bring about in order to reduce the disease burden. Through more rigorous research, the evidence based recommendation of some traditional medicines therapies and the evidence-based rejection of others will become more definitive (Eisenberg *et al.*, 2002). Today, in the West, there is an overwhelming effort towards integration of alternative medicine with the mainstream allopathic therapeutics, Pakistan being no exception (WHO, 2001). However, before this can be done, research into traditional medicines itself needs to be recognized as a mainstay to design any public health interventions (Travis *et al.*, 2004). Guidelines for policy formulation, regulation, promotion and development of traditional medicine need to be developed. With the current state of affairs of health system utilization and health-seeking behavior in Pakistan, it is highly desirable to reduce the polarization in health system utilization by exploring more opportunities for integration of traditional and modern medicine. For instance, conservation and sustainable utilization of resources can be achieved through community participation. Non-governmental organizations need to be involved in bio-prospecting and benefit sharing (Gilani, 1992). A true partnership would make an invaluable contribution towards achieving the goals of environmental and biodiversity conservation; and an increased share of international trade in raw materials relating to medicinal plants. This would require the implementation of government policies and incentives for the exporters (Fink, 2002). A close collaboration among all stakeholders including allopathic practitioners, traditional medicine practitioners, ethno-botanists, phytochemists, pharmacologists, agricultural experts and other related disciplines would be encouraging.

8.2 Limitations

The relationship between the conventional allopathic physician and the traditional medicines provider is of rivalry and animosity, just as happens in any other part of the world (Fink, 2002). Orthodox medicine has never been in favor of traditional medicine; therefore, these practices are denounced vigorously by restricting their access, labeling them as antiscientific and imposing penalties on their practice.

Some understandable factors for this rejection include lack of education, training, regulation and the evidence base for traditional medicines practitioners. Moreover, lack of accountability in the medical profession, both modern and complementary, results in untrained quacks practicing medicine in different names, thus giving traditional medicines practitioners a bad name and lowering respect for them in the community. In terms of political economy, the allopathic system of cure is a British colonial legacy that retained influence on the entire health care system of the country. With this elite-backed system, the attitude of looking down on the indigenous systems has been coupled with an established antagonism between the practitioners of the two systems (Zaidi, 1988). Current evidence, although limited, suggests that physicians may reasonably accept some traditional medicines therapies as adjuncts to conventional care and discourage others. The National health policy of Pakistan just mentions a plan to bring amendment to the existing law on tibb to recognize the post-graduate level education; however, the stance on its integration or

development is unclear (NHP, 2001). Other policy documents bear certain lacunae on profit sharing, intellectual property rights, registration of herbal products and other related legislation (Gilani, 1992). The traditional medicines therapies being used have not been thoroughly researched, and by and large there is only evidence from old documents. Furthermore, indigenous people have no training in gathering and storing of medicinal plants, and hence the sustainability of such plants is threatened. The indigenous knowledge of identification and use of medicinal herbs is dying out. Deforestation and threat of extinction is also alarming because the area covered by forests is decreasing day by day due to lack of water and repeated droughts.

9. Conclusion

The health care system the world over and more so in developing countries, seems to have become more complex in the last half century, quite contrary to the astonishing advances in medical sciences and technologies. Increase of chronic diseases, awareness about limitations of modern medicine, proven efficacy of TCAM systems in selected conditions, emerging interest in holistic preventive health, integrated approach to medical education and increasing awareness among physicians are some of the reasons for renewed interest in traditional medicine. Against modern medicine, TMs may not appear much but they are like catalysts and enzymes in biological processes - small in size and amount but beacons and guides to macro-processes. It is hoped that researchers, policy makers and practitioners will see the pivotal place of TCAM in the global health-care system and use them wisely to enable the peoples to alleviate their miseries due to number of diseases.

The people of Islamic Republic of Pakistan have a great faith in TCAM, which has thousands of year's history. The practice/prescriptions are traditionally and empirically passed from generation to generations despite relatively less research in the modern era, concerted efforts have been made to revive to improve and promote the TCAM by introducing change in the education and bring reforms in the policy of sale, storage, import and export of TCAM. Commitments have been shown by the Government to bring it into main health care system in spite of numerous challenges being confronted by TCAM.

Among the measures taken to revive and promote the system are as follows;

i. Development of proposals for National Policy on Traditional Medicines
ii. Finalization of Master Plan for the implementation of National Policy on TRM
iii. An ACT named "Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal and Bio-chemic Medicines drugs 2010" to regulate the manufacture, storage, import and export of Traditional Medicines has been approved by the Federal Cabinet and Standing Committee on Health of the National assembly and will be enacted very soon.
iv. Development of standards and specifications for medicinal plants are in progress.
v. Following documents has been developed in consultation with the stakeholders;

    a. Guidelines for Good Agriculture and Field Collection Practices
    b. Manual for training of collectors for the collection of medicinal plants.
    c. Manual for sustainable cultivation, preservation, propagation and collection of medicinal plants
    d. Manual for the conduction of clinical trials on traditional medicines
    e. Manual containing GMP and QA guidelines for the Traditional Medicines.

vi. Monographs of commonly used medicinal plants vol-1
vii. Inventory of the commonly used medicinal plants in Pakistan.
viii. List of essential TRM for use at Primary Health Care level.

There is a need to foster effective collaboration between allopathic and traditional health practitioners along with research institutes, universities and close collaboration amongst traditional health practitioners associations. The creation of information network on TCAM and monitoring of emerging trends will help collection of data and subsequent analysis. The above measures will help promote the scientific and rational integration of TCAM into main health care system especially at primary health care level.

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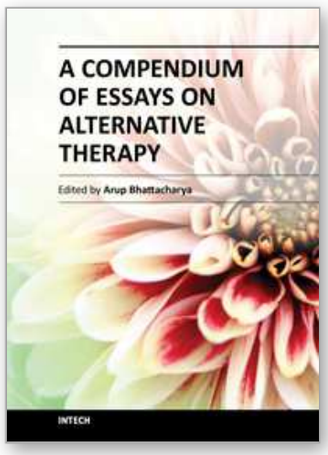

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A Compendium of Essays on Alternative Therapy is aimed at both conventional and alternate therapy practitioners, besides serving as an educational tool for students and lay persons on the progress made in the field. While this resource is not all-inclusive, it does reflect the current theories from different international experts in the field. This will hopefully stimulate more research initiatives, funding, and critical insight in the already increasing demand for alternate therapies that has been evidenced worldwide.

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