IJPSR (2012), Vol. 3, Issue 06 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 19 February, 2012; received in revised form 20 March, 2012; accepted 23 May, 2012

REGULATORY ASPECTS OF TRADITIONAL MEDICINE: FOCUS TOWARDS UNANI COSMECEUTICAL PRODUCTS

Abdullah Bin Junaid* and Reshma Nasreen

Department of Management, Jamia Hamdard, New Delhi, India

Keywords:
Cosmeceuticals, Counterfeiting, Efficacy, Quality, Regulatory Issues, Safety, Traditional, Medicines

Correspondence to Author:

Abdullah Bin Junaid

Ph. D., Scholar, Department of Management, Jamia Hamdard, New Delhi, India

ABSTRACT

The regulatory authorities are now focusing on the regulatory issues of traditional medicines under which Unani system of medicine falls. Today we are witnessing an increase in the use of traditional medicines throughout the world raising the questions as to how safe these preparations are. People are now bending towards the Unani system of medicine because of its safety, efficacy and lesser side effects and hence raising the popularity of the Unani system of medicine. The major problem associated with Unani system of medicine is the lack of regulatory issues that ultimately leads to counterfeiting of Unani medicines. In the present article an endeavour has been made to present an overview of Unani system of medicine with special attention towards the Unani Cosmeceuticals products. This article intends to contribute towards the regulatory knowledge by giving a survey of published information regarding the regulations of the Unani Cosmeceuticals products. This article also focuses on the good manufacturing practices along with the standards for Unani Cosmeceuticals drug contents. This present article also deals with the measures to be adopted by the regulatory authorities so as to make the Unani Cosmeceuticals products of high standard quality which have much safety and efficacy.

INTRODUCTION: Traditional medicine (also known as indigenous medicine) comprises medicinal knowledge systems that developed over generations within various societies before the era of modern medicine. There are several practices that are under traditional medicine and these are known as Ayurveda, Herbal, Unani, Ancient Iranian Medicine, Siddha Medicine, Muti, Ifa, Traditional African Medicine and other medicinal knowledge and practices all over the globe.

The World Health organization (WHO) has defined traditional medicine as "The health practices, approaches, knowledge and beliefs in corporation plant, animal and mineral-based medicines, spiritual therapies, manual techniques and expertises, applied singularly or in combination to treat, diagnose and prevent illness or maintain wellbeing".

In some Asian and African countries, upto 80 percent of the population relies on traditional medicine for their primary health care needs. When adopted outside of its traditional culture, traditional medicine is often called Complementary and Alternative Medicine.

Herbal medicine can be very lucrative, generating billions of dollars in sales, but alternative or counterfeit herbs can also be a health hazard. WHO also pointed out that "inappropriate use of traditional medicines or practices can have negative or dangerous effects "and that "further research is needed to ascertain the efficacy and safety" of several of the practices and medicinal plants used by traditional medicine system? Core discipline which studied traditional medicine includes ethno medicine, ethno botany and medicine anthropology.

Traditional medicine caves a wide variety of therapies and practices which vary from country to country and religion to religion. Traditional medicine has been used for thousands of years with great contributions made by practitioners to human health, particularly as primary health care providers at the community level. Traditional medicines or complementary and alternative medicine has maintained its popularity worldwide. Since 1990s its use has surged in many developed and developing countries. Traditional medicine is growing in popularity, yet standardised international regulation has still to be formulated and the excessive use of medicinal plants can threaten biodiversity.

Challenges related to Traditional Medicine: Traditional medicines have been used in some communities for thousands of years. As traditional medicine practices are adopted by new populations there are challenges:

1. **International Diversity:** Traditional medicine practices have been adopted in different cultures and regions without the parallel advance of international standards and methods for evaluation.

2. **National Policy and Regulation:** Not only countries have policies for traditional medicine but regulating traditional medicine products, practices and practitioners is difficult due to variations in definitions and categorization of traditional medicine therapies. A single herbal product can be defined as either a food or dietary supplement or a herbal medicine depending on country. This disparity in regulations at international level ha implications for international access and distribution of products.

3. **Safety, efficacy and quality:** Scientific evidence from test to evaluate the safety and effectiveness of traditional medicine products and practices is limited. While evidence shows that acupuncture, some herbal medicine and some natural therapies (Ex, Massage) are effective for special conditions; further study of products and practices is needed. Requirement and methods for research and evaluation are complex. For example it can be difficult to assess the quality of finished herbal products. The safety, efficacy and quality of finished herbal medicinal products depend on the quality of their source material (which can include hundreds of natural constituents) and how elements are handled through production process.

4. **Knowledge and Sustainability:** Herbal materials from products are collected from wild plant population and cultivated medicinal plants. The expanding herbal products market could drive over harvesting of plants and threaten biodiversity. Poorly managed collection and cultivation practices could lead to the extinction of endangered plant species and the distribution of natural resources. Efforts to protect both plant population and knowledge on how to use them for medicinal purposes is needed to sustain traditional medicine.

5. **Patient safety and use:** Many people believe that because medicine s are herbal (natural) or traditional they are safe (or carry no risk or harm). However, traditional medicines and practices can be harmful, adverse reactions if the product or therapy is of poor quality or it is taken in appropriately or in conjunction with other medicine. Increased patient awareness about safe usage is important, as well as more training, collaboration and communication among providers of traditional and other medicines.

6. **WHO response:** WHO and its member states corporate to promote the use of traditional medicine for health care. The collaboration aims to:

    a. Support and integrate traditional medicine into national health systems in combination with national policy and regulations for products, practices and providers to ensure safety and quality.

    b. Ensure the use of safe, effective and quality products and practices based on available evidences.

    c. Knowledge traditional medicine as part of primary health care to increase access to care and preserve knowledge and resources.

d. Ensure patient safety by upgrading the skills and knowledge of traditional medicine.

Herbal Medicine: Herbal medicine also called botanical medicine or phytomedicine refers to using a plant's seed, berries, roots, leaves, barks or flower for medicinal purposes. WHO estimate that about 80 percent of world population presently uses herbal medicine for some aspect of their primary health care? WHO notes that of 119 plants derived pharmaceutical medicine; about 74 percent are used in modern medicines in ways that are correlated directly with their traditional uses as plant medicine by native cultures. According to WHO global survey on the national policy and regulation of traditional medicine, there are three common difficulties and challenges.

a) Lack of information sharing.

b) Lack of safety monitoring of herbal medicines.

c) Lack of methods to evaluate safety and efficacy.

In pharmacological, toxicological and clinical studies with herbal drugs their composition need to be well documented in order to obtain reproducible results.

Classification of Herbal Medicine: The herbal medicines are classified broadly in four categories. These are as follows:

a) **Category 1: Indigenous herbal medicines:** This category for herbal medicines is historically used in a local community or region and is very well known through long usage by the population in terms of its consumptions, treatment and dosage.

b) **Category 2: Herbal medicine in systems:** Medicines in this category have been used for a long time and are documented with their special theories and concepts, and accepted by the countries. For example, Ayurveda, Unani and Siddha would fall into the category of Traditional Medicines.

c) Category 3: Modified herbal medicines: These are the herbal medicines as described above in category 1 and category 2, except that they have been modified in some way – either shape or form including dose, dosage form, mode of administration, herbal medicinal ingredient, method of preparation and medical indication. They have to meet the national regulatory requirements of safety and efficacy of herbal medicines.

d) **Category 4: imported products with a herbal medicinal base:** This category covers all imported herbal medicines including raw material and products. Imported herbal medicines must be registered and marketed in the countries of origin. The safety and efficacy data have to be submitted to the national authority of the importing country and need to meet the requirements of safety and efficacy of regulation of herbal medicines in the recipient country.

Global scenario of Traditional Medicines: Medical knowledge system have developed over centuries with in various communities before the era of modern medicine by the knowledge gained by trails and error process and also by observing the behaviour of the diseased animals. Perhaps the earlier use of plants has been documented in Vedas about 4,500 to 600 BC. This represents the oldest reporting of human knowledge and comprises 67 plant species.

In China, Sheng-Nongs herbal book is tough to be one of the earliest sources of folk knowledge on the use of herbal, it comprises 365 pants, animals and minerals useful for the period of Sheng-Nongs (3000 BC) (Pei 1987, 2001). Studies on Tibetan medicine have shown that the earliest literature on Tibetan medicine is dated eighth century Ad (Yang 1988). The global herbal market is of size 62.0 billion dollars. European Union is the biggest market with the market share 45 percent of the total herbal market.

North American accounts for 11 percent, Japan 16 percent, ASEAN countries 19 percent and rest European Union 4.1 percent. Countries like Japan and China have successfully marketed their traditional medicine abroad. Their alternative therapies are well accepted in Europe and US. The forecast is that the global market for herbal products is expected to be 5 trillion dollars by 2050. Herbal remedies would become increasingly important especially in developing countries.

India, with its biodiversity has a tremendous potential and advantage in this emerging area. Acupuncture is one such therapy that has gained worldwide reorganization.

Global Traditional Market: The export of Ayurvedic and Unani medicines put up for retail sale to other countries have increased from Rupees 17 crores in 1992-93 to 98 crores in 1990-99. The experts at WHO have identified and enlisted more than 100 types of traditional medicine practice, which are in use throughout the world.

These types of medicines are variously known as traditional medicines (as most of these are practiced from time immemorial), complementary medicine (as these medicines supplement the allopathic medicines in many a cases as they differ from the orthodox medicine), holistic medicine (most of the alternative medical systems consider the human body as a complete being comprising of physical, mental, social and spiritual dimensions), ethno medicine (as these traditional health care systems are closely associated with the life and culture of the masses), natural medicine (as these methods of treatment are based on the laws of nature and natural substances are used to treat the patient.

Some examples of traditional medicine systems practiced in different countries in clued acupuncture by the Chinese, magnetic healing by the French, Heilpraxis by German, Herbalism by the Swedish, Ayurveda, Siddha, Yoga and Unani by Indians, Shiatsu in Japan, Sowa Ring-pa in Bhutan etc. some of the most popular alternative system of medicine are Ayurveda, Unani, Siddha, Naturopathy, Yoga, Acupuncture, Acupressure, Shiatsu, Medical Herbalism, Meditation, Hydrotherapy, Diet therapy etc.

Popularity of Traditional Medicine: Countries in Africa, Asia and Latin America chiefly use traditional medicines (TM) to help meet some of their primary health care needs. Even industrialized countries are turning towards traditional medicine for health care purposes. Traditional medicine thus has not only mentioned its popularity in all regions of the developing world, its use is rapidly spreading in industrialized countries which are exemplified from the following facts:

a) In China traditional herbal preparations accounts for 30 percent to 50 percent of the total medicinal consumption.

b) In Ghana, Mali, Nigeria and Zambia the first line treatment for 60 percent children with high fever resulting from malaria is the use of herbal medicine at home.

c) WHO estimates that in several African countries traditional birth attendants assist in the majority of births.

d) In Europe, North America and other industrialized regions over 50 percent of the population have used complementary or alternative medicine at least once.

e) 70 percent of the population in Canada have used complementary medicine at least once.

f) In United States, 158 million of the adult population use complementary medicine and according to the USA commission 17 billion US dollars were spent on traditional remedies in 2000.

g) In the United Kingdom, annual expenditure on alternative medicine is 230 million US dollars.

h) The global market of herbal medicines currently stands at over 60 billion US dollars annually and is growing steadily (WHO; 2003). The popularity and renewed interest in the traditional system of medicine is due to the following reasons:

   i. Lesser side effects as compared to allopathic medicines.

   ii. Affordability of traditional drugs by large number of people of the third world countries.

   iii. The effectiveness of these time tested systems particularly for diseases that are chronic in nature or not adequate addressed in the modern system of medicine.

Beside the above primary reasons, there are some subsidiaries or secondary reasons of the growing popularity of the traditional medicines such as:

i. Cultural link in many rural areas to the traditional medical system lead to easy acceptance.

ii. Simplicity of remedies and practices attracts people.

European Union is the biggest market in global herbal products. Indian products to other countries like Germany, France, Italy and Netherland have also increased. In 1992-93 Germany was the biggest importer of the Ayurvedic and Unani medicines followed by Nigeria but their importance decreased dramatically in terms of the share of exports on Indian Ayurvedic and Unani products.

National Policy on Traditional Medicine: The concept of National policy primarily involves three key elements which are firstly a definition of traditional medicine, secondly provisions for the creation of laws and thirdly consideration of intellectual property issues. Besides these key elements, national policy can reflect the strategies that the government may adopt for achieving the objective of the policy and may also includes laws and regulations on Traditional medicine (WHO 2005).

In a global survey carried out by WHO (WHO 2005), where in data was collected from 141 member states, 32 percent countries were found to have National on traditional medicine where as 64 percent countries do not have National policies and 4 percent countries do not provide satisfactory reply. However, 55 percent countries indicated that such policies are in the process of development. This study indicates that developing of a National policy is prerequisite for further growth of traditional medicine in these countries.

It was also noticed in the study that the National policy on the Traditional medicine increased significantly in the last decade. There is a growing trend in recent past for member states to establish National policies on traditional medicine. The trend is likely to continue as more member states are likely to have their National policy shortly.

Indian Senario of Traditional Medicine: There are a number of traditional and complementary therapies practiced widely in India including Ayurveda, Homeopathy, Siddha, Unani, Yoga and Naturopathy. Alternative medicines are particularly popular in rural and semi-urban areas and utilization is higher in these areas than in the city (Srinivasan 1995; Gog tay et al 2002). During colonialism, biomedicine sidelined the traditional practice of Ayurveda. The Bhore committee, which was set up by British Indian government in 1943 and which plays a significant role in drafting National Health Policy, overlooked integration of traditional medicine into the newly established health care system (Jeffery 1982; Srinivasan 1995; Banerjee 2002). Increasing international interest in complementary medicine in recent years has resulted in renewed interest in traditional medicine.

The Indian government has established a strategy to strengthen traditional health practices and all complementary therapies. In 1955 the Ministry of Health and Family Welfare established the department of Indian Ayurveda, Yoga, Naturopathy, Unani, Siddha and Homeopathy (AYUSH-meaning 'long life'). The responsibilities of the department include the formulation of policy, the development of educational and research institutes, drug development programmes and the integration of various systems in the health care delivery system as well as the drafting and implementation of programmes.

The recent upsurge in use of herbal medicines has led to a sudden increase in herbal manufacturing units. In India, there are about 14 well recognized and 86 medium scale manufacturer of herbal drugs. Other than this about 8,000 licensed small manufacturer in India on record. The estimated current annual production of herbal drugs is around Rupees 3,500 crores.

In the last few decades, there has been an exponential growth in the field of herbal medicine. It is getting popularized in developing and developed countries owing to its natural origin and lesser side effects. Large quantities of botanicals in India are consumed by the herbal industry (1,77,000 MT) and by millions of rural households (86,000 MT) that depends for their primary health care of this resource. Traditional medicines are delivered in a range of providers setting. The large hospitals are mostly owned by the government while smaller practices are privately run. In 1999, India spent 0.9 percent of its gross domestic product on health of

which only 2-4 percent was spent on alternative, medicine (srinivasan 1995; AYUSH 2002). There has, however, been a recent trust to increase the spending by 10 percent through the grant in aid programme of the department of AYUSH (GOI 2005). In the private and non for profit sector, there are several thousand AYUSH clinics and around 250 hospitals and nursing homes for in patient care and specialized therapies. There are 725,338 registered traditional medicine practitioners and homeopaths who are both institutionally (506,229) and non institutionally (219,109) qualified. There are 13 government assisted pharmacies and over 5,000 licensed pharmacists.

WHO developing new Traditional Medicine Classification: The World Health Organization (WHO) recently announced a new project that could bring greater respect and more wide spread recognition to traditional medicine system across the world. With the goal of easing and encouraging the use of traditional medicine in clinical, epidemiological and statistical settings, WHO's International classification of traditional medicine (ICTM) will provide a harmonized traditional medicine evidence base with stated terminologies and classification of diagnoses and interventions.

In a recent press release, WHO said ICTM is in part a response to the increasing world wide range of traditional medicine while classification and terminology tools remain sparse. The classification will initially include information on practices and customers in China, Japan and the Republic of Korea and will use an interactive online platform that traditional medicine users can use to document terms and concepts with which they are familiar. Joining other significant activities like the 1978 Alma Alta Declaration and the recent 2008 Beijing Declaration, the ICTM further illustrates WHO's dedication to aiding traditional medicines globalization and integration to worldwide health care.

A few of the expected outcomes that WHO has for the ICTM includes the production of the data that can be used to objectively evaluate traditional medicine benefits, safety, use, spending and trends as well as the ability to study traditional medicine role in disease prevention and treatment.

Additionally one accepted classification system will allow all countries throughout the world to base their monitoring of traditional medicine on the same set of data. The ICTM may have wide impact on both traditional and allopathic practitioners as well as hospital administrators, insured companies and policy makers, said Ryam Abbott, director of research and project management for Nova worldwide consulting and a former member of WHO traditional medicine team (e-mail, January 8, 2011).

Abbott noted that this impact will likely be greater in countries such as the United States where no comparable domestic classifications exists as opposed to some Asian countries that already have standardized, domestic version of traditional medicine disease classification. "International standard should improve communication between providers in different nations and endorsement by WHO still carries significance weight", he continued. Though just announced by WHO in December 2010, the first meeting discussing the project took place in May of 2010. The ICTM is currently being drafted and WHO hopes for it to be completed in time for approval voting at the May 2010 World Health General Assembly.

The International classification of traditional medicine project will assist in creating evidence based for traditional medicine producing terminologies and classification for diagnosis and intervention. We recognise that the use of traditional medicine is wide spread. For many people specially in the Western Pacific, South East Asia, Africa and Latin America traditional medicine is the primary source of health care, said Marie-Paule Kieny, assistant director, general of innovation, information, evidence and research at WHO.

Throughout the rest of the world, particularly Europe and North America, use of herbal medicine, acupuncture and other traditional medicine practices is increasing. Global classification and terminology tools, for traditional medicine however have been lacking. The International classification of traditional medicine will be web based to allow users from all countries to document the terms and concepts used in traditional medicine.

Several countries have created national standards for the classification of traditional medicine but there is no International Platform that allows the harmonization of the data for clinical, epidemiological and statistical use. There is a need for this information to allow clinicians, researchers and policy makers to comprehensively monitor safety, efficacy, use, spending and trends in health care, added Kieny. The classification will initially focus on traditional medicine practices from China, Japan and republic of Korea, which have evolved and spread worldwide.

Regulations of Traditional Medicine: It is known fact that millions of people around the world will always use traditional medicines because they believe in them. They also regard it as "their" system of medicine. These people only deal with practitioners whom they have always known and with whom they are comfortable. Most of the government bodies in third world countries, and increasingly in western world, treat this faith of population in traditional medicine and herbal remedies as an asset.

We should also remember that many people in Europe, USA and Japan are turning to alternative medicines due to largely to the fact that there are frequently side effects to be faced by taking powerful synthetic allopathic drugs. Indeed, most of the people in these countries refer to the herbal medicine system as alternative system of medicine. It is essential to know what regulatory and legislative controls on the manufacture and sales of such herbal medicine exist or required to be implemented in various places around the world. Linked to this area of course the issues of quality control of both the raw material as well as the furnished product and standardisation of the herbal medicines.

Worldwide Regulations of Unani Medicines: The structure and comprehensiveness of laws and regulations on traditional medicine/complementary Alternative medicine varies from country to country and further more in member states where no policy exists, laws and regulation cover different areas of TM/CAM. A law in the first stage of legislative procedure and is the rule of conduct imposed by the authority. A law establishes necessary conditions under which TM/CAM needs to be organized in line with the national or other relevant policies.

The law may cover various areas in the TM/CAM field including education of professionals, licensing of practitioners and manufacturers, manufacture and trade product used in TM/CAM, sales practices etc (WHO, 2005). A regulation is the second stage of the legislative procedure, specially designed to provide the legal machinery required to achieve the administrative and technical goals of law. Many activities such as description of obligation and responsibility of licensed practitioners, the penal sanctions if the rules are contravened, the obligation of incumbents on manufacture of TM/CAM production etc, come under regulations (WHO, 2005).

The study carried out by WHO indicates that 38 percent countries have law or regulation where as 60 percent countries don't have laws and regulations. Countries face major challenges in the development and implementation of the regulation of traditional medicines. These challenges are related to regulatory status, assessment of safety and efficacy, quality control, safety monitoring and lack of knowledge about TM with in national regulatory authorities. Before manufactured drugs came into widespread use, herbal medicine played an important role in human health. There are great differences between member states in the definition and categorization of herbal medicines.

A single medicinal plant may be defined as a food, a functional food, a dietary supplement or a herbal medicine in different countries depending on the regulations applying to food and medicine in each country. This makes it difficult to define the concept of herbal medicine for the purpose of national drug regulation and also confuses patients and consumers.

The global survey conducted by WHO (WHO, 2005) on regulation of herbal medicines particularly the regulatory status of herbal medicines, regulation requirements, number of registered herbal medicine products and quality control requirement such as GMP, monograph etc gave the following results: Before 1988, there were only 14 member states with regulation regulating herbal medicine, but the figure increased to 53 member states (37 percent) having laws and regulations in 2003. Of these member states without current laws or regulations 42 (49 percent) declared that their regulations were in the process of

being developed. Such result shows that member states are increasing involved in developing the regulations of herbal medicines. The questions about the regulatory status of herbal medicines also shows, interestingly that in most member states (97 out of 142 respondents) herbal medicine are sold as over the counter medicines, in contrast to 50 member states where herbal medicine are also sold ad prescription medicines.

Medical claims, health claims and nutrient content claims are the most common type of claims with which herbal medicine may legally be sold (90 member states allow medical claims, 62 allow health claims and 49 allows nutrients claims). The collected information about herbal medicine also shows that 86 member states (61 percent) have registration system for the herbal medicine and 17 have 1000 or more registered herbal medicines. Judging from this data, many member states are giving the regulations of herbal medicines careful consideration. (WHO, 1995)

Standardization, Quality Control and Safety of Traditional Medicines: The safety and efficacy of traditional medicine as well as quality control have become important concern for both health authorities and the public. Diverse TM practices have been developed in different cultures and in regions, but without a parallel development of international standards and appropriate methods for evaluating traditional medicines. Requirements and methods for research and evaluation of the safety and efficacy of traditional medicines are more complex than those of conventional pharmaceuticals. A single medicinal plant may contain hundreds of natural constituents and a mixed herbal medicinal plant may contain several times that number.

If every active ingredient were to be isolated from every herb the time and resources required would be tremendous. Such an analysis may actually be impossible in practice, particularly in case of mixed herbal medicines. The safety and efficacy of herbal medicines is closely correlated with the quality of the source materials used in their production. The quality of source material is in term determined by intrinsic factors (genetic) and extrinsic factors (environmental conditions, cultivation and harvesting, field collection and post harvest collection and transport and storage). Therefore it is very difficult to perform quality control on raw materials of the herbal medicines. In the quality control of the furnished herbal medicinal products, particularly mixed herbal products, it is more difficult to determine whether all the plants or the starting materials have been included. Good manufacturing practice (GMP) lay down many requirements for quality control of starting materials, including correct identification of species of medicinal plants, special storage and sanitation as well as cleaning methods for various materials.

Several efforts have been made in recent times to ensure the quality, safety and standardisation of drugs used in traditional medicine systems. Some of these are briefly enumerated below:

1. The pharmacological screening of plant materials from different eco systems and traditional formulations for various texts for continuing. However, there is a need to enhance these activities to a much larger scale.

2. Clinical trials are also being carried out on certain potentially active herbal molecules or isolates, candidates which are in Phase-I and Phase-II trials to evaluate novel activity. This will ensure standardization of starting and furnished materials ensuring a healthy and growing market for herbal products.(Chaudhary, 2003)

3. Even though there has been a rapid development in screening of biological samples through complex analytical methods, the quality control of the furnished products has been a challenge.

4. Clinical evaluation of branded formulations is also taking place but the efforts need to be speeded.

5. The pharmacopoeias often form the basis of quality control in the drug industry of any country. Several countries have already made progress in the completion of their National Herbal Pharmacopoeias. However, this exercise needs to be continued further with added vigour and speed.

6. There is also a need of providing adequate testing facilities, contract research laboratories and other facilitating agencies to meet the need of small scale sector traditional drug manufacturers.

7. It has been felt that without a stringent regulatory policy on quality control of natural products there will never be adequate motive for private initiative in this field. There is also a need to have adequate infrastructure to fulfil the requirements and then vigorously implement the existing provisions of health regulations or to amend the existing laws (Chaudhary, 2003).

It may be pertinent to mention here that the World Health Organization launched its first ever comprehensive traditional medicine strategy in 2002. The strategy is designed to assist countries to:

a) Develop national policies on the evaluation and regulation of Traditional Medicine practices.

b) Create a strong evidence based on safety, efficacy and quality of the traditional medicine\products and practices.

c) Ensure availability and affordability of traditional medicines including essential herbal medicines.

d) Promote therapeutically sound use of traditional medicines by providers and consumers.

e) Document traditional medicines and remedies.

It is estimated that 70 countries have a national regulation on herbal medicines but the legislative control of medicinal plant has not evolved around a structured model this is because medicinal products or herbs are defined difficultly in different countries and diverse approaches have been adopted with regard to licensing, dispensing, manufacturing and trading.

It has been suggested that due to limited evidences about Traditional Medicine safety and efficacy as well as on other considerations the government needs to:

a) Formulate a new policy and regulation for the proper use of Traditional Medicines and its integration into national health care systems in line with the provisions of the WHO strategies on Traditional Medicines.

b) Establish regulatory mechanisms to control the safety and efficacy of products and of Traditional Medicine practice.

c) Create awareness about safety and effective Traditional Medicine therapies among the public and consumers.

d) Cultivate and conserve medicinal plants to ensure their suitable use and prevent adulteration.

Some governments have drawn up regulations for good manufacturing practices for traditional system of medicine so that the industry can compete in international markets. T51Phese steps overcome a serious short coming. Drug standardization and quality control have been identified as the most important challenges affecting the future of the Traditional Indian System of Medicine. For enhancing the export market, China and Hong Kong have braced upto the stringent requirements of more rigorous clinical trials and modelled after western regulatory protocols.

Hong Kong is funding 18 Chinese medicine research projects that include clinical trials, development of quality standards and basic pharmacological studies (Basu, 2004). The European Union has introduced a new legislation called the Traditional Herbal Medicinal Product Derivative for fast track regulations of Traditional Medicinal products of plant origin. This directive seeks from traditional medicine makers to show evidence of safe usage in EU member nations for market authorization for a product. For limited therapeutic conditions and in the absence of adequate clinical data, companies have the option of demonstrating safe use of traditional medicinal herbal products.

Asia: In more developed Asian countries like Japan, China and India “patent” herbal remedies are composed of dried and powdered whole herb or herb extracts are used directly in liquid and][tablet form of medicinal syrups, tinctures, cordials and wines. IN China, traditional herbal medicines are still the backbone of medicine. Until 1984 there was no virtual regulation of pharmaceuticals or herbal preparations. In 1984, the People’s Republic implemented the Drug Administration Law, which said that traditional herbal preparations were generally considered old Drugs” and except for new uses, were exempt form testing for efficacy or side effects.

The Chinese Ministry of public Health would oversee the administration of new herbal products. Traditional Japanese medicine, called Kampo, is similar too and historically derived from Chinese medicine but includes traditional medicines from Japan folklore. Today 42.7 percent of japans' western trained medicinal practitioners prescribe Kampo medicine and Japanese national health insurance pays for these medicines. In 1988, the Japanese herbal medicine industry established regulations to manufacture and control the quality of extract products in Kampo medicine. These regulations comply with the Japanese Government's Regulations for Manufacturing Control and Quality Control of Drugs.

Developing Countries: Herbal medicines are the staple of medical treatment in many developing countries. Herbal preparations are used for virtual all minor ailments. Visits to western trained doctors or prescription pharmacists are reserved for life threatening or hard to treat disorders. Individual herbal medicines in developing regions vary considerably, healers in each region have learned over centuries which local herbs have medicinal worth. Although trade brings a few important herbs from other regions, these herbs rely mainly on indigenous herbs.

A few regions such as South East Asia, import large amount of Chinese herbal preparations but the method and form of herb use are common to developing regions. In the developing world, herbs used for medicinal purposes are "crude drugs". These are unprocessed herbs, plants or plant parts, dried and used in whole or cut form. Herbs are prepared as teas (sometimes as pills or capsules) for internal use and as salves and poultices for external use. Most developing countries have minimal regulations and over sight.

Guidelines for the assesment of Herbal Medicines: For the purpose of these guidelines, herbal medicines are defined as follows:

Finished, labelled medicinal products that contain active ingredients or underground part of plants, other plant material or combination thereof, whether in the crude state or as plant preparation. Plant material included juices, gums, fatty oils, essential oils and any other substance of this nature. Herbal medicine may contain excipients in addition to the active ingredient. Medicines containing plant material combined with chemically defined active substances, including chemically defined isolated constituents of plants are not considered to be herbal medicines.

Regulations in India: Globally there have been concerted efforts to monitor quality an regulate the growing business of herbal drugs and traditional medicine. Health authorities and governments of various nations have taken an active interest in providing standardized botanical medication. Government of India has also plunged into their opportunity and initiated some regulations in this sector. To ensure and enhance the quality of ASU medicines, the government of India has notified Good Manufacturing Practices (GMP) under schedule 'T' of Drugs and Cosmetic Act 1940 which also ensures raw materials used in the manufacture of drugs are authentic, of prescribed quality and are free from contamination.

The guidelines for Good Agriculture Practices (GAP) seeks to lay down a cultivation programme designed to ensure optimal yields in terms of both quality and quantity of crop intended for production of raw material that goes into the making of ASU medicines and standardizes the process from factory. As a matter of fact it can be seen that there is a direct correlation between efficacy of a herbal drug with the quality of raw material used and process of manufacturing. It is of paramount importance that no compromise is made on quality. Quality of a raw material being watched over by following GAP and GACP, for manufacturing and marketing the prepared drugs, government has formulated the Drugs and Cosmetic act 1940.

It is an act to regulate the import, manufacture, distribution and sales of drugs and cosmetics. This act was basically initiated for chemical drugs but later in the year 1969 a separate chapter relating to Ayurveda, Siddha and Unani drugs was inserted by at of 1964. Law are partly same as those for conventional pharmaceuticals. Later this was again modifies with some substitutions in the year 1983, 1987, 1994 and 2002. The schedule and rules pertaining to Ayurveda, Siddha and Unani systems in the act are:

Schedules:

a) First schedule substituted by act 13 of 1964 came into force w.e.f. 01/02/1969. The schedule lists the standard Indian pharmacopoeias to be followed for manufacturing Ayurveda, Siddha and Unani drugs. About 57 books of Ayurveda (with insertions in 197, 1994, 2002), 29 of Siddha (1987), 13 of Unani Tibb System are listed.

b) Second schedule came into force w.e.f. 15/09/1964. It states about the standards to be compiled for manufacturing drugs. [Subs. Notification No. G.S.R. 885 dated the 4th August, 1973, Gazette of India, Pt.I, S.3 (i), p. 1643].

c) Schedule- E (i): List of poisonous substances under the Ayurvedic (including Siddha) and Unani System of Medicine (added by Notification No. 1-23/67-Dated 02/02/1970) differentiated in vegetable, animal and mineral origin.

d) Schedule T; Good Manufacturing Practices (GMP) for Ayurvedic, Siddha and Unani Medicines. (Ins by G.S.R. 561 (E) dated 23/06/2000 and Subs. By G.S.R. 198 (E), dated 07/03/2003). Under schedule 'T' of the drugs and cosmetics act 1940, the government has made it mandatory for all manufacturing units to adhere to GMP.

Rules:

a) Rules: Part XVI (Parts XVI, XVII and XVII added by S.O. 642, dated 02/02/1970 (w.e.f. 21/02/1970) manufacture for sale of Ayurvedic (including Siddha) or Unani drugs. It notifies about how to acquire license, loan for establishing a unit and also on the identification of raw materials and its quality.

b) Part XVIA: Approval of institutions for carrying out tests on ayurvedic, Siddha and Unani drugs and raw material used in their manufacture on behalf of licences of manufacture for sale of ayurvedic, Siddha and Unani drugs (Ins. By G.S.R. 701 (E), dated 27/07/2001 and subs by G.S.R. 73 (E), dated 31/01/2003).

c) Part XVII: Labelling, packing and limit of alcohol in ayurvedic (including Siddha) or Unani drugs (subs by G.S.R. 904 (E), dated 02/11/1992).

d) Part XVIII: Government analysts and inspectors for ayurvedic (including Siddha) or Unani drugs.

e) Part XIX: Standards of ayurvedic, Siddha and Unani drugs (Ins. By G.S.R, 519 (E), dated 26/06/1995).

In 2002, for the first time, National Health Policy on the Indian System of Medicine and Homoeopathy was drafted. In order to streamline policies and guidelines, the government brought together all previous rules and regulations and all medical systems under one regulatory umbrella and created separate committees responsible for education, research and development. The Indian union consists of several state governments and a union government. The union government is responsible for laying down the standards of education and drug development and encourages research, while the state governments are responsible for health care delivery.

Directorates have been created in 18 states to administer the traditional and complementary medicine sector throughout the country. The government of India has streamlined and expanded existing policies aimed at the promotion and regulation of traditional and complementary medicine practice. The complex and diverse nature of the Indian Medicinal System still presents many challenges for regulations. The impact of the policies on the quality and level of integration of traditional and complementary medicine services and on public health in India is yet to be seen.

WHO guidelines for Herbal Medicine: In 1992, the WHO regional office for the western pacific invited a group of experts to develop criteria and general principles to guide research work on evaluating herbal medicines (WHO, 1993). This group recognized the importance of herbal medicines to the health of many people throughout the world, stating: A few herbal medicines have with stood scientific testing but other is used simply for traditional reasons to protect, restore or improve health. Most herbal medicines still need to be studied scientifically, although the experience obtained from their traditional use over the

years should not be ignored. As there is not enough evidence produced by common scientific approaches to answer questions of safety and efficacy about most of the herbal medicines now in use, the rational use and further development of herbal medicine will be supported by further appropriate scientific studies of these products and thus the development of criteria for such studies. The document covered such topics as developing protocols for clinical trials using herbal medicines, evaluating herbal medicine research, guidelines for quality specifications of plant materials and preparations and guidelines for pharmacodynamic and for toxicity investigations of herbal medicines.

WHO has also issued Guidelines for assessment of Herbal Medicines (WHO, 1996). The guidelines defined the basic criteria for the evaluation of quality, safety and efficacy of herbal medicines with the goal of assisting national regulatory authorities, scientific organizations and manufacturers in assessing documentation, submissions and dossiers in respect of such products. It was recommended that such assessments take into account long term use in the country (Over at least several decades) and description in the medicinal and pharmaceutical literature or similar sources or documentation of knowledge on the application of a herbal medicine, and marketing authorization for similar products. Although prolonged and apparently uneventful use of a substance usually offers testimony of its safety, investigation of the potential toxicity of naturally occurring substances may reveal previously unsuspected problems.

It was also recommended that regulatory authorities have authority to respond promptly to new information on toxicity by withdrawing or limiting the licences of registered products containing suspected substances or by reclassifying the substances to limit their use to medical prescriptions. The guidelines stressed the need for assessment of efficacy including the determination of pharmacological and clinical effects of the active ingredients and labelling which includes a quantitative list of active ingredients, dosage and contraindications.

Several regulatory models for herbal medicines currently exist, including prescription drugs, over the counter drugs, traditional medicines and dietary substances. Thus, the need to establish global and/or regional regulatory mechanism for regulating herbal medicines seems obvious. Insufficient data exists to provide an accurate assessment of quality, efficacy and safety of most herbal medicines. Trails need to be conducted in such a way as to take into account the international guidelines that define such studies. An improvement in the process of regulation and a global harmonization will be desirable and certainly necessary and the general tendency is to utilize German Commission E experience which combines scientific data and traditional knowledge (Monograph). A more detailed legislation about the intellectual property of herbal drugs is urgently needed.

1. **Husn-E-Afza Powder:**

Description: Made of effective herbs, leaves and seeds it is complete nourishment for facial skin and a trusted treatment for pimples, acne and back heads. Enriched with natural benefits, it corrects and regulates circulation of blood towards the face providing complete nourishment for the skin.

Dosage:

- Make a paste of Ghaza Husn -e- Afza with water and apply on your face.
- Wash off with water after sometime
- Product Description & Composition (as on package)

Use of medicine is known to effectively remove blemishes blackheads, freckles, undesired spots on the face, improve complexion and cure pimples leaving clean soft and glowing skin.

FIGURE 1: HUSN-E-AFZA

Composition:

Each 10 g contains:

- Badam Cake- 4.0 g
- Gile Makhtoom (Multani Mitti)- 2.50 g
- Adas Musallam Muqashshar (Daal masoor)- 1.50 g
- Post Turanj- 0.50 g
- Balchhar- 0.50 g
- Sandal safaid- 0.50 g
- Neem Leaves- 0.30 g
- Chobzard (haldi)- 0.20 g
- Khushbu Rose- 0.20 ml

2. **Hamdard Roghan Badam Shirin:** Roghan Badam Shirin (Sweet Almond Oil) Strengthens brain and nerves, is a nutrient, improves body strength and removes constipation in a natural way.

Usage: 5-10 ml to be taken with 250 ml of milk at night. Apply externally on head and in still 2-3 drops in the nose and ears.

Roghan Badam Shirin's Secrets to Perfect Health.

- Relieves Tension
- Strengthens Brain Power
- Good for Heart
- Relieves constipation
- Fights dandruff
- Keeps body warm in winter
- Nourishes Skin
- Helps build stronger bones
- Good for infants

FIGURE 2: HAMDARD ROGHAN BADAM SHIRIN

TABLE 1: REGULATORY ASPECTS OF THE TWO UNANI COSMECEUTICALS PRODUCTS

Issues / Products	Good Manufacturing	Uniformity of Weight	Quality Control	Premises and Equipment	Heavy metals	Adulterants	Adverse Effects	Labelling
Husn-E-Afza Powder	✓	✓	✓	✓	✗	✗	✗	✓
Hamdard Roghan Badam Shirin	✓	✓	✓	✓	✗	✗	✗	✓

REFERENCES:

1. Adams, A (2007), Cosmetics: New Regulations, viewed 15 October 2010, <http://www.nicnas.gov.au/current_issues/cosmetics/cosmetics-%20new%20regulations_pdf.pdf>
2. Gupta, V (2009), Traditional Knowledge Documentation: The Traditional Knowledge Digital Library, viewed 19 November 2010, <http://www.wipo.int/meetings/en/2009/tk_sem_delhi/documents/theme2-topic4-gupta.pdf>
3. Government of India (2003), Drug and Cosmetic Act 1945, viewed September 13, 2010, <http://www.cdsco.nic.in/html/Copy%20of%201.%20D&CAct121.pdf>
4. Indianmedicine.nic.in, (2001), India Systems of Medicine & Homoeopathy: Annual Report 2000-2001, viewed 17 October 2010, <http://unpan1.un.org/intradoc/groups/public/documents/apcity/unpan009845.pdf>
5. Kondkari, I 2009, *Unani medicine in India*, viewed 14 November 2010,<http://forum.indianetzone.com/5/unani_medicine_india.htm>
6. LifeMojo Team, 2010, All about Unani medicine, viewed 6 October 2010, <http://www.lifemojo.com/lifestyle/all-about-unani-medicine-14593204>
7. Medhelp, 2010, Unani, viewed 10 August 2010, <http://www.medhelpindia.com/unani.htm>
8. Mediescapes India, 2006, *Unani medicine system in India*, viewed 22 October 2010, <http://www.mediescapes.com/Unani_Medicine_India.html>
9. Mehta, R, Akhauri, A and Bharti, A 2008, Integrating AYUSH system in health care delivery, viewed 15 October 2010, <http://www.technopak.com/Perspective/vol4/Integrating%20AYUSH%20System%20in%20healthcare%20delivery.pdf>
10. Niamath research foundation, 2010, *Unani medicine origin and development*, viewed 11 November 2010, < http://www.herbalniamaths .com/um.htm>
11. Nesari, M Lohar, D (2008), Indian Systems of Medicine (Ayurveda, Siddha, Unani) and issues for regulating TM at

International level, viewed 24 October 2010, <http://traitdunion.info/GUERRY/AGENDA/2008/20081100CHINE-OMS/IndGvtWHO.pdf >
12. Rahman, S 2010, *Though effective, inexpensive and easily available, the Unani system of medicine still continues to lurk on the fringes of alternative healing, perhaps due to its unfamiliarity or due to its Muslim association*, viewed 15 November 2010, <http://www.lifepositive.com/body/traditional-therapies/unani.asp>
13. Rao, S (2009), Ayush Sector in India and Potential in African Countries, viewed 23 September 2010, <http://pharmexcil.org/data/uploads/PresentationTSIII_1.pdf>
14. Siddiqui, HMK 2008, *Unani medicine in India*, Central council for research in Unani medicine, New Delhi
15. Siddiqui, HMK 2009, *Unani medicine in India*, Central council for research in Unani medicine, New Delhi
16. Sharma, M (2009), Ayurveda: Scientific aspects, Strengths, Infrastructure and Regulations, viewed 10 September 2010, <http://www.ayurveda.hu/doc/10__ayu_.pdf>
17. Sachan, V Kohli, Y and Gautam, R (2009), Regulatory Issues for Herbal Products - A Review, viewed 04 October 2010, <http://www.pharmainfo.net/justvishal/publications/regulatory-issues-herbal-products-review>
18. Unani herbal, 2010, History of Unani, viewed September 2010, <http://www.unaniherbal.org/history_unani_.htm>
19. Vassilopoulos, Y 2002, *Unani medicine by Yannis Vassilopoulos,* Viewed 19 September 2100, <http://www.newsfinder.org/site/more/unani_medicine/>
20. Zareen, N (2008), Regulations of Herbal Medicines, viewed 30 October 2010, <http://www.pharmainfo.net/nazia-zareen/regulation-herbal-medicines-part-2 >
21. http://www.dsir.gov.in/reports/ittp_tedo/ism/ISM_USM_Intro.pdf
22. http://unanimedicine.com/About_ccrum.aspx
23. http://unanimedicine.com/Publication_pdf/Action%20Plan.pdf
24. http://unanimedicine.com/Origin_And_Development.aspx
25. http://indiacurrentaffairs.org/strengthening-the-unani-and-other-systems-of-indian- medicine-m-hamid-ansari/

****