

REVIEW ARTICLE

SHIFTING PARADIGM FOR VALIDATION OF MEDICINAL PLANTS IN INDIAN TRADITIONAL MEDICINE

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ABSTRACT

The use of herbal drugs for the prevention and treatment of various health ailments has been in practice from time immemorial. Scientific validation and documentation of indigenous knowledge to work on patenting and research based on literature are necessary for the growth of Indian system of medicine. The Indian government has taken several initiatives for promotion and development of medicinal plants. Traditional medicine plays an inevitable role in drug discovery and development. Most of the therapeutically useful molecules used in the present day are inspired by traditional medicine. Several thrust areas of research need to be focused to develop scientifically validated data on their quality, safety and efficacy, to improve the consumer's need of modern days. The products developed through validation will be of immense use for the betterment of healthcare and will help the industries to compete with their products to export to other countries. A paradigm shift is required for the promotion and development of traditional medicine, which can significantly convey the important task in economic growth. An attempt has been made through this article to highlight the major thrust areas and challenges in medicinal plant research and development.

Keywords: Thrust area, Shifting paradigm, Traditional Medicine, Regulatory affairs, Validation, Integrated approaches.

TRADITIONAL MEDICINE SYSTEMS IN VARIOUS COUNTRIES

Traditional medicine (TM) includes the longstanding remedies passed on and practiced by the people for prevention and treatment of diseases. It is composed of several systems of medicine from different parts of the world. Plants have formed the basis of traditional medicine systems. This includes traditional Chinese medicine (TCM) from China, Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) from Indian systems of medicine (ISM), Kampo medicine (Japan), Native American medicine (USA), Tibetan medicine (Tibet), Jamu Gendong (Indonesia), Traditional African Medicine (Africa) and Traditional Hawaiian Medicine (Hawaii)¹. It has been estimated that two-thirds of the world's population seek healthcare from sources other

than conventional biomedicine, while many of these individuals undoubtedly seek their remedies from various TM including Ayurveda, TCM, Kampo, native American medicine, traditional Hawaiian medicine, Unani, Latin American folk systems, etc².

To compensate the global market demand of herbal drugs, scientific and clinic experiments in TCM are continuously advancing. The achievements have been made in areas such as in circulating paths of meridians; in Zheng-syndrome, in diagnostic indexes, in therapeutic principles, in healing emergency patients with shock, acute disseminated intravascular coagulation, acute myocardial infarction and acute renal failure³. TCM has been known for efficient treatment of diseases like tumors, cardio-cerebro-vascular, bone fracture, etc. As an example, the theory of combination of mobilization and immobilization was enforced for treatment of bone fracture; Non-antibacterial compound prescriptions are still being used in treatment of bacterial infections. Fuzheng Guben compound prescriptions cause the shrinkage of the mass of cancer in the treatment of cancers. TCM provides an advantage in the non-surgical approach to the treatment of acute abdomen, which can be easily adopted in TM⁴. Demand for Chinese herbal products is surging not just domestically as consumer power increases, but also overseas as China's economy is liberalized and TM is more widely accepted.

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India has 15 Agroclimatic zones and 17000-18000 species of flowering plants, of which 6000-7000 are estimated to have medicinal usage in folk and documented systems of medicine, like Ayurveda, Siddha, Unani and Homoeopathy. About 960 species of medicinal plants are estimated to be in trade of which 178 species have annual consumption levels in excess of 100 metric tons. Medicinal plants are not only a major resource base for the traditional medicine and herbal industry but also provide livelihood and health security to a large segment of Indian population. The domestic trade of the AYUSH industry is of the order of Rs. 80 to 90 billion (USD 1.3-1.5 bn). The Indian medicinal plants and their products also account of exports in the range of Rs. 10 billion. There is global resurgence in traditional and alternative health care systems, resulting in world herbal trade which stands at US\$ 120 billion and is expected to reach US\$ 7 trillion by 2050⁵.

India has an ancient heritage of TM. Materia medica of India provides a wealth of information on the folklore practices and traditional aspects of therapeutically important natural products. Each of these traditional systems has unique aspects, but there is a common thread among their fundamental principles and practices in the use of natural products, mostly herbs. The Indian traditional medicines are time tested and are being used by the people for a long time for their own health care. Before the British rule, in India these were the main systems of treatment, which was changed later with the Western influence⁶. So these systems are well rooted with profound clinical basis, where scientific validation is sometimes the major constrains for their development. In spite of all these setbacks, TM remains in India with a constant growth in the global market. With the developing attention of the Western world towards the herbal drugs in general and TM in particular, it is necessary to take appropriate measures to validate these systems and to bring back the concept of TM as a major medicine system for treatment⁷.

With a view to revitalize TM, several main research areas should be focused and adequate novel concepts and/or approaches should be developed in line with the conventional approaches, so that the appropriateness of the system can be proved scientifically without any doubt. With the emerging interest in the world in adopting and studying the traditional system and in exploiting their potentials based on different healthcare systems, the evaluation of the rich heritage of the TM is essential for their globalization for health care of the people at large. This article highlights on the present concept of TM, the thrust areas of research to be focused for TM-inspired

drug development so much so the role of TM in global health care at large⁸.

CHANGING SCENARIO ON DEVELOPMENT OF TRADITIONAL MEDICINE

Scientific validation and documentation is the major need to demonstrate safe, effective and consistent use of TMs. Wisdom and compassion, enhanced global collaboration and leadership are needed to change the contemporary paradigms and develop new strategies for the promotion of traditional medicines and dietary supplements. From the history on discovery and development of drugs, it is understood that eventually, and with adequate support, an important health outcome of the evidence based approach to the study of traditional medicines has developed several safe and effective medicines. The traditional medicinal products' scientific documented evidence for safety and efficacy is inadequate whereas these products have been used for centuries⁹. The huge secondary metabolite resources of medicinal plants and their phyto-constituents are widely accepted for their unique chemical and biological features. They are gaining global acceptance because they offer natural ways for treatment of diseases and promote healthcare. Scientists around the world are highly emphasizing on medicinal plants as alternative medicine and their commercial potential in health care¹. Globalization of TM is necessary for the establishment of the evidence-based health care, based on traditional medicine in consideration of its safety, efficacy, therapeutic and clinical evidences. Technology and science have developed many techniques and systems for the core disciplines including ethno-medicine, ethno-botany, ethno-pharmacology and medical anthropology to raise the traditional medicine compounds for global existence¹⁰. Establishment of global and/or regional regulatory harmonization is obligatory for its development and promotion through scientific validation¹¹. The development of traditional medicine and natural products requires the convergence of modern techniques and integrated approaches related to their evidence based research in various fields of science through coordination and cooperation nationwide. The question is raised that "What are the global health care needs for medicinal agents?". The answer is hidden in the basic pillars which are the foundation of global health care through natural resources. The pillars include information systems, botany, chemistry and biology along with appropriate biotechnology tools with well-designed and reported clinical studies. Thus, the systematic approach of traditional medicines is not about a single science or technique but also amalgamation of these concomitant areas, which are mutually interrelated¹².

The International Union of Pure and Applied Chemistry (IUPAC) has published a series of protocols on quality control, safety, efficacy, standardization and documentation of herbal medicine in which various significant aspects and features of phyto-chemistry and analytical chemistry have been described. If these strategies are fully implemented by the IUPAC, World Health Organization (WHO) will explore traditional medicine from its pessimistic view to modern medicine¹³. One of the great challenges for traditional medicine is quality control, safety and efficacy therefore to create a series of evolving standards which inter-relate botany, phyto-chemistry and biology, and which can be used to describe and standardize medicinal plants along with the assured outcomes¹⁴.

Thrust areas on Research and Development of Medicinal Plants and Traditional Medicine

Traditional medicine (TM) can very useful take the challenges for developing suitable products for development of human healthcare. There are a lot of phyto-derived herbal molecules which have been established clinically for diverse mechanisms of action⁵. A paradigm shift towards TM for the management of healthcare issues can significantly convey the main task in economic growth. Major thrust area for research in TM includes:

- Phyto-chemical and pharmacological screening
- Chemo-profiling
- DNA Bar coding
- Phyto-informatics
- Metabolomic study
- Phyto-equivalence
- Reverse pharmacology
- High - throughput screening
- Safety evaluation
- Value added drug delivery system
- Quality control and standardization
- Clinical evaluation

There are several thrust areas which need to be focused upon for promotion and development of TM, as shown in Figure 1. India has a special position in the world, because it acquires a good position for producing most of the important plants that are used in not only modern but also in traditional systems of medicine. In India, approximately 70% herbs are used as modern medicines based upon their therapeutic potential¹⁴. Among

them 6% species have been reported chemically while some species are investigated pharmacologically. India is a major exporter of raw medicinal plant materials and processed plant based drugs due to its vast area with a wide variation in climate, soil, altitude and latitude. Around 25,000 effective plant-based formulations are used as folk medicines in different rural communities of India¹⁵.

In India about 95% of medicinal plants are available from wild sources, among them only 150 species are used commercially. Approximately, 5-15% of the total 250,000 species of herbs have been validated scientifically. The annual turnover of the Indian herbal medicinal industry is about Rs. 2,300 crore as against the pharmaceutical industry's turnover of Rs. 14,500 crores with a growth rate of 15 percent. There are over 1.5 million traditional practitioners and approximately 7000 medicinal drug manufacturing units which are using medicinal plants for prevention and treatment of different ailments¹⁶. Department of AYUSH (Ayurveda, Yoga, Unani, Siddha and Homeopathy), Ministry of Health and Family Welfare, Government of India control all the aspects for the promotion and development of natural products being used in Indian systems of medicine. In modern era, combinatorial chemistry and high throughput screening are very useful methods and so many new drug molecules are coming out from herbal resources¹⁵. In most of the cases preclinical and clinical study being performed to reveal the pharmacological activity, mode of action, toxicity as well as safety. Traditional use of medicinal plants needs to be systematically investigated and standardized in the prospective of the quality, safety and efficacy. Although there has been an increase in interest in science based research into herbal medicine, some of the research to

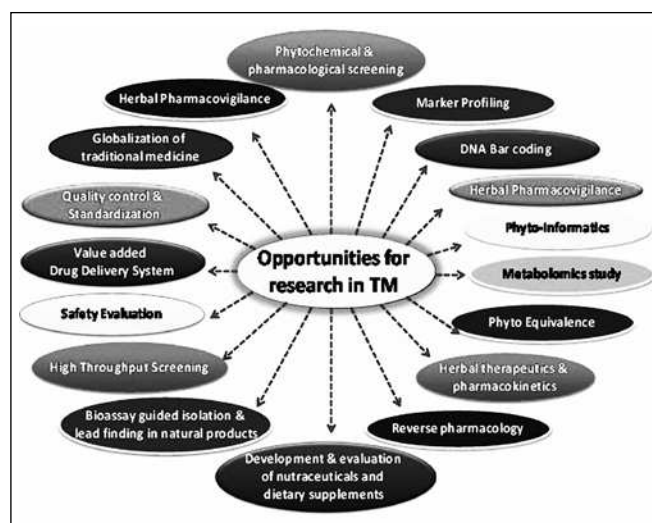


Figure 1: Thrust areas for research in traditional medicine

date has been overwhelmed by studies conducted using unauthenticated, uncharacterized products¹⁷. In reverse pharmacology researchers start with the end product, a clinically useful compound, for example, and work backwards to find out what it contains and how it functions. This can offer clues about how particular medicines work, and where they act in the body.

High-throughput screening is the advanced screening technology that relies on high-speed data processing and sensitive detectors to conduct millions of biochemical, genetic or pharmacological tests in a few minutes. The process can quickly identify active compounds that affect particular biological pathways.

Systems biology deal with the holistic approach to know different chemicals and metabolic processes to interact within the body. Since traditional medicines often have numerous active ingredients, it could be used to measure the whole body's response to the mixture of compounds¹⁸. Metabolomic study reveals to the quantitative and qualitative estimation of "whole" metabolite found in a cellular/organism system. It may be defined as the systemic study of the individual chemical fingerprints that definite cellular process leaves behind and even more particularly, the technique of the metabolite profile of molecules in an organism. The combined data of all the metabolites in a biological system, which are the final products of its gene expression, is known as metabolome. These approaches deal with the study of genomics, transcriptomics and proteomics of biological systems¹⁹.

Herbal medicines are complex products because a single medicinal plant can contain hundreds of phytoconstituents and their pharmacological properties are influenced by the time of collection, area of plant origin, and environmental conditions, so special attention is needed for its cultivation and collection for quality of products²⁰. Fixing strategies regarding various issues are urgently needed, including: legislation and regulation for herbal products and practice of therapies, education, training and licensing of providers, research and development, allocation of financial support and other resources²¹.

Integrated Approaches for Development of Medicinal Plant and Their Uses in Traditional Medicine

Plants and plant-derived products are part of health care system since ancient human civilizations. The need of new chemical entities (NCEs) for health care is explored and served through the plant sources. In India, the history of health care goes back to 5000 years B.C., when

health care needs and diseases were noted in ancient literatures like '*Rig-Veda*' and '*Atharva-Veda*'. Later, the texts like '*Charak Samhita*' and '*Sushruta Samhita*' were documented around 1000 years B.C., where use of plants and polyherbal formulations was highlighted for health care. Evolution of Ayurveda and plant-based remedies for health care through day-to-day life experiences is a part of cultural heritage of India. In traditional systems of medicine, the medicinal plants play a major role and constitute their backbone. Indian Materia Medica includes about 2000 drugs of natural origin, almost all of which are derived from different traditional systems and folklore practices²². It is difficult to get reliable figures for the total number of medicinal plants on earth; according to some estimation, around 35,000-70,000 plant species are being used worldwide in health care systems²³. According to WHO reports the populations in developing countries like India (70%), Ruwanda (70%), Uganda (60%), Tanzania (60%), Benin (80%) and Ethiopia (90%) extensively use traditional and alternative medicines for health care. Plants and plant-based products are an integrated part of most of the traditional and alternative systems of medicines worldwide. In developed countries like Belgium (31%), USA (42%), Australia (48%), France (49%), Canada (70%), a significant percentage of the population has used traditional and alternative remedies at least once for health care²⁴.

The global market of trade related to medicinal plants is estimated around US \$60 billions per year and is growing at the rate of 7% annually with varying shares of developed and developing countries²⁵. A study reveals that about 42% of the best selling pharmaceutical products in 1997 were biologicals or natural products or chemical entities derived from natural resources, worth of US \$17.5 billion²⁶. Traditional medicine (TM) generally refers to those medical and healthcare systems that are

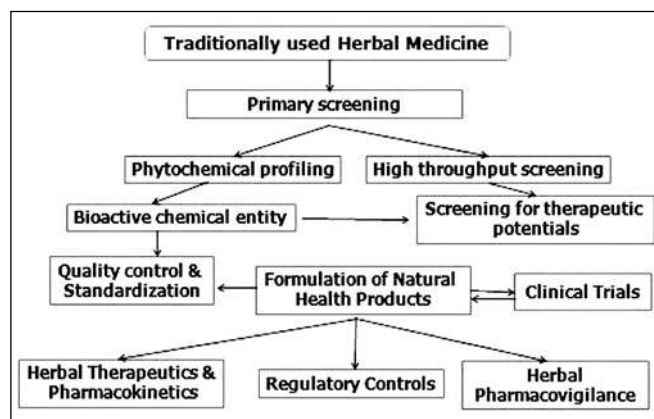


Figure 2: Integrated approaches for the development of herbal medicine

practiced in a traditional manner from ancient time and this discipline is not considered to be a part of conventional modern medicine. The practices and public interest in natural therapies, namely herbal medicine, have been increased dramatically not only in developing countries but also in industrialized countries.

This has increased the international trade in herbal medicine enormously and has attracted most of the pharmaceutical companies, including the multinationals. Until a few years ago, only small companies had interest in the marketing of herbal medicines. Currently, most large multinational companies are interested in commercializing herbal drugs¹⁹. The discovery of new drugs is facing serious challenges due to reduction in number of new drug approvals coupled with excessive increasing cost. Integrated approaches for drug development from the traditional medicine has been represented in Figure 2. Arrival of combinatorial chemistry provided new expectation of higher achievement rates of new chemical entities but this scientific development has failed to improve the success rate in novel drug discovery. This scenario has prompted researchers to come out with a novel approach of integrated drug discovery. Initial steps in new drug discovery involve identification of NCEs, which can be either sourced through chemical synthesis or can be isolated from natural products through biological activity guided fractionation¹. The sources of several of the new drugs and active ingredients of medicines are derived from natural products. The starting point for plant-based new drug discovery should be identification of the right candidate plants by applying traditional documented use, tribal non-documented use, and exhaustive literature search. Bioassay-guided fractionation of the identified plant may lead to standardized extract or isolated bioactive druggable compound as the new drug. This integrated approach would lead to saving of cost and time, coupled

with enhanced success rate in drug discovery²⁷. With the worldwide emerging interest in executing traditional practices in the healthcare system by exploring their therapeutic as well as preventive potential, the evaluation and scientific validation of the botanicals in these systems of medicine is utmost important. In traditional medicine, various regulations and control on use of botanicals has come up which will not only help to cure different ailments through indigenous natural resources but also in screening and evaluation of the medicinal plants in a better way to use them in traditional healthcare system²⁸. The development of traditional medicine and natural products requires the convergence of modern techniques and integrated approaches related to their evidence based research in various fields of science through coordination and cooperation nationwide²⁹.

Validation of Medicinal Plants used in Traditional Medicine

Traditional Medicine (TM) has a long history of traditional use. However, the efficacies of some of these are unproven. The lack of evidence does not necessarily mean that TM lacks efficacy or is unsafe³⁰. Some evidences of efficacy for herbal medicines, safety and quality, if they exist, are considered to be anecdotal or empirical at best and rarely is it subjected to the rigorous prospective randomized controlled trial. Until 1899, when Bayer introduced aspirin, ethno-medicine was the basis of health care for humankind. Through a slow throughput process of clinical trial and error each culture developed a local, natural resources-based tradition of healing. These systems of traditional medicine, today, provide the basic drug supply for an estimated 4.6 billion people worldwide¹⁴.

'Triphala' is a classical example of polyherbal formulation in Ayurveda having synergistic and counter

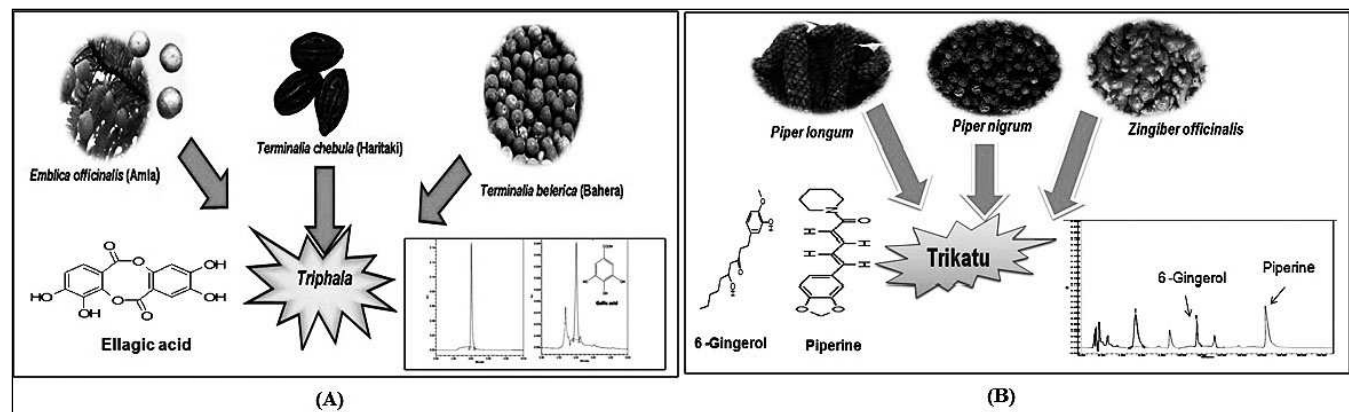


Figure 3 Validation of poly-herbal formulation (A) Triphala and (B) Trikatu by HPLC

balancing properties which contain dried fruits of *Emblica officinalis* Gaertn. (Euphorbiaceae), *Terminalia belerica* Roxb. (Combretaceae) and *T. chebula* Retz. (Combretaceae) in equal proportions (1:1:1), prescribed as laxative in chronic constipation, colon detoxifier, and as rejuvenator of the body due to its gallic acid and ellagic acid content⁴⁷. These three fruits were mixed and the polyphenols of those plants collectively produced synergistic effect and formulation have been validated by Ponnusankar et al., as shown in figure 3.

Mixture of three spices known as Trikatu consists of *Piper longum* L. (Piperaceae); *P. nigrum* L. (Piperaceae); and *Zingiber officinale* Rosc. (Zingiberaceae) in the ratio of 1:1:1. It has been traditionally used to promote digestion and assimilation due to their alkaloidal constituent piperine. This bioactive compound is having number of pharmacological properties including anti-inflammatory activity. These examples of Ayurvedic medicine make it more attractive to the researcher and scientific community for further research for its validation that explore the scientific evidence in all aspects⁴⁸. An RP-HPLC method for the identification and quantification of piperine and 6-gingerol from Trikatu has been developed by Harwansh et al., 2014 (Figure 3).

All patients have the right to expect that a medicine will “work”, i.e., that it will be safe, effective, and consistent. Ethically, it should not matter whether the medicine is an approved prescription product, over-the-counter medication, dietary supplement, phyto-therapeutical, or traditional medicine; human health is at stake. To diminish that right is to diminish the value of one human life over another. Global implementation of a solid, evidence-based regulatory foundation for traditional medicines and dietary supplements would transform health care for all. Scientific validation and quality control of traditional medicines is a critical and essential matter to be considered in assuring the therapeutic efficacy, safety and to rationalize their use in the health care. Quality assurance is an integral part of traditional medicine, which ensures that it delivers the required quantity of quality medicament. Today, quality assurance is the thrust area for traditional formulations like churnas, bhasmas, liquid orals, Lehas, etc³¹⁻³². Finger printing and marker compound analyses are nowadays getting momentum for the standardization of traditional medicinal formulations. This technique helps not only in establishing the correct botanical identity but also helps in regulating the chemical holiness of the herbs³³. Natural products have been regarded as strongholds in drug discovery and drug development as they offer several unmatched chemical diversity with structural complexity and biological potency.

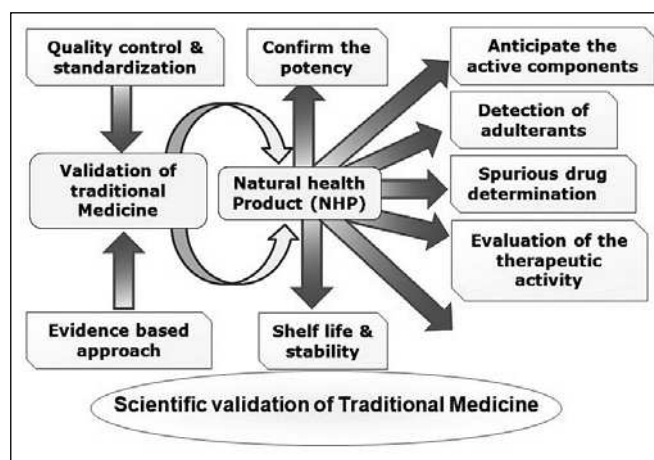


Figure 4: Validation prospective of traditional medicine

Searching for the natural products in untapped sources can lead us to new horizons where we can find novel, potent and selective drug leads. Such leveraging innovations in the development of natural health products suggested an immense growth potential in future for their validation in every aspects³⁴ (Figure 4).

However, for most herbal medicines, the therapeutic components have not been fully elucidated or easily monitored. The European Medicines Agency (EMA) defines chemical markers as chemically defined constituents or groups of constituents of herbal medicinal product, which are of interest for quality control purposes in spite of whether they possess any therapeutic activity. Classification of different chemical markers can be as follows:

- Therapeutic components
- Bioactive components
- Synergistic components
- Characteristic components
- Main component
- Correlative components
- Toxic components
- General components

A total of 282 chemical markers are listed in the Chinese Pharmacopoeia (2005 edition) for the quality control of Chinese herbal medicines. As discussed in the monographs of the American Herbal Pharmacopoeia (AHP), the use of single or multiple chemical markers was important to quality control^{10, 28}. Apart from proper cultivation, collection and quality, optimum extraction and standardization of raw materials the evaluation of

herbal medicine should be done in a better way to get meaningful results³⁵.

Regulatory Harmonization for Developing of Herbal Medicine

Herbal drugs and their marketed products are widely used for the prevention, diagnosis, treatment and management of disease for better health of human beings while quality control and proper regulation are still a big challenge globally. Its wide application and continuous use has created a global health challenge in terms of quality, safety and efficacy^{10, 12}. Scientific validation and standardization of herbal medicine is needed for the globalization of traditional medicine³⁶. Appropriate use of products of assured quality could also do much to decrease any risks. However, regulation and legislation of herbal medicines has been endorsed in very few countries; most countries do not have any proper regulation of natural products and the quality of herbal products sold is generally not guaranteed³⁷.

Recently, many European countries adopted 'The European Directive on Traditional Herbal Medicinal Products' (formally The Directive 2004/24/EC amending) which aims to assure the quality and regulation of herbal products. In the United Kingdom this is implemented by the Medicines and Healthcare Products Regulatory Agency (MHRA) established in April 2003 by the union of the Medicines Control Agency and Medical Device Agency. The MHRA is responsible for the quality and safety of all types of medicines. Most of the developing countries do not have specific regulation for herbal products, thus developing such regulations globally is urgently required³⁸. There is an urgent necessity for implementing the good manufacturing practices (GMP) to assure the high quality of herbal drugs and products. In order for a drug regulatory agency to meet the high demand of the public, there is a need for well-designed, randomized, double-blind, and placebo-controlled clinical trials to establish the safety and efficacy of herbal drugs along with modern drugs³¹. In this context the safety profile of herbal products are big challenges for evaluation of herb-drug interaction and its proper documentation¹⁰. Proper methodology and clinical trials will offer new opportunities for basic and applied research in the areas of herbal medicines used in India. The Indian Pharmacopoeia 2014 included 39 monographs on herbs and herbal products, while the Indian Pharmacopoeia 2010 included 89 monographs of medicinal plants^{29, 40}. In 2005, the Ayurvedic Pharmacopoeia of India included 258 different drugs and the Indian Herbal Pharmacopoeia included 52 monographs of widely used medicinal plants³⁷.

Education and guidance regarding herbal medicine and its wide application are needed at high extent. Ensuring the knowledge, qualifications and training of herbal product suppliers should be ensured. The traditional medicine providers, practitioners and allopathic practitioners understand and appreciate the complementary nature of this type of healthcare which is essential¹¹. Difficulties relating to the protection of indigenous traditional knowledge and problems in ensuring its proper use need to be addressed quickly although there are varying degrees to which it is recognized by governments. The lack of sound scientific evidence on the therapeutic efficacy of many herbal drugs are still challenge. Attention should also be paid to intellectual property issues to stop biopiracy of indigenous ancient knowledge and natural resources that are used in traditional medicinal products²⁰. According to Associated Chambers of Commerce and Industry of India (Assocham) of the 700 medicinal plant species commonly used in India, only 20% were being cultivated on a commercial scale and 90% of medicinal plants used are collected from wild resources⁴¹.

Unscientific collection leads to the destruction of medicinal plants and their diverse activity. As per the information provided by Assocham, over 70% of plant collection involves destructive harvesting due to use of roots, bark, wood, stem or the whole plant, which particularly in the case of herbs causes damage of that plant. This possesses a specific threat to genetic stocks and medicinal plant diversity, therefore sustainable use of natural products is necessary⁴². There are several acts and their amendments time to time as per regulation of ISM as following: Central Council of Indian Medicine Act (1973); Central Council of Homoeopathy Act (1973); Drugs & Cosmetics Act (1940) and Rules thereunder; Drugs & Magic Remedies [Objectionable Advertisement] Act (1954, 1955) and Rules thereunder; Medicinal and Toilettries Preparation acts and Rules (1995-96); Manual for inspectors for ASU drugs (2013)⁴³.

According to the European Medicines Agency (EMA), chemical markers are defined as categories of constituents or groups of constituents including principle markers (constituents having well known clinical activities), active markers (constituents that have some known pharmacological activities), negative markers (constituents that may have allergenic or toxic properties) and analytical markers (constituents that are chosen as markers for identification and quantitative determination)⁴⁴. The herbal manufacturers and researchers need to establish the harmonization of specifications and analytical methodologies. Usually, determination of single or several marker compounds

by a developed method is required for quality control purpose⁴⁵.

The National Medicinal Plants Board (NMPB)

The National Medicinal Plants Board (NMPB) was set up in India under a Government Resolution (No. Z.18020/19/97-M.P.Cell) notified on 24th November 2000 under the Chairpersonship of Union Health & Family Welfare Minister. The primary consent of NMPB is to coordinate all matters relating to medicinal plants and support policies and programmes for growth of trade, export, conservation and cultivation. The Board is located in the Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha & Homeopathy (AYUSH) of the Ministry of Health & Family Welfare. India has 15 agroclimatic zones and 17000-18000 species of flowering plants, of which 6000-7000 are estimated to have medicinal usage in folk and documented systems of medicine, like Ayurveda, Siddha, Unani and Homoeopathy. About 960 species of medicinal plants are estimated to be in trade of which 178 species have annual consumption levels in excess of 100 metric tones.

Medicinal plants are not only a major resource base for the traditional medicine & herbal industry but also provide livelihood and health security to a large segment of Indian population.

The objectives of the NMPB Board is to establish an agency which would be responsible for co-ordination of all matters relating to medicinal plants, including drawing up policies and strategies for conservation, proper harvesting, cost-effective cultivation, research and development, processing, marketing of raw material in order to protect, sustain and develop this sector. The work would continue to be carried out by the respective departments, organisations but the Board would provide a focus and a direction to the activities. An appropriate mechanism for coordination and implementation of policies relating to medicinal plants both at the Central and State levels is necessary to facilitate inter-ministry, inter-state and institutional collaboration and to avoid duplication of efforts⁴⁵.

Globalization of Traditional Medicine

Globalization of traditional medicine is obligatory for human health care system based on quality, safety, and efficacy, therapeutic and clinical evidences. Technology and science have developed many techniques and systems for the global acceptance of TM. For the development of TM, there are some approaches such as (i) addition in the health care system, (ii) promoting secure and

valuable use, (iii) rising access, (iv) rising communication and (v) cooperation in generating and distribution of TM information. These strategies based on information, botany, chemistry and biology of medicinal plant validation and quality control are essential⁶. Due to an increasing herbal market demand, there is urgency to expeditiously utilize and scientifically validate more medicinally useful plants globally which needs globalizing local knowledge and localizing global technologies, through international collaboration and co-operation^{1,5}. This elaborates various approaches and technology to find out the perspective on globalization of the traditional medicine and multiple objectives underlying efforts to develop, protect and promote TM for the betterment of the healthcare. International harmonization on regulation of TM would be helpful for the herbal manufacturers to penetrate regulate markets across the world. Wisdom and compassion, enhanced global collaboration and leadership are needed to change the contemporary paradigms and develop new strategies for the enhancement of traditional medicines and dietary supplements. Thus it can be appropriately supposed that globalization of natural products is the thrust area of the 21st century. This will help to develop a system to bring representatives together to discuss the global issues and implications in new strategic terms, with a new set of goals, a new agenda, but most importantly, a new vigor is vital for the global development⁴⁶.

The first ethnopharmacology laboratory in India started functioning at Regional Research Laboratory, Jammu under the All India Coordinated Research Project on Ethnobiology (AICRPE) funded by the Ministry of Environment and Forests, Govt. of India. The Society for Ethnopharmacology (SFE), Kolkata, India in association with International Society for Ethnopharmacology (ISE), UK was constituted by the eminent academicians, researchers and industrialists with the vision of providing an environment for knowledge sharing among researchers, healthcare practitioners and decision makers interested in ethnopharmacology activity with headquarters at 23/3, Shaktigargh, Kolkata – 700032 (web: www.ethnopharmacology.in). The main aim of the society is to dissemination of knowledge on natural health products through globalization of local knowledge and localizing global technologies. The society has various targets to organize conferences, seminars, symposiums, workshops etc in different parts of India for discussion and sharing knowledge on different issues on cultivation, production, quality evaluation, safety, clinical studies, biological screening and several other issues of natural product research. The society is helping to inculcate the modern global knowledge on herb, herbal remedies, herbal quality assurance, herbal trade and commerce and

herbal drug development, so that the person with local knowledge can be upgraded. It will form a bridge between academia and industry to gather scientific and teaching professionals in ethnopharmacology and professionals of other area interested in developing cost effective natural remedies, under one umbrella. The society will publish newsletters, documents and books for promotion of knowledge in the field of natural product research. The SFE has been organizing annual conferences every year with the involvement of stakeholders in this area around the globe.

CONCLUSION

Using medicinal plants is an old treatment strategy by traditional healers and is very useful in traditional medicine, despite the advent of modern medicine. Medicinal plants are compatible with the physiology of human body, which has adapted over the centuries. Today's scenario is that the scientist has to focus to find out the actual compounds of herbs, which are responsible for cure, mitigation and healing of disease. Traditional medicines have several challenges, such as regulatory aspects, consumer acceptance and market competition to deliver safe and effective herbal products. As the world market is expanding, the herbal industries are mainly focusing on GMP based exercise of their products to be exported. Government of India have taken several potential initiatives for quality and safety of TMs. Regulatory authorities from different countries have established regulatory mechanisms to control the safety and quality of the raw/ finished products obtained from traditional practice. This should be taken as priority for development of quality oriented research programme, GMP, consumer friendly products and market surveillance to meet the challenge of global expectations.

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