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विषय सूची

AYURVEDA AT GLOBAL FRONT

Konica Gera[1], Nellufar[2], Baldev Kumar[3], Hetal Dave[4]

ABSTRACT

Ayurveda is the most ancient system of medicine accepted by W.H.O. Ayurveda, the traditional medicine of India, believes in cure at the root cause, it believes in curing the diseased, not only the disease. World Health Organization (WHO) has given considerable importance to Ayurveda in its activities related to traditional medicine. The Alma Ata in 1978 with the slogan-"Health for All" emphasized the role of traditional and alternative medicine in developed as well as in developing nations. Demand for herbal products world-wide has increased at an annual rate of 8% during the period of 1994–2001, and according to WHO forecast, the global herbal market would be worth $5 trillion by the year 2050. The data clearly state the international potential of Ayurveda, which is undergoing a phase of resurgence and revival "in the world". This review attempts to evaluate the state of Ayurveda at Global level and the problems in its Global acceptance. The provisions for the development and acceptance of Ayurveda globally were studied and looked for their implementations and hindrances in the recognition of Ayurveda as evidence-based medicine for its global acceptance. The present modern system of scientific world believes in statistics and data to validate any theory while the parameters mentioned in Ayurveda system of medicine are majorly qualitative which lose their relevance in the process of objectivization for the acceptance in the present age. Moreover, lacunae in the regulation of herbal medicines, standardization of the drugs at raw and processed stages, pharmacovigilance of drugs, safety and efficacy studies of Ayurveda drugs etc. stand in the way of implementation of the policies in their true spirits.

Keywords: *Globalization of Ayurveda, Traditional Medicine, Ayurveda, Alternative system of Medicine, TRM*

INTRODUCTION

Ayurveda, a system of medicine with its historical roots in Indian subcontinent, is said to be transmitted from God to Sages and then to human physicians. Several inspirational efforts are being made to promote Ayurveda at national and international fronts to achieve the goal of proper recognition of Ayurveda in modern day sciences. The current issue is not globalization of Ayurveda as it is already achieved in a big way. The question is to save the face of Ayurveda from the branded images and get it recognized over the globe as a scientific system of medicine in its own capacity. In the Western World Ayurveda therapies and practices have been integrated in general wellness. It has been misinterpreted by various custodians of the system in the west under various labels like "herbal medicine", "natural medicine", "holistic medicine", "CAM" etc. to suit their convenience to get themselves established in accordance with the situations in the country of practice. The challenge is to participate in evolving the integration of Ayurveda without compromising its core values and basic principles.

A major part of the population in India use some form of traditional medicine, about 75%-80% of the population of Nepal use Ayurveda, and it is the most practiced form of medicine in the country[1]. The eighth decade of 20th century witnessed upsurge in the popularity of Ayurveda among Westerners due to the lack of cure for chronic diseases and side effects of conventional medicines, developed countries started looking toward Ayurveda for treatments

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to restore wellness of their citizens[2]. Americans spend more out of pocket on Complementary Medicine than on all prescription drugs. Major American medical insurers now routinely cover complementary medical services, a development which is emerging in Britain as well[3]. United Nations, working with the health of mankind as one of its primary mandates through World Health Organization forecasts, $5 trillion worth global herbal market by the year 2050. As of today, Europe and the United States are two major herbal product markets in the world, with a market share of 41% and 20%, respectively. Ayurveda is undergoing a phase of resurgence and revival "in the world" similar to the one "at home"[4].

A newly emerging trend of "Herbal Medicine" among Indian Ayurveda Industry is surrendering the interest of Ayurveda at large to some vested market interests. There is an urgent need to transmit an appropriate message at a global level for the acceptance of Ayurveda as a valid system of medicine with an independent status. It's high time to implement a rapid action strategy as done by the Chinese under Mao for the promotion of our own traditional knowledge bank.

Ayurveda Empowered at National Front

AYUSH an abbreviation for Ayurveda, Yogā and Naturopathy, Unani, Siddha, and Homoeopathy, the six Indian systems of medicine (ISM) is prevalent and practiced in India and in a few neighboring Asian countries it was created as ISM in March 1995[5] and renamed as AYUSH in November 2003[6] with an objective to provide augmented attention to the expansion of these systems. The latest developments in the sector of AYUSH are many, such as mainstreaming of AYUSH and revitalization of local health traditions, inception of many national level institutions such as All India Institute of Ayurveda and above all creation of a separate ministry under the union Government of India[7]. Planning regarding these systems of medicine was a part of five-year planning process since 1951. Currently, AYUSH system is a part of mainstreaming of health system under National Rural Health Mission (NRHM). NRHM came into picture in 2005 but implemented at ground level in 2006 and introduced the scheme of "Mainstreaming of AYUSH and revitalization of local health traditions" to strengthen public health services. This scheme is currently in operation in its second phase, since 1st April 2012, with the 12th Five- year plan.

Most importantly 9th Five-year plan promoted research and development and a therapeutic trial of especially on new drug formulation therapeutic trial of potential drugs through strengthening of the central research councils and coordination with other research agencies. It focussed on preservation, promotion and cultivation of medicinal plants and herbs and completion, of the pharmacopoeia for all systems of AYUSH. It focussed on drawing up a list of essential drugs belonging to these systems and encouraged good manufacturing practices (GMP) to ensure quality control of drugs[8].

In 1989, the University of Pune took a major decision to promote evidence-based research in Āyurveda. This was a forward-looking initiative that led to the establishment of the Inter-disciplinary School of Ayurveda Medicine (ISAM) under the Faculty of Science. A major thrust for scientific research on Āyurveda was given by R. A. Mashelkar through his Golden Triangle and New Millennium Indian Technology Leadership Initiative (NMITLI) which brought CSIR, ICMR and AYUSH institutions together to generate evidence-based Āyurveda. AyuSoft is a collaborative project between the Government of India's Centre for Development of Advanced Computing (C-DAC) and the University of Pune. While the Traditional Knowledge Digital Library (TKDL) helps in protecting intellectual property. AyuSoft converts the logic of classical Ayurveda texts into comprehensive, authentic, intelligent and interactive knowledge repositories with the help of complex analytical tools. The AyuSoft database includes more than 5 lakh records, capturing information from nine texts, including the v hattrayi and *mādhava nidāna*. The term Ayugenomics was coined and proposed in 2002. In 2003, a first paper on the concept was published. Ayugenomics was planned as a platform to undertake the challenge of developing new strategies of drug discovery by integrating the ancient science and knowledge of Āyurveda with modern science and the technologies of genomics, proteomics and pharmacogenetics[9].

The setting up of Indians Pharmacopoeia Committee and the establishment of the pharmacopoeia laboratory of Indian medicines in Ghaziabad by the Department of ISM are landmarks in the attempts for standardization. Lot of efforts are done by CCRAS and NBRI (Central Council for Research in Ayurveda & Siddha and National Botanical Research Institute) and already 800 formulations have been standardized. Simultaneously the work of standardization

was undertaken at specially established centers in different parts of India under the Central Council for Research in Ayurveda and Siddha. The standardization and research activity consisted of Pharmacognostic evaluation of authenticated drugs, pharmacological studies, phytochemical studies, pharmaceutical studies, microbiological studies, identification, preservation, isolation and characterization of active chemical constituents, etc. The elaborate studies have been carried out and are still being carried out at centers of National repute such as CDRI; Lucknow, NBRI; Lucknow, Gujarat Ayurevd University, Jamnagar, Banaras Hindu University; Varanasi, CSMRIA; Chennai, National Institute of Ayurveda; Jaipur, AIIMS; New Delhi and other regional research institutes and centers established by CCRAS. Some of these institutes are equipped with most sophisticated instruments like NMR, Mass spectrometers. AAS, HPTLC, HPLC, etc. They are also having very good Pharmacognostic, pharmacological and pharmaceutical laboratories with animal house facilities. The activities on establishment of standards over the last 30 years have resulted in the publication of Ayurvedic Pharmacopoeia of India Part-I, II & III and Ayurvedic Formulary of India Part I & II which are comparable to any international standard. Lot of research is being carried out at different Laboratories on compound Ayurvedic formulations so as to lay down internationally acceptable standards.

Recently, in August 2010, Department of AYUSH of the Government of India has modified Rule 158 of The Drugs and Cosmetics Rules, 1945 to facilitate licensing and export of Ayurvedic herbal medicines under categories of Ayurvedic cosmeceuticals, Ayurvedic nutraceuticals and Ayurvedic extracts[10]. This classification is in addition to the classification of Āyurvedic medicines as "Classical and Patent proprietary Ayurvedic medicines" as defined under section 3(a) and (h), respectively[11]. On the issue of safety and efficacy of Ayurvedic medicines, Rule 170 of The Drugs and Cosmetics Rules, 1945 has been notified by the Department of AYUSH in December 2008 which has been outlined as per properties of these medicines.

World Health Organisation and Ayurveda

WHO is directing and coordinating with health authorities in the respective countries around the globe and is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends, and these responsibilities of WHO hold good for TRM too[12].

The Government of India, at the insistence of WHO, initiated the scheme of appointment of one medical officer of every traditional system of medicine, namely, Ayurveda, Unani and Siddha, at every primary health center of conventional medicine in 1985 although this scheme could not be implemented in its true spirit. The Government of India established a separate Department of AYUSH in 1995 to look after the all-round development of the heritage of the nation with complete attention. WHO moved ahead with several programs for global acceptance of Ayurveda, which include preparation of guidelines for safe use of Ayurveda medicines, parameters and measures for standardization of Ayurveda medicines and many more substantial measures to promote the system of Ayurveda.

For standard production of Ayurveda medicines, WHO sponsored many Direct Financial Cooperative (DFC) projects in 2001 at Pharmacopeial Laboratory of Indian Medicine, projects on safety profile of Ayurveda medicines in 2007 at Banaras Hindu University and WHO sponsored programmers for the planning of pharmacovigilance program in 2008 at Gujarat Ayurved University. More recently, in 2010 and 2011, under DFC program, WHO had sponsored four capacity building training programs for coordinators of regional and peripheral centers of pharmacovigilance of Ayurveda system of medicine. Further, Ayurveda Clinical Trial project might be a sustainable programmes for evidence-based data generation of Āyurvedika classical medicines for certain diseases[13], whereas data available on Ayush Research Portal and in other research papers ensure safety of Ayurveda medicines[14]. In all these programmes of Department of AYUSH, WHO is cooperating as an academic associate and also providing some logistic support.

In 2003, WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) was formed. This Commission is examining contribution of TM in improving healthcare and suggesting developmental measures for the same. In the 9th meeting of health secretaries in July 2004 (convened by WHO), the focus was on globalization, trade, intellectual property rights (IPR) and health. Member states endorsed and appreciated the work of the CIPIH. It was recommended that SEARO facilitate the preparation

of a common regional perspective focusing on the burden of disease and related health research and development, IPR and public health, other incentives for innovation, traditional systems of medicine and capacity building to be presented to the CIPIH[15]. WHO is mainstreaming TRM in health system with definite strategies that cover each and every potential of TRM.

Rules for Regulation of Herbal Medicine

WHO has emphasized upon institution of proper rules and regulations for the practice of TM in the country of origin as well as for its global accreditation among the member countries. The Government of India has already recognized Ayurveda as one of the official systems of medicine to be practiced in this country. Rules for education and practice of Ayurveda in India have been laid out in the Indian Medicine Central Council Act, 1970[16], whereas herbal medicines of Ayurveda are regulated by the provisions of chapter IV A of Drugs and Cosmetics Act, 1940 and rules instituted in part XVI-XIX of Drugs and Cosmetics Rules, 1945, along with relevant schedules for Ayurveda[17].

Scheme for Standardization of Herbal Medicine

WHO has observed that quality assurance of herbal medicinal products is the shared responsibility of manufacturers and regulatory bodies. National drug regulatory authorities have to establish guidelines on all essentials of quality assurance, evaluate dossiers and data submitted by the producers, and check post-marketing compliance of products with the specifications issued by the producers as well as compliance with Good Manufacturing Practices (GMP).

WHO has declared that the purpose of quality control is to ensure quality of the products by adhering to appropriate specifications and standards. Information on appropriate standards can be found in official pharmacopoeias, monographs, handbooks, etc. In choosing analytical methods, the availability, robustness and validity of the methods must be considered and if such advanced methods are used, a full validation for each test would be necessary[18].

To comply with the spirit of WHO regulations, Department of AYUSH, Government of India, took several measures to standardize Ayurveda medicines. Some of these schemes are implemented with WHO assistance, such as the first workshop on "Production of ISM Drugs with Current Good Manufacturing Practices" organized in April 2001 covering different aspects of GMP, was highly appreciated by those concerned with this subject[19]. The second workshop was organized in October 2001 exclusively to throw light on the need for isolation and characterization of the active chemical constituents that should have the desired therapeutic action to cure different ailments as evidenced by various marker compounds, that can be used as an important tool for testing /analysis of single and compound formulations (whether "Classical" or "Patent Proprietary" medicines) available in the market[20]. In addition to these activities, WHO also impressed upon Central Council of Research in Ayurveda and Siddha (CCRAS) to prepare HPTLC-Fingerprint atlas of Ayurveda single plant drugs which are mentioned in Ayurveda Pharmacopoeia Vol. III and IV as a published document for standardization purposes. [21]

Projection of pharmacovigilance program for herbal medicine

The WHO persuaded the Department of AYUSH, Ministry of Health and Family Welfare, Government of India, to implement a comprehensive pharmacovigilance programme for Ayurveda, as means to ensuring the safety and efficacy of Ayurveda medicines which was launched nationally on 29 September 2008. This programme is running successfully at present.[22]

Commencement of Consumer Guidelines of Herbal Medicines

Most recently, WHO country office has agreed to sponsor a short-term project meant to prepare consumer guidelines for appropriate use of Ayurveda medicines on recommendations of the Department of AYUSH, Government of India. [23]

Hurdles in the Quest

Well-defined policy: India doesn't have a well-defined policy on Globalization of Āyurveda; neither is there any accepted road map to achieve the goal. It is necessary to resort to a rapid action strategy as done by the Chinese under Mao for the promotion of our own traditional knowledge bank.

Safety status: Safety is a primary concern regarding traditional and complementary therapies. There are two aspects of safety evaluation: First, to ensure that the right qualities of material

and appropriate processes are used from source till marketing and secondly, ensuring that there is no contamination, adulteration or spiking. WHO global survey on the national policy and regulation of TM, has identified three common difficulties and challenges, viz., lack of information sharing, lack of safety monitoring for herbal medicines and lack of methods to evaluate their safety and efficacy.

Self-interest over Ayurveda: It is evident from the present picture that people linked with the science in some or the other way are actually not bothered about the growth of Ayurveda as a science rather focussing on establishment of Ayurveda in a way they can fulfil their interests is prevalent. Government started paying more attention to Ayurveda, not because of its immense healing powers, but for its tourist potential. Today the promotion and gradation of Ayurveda practice is done not by the health sector but by the tourism sector. Ayurveda Clinics gave way to the Ayurveda Centers attached to star hotels and the government has a policy and guidelines to certify these Centres.

Misnomers of Ayurveda: Ayurveda HMPs (Herbal Medicinal Products) are marketed as dietary supplements, they are regulated under the Dietary Supplement Health and Education Act (DSHEA), which does not require proof of safety or efficacy and hence bypasses the stringent quality tests of Drugs and Cosmetics Act 1940.[24]

Research in Ayurveda: Conventional medicine and its research methodologies are largely based on classical Newtonian physics and related biological considerations. In contrast, Ayurveda life sciences are based on a holistic logic now emerging in quantum science. This is why Ayurveda does not follow the organ-oriented anatomy and physiology, and adopts its own function-oriented approach through its alternative theories of *Panchamahabhut, Tridosha, Dhatu, Agni, Ama, Ojas, and Srotas*, which cannot be fully explained in terms of conventional anatomy and physiology.[25]

Access to information: Ayurveda is one of the oldest system of traditional medicines still the number of scientific research publications is almost negligible as compared to other systems of medicine. At present a list of 3 PUBMED indexed journals of Ayurveda, 38 non PUBMED indexed journals, 4 Hindi Ayurveda Journals, 26 Journals of Complementary and Alternative Medicine and 11 magazines of Ayurveda have been documented.[26] Data in Table 1 highlight variation in the number at the scientific drafts of Ayurveda and Chinese traditional medicine:[27]

Inevitable Requirements for Globalising Ayurveda

Global acceptance of Ayurveda is gearing up and there has been a steep rise in the demand for information. Ayurveda has sound philosophical, experiential and experimental basis which need to be re-searched and re-established along with appropriate state recognition of Ayurveda in as many countries as possible, and appropriate regulatory status for Ayurveda products. Development of research programmes in Ayurveda, appropriate training, education and certification of Ayurveda practitioners, generation and protection of intellectual property of Ayurveda, and co-operation with international and regional organizations are important to ensure the global recognition of Ayurveda.

In order to walk, hand-in-hand with expectations, raised by virtue of Global acceptance of Ayurveda, it is needed to elevate additional funds and laboratories well equipped with sophisticated instruments. In order to satisfy the taste of modern day's technological advancements, there is a need to enrich the researches by adding vital departments like Bio-chemistry, Molecular Biology, Genomics and Proteomics, Central Dogma of Life, and Related Investigations cum Analysis.

CONCLUSION

Ayurveda entered the global health arena initially as a massage system few decades back. Later it was interpreted merely as a system of general wellness. With the advancements in the field of research and efforts at national and international levels the picture has changed, still a lot more sincere effort is required for the maintenance of its position and for further improvement. Regulatory reforms at the level of Department of AYUSH, Central Council of Indian Medicine (CCIM), CCRAS and amendments in the Drug and Cosmetic Act would help accelerate the development of both Ayurveda's evidence-base and its globalization. On many occasions, faulty regulatory provisions become a real barrier even for scientific growth in multidisciplinary fields, and this should not be undermined. The extensive, currently unutilized infrastructure and human resource in the AYUSH sector needs to be mainstreamed and fruitfully utilized[25]. The lack of data and scientific evidences in modern parameters are holding us back for the past so many years

and no collective effort has been made to push the science forward as an effective CAM system. The fortification of infrastructure and scientific staff can change the mandate and specific research line will take momentum and eventually, pharmacognostic, phytochemical and literary research work will accelerate.

Table 1: Variation in the Number of the Scientific Drafts of Ayurveda and Chinese Traditional Medicine

Publication	Āyurveda	Chinese Traditional Medicine
Pubmed	2,807	23,964
Medicine	42	656
Lancet	39	204
B.M.J.	36	1821

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सारांश

अंतर्राष्ट्रीय स्तर पर आयुर्वेद

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आयुर्वेद विश्व स्वास्थ्य संगठन द्वारा स्वीकृत प्राचीनतम प्रणाली है। आयुर्वेद, भारत की पारम्पारिक चिकित्सा पद्धति, रोग के मूल कारणों का निवारण करता है तथा मात्र रोग नहीं अपितु रोगी की चिकित्सा करता है। विश्व स्वास्थ्य संगठन पारंपारिक चिकित्सा पद्धतियों से सम्बधित गतिविधियों के लिए आयुर्वेद को विशेष महत्व देता है। 1978 में अल्मा आटा में दिये गये नारे 'सब के लिए स्वास्थ्य' के लिए विकसित एवं विकासशील राष्ट्रों में पारंपारिक एवं वैकल्पिक औषधियों की भूमिका पर जोर दिया है। वर्ष 1994 से 2001 की अवधि में 'वानस्पितिक औषधियों' की मांग विश्व में 8 प्रतिशत वार्षिक दर से बढ़ी है एवं विश्व स्वास्थ्य संगठन के अनुसार वर्ष 2050 तक इनका विश्व में 5 खरब अमरीकी डॉलर तक हो जाएगा। ये आकड़े स्पष्ट रूप से दर्शाते है कि आयुर्वेद अंतर्राष्ट्रीय क्षमता में पुनरूत्थान एवं पुनरूद्धार की अवस्था से गुजर रहा है। यह समीक्षा वैश्विक स्तर पर आयुर्वेद की स्थिति एवं वैश्विक स्वीकृति की समस्याओं का मुल्यांकन करती है। विश्व स्तर पर आयुर्वेद के विकास एवं स्वीकृति के प्रावधान पर अध्ययन किया गया है तथा इसकी वैश्विक स्वीकार्यता हेतु 'साक्ष्य आधारित चिकित्सा' तथा कार्यन्वयन एवं बाधाओं की पहचान की गई। वर्तमान स्थिति में आधुनिक विज्ञान किसी भी सिद्धांत को सांख्यिकी एवं आकड़ों के आधार पर ही विधिमान्यता देता है, जबकि आयुर्वेद में उल्लेखित अनेक मापदण्ड गुणात्मक होते है तथा ऑब्जेक्टिव न होने के कारण, वर्तमान में अपनी प्रासंगिकता खो रहे है। इसके अतिरिक्त वानस्पतिक औषधीयों के नियमों में, दवाओं के प्राथमिक एवं निर्माण स्तर पर मानकीकरण, फार्माकोविजिलन्स, आयुर्वेद दवाओं की सुरक्षा एवं प्रभावकारिता का अध्ययन आदि में कमियाँ आयुर्वेद की नीतियों को इनके मूल रूप में कार्यान्वित करने में बाधक है।