Contribution of world health organization in the global acceptance of Ayurveda

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ABSTRACT

Amongst the mandates of United Nations, health of mankind is the thrust area of UN through World Health Organization (WHO). Planning and execution of policies for mainstreaming of traditional medicines (TRM) of respective countries along with conventional system of medicine (allopathy), first in the country of origin followed by the international arena, is the priority agenda of operations of WHO. Within Indian context, WHO accorded prime focus to Ayurveda in its activities related to TRM. Sponsorship and encouragement of studies substantiating parameters of standardization, safety and efficacy of herbal medicines of Ayurveda are under chief consideration of WHO. In this review, several guidelines of WHO are summarized. Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH), Central Council of Research in Ayurveda and Siddha and numerous other collaborative centers of WHO in India are assigned with several Appraisal Project Work (APW) and Direct Financial Cooperation (DFC) projects that will strengthen Ayurveda as evidence-based medicine for its global acceptance. Implementation of pharmacovigilance program in Ayurveda, publication of documents for rational use and initiatives to prepare consumer guidelines for appropriate use of Ayurvedic medicines are some other contributions of WHO toward advancement of Ayurveda at national as well as global level. Here, we suggest further exploration, interaction and interpretation of traditional knowledge in the light of contemporary core sciences and biomedical sciences that can pave the way for accreditation of Ayurveda worldwide as an established system of medicine.

Key words: Ayurveda, efficacy, standardization, safety, traditional medicine

INTRODUCTION

World Health Organization (WHO) realized at Alma Ata in 1978 the role of traditional, alternative and complementary systems of medicine in the healthcare sectors of both developing and the developed nations with the slogan of "Health for All". Later, this issue has been globally addressed by the Traditional Medicine Program of WHO on several perspectives ranging from cultivation of herbs, manufacturing, dispensing, to preparation of guidelines

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for common masses in TM.

As per definition, "Traditional medicine is the knowledge, skills and practices of holistic healthcare, recognized and accepted for its role in the maintenance of health and the treatment of diseases. It is based on indigenous theories, beliefs and experiences that are passed on from generation to generation".^[1]

Ayurveda [traditional medicine (TRM) of India as per WHO], the holistic science of medicine, as practised and utilized by Indians at large since centuries, is getting global at present by virtue of its qualitative strength, essential elements of health and important clues for consistent functioning of life. Ayurveda is basically more oriented toward the management of lifestyle disorders which are in prominence due to stress-related phenomena and some other reasons among certain age groups in the society. Worldwide recognition of academic courses in Ayurveda is an additional accreditation of the establishment of wellness centers in general and its therapeutics value as a system of medicine in particular.

WHO has a mandate of United Nations Organization to promote health programs of every member country

and is continuously functioning in this area of service to humanity. This review summarizes the efforts of WHO in advancement of Ayurvedic system of medicine with a futuristic approach.

AYURVEDIC ASTUTENESS

Classical connotation

As per Charak Samhita, the main aim of Ayurveda has been described as "Ayurveda not merely being a system of medicine, but a way of life". Its objective is to accomplish physical, mental, social and spiritual well-being by adopting preventive and promotive approaches as well as treating disease with a holistic approach. [2] Definition of health as per Sushruta Samhita is "He/she in whom, the dosas (body humour), agni (digestive powers), dhatus (tissues), malas (waste product) and their activities are normal, his/her soul, sense organs and mind are calm and clear, is called 'Svastha' (healthy person)". [3] This basic intrinsic worth of Ayurveda therapy is awarding an excellent health status to its users. These descriptions of Ayurveda have covered basic philosophy of health along with all fundamentals of pharmaceutics and therapeutics. Classical books of Ayurveda dealing with these measures of holistic healthcare are described in the First Schedule of Drugs and Cosmetics Act, 1940, as authoritative text books of Ayurveda for several purposes, especially for licensing of Ayurvedic medicines.[4]

Augmentative Ayurveda

The eighth decade of 20th century witnessed third upsurge in the popularity of Ayurveda among Westerners. The first few attempts to foster Ayurveda in 1920s and 1940s failed to sustain on account of the discovery of antibiotics like sulfa drugs and penicillins. But once again due to lack of cure for chronic diseases and side effects of conventional medicines, developed countries started looking toward Ayurveda for treatments to restore wellness of their citizens.^[5]

Moreover, modern medicine is mostly governed by a demand for evidence-based practice and biomedical research increasingly moves toward molecular approaches in the search for new treatments. However, public preferences are moving in a different direction where science is not the sole starting point for decision making. Concerns over side effects of synthetic drugs and a need for more humanistic management of illnesses have led majority of the people in most industrialized nations to move toward traditional and complementary medicines (CM). There is an economic aspect to this trend too since Americans and Australians typically pay out of pockets for CM services. Americans spend more out of pocket on CM than on all prescription drugs. Major American medical insurers now routinely cover complementary

medical services, a development which is emerging in Britain as well.^[6]

So, Ayurveda is receiving momentum as an effective alternative to the conventional system of medicine by virtue of its systematic approach to cure and prevent ailments using natural resources. However, previously, there were irreconcilable conflicts between the mechanist and reductionist approaches of modern medicine and dialectic and holistic approaches of TRM, and between modern medicines' analytical approach to arriving at conclusions and TRM's method of comprehensive observation. But the prospects of interface seem brighter now since the biomedicine has progressed from the cellular to the molecular level. The combined analytical synthetic methodology is replacing the purely analytical methodology in the medical sciences and the biomedical model is being transformed into a bio-psycho-sociomedical model, developments that are bound to facilitate interface and harmonization of these two system of medicines.[7] Ayurveda too is not away from this new trend.[8]

In India, Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) in the Ministry of Health and Family Welfare has been officially accorded with the responsibility of undertaking all activities related to production, development, quality assurance and standardization of these medicines and to disseminate the guidelines for production of raw material used in Ayurvedic Siddha and Unani medicines.

[9] Apart from this, many individuals and organizations such as Banaras Hindu University, Gujarat Ayurveda University, National Institute of Ayurveda and, most recently, Institute of Ayurveda and Integrative Medicine are promoting Ayurveda on scientific lines which may prove to be a boon for its global acceptance. [10,11]

STRENGTHENING OF TRADITIONAL MEDICINE BY WORLD HEALTH ORGANIZATION

WHO is directing and coordinating with health authorities in 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]

Policy planning

To accomplish its duties regarding health through incorporation and strengthening of TRM, in 2003, at the 56th Session of the WHO Regional Committee for South-East Asia, member states requested for inter-country

collaboration to develop and enhance health research efforts, human resources and exchange of information in TRM. They decided that measures should be taken to protect, preserve and improve traditional knowledge and medicinal plant resources for sustainable development of TRM, and that there was a need to promote the safety and efficacy of drugs belonging to TRM. Yet again 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.^[13]

In compliance with this resolution in which the role of TRM has been duly appreciated in the service of humanity, WHO Strategy for Traditional Medicine (2002–2005, 2005–2010) has been framed which acknowledges the widespread use of TM, not merely in the region but worldwide. World Health Assembly resolution (WHA 56.31) assigned specific roles/activities for countries and WHO, which form the basis of this working group for the strengthening of TM globally and for Ayurveda in the Indian context.

The role for WHO has been identified which is as follows: [14]

- To facilitate the efforts of interested member states in formulating national policies and regulations on traditional, complementary and alternative medicine, and promoting the exchange of information and collaboration on national policy and regulation of TRM among member states;
- To provide technical support for the development of methodologies to monitor or ensure product quality, efficacy and safety, preparation of guidelines, and promotion of exchange of information; and
- 3. To provide technical support to member states in defining indications for the treatment of diseases and conditions by means of TM.

Execution elegance

In 2003, the WHO Regional Committee for South-East Asia adopted a resolution (SEA/RC56/R6) urging the establishment of a regional task force on TRM to review regularly the regional situation and facilitate the

development of national and regional strategies and policies on traditional systems of medicine. The objective of these guidelines is to propose to member states a framework for facilitating the regulation of herbal medicines/products used in TM. The proposed framework, which has a regional perspective, should help accelerate the establishment of appropriate mechanisms for registration and regulation of herbal medicines within SEAR, based on criteria for safety of use, therapeutic efficacy, quality control and pharmacovigilance.^[15]

With this broad perspective, further consultation was undertaken by WHO, with an attempt to bring together scholars from different disciplines who had examined key issues in both the provision of healthcare to the human population and in the protection of public health through TM, thereby throwing new light on current problems. In these consultations, it was resolved that representatives of various countries would present their country profile on TM under the following headings:^[16]

- Policy
- Safety, efficacy and quality
- Access
- Rational use

SPECIFIC STRATEGIES

Considering all these issues, WHO is mainstreaming TRM in health system with definite strategies that cover each and every potential of TRM. [Table 1] TRM involve not only the use of herbal medicines, but also the use of animal parts and minerals. As herbal medicines are the most widely used of the three, and as other types of materials involve other complex factors (in pharmaceutical processes), this review focuses on herbal medicines and on Ayurveda in the Indian scenario. Certain contributory steps of WHO are mentioned below.

Rules for regulation of herbal medicine

WHO has always 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. Since the dawn of human civilization in this geographical part of the world, viz.,

Table 1: Specific strategies of WHO for promotion of TRM

- o1- Rules for regulation of Herbal Medicine
- 02- Criteria for classification of Herbal Medicines
- 03- Scheme for standardisation of Herbal Medicine
- 04- Reason for rational use of Herbal Medicine
- 05- Projection of pharmacovigilance programme for Herbal Medicine
- o6- Commencement of consumer guidelines of Herbal Medicines
- o7- Fellowship at Collaborative Centres

Indian subcontinent, Ayurveda has got the distinction of being the first indigenous medical system. Therefore, 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, [17] 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. [18]

Criteria for classification of herbal medicines

As per the WHO guidelines, for all practical purposes, herbal medicines can be classified into four categories, based on their origin, evolution and the forms of current usage. While these are not always mutually exclusive, these categories have sufficient distinguishing features for a constructive examination of the ways in which safety, efficacy and quality can be determined and improved.^[19]

Category 1: Indigenous herbal medicines

This category of herbal medicines is historically used in the folklore of a local community or region and is very well known through ages by the local population in terms of its composition, treatment and dosage. Detailed scientific information on this category of TRM, which also includes folk medicines, may or may not be available. It can be used freely by the local community or in the local region.

Category 2: Herbal medicines in systems

Medicines in this category have been used for a long time and are well documented with their special theories and concepts, and are duly accepted by the respective countries. For example, Ayurveda, Unani and Siddha fall into this category of TRM.

Category 3: Modified herbal medicines

These are herbal medicines as described above in categories 1 and 2, except that they have been modified in some way or the other with respect to their shape, dosage form, mode of administration, ingredients, methods of preparation or medical indications. They have to meet the national regulatory requirements of safety and efficacy of herbal medicines.

Category 4: Imported products with a herbal medicine base

This category covers all imported herbal medicines including raw materials 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 also

need to meet the requirements of safety and efficacy of herbal medicines in the recipient country.

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.^[20]

To comply with the spirit of WHO regulations, Department of AYUSH, Government of India, took several measures to standardize Ayurvedic 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, which was highly appreciated by those concerned with this subject. [21] The second workshop in October 2001 was organized 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.[22]

In addition to these activities, WHO also impressed upon Central Council of Research in Ayurveda and Siddha (CCRAS) to prepare HPTLC-Fingerprint atlas of Ayurvedic single plant drugs which are mentioned in Ayurvedic Pharmacopoeia Vol. III and IV as a published document for standardization purposes.^[23]

Reason for rational use of herbal medicine

Rational use of medicines is essential in today's situation, especially in a country like India, where there is a wide disparity in the availability of medicines between cities and villages. The concept of rational use of medicines has not yet fully penetrated into the minds of healthcare providers

or the public, and as a result there is large scale irrationality seen in availability and prescription of medicines.^[24]

Therefore, Department of AYUSH has launched a few projects in association with WHO under APW and DFC programs to address this issue, and several documents are being prepared which will promote rational use of herbal medicines of Ayurveda. Institute of Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurved University, as well as WHO country office have published two documents which are serving the purpose. [25,26] But still much more needs to be done in this arena.

Projection of pharmacovigilance program for herbal medicine

The recommended approach of WHO is to include herbal medicines in the existing national pharmacovigilance programs. However, in view of the unique characteristics of the Ayurvedic medicines, there are several technical issues that need to be addressed along with basic fundamentals of Ayurveda if adequate and effective monitoring is to be done. Any pharmacovigilance program should identify the inherent challenges faced in monitoring the safety of herbal medicines effectively and propose adequate measures for overcoming them. Special attention has to be paid toward the reporting system for adverse reactions of herbal medicines and to the causality analysis of the reported adverse reactions.^[27]

The increasing international acceptance of Ayurveda has led the regulators of Department of AYUSH to implement a similar program for Ayurveda, particularly after some medical professionals, scientists and citizens reported adverse reactions upon consuming Ayurvedic formulations. Hence, the WHO persuaded the Department of AYUSH, Ministry of Health and Family Welfare, Government of India, to implement a comprehensive pharmacovigilance program for Ayurveda, as a means to ensuring the safety and efficacy of Ayurvedic medicines which was launched nationally on 29 September 2008. This program is running successfully at present.^[28]

Commencement of consumer guidelines of herbal medicines

Most recently, WHO country office agreed to sponsor a short-term project meant to prepare consumer guidelines for appropriate use of Ayurvedic medicines on recommendations of the Department of AYUSH, Government of India.^[29]

Fellowship at collaborative centers

WHO believes that human resource associated with TRM must be skilled enough to perceive multidisciplinary knowledge of the existing era. The organization has identified some institutions of excellence as collaborative centers for training of personnel in TM all across the world. Every year, good number of selected health professionals and administrators of TM are sponsored for training at international level.

DISCUSSION

At present, traditional, alternative and complementary systems of medicines account for a major part of the healthcare being provided worldwide. However, little attention has been paid to understand the current scenario in which dynamism in the choice (or demand) and utilization of these systems for healthcare exists. Societies, especially those of the developing countries with limited resources, could significantly improve the healthcare means at their disposal by exploring the scope of these systems of traditional medicine.^[30]

Demand for herbal products worldwide 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. 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. These data are in consonance with the hype surrounding the international potential for Ayurvedic products. It seems that Ayurveda is undergoing a phase of resurgence and revival "in the world" similar to the one "at home".^[31]

However, all advanced approaches for TRM in general and Ayurveda in particular may be fruitful, meaningful and purposeful only if few more issues as discussed below could be addressed by the concerned authorities of health.

Safety status

Traditional medicines, an age-old heritage inherited from years of experience, are bound to contain some valuable elements but inevitably they also contain some ingredients which are no longer useful. It is therefore necessary to carry out scientific research in order to separate the grain from the chaff and to develop and improve the useful elements.^[32]

Therefore, safety is a primary concern regarding traditional and complementary therapies. There are two aspects of safety evaluation: First, to ensure that the right quality of material and appropriate processes are used from source till marketing and secondly ensuring that there is no contamination, adulteration or spiking [33]

Safety and efficacy studies of Ayurvedic medicines presently going on may overcome the lacunae indicated in the observations made under WHO global survey on the national policy and regulation of TM, which 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.

Interface between core science and modern medicine

Professional healthcare providers, folk healers, and common masses possess knowledge about diseases, their causes and their remedies. Common medical knowledge is shared by regionally formed groups of professional people who study similar disease categories (nosology), disease explanations (aetiology) and treatments (therapy) so as to evolve a common medical culture or ethos (outlook).

Such expert opinions and layman's perspectives on health, disease and the body are embedded in the concept of cosmovision – a wider worldview. Therefore, many current medical theories that are current in today's world may be seen as different perspectives in future. In other words, all medical systems of the world have their own unique way of understanding and treating the signs of a disease. Both experts and laymen of any medical culture may represent any one out of many possible interpretations of disease. [34]

Taking into consideration the above-mentioned facts, one may elucidate an exact explanation of theories of traditional and conventional medicines which are promising and may pave way for greater achievements in the days to come. An interesting example of this is a schematic understanding of the relationship between modern medicine, modern science and traditional medicine, called the Golden Triangle Partnership concept evolved by Professor Mashelkar, former Director General of the Council of Scientific and Industrial Research (CSIR). This Golden Triangle Scheme aims to have AYUSH, CSIR and Indian Council of Medical Research (ICMR) in a mutual partnership to bring safe, effective and standardized Ayurvedic Products for identified disease conditions.^[35]

WHO, INDIA AND AYURVEDA – A REASONABLE ADVANCEMENT

For the last few decades, WHO has been maintaining a policy to encourage TRM of a country to be in the mainstream of healthcare system of that particular nation. 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. But due to some unavoidable technical and administrative reasons, this scheme could not be implemented in its true spirit. Taking lessons from these experiences, the Government of India established a separate Department of AYUSH in 1995 to undertake full-fledged development of traditional system of medicines in India. Thereafter, WHO moved ahead with several programs for global acceptance of Ayurveda, which include preparation of guidelines for safe use of Ayurvedic medicines, parameters and measures for standardization of Ayurvedic medicines and many more substantial measures to promote the system of Ayurveda.

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. [36] This classification is in addition to the classification of Ayurvedic medicines as "Classical and Patent proprietary Ayurvedic medicines" as defined under section 3(a) and (h), respectively.[37] 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. For standard production of Ayurvedic medicines, WHO sponsored many Direct Financial Cooperative (DFC) projects in 2001 at Pharmacopeial Laboratory of Indian Medicine, projects on safety profile of Ayurvedic medicines in 2007 at Banaras Hindu University and WHO sponsored program for the planning of pharmacovigilance program in 2008 at Gujarat Ayurveda 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 Ayurvedic system of medicine. Further, Ayurvedic Clinical Trial project might be a sustainable program for evidence-based data generation of Ayurvedic classical medicines for certain diseases, [38] whereas data available on Ayush Research Portal and in other research papers ensures safety of Ayurvedic medicines.[39-41] In all these programs of Department of AYUSH, WHO is cooperating as an academic associate and also providing some logistic support.

Moreover, Ayurveda, based on genuine fundamentals, has the longest uninterrupted tradition of healthcare practice, and its holistic approach to healthcare management emphasizes upon disease prevention and health promotion. If it opens up to incorporate emerging new knowledge into mainstream Ayurveda while maintaining fidelity to Ayurvedic fundamentals, it will certainly provide a broadbased opportunity to address the majority of the problems that have emerged from the advent of new diseases and healthcare related issues.^[42]

As such, the final inference is that principles of common sense, logic and clarity provide an ageless quality to Ayurveda knowledge for healthcare. Ayurvedic institutions including teachers, students and practitioners are in despair and are encountering a crisis similar to that faced by contemporary Western medicine compatriots. To cope up with this situation, *Vaidya*-scientists are a need of the hour, which is a scholarly group of change agents, who are well versed in the richness of the Ayurveda classics as well as with the details and insights of modern biology. [43]

CONCLUSION

In light of the worldwide changing healthcare environment, it has become abundantly clear that there is need for a comprehensive policy review of traditional, complementary and alternative systems of medicine and for individual nations to share information about their experiences with policy, legislation, regulation, research, development, financing, training and professional development, quality control and safety regulations of these systems of medicine.

Political commitment and the decision-making capability of the governments to define the contours of a TRM/CM policy and the activities that need to be undertaken for achieving these national objectives is required. A national policy is an expression of goals for improving the role of TRM/CM in national healthcare delivery system, ensuring the creation of regulatory and legal mechanism for promoting and maintaining good practice of effective TRM/CM therapies, as well as stimulating research and educational efforts. [44] Among TRMs, unique pro-nature vision of Ayurveda is gaining global relevance. This new upsurge of interest in Ayurveda and its rapidly increasing public utilization has given rise to many newer issues and challenges. [45,46]

Essence of WHO resolutions for development and mainstreaming TRM/CM are reasonably applicable to the Union and state governments of India, so as to frame more concrete policies and their execution through every sincere stakeholder of TRM (Ayurveda) and to organize and recognize Ayurveda as an authentic system of medicine worldwide.

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