



World Federation of Chinese Medicine

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Introduction of society member

Training and Research Center of Human and Medical Sciences

The Australian Government Funded TCM Endangered Species Certification Scheme

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The Convention on the International Trade in Endangered Species (CITES) prohibits the illegal international trade in endangered species of wildlife fauna and flora. The historical use of some endangered species in Chinese medicine has resulted in significant bad publicity for the Chinese medicine profession even if these substances are not used by qualified and ethical practitioners.

The Traditional Chinese Medicine Endangered Species Certification Scheme (ESCS) is an innovative program funded by the Australian Government Department of the Environment, Water, Heritage and the Arts (DEWHA) and administered by the Australian Acupuncture and Chinese Medicine Association Ltd (AACMA).

The aims of the scheme are to:

- raise the level of awareness, education and compliance with the legal requirements associated with international wildlife trade;
- recognise professionals and traders involved in the ethical research, recommendation, prescription, supply, export or import of traditional Chinese medicines;
- provide a credible mechanism to acknowledge and support professionals and traders to publicly promote that they do not use or support the use of Chinese medicines containing illegally traded wildlife ingredients.

Participation in the certification system is open to TCM practitioners, traders and other organisations and individuals involved in the research, recommendation, prescription, supply, and import or export of traditional Chinese medicines.

Access to restricted Chinese herbs and the implications of a national registration scheme

Peter Gigante

Consistent with its responsibilities the Chinese Medicine Registration Board of Victoria (CMR Board) monitors the practice of Chinese medicine by Chinese herbal medicine practitioners, Chinese herbal dispensers and acupuncturists. Since 2002, 1695 practitioners have applied for registration. Currently there are 1015 practitioners registered, 640 in the division of Chinese herbal medicine.

Treating people with traditional herbs is an important aspect of the practice of Chinese medicine. Currently in Victoria – the only state where Chinese medicine is regulated – registered Chinese herbal medicine practitioners and herbal dispensers are limited in their ability to prescribe and dispense some traditional herbs.

Under the Victorian Poisons List (Schedules 2-9 are adopted automatically by reference from the national Standard for Uniform Scheduling of Drugs and Poisons), it is currently illegal for a Chinese herbal medicine practitioner or herbal dispenser to ‘obtain, possess, use, sell or supply’ certain Chinese herbs listed in the various schedules of the list. Similar regulations apply in other states and territories.

With the passage of the Victorian Chinese Medicine Registration Act 2000¹, a new regulatory scheme was established, requiring any practitioner or dispenser who offers Chinese herbal medicine services to the public of Victoria to be registered with the CMR Board. This Act also made amendments to the Victorian Drugs Poisons and Controlled Substances Act 1981 (DPCS Act) to establish a mechanism for suitably trained and endorsed Chinese medicine practitioners or dispensers to legally prescribe and dispense potentially toxic Chinese herbs from an identified list.

The CMR Board has submitted to the Victorian government that certain arrangements for some currently restricted herbs are sufficient to support safe prescribing practice for the benefit of the community. The key features of the proposed system in this submission include:

- careful selection of the appropriate herb
- proper education and training
- robust administrative process for endorsement
- quality-assurance systems
- supplier controls
- practice guidelines and monitoring and disciplinary arrangements

The selection criteria applied by the CMR Board in selecting the herbs (S1 herbs) are herbs that:

- are known to potentially produce toxic effects
- have a well-established therapeutic use
- do not have a satisfactory substitute herb
- can be used safely by those properly trained

The Chinese herbs now proposed for inclusion in S1 are ban bian lian, zhi fu zi and ma huang. These are established traditional Chinese herbal medicines; each has significant therapeutic value and there are no satisfactory substitutes. Ban bian lian is restricted due to the potential toxic effects of a known chemical constituent (S2 Lobeline), however as a raw herb it has a sound safety profile. Fu zi has demonstrated toxic effect when it is inappropriately processed or used as a raw herb associated with the role of aconitine (S2 and S4). In this document the term zhi fu zi is used to specify the prepared herb.

The CMR Board recommends that the herb to be inserted into S1 be termed zhi fu zi. Ma huang has clear contraindications and dosage restrictions due to the known chemicals such as ephedrine and pseudoephedrine.

Over the past several years, the CMR Board has assessed the risks of these three herbs. It is now satisfied that, with proper safeguards in place, the benefits outweigh the risks. The benefit is increased efficacy of treatment for a widespread range of common conditions.

The CMR Board has conducted extensive research to prepare detailed herbal profiles. The herbs proposed are well described in Chinese medicine classics, and are used and recommended widely. Analyses of adverse events reported in association with each herb indicates widespread and documented use over a long period of time, ongoing use in contemporary Chinese medicine practice, and very few adverse reactions. In the case of ma huang, for example, most adverse events reported in the countries outside China were due to nontraditional, long-term or overdose intake of ephedra containing dietary supplements for weight loss or energy enhancement.

Education and training

Proposed standards for education and training include the following.

- Phytochemistry and pharmaceuticals
- Dispensing Chinese medicinal substances: theory and practice
- Guidelines herbal dispensing
- Guidelines herbal prescribing
- Herb-specific training

For each individual herb the training must cover:

- safe responsible prescribing
- appropriate indications for and use of the herb
- known and potential adverse reactions
- inappropriate use of the herb
- regulatory requirements
- instructions to patients
- adverse event reporting procedures and requirements
- dispensary management of S1 herbs (herb specific)

Endorsement processes

Only registered Chinese herbal medicine practitioners and dispensers who have successfully completed the required specific training for S1 herbs can be endorsed and these practitioners will be subject to monitoring.

A code of practice for suppliers covers:

- staffing, expertise and supervision
- analytical and testing services
- requirements for suppliers in Australia
- batch documentation
- record keeping
- labeling and storage
- supply to authorized end-users
- condition of herbs
- packaging and labeling
- providing information
- requirements for a ledger and supporting documentation
- requirement to notify the CMR Board
- licensing requirements.

The CMR Board proposes to limit registered persons to using CMR Board approved suppliers who have agreed to abide by the abovementioned code of

practice.

Monitoring and disciplinary processes

The existing authority of the CMR Board as a statutory authority ensures effective arrangements to monitor the practices of registered persons via investigation of notifications. Due to the somewhat reactive nature of this mechanism, the CMR Board proposes an auditing system by CMR Board inspectors on an unannounced basis to ensure compliance.

Potential risks

Herbal profiles outline the risks and benefits associated with each herb. Each profile has been thoroughly researched with extensive literature reviews.

Analyses of adverse events reported in association with each herb have been undertaken. These herbs have had widespread and documented use over a long period of time, and ongoing use in contemporary Chinese medicine practice, and there have been few adverse reactions.

The CMR Board's research has confirmed that the benefits outweigh the risks in relation to the proposed herbs.

A range of risks have been identified, by the CMR Board when researching the herbal profiles, in terms of the supply, prescribing and dispensing of Chinese herbs including:

- clinical risks, such as toxicity, interaction with other prescribed medicine, incorrect preparation and allergic reaction
- poor quality-control systems leading to inaccurate labeling, misclassification of quality, contamination, substitution or adulteration
- poor standards in the labeling of herbs in terms of grade, source or time of harvesting, whether they are harvested from the wild or farmed, their storage history and age

Managing risk

The CMR Board proposes to put in place a system of good practice and quality assurance for the prescribing and dispensing of scheduled herbs that ensures:

- proper prescribing and dispensing practices through rigorous and robust training, endorsement and monitoring of practitioners and dispensers
- appropriate tracking and monitoring of the sale and supply of the S1 herbs

- an effective system for notification of adverse events
- effective procedures to prevent diversion of herbs for illicit use or abuse

Key elements of the CMR Board's proposed quality assurance system are:

- CMR Board-approved or delivered training of practitioners, dispensers and CMR Board-approved suppliers
- publication of practitioner and dispenser guidelines, and a CMR Board approved suppliers' code of practice
- public education materials and strategies
- monitoring of compliance with CMR Board training and practice requirements
- receipt and investigation of complaints and conduct of disciplinary processes where necessary.

Quality-assurance testing and assaying

The following quality-assurance testing have been recommended to ensure the consistent quality of herbs:

- identification tests to confirm the presence of active constituents and ensure batch-to-batch reproducibility
- assay methods to quantify active constituents, or chromatographic fingerprinting, where active ingredients have not been identified.

The CMR Board anticipates that inspection and batch testing before supply is the most practical system to adopt, given the absence of sufficient controls in the supply chain. The CMR Board acknowledges that there are significant challenges involved in establishing such a testing regime and in determining the standards that might be applied for testing of each herb.

Need for quality-control systems

Good quality-control systems are important to ensure the quality and safety of all Chinese herbs and, in particular, to assure practitioners, dispensers and end-users, of the identity and quality of the herbs. For potentially toxic herbs, such as those proposed for inclusion in S1 of the Victorian Poisons List, it is essential that good quality-control systems are in place to support accurate prescribing and dispensing by practitioners.

Schedule 1 herbs must be:

- accurately identified and labeled
- of known medicinal quality and strength

- free from contamination by heavy metals, microbial toxins, micro-organisms, pesticides, fumigation agents and radioactivity inadvertent or deliberate substitution of other herbs adulteration with pharmaceutical drugs.

These risks have been identified these as potential problems related to the handling and manufacturing processes of herbal medicines used in Australia.

Correct identification and labeling of herbs

Standards for the identification and labeling of herbs are necessary to assist practitioners or dispensers (and their patients) to be confident that the packet contains what it says it contains. Correct identification and labeling allows toxic herbs to be distinguished from nontoxic herbs that might otherwise be confused.

Standardization of herbs

Herbs may vary due to differences in grade, source or time of harvesting, whether they are harvested from the wild or farmed their storage history and age. This variability can affect the medicinal quality of herbs. A lack of standardization can lead to subpotent or superpotent therapeutic preparations, which may result in the compromise or failure of a herbal treatment. This can place the patient at risk of an adverse reaction.

Practitioners also need to know how long the herb can be expected to be clinically efficacious from the date it was packaged.

Board to issue guidelines for practitioners and dispensers

Under Section 118(2) of the HPR Act, the CMR Board has the power to issue guidelines in relation to standards of practice for registered Chinese medicine practitioners and herbal dispensers. Registered Chinese herbal medicine practitioners and Chinese herbal dispensers who have been granted S1 endorsement will be expected to adhere to these guidelines.

The proposed endorsement process is the principal mechanism for ensuring this risk minimization. Only registered Chinese herbal medicine practitioners and dispensers who are adequately trained will be endorsed and these practitioners will be subject to guidelines, disciplinary processes, and so on.

On balance, the CMR Board is satisfied that the benefits clearly outweigh the mitigated risks.

National Registration

The Council of Australian Governments (COAG) at its meeting in March 2008 took a major step towards improving Australia's health system by signing an Intergovernmental Agreement on the health workforce.

The new system will for the first time create a single national registration and accreditation system for the health professions. The new arrangement will help health professionals move around the country more easily, reduce red tape, provide greater safeguards for the public and promote a more flexible, responsive and sustainable health workforce. For example, the new scheme will maintain a public national register for each health profession that will ensure that a professional who has been banned from practicing in one place is unable to practice elsewhere in Australia. Currently Victoria is the only Australian state or territory with legislation that specifically regulates the practice of Chinese medicine within its jurisdiction. This was established under Victorian legislation in 2000, which was replaced by later legislation in 2005. In this time the board has approved courses, assessed qualifications, administered complaints, developed policies and guidelines and worked with other Chinese medicine stakeholders nationally and internationally, including the signing of a memorandum of understanding with SATCM in December 2005.

Chinese medicine will join the national scheme in July 2012. A National Board will be established prior to this and it is anticipated that most of the policies and guidelines of the Victorian board will be adopted, at least initially, by the new entity. Many of the challenges faced by the inaugural board in Victoria, such as "grand parenting" of existing practitioners, education and information for practitioners, assessment of existing courses, public education and political familiarization, administrative and governance requirements and migration of related regulations such as the Victorian Poisons List to national codes will be confronted over the final term of the current board and the initial term of the national board. Additionally, balanced representation across all states and development of experience in statutory governance for practitioners from other states will require additional resources and support. The Chinese Medicine Registration Board of Victoria strongly supports the move to a national registration scheme and will be endeavoring to meet these challenges in a constructive way while continuing to administer its current functions and contributing to international developments. As such it is proud to be a participant in this forum, and wishes the organizers well in meeting its goals.

International Traditional Chinese Medicine Program for Cooperation in Science and Technology

Developed and refined over the course of thousands of years by the Chinese people for use in the prevention and treatment of disease, traditional Chinese Medicine (TCM) is one of mankind's greatest treasures. It should be possible for this medical system, together with other traditional medical systems, to play an important role in the maintenance of human health and well being the world over. In order to further enhance the ability of traditional medical systems, including TCM, to serve the needs of human health and well being, Chinese government has specially initiated this "International Traditional Chinese Medicine Program for Cooperation in Science and Technology" (hereinafter referred to as the " Program").

1 Background

As society and the economy have continued to develop, and in the wake of the concurrent advances in modern science and technology, dramatic changes have taken place in the lives and living standards of people. These changes have led to differences in the types of diseases faced by health care professionals and are also leading to gradual changes in medical and therapeutic models. As the limitations of western medicine in the treatment of certain diseases and in some areas of health maintenance and well being become more apparent, the international community has come to realize that the integration of the health concepts and effective practices of traditional medicines, including TCM, with western medicine has great potential to result in the formation of new health care models. As a result, many countries and regions have increased their support for traditional medicines in terms of their development and have begun to implement regulations, standards, and marketing channels. World Health Organization (WHO) emphasizes that traditional medicine can play an important role in achieving the goal of "Health for All", and is dedicated to facilitating the integration of traditional medicine with western medicine all over the world. As a consequence, the considerable scientific significance and market potential of traditional medicines, including TCM, are gaining international attention, and there is an ever increasing global market demand for the products of these health strategies.

However, differences in culture, history, and religion from country to country, have meant that a truly western scientific understanding of TCM theory has yet to be developed and its acceptance by the international community has

been slow. Even finding a common language between TCM and western medicine or other traditional medical systems has proven difficult and is, in fact, largely lacking. In addition, research protocols for the evaluation of the safety and efficacy of TCM are more complex than those for conventional pharmaceuticals, and there are still issues with the standardization of the objectivity and reproducibility of such research. Although TCM products are sold in many countries, the post-market surveillance system already in place that is used to monitor the adverse effects of such products is less than perfect. Moreover, there is a lack of technology and methods to effectively deal with the sharing of both the enormous amount of TCM information accumulated over thousands of years as well as the volume that is and will be continuously produced from current and future research and development ? information that would be useful in helping to avoid duplication and the waste of resources. There are also problems with how to fairly share TCM intellectual property rights with all the parties concerned, and how to conduct international research, education and training in TCM. At the moment, there is no efficient way to accurately and completely disseminate TCM knowledge to the world and assure the safe and effective use of TCM. The utilization of TCM in the prevention and treatment of diseases and the maintenance of health and well being is far from fully realized, and its potential warrants further exploration.

Rapid development at the frontiers of research into the life sciences, biotechnology, information sciences, systemic sciences, etc., has led to the continuous expansion of knowledge, the emergence of a large number of databases, and the development of analytical tools and technology, which have offered new methods and approaches for use in addressing the key scientific issues surrounding the development of traditional medicines such as TCM. The resolution of these issues is likely not only to promote multidisciplinary integration and the emergence of new disciplines, but also to lead to historic changes not just in the development of biomedical and life sciences, but also to the whole of science itself. Within the context of these changes, it is obvious that those methods and approaches which facilitate the understanding of life processes and disease progression will be enriched and improved from holistic and integrating points of view.

2 Mission

The mission of the Program is:

to improve mankind's understanding of the phenomenon called life so as to promote the development of medical sciences;

to enhance the ability of traditional medicine, including TCM, to serve mankind's health and well being needs; and to promote the development of

traditional medicine industry so as to effectively reduce the socio-economic cost of maintaining human health and well being;

to promote the integration of TCM with western medicine so as to create new models of health care and health service delivery; and

to facilitate East and West communication and promote the integration of traditional and modern culture so as to increase mutual understanding between different countries and nations, leading to the harmonious development of the world.

3 Principles

3.1 To put health first

Principle 1 is to advance research on the prevention and treatment of major diseases around the world with a view to facilitating the building of a harmonious society, and improving the standard of health care.

3.2 To integrate TCM with western therapies

Principle 2 is to encourage communication between TCM and western or other traditional medicine, and to increase the scientific understanding of TCM in order to promote the integration of the effective means and practices of TCM with western and other traditional medicines.

3.3 To develop cooperation for mutual benefit

Principle 3 is to develop broad bi- or multi-lateral cooperation tailored to the health needs and natures of the participating countries in accordance with international common practices, with emphasis on both the protection of the economic interests and intellectual property of all parties concerned as well as facilitation of mutual benefit from cooperation.

3.4 To share information and resources

Principle 4 is to enhance communication and cooperation on the development of regulations for governing and the protocols for evaluating such traditional medicines as TCM, in order to promote the sharing of information and resources and to assure their rational and widespread use.

4 Goals

The goals of the Program are:

to elucidate mechanisms underlying selected TCM products and practices and to promote the understanding and recognition of TCM through international science and technology cooperation utilizing TCM as a model of traditional medicines;

to research and develop safe and efficacious TCM products of consistent quality and high market demands so as to further improve the safety and efficacy of TCM as a whole and enhance the ability of TCM to serve the needs of human health and well being;

to prepare technical guidance on quality assurance and regulatory requirements for TCM and to stipulate international standards and protocols, so as to meet the needs of governments interested in the development and implementation of regulations and national policies on traditional medicines including TCM;

to encourage health care systems in different countries and regions to integrate TCM with other medicine, so as to enhance the availability, accessibility and affordability of TCM;

to support the training of talented professionals in various countries and regions, especially high-level native professionals. These people will be capable of accurately disseminating TCM information worldwide to consumers and practitioners to help them make better-informed decisions; and

to promote the entry of TCM as well as other traditional medicines into the mainstream international medical care system, ensuring that TCM is able to play a role in meeting the health needs of mankind.

5 Priorities and major tasks

5.1 Clinical studies

The task is to utilize methods and technology from various disciplines such as epidemiology, evidence-based medicine and information technology, to conduct clinical studies on diagnostic and treatment procedures, to evaluate the diagnostic standards used by traditional medicines for evaluating a number of commonly seen major chronic and refractory diseases, including neuropsychosis, cardiovascular and cerebrovascular diseases, tumors, autoimmune diseases, malaria, AIDS, against which certain TCM practices have been demonstrated to have a unique advantage over western medical practices; to establish means and standards for the clinical evaluation of

selected TCM practices so as to enable them to be recognized and accepted by the international community and to promote the use of these effective practices.

Tailored to the diverse health needs and requirements of different countries and regions, studies are to be conducted on the effective application of selected practices such as acupuncture, massage and Qi-Gong in the prevention of chronic diseases and disease and to work toward elucidating the mechanisms underlying these practices through modern scientific technology. In this way, the ability of TCM to prevent diseases and maintain health and well being will be enhanced and will better enable it to serve modern society's increasing demands on the health care system.

5.2 Research and development of TCM products

In consideration of the different health needs and characteristics of different countries and regions, studies will be conducted using internationally accepted protocols utilized by western medicine and target products developed out of the theories and practices of TCM. Such studies will be conducted using the highest standards of rigorous science to examine TCM resources accumulated over thousands of years in order to facilitate the development of safe and efficacious TCM products of consistent quality and high market demand for use in the prevention and treatment of certain common major and refractory diseases and to thereof increase the contribution TCM makes to human health care.

With regard to some of the issues surrounding the development of TCM products including the complexity of the ingredients, difficulties with quality control, the length of the production chain and the complexity of the manufacturing process, it will be a high priority to introduce and/or develop new technology and equipment applicable to the manufacture of TCM products. Pharmaceutical companies will be encouraged to invest in the set-up of R&D centers, manufacturing or cultivating bases and international sales departments, with a view to enhancing the availability, accessibility and affordability of TCM internationally.

5.3 Research into international standards and protocols for TCM.

With an eye towards scientific and technological progress, the Program is to foster the establishment of standards and protocols for TCM, created in part by drawing on the experience and lessons learned from previous attempts to formulate standards and protocols for TCM or other traditional medicines. Such standards and protocols will be adopted for the implementation of tests and trials concerned with the diagnosis and treatment of disease, the

evaluation of therapeutic efficacy, pharmacological and safety evaluations, quality control, etc., in the areas of medical practice, education, R&D and manufacturing. They must not only be subject to the recognition and acceptance of the international community but must also conform to the unique character of TCM. In addition, the Program will also support the creation of multiple language standard translations for TCM terminology as well as the preparation of technical guidance on international TCM product registration procedures. It will furthermore promote the gradual establishment of international TCM certification centers as a way of developing regulatory and quality assurance systems for use as reference standards in international TCM markets and to ensure its safe and effective use.

5.4 Infrastructure support networks

The Program will focus on the promotion of collaborative ventures between international universities and colleges, research institutions, hospitals and pharmaceutical companies with a view to supporting the establishment of bi- or multi-lateral TCM collaborative centers of international excellence, including collaborative centers for clinical studies, safety evaluation and R&D, as well as other relevant collaborative centers/laboratories. Such centers will be tailored to the interests of governments and the academic community of the various countries and regions in question. These infrastructure networks are intended to focus research on clinical outcomes, the mechanisms underlying effective practices, new TCM products, as well as into the development of standards and methods, all of which will be subject to both recognition and acceptance by the international academic community as well as continuing to conform to the unique character of TCM.

5.5 Dissemination of TCM information and knowledge

The Program aims to foster the establishment of a multi-channel, multi-level, multi-model system for the international dissemination of TCM information and knowledge. The main tasks of international dissemination include:

Establishing TCM related internationally recognized scientific journals;

Creating regional multilingual TCM information clearinghouses containing information on traditional medicines related to research, medical practices, laws and regulations, education and sales;

Translating, editing and publishing textbooks, as well as ancient and modern works related to TCM;

Conducting international TCM educational and medical activities as well as strengthening public education and the cultural advocacy of TCM;

Promoting the use of appropriate TCM practices and products;

Supporting exchange and cooperation between TCM associations and other academic institutions/organizations, e.g. associations of traditional indigenous medicine, offering to the international community a completely accurate, scientific and authoritative channel through which to understand TCM.

5.6 Human resource training

The Program aims to encourage the training of professionals in the new paradigm of TCM in fields related to medical practice, education, R&D, manufacturing, sales and management and will integrate both modern and traditional medical experience in regulations, medical practices, education, R&D and the manufacturing of TCM products. Training will be especially focused on high-level native professionals from those countries and regions where professionals in traditional medicine are largely deficient in an effort to enhance the development of a local traditional medicine practice.

6 Organization and Management

6.1 Establishing a Council for the Program

On behalf of the Chinese government, the Ministry of Science and Technology of the People's Republic of China shall collaborate with foreign governments and international organizations concerned to implement this Program and shall establish a Council for the Program to facilitate the initiation of a multi-lateral cooperative mechanism.

The Ministry of Science and Technology of the People's Republic of China shall work towards organizing the invitation of well-known experts in the field of TCM or other relevant fields and the establishment of an international expert committee. The latter shall be responsible for detailing the priorities, tasks and patterns of cooperation overseen by this Program for the Council's consideration.

6.2 Establishing special funds

The Chinese government shall provide funds for the initiation of this Program, and establish special funds for the implementation of the Program accordingly. At the same time, attempts shall be made to draw on the resources foreign

governments have set aside for research into traditional medicines to jointly manage and implement this Program. Multinational pharmaceutical companies will also be approached and encouraged to invest in the Program.

Incorporation of Chinese Medicine into the Mainstream

Health System in Hong Kong

Western medicine has been the mainstream of Hong Kong's healthcare system while Chinese medicine has also played an important role in the areas of disease prevention, treatment and health maintenance. In accordance with the Basic Law, the Government of the Hong Kong Special Administrative Region formulated the policy for the development of Chinese medicine in Hong Kong. With the concerted efforts of the Chinese medicine profession and trade, the academia, the community and the Government, we have enhanced public acceptance of Chinese medicine through implementing a system for regulation of the practice and trading of Chinese medicine; setting up Chinese medicine clinics in public sector; supporting training and research; and promoting the standardization of Chinese medicine.

Traditional Medicine in Moldova

Victoria Ceres/Oleg Pascal

The types of traditional medicine (alternative and complementary medicine), recognized by medical science and classified as medical specialties in Republic of Moldova, which are officially approved by the Ministry of Health and the Government for application in medical practice and are published in the State Register of new medical specialties:

Acupuncture

Homeopathy

Phytotherapy (Herbal medicine)

The countries of Europe can be divided into three categories, on the basis of their broad legislative approaches to TCAM practice. Republic of Moldova belongs to the first category corresponding to a monopolistic system, which states that only qualified and licensed allopathic physicians may practice TCAM.

The Ministry, following the WHO recommendations, has taken a number of organizational measures to support, develop and integrate traditional medicine into the country's public health system:

In 1994, acupuncture has been officially recognized as a medical specialty and regulated by order 5p. § 1 "The acupuncture service organization in Moldova" by Minister of Health, academician Gheorghe Ghidirim;

Since 1991 a department of traditional medicine (nowadays Alternative and Complementary Medicine) was founded within the State University of Medicine and Pharmacy "Nicolae Testemitanu", with graduate and postgraduate educational programs developed for specialists in traditional medicine, which varies from optional courses within the undergraduate medical curriculum, to full-time postgraduate diplomas with formal medical specialty status and in years 1991-2008 over 250 physicians obtained additional qualifications in specific areas of traditional medicine (of which 60 – during 3 years full-time residency program). Postgraduate medical specializations in TCAM can be obtained in acupuncture, homeopathy and phytotherapy. The chief of the department is the academician Victor Lacusta, who has studied acupuncture at the Nanjing University of TCM and has had clinical experience in a variety of clinics in the People's Republic of China. He is the author of 24 books in the field of traditional medicine; one of them was reviewed and recommended by Peigen Li professor of Nanjing University of Traditional Chinese Medicine, WHO Collaborative Centre on Traditional Medicine.

In the R. Moldova exists a certification system- Republic Commission for Attestation and Merit Rating. Public health authorities certify potential candidates as having the requisite professional skills in different forms of traditional (alternative and complementary) medicine.

A national system of licensing of traditional medicine practices has been established and is currently being implemented. In order to get a new license to practice the approved traditional medicine methods, it is necessary to have a high medical education degree.

There is one unified professional medical association in the Republic of Moldova that unites and regulates all traditional medicine specialists – The Association of Alternative Medicine - practitioners of medical acupuncture, homeopaths and herbalists. The self-regulation implies that membership of the association is restricted to appropriately trained and licensed practitioners; that there is a code of ethics for members; and that individuals who do not maintain appropriate standards of practice will have their membership revoked.

The Republic of Moldova has a national medical scientific journal "Alternative Medicine: clinical physiology and methods of treatment" relating to TCAM, published by professional associations. It is a practical, scientific edition designed for specialists in alternative medicine, neurology and clinical physiology. The journal was founded by the European Postgraduate Centre of Acupuncture and the Association of the Traditional Medicine of the Republic of Moldova in 1997. The journal publishes official papers as well as independently submitted scientific articles, editorials, clinical studies and cases, lectures, methodological guides, reviews, brief reports and correspondence.

The National Council for Attestation and Accreditation assigned scientific research cipher 14.00.46. to Traditional Medicine. This has allowed conducting broad clinical and experimental scientific research in this area and defending 12 doctoral (PhD) theses on acupuncture by now.

Presently, the focus of researches conducted by Moldovan acupuncturists is the study of neurocognitive disorders and possibilities of their correction by applying methods of alternative and complementary medicine, particularly acupuncture.

Scientific meetings and practical conferences on topics related to traditional medicine are regularly held under the guidance of the Ministry of Health. It is remarkable the organization and holding in Chisinau of the first European Congress of the European Association of Acupuncture with representatives from 22 countries. It strengthens relations with scientific and academic centers of alternative medicine (traditional) in Romania, Greece, Russia, and Spain.

Public health insurance can only reimburse treatments identified within the framework of certain special cases – for example, facial neuritis, trigeminal neuralgia, migraine or some other disturbances of peripheral nervous system in case if previous allopathic treatment has failed. Public finance funds only specific form of therapy, in R. Moldova that is acupuncture.

Thus the application of approved traditional medicine methods in the Republic of Moldova is developing dynamically with the support of the state system of public health care. Active scientific research is being conducted on the problems of application of traditional medicine methods. A system of preparation and licensing of specialists in the traditional medicine sphere has been created.

Obviously we need a further development of policies and regulations on

TCAM, an establishment and application of international standards on this field, a more wide dissemination of traditional medicine culture.

Under this context, “International Conference & Exposition on Traditional Medicine 2009” is a great opportunity for us to cooperate on traditional medicine on a government level. We would also like to ask all the practitioners of traditional (alternative and complementary) medicine over the world for collaboration in scientific research.

Strategy for TCM Development: Its Role in Chinese

Healthcare As a Pattern of Leadership of TCM

Development in the World

Dr. Ramón

During the last 30 years there have been big changes at an international, national and local level, in the background in which frame all values of the health care should be translated into measures. In the following study our main aim is to carry out a strategic planning for the development of the TCM in China, without forgetting that China has to lead also the development of the TCM at a global level.

Firstly it is to point out that a health care system is embraced by all those organizations, institutions and resources aimed to develop initiatives in order to improve health care. In China, the context of its Health Care System includes both the Traditional Chinese Medicine as the allopathic or western medicine, and also other traditional medicines featured by a more minority character. In this study we are going to concentrate in the Traditional Chinese Medicine without forgetting the possible conflicts of interest with the other medicines. Starting from the basic point that the TCM has to play a main role in the Health Care System of China, the objective is to be able to establish some strategies to make it possible.

In a globalised world, we can never forget all the recommendations and proposals of the World Health Organization (WHO) regarding the discussed topic. Although in China there exist own features which are very different from other countries' and which have to be taken into account, the strategic lines cannot miss the international tendencies in the subject in a more and more globalised environment. For that reason we will take into account the Declaration of Alma-Ata adopted by the World Health Organization in 1978,

since nowadays, 30 years later, its values and principles do still receive a strong international support. In the mentioned Declaration, the Primary Health Care became the central policy of the WHO. Consequently we encounter a strategy of development of a Health Care System that mainly concerns on the Primary Health Care, understanding a Primary Health Care System as the institutions, the people and the resources involved in the health care assistance for individuals.

It is necessary to understand the Primary Health Care as a concept regarding all main principles as a variable group of basic activities. In this sense we have adopted the principles advocated by the WHO as our main principles:

- A. Universal access to the health care and coverage depending on the special needs.
- B. Adhesion to the health equity as part of a development directed to the social justice.
- C. Participation in the community in the definition and application of the health agencies.
- D. Intersectorial approaches of health.

Obviously these principles remain valid and concern both the Traditional Chinese Medicine and the other traditional medicines and the allopathic medicine.

We should not forget the existing conflicts of interest and others that could arise in the future between the different operators of the Health Care System in China, as a consequence of the different medicines operating in it. In our opinion, the way to minimize the before mentioned conflicts consists in the establishment of a well-defined strategy of development for each of the medicines, granting all them with enough autonomy as to define its own development and at the same time, permitting the creation of integrative policies between them.

It is obvious that the point of view that we defend lies on the idea that the TCM has to configure an own and autonomous Health Care System inside the Health Care System of China, and we also defend that there have to be adopted particular policies and provide it with all necessary resources in order to turn the TCM Health Care System into the predominant System in China. This fact may not be an obstacle to the progress of other branches as the integrative medicine, which are not object of this lecture.

Our attitude is based on the fact that TCM has shown its efficacy and efficiency in the health care of the Chinese citizens for many centuries and it is also perfectly integrated in the Chinese culture. It is also to mention that the

world population ageing tendency requires a more preventive medicine, main feature of the TCM, apart from its shown efficacy in the treatment of chronic illnesses, which are becoming more and more usual. In addition, the growth of the TCM in many countries of the world, abroad the area of influence of the Chinese culture, discloses a potential of growth that will only become sustainable and will consolidate if the TCM Health Care System in China is able to play a leading role at an international level.

Leaving the analysis of a health care strategy in the Chinese authorities hands at the highest level, we want to underline some of the parameters that are to be taken into account for the design of a strategy for the development of the TCM in China under the premise that our basis lies in a Health Care System based in the TCM, without excluding other health care systems, also autonomous, of the other medicines.

The problematic that we will have face according to the proposed TCM Health Care System, in general terms, does not differ much from the problematic that we would have to face in any other health care system of many of the countries of the world:

- a) The chronic lack of enough financing.
- b) The many forms of inefficiency undermining the system.
- c) The shortage of health staff, the lack of adequacy of its education and training to the real needs and its emigration to urban areas, of the same country and also to more developed countries.
- d) The lack of appropriate health care information.

Evidently the current Health Care Systems are affected by the changes in the population (ageing, food habits, pollution...and so on), more exigent citizens, the increase of chronic illnesses, more expensive treatments, and so on. These factors generate a progressive increase in the costs and in the demand of health care. Besides, these are joined with other factors that, though the will of change of the government, mean a restrain to transformation, as it is the exigency of a budget balance, the lack of homogenation and health care standards that obstruct the obtaining of data for the evaluation of the assistance practice, the short term urgency that obliges to make investments that would turn out to be long term investments, the less healthy habits of citizens... Apart from the fact that the government should display a more decisive policy to increase the volume of resources concerning the TCM Health Care System, there should be initiated a process of transformation based in the value, investing in order to favour an assistance aimed in the prevention and the proactivity with the patients, with a higher involvement of the citizens and developing best options to promote health and to provide the health care assistance. We do not have to forget that many of the functions of

the health care systems are conditioned to the previous achievement of an adequate financing. If there are not created sustainable mechanisms of financing, the innovative ideas direct towards the reinforcement of the health care systems will not generate the expected results.

Taking into account the changes produced in the institutional context of the planning regarding health care policies and the TCM Health Care System supply, if there exists the determined motivation to bet for the reinforcement of a TCM Health Care System, we consider that the responsibilities and targets should be redefined. For that a committee of experts should be entrusted with the development of a white book in which they should propose a strategy for the following years. Then the appropriate policies should be established from the mentioned strategy, foreseeing the needed financing, establishing the targets to achieve and redesigning the system, improving its efficacy and its efficiency. All along this process it should be necessary to count with the participation and implication of all TCM health care operators, from the educative to the health care institutions, and from system suppliers to associations of professionals.

Another of the delicate problems which is to be faced by the TCM Health Care System is the shortage of staff to make it work properly. We are living in an economic and politic environment which has experienced a great functional increase in Health Care from non-governmental organizations and private suppliers. In addition, all countries are already part of the world market of health care professionals and the effects of the imbalance between offer and demand will become more and more significant in accordance with the increase of the trade with health care services. It is accordingly necessary to develop and evaluate new models to reinforce health care staff. We also have to add other factors as the profile of aptitudes of the health care professionals, its geographic and functional distribution and its productivity. Moreover, the emigration of health care staff worries those planning policies in all countries. The movements of health care professionals reproduce accurately the general emigration patterns of professionals. Although doctors and nurses constitute only a small proportion of the professional emigrants, these loses weaken the health care system. We think that in the field of the TCM this tendency will be increasing in the following years and, consequently, it must be foreseen. There have to be adopted policies on retribution, promotion and incentives to allow the decrease of the problem and, moreover, the health care suppliers should think about investing in health care in the countries that receive the TCM health care professionals, as to be able to take part in the benefits, and to be able to establish rotating policies of its health care professionals. The process of the establishment of a workforce motivated by the pertinent aptitudes can commence immediately with the existing budgets and staff, but these activities require also continuing investments in time and leading matters.

The reorientation of the managing staff to new functions developments requires time and planning. To take measures to resolve the crisis of the staff is not an easy task and obliges to pay attention to all aspects of the needs of the staff, from its education to its mood, and from local to global determinants. The design, the approval and the implementation of changes in institutions, the policies and the legislation requires studies and analysis that take time and that will have repercussions, visible only at medium term. It is necessary to consider seriously the dynamic nature of the work market and to acknowledge the limits and expectations at long term for health care workers.

Concerning the lack of proper health care information, it is important to comment that added to the before mentioned lack of staff there exists a risk of collapse of the Health Care System. The management of the TCM Health Care System requires a tough system of health care information in order to understand the needs of the population concerning health. This system of information must allow checking the proper working of the programmes, seizing the effects of the interventions and evaluating and improving its performance. The tools and structures assigned to obtain, organize and share information are indispensable to improve the task of each of the suppliers of health care and to increase the quality of the entire system. For the WHO, a system of health care information can be defined as an integrated effort of gathering, processing, notification and use of health care information and knowledge with the objective to influence on the policy making, on the programmatic action and on research.

Health care information has to be employed at least with four different though related objectives: the strategic decision making, the application or management of programmes, the monitoring of results or achievements and the evaluation of what works and what does not work. The strategic decision making of the planners of health care policies should be based in the best available evidence. The use of new technologies in a well-designed system enables a more precise and opportune monitoring of the programmes.

To conclude, just underline that the perspective to develop a TCM Health Care System has to assure the universal access to a service of quality. The universal coverage of the TCM will ensure that the general improvement of the Health Care System of China avoids the imbalances in health care. Future offers bigger challenges for the Health Care System of China. In the next years, the environment changes will have effects on the population health by mechanisms that are not completely understood yet. The Health Care System of China is already fighting against the effects of the economic globalisation, including the migrations and the impact of trade patterns and practices in the health care of the population. While in the international forums there will continue the debates about issues as the copyrights and the trading with

services, the health care systems will face new pressures. In this context, the steady adherence to the values of equity and universal access to assistance will become more important than ever.

In case that the Chinese authorities assign the necessary resources and establish a strategy that allows, at medium term, the achievement of a health care system based on TCM featured by its effectiveness, equity and universal access, they will not only benefit all the population of China, but they will also turn into a world reference. This will permit the exportation of the model to other countries, achieving important benefits in addition to the improvement of the health of the population in those countries.

We consider that in this plan there have to be implied all health care operators from government and non-government organizations to the professionals themselves through their organizations without forgetting the TCM Universities and education institutes, pharmaceutical laboratories suppliers of TCM, the Commerce Chamber, editorials specialized in TCM, TCM institutes and research centres, and definitively all those who can contribute, as we, to the development of the TCM in China and in the world.

Imminent Crisis and Solutions to European Directive on Traditional Herbal Medicinal Products

Professor Man Fong Mei

Abstract

This paper analyses the implications of EU THMPD and the UK statutory registration of practitioners in relation to Chinese Medicine and the possible consequences to the globalisation of Chinese Medicine. It is necessary to gain legal status to ensure mainstream development, but unsuitable regulation could damage the future of Chinese Medicine. The EU directive on traditional medicine in the current form as implemented in the UK after April 2011 may cause such a crisis. In explaining the relationship between the two regulations, we can understand the concerns of both practitioners and businesses in their search for an urgent solution. This report urges immediate communications and proper consultation between EU and China on the issues. Technical difficulties such as stability test for compound herbs as well as different medical methodology are preventing an integrative regulation regime. Compromise and negotiation as proposed in this report may lead to a solution in legislation, thus enhancing safety and good practice of Chinese Medicine.

We cannot wait for the advances of Systems Biology or other sciences in order to validate Chinese Medicine. Regulators on the west seek to protect consumers, yet by doing so they restrict consumer choice. The report looks into future perspectives for Chinese Medicine in the current legislative environment, and point out the consequences of failure in finding a solution may go beyond patients and doctors.

Reflexotherapy in Ukraine:

Educational and Medical Aspects

O. Kovalenko (Ukraine, Kyiv)

The whole world suffers from identical problems: negative consequences of technogenic catastrophes and contamination of environment, surplus use of medicinal preparations with increasing their unbearableness and resistivity to the receipt of medical effect from their application, by the allergisation of population, psychical and emotional overloads. On this background remains solid and actual traditional Chinese medicine, from the sources of which the treat and diagnostically system began to develop under the name "reflexotherapy".

In Ukraine acupuncture is successfully used more than 30 years. It was improved by Professor Y. Macheret and her colleagues. Got also development and another ways of affecting points of acupuncture is an electropuncture, lasypuncture, pharmacopuncture and other, and also vacuum-therapy, cauterization (warming up), incorporated by a general term " reflexotherapy ". Reflexotherapy is used for treatment of different diseases: neurological, gastroenterology, allergic, pulmonary, dermatological, and gynaecological, at the consequences of traumas, stresses and other. Most essential is circumstance that reflexotherapy main principle of medicine is the basis of - to treat a patient, but not illness. In fact, indeed, the greatest result of medical art can be got, if to take into account the different syndromes of patient.

Reflexotherapy, above all things classic acupuncture, both monotherapy is widely used and in combination with classic European medicine. The puncture method of introduction of medications is used - pharmacopuncture. Along with classic corporal reflexotherapy (by acupuncture, lasypuncture et cetera) auricular therapy is used. Traditional Chinese diagnostics is used: on a language, on eyes, auricle, on puls, and also electropuncture vehicle methods (Nakatani - Riodoraku).

The whole departmental to reflexotherapy teaching is developed in Ukraine. More, than for 30-years-old period more than 17 500 specialists are trained on reflexotherapy not only from Ukraine but also from other countries, the government programs of education are ratified on reflexotherapy.

In Ukraine service is created to reflexotherapy which is headed by the Chief specialist of Ministry of Health of Ukraine, in each of areas of Ukraine also there is a main specialist.

For all period of existence of reflexotherapy in Ukraine carried out researches in area of study of its efficiency at different pathologies. So, under the direction of professor Macheret dissertations are protected after the themes of proof of efficiency of reflexotherapy at neurological diseases (neuritis, polyneuritis, hypertensive encephalopathy, and others). Now scientific researches on the study of degree of efficiency of reflexotherapy in an early period after an ischemic stroke are being carried out.

Interest to traditional Chinese medicine continues to grow; reflexotherapy is all wider inculcated in practical medicine: in domestic medicine, paediatrics, rehabilitation and others.

Undoubted is circumstance that the whole world must be thankful Chinese traditional medicine, because its efficiency is well-proven by millenniums.

Ukraine is a country in Eastern Europe. The area of the Ukraine is estimated at being 603,700 square kilometres, biggest country in Europe. Ukraine is a flat country for the most part, and in the west and south it is bordered by mountains; also it is washed by 2 seas: The Black Sea and The Sea of Azov. The Ukraine is an industrial as well as agricultural country.

Powerful medieval monarchy “Kyivska Rus” developed from Kyiv - modern capital of Ukraine, situated on the Dnipro River. Kyiv is a scenic city of close to 3 million people situated on the Dnipro River. Kyiv is a really beautiful city with its marvellous hills and unique sightseeings. Having bunch of trees and flowers it is always associated with chestnuts. Kyiv architectural landscape is unique. Due to the huge number of orthodox churches it is called sometimes the Gold-Domed city.

The Position and Role of Standards of International Organization of TCM

Li Zhenji Vice-Chairperson & Secretary-General of WFCMS

The International Organization Standards are standards made by international organizations other than three main International Organizations for Standardization ISO, IEC and ITU,. Currently, more than 300 international and regional organizations have established standards or technical regulations. With the advent of era of network economy, the demands for international standards and standardization become increasingly prominent, which provides great opportunity for the development of International Organization Standards.

A. International Institutions for Standardization and variety of International Standards

(a) International Institutions for Standardization

a. ISO: ISO is the world's largest International Institution for Standardization. Founded in 1947 ,its Central Secretariat was located in Geneva. It's a non-governmental organization, not affiliated to the United Nations.

b. IEC: IEC is a non-governmental international standards organization that prepares and publishes International Standards for all electrical, electronic and related technologies. Founded in London, England in 1906, IEC was merged into ISO and moved to Geneva in 1947. In 1976, it separated from ISO and became two complementary international organizations with ISO.

c. ITU: ITU is an international inter-governmental organization, dealing with telecommunications issues in the United Nations. Its headquarters is in Geneva.

d. Other International organizations related with standardization: some international organizations with solid foundations and relatively mature conditions are recognized by ISO. Among these, more than 40 ones are published on the website of ISO as international organizations related with standardization, such as FDI, FID, IDF, WHO and WMO. Some others have not been recognized by ISO, such as IWS, IIW and so on.

e. Regional standardization Institutions includes CEN, PASC, COPANT, ARSO and so on

(b)Variety of International standards

a. International standards: They are composed of two parts. One is the standards made by ISO, IEC and ITU. The other is the standards made by other international organizations recognized by ISO and published on the standards catalog of ISO website.

b. International Organization Standards: they also consist of two parts. One is standards made by over 40 recognized organizations which are not included in the list of ISO standards, The other is standards made by those more than 200 unrecognized international organizations.

c. Regional standards are ones made by regional standardization organizations.

d. International standard can be divided into many categories. For example, they are divided into standards, criterion, and technical reports and so on in terms of style. In terms of field, they are divided into universal, basic, scientific, health, safety and environmental standards and so on. In terms of administering, they are divided into compulsory and recommended standards. B. The relationship of Standards of International Organization of TCM with that of ISO and WHO Standards of International Organization of TCM are made by TCM International Organizations. Since TCM International Organization was an alliance, its standards are jointly made and respected by all members Although these standards primarily apply to its own members, they can be universal, applicable to all regions and countries, for the healthy development of TCM in the world.

ISO is the world's most authoritative organization for Standardization. Its standards are the highest level of international standards. The establishment of technical committee for TCM under ISO made it possible for TCM standards to elevate to higher level of international standards. However, the higher the level is, the greater the difficulty is and the longer the cycle is, and thus it doesn't affect the function of international organization standards. As field standards can not be replaced by national standards, Some international organization standards can serve as "trial standards" for ISO standards. When the international organization standards are published, they may go through ISO technical procedures and be adopted as ISO standards finally.

As a government agency, WHO an international organization recognized by ISO as one related with standardization. The standards it make are not regarded as international standards until written on the ISO directory. Thus, International Organization Standards may be adopted by ISO or WHO

according to their different field.

It ought to say, some international organizations can be recognized as one related with standardization if their standards represent the development level of contemporary science and technology, if their standards pass some strict scientific trials, and if they meet the needs of all parties concerned.

C. The relationship between Standards of International Organization of TCM and various national laws, regulations and standards

(a) In the market economy, there are subjects and objects. The market subjects mainly refer to legal and natural persons, while the market object means product. Laws and regulations manage people and the market actors. The object of the market actors is the product, which was mainly regulated by the quality standards. Because the object of the International Organization Standards is different from that of various national laws, regulations and standards, it doesn't affect the implementation of various national laws, regulations and standards.

(b) TCM has been introduced to more than 120 countries and regions. Due to different cultural background, the widespread extent and the professional level, national standards of various countries vary. Because the basic principle of standard is "Consensus", the standard it forms must be "basic measurement rule" which is approved by most countries. Some countries' standards may be higher than this one, and then such countries will enjoy the reputations and form its own characteristics and brand. Some countries' standards may be lower than this one, then those countries may try hard to reach this one. As time goes on, standards keep up with the time and the overall level will be improved. Besides, international organization standard belongs to the recommended standard. So, it won't be conflict with various national standard systems.

D. market mechanism drives the implementation of international organization standards.

Market mechanism is the inner power for adopting international standards. If any unit, any organization or any individual wants to top the market in the competition, it has to make sure its services or products meet the required standards. The one in line with the standards will win the credibility and grab the market,. The main method of implementing international standard is CAB.

E. As an international academic organization of TCM, World Federation of Chinese Medicine Societies work for constituting international organization

standards of TCM.

(a) WFCMS is an international academic organization of TCM with its secretariat located in China. Currently, WFCMS has 186 societies in 56 countries and regions. The total membership is about 300 thousand.

(b) From its inception, WFCMS has always been devoted to constituting, publishing and implementing International Organization Standards of TCM.

(c) it has made and published three international organization standards:

a. working principle of WFCMS for making and publishing its standards

b. The standard Chinese and English TCM nomenclature

c. The standards for undergraduate education of TCM

(d) Currently, WFCMS is drafting Chinese-French, Chinese-Spanish and Chinese- Portuguese version of standard TCM nomenclature

Introduction of society member

Training and Research Center of Human and Medical Sciences

Established in 1990, our association has for objective the activities of information, distribution and training in the field of the Chinese Traditional Medicine and Homoeopathy.

Our association includes practitioners of health: doctors (general practitioners, gynecologists, rheumatologists...), chemists, physiotherapists, nurses, dental surgeons (implantology)... At present our association registers 250 members.

We organize courses of training and lectures information in various areas of medical specialization to develop the TCM and the homoeopathy, and the interest of these practices associated with the western medicine.

Every year we send to the members of the association several publications on various diseases, their diagnosis and their treatments in TCM.