BUSINESS PLAN

ISO/TC 249
Traditional Chinese Medicine "Provisional"

EXECUTIVE SUMMARY

In many parts of the world, Traditional Medicine (abbreviated as TM, hereinafter) provides health care to a significant portion of the population as part of the general health services. Various distinctive Traditional Medicine systems have evolved such as Traditional Chinese Medicine (abbreviated as TCM, hereinafter), Ayurveda, Kampo Medicine and Korean Medicine.

For a number of reasons including population movements, affordability and reputation, some Traditional Medicine systems have extended well beyond their traditional geographical regions of use and becoming increasingly utilized in many other countries. As this occurs, the need for international standards to underpin their wider use is recognized.

TCM is a traditional medicine system which originated from China on the basis of clinical experience, theory and technology and to varying degrees, disseminated, applied and further developed in many other countries such that it is now used globally.

In June 2009, the ISO Technical Management Board established ISO/TC 249 with the provisional title of Traditional Chinese Medicine which reflects the current work of the committee. The Business Plan is currently based on the provisional title and it will be reviewed at each plenary meeting to ensure that the Business Plan remains up to date.

The current scope of TC249 primarily focuses on standardization in the fields of quality and safety of raw materials, manufactured products and medical devices and informatics, all of which are relevant to Traditional Chinese Medicine.

The main activity of ISO/TC 249 is to develop international standards supporting the international practice of TCM; the committee aims to contribute to the maintenance of health and improvements of health care through the use of Traditional Medicine, to support the quality, safety and effectiveness of products, and to assist in the trade and commerce of related goods and services.

Its work shall omit medical standards not exclusive to TCM and any clinical practice guidance as proposed by the World Health Organization (WHO). The clinical practice guidelines for Traditional Medicine are better developed at the national level to reflect the medical practice of that country.

In carrying out this work, the committee aims to:

- ensure its work is timely
- optimize participation by the stakeholders
- reach consensual and practical outcomes that are cost effective
- complement and not duplicate existing resources and standards

- accommodate the differing proficiencies and approaches between countries

In order to achieve these objectives and its current work for TCM, ISO/TC 249 will utilize the involvement of National Member bodies (abbreviated as NMBs, hereinafter) in order to meet their requirements for TCM standards in a number of specific areas. In the first plenary meeting of ISO/TC 249 in June 2010, the committee resolved to work on the following priorities:

- The top priority is Quality and Safety.
- With regard to Informatics, the committee has embarked on a process of consulting with other bodies, such as WHO (ICD 11) and ISO/TC 215, to identify the contribution of the committee. A Joint Working Group (*abbreviated as JWG, hereinafter)* has been proposed between TC249 and TC215 titled “Informatics of TCM”.
- Training, Education and Practice of Practitioners, and Research Methodology shall be lower order priorities to be considered at a later date.

1 INTRODUCTION

1.1 ISO technical committees and business planning

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure which forms part of a major review of business. The aim is to align the ISO work programme with expressed business environment needs and trends and to allow ISO/TCs to prioritize among different projects, to identify the benefits expected from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

1.2 International standardization and the role of ISO

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: ISO (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of IEC (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of ITU (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 140 countries (organizations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the International Standard.

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public

comment phase (the ISO Technical Enquiry). ISO and its Technical Committees are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction is that the IWA is developed by ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.

2 BUSINESS ENVIRONMENT OF ISO/TC 249

2.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal and social dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of this ISO/TC, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards.

The increasing international utilization of TCM together with the modernization of the traditional presentations and manufacture of TCM products are creating an urgent need for internationally recognized and accepted standards. The presence of such standards can support the reputation of TCM and positively affect expansion of its markets.

There are many interested stakeholders in this area including:

- Government agencies providing access to health services and protecting public safety through policy, service provision, legislation
- Government agencies supporting trade and commerce
- Regulatory authorities
- Industry, being manufacturers and suppliers of medical devices
- Industry, being manufacturers and suppliers of medicinal products
- Cultivators and harvesters of natural materials
- Funders of health care services
- Public interest and consumer groups
- TCM professional associations
- Practitioners
- Researchers
- Education and training providers: agencies and schools, e.g. TCM universities, colleges, etc.

The 2005 WHO global survey showed that around 90 countries, less than half of WHO's Member States, currently regulate herbal medicines, and an even smaller proportion has systems for the regulation/qualification of providers of herbal medicines. Moreover, there are disparities in regulation between countries, and this has serious implications for international access to the

performance and the distribution of such products. At the 56th World Health Assembly in May 2003, Member States were urged to set up or expand and strengthen existing national drug safety monitoring systems to regulate herbal medicines and other traditional practices.

The absence of international standards and much attention for TCM, particularly in the area of quality and safety of natural materials has created an urgent need for international standards development. Side effects and safety issues in the practice of herbal medicine, acupuncture and related techniques are important aspects.

In addition, the lack of reliable information about TCM is a barrier and reflects the adage that it does not count unless we can count it. Currently, the data collection practices for TCM are frequently not integrated within national or international health information systems. The development of standardized TCM terminology may assist various stakeholders to gather data and to meaningfully exchange information on TCM globally. It is essential to produce international health information standards on TCM terminologies and nomenclature.

Countries without minimum requirements for practitioner training or education may benefit from a voluntary international standard that would provide assistance for improving regulation of TCM practitioners. Such improved regulations may reduce risks for consumers of TCM goods and services and preserve the reputation of TCM internationally, which would have both positive health and trade consequences. However, some countries already have established requirements for the training of TCM practitioners. The scope of the committee may therefore include education and training, though as a lower priority.

2.1.1. Business and regulatory environment of NMB's

Health care operates in a complex environment reflecting the different approaches to medical care and funding across many countries. Reflecting this, to varying degrees, TCM is regulated in many countries but with rather different contexts. The information from other countries is to be completed as the Business Plan is reviewed periodically.

Australia

Australia regulates Traditional Medicines (TM) as complementary medicine products (abbreviated as TM/CM, hereinafter) products including manufactured Chinese herbal products and acupuncture devices through the Australian Government's Therapeutic Goods Administration (TGA). The TGA Office of Complementary Medicine regulates CM product, whereas medical devices are regulated by the TGA Office of Devices Authorization.

Manufactured TM/CM products (other than raw materials, individual "start" ingredients such as granules, powders, tinctures etc, and substances deemed to be foods) must be approved for inclusion on the Australian Register of Therapeutic Goods (ARTG) before being legally sold in Australia. Entry onto the ARTG as a listed medicine (AUSTL) is via a self assessment procedure for product made up only of ingredients deemed safe for human use. Some labeling warnings may be required. Products of higher consumer risk such as those labeled for treatment of a serious condition or substances containing scheduled medicines are regulated by the Australian government and evidence of efficacy before being included as a registered medicine (AUSTR).

Medical devices, such as acupuncture needles and moxibustion products, are also regulated by the TGA and are required to be included on the ARTG as registered medical devices before being legally sold in Australia.

Australian manufacturers of therapeutic products (medicines and devices) are required to be licensed and overseas manufacturers need to demonstrate Good Manufacturing Practice before their product can be included on the ARTG. Products extemporaneously prescribed and dispensed by practitioners as part of the treatment of a patient are exempt from the manufacturing requirements.

The legal prescription or supply of potentially harmful substances via the various State and National medicines and poisons bodies restricts the use of some Chinese herbal medicines, such as mahuang (Ephedrae herba) and fuzi (Aconiti lateralis radix praeparata). Customs and Quarantine as well as Wildlife Trade regulators also have an indirect role in regulating the supply of herbal product.

The TCM profession has been registered in one state (Victoria) since 2001 and will become a nationally registered profession from 1 July 2012. Registration also incorporates regulation of educational TCM standards and programs of study.

Canada

Health Canada in its role as the Federal Department responsible for helping Canadians maintain and improve their health, comprises of several branches and agencies that carry out activities of potential complement to the aims of the committee. As an example, the Natural Health Products Regulations (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/acts-lois/prodnatur/index-eng.php) applies to an array of products that are suitable for self-selection by the consumer (without a need for individualized instructions and/or direct practitioner supervision). Similarly, Health Canada is tasked with the review of medical devices (i.e. a wide range of health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition) to assess their safety, effectiveness and quality before being authorized for sale in Canada.

It is important to recognize that the compounding by healthcare providers of natural health products (NHPs), including TCM herbs does not constitute manufacturing and thus is an activity that falls outside the scope of the Natural Health Products Regulations. Compounding is an activity performed by a health care practitioner in the context of a practitioner-patient relationship. It is an activity that generally falls under provincial or territorial jurisdiction. (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/pol/policy_compound-politique_compose-eng.php).

China

As a primary health care system, TCM is being advocated by Chinese government as medical care for the masses. China attaches great importance to the national legislation on TCM. The supervision on traditional Chinese medicines is as strict as that of chemical drugs and biological products. Registration of Chinese medicines shall be subject to strict technical evaluation and clinic trial. The manufacturing, sales, use and supervision on TCM shall strictly conform to “Law of the People’s Republic of China on the Administration of Drugs”.

The *Pharmacopoeia of the People's Republic of China (2010)* is the national drug standard, of which, *Volume I* is an official collection of standards for 2165 monographs of Chinese materia medica， prepared slices of Chinese crude drugs, oils, fats, extractives, TCM patent medicines and simple preparations, etc. The *Pharmacopoeia* encourages technical innovation and introduce many modern analysis methods including Liquid Chromatograph-Mass Spectrum (LCMS), Thin Layer Chromatography-bioautography, Chromatography of Ions and High Performance Liquid Chromatography (HPLC), etc. HPLC fingerprint method, which is in accordance with integrity of TCM, has been established to ensure quality stabilities of Chinese materia medica. The Pharmacopoeia also introduces requirements for control of impurities in drug products and sterility tests which international organizations for medication require.

In China, TCM practitioners could be categorized into physicians, nurses and pharmacists who are required to be registered before practicing. All qualification exams and registration are in accordance with “Law of The People's Republic of China on Medical Practitioners”, “Management Measures of the People's Republic of China on the Nurses”, “The Provision(tentative) on the Licensed Pharmacists”, etc.

The establishment and operation of TCM medical institutions including hospitals and associations shall be based on the regulations and standards by the Ministry of Health under the state council.

According to “Regulations on Management of Medical Institutions”, the institute can start its medical activities only after receiving the practicing license.

The Ministry of Health and the Ministry of Education under the state of council are responsible for the formulation of standards of TCM education institutions. The standards on TCM clinic and apprentice teaching bases are drafted by the Ministry of Health.

Spain

In Spain, herbs cannot be registered as a “food supplement” and are considered unregistered and illegal drugs, so Chinese herbs consumed in Spain come from other countries of the European Union. They are bought directly by each individual patient who has to pay very expensive prices due to the costs of individual shipments.

As of May 2009, Spain implemented a rule of mutual recognition between the different countries of the European Union, unless there was justification based on public health reasons for exclusion. However there are currently no regulations in place where Chinese herbs are sold freely within the EU.

The right to practice acupuncture is a contentious issue which appears to be more favourable to Western doctors than Chinese Medicine practitioners. Western doctors believe that acupuncture should be considered a medical specialty reserved for Western medical practitioners only. Chinese Medicine practitioners are allowed to be registered under ‘other parahealth practitioners’ if they comply with special tax and labour rulings although some Chinese Medicine practitioners have still had their businesses closed down for not being doctors. The other issue is that the level of training of parahealth practitioners varies markedly.

The Spanish government has manifested its engagement to regulate CAM, because it agrees that the regulation is necessary.

2.2 Quantitative Indicators of the Business Environment

The following quantitative information reflects the need for international standards, and additional information will be added on an ongoing basis to create a more complete report of the TCM environment and as a support for the actions of the ISO/TC 249.

2.2.1 Gaps in national policies and regulations

According to the 2005 WHO global survey of which responses were received from 141 countries out of 191 Member States, 45 of the responding Member States reported having a policy on TM/CAM. Of those Member States which currently do not have a national policy, 51 (56%) indicate that such policies are currently being developed. Most Member States with a national policy established it recently, since only five States reported having a national policy before 1990. Forty Member States (28%) reported that they had issued a national program on TM/CAM. Seventy five countries (53% of the responding Member States) reported having a national office in charge of TM/CAM. In most of these countries, the national office is located within the Ministry of Health. Sixty one countries (43% of the responding Member States)

reported that they have expert committees for TM/CAM. In all, 58 Member States indicated that they had at least one national institute on TM, CAM or herbal medicines. (*From "National policy on Traditional Medicine and regulation of herbal medicines" by WHO*)

The most recent WHO resolution on Traditional Medicine (2009) urges its Member States to formulate national policies, regulations and standards, as part of a comprehensive national health strategy, to promote appropriate, safe and effective uses of Traditional Medicine in order to strengthen the health system's ability to provide holistic primary health care.

2.2.2 Use of natural health products(abbreviated as NHPs, hereinafter)

Canada

Canada does not have any statistics on Canadian exports of NHPs which include TCM products. In 2010, a survey was conducted concerning the current levels of awareness, attitudes, knowledge, and behaviors among Canadian consumers of NHPs and this information is available on the (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php) with the following findings:

According to the study, nearly three in four (73%) have used a natural health product in the past, which has increased two percentage points since 2005 (71%). But the findings of the study also suggest that there are many Canadians who are not particularly familiar with NHPs.

- Making information available to the general public through traditional health care practitioners, such as (primarily) medical doctors, pharmacies/pharmacists, registered dietitians, and nurses, would be very effective as Canadians offer them high ratings as providers of this type of information.

- Of those who have used natural health products in the past, most respondents are split between using them either daily or only during certain seasons. About one third (32%) say they use them daily, which represents a significant decrease compared to 2005 (38%), and four in ten only use them during certain seasons (41%, up significantly from 37%). About one in ten respondents use them on a weekly (13% vs. 11% in 2005) or monthly (10% vs. 9%) basis.

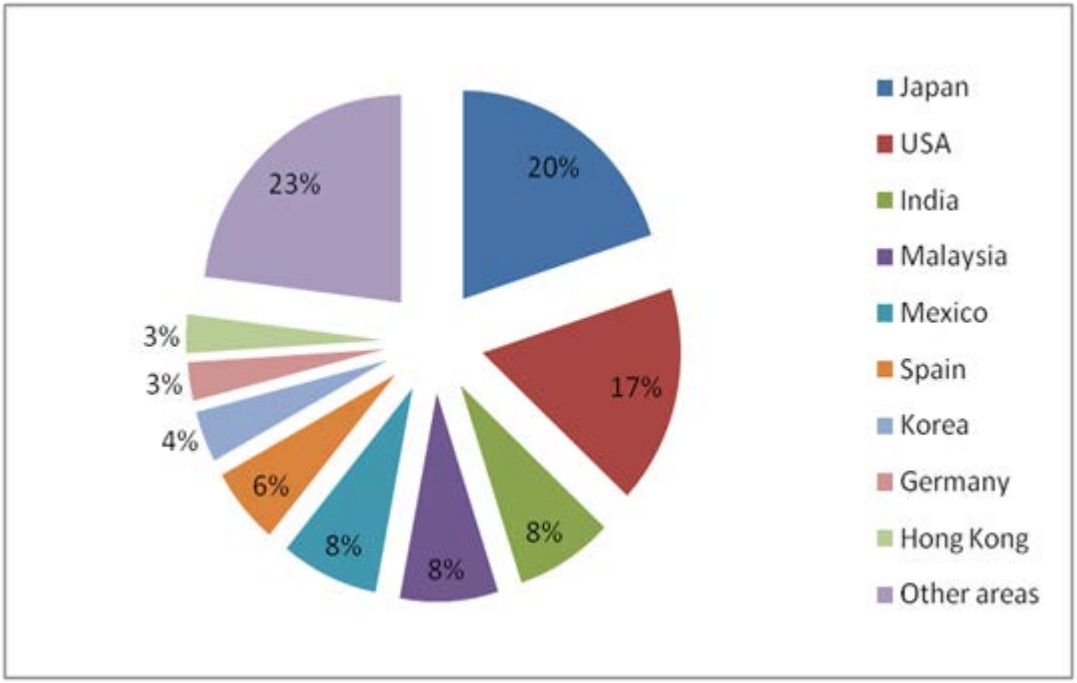
- The most commonly used NHPs include: vitamins or minerals (53%), Omega 3 or essential fatty acids (18%), Various kinds of teas (11%), herbal remedies (10%), Antioxidants (8%). (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

China

In 2010, the value of exports and imports of TCM products from China reached US$ 2.6 billion and of which, the export is US $1.9 billion in exports increased by 22.8% than the previous year. [*Compiled by China Chamber of Commerce for Import& Export of Medicines and Health Products(CCCMHPIE)]*

The range of countries to which China exported herbal products is shown in the following diagram.

Diagram (1). China's distribution of exporting herbal extracts in 2009



Compiled by CCCMHPIE according to China Customs

Korea
In 2007, the volume of herbal medicine in Korea reached to 84,000 tons, of which 70% were produced domestically. (*International Information on Traditional Chinese Medicine*)

2.2.3 Use of medical equipment

The use of acupuncture-moxibustion dates back to prehistoric times with written records from the second century BCE. Different variations of acupuncture are practiced and taught throughout the world. This wide application acknowledges acupuncture-moxibustion as an effective and feasible health care resource, e.g. the US Food and Drug Administration conducted their initial review twenty years ago with the conclusion that acupuncture needles are safe and effective

Currently, the associations, educational institutions and clinical agencies of acupuncture have been established in more than 140 countries and regions. More and more people have begun to practice acupuncture treatment. It is estimated that about 2 billion acupuncture needles are used every year in the world, and increasing progressively by about 5% -10% each year.

2.2.4 Number of practitioners

It is estimated that outside China there are 300,000 to 500,000 qualified TCM practitioners which includes 100,000 in Europe. Further data breakdowns are provided by MBs in Table (1), which will continue to grow as more data becomes available. Table (1) shows the statistics to date of TCM practitioners globally.

Table (1)

Australia	Approximately 5,000 acupuncture and Chinese herbal medicine practitioners; an unknown number of other health practitioners using acupuncture Techniques
Canada	Over 10,000 TCM doctors and acupuncturists
China	Over 350,000 herbalists, assistant physicians and intern physicians
France	Over 7,000 acupuncturists
Japan	Over 80% of medical doctors are using Kampo medicines. Also, the nation-wide network of "Kampo Consultation Pharmacy" and "Kampo pharmacists" has been playing important roles in the development of Kampo Medicine. There are approximately 147,000 licensed practitioners of acupuncture and moxibustion in Japan.
Korea	Over 18,358 Korean Medicine doctors and 1,354 Korean Medicine pharmacists
Singapore	1,800 TCM doctors
Spain	Over 15,000 CM practitioners including about 1,500 western doctors and the rest are non medical therapists (mainly physiotherapists and nurses).
Thailand	6,000 TCM doctors
UK	Over 11,000 TCM doctors and acupuncturists
USA	Over 35,000 licensed acupuncturists of which approximately 20,000 are currently in practice.

In many countries, there are still no government registration requirements for practitioners to ensure their competency to practice TCM safely.

3 BENEFITS EXPECTED FROM THE WORK OF ISO/TC 249

The following benefits are expected through ISO/TC 249 activities:

- assist emerging definitions of TCM that will support international development
- facilitate international trade
- assist in setting national standards for TCM in countries with health systems that are evolving to regulate TCM
- protect the reputation of TCM
- enhance the benefits of TCM to patients and the broader community
- establish minimum standards for the safety and quality of TCM natural materials and equipment

- help increase acceptance of TCM by governments, health care funders, health practitioners, regulators and the public
- assist in harmonizing national standards
- assist in developing consistent terminology and understanding of TCM
- allow reliable information, data collection and exchange
- support integration of TCM with other health care systems
- the experience of the committee with TCM can provide a template for dealing with other internationally-used Traditional Medicine systems

4 REPRESENTATION AND PARTICIPATION IN ISO/TC 249

4.1 Participating and Observer members of the ISO committee

(a) Currently ISO-TC 249 consists of 23 Participating ISO Member Bodies and 9 Observer Member Bodies. These are:

Table (2)

Participating Member Bodies			
Austria	Australia	Canada	China
Finland	France	Germany	Ghana
India	Israel	Italy	Japan
Korea	Mongolia	Netherlands	Norway
Singapore	South Africa	Spain	Thailand
Tunisia	USA	Vietnam	
Observer Member Bodies			
Barbados	Hong Kong, China (Correspondent)	Lithuania	Ireland
New Zealand	Poland	Sweden	Switzerland
United Kingdom			

(b) The participation represents the following regional representation:

Table (3)

Region	**Participating (23 NMBs)**	**Observer (9 NMBs)**
Africa	13%	0%
Asia	39%	11%
Europe	35%	67%

America	9%	11%
Oceania	4%	11%

(c) Liaison establishment

Relevant and potential organisations and groups for liaison with ISO/TC 249 are:

(i) Internal Liaisons

Table (4)

ISO-TC 215 : Health informatics (established)	ISO-TC210: Quality management and corresponding general aspects for medical devices	ISO-TC198: Sterilization of health care products
ISO-TC84: Devices for administration of medicinal products and intravascular catheters	ISO-TC194: Biological evaluation of medical devices	

(ii) External Liaisons.

The established liaison organisations with ISO/TC 249 are:

Table (5)

WHO	World Federation of Acupuncture-Moxibustion Societies (WFAS)	World Federation of Chinese Medicine Societies (WFCMS)

4.2 Participation Analysis

From the above distribution in Table (2), P-members include 9 Asian countries, 8 from Europe, 3 from Africa, 2 from America, 1 from Oceania. Asian countries are highly represented in this field. From Table (3), there are 14 European countries participating as either participating or observer members of the committee. In Europe, both the government and the public are realizing the need for greater support of the standardization of Traditional Chinese Medicine.

It is important to broaden the involvement of other countries considering the global use of TCM, as their participation is still limited. Possible reasons could include a lack of resources such as finances for traveling costs, the limited number of national experts and relevant and updated information. Their active participation in ISO/TC 249 will be encouraged.

ISO/TC 249 will continue to liaise with related organizations. Educational sessions on the work of various international standards and developments will enhance communications and a committee

Newsletter has been arranged for this purpose.

5 OBJECTIVES OF ISO/TC 249 AND STRATEGIES FOR THEIR ACHIEVEMENT

5.1 Defined objectives of ISO/TC 249

ISO/TC249 aims to contribute to the maintenance of health and improvements of health care through the use of Traditional Medicine, to support the quality, safety and effectiveness of products, and to assist in the trade and commerce of related goods and services. The work of the Committee will reflect the objectives of the ISO's Strategic Plan 2011-2015:

- maximize participation by all National Member Bodies, preferably as "Participating" members, and to maximise the involvement of those who are expected to be affected by ISO-TC 249 standards, in both the planning of the TC's work programme and in the production of standards, in a manner which satisfies the users' identified needs

- develop robust standards and other deliverables relevant to TCM
  a. generic standards
  b. specific standards
  c. other standards and deliverables relevant to TCM

In order to achieve its current work for TCM, ISO/TC 249 will utilize the involvement of NMBs to meet their requirements for TCM standards in a number of specific areas. The initial priorities of ISO/TC 249 are the quality and safety of TCM materials, products, and devices and informatics associated with TCM.

5.2 Identified strategies to achieve ISO/TC 249's defined objectives

The identified strategies to achieve the TC249 objectives are listed as following:

- invite or sponsor presentations on TCM needs by nations representing a range of economic means and healthcare programs
- extend liaising networks for the purpose of a more cohesive standardisation process
- enhance communication and knowledge through the implementation of a committee newsletter and the use of other communication tools
- determine specific standardization needs of NMBs
- review existing resources such as national pharmacopoeias, other standards and guidelines and contact with groups doing related work so as to ensure excellence in coordination, relevance and efficient use of resources
- adopt the existing standards where appropriate and promote to ISO standards
- produce and develop robust standards and other deliverables relevant to TCM in the following topics:

  a. Safety and quality of natural materials (high priority)
  b. Safety and quality of medical equipments (high priority)

c. Informatics (high priority)
d. Education and research (low priorities)

- establish Working Groups and, where appropriate, Joint Working Groups with other Technical Committees and a Chairman's Advisory Group and other structure
- Maintain the unique characteristics of TCM basic theories and application, also take advantage of the modern research methodology properly ranging from microbiological, biological, chemical, etc in quality and safety of Chinese medicines. The Working Groups can be advising the committee on the tests for a particular draft standard and how to balance these two different methodologies.
- establish standard operating procedures for the committee's work
- ensure the timely delivery of ISO/TC 249 Work Programme

Much of its work will be carried out through electronic communication with plenary meetings being convened when the volume and complexity of work to be considered warrants this.

5.3 Resources to support the work of the Committee

The committee is supported by a well resourced and full time Secretariat located in Shanghai, People's Republic of China.

The Chair of the committee is Dr David Graham and the Secretary is Prof Shen Yuandong. Both are available to provide as much support to the committee as needed.

6 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF ISO/TC 249 WORK PROGRAMME

The committee has identified the following risks to be managed in carrying out its work:

- The magnitude of the scope of the work. In this regard, under the provisional title, ISO/TC 249 will focus on TCM only at this time. In addition, the committee will carefully prioritise its work on TCM issues.

- Inability to accommodate the country-to-country variations in approaches to TCM, levels of proficiency in the use of TCM and its usage. The committee will therefore place a high value on accommodating national variations, and those with greater proficiency and expertise will offer their experience to the broader committee.

- Difficulties in reaching agreements among the participating countries on certain basic elements, such as title and scope. To address this, the committee will commit to a consensus approach to resolving differences, and each will consider compromising as needed to reach consensus, so that the practical work of the TC can be launched.

- The need for a new standard has not been fully justified

7 STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF THE ISO/TC

This section gives an overview of the ISO/TC249's structure, scopes of the ISO/TCs and any existing subcommittees and information on existing and planned standardization projects, publication of the ISO/TC and its subcommittees.

Work programme

7.1. Working group 1

Title: Quality and safety of raw materials and traditional processing

Scope: The scope of WG1 is to create standards related to raw materials at any stage up to and including harvest of a plant ingredient and collection of an animal or mineral ingredient, and the traditional processing of raw materials.

Date established: May 4th, 2011

Convenor: LIU Liang, China

Projects:

Project name	**project leader or convenor and timeframe where relevant**	**Preparatory stage- first working draft**	**Committee stage- first committee draft**	**Enquiry stage – circulation of enquiry draft**	**Approval stage – circulation of final draft IS**	**Publication stage – publication of IS**
(ISO indicative time frames)		**Complete first WD 6 months after project approval**	**First CD in 12 months**	**DIS in 24 months**	**FDIS in 33 months**	**IS in 36 months (in agreement with Office of CEO)**
1.ISO/CD 17217 *Ginseng Seeds and Seedlings: Panax ginseng C.A. Meyer*	HUANG Luqi	WD registration on Jan 13, 2012				

7.2. Working group 2

Title: Quality and safety of manufactured TCM products.

Scope: The scope of WG2 is to create standards for testing, processing (other than traditional processing) and manufacturing of TCM products, from starting materials to finished products, in a framework of quality and safety.

Convenor: Hans Rausch, Germany

Projects:

Project name	project leader or convenor and timeframe where relevant	Preparatory stage- first working draft	Committee stage- first committee draft	Enquiry stage – circulation of enquiry draft	Approval stage – circulation of final draft IS	Publication stage – publication of IS
(ISO indicative time frames)		**Complete first WD 6 months after project approval**	**First CD in 12 months**	**DIS in 24 months**	**FDIS in 33 months**	**IS in 36 months (in agreement with Office of CEO)**

7.3. Working group 3

Title: Quality and safety of acupuncture needles (tentative)

Scope: The scope of WG3 is standardization of all kinds of potentially invasive needles for single use that are commonly used in the acupuncture field.

Date established: May 4th, 2011

Convenor: HUANG Longxiang, China

Projects:

Project name	project leader or convenor and timeframe where relevant	Preparatory stage- first working draft	Committee stage- first committee draft	Enquiry stage – circulation of enquiry draft	Approval stage – circulation of final draft IS	Publication stage – publication of IS
(ISO indicative time frames)		**Complete first WD 6 months after project approval**	**First CD in 12 months**	**DIS in 24 months**	**FDIS in 33 months**	**IS in 36 months (in agreement with Office of CEO)**
1. ISO/CD 17218 *Sterile acupuncture needles for single use*	CAO Yang	WD registration on Jan 13, 2012	CD registration on June			

7.4. Working group 4

Title: Quality and safety of TCM medical devices other than acupuncture needles

Scope: The scope of WG4 is to develop standards for quality and safety of medical devices other than acupuncture needles.

Date established: May 4th, 2011

Convenor: KIM Yong-Suk and CHOI Sun Mi, Korea

Projects:

Project name	project leader or convenor and timeframe where relevant	Preparatory stage- first working draft	Committee stage- first committee draft	Enquiry stage – circulation of enquiry draft	Approval stage – circulation of final draft IS	Publication stage – publication of IS
(ISO indicative time frames)		Complete first WD 6 months after project approval	First CD in 12 months	DIS in 24 months	FDIS in 33 months	IS in 36 months (in agreement with Office of CEO)

7.5. Working group 5

Title: Informatics of TCM

Scope: The scope of WG 5 shall be the standardization of TCM nomenclature, terminology, classification, and ontology. Health informatics technology shall be standardized by a joint working group between TC 249 and TC 215.

Date established: May 4th, 2011

Convenor: KOH Byung-Hee, Korea and WANG Kui, China

Projects:

Project name	project leader or convenor and timeframe where relevant	Preparatory stage- first working draft	Committee stage- first committee draft	Enquiry stage – circulation of enquiry draft	Approval stage – circulation of final draft IS	Publication stage – publication of IS
(ISO indicative time frames)		Complete first WD 6 months after project approval	First CD in 12 months	DIS in 24 months	FDIS in 33 months	IS in 36 months (in agreement with Office of CEO)

Glossary of terms and abbreviations used in ISO/TC Business Plans

Term	Abbreviation
National Member Body	NMB
New Work Item Proposal	NP
Traditional Medicine	TM
Joint Working Group	JWG
Complementary and Alternative Medicine	CAM
Therapeutic Goods Administration	TGA
Australian Register of Therapeutic Goods	ARTG
Natural Health Product	NHP
China Chamber of Commerce for Import& Export of Medicines and Health Products	CCCMHPIE
Working draft	WD
Committee draft	CD
Draft international standard	DIS
Final draft international standard	FDIS
International standard	IS