BUSINESS PLAN
ISO/TC 249
Traditional Chinese Medicine

EXECUTIVE SUMMARY

With the continued growth in aging populations and the associated increases in chronic disease and disability coupled with changes in the disease spectrum, across the globe there are increasing challenges to providing health care. This has meant that there is a need for a more holistic approach to support wellness and prevent illness, as well as for the treatment of disease. Biomedicine alone does not fulfil the current needs for healthcare and the role of traditional medical systems should also be supported. As an essential component of many health systems, Traditional Medicine (abbreviated as TM, hereinafter) provides health care to a significant portion of the population both within the public and private healthcare sectors.

According to WHO Survey 2016-2018, 88% Member States have acknowledged their use of T&CM which corresponds to 170 Member States. In recognition of the need for international standards to underpin this wider use, in 2009 ISO established ISO Technical Committee 249 Traditional Chinese Medicine (ISO/TC 249) which focuses on the field of medical systems derived from ancient Chinese medicine which are able to share one common set of standards. Both traditional and modern aspects of these systems are included. ISO/TC 249 has recognised the benefits of developing shared standards with these other medical systems which have a common basis with TCM in ancient Chinese medicine. The standardization process aims at benefitting and protecting the public through the provision of safe and quality products and services which would greatly assist international trade and commerce. The gained experiences will also help the development of international standardization for other traditional medical systems.

Being a well-developed and functioning committee over the past 10 years, ISO/TC 249 continues its efforts in developing standards for quality and safety of raw materials, manufactured products and medical devices and informatics, including service standards limited to involving the safe use and delivery of devices and medicines*, but not including the clinical practice or application of those products. Its domains of work are kept under review and modified in response to actual needs.
The scope of ISO/TC 249 includes items that are also within the scopes of other ISO and IEC committees and potential overlaps have been addressed through cooperation such as setting up Joint Working Groups (JWG).

Membership of ISO/TC 249 is open to ISO members (National Member Bodies or NMB's) and eligible liaison organizations.

* The committee agreed on the following definition of 'safe use and delivery of medicines and devices':

**Definition:** risk management of processing, manufacturing, packaging, labelling and the presentation, storage, re-use, servicing of devices, and disposal of those products.

1 BUSINESS ENVIRONMENT OF ISO/TC 249

1.1 Description of the Business Environment

The 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 ISO/TC249, 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 and other medical systems derived from ancient Chinese medicine together with the modernization of the traditional treatment presentations and their manufacture are creating an urgent need for internationally recognized and accepted standards. International standards assist in ensuring consumers receive suitable products, they promote international commerce by establishing common requirements and removing barriers to trade and they encourage innovation in the industry in providing certainty around expectations for performance.

Consequently, the role of international standards in supporting quality and consistency in the products and services provided by TCM and related health systems is now drawing much attention particularly by governments, international organizations and regulators.

*WHO Global report on traditional and complimentary medicine 2019*, reported in 2018 that the number of WHO Member States regulating herbal medicines had increased from 92 in 2005 to 124. However, there are still large disparities in the levels of regulation between countries which have serious implications for the performance, distribution and use of such products.

In addition, the lack of assurance around performance because of inadequate or no regulation in many markets means that there can be great variation in products and services such as
adulterated or counterfeit products and poorly trained practitioners hiding behind and diminishing the reputation of Traditional Medicine.

Furthermore, while there is a great need for ongoing research to support TM products and services, this is severely handicapped unless information can be reliably collected and exchanged. For example, the data collection practices for TCM are frequently not integrated within national or international health information systems. There is a fundamental need for standardized terminology to assist various stakeholders to gather data and to exchange meaningful information globally.

International standards provide a resource to assist in all these areas and support the reputation of these medical systems, positively support expansion of their markets and safeguard the communities where they are used.

There are many stakeholders within this area of standardization including:

- Government agencies providing access to health services and protecting public safety through policy, service provision and 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
- Wholesalers
- Funders of health care services
- Public interest and consumer groups
- Professional associations
- Practitioners
- Researchers
- Education and training providers: agencies and schools such as TCM universities and colleges.

1.2 Business and Regulatory Environment of NMBs

Health care operates in a very complex environment primarily due to the different approaches between countries to medical care and its funding. This variation is also reflected in the variety of ways that Traditional Medicine such as TCM is regulated in different markets as the information in Appendix I indicates (further Information from other countries will be included in Appendix 1 through the regular reviews of the Business Plan).
For example, Traditional Chinese medicine is a very important part of the current health care system in China however it is also classified in various ways between countries including as a complementary medicine (CM), complementary alternative medicine (CAM) or as a natural health product (NHP). There are also many other natural products similarly classified in these markets which are not related to Traditional Medicines and some of the standards developed by ISO/TC 249 may also be useful to these products.

1.3 Quantitative Indicators of the Business Environment
The following quantitative information indicates the size and diversity of the TM market and reflects the need for international standards. Additional information will be added on an ongoing basis to create a more complete report of the environment and as a support for the actions of ISO/TC 249.

1.3.1 Gaps in National Policies and Regulations
According to the WHO Global report on traditional and complimentary medicine 2019, in 2018 there are 98 WHO Member States who responded to a survey reported having a national policy on TM/CAM and 124 were regulating herbal medicines. Many of these Members reported having a national office in charge of TM/CAM with, in most cases, the national office being located within the Ministry of Health. While the number of Members regulating herbal products is increasing, many do not.

1.3.2 Use of TM and CM Medicinal Products
According to the WHO Traditional Medicine Strategy for 2014-2023, TM/CM products includes herbs, herbal materials, herbal preparations and finished herbal products that contain parts of plants, other plant materials or combinations thereof as active ingredients. Due to the diversity of regulations and regulatory categories for TM/CM products, it is difficult to assess the size of the market for TM/CM products across Member States with any degree of accuracy. However, available data suggests that the market size is substantial. Cited from the WHO Traditional Medicine Strategy for 2014-2023, the output of Chinese materia medica was estimated to amount to US$83.1 billion in 2012, an increase of more than 20% from the previous year. For more detailed statistics, please refer to Appendix II.

1.3.3 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 use 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 treatment with acupuncture needles is safe and effective.
Currently, practitioner associations, educational institutions and clinical agencies of acupuncture have been established in more than 140 countries and regions. It is estimated that about 4 billion acupuncture needles are used every year in the world, and this is increasing progressively by about 5% -10% each year.

There is increasing use of medical equipment in the clinical practice of acupuncture-moxibustion. Most of these products are based on the combination of electronic techniques and TCM theory for example an electro-acupuncture stimulator, electric radial pulse tonometric devices, therapeutic fumigation devices, a computerized tongue image analysis system and a laser acupoint radiation device. Some electrical medical equipment can be used in the home health care environment because of their ease of use and because they don’t need complex manipulation by the operator. In China there are 23 different kinds of devices with more than 400 Registration Certificates for TCM medical equipment. Some of these products have been approved for sale as medical devices in countries such as Australia, Germany, Japan, Korea and Saudi Arabia. Information technology is also allowing some products to be worn by the person with their diagnosis and therapy remotely controlled. As this approach becomes more popular the need for consistent data rules such as for encoding data will increase.

This increasing use of medical devices in TCM has created an urgent demand for International Standards to support their safety and performance.

1.3.4 Number of Practitioners
It is estimated that for TCM alone, there are more than 550,000 TCM practitioners all over the world. Further data breakdowns are provided by NMBs in Table (1) which shows the statistics to date for practitioners globally and which will be updated as more data becomes available.

| Australia | There are approximately 4,900 nationally registered Chinese medicine practitioners covering acupuncturists (98%), Chinese herbal medicine practitioners (64%), and Chinese herbal dispensers (21%); plus, around 630 other registered health practitioners, mainly medical practitioners, authorised to practise acupuncture. (source: Australian Health Practitioner Regulation Agency; Board Statistics, June 2019. <https://www.ahpra.gov.au/>)

Additionally, there is an unknown number of registered and unregistered health practitioners (mainly medical practitioners, massage therapists, physiotherapists, myotherapists, and chiropractors) using acupuncture techniques, often under a different designation such as ‘dry-needling’. |
<table>
<thead>
<tr>
<th>Country</th>
<th>Number of TCM practitioners</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Over 10,000 TCM doctors and acupuncturists.</td>
</tr>
<tr>
<td>China</td>
<td>526,000 licensed practitioners and assistant practitioners of TCM (including practitioners of ethnic minority medicine and integrated Chinese and Western medicine) (source: China Statistical Yearbook of Chinese Medicine 2017).</td>
</tr>
<tr>
<td>France</td>
<td>Over 7,000 acupuncturists.</td>
</tr>
<tr>
<td>Japan</td>
<td>There are approximately 303,000 physicians, 280,000 pharmacists, 108,000 acupuncturists and 106,000 specialist moxibustionists in Japan (2014). Approx. 90% of physicians in Japan are using Kampo medicines. Also, the nation-wide network of “Kampo Consultation Pharmacy” and “Kampo pharmacists” has been playing an important role in the development of Kampo Medicine.</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Over 3,500 acupuncturists.</td>
</tr>
<tr>
<td>Saudi Arabia</td>
<td>There are 96 licensed cupping centers and 343 licensed and certified cupping practitioners (NCCAM, 2019)</td>
</tr>
<tr>
<td>Singapore</td>
<td>1,800 TCM doctors.</td>
</tr>
<tr>
<td>Spain</td>
<td>Over 15,000 CM practitioners which includes about 1,500 western doctors and the rest are non medical therapists (mainly physiotherapists and nurses).</td>
</tr>
<tr>
<td>Thailand</td>
<td>1,285 TCM doctors (as of 2018) and 1,940 Acupuncture doctors (as of 2019).</td>
</tr>
<tr>
<td>UK</td>
<td>Over 11,000 TCM doctors and acupuncturists.</td>
</tr>
<tr>
<td>USA</td>
<td>Over 35,000 licensed acupuncturists of which approximately 20,000 are currently in practice.</td>
</tr>
</tbody>
</table>

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

2  BENEFITS EXPECTED FROM THE WORK OF ISO/TC 249

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

- Protect public safety by establishing minimum standards for the safety and quality of natural materials, equipment and services and enhance the benefits of TCM and related health systems to patients and the broader community.
- assist in harmonizing national standards which will facilitate international trade.
• encourage innovation in the sector by providing certainty around performance expectations.
• assist in developing consistent terminology and understanding of TCM and related health systems thus allowing reliable information, data collection and exchange.
• protect the reputation of TCM and related health systems.
• assist in setting national standards within the scope of ISO/TC 249 in countries with health systems that are evolving and to contribute to the regulation of TCM and related health systems.
• help increase acceptance of TCM and related health systems by governments, health care funders, health practitioners, regulators and the public which will also support the integration of TM with other health care systems.
• the experience of the committee can provide a template for dealing with other internationally-used Traditional Medicine systems.

3 REPRESENTATION AND PARTICIPATION IN ISO/TC 249

3.1 Participating and Observer Members of the ISO Committee
Currently ISO-TC 249 consists of 24 Participating ISO Member Bodies and 19 Observer Member Bodies. Please refer to website for the most up to date listing: https://www.iso.org/committee/598435.html?view=participation

Table (2): Participating and Observer members for ISO/TC 249

<table>
<thead>
<tr>
<th>Participating Member Bodies</th>
<th>Participating Member Bodies</th>
<th>Participating Member Bodies</th>
<th>Participating Member Bodies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (SA)</td>
<td>Canada (SCC)</td>
<td>China (SAC)</td>
<td>Czech Republic (UNMZ)</td>
</tr>
<tr>
<td>Germany (DIN)</td>
<td>Ghana (GSA)</td>
<td>Hungary (MSZT)</td>
<td>Italy (UNI)</td>
</tr>
<tr>
<td>Japan (JISC)</td>
<td>Kenya (KEBS)</td>
<td>Korea, Republic of (KATS)</td>
<td>Mongolia (MASM)</td>
</tr>
<tr>
<td>Netherlands (NEN)</td>
<td>Norway (SN)</td>
<td>Portugal (IPQ)</td>
<td>Russian Federation (GOST R)</td>
</tr>
<tr>
<td>Saudi Arabia (SASO)</td>
<td>Singapore (SPRING SG)</td>
<td>South Africa (SABS)</td>
<td>Spain (UNE)</td>
</tr>
<tr>
<td>Switzerland (SNV)</td>
<td>Thailand (TISI)</td>
<td>Tunisia (INNORPI)</td>
<td>Viet Nam (STAMEQ)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Observer Member Bodies</th>
<th>Observer Member Bodies</th>
<th>Observer Member Bodies</th>
<th>Observer Member Bodies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria (ASI)</td>
<td>Finland (SFS)</td>
<td>France (AFNOR)</td>
<td>Hong Kong</td>
</tr>
</tbody>
</table>
The regional participation is presented in Table 3.

**Table (3): Regional representation on ISO/TC 249**

<table>
<thead>
<tr>
<th>Region</th>
<th>Participating (24 NMBs)</th>
<th>Observer (19 NMBs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Africa</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Asia</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Europe</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>America</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Oceania</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Liaison arrangements with ISO/TC 249

The current organisations and groups with a liaison arrangement with ISO/TC 249 are:

(i) **Internal Liaisons**

- ISO/TC 215 ‘Health informatics’
- ISO/TC 304 ‘Healthcare organization management’
- ISO/TC 314 ‘Ageing societies’

(ii) **External Liaisons**
In addition, the Committee corresponds with other ISO committees such as ISO/TC 34 Food products and ISO/TC 210 Quality management and corresponding general aspects for medical devices and with the International Health Terminology Standards Development Organisation (IHTSDO)

The committee is also communicating with Pharmacopoeial Commissions such as those for the Chinese Pharmacopoeia, the United States Pharmacopoeia and the European Pharmacopoeia which develop monographs for herbal materials.

### 3.2 Participation Analysis

It’s noted that in the participation of ISO/TC249 technical work, some larger delegations are primarily from China, Japan and Korea. From the above distribution in Table (2), P-members include 8 Asian countries, 10 from Europe, 4 from Africa, 1 from America, 1 from Oceania. There are 19 European countries participating as either participating or observer members of the committee. It is important to broaden the involvement of other countries in the work of the committee considering the global use of TCM and related health systems, as participation is still limited. Possible reasons for the limited participation could include a lack of appropriate organizational structures in a country or limited resources such as financial supports, a limited number of national experts and a lack of relevant and updated information.

ISO/TC 249 will continue to liaise with related organizations and encourage active participation. The secretariat has arranged educational sessions related to the development of international standards and the committee Newsletter is circulated to enhance communication and knowledge of the work. The secretariat hosted a workshop with a number of potential participants in 2017 to encourage wider participation in the Technical Committee.

### 4 OBJECTIVES OF ISO/TC 249 AND STRATEGIES FOR THEIR ACHIEVEMENT

#### 4.1 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 Chinese medicine and related health systems, to support the quality,
safety and effectiveness of products and their use, and to assist in the trade and commerce of related goods and services. By developing ISO International Standards, the committee’s work will support public policy initiatives and protect the health and safety of customers and consumers.

The work of the Committee will reflect the objectives of the ISO’s Strategic Plan 2016-2020:

- To 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

- To develop robust standards and other deliverables relevant to the scope of the committee which meet the global market needs
  i. generic standards
  ii. specific standards
  iii. other standards and deliverables

In order to achieve its current work, ISO/TC 249 utilizes the involvement of NMBs to meet their requirements for standards in a number of specific areas thus supporting the development of TCM and related health systems. The initial priorities of ISO/TC 249 are the quality and safety of materials, products, and devices and informatics associated with TCM and related health systems, including service standards. Services make up an overwhelming part of the global economy, accounting for around 75 % of GDP in developed countries and around 50 % in developing countries according to World Bank data. The committee will explore the market interests in developing service standards in the upcoming years.

Areas such as the education and training of practitioners have been given a lower priority at this stage. The committee agreed to exclude clinical practice from its scope.

4.2 Identified Strategies to Achieve ISO/TC 249’s Defined Objectives

The identified strategies to achieve the ISO/TC 249 objectives are listed as following:

- invite or sponsor presentations on areas of need for standards by parties involved in the policy, implementation and delivery of healthcare programs,
- review existing resources such as national pharmacopoeias, other standards and guidelines,
- determine specific standardization needs of NMBs,
- extend liaison networks and encourage participation by a wide range of stakeholders for the purpose of a more cohesive and coordinated standardisation process,
• enhance communication and knowledge through a committee newsletter and the use of other communication tools to promote the committee’s work and ISO standards,

• produce and develop robust standards, including updating or amending existing standards where appropriate, and other deliverables relevant to TCM and related health systems in the following topics:
  a. Safety and quality of natural materials and their correct use (high priority)
  b. Safety and quality of medical equipment and their correct use (high priority)
  c. Informatics (high priority)
  d. Education and research (low priorities)

• establish excellent governance arrangements for the committee including:
  a. Working Groups and, where appropriate, Joint Working Groups, Chairman’s Advisory Groups, other Technical Committees.
  b. Maintaining the unique characteristics of TM basic theories and application, including taking advantage of the modern research methodology properly ranging from microbiological, biological, chemical, etc. in quality and safety of traditional medicines.
  c. Encouraging the development of new work items in accordance with the principle of sharing one common set of standards whenever possible.
  d. Avoiding redundancy and overlaps by a recognized process of assessment and project management by the ISO/TC249 Secretariat.
  e. Implementing standard operating procedures for the committee’s work.
  f. Ensuring the timely delivery and controlling the quality of ISO/TC 249’s Work Program.

• as far as possible, monitor the usefulness and impact of published standards

Much of the committee’s work is carried out through electronic communication with plenary meetings being convened on an annual basis when the volume and complexity of work to be considered warrants this.

The committee publishes a public newsletter to keep people and organisations informed of its work and to encourage participation in the work and is in the process of implementing a broader Communication Plan.

4.3 Resources to Support the Work of the Committee

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

The Chair of the committee is Prof Shen Yuandong and the Committee manager is Dr Sang Zhen.

All are available to provide as much support to the committee as needed.
The Chair and the Committee manager are supported by a Chair’s Advisory Group for the Governance of ISO/TC 249 which convenes as needed to provide advice to the Chair on matters related to the governance of the committee and a Chair’s Advisory Group for Work Coordination of ISO/TC 249 to assist in managing the work programs of the Working Groups.

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

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

a. *Inadequate management of the magnitude of the scope of the work.*
In this regard, the committee regularly reviews the priority setting of its work on the basis of scope, capacity, need and urgency. The committee seeks input into the priority areas for international standards and encourages members to ensure that proposals for new work items are carefully considered when voting. The committee has introduced a check list for members to assist in prioritising the new proposals.

b. *Inability to adequately accommodate the country-to-country variations in approaches to health systems which would reduce the usefulness of the standards.*
The committee places a high value on consultation and accommodating national variations, and those with greater proficiency and expertise offer their experience to the broader committee.

c. *Importance in reaching agreement among the participating countries on certain basic elements.*
Considering the divergence among members, the committee is committed to a consensus approach to resolving differences and reaching outcomes, with a respectful and understanding consideration of issues and the objective of progressing the important work of the committee for the benefit of the world community.

d. *Enhancing the justification for developing a new standard*
The responsibility of the TC members is to ensure the need and priority of any proposed standard and therefore that the final standard is useful and used in the global marketplace. To assist proposers of new project and their mirror committee, the checklist is used to ensure all ISO criteria for new projects are duly considered.

e. *Inadequate representation in the work of the committee from the range of potential users of the standards*
The committee encourages experts covering the range of affected stakeholder groups to be involved with the work of the committee. The secretariat is active in seeking new NMBs to join ISO/TC 249.

6 STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF ISO/TC 249

This section gives an overview of the ISO/TC 249's structure and the technical scope of its Working Groups.

6.1 Structure of ISO/TC249

Five working groups have been set up and operating in an ongoing manner for the standards work of ISO/TC 249. Each Working Group covers a technical area such as the quality and safety of manufactured products and their work plan is regularly reviewed and approved by the Technical Committee. Each Working Group is responsible for a number of projects with each project having a project leader, or in some cases co-project leaders, together with experts to develop an international standard. Currently there are also two Joint Working Groups, one with ISO/TC 215 to address joint work related to TCM informatics and the other with the IEC to deal with certain electrical medical devices. The committee structure is shown in Diagram (1).

Diagram (1): Structure of ISO/TC 249
6.2 Technical Scopes of the Working Groups

The information about WGs is reviewed annually by the Technical Committee and the current information for each of groups is as follows:

6.2.1 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.

Work plan and priority:

a) Projects for raw materials used in or as traditional Chinese medicine with high priority identified by WG1 based on a priority list of top 100 single herbs in ISO/TR 23975;

b) Projects for detection methods related to the safety of herbs, including detection method of toxins; and unwanted substances, etc.

c) Projects for improving the quality of herbs, including general requirements for herbal raw material and materia medica; and general requirements for primary processing of raw materials, etc.

6.2.2 Working Group 2

Title: Quality and safety of TCM manufactured products.

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

Work plan and priority:

The work priority within ISO/TC 249/WG 2 is to develop standards which contribute to the framework of manufactured TCM products.

Priority is given to generic standards such as,

• ISO/NP 19609-1, Quality and Safety of natural materials and manufacturing products made with natural materials used in and as traditional Chinese medicine (TCM) – Part 1: General
• ISO/NP 19609-2, Quality and Safety of natural materials and manufacturing products made
  with natural materials used in and as traditional Chinese medicine (TCM) – Part 2: Identity testing

6.2.3 Working Group 3

Title: Quality of acupuncture needles and safe use of acupuncture.

Scope: The scope of WG3 is standardization in the field of quality of acupuncture needles and
safe use of acupuncture, not including the clinical treatment or efficacy of acupuncture.

Work plan and priority:

a) To ensure the consistent understanding of the scope of WG3 under the guidance of
   ISO/TC249 to substantially contribute to a proposal’s preparation and the progression of every
   specific standard on acupuncture and its safe use and especially avoid repetition of the
   common issues during the development of individual standards on acupuncture and its safe
   use.

b) To ensure the consistent understanding of the terms and the definitions in standard
   development and to draw up a specific and applicable standards framework (roadmap) of
   WG3.

c) Quality control and improvement of projects based on the criteria of standard prioritization and
   project management procedures.

d) Standardization of the quality and safety of all types of acupuncture needles within the scope
   of WG3.

e) Project development on safe use of acupuncture consistent with the definition of “safe use”.

6.2.4 Working Group 4

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

Scope: The scope of WG 4 is to develop standards for quality, safety and safe use of medical
devices other than acupuncture needles, not including clinical treatment and efficacy of medical
devices. Exclusion: the safety and/or performance of electromedical equipment (see
ISO/TC249/JWG6).

Work plan and priority:

WG4 considers level of risk, scale of use, lack of standards or harmonization, importance for
international trade and commerce as prioritizing factors.
6.2.5 Working Group 5

**Title:** Terminology and informatics

**Scope:** The scope of WG5 is standardization of TCM nomenclatures, terminology, classification and ontology.

Health informatics technology, as it relates to TCM, shall be addressed within the scope of JWG1.

**Work plan and priority:**

a) prioritize the task to make the terms and informatics to be used by other WGs

b) industrial benefits and market needs should be considered in WG projects preferentially

c) WHO terminology standard should be reviewed closely prior to submitting the new proposals in order to avoid the redundancy

6.2.6 Joint Working Group 1 with ISO/TC 215

**Title:** Informatics

**Scope:** Health informatics technology related to TCM.

6.2.7 Joint Working Group 6 with IEC subcommittee 62D

**Title:** Electromedical equipment

**Scope:** The scope of JWG6 is standardization of the safety and/or performance of electrical equipment used in medical practice.

6.3 The Work Program of TC249

For information of the projects under development refer to the link at

http://www.iso.org/iso/home/store/catalogue_tc/catalogue_tc_browse.htm?commid=598435&development=on
APPENDIX I REGULATION of TM in NMBs

1. Australia

Australia regulates Traditional Medicines (TM) as complementary medicine products (abbreviated as TM/CM products, hereinafter), including manufactured Chinese herbal products and acupuncture devices, through the Australian Government's Therapeutic Goods Administration (TGA). The TGA’s Complementary and Over-the-counter Medicines Branch regulates TCM/CM medicinal products whereas medical devices are regulated by the TGA’s Medical Devices Branch.

Manufactured TM/CM products (other than raw materials, individual “starter” ingredients such as granules, powders, tinctures etc., substances deemed to be foods and individually prescribed prescriptions) must be approved for inclusion in the Australian Register of Therapeutic Goods (ARTG) before being legally sold in Australia. Entry onto the ARTG as a low consumer risk, listed medicine (AUSTL) is via a self-assessment procedure by the supplier of product which can only contain ingredients deemed safe for human use and are intended for self medication of certain illnesses. Some labeling warnings may be required. Products of higher consumer risk such as those labeled for the treatment of a serious medical condition or containing restricted substances require evidence of efficacy which is evaluated by the TGA before being included as a registered medicine (AUSTR). A new level within listed medicines has recently been introduced allowing for higher health claims where relevant evidence exists and has been assessed by the TGA.

Medical devices, such as acupuncture needles, moxibustion products and electroacupuncture stimulators are required to be included in the ARTG as registered medical devices before being legally sold or used therapeutically in Australia.

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

The legal prescription or supply of potentially harmful substances is regulated by various State and National medicines and poisons bodies and 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 products. Other than relegation related to toxicity, customs and quarantine, herbal retail outlets, and CITES-listing, there is minimal regulation of raw and traditionally processed herbal medicines.
Since 1 July 2012, Chinese medicine practitioners have been registered in Australia on a similar basis to 14 other nationally registered health professions. Registration with the Chinese Medicine Board of Australia involves holding a suitable tertiary qualification and complying with registration Standards, Codes and Guidelines which include Continuing Professional Development, English proficiency and Recency of Practice. Higher education TCM programs in Australia are assessed and approved against an Accreditation Standard developed by the Chinese Medicine Board of Australia.

2. 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 which complement the aims of ISO/TC 249. 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.

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 and generally falls under provincial or territorial jurisdiction. (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/pol/policy_compound-politique_compose-eng.php).

3. China

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

China promotes equal attention to and coordinated development of TCM and Western medicine.

The Pharmacopoeia of the People’s Republic of China (2015) is the national drug standard, of
which Volume I is an official collection of standards for 2598 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 introduces many modern analysis methods including Liquid Chromatograph-Mass Spectrum (LCMS), Thin Layer Chromatography-bioautography, Chromatography of Ions and High Performance Liquid Chromatography (HPLC). A 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 the control of impurities in drug products and, where appropriate, sterility testing.

In China, TCM practitioners are 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 are based on the regulations and standards by the Ministry of Health under the state council. According to “Regulations on Management of Medical Institutions”, an institution can start its medical activities only after receiving the practicing license.

The Ministry of Health and the Ministry of Education under the State Council are responsible for the formulation of standards of TCM education institutions. The standards on TCM clinics and apprentice teaching bases are drafted by the Ministry of Health.

4. Japan

The Kampo system of medicine evolved over time from ancient Chinese medicine. It was introduced into Japan from the Korean Peninsula in the year 562. After that Kampo medicine has evolved as a traditional Japanese medical system with over 15 centuries of history.

When Japan opened up to Western influences in the middle 19th century, and the Meiji Government took over in 1868, westernized medicine came to the fore and Kampo medicine declined. Formal Kampo medicine education was stopped in 1895, while acupuncture practice was legalized on the condition that it was practiced under a physician’s control. In the 1930s, some medical schools produced Practice of Clinical Kampo Medicine. The medical system proposed was based on further training following Western medical training, and this was eventually supported by the Government.
Current Status

The Kampo system of medicine evolved over time from ancient Chinese medicine. It has evolved as a traditional Japanese medical system with over 15 centuries of history. In 1967, Kampo extracts were first added to the National Health Insurance Drug Tariff in Japan, and now there are 148 prescription preparations and 696 products included in the Tariff, all of which are covered by national insurance plans. Kampo extracts were also adopted into the Japanese Pharmacopoeia (JP17) and its supplements, which now also have 33 kinds of Kampo extracts. At the present time, of the 148 Kampo medicines which are approved, the top 20 of these account for 67% of total sales. In addition, “the new guide book of the approval standards for OTC Kampo products” was published in 2013, and these are the basis of the over-the-counter (OTC) Kampo medicines, including 294 Kampo formulas. There are a large number of brands of OTC products.

In the current Japanese Pharmacopoeia, 226 crude drugs (medicinal herbs) are listed, and their original plants, minerals and animals and their quality including the limitation of foreign materials are defined.

Kampo medicines are prescribed by licensed physicians, sometimes on the recommendation of pharmacists. Based on surveys, approximately 90% of physicians prescribe Kampo products.

In 1947, the new legislation for acupuncturists and moxibustionists (Legislation No. 217, Article 1) was established and it accepted that licensed acupuncturists (moxibustionists) have their own clinic for practice. There are approximately 303,000 physicians, 280,000 pharmacists, 108,000 acupuncturists and 106,000 moxibustionists in Japan.

Government Policy and Regulations

The basis for the control of drugs in Japan is the Pharmaceutical Affairs Law which dates back to the 1960s. The overall purposes of the law are to assure quality, efficacy and safety of drugs, quasi-drugs, cosmetics and medical devices, and to improve public health and hygiene. The Pharmaceutical and Medical Devices Agency (PMDA), organized since 2004, is the group which reviews new OTC applications and then communicates their review to the Ministry of Health, Labour and Welfare (MHLW), which also consults with the Pharmaceutical Affairs and Food Sanitation Council (PAFSC). The PAFSC performs under the request of the MHLW and has two councils. The standards for medical devices used in acupuncture field are also reviewed and developed under control of the MHLW and PMDA.
Safety and Efficacy

Production of plant materials for Kampo medicine is highly recommended to be controlled under Good Agricultural and Collection Practice (GACP). About 80% of the crude drugs used in Kampo medicines are imported from China and about 15% are cultivated in Japan, with the rest originating in Vietnam, India, etc. The leading manufacturer of Kampo medicines provides inspection and quality control in China and Japan for its raw materials.

Good Manufacturing Practice (GMP) standards are a guideline for production, which includes both the finished product and the raw materials. The Japan Health and Nutritional Food Association and the Japanese Institute for Health Food Standards have established their own regulatory and certification systems for the production facilities and the products. Also there are self-imposed production standards set by the Japan Kampo Medicines Manufacturers Association. They are in addition to the GMP Ministerial Ordinance.

Adverse drug reactions (ADR) of Kampo medicines are required to be reported in the same way as for synthetic drugs, and physicians and pharmacists are required to report them to a central database. This results in about 150-200 reports per year. In the event of issues with a product, the MHLW issues a recall statement.

In the field of acupuncture and moxibustion, the Japan Industries Association of Physical Therapy Device is responsible for standards development. Up to now, national standards for “acupuncture needle for single use”, “electroacupuncture stimulator device” and “moxibustion device” have been issued.

Education and Research

Unlike China and Korea, there is no separation of Western medicine and Kampo medicine in the Japanese education system. Therefore, all physicians and pharmacists are educated and trained by the Western medicinal system. Practitioner is trained in Western medicine first, and then can choose to take specialty courses in Kampo medicine. There is no independent licensing requirement for a person trained in Kampo medicine in Japan however the Japan Pharmacists Education Center and the Japanese Society of Pharmacognosy have a special training course for the pharmacists on Kampo medicine and herbal materials. This program is supported in part by the Government.
All 80 Schools of Medicine in Japan now teach Kampo medicine. In the school of pharmacy, Kampo medicine is included in the core curriculum. Medical acupuncture is taught in 28 of the 80 schools of medicine as an elective.

For acupuncture and moxibustion, there are two types of training program. There are 11 universities with four-year programs and 157 colleges with three-year programs. Six of those 11 universities, in addition to undergraduate schools, have Graduate schools and produce researchers. As the major members of Japan Liaison of Oriental Medicine, both the Japan Society for Oriental Medicine and the Japan Society of Acupuncture and Moxibustion (JSAM) have been involved in promoting education and developing evidence reports on traditional medicine.

5. Korea

Korean Medicine has been recognized as a part of the main health system in Korea and through ongoing research and development of Korean Medicine, it is expected to play a distinctive role in public health at both a national and an international level.

The Ministry of Health and Welfare regulates clinical practice and policies on Korean Medicine in accordance with the Medical Service Act and Medical Device Act. Herbal medicine or medicinal products made of Korean medicinal herbs are managed by the Ministry of Food and Drug Safety. The Korean government established the ‘Korean Medicine and Pharmaceutics Promotion Act’ to promote Korean Medicine industries in 2004.

Furthermore, the Korean government has set up and operated the 5-year National plan for developing Korean Medicine since 2006.

The Korean Pharmacopoeia and the Korean Herbal Pharmacopoeia specify 602 types of herbal medicines.

Korean Medicine practitioners and Korean Medicine pharmacists have been registered with a license approved by the Ministry of Health and Welfare.

6. Spain

Generally in Spain there is no regulation regarding acupuncture/TCM and there is also no specific regulation on training or certification of persons applying for TCM.

TCM and acupuncture therapies are not funded by the public health system. However, in the case of acupuncture there are several units of acupuncture in hospitals and primary care centres.
The right to practice acupuncture is a contentious issue which appears to be more favourable to Western doctors than to TCM practitioners. Western doctors believe that acupuncture should be considered a medical specialty reserved for Western medical practitioners only. TCM practitioners are allowed to be registered under 'other parahealth practitioners'.

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.

7. Singapore

(1) TCM Practitioners Registration
The Traditional Chinese Medicine Practitioners Act, which was passed in Parliament in 2000, requires all TCM Practitioners to be registered with the TCM Practitioners Board. The registration of TCM Practitioners began in 2001 with the registration of acupuncturists. This was followed by the registration of TCM physicians from 2002. From January 2004, all who practise TCM are required to be registered with the TCM Practitioners Board and possess a valid practising certificate. From December 2005, Chinese Medicinal Materials dispensers who graduated from the Chinese Medicinal Materials (CMM) Training course (Intermediate module) are voluntarily listed with the TCM Practitioners Board.

(2) Chinese Medicines Regulation
All Chinese Proprietary Medicines (CPM) i.e. products in the finished dosage forms (e.g. tablet, capsule, liquid) are regulated by the Health Sciences Authority (HSA) and must comply with a set of safety and quality criteria before they are allowed to be sold in Singapore. In addition, CPM dealers (importers, wholesale dealers and manufacturers) are also required to be licensed by the HSA. The sale or use of suspicious CPM should be reported to HSA for further investigation. For information on the regulation of Chinese Proprietary Medicines and Raw Medicinal Herbs, please refer to the HSA's website on Complementary Health Products.

8. Thailand
In 2000, Ministry of Public Health announced the legal status of TCM. In 2004, the Thai law started to recognize TCM. Universities set up TCM curriculum in undergraduate education and training schools for acupuncture education. In 2009, the King of Thailand signed the document of TCM’s legislation and announced the Professional Committee in Chinese Medicine. In 2015, acupuncture has been included in the Health Insurance System of Thailand.

9. South Africa

The National Association for Chinese Medicine and Acupuncture of South Africa (NACMASA) is registered with the Allied Health Professions Council of South Africa and was founded in July 2004. It has 450 members, among whom 200 are doctors of acupuncture and TCM, 150 are western medical doctors with acupuncture certificates and 100 acupuncturists.

Since its founding, NACMASA has organized proficiency tests for TCM practitioners and acupuncturists on several occasions with the passers recognized by the state. NACMASA also organizes workshops and training on Chinese medicine and acupuncture with lectures by internationally renowned doctors.

APPENDIX II USE of TM/CM PRODUCTS in NMBs

1. Canada

In 2010, a survey was conducted concerning the current levels of awareness, attitudes, knowledge, and behaviors among Canadian consumers of Natural Health Products and this information is available on the (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php). According to the study, nearly three in four consumers (73%) have used a NHP in the past, which has increased two percentage points since 2005 (71%). However, the findings of the study also suggest that there are many Canadians who are not particularly familiar with NHPs and the following observations were made:

- 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% in 2005) 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%) and antioxidants (8%).

Canada does not have any statistics on Canadian exports of NHPs which include TCM products.

2. China

In 2015, the value of exports and imports of TCM products from China reached US$ 4.79 billion which included US$ 3.77 billion in exports which had increased by 4.9% over 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: Countries to which China exported Chinese medicine products in 2012](Compiled by CCCMHPIE according to China Customs)

3. Japan

The value of Kampo medicines is about 1.6-1.9% of the overall drug market in Japan or about USD$1 billion per year, and represents about 3.4% of the OTC market. Of the herbal market in Japan, 81% is in prescription Kampo medicines and 17.7% is in OTC Kampo medicines and decoction pieces. In Japan, 90% of the hospitals with more than 500 beds have Kampo clinics.

In Europe, the activity of ISJKM (International Society for Japanese Kampo Medicine) has been included as an example of Kampo societies since 2009. Kampo medicine has been practiced in
Germany, Spain, UK and Austria by some medical doctors. Another society, the German Medical Doctors’ Association for Acupuncture (DÄGfA), works in close cooperation with ISJKM.

Although it does not seem that there is reliable market research or a result reported about traditional herbal products in the US market, it could be roughly estimated that 60% of the total products are supplied in the form of powder, 30% will be pills and the rest of 10% will be raw herbs. This means that 60% of the herbal products are processed products and the remaining 40% are non-processed ones which are pills and raw herbs. The powder products of traditional herbal medicine are very popular in the US market mainly because of user-friendliness and convenience. Every single powder product is processed using the extracting technology which Japan is the inventor and originator in the mid-20th century.

4. Korea

The export amount of Korean Medicine products is as follows (as of 2013):

<table>
<thead>
<tr>
<th>Type</th>
<th>Amount (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ginseng</td>
<td>174 million</td>
</tr>
<tr>
<td>Raw materials</td>
<td>11 million</td>
</tr>
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</table>

The import amount of Korean Medicine products is as follows (as of 2013):

<table>
<thead>
<tr>
<th>Type</th>
<th>Amount (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ginseng</td>
<td>3 million</td>
</tr>
<tr>
<td>Raw materials</td>
<td>112 million</td>
</tr>
</tbody>
</table>
## Glossary of terms and abbreviations used

<table>
<thead>
<tr>
<th>Term</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australian Register of Therapeutic Goods</td>
<td>ARTG</td>
</tr>
<tr>
<td>China Chamber of Commerce for Import &amp; Export of Medicines and Health Products</td>
<td>CCCMHPIE</td>
</tr>
<tr>
<td>Complementary and Alternative Medicine</td>
<td>CAM</td>
</tr>
<tr>
<td>Complementary Medicine</td>
<td>CM</td>
</tr>
<tr>
<td>International Electrotechnical Commission</td>
<td>IEC</td>
</tr>
<tr>
<td>International standard</td>
<td>IS</td>
</tr>
<tr>
<td>Joint Working Group</td>
<td>JWG</td>
</tr>
<tr>
<td>Natural Health Product</td>
<td>NHP</td>
</tr>
<tr>
<td>National Member Body</td>
<td>NMB</td>
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<tr>
<td>Over The Counter</td>
<td>OTC</td>
</tr>
<tr>
<td>Traditional Chinese Medicine</td>
<td>TCM</td>
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<tr>
<td>Therapeutic Goods Administration</td>
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<td>Traditional Medicine</td>
<td>TM</td>
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<td>Technical Management Board</td>
<td>TMB</td>
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<tr>
<td>World Federation of Acupuncture-moxibustion Societies</td>
<td>WFAS</td>
</tr>
<tr>
<td>World Federation of Chinese Medicine Societies</td>
<td>WFCMS</td>
</tr>
<tr>
<td>World Health Organisation</td>
<td>WHO</td>
</tr>
<tr>
<td>Working Group</td>
<td>WG</td>
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