The Importance of International Standards and the Role of ISO/TC 249

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It is very impressive when a traditional medicine (TM) system transcends its cultural boundaries and becomes an accepted health modality in other countries. Where this uptake is sustained and increases, it suggests that the system is offering more than simply a response to smart marketing or an interest in a fad but is seen by the society as providing true benefits. This is the case with traditional medicine systems derived from ancient Chinese medicine, namely traditional Chinese medicine (TCM), Korean medicine and Kampo, as their use extends internationally.

However, this wider use also brings risks and challenges, as the traditional medicine system moves away from the environment of its cultural heritage with its inherent checks and balances and, as a complementary medical system in another country, is exposed to many commercial and competing pressures. These risks include a lack of quality control and distortion of the traditional medicine system, with consequent damage to its reputation, public safety and trade.

For a medical system to become an integral part of a country's health system, it requires a number of elements to be in place:

- Informatics – there is the need for a common language and understanding of the terminology, classification and coding of relevant information to support the sharing of research, clinical practice etc.
- Quality education and training for health practitioners.
- Research, innovation and an evidence base to support practice and products. It is a difficult transition to move the evidence base from experiential to scientific; however, this is being increasingly required by regulators and others. The modernisation of traditional medicine – which includes new methods of manufacture, pre-packaged dosage forms and new formulations and methods of delivery – will increase the demands for appropriate levels of scientific evidence that should be commensurate with the risk represented by the product or practice.
- Clinical guidelines and other documentation.
- Means to establish the quality, safety and efficacy (or effectiveness) of treatments, many of which are complex mixtures of natural materials.
- Appropriate use of the treatments by the consumer, including such aspects as product labelling and product information.

When these elements are firmly in place, they provide the basis for appropriate regulation of products and registration of practitioners, which benefits consumers, the profession and industry. These elements protect the reputation of the health modality and support its wider acceptance and integration into the national health care and funding systems, while also supporting international trade and commerce associated with the health modality.

Defining standards or benchmarks for each of these elements is a priority. While national standards often suffice, they can vary markedly between countries in their quality, and these differences can undermine public safety, the reputation of the modality and trade. In some cases where standards are most needed, the country may not have the resources or skills to develop the standards.

The International Organization for Standardization (ISO) provides a structure for developing international standards. ISO defines a standard as 'a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose'.

Important benefits of the ISO approach are:

- The consultative and consensus-based processes, where the standards are developed by experts nominated by member bodies and organisations and the standards evolve through rigorous consultative processes. The standards represent global expert opinion drawing on the knowledge of consumers, practitioners, industry and government.
- Defining an expected set of specifications for a product or service which are harmonised across countries and markets. The role of ISO is not to duplicate existing national or regional standards, many of which are already adequate, but to provide a means of harmonising expectations across markets or to provide access to standards where none exist.
- The standards are provided by ISO as an international resource to be used on a voluntary basis and, where deemed necessary, can be adjusted by a country to meet its particular national needs and also mandated in its legislation.

- Providing review processes for keeping ISO standards up to date.

Through these processes, ISO standards can assist in putting into place internationally agreed specifications which protect users and assist commerce.

ISO is well aware of the risks inherent in defining expectations through developing standards and has defined criteria for the global relevance of standards. These are that a standard:

- meets regulatory and market need i.e. the need for a standard must be carefully assessed and prioritised
- does not distort the market nor impair fair competition; for example, by guarding against a proposal for a standard where the motivation is to create a barrier to competitors
- does not stifle innovation and technological development – in fact, a standard should encourage innovation by establishing an environment of confidence
- where possible, is performance-based and not design prescriptive i.e. it should define the outcomes sought rather than the processes for getting there, thus encouraging innovation.

Countries can become members of ISO, usually through their principal national standards organisation. At this time, 111 countries are full ISO members with additional correspondent (observer) members. Australia is a full member represented by Standards Australia. If ISO accepts a proposal from a member showing a need to develop standards in a new work area (such as an industry sector not previously covered by ISO) then ISO establishes a Technical Committee (TC) to perform that work. At present there are 224 Technical Committees.

Both South Korea and China were concerned that as the international use of their traditional medicine systems expanded, they should be underpinned by access to appropriate standards. Proposals were made to ISO and ISO established a Technical Committee (ISO/TC 249) in 2009 to oversee the development of international standards in traditional Chinese medicine. However, ISO also asked the committee to consider whether it could cover other TM systems as well. While the committee still operates under a provisional title of TCM, it was agreed in May 2013 that its scope includes TM systems derived from ancient Chinese medicine, which brings Kampo and Korean medicine within its purview.

Twenty-one national members have chosen to be active in the work of ISO/TC 249 and can vote on outcomes, and 12 national members have chosen to be kept informed of the work but do not vote (Table 1).

Each national body establishes a national mirror committee to the ISO Technical Committee. The role of the mirror committee is to consult nationally and bring that country's input to the discussions and work of the ISO Technical Committee. The shadow committee supported by Standards Australia brings the Australian input to the work of ISO/TC 249, and is very capably chaired by Associate Professor Chris Zaslawski, University of Technology, Sydney.

In addition, certain international, not-for-profit organisations can be accepted as Liaison members of Technical

TABLE 1 National Members participating in ISO/TC 249

Australia	Israel	South Africa
Austria	Italy	Spain
Canada	Japan	Switzerland
China	Korea, Republic of	Thailand
Germany	Mongolia	Tunisia
Ghana	Netherlands	United States of America
India	Singapore	Vietnam
National members with the status of observers		
Barbados	Ireland	Seychelles
Finland	Lithuania	Sweden
France	New Zealand	United Kingdom
Hong Kong	Poland	Zimbabwe

Committees. The World Federation of Acupuncture-Moxibustion Societies (WFAS) and the World Federation of Chinese Medicine Societies (WFCMS) have made valuable contributions to the work of ISO/TC 249. The World Health Organization (WHO) (particularly the area dealing with the International Classification of Traditional Medicine) is also an alliance member. Liaison members do not have a vote on the work outcomes.

There are also a range of other Technical Committees within ISO dealing with health and related sectors. Important to the work of ISO/TC 249 are ISO/TC 34, which deals with food products, ISO/TC 210 which deals with quality management and corresponding general aspects for medical devices, and ISO/TC 215 which deals with health informatics. We aim to ensure that we coordinate our work with their activities.

The Committee is fortunate to have a very strong secretariat headed by Prof Yuandong Shen, Professor of the Shanghai University of TCM, which is financially supported by China and located in Shanghai. The Technical Committee provides the governance of the work, while the technical work is largely carried out by experts operating within Working Groups (WG) that report to the Committee. ISO/TC 249 holds an annual meeting hosted by one of its member countries while the Working Groups meet as needed. Much of the work is done electronically in between face-to-face meetings.

At this stage, the work priorities for the Committee have been to develop standards in the areas of

- Informatics
- Quality and safety of treatments

The Committee has established five Working Groups which have responsibilities as follows:

- **WG1:** quality and safety of raw materials and traditional processing
- **WG2:** quality and safety of manufactured products
- **WG3:** quality and safety of acupuncture needles
- **WG4:** quality and safety of other medical devices
- **WG5:** terminology and informatics. There is also a Joint Working Group with the technical committee which deals with Health Informatics (ISO/TC 215).

In a relatively short period, the outcomes of the work of the committee are becoming apparent. Table 2 lists the current projects, covering both traditional aspects and the modernisation processes of these traditional medicine systems with their common origins in ancient Chinese medicine. The objective of each project is an international standard, the development of which follows a process defined in detail by ISO and generally takes three years to complete.

A range of other projects are progressing through the initial approval stages.

The work of ISO/TC 249 has made, and will continue to make a very important contribution to supporting the appropriate international use of TM systems derived from ancient Chinese medicine. The Committee is very appreciative of the strong contribution of Australian experts to its work. The Committee publishes a periodic newsletter of its activities, which people can receive by contacting the committee secretariat on email: mscsh2009@gmail.com.

TABLE 2 Current approved projects of ISO/TC 249, indicating the relevant Working Group.

Ginseng seeds and seedlings – Part 1: *Panax ginseng CA Meyer*	WG1
Sterile acupuncture needles for single use (now ISO standard 17218: 2014)	WG3
Requirements for basic safety for electroacupuncture stimulator	WG4
General requirements of electrical radial pulse tonometric devices	WG4
TCM Vocabulary Part 1: *Chinese Materia Medica*	WG5
Electroacupuncture stimulator device for quality	WG4
Heavy metals in natural materials used in traditional Chinese medicine	WG1
Herbal decoction apparatus	WG4
Moxibustion devices – general requirements	WG4
Coding system of Chinese medicines – Part 1: Coding rules for decoction pieces	WG5
Intradermal acupuncture needles	WG3