Traditional Chinese Medicine Forum
Background to ISO/TC 249 and HE- 031

Associate Professor Chris Zaslawski
HE – 031 Chair

6th December 2012
Factors driving standardisation of Chinese medicine

- Development of new technologies
- Increasing commercialisation of herbal medicine
- Research activity within the field
- National regulation of the practice of TCM by Chinese Medicine Board of Australia
- Regulation and integration of traditional medicines into the public, private and community health care sector
- Integration of TCM into higher education sector
Standards will impact on

- clinical practice
- trade
- research
- policy development
- education

- Will require extensive consultation and discussion if all stakeholders and interested parties are to achieve suitable outcomes.
History of standardisation in China

- Standardisation is not new to China’s traditional medicines
- Song dynasty as well as the Jin-Yuan era provides a very good example of the Imperial Courts attempt to standardize
Revision of the location of the acupoints by Wang Weiyi “Illustrated Manual on the Points for Acupuncture and Moxibustion on a New Bronze Figure”

Casting of the two bronze figures which were used for examination
Historical Background

- Recent period of 1957 to 1963 was also a time when China's medical practices were markedly institutionalised and standardised

- First sets of edited national textbooks were produced and a comprehensive theory of the medicine was developed to become what is now known as Traditional Chinese Medicine (TCM)

- More recently the Western Pacific Region of WHO initiated the second wave of standardisation. A recent search of their website found thirteen documents associated with standardisation
In July 2006 the State Administration of Traditional Chinese Medicine issued an ambitious developmental plan (2006-2010) to standardise Chinese medicine.

In January 2010, 305 TCM standards had been issued including 47 national standards, 258 at a professional level covering 13 basic standards, 234 technical standards and 49 standards associated with management.
Japan

- In May 2005, several societies and institutions organised a summit whereby they established the Japanese Liaison of Oriental Medicine (JLOM)
- Appointed JLOM as the mirror committee for the newly established international standards Technical Committee for traditional Chinese medicine (TC 249).
- Had established a standard for the filiform needle (JIS 9301)
Korea

- The Korean Institute of Oriental Medicine (KIOM) located in Daejeon, was instrumental in organising a number of international non-governmental forums which have lead to several national Korean standards being developed.

- President of KIOM was previously traditional medicine advisor for WPR WHO
Currently China (GB 2024-94), Korea (KSP 730) and Japan (JIST 9301) all have a national standard for the acupuncture needle

These three national needle standards developed by China, Japan and Korea demonstrate similar content and potential for developing an international standard

Indeed projects for developing standards for devices such as the single use filiform acupuncture needle have been the easiest to achieve and gain consensus from all stakeholders
Background to TC 249

  - Submission by South Korea (KATS) of needle standard to ISO for consideration
  - China (SAC) also submit application for TCM
  - Active program of standard development in China
Preliminary Meeting of ISO/TC Traditional Chinese Medicine (TCM)

Consult on the two applications from PRC and Korea [to establish a TC for Traditional Asian Medical Devices (Korea) and Traditional Chinese medicine (PRC)] with a view to refining the proposal from the China for a TC for TCM

Four countries present - China, Japan, Korea and Australia (41 technical experts and representatives) plus representatives from ISO central
Title of TC. There was considerable discussion regarding the name of the proposed TC. China wanted Traditional Chinese Medicine (TCM), Japan wanted Traditional East Asian Medicine (TEAM) and Korea wanted Asian Traditional Medical Devices. Australia could not agree to a change in title from TCM without further consultation with Standards Australia.

Scope of TC. This was the subject of vigorous debate. China proposed a wide scope for the TC including herbal medicine, education and terminology, all aspects of practice, etc whereas Japan and Korea wanted to restrict the scope to devices and related quality control. Australia proposed the scope be restricted to devices and terminology.
Beijing 24th August 2009

Recommendation 01/2009

• The preliminary meeting of the ISO/TC Traditional Chinese Medicine recommends to ISO/TMB to formally establish a new ISO/TC.

Recommendation 02/2009

• The preliminary meeting of the ISO/TC on Traditional Chinese Medicine recommends that the scope initially include devices, safety and quality standards, but not limited to these items in the future. China and Australia recommend the inclusion of terminology (excluding the items related to ISO/TC 215) but Japan and Korea disagree on including terminology. The scope should be further discussed in the first plenary meeting of the new TC among all participating (P) members and then would be submitted to ISO/TMB for approval. However, the scope should avoid overlapping with the existing ISO/TCs. At the same time, further coordination with the World Health Organisation (WHO) will be needed after the establishment of the new TC.
Recommendation 03/2009

The Preliminary Meeting of ISO/TC on Traditional Chinese Medicine recommends that the proposal on Asian Traditional Medicine Devices (ATMD) from KATS (Korea) be considered by a group established within the new TC to carry out its work after the establishment of this new ISO/TC.
Shortly after, based on the recommendations from this meeting, the Technical Management Board of ISO voted for the establishment of a technical committee (TC 249) for Chinese medicine.

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.
Shanghai 25-26\textsuperscript{th} February 2010

- Seminar on Standardisation of Traditional Chinese Medicine (TCM)
- In preparation for the newly proposed technical committee 249 (TCM)
- Nineteen countries (either technical experts or members of the national standards bodies attended) totalling 51 delegates
First Plenary of TC 249

- 13 P members and two O members attended (72 delegates)
- Productive discussions on the issues of title, scope, liaisons with other bodies and preparations for the Business Plan of ISO/TC249
- It was agreed that Training, Education and Practice of Practitioners and Research methodology will be lower priorities which could be reconsidered at a later date.
Hague, Netherlands 2-4th May 2011

- Second plenary of ISO/TC 249
- 14 member bodies (84 participants)
- Establishment of working groups
- Establishment of Chairman's Advisory Group
- Draft business plan
- Agreed to operate under the provisional title of Traditional Chinese Medicine (TCM)
Daejeon, Korea  
21-24th May, 2012

- Second plenary of TC 249
- Development of working group projects
- 14 member bodies attended (166 delegates)
- Sandwich format (plenary-WG meetings-plenary)
- Further development of several new projects and confirmation of two developing standards (Single use needle and ginseng seed and seedling standards)
- Agreement of a Joint Working Group (Informatics of TCM) between TC249 and TC215 (Health Informatics) was approved
Each participating member country is required to establish a “mirror” committee which will be responsible for developing, debating and eventually agreeing on their national perspective.

A member from the mirror committee (HE 031) will then represent the national opinion regarding the particular standard at the larger international ISO technical committee meeting.

Established after the first plenary in 2010.
- Broad representation of all interests and adherence to committee protocols and procedures
- Committee members representing education, and research institutes, professional practitioner bodies, appropriate government regulators, consumers and industry groups will ensure a broad and diverse opinion
- Chair - Chris Zaslawski
- Members - Sue Cochrane, Wendy Morrow, Chunguan Li, Max Ma, Hong Xu
- Meet regularly (F2F, teleconference)
- Members of mirror group can attend WG meetings and plenary
Elements of an ISO/TC

- Secretariat
- Technical committee (TC)
- Work groups (WG)
- Plenary meeting
Secretariat

- Appointed by Technical Management Board of ISO to manage and support the TC
- Situated in Shanghai, PRC
- Teams of experts from as many countries that want to be involved
- Propose (one nation) and develop the standard to a level of consensus
- Don’t represent country but expertise (eg needle manufacture, herb manufacture, terminology etc)
- Five (5) WGs for ISO/TC 249 and for HE-031
ISO/TC 249 Plenary

- Main TC committee meeting - one country, representing one member body, head of delegation speaks only
  - Decision making body
  - One country-one vote
  - All discussion in English
Plenary

- Main TC committee meeting - one country, representing one member body, head of delegation speaks only
- Decision making body
- One country-one vote
- All discussion in English
Active discussion
Time for reflection?
Important questions

- Who should and wants to be involved?
- What aspects of Chinese medicine should be standardised?
- How can consensus be achieved given the complexity and diversity of opinion from stakeholders?
- Chinese medicine has inherent cultural values
- Stakeholders will need to reflect on their national and regional interests which may lead them to assert their own priorities.
AUSTRALIA IN THE ASIAN CENTURY WHITE PAPER

- Our economy will be deeply integrated; our trade links with Asia will be at least one-third of GDP, up from one-quarter today.
- Globally we will be ranked in the top 5 countries for ease of doing business and our innovation system will be in the world’s top 10.
- Our diplomatic network will have a larger footprint across Asia supporting stronger, deeper and broader links with Asian nations.
Media Releases

- Arts Minister Simon Crean: *Australia in the Asian Century* White Paper sets a clear objective for cultural diplomacy and exchange to drive a stronger, deeper and broader engagement with Asian nations.

- Trade and Competitiveness Minister Craig Emerson: Australia is rising to the Asian Century challenge by devoting more of its diplomatic and commercial resources to the region and “The Gillard Government will position Australia as a connecting rod between Latin America and Asia in pursuit of a free trade area of the Asia-Pacific.”
THANK YOU