THE PAST
History of ISO/TC 249

- ISO/TC proposed by SAC at 45th TMB, June 2009
- Preliminary meeting August 2009, Beijing
- ISO/TC 249 approved at 46th TMB, Sept 2009
- 1st Plenary meeting, Beijing, June 2010
- 2nd Plenary meeting, the Hague, May 2011
- 3rd Plenary meeting, Daejeon, Korea, May 2012
- 4th Plenary meeting, Durban, May 2013
Why the technical committee was formed?

TCM is used in over 120 countries and the PRC wants to:

- protect the IP, standards and reputation of TCM
- support national and international trade and commerce
- protect public health and safety
The TMB established ISO/TC 249 with the provisional title of ‘Traditional Chinese Medicine’ and asked whether other forms of Traditional Medicine can be accommodated.
Supply chain for therapeutic products

SUPPLIER → PRACTITIONER → PATIENT

- devices
- medicines
- methodology

QUALITY
SAFETY
EFFICACY

TRAINING
&
PRACTICE

RATIONAL USE

INFORMATICS
EVIDENCE BASE
Two dimensions of the scope

1. Scope of modalities (title)

TCM (one project) ➔ TMs (multiple projects)

2. Each modality scope

- Practitioner education and training
- Quality and safety of products/services
- Evidence base (efficacy)
- Other: rational use, informatics
THE PRESENT
Modality scope of ISO/TC 249

Supply chain for therapeutic products

- SUPPLIER
- PRACTITIONER
- PATIENT

- devices
- medicines
- methodology

QUALITY
SAFETY
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Scope of ISO/TC 249 (Title)

- Still operating under the provisional title of TCM
- Aspects of the work cover TCM and related TMs (Korean Medicine and Kampo)
Main Technical Committee

5 Working Groups

- WG 1: Quality and safety of raw materials and traditional processing
- WG 2: Quality and safety of manufactured products
- WG 3: Quality and safety of acupuncture needles
- WG 4: Quality and safety of other medical devices
- WG 5: Informatics of TCM

One joint working group with ISO/TC 215 (health informatics)
<table>
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<th>Participants</th>
<th>P (Participating Members)</th>
<th>Korea, Republic of (KATS)</th>
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<tr>
<td>Australia</td>
<td>(SA)</td>
<td>Mongolia (MASM)</td>
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<td>Singapore (SPRING SG)</td>
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<td>Italy</td>
<td>(UNI)</td>
<td>Viet Nam (STAMEQ)</td>
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(24)
### Participants

**O (Observer) members (8)**
- Barbados (BNSI)
- Hong Kong, China (ITCHKSAR) (Correspondent member)
- Ireland (NSAI)
- Lithuania (LST)
- New Zealand (SNZ)
- Poland (PKN)
- Sweden (SIS)
- United Kingdom (BSI)

### Liaison organisations

- World Health Organization (WHO)
- World Federation of Acupuncture and Moxibustion Societies (WFAS)
- World Federation of Chinese Medicine Societies (WFCMS)
Draft International Standards for:

✓ ISO17217 Ginseng seed and seedlings

✓ ISO17218 Sterile acupuncture needles for single use

Working Drafts under development:

• N40 Computerized tongue diagnosis system

• N41 Requirements for basic safety and essential performance for electroacupuncture stimulator

• N42 General requirements of electric radial pulse tonometric devices
Current activities of ISO/TC 249 (continued)

Items under development:

- **N45** Heavy metals in natural materials of TCM
- **N47** Moxibustion devices
- **N44** Quality requirements for electroacupuncture stimulator
- **N46** Herbal decoction apparatus
- **N46** Herbal decoction apparatus
- **N46** Intradermal acupuncture needle
- **N43** Basic terms of Chinese Materia Medica
- **N48** Coding system of Chinese Medicine
ISO/TC 249

- Chair: Dr David GRAHAM
- Secretary: Prof SHEN Yuandong
- Assistant Secretary: Dr SANG Zhen
- Secretariat: Ivy Lee, Shirley Xu, Huang Yufeng
- Location: Shanghai
- Secretariat host: Standardization Administration of China (SAC)
THE FUTURE
Underlying principles guiding our work

- We deal with internationally-used health modalities rather than those used solely within one country
- Our outcomes are based on consensus and we optimise participation by stakeholders
- Sensitive to differing proficiencies between countries
- We create International standards that accommodate national adjustments
- Compliments rather than duplicates existing resources
Considerations

- A traditional medicine is a complementary medicine in other countries.
- Modernisation of TMs through different formulations and methods of manufacture and presentation.
- The need to put the issue over the committee’s Title behind us.
- Ensuring the correct motives and need for new standards.
- The deficiencies in the evidence base for TMs.
- Effective engagement with WHO on informatics.
The benefits of an International Standard

- Underpins the international use and acceptable practice of a health modality
- Assists global consistency, e.g. practice, terminology, common understanding
- Protects the reputation of the modality
- Assists in setting national standards
- Assists harmonisation, trade and information exchange
- Protects the community
- Assists acceptance and use of the health modality
- Supports integration within health care more generally
THANK YOU