



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 areas of 'safe use and delivery of medicines and devices' include 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 complementary 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 complementary 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. By the end of June 2021, there were 2198 valid product registration and filing certificates of traditional Chinese medicine medical devices in China, including 561 registration certificates of class II products and 1637 filing certificates of class I products. 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 and some related health systems, there are more than 1.4 million 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.

Table (1): Number of TCM and related health system practitioners globally

Australia	There are approximately 4,900 nationally registered Chinese medicine practitioners covering acupuncturists (98%), Chinese herbal medicine practitioners (64%), and Chinese herbal dispensers (23%); plus, around 640 other registered health practitioners, mainly medical practitioners, authorised to practise acupuncture. (source: Australian Health Practitioner Regulation Agency; Board Statistics, December 2021. < https://www.ahpra.gov.au/ >) Additionally, there is an unknown number of registered and unregistered health practitioners (mainly medical practitioners, massage therapists,
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	physiotherapists, myotherapists, and chiropractors) using acupuncture techniques, often under a different designation such as 'dry-needling'.
Canada	Over 10,000 TCM doctors and acupuncturists.
China	682,770 licensed practitioners and assistant practitioners of TCM (source: Statistical Summary Report on the Development of Traditional Chinese Medicine 2020).
France	Over 7,000 acupuncturists.
Japan	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.
Korea	KM Doctors:25,524 (2019) Korean Medicine pharmacists: 2,649 (2019)
Netherlands	Over 3,500 acupuncturists.
Saudi Arabia	There are 96 licensed cupping centers and 343 licensed and certified cupping practitioners (NCCAM, 2019)
Singapore	1,800 TCM doctors.
Spain	Over 15,000 CM practitioners which includes about 1,500 western doctors and the rest are non medical therapists (mainly physiotherapists and nurses).
Thailand	1,834 TCM doctors (as of 2022) and 2,131 acupuncture doctors (as of 2022).
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 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 22 Participating ISO Member Bodies and 23 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

Participating Member Bodies			
Australia (SA)	Canada (SCC)	China (SAC)	Czech Republic (UNMZ)
Germany (DIN)	Ghana (GSA)	Hungary (MSZT)	Iran, Islamic Republic of (ISIRI)
Italy (UNI)	Japan (JISC)	Kenya (KEBS)	Korea, Republic of (KATS)
Netherlands (NEN)	Portugal (IPQ)	Russian Federation (GOST R)	Saudi Arabia (SASO)
Singapore (SPRING SG)	South Africa (SABS)	Spain (UNE)	Switzerland (SNV)

Thailand (TISI)	Viet Nam (STAMEQ)		
Observer Member Bodies			
Argentina (IRAM)	Bahrain (BTMD)	Burundi (BBN)	Egypt (EOS)
Finland (SFS)	France (AFNOR)	Hong Kong (ITCHKSAR) <i>(Correspondent member)</i>	India (BIS)
Ireland (NSAI)	Israel (SII)	Lithuania (LST)	Macao (CPTTM) <i>(Correspondent member)</i>
Mongolia (MASM)	Nepal (NBSM)	New Zealand (SNZ)	Poland (PKN)
Romania (ASRO)	Seychelles (SBS) <i>(Correspondent member)</i>	Sweden (SIS)	Togo (ATN)
Tunisia (INNORPI)	United Kingdom (BSI)	Zimbabwe (SAZ)	

- (a) The regional participation is presented in Table 3.

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

Region	Participating (22 NMBs)	Observer (23 NMBs)
Africa	3	6
Asia	8	7
Europe	9	8
America	1	1
Oceania	1	1

- (b) 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

World Health Organization (WHO)

World Federation of Chinese Medicine Societies (WFCMS)

World Federation of Acupuncture-Moxibustion Societies (WFAS)

IEC/SC 62D 'Electromedical Equipment'

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, 9 from Europe, 3 from Africa, 1 from America, 1 from Oceania. There are 17 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 Strategy 2030*:

- 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, Advisory Group, 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 by measures including using a check sheet when the new items being submitted and using the OSD platform to comment and consolidate comments online during the key standards development stages.
- as far as possible, monitor the usefulness and impact of published standards to ensure that they remain up-to-date and globally relevant.

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.

The Working Groups have been expected as well to set the priority of the technical areas within its scope and assess whether there are sufficient resources available for the project to meet the ISO timeframes taking account of the overall work plan of the Working Group. The criteria of setting such priority should be considered and reached consensus first.

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.

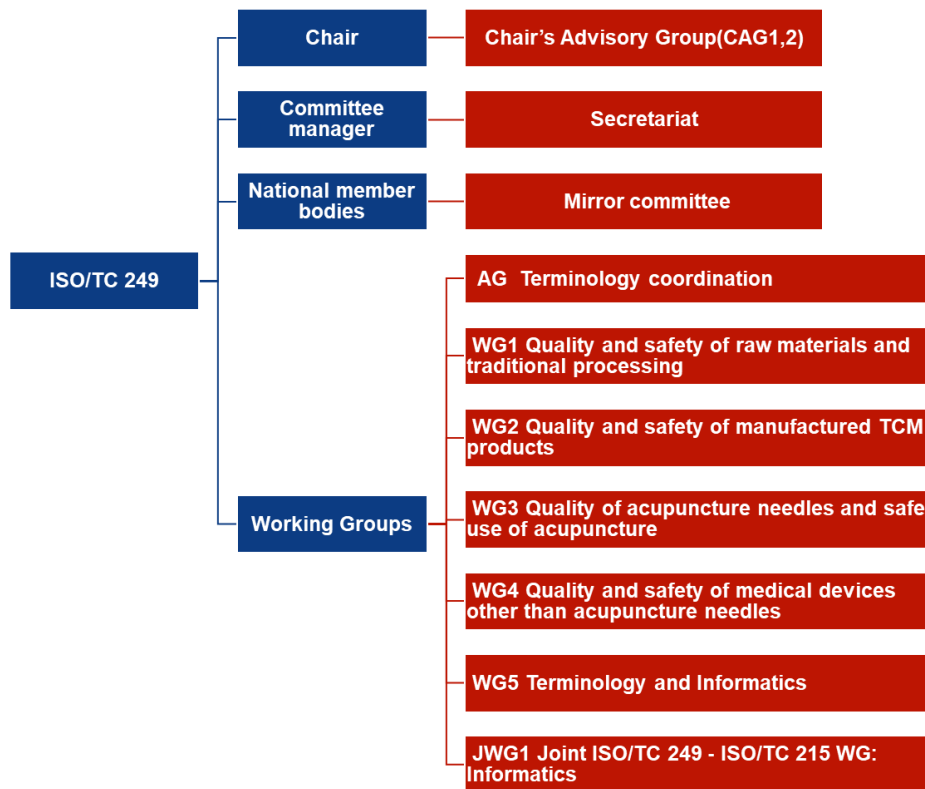
6 STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF ISO/TC 249

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 is one Joint Working Groups, one with ISO/TC 215 to address joint work related to TCM informatics. 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 and service standards limited to the safe use and delivery of TCM manufactured products, but not into the clinical practice or application of those products.

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.

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 Advisory Group

Title: Terminology coordination

Scope: The group is to support the consistency of terms between working groups of TC 249 and to assist WG 5 to prioritize work program and provide possible solutions.

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 regulation 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-mpps/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-mpps/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 (2020) is the national drug standard, of which Volume I is an official collection of standards for 2711 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 from ancient Chinese medicine. It was introduced into Japan from the Korean Peninsula around the sixth century, and since then has evolved as a traditional Japanese medical system over 15 centuries of history. The Meiji government, which replaced the Tokugawa shogunate in 1868, adopted Western medicine as orthodox medicine, and Kampo medicine was left outside the medical system. Despite vigorous campaigns by many Kampo doctors to continue Kampo medicine, the Meiji government enacted a law to issue medical licenses only to those who had studied Western medicine. The decline of Kampo medicine became decisive when a bill to revise the medical permit was rejected by the Imperial Diet in 1898. However, with the publication of *Kokan Igaku* in 1927, the momentum to reevaluate traditional medicine was rekindled and then increased throughout the 1930s. Physicians who practiced Kampo medicine transcended schools and banded together to revive Kampo medicine.

Current Status

After World War II, although qualifications for doctors specializing in Kampo medicine were not legally recognized, the number of doctors who both were familiar with Western medicine and practiced Kampo medicine gradually increased, resulting in a fusion of Western medicine and traditional medicine. In 1967, Kampo extracts were first added to the National Health Insurance Drug Tariff, and to date, 148 prescription preparations have been included in the Tariff, all of which are covered by national insurance plans. Kampo extracts were also included in the 18th edition of the Japanese Pharmacopoeia (JP18). In addition, the “New Guidebook of Approval Standards for Over-the-Counter Kampo Products” was published in 2013, and this publication, which includes 294 Kampo formulas, is the basis of the over-the-counter (OTC) Kampo medicines. There are a large number of brands of OTC products. In the current Japanese Pharmacopoeia, many crude drugs (medicinal herbs) are listed, and their original plants, minerals and animals are defined, as are their qualities, including limitations on foreign materials. Kampo medicines are prescribed by licensed physicians, sometimes on the recommendation of pharmacists. According to surveys, approximately 90% of physicians prescribe Kampo products.

In 1947, new legislation for acupuncturists and moxibustionists (Legislation No. 217, Article 1) was enacted, granting qualified acupuncturists and moxibustionists the right to practice at their own treatment clinics. Today, there are approximately 340,000 physicians, 322,000 pharmacists, 186,000 acupuncturists and 185,000 moxibustionists in 2020 (Survey by the Ministry of Health, Labour and Welfare in Japan).

Government Policy and Regulations

The basis for the control of drugs in Japan is the Pharmaceutical and Medical Devices Act, which dates back to the 1960s. The overall purposes of the law are to ensure the 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 in 2004, reviews new OTC applications and then communicates their recommendation to the Ministry of Health, Labour and Welfare (MHLW), which also consults with the Pharmaceutical Affairs and Food Sanitation Council (PAFSC). The PAFSC is a deliberative body for the approval of manufacturing and marketing of pharmaceuticals and medical devices under the consultation of the Minister of Health, Labour and Welfare. The standards for medical devices used in acupuncture are also reviewed and developed under the control of the MHLW and the PMDA.

Safety and Efficacy

It is highly recommended that the production of plant materials for Kampo medicine be controlled under Good Agricultural and Collection Practice (GACP). Approximately 80% of the crude drugs

used in Kampo medicines are imported from China and about 10% 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 production facilities and products. There are also self-imposed production standards set by the Japan Kampo Medicines Manufacturers Association, which are in addition to the GMP Ministerial Ordinance. Adverse drug reactions (ADRs) to Kampo medicines must be reported in the same way as ADRs to synthetic drugs: physicians and pharmacists are required to report them to a central database. This results in some 150-200 reports per year. In the event of issues with a product, the MHLW issues a recall statement. In the fields of acupuncture and moxibustion, the Japan Industries Association of Physical Therapy Devices is responsible for the development of standards, and has established national standards for “acupuncture needles for single use” (JIS T 9301), “electroacupuncture stimulator devices” and “moxibustion devices.”

Education and Research

Unlike in China and Korea, there is no separation of Western medicine and Kampo medicine in Japan's education and certification system. Therefore, all physicians and pharmacists are educated and trained in Western medicine. Practitioners are trained in Western medicine first, and then can choose to specialize 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 pharmacists on Kampo medicine and herbal materials. This program is supported in part by the government.

All 82 Schools of Medicine in Japan now teach Kampo medicine. In pharmacy school, Kampo medicine is included in the core curriculum. Acupuncture is taught in 28 of the 80 medical schools as an elective. For acupuncture and moxibustion, there are two types of training program. There are 11 universities with four-year programs and 142 colleges with three-year programs. Nine of those 11 universities, in addition to undergraduate schools, have graduate schools and produce researchers. As significant members of the Japan Liaison of Oriental Medicine, both the Japan Society for Oriental Medicine and the Japan Society of Acupuncture and Moxibustion (JSAM) have promoted education and developed 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 Pharmaceuticals 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

Traditional Chinese medicine (TCM) service started when the first TCM hospital (Tian Fah Foundation Hospital) and the first Chinese pharmacy were established in 1903 and 1906, respectively, to mainly serve the Chinese community in the China town in Bangkok. The attempt to increase the role of TCM in the public health service system began after the establishment of the Collaborating Center of Thai-Chinese Medicine in the Ministry of Public Health in 1995, and the Department for Development of Thai Traditional and Alternative Medicine (DTAM) in 2002.

TCM practitioners in Thailand previously learned and gained experience in TCM from their ancestors or from universities in China before the start of the five-year Bachelor's degree program in Thailand and the establishment of the first school of TCM (Faculty of Chinese Medicine at Huachiew Chalermprakiet University) in 2004.

TCM was legally recognized as a branch of the practice of the art of healing in 2009 under the Practice of the Art of Healing Act B.E. 2542 (1999). In 2011, the Profession Commission in the Branch of TCM issued two notifications involving the criteria and the assessment system for the accreditation of educational institutions that provide a degree program or degree-equivalent certificate program and produce graduates with degree or degree-equivalent certificate in the branch of TCM. Since then, the schools and faculties offering Bachelor's degree program in TCM have to be accredited by both the Profession Commission in the Branch of TCM and the Office of the Higher Education Commission. Currently, there are 9 universities with accredited TCM faculties and colleges producing about 200 graduates each year. Under the Practice of the Art of Healing Act (No. 4) B.E. 2556 (2013), the Profession Commission in the Branch of TCM is responsible for organizing annual TCM knowledge test and the issuance of TCM practitioner license.

In addition, there is also a three-month acupuncture and moxibustion training course for medical doctors offered by 2 institutions; i.e. DTAM and the Thai Army Medical Department, in collaboration with TCM universities in China. Medical doctors completed the training course will receive the certificate from the university in China that provided the training.

Regarding the regulation of Chinese medicinal products, before June 2019, the production, import, sale and advertisement of such products were regulated under the Drug Act, B.E. 2510 (1967). Nowadays, TCM products are regulated under the Herbal Products Act, B.E. 2562 (2019).

A wide range of TCM therapies are available in private TCM clinics (259 private clinics as of 2019). However, presently, acupuncture is the only TCM treatment modality available in some public health service facilities (224 hospitals under MoPH as of 2020) depending on whether there is a TCM doctor or medical doctor trained in acupuncture in the hospital settings or not. Since the fiscal year 2021, the Universal Health Coverage scheme has covered for its beneficiaries 20 sessions of electroacupuncture therapy as a part of intermediate care of new cases of stroke in addition to physiotherapy and traditional Thai massage.

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 2021, the value of exports and imports of TCM products from China reached US\$ 7.74billion which included US \$ 5 billion in exports which had increased by 16.5% 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.

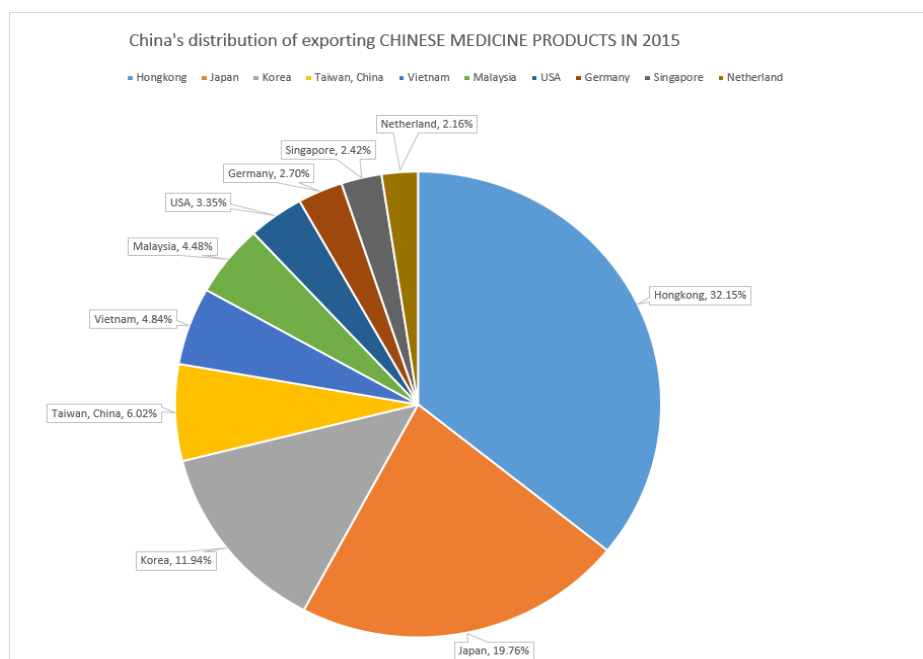


Diagram: Countries to which China exported Chinese medicine products in 2012

(Compiled by CCCMHPIE according to China Customs)

3. Japan

Kampo medicines account for approximately 2.3% of the overall drug market in Japan or about USD \$1.6 billion per year. Regarding the herbal market in Japan, prescription Kampo medicines account for 76% of all transactions and the remaining 24% 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 the International Society for Japanese Kampo Medicine (ISJKM) has been included as an example of Kampo societies since 2009. Kampo medicine has been practiced by medical doctors in Germany, Spain, the UK and Austria. Additionally, the German Medical Doctors' Association for Acupuncture (DAGfA), works in close cooperation with the ISJKM.

4. Korea

a) Annual statistics of major agricultural herb (medicinal crops) production by items

Item	2017	2018	2019
Maximowiczia chinensis	9,893	8,517	7,687
Codonopsis lanceolata	7,927	8,457	11,314
Dioscorea batatas	10,705	8,444	8,814
Zingiber officinale Rosc	11,147	7,780	8,927
Platycodonis Radix	6,395	6,386	4,918

Rubus coreanus	6,411	4,567	5,497
RADIX ANGELICAE PUBESCENTIS	1,302	2,068	1,289
Paeoniae Radix	713	1,484	3,479
Peucedanum japonicum Thunberg	1,602	1,412	1,351
Angelica	1,461	1,135	1,267

Data: Ministry of Agriculture, Food and Rural Affairs, 2019 Production of special crop

b) Annual statistics of medicinal herb (standardized products) production

Division	Unit	2017	2018	2019
Manufacturer	Company	183 (124)	182 (132)	179 (179)
Item	Item	455	428	450
Product amount	100 million KRW	1,623	1,739	1,969

c) Annual export and import amount of all items of medicinal herbs (standardized products)
unit: thousands \$

Division	2017	2018	2019
Import	126,175	146,960	145,385
Export	9,694	7,957	11,218

Data: Korea Pharmaceutical Traders Association internal data; Ministry of Food and Drug Safety, *Food and Drug statistical year book*

d) Annual statistics of ginseng cultivation

Division	Unit	2017	2018	2019
Farm	farm	21,008	20,556	16,981
Cultivation area	ha	14,832	15,452	14,770
-Harvest area		3,737	3,984	2,967
-New area		2,977	3,209	3,191
Product output	ton	23,310	23,265	19,582
Product amount	100 million KRW	8,134	8,307	7,029
Cultivation area per farm	ha/farm	0.7	0.7	0.8
Product output per farm	ton/farm	1.1	1.1	1.1
Government support	100 million KRW	1,316	1,283	1,052

Data: Ministry of Agriculture, Food and Rural Affairs, *Ginseng statistics source book*

Glossary of terms and abbreviations used

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