

Research on international standard discourse of Traditional Chinese Medicine——Taking ISO/TC as an example

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Abstract

The international standardization of Traditional Chinese Medicine (TCM) is a strategic development goal in TCM, with international organizations serving as key channels for promoting global standard dissemination. As the world's largest and most influential international organization, ISO (International Organization for Standardization) sets standards that significantly impact economic, trade, and collaborative exchanges worldwide. This paper begins by providing a brief overview of ISO before conducting discourse analysis on its formulation of TCM international standards. Through a cultural discourse lens, we systematically examine the characteristics of TCM international standards and related organizational operations, summarize current developments in TCM standardization, identify existing challenges, and propose solutions. The research aims to provide actionable insights for advancing TCM's international standardization efforts.

Keywords

ISO; Traditional Chinese Medicine; International standards; Discourse

1. Introduction

In recent years, traditional Chinese medicine has been elevated to a national strategy. Leveraging the Belt and Road Initiative, the immense medical value and market potential of TCM have gradually emerged, making it an essential component in China's international cultural exchanges and trade. According to the common definition standards jointly established through consultation and approved by the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and the International Telecommunication Union (ITU) — three major international standard organizations — these normative documents possess authority, democracy, and scientific rigor¹. The decisive role of standard development in various industries is becoming increasingly evident. Against this backdrop,

the international standardization of TCM has become a focal point of global attention. As primary actors in international activities, international organizations play a significant role in promoting the dissemination of TCM's international standards². The International Organization for Standardization (ISO), a worldwide federation composed of national standardization bodies, has established standards that exert substantial influence on global economic, trade, and collaborative exchanges. The establishment and quantity of international standards for traditional Chinese medicine (TCM) exemplify China's authority and influence in the global TCM community. By examining ISO practices, we can analyze the characteristics of TCM standardization within international organizations, identify current challenges, and provide actionable insights for advancing TCM's global standardization efforts. As TCM's prominence in international healthcare continues to grow, its standardization has become a focal point in academic circles. However, existing research predominantly focuses on specific aspects such as internationalizing TCM terminology, evaluating standard implementation effectiveness, or studying standard development entities. Comprehensive studies that holistically integrate these elements into TCM standardization frameworks remain scarce.

The theory of cultural discourse posits that discourse refers to communicative practices conducted by individuals or groups through language and other means for specific purposes³. From the perspective of cultural discourse systems, we can interpret the international standardization of Traditional Chinese Medicine (TCM) as a complete communicative event where the discourse system serves as both the foundation and core. The formation, development, and application of such systems are constrained by—and thus reflect—cultural traditions (including cosmological concepts, cognitive patterns, behavioral ethics, and communication techniques) and contemporary contexts (real-world conditions). These systems support and shape communicative practices. Guided by this theoretical framework, we can conduct comprehensive analyses of TCM's international standardization discourse practices. By holistically considering key elements like communicative actors, cultural contexts, outcomes, and verbal actions, we gain a more holistic understanding of TCM's global standardization efforts.

2. Research data methodology

2.1. Data sources

The application materials of TCM standards were collected on the ISO website, and the octopus collector was used to collect and manually screen the data such as standard name, application year and different working groups. Meanwhile, the literature collection method was used to cite the relevant ISO international standards of TCM.

2.2. Data analysis

The data were analyzed descriptively by frequency analysis and cultural discourse analysis.

3. Research results

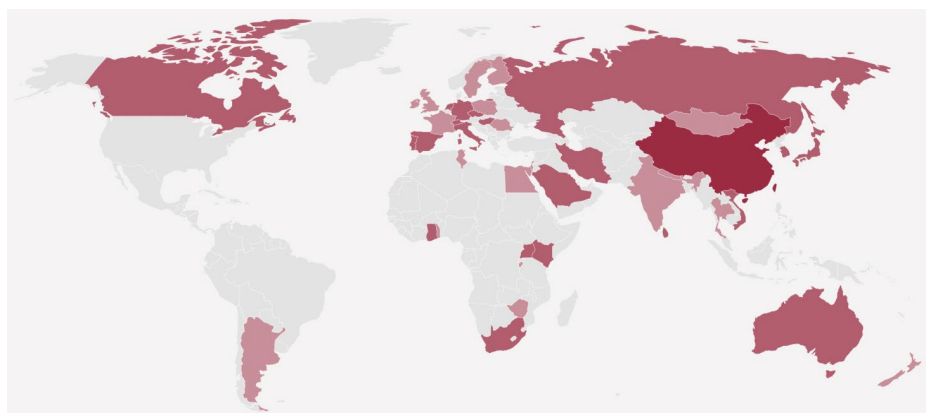
3.1. Number of participants in international standards for TCM

From the changes in the pass rate and the approval rate, we can clearly perceive the transformation of international standards for traditional Chinese medicine in China over the past few years. Notably, while the number of international TCM standards has been increasing annually, both domestic approvals and international project designations have experienced a steady decline (see Table 1). On the global stage, China continues to dominate TCM standard-setting processes (Figure 1), though countries like Japan and South Korea are actively participating with substantial contributions.

Table 1. Annual number of ISO international standard applications submitted by China⁴

Year of declaration	Number of declarations	Number of domestic approvals	throughput rate	Number of international publications	Project initiation rate
2010	5	0	0.0%	0	0.0%
2011	2	2	100.0%	0	100.0%
2012	7	7	100.0%	6	100.0%
2013	14	11	78.6%	4	36.4%
2014	22	15	68.2%	11	73.3%
2015	21	14	66.7%	8	57.1%
2016	29	29	100%	17	62.1%
2017	25	16	64.0%	5	31.3%
2018	36	24	66.7%	4	41.7%
2019	27	11	40.7%	0	18.2%
2020	27	14	51.9%	0	28.6%
2021	31	8	25.8%	0	62.5%
2022	30	17	56.7%	0	0%
Total	276	168	60.9%	57	45.2%

Figure1. Member participation diagram(The darker the color, the higher the degree)



3.2. Application status of each project

As shown in Table 2, the Working Group 1 (WG1) for Raw Materials and Traditional Processing Safety and Working Group 2 (WG2) for Traditional Chinese Medicine Products and Safety hold the primary positions in international standard submissions for TCM. However, an interesting phenomenon is that the number of final releases by Working Group Four is not much different from that of the former two. It can also be seen that when applying for international standards of traditional Chinese medicine, the distribution of application numbers is extremely uneven.

Table 2. Application status of various items of international standards for Traditional Chinese medicine^{4,5}

project number	project name	Number of declarations	Number of releases
WG1	Working Group on the Quality and Safety of Traditional Processing of Raw Materials	125	23
WG2	Working Group on the Quality and Safety of Chinese Herbal Products	52	14
WG3	Working Group on Needle Quality and Safe Use	18	5
WG4	Working Group on the Quality and Safety of Medical Devices other than Acupuncture Needles	34	18
WG5	Working Group on Terminology	16	8
JWG1	ISO/TC 249-ISO/ TC 215 Joint Working Group on Information	16	8

3.3. Distribution of reporting agencies

From Table 3, we can see that higher education institutions and research institutes together account for 79% of the applications for international standards in traditional Chinese medicine, holding an absolute dominant position. However, enterprises that should have actively participated in the process of traditional Chinese medicine only account for a small proportion, which shows that there are significant differences in the distribution of the application subjects for international standards of traditional Chinese medicine.

Table 3. Distribution of institutions applying for international standards of Traditional Chinese medicine⁴ According to (Wang Dingyi, 2023) literature data calculation

Reporting unit	WG1	WG2	WG3	WG4	WG5	JWG1	sum up	Proportion
institutions of higher learning, colleges and universities	65	16	16	19	12	10	138	52.9%
Research enterprises	41	17	1	4	2	3	68	26.1%
business corporation	10	12	1	7	0	1	31	11.9%
Learning groups	1	0	0	0	1	2	4	1.5%
Other organ-	8	7	0	4	1	0	20	7.7%

izations								
summation	125	52	18	24	16	16	261	100%

Table 4. Failure to pass the international standard review of Traditional Chinese Medicine⁴

Main categories of causes	frequency	proportion
Weaknesses in the basis of work	14	38.9%
Project justification and material issues	14	38.9%
The technical content is immature	4	11.1%
Other reasons	4	11.1%

(According to (Wang Dingyi, 2023) literature data calculation and collation)

4. A study on the discourse of international standardization of Traditional Chinese Medicine

4.1. Discourse subject

4.1.1. The Chinese side takes the lead, but the competition is fierce

As shown in Figure 1, China holds an absolute dominant position in the international standardization research of traditional Chinese medicine within ISO international organizations. However, it is noteworthy that Asian countries led by Japan and South Korea are also vying for the market share in TCM standardization. Japanese "Hanfang Yao" (traditional Chinese herbal medicine) and South Korean "Hanyoumiao" (traditional Korean medicine), which share the same roots as TCM, have strong competitiveness in traditional medicine and have been seizing the commanding heights of international standards for traditional medicine, creating a reverse pressure on China. For instance, the international standard "General Requirements for Preparation Process of Korean Ginseng in Traditional Chinese Medicine" led by South Korea was formulated by Japan-led "Labeling Requirements for Oral or Topical Application of Traditional Chinese Medicine Products 4". This indicates that at the international level, the international standardization research of TCM is not dominated by China alone but involves more national entities participating in the competition for discourse power. The participation of multiple stakeholders can, on one hand, promote the development of TCM international standards toward greater internationalization and diversification, while on the other hand, it compels China to accelerate the standardization process of TCM. As shown in Table 1, although China holds a dominant position in TCM international standardization, the number of domestic standardized projects approved domestically and international projects has been decreasing year by year.

4.1.2. The distribution of Chinese discourse subjects is uneven

As shown in Table 3, the participation of enterprises and industry associations in the international standardization of Traditional Chinese Medicine (TCM) remains remarkably low, with most standardization projects being developed by universities

or research institutions. However, international TCM standards constitute a vital component of global trade regulations and play a crucial role in facilitating international commerce, which is closely tied to corporate interests⁶. As key social entities, the limited engagement of enterprises and trade unions hinders the advancement of these standards. On one hand, they may underestimate the substantial economic benefits of establishing international TCM standards. On the other hand, their lack of awareness regarding discourse power means they fail to recognize national standardization efforts as significant platforms for shaping policy narratives, resulting in minimal participation in this critical process.

4.2. Verbal action

4.2.1. The distribution of international standards is uneven

On one hand, although China occupies a dominant position in the formulation of international standards for traditional Chinese medicine (TCM), and as of 2022, China has submitted 276 standardization projects to ISO, the lack of international standards still falls far short of meeting the needs of international trade. In many areas of TCM international trade, international standards remain absent or exhibit inconsistencies, making it difficult for China's TCM international standards to exert strong global influence. On the other hand, there is an imbalance in the field of TCM international standard formulation in China, lacking a systematic and comprehensive discourse system to coordinate the overall situation. As shown in Table 2, the number of applications for TCM international standards across various fields is highly uneven: the safety of raw materials and processed TCM products account for the majority of international standardization applications, while acupuncture and terminology naming receive less than half of the TCM-related projects. This significantly constrains the development of China's TCM international standards.

4.2.2. The standard application lacks a global perspective

On one hand, the rapid development of traditional Chinese medicine has led to an increasing number of stakeholders participating in the formulation of international standards for TCM. However, many project teams, due to a lack of proper understanding of standards and unfamiliarity with the international standard landscape, have engaged in "following trends" in standard-setting—formulating standards merely for the sake of it. In recent years, the number of international standard applications in the field of traditional Chinese medicine has remained high, yet only a handful have ultimately gained international recognition through standard approval and expert endorsement. These phenomena directly impact the effective formulation of international standards for TCM, reflecting a lack of proper understanding of the seriousness and rigor required in international standard development. On the other hand, the quality of China's own project applications is subpar. As shown in Table 4, we can observe that Chinese national standardization project applications

still exhibit professional deficiencies such as incomplete materials, weak foundational work, and content inconsistencies with ISO standards. Additionally, many Chinese projects lack a global perspective, resulting in projects with insufficient international relevance that fail to meet international market demands. Finally, due to inconsistent terminology, Chinese project applications often suffer from redundancies and non-standardized terminology, leading to low application efficiency.

4.3. Cultural relations

Due to varying historical and cultural backgrounds and institutional frameworks across nations, there are significant differences in the understanding and demands for international standards for traditional Chinese medicine (TCM)⁷. This often leads to disputes during standard-setting processes. Western societies harbor biases against TCM applications, particularly holding stereotypical views that perceive TCM as posing substantial safety risks. Compounded by the stigmatization of TCM through Western media coverage, these factors create substantial obstacles in establishing international standards for TCM.

4.3.1. Translation strategies and cultural power relations in ISO/TC249

As a source culture, China tends to adopt strategies such as phoneticization (e.g., Qi) or literal translation (e.g., Meridian), aiming to preserve the original cultural concepts to the greatest extent possible and reinforce its "China origin" identity, which is a commitment to cultural ontology. In contrast, Japan and South Korea, due to their long histories of Hanfang medicine and Korean medicine respectively, often propose translations based on their own linguistic and cultural practices (e.g., Japan may prefer using "Ki" while South Korea uses "Gi"). This reflects their intentions to contest the dominance of traditional East Asian medical discourse and highlight their unique cultural identities. As "target audiences", Western countries tend to adopt free translation or analogical translations rooted in modern biomedical concepts. This approach aims to lower comprehension barriers and facilitate the acceptance of standardized practices within Western medical systems. However, it risks "cutting off one's feet to fit the shoes" — simplifying or distorting the holistic philosophy and foundational principles of Traditional Chinese Medicine (TCM). Essentially, this represents a scientism-driven "domestication" strategy that erodes cultural uniqueness.

Therefore, the terminology standards of ISO/TC249 are by no means merely a technical translation issue, but rather a cultural-political process. Each standard term ultimately released is the result of negotiations, compromises, and even strategic games among various stakeholders. It not only reflects the challenges faced by China's cultural "going global" initiative, but also reveals the reality that Western scientific discourse systems still dominate in the international standardization process. Through active participation in this process, China is seizing opportunities to "in-

corporate" its own cultural knowledge system into global regulations—a challenging yet crucial endeavor in building cultural discourse power.

4.3.2. Differentiated understanding and acceptance

The differences in the understanding of TCM among member states are rooted in their completely different medical philosophy and cultural traditions. For China, traditional Chinese medicine is not merely a medical discipline but also a profound cultural entity and philosophical practice. Its cognitive foundation lies in the holistic view of "harmony between heaven and humanity," the theory of yin-yang balance and five elements, as well as the individualized treatment philosophy of syndrome differentiation and treatment. Traditional Chinese medicine emphasizes holistic functions (such as "qi" and "shen") rather than mere anatomical entities. In the eyes of China's representatives, standardizing this complex system represents an international expression of cultural identity, with the core purpose of safeguarding cultural sovereignty and ensuring that traditional Chinese medicine retains its fundamental essence during global dissemination. Therefore, China's proposals often demonstrate adherence to the integrity of holistics and traditional theoretical frameworks. Therefore, China often encounters great resistance in formulating national standards for traditional Chinese medicine. Japan and South Korea both belong to the East Asian cultural sphere, sharing the cultural origins of ancient Chinese medical classics. However, after centuries of localized development, they have formed unique cognitive filters. Japanese Kampo medicine largely abandons the extensive theoretical deductions of traditional Chinese medicine, instead emphasizing pragmatism through "form-symptom correlation." This approach utilizes relatively fixed formula combinations to address specific, objective symptom patterns, with diagnostic methods prioritizing physical examinations such as abdominal palpation. Consequently, Japanese experts in TC249 focus more on the precision standardization of prescriptions, stability of chemical components, and large-scale production, while their criteria for "zheng" lean toward observable and quantifiable indicators. Similarly, Korean Han medicine has evolved from traditional Chinese medicine but emphasizes its uniqueness (such as "Four Symbols Medicine"), with a strong sense of ethnic medical identity. Thus, the participation of Japan and South Korea represents differentiated competition within a shared cultural origin. They aim to expand the influence of their traditional medicine through international standard platforms while ensuring their distinctive features are not overshadowed by the China paradigm.

For developed nations in Europe and America (represented by the United States, Germany, Australia, etc.), their cognitive frameworks are firmly rooted in the reductionist and positivist traditions of modern biomedicine. This system is built upon anatomy, physiology, biochemistry, and randomized controlled trials (RCTs), pursuing universal pathological mechanisms and clear causal relationships. Experts and

regulators from these countries naturally tend to evaluate traditional Chinese medicine (TCM) using this “scientific yardstick.” Their primary concerns revolve around: the safety and efficacy evidence of herbal medicines, and the standardization and safety of acupuncture practices (sterile needles, standardized procedures). Their acceptance of TCM essentially involves a process of “scientific screening” and “localized adaptation,” aiming to integrate its verifiable components into their national complementary and alternative medicine systems—not to embrace its cultural and philosophical core wholesale. Precisely because of their deeply ingrained dualistic thinking and Western-centric perspectives, they often adopt a passive stance toward establishing international standards for TCM.

5. International standardization discourse strategy of Traditional Chinese medicine

5.1. Overall context: Create a new media global communication ecology conducive to the formulation of international standards for TCM

Under the dominant discourse system of the West, if we do not actively engage in dialogue and criticism, and if we fail to deconstruct Western hegemony—including digital network hegemony—the formulation of international standards for Traditional Chinese Medicine will always face obstacles. On one hand, efforts must be made to reform the unequal discourse order of cultural power, exposing the limitations, defects, and consequences of Western centrism, binary opposition, and universalism. On the other hand, we should actively cultivate new contexts, participate in activities on international new media platforms, promote equal dialogue and exchanges between China and the world, thereby shaping a healthier, safer, and more effective image of Traditional Chinese Medicine and advancing the establishment of its international standards. At the same time, we must be aware that the ever-changing new media has played an irreplaceable role in the formulation of national standards for traditional Chinese medicine. The most important point is that the new media can enable more people to recognize the profound and unique traditional Chinese medicine culture behind the international standards of traditional Chinese medicine, thus allowing more people around the world to know, understand and like traditional Chinese medicine. Therefore, we should take new media as the core, establish media during external publicity, and integrate all media communication channels. At the same time, to tell the story of traditional Chinese medicine well, it is necessary to clarify the cultural differences and interactivity of traditional Chinese medicine between China and other countries. For overseas audiences, it is necessary to adopt a microstructure of personality narrative based on their characteristics and avoid grand narratives. At the same time, efforts should also be made to actively seek cultural resonance, highlighting the irreplaceable and significant role of traditional Chinese medicine in the global health system, which can become a common treasure for people all over the world.

5.2. Establish an international standard discourse system of Traditional Chinese medicine based on local and global perspective

In formulating international standards for traditional Chinese medicine, it is essential not only to ground efforts in local culture and draw upon China's traditional medical heritage, but also to adopt a global perspective to identify cultural consensus between China and the world. The key initiative lies in establishing a comprehensive, systematic, and globally-oriented discourse system for developing TCM standards. This system should not only be rooted in China's indigenous practices and embody the "holistic, balanced, and harmonious" cultural characteristics of TCM, while simultaneously addressing global understanding of TCM standardization. Such a discourse framework supports the shaping of effective communication practices that effectively present China's story. It requires a holistic approach to coordinate the formulation of international TCM standards, balancing relationships across different domains as well as domestic and international relations.

5.3. Diverse cultures, promoting diverse and balanced international standards of TCM with a community with a shared future for mankind

Culturally, we should maintain an inclusive mindset toward the coexistence of diverse traditions in traditional Chinese medicine (TCM). Guided by the vision of a shared future for humanity, the development of international TCM standards serves as a global health initiative that seeks common welfare. In this era of globalization, it is crucial to enhance cross-cultural exchanges and mutual learning in TCM practices, thereby achieving a balance between national interests and the well-being of all humanity⁸. China's fundamental stance is to advocate an integration paradigm of "harmony without uniformity" and reshape international rules. China's cultural confidence does not lie in making traditional Chinese medicine resemble Western medicine, but in gaining global recognition and acceptance of a parallel, complementary medical paradigm. In TC249 negotiations, the Chinese delegation's strategic approach is as follows: On globally shared issues such as safety and quality control (e.g., heavy metal and pesticide residue standards), China adopts maximum openness and cooperation, proactively aligning with international norms; while maintaining firm ground on culturally specific issues like theoretical foundations and clinical reasoning (e.g., syndrome differentiation and treatment), patiently persuading international peers to understand its inherent logic through sustained education, demonstrations, and communication. From China's perspective, cultural integration is by no means passive assimilation, but rather an active endeavor to build discursive leadership. This is consistent with the cultural philosophy of harmonious integration that underlies traditional Chinese medicine. Therefore, more proactive and effective cultural exchanges play a very important role in the formulation of national standards for traditional Chinese medicine and the recognition of traditional Chinese medicine culture.

6. Summary

The standardization process of ISO/TC249 is a cultural and political practice driven by multiple discourse subjects and full of power games. The main participants in the committee, including China, Japan, South Korea and developed countries in Europe and America, have adopted completely different discourse strategies based on their respective national interests, cultural traditions and industrial strategies. China, as the "system leader" of cultural origin, Japan and South Korea, as "differentiated competitors", and European and American countries, as "technological regulators", together form a discourse power structure where cooperation and competition co-exist. We need to establish a more diverse and inclusive cultural discourse system to promote the better dissemination of traditional Chinese medicine culture.

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