

Contributions of International Standards to the Internationalisation of Traditional Chinese Medicine (TCM)

—— 論國際標準對中醫藥國際化發展的貢獻 ——

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Nowadays, with the transformation of the human disease spectrum and the aging of the population, the status and role of TCM in maintaining human health are increasingly significant. Under the new circumstances, how to apply TCM more safely, effectively, and scientifically has become a major issue of global medical concern. Due to the lack of a unified global standard for the quality and safety control of TCM, its internationalisation has encountered obstacles and challenges. Upon application by the Standardisation Administration of China (SAC), the International Organisation for Standardisation (ISO) established a technical committee for Traditional Medicine (ISO/TC 249) at the end of 2009.

ISO is the world's most authoritative international standardisation organisation. ISO standards serve as a global common language, aiming to break down trade "technical barriers", promote global trade and facilitate social and economic development. So far, ISO/TC 249 has 45 member bodies, and published 125 ISO standards for TCM. Among them, 51 standards published for more than five years have passed ISO systematic review. Moreover, the standards published by ISO/TC 249 have become a successful model for ISO standards to promote social and economic development. For example, the Shanghai Municipal Government invested RMB 500 million to establish the Shanghai Academy of International Standardisation for Traditional Chinese Medicine to support the work of ISO/TC 249 Secretariat. The international standards such as *Ganoderma lucidum* and *Dendrobium*, acupuncture needles and herbal decocting apparatus, and the coding system for Chinese medicines, have made outstanding contributions to promoting the import and export trade of TCM and improving its quality and safety control.

International standards are the synthesis of mature experience and advanced scientific research. The achievements of ISO/TC 249 have promoted the modernisation and internationalisation of TCM. In line with ISO's strategic adjustments in 2025, ISO/TC 249 has now been elevated to serve as the international standardisation platform for global traditional medicine. Seizing this new opportunity, ISO/TC 249 will share the experience gained from TCM standardisation with other traditional medicine systems and take a leading role in driving the development of international standards for global traditional medicine.

當今時代隨著人類疾病譜的改變和人口的老齡化，中醫藥在維護人類健康方面的地位和作用正日益增長，在新形勢下，如何更加安全有效和科學地應用中醫藥成為全球醫藥界關注的重大問題。由於缺乏全球統一的中醫藥質量和安全控制標準，中醫藥的國際化發展受到了障礙和挑戰，經中國政府申請，國際標準化組織於2009年底成立了國際標準化組織/傳統醫藥技術委員會（ISO/TC 249）。

ISO是全球最具有權威性的國際標準化組織，ISO國際標準是一種全球的共同語言，它是以打破貿易「技術壁壘」，促進全球國際貿易、社會和經濟發展為宗旨的國際組織平台。自ISO/TC 249成立至今，目前有45個成員體，並已發佈了125項中醫藥國際標準。其中發佈五年以上的51項國際標準全部通過ISO總部評估。ISO/TC 249發佈的部分國際標準已成為ISO標準促進社會和經濟發展的成功範例，如上海市政府為加強ISO/TC 249秘書處的建設投資5億元人民幣創建了上海市中醫藥國際標準化研究院，靈芝和石斛的中藥材國際標準，針灸針，煎藥機，以及中藥材的可追溯二維碼標準等，為促進中醫藥進出口貿易和提高質量和安全控制做出了卓越的貢獻。

國際標準是成熟經驗和先進科研成果的總結，ISO/TC 249的工作成就促進了中醫藥的現代化和國際化發展。2025年，在ISO戰略調整背景下，ISO/TC 249已提升為負責承擔全球傳統醫藥國際標準化平台，ISO/TC 249在新的機遇面前，將與其他傳統醫藥分享中醫藥國際標準化的經驗，並引領全球傳統醫藥國際標準化發展。