Traditional Chinese medicine: research and development, globalization, and regulation

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In this issue of *Chinese Journal of Natural Medicines* (CJNM), we are pleased to publish two comprehensive and timely review articles [1-2] addressing the registration regulation of traditional Chinese medicine (TCM), a critical issue in the development, regulation, and internationalization of TCM.

In the first review [1], Drs. YUAN, WU, and SHAO provide a comprehensive historical overview on the development and establishment of a registration system of TCMs in China. In the last some 100 years, the TCM administrative policy and practice at the central and local governmental levels in China have been undergoing tremendous changes, witnessing numerous ups-and-downs and even setbacks and missteps in the past and remarkable even revolutionary changes recently. Thanks to the rapid economic development and social reform in the last 30 plus years, the research and development of TCM in China have made tremendous progress and the Chinese central government has established a sophisticated yet enforceable TCM registration regulation system, which is led by SFDA and provides guidelines for the research, development, and marketing of TCM preparations. The current system encourages innovation and development of high-quality products. For instance, as reviewed in their article [1], the SFDA-issued *Technical Requirements on Research of New Natural Medicines* provide systematic guidelines on the research and development of modern TCMs. With the recent impressive advances in production processing and quality control of TCMs, along with the availability of cutting-edge systems biology and information technology, we should be confident that our R&D strategies and administrative approval and regulation system will be further developed and improved in the future, which would lead to better practice of TCMs in the clinic. Interested readers are directed to recent outstanding publications in this field [3-8].

In the second review in this CJNM issue [2], based on his extensive experience in regulatory affairs in drug administration, Dr. Graham describes the regulation of TCMs for the Australian market, a system that would allow many TCMs to have a simplified process of marketing access if the governmental criteria concerning public risk are met. TCM has a long history of utilization and marketing worldwide, although regulations and regulatory affairs vary significantly across the globe [9-15]. The regulatory issues for registration of herbal products are complicated and varying among different countries and regions, which is associated with the complex nature of these products themselves, variations in understanding of therapeutic agents and supplements as well [3-5, 11, 14-19]. Of note, as being observed in China [1], the regulations and legislation processes have be dynamic and evolving worldwide. The experiences developed from global regulation of TCM in the past years will provide valuable insights for regulation of other traditional medicines as well. Future TCM research and development requires collaboration and coordination of actions in the post-genomic era. In this regard, the Chinese SFDA and WHO are well positioned to coordinate a consultation process with the aim of putting forward suggestions for harmonization to key regulatory agencies facing in globalization of TCMs [9, 18-19]. Among the evolving research and development efforts, including internationalization of TCMs, the coordination actions aiming to inform the best practice and harmonize research on the safety and efficacy of TCM through interdisciplinary approaches are critical. Communications and collaborations such as data-sharing platforms and consortia among different parties from academic, industrial, governmental institutions and healthcare organizations would provide forums on various aspects of TCMs regulation such as quality control, extraction technology, component analysis, toxicology, pharmacology, and regulatory process.

One of the best examples in collaboration on TCM research and development is the toxicological studies [16-19]. For instance, the US FDA has recently published a guidance...
for academic and industry sponsors in the development of this unique group of drug products, and has recently approved an new drug application (NDA) based on green tea extract (Veregen) [10]. In the development of Veregen, various regulatory requirements are met, including toxicology studies. Therefore, we are confident that toxicological development of botanical drug products can be significantly facilitated in the future through a proactive two-way communication between the regulatory agencies and the sponsors of various TCMs. Another example is recent research on hepatotoxicity of plants and natural products, including TCMs [13-17]. Herbal hepatotoxicity is increasingly recognized as an important clinical and regulatory issue, and various international academic and industrial organizations have scaled-up their efforts to identify the etiology, pathogenesis, and mechanism of action, develop biomarkers and clinical procedures for diagnosis and evaluation of progression, and discover preventive and therapeutic approaches for this common clinical toxicity. Advances in the field of herbal hepatotoxicity have been made by introducing analytical methods to identify cases of hepatotoxicity in early stage, including genomics, proteomics, and metabolomics technologies. With recent increasing global recognition of TCM and TCM-based natural compounds (such as Artemisinsins) in fighting major human diseases and the endless efforts of Chinese scientists devoted to enhance its globalization, we propose that herbal medicines, including TCMs should gradually be marketed as herbal drugs under strict regulatory surveillance in analogy to regulations for chemical drugs, based on risk/benefit analysis, evidence-based clinical trials, and excellent herbal drug quality.

As did in the past [6, 8, 20-22] and the current issue [1-2], we at CJNM will continue to bring our readers with the latest information on regulatory approaches and internationalization of natural medicines. Interested readers and authors are encouraged to participate in our discussion by submitting their original research and timely review articles to our journal for consideration of publication in CJNM.

References


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Professor Zhang has a longstanding research interest in the field of translational biomedical research, particularly in translational medicine, cancer therapy and prevention, clinical pharmacology and therapeutics, pharmacogenomics, pharmaceutical and toxicological researches. Thanks to continuously funding from NIH and other governmental and private agencies, Dr. Zhang has maintained a strong research program, making significant contributions to several research fields, including pharmacogenomics of anticancer agents, oncogene and tumor suppressor, molecular targeted cancer therapy, dietary and chemical cancer prevention, drug discovery and development, preclinical and clinical pharmacology, toxicology, and cancer biomarkers. For his outstanding contributions to sciences, Dr. Zhang was elected as a Fellow of American Association for the Advancement of Science (AAAS) in 2009. He has published more than 220 papers, 2 books, and more than 50 invited reviews/book chapters; his publications have been cited more than 9900 times, with an H-index of 53 and an i10-index of 156. He has been invited to give more than 190 presentations in prestigious universities, institutions, and organizations. Dr. Zhang has been a certified toxicologist by the American Board of Toxicology (D.A.B.T.) since 1999 and served on Board of Directors of ABT between 2009 and 2013. He has been an FDA advisory committee member and served as a study section member for NIH, DoD, CDC, FDA, and NIOSH and other international panels. Dr. Zhang is Editor-in-Chief of Current Cancer Drug Targets, Associate Editor-in-Chief of Chinese Journal of Natural Medicines, and also an associate editor, senior editorial board member, or editorial board member of more than 20 scientific journals. He has been an honorary professor of seven universities.