

Development of National Guidelines for Conducting Research and Development of Herbal Medicine in Thailand According to International Standards

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Abstract : Background: Herbal medicines constitute a vital component of Thailand's healthcare system and possess significant potential for international recognition. However, the absence of standardized clinical research guidelines aligned with international standards, coupled with unique local challenges, has hindered the development and registration of Thai herbal medicines in the global market. Objective: To establish comprehensive research and development guidelines for herbal medicine formulations that comply with international standards, with particular emphasis on enhancing research quality, scientific credibility, and facilitating both domestic registration and international market acceptance. Methods: The research methodology comprised eight sequential phases: (1) systematic collection and review of relevant documentation and regulatory frameworks; (2) development of preliminary content structure and template designs; (3) systematic analysis and synthesis of scientific evidence and regulatory data; (4) creation of detailed research guidelines and accompanying templates; (5) execution of domestic and international consultation meetings and study visits involving nine stakeholder groups; (6) systematic expert review of the draft guidelines; (7) incorporation of feedback from relevant regulatory and research agencies; and (8) finalization and validation of the comprehensive guidelines. Results: The study produced comprehensive research and development guidelines for herbal medicines that meet international standards, encompassing the complete development pathway from initial concept through pre-clinical studies, product development, preparation protocols, clinical trial conduct, and product registration procedures. The guidelines include standardized templates and forms specifically designed for clinical research documentation. Conclusion: The established guidelines represent a significant advancement in standardizing clinical research for Thai herbal medicines, enhancing their scientific credibility and potential for international acceptance. Nevertheless, Thailand continues to face specific challenges, including insufficient specialized personnel in herbal research (particularly in clinical trials), challenges in integrating traditional Thai medicine principles with modern scientific methodology, limited research infrastructure, inadequate funding mechanisms, complex registration procedures, and public skepticism toward herbal products. The policy recommendations outlined in this research provide a strategic framework for addressing these challenges and promoting sustainable development of Thai herbal medicines within the national context.

Keywords : herbal medicine, clinical research, international standards, research guidelines, drug development, traditional thai medicine, regulatory compliance

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