MASTER'S THESIS

海外中藥/植物藥/傳統草藥質量標準和法規研究

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論文摘要

國際市場對植物藥和中藥的需求不斷增加而且市場潛力巨大，植物藥為主的中藥進入國際市場，必須符合國際植物藥的質量要求及規管。可是一直以來成功在海外註冊的中藥產品寥寥無幾，這都源於海外法規對中藥及植物藥的要求比較嚴謹，尤其重視中草藥安全性、質量性和有效性的標準。本文研究分為兩部分：(一)介紹海內外主要藥典包括中國(CP)、日本(JP)、歐洲(EP)、英國(BP)及美國藥典(USP-NF)，其應用地區廣泛、影響力大，建立的檢測方法水準較高。主要研究各藥典對植物藥及傳統草藥質量標準的概況，及對各國藥典收載的 5 種基原植物相同生藥與中國藥典的質量檢測標準作比較，為完善中藥質量標準提供借鑒；(二)研究闡述了海外相關政府機構包括歐盟對註冊植物藥或中藥的規管和註冊要點，通過分析歐盟針對草藥藥品的簡化註冊程序 (Simplified registration procedure, SR)，探討其註冊的難度及關鍵問題，以成功註冊之例子，為中藥進入國際市場提供參考，對中藥國際化之路有所啟示。中藥要解決的註冊的限制，需要從提升中藥自身質量標準及國際合作等方面，才能使中藥增強國際競爭力，順利跨越國際技術性註冊的限制。中藥走向國際的過程，是中醫藥與現代西醫藥相互融合的必經階段，最終達到標準統一的過程，二者的不斷融會和貫通，將成為新世紀醫藥產業的一大熱點。

關鍵詞：

中藥規管；植物藥規管；藥典；質量檢測標準；歐盟註冊；簡化註冊程序；中藥國際化

The international market demand for herbal and traditional Chinese medicine is increasing recently. To get marketing authorization from global regulatory bodies, herbal-based Chinese medicine must be complied with international quality and regulatory requirements. However, there are only a few successful cases that Chinese herbal products have been registered overseas due to the high standard of overseas requirements, which emphasis on safety, quality and effectiveness of herbal products. This article is divided into two parts: (a) To introduce the worldwide pharmacopeias including the Chinese Pharmacopeia (CP), Japanese Pharmacopeia (JP), European Pharmacopeia (EP), British Pharmacopeia (BP), the United States Pharmacopeia and the National Formulary (USP-NF). This section aims to collate data from the aforementioned pharmacopoeias and draw comparison on their quality standards and requirements for the five crude drugs / herbal medicine from the same botanical origin for the harmonization of global herbal medicine quality standards. (b) To investigate information of the existing requirements for registration of herbal medicine in the European Union. Through the analysis of a pathway for marketing traditional herbal medicinal products, the "simplified registration" procedure, the key issues and difficulties are discussed and some suggestions with an example are put forward for the registration of Chinese Medicine to enter the international market. To conclude, it is crucial to improve the quality standards of Chinese Medicine to overcome the technical registration problem and facilitate international authorities' cooperation for enhancing the international competitiveness of Chinese medicine. The internationalization of Chinese medicine will become a hot topic in pharmaceutical industry for the new century.

Keywords

Regulation of Chinese medicines; Herbal regulation; Pharmacopoeia; Quality testing standards; EU registration; Simplified registration; Internationalization of Chinese medicine

內容目錄