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中药上市后再评价关键问题商榷

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中文摘要:由于中药上市前研究目的比较单纯、试验人群范围较窄、临床试验病例数有限、用药条件控制较严格、用药时间较短等,很难得出药品全面的安全性和有效性数据,这不利于药品上市后的合理安全应用。安全性再评价是中药上市后再评价的首要环节,包括中药不良反应 / 事件的报告、监测和评估3方面,必须采取严格的规范措施。有效性再评价仍然是中药上市后再评价的重要内容,包括临床适应病证、剂量和疗程的再评价,这是保证用药安全性的重要前提之一。同时,要关注中药在特殊人群中应用的安全性和有效性,高度重视中药注射剂的上市后再评价,以及采取合适的研究方法开展再评价研究。国家药品管理部门要加强管理和监督,制定和健全中药上市后再评价的政策、法规和技术标准,使相关工作的开展有法可依、有理可循。

中文关键词:中药 上市后再评价 安全性 有效性

A discussion of key issues on postmarketing reevaluation of Chinese medicine

Abstract: Because of relatively simple purposes, narrow population range,small samples, stringent controlled conditions for using medicine, and short time of clinical trials,the researches for listing approval of Chinese medicine can not draw to comprehensive conclusions on safety and effectivenes, which is not conducive to the reasonable and safe application of postmarketing Chinese medicine. Safety reevaluation is the most important issue of the postmarketing reevaluation of Chinese medicine, including adverse reaction/incidence reporting, monitoring and evaluation three aspects, which must be taken into action with strict regulatory measures. Effectiveness reevaluation is still an important part of the postmarketing reevaluation of Chinese medicine, including reevaluation of diseases and syndromes adapted for using Chinese medicine, precise doses and appropriate treatment periods, which is an important prerequisite to ensure the safety of using Chinese medicine. At the same time, we should pay attention to the safety and effectivenes of Chinese medicine on special populations, attach great importance to postmarketing reevaluation of Chinese medicine injection,and apply appropriate research methods to carry out reevaluation studies. National drug administrative departments must strengthen management and supervision on postmarketing Chinese medicine, develop and improve policies, regulations and technical standards on the reevaluation, forming a legal basis for carrying out postmarketing reevaluation of Chinese medicine.

keywords: Chinese medicine postmarketing reevaluation safety effectiveness

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