



## 中药上市后药物警戒的实例研究

投稿时间: 2011-08-06 责任编辑: [点此下载全文](#)

引用本文: 向永洋,谢雁鸣,易丹辉.中药上市后药物警戒的实例研究[J].中国中药杂志,2011,36(20):2836.

DOI: 10.4268/cjmm20112021

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基金项目:国家“重大新药创制”科技重大专项(2009ZX09502-030);中国中医科学院自主选题研究项目(Z0171)

**中文摘要:**近年来随着各类中药不良反应报告,特别是中药注射剂的不良报告数量的累积,人们对中药药物警戒的安全意识也越来越强。中药药物警戒已经成为了热门的研究方向,但中医和西医的历史不同,理论也不是一个体系,中药药物警戒和西医比还是有很多差距。该文归纳整理了国家食品药品监督管理局中药的不良报告数据库,运用3种WHO,美国食品药品监督管理局等使用的数据挖掘方法,建立适合中药上市后再评价的药物警戒体系。

**中文关键词:**[药物警戒](#) [中药注射剂](#) [数据挖掘](#)

### Case study of Chinese medicine after listing of pharmacovigilance

**Abstract:**With the continuous increase of adverse Chinese drug reaction reporting, especially Chinese traditional medicine injection, it becomes the key part of the post-marketing evaluation. The issue based on this research background becomes the hot research direction. But the truth is that the history of Chinese medicine and western medicine is different and the theory is not a system either, here different means between pharmacovigilance of Chinese medicine and western medicine, there are still many gaps. This becomes a barrier for Chinese medicine entering the international market. This article summarizes try to order the SFDA's adverse reaction reporting database of traditional Chinese medicine, and using three kinds of data mining methods used by WHO, the U.S. Food and Drug Administration, to establish suitable system for Chinese market after the evaluation of pharmacovigilance.

**keywords:**[pharmacovigilance](#) [traditional Chinese medicine injections](#) [data mining](#)

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