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## 某院中成药说明书缺项和不完整项调查分析

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### 摘要:

目的: 为促成中成药说明书规范化、完整化提供参考。方法: 收集某院药房中成药说明书206份, 根据国家食品药品监督管理局制定的《药品说明书和标签管理规定》《中药、天然药物处方药说明书撰写指导原则》《中成药非处方说明书规范细则》对各项内容进行调查分析, 重点调查缺项和不完整项。结果: 206份中成药说明书中, 缺项和不完整项涉及注意事项、禁忌证、不良反应、药物相互作用、孕妇用药、药理毒理, 总体比例分别为13.59%、47.09%、42.23%、60.68%、70.87%、74.27%; 其中口服制剂说明书缺项和不完整项情况最严重。中成药说明书对于特殊人群儿童 (<18岁)、老年患者 (>60岁) 的用法用量多未作明确标注, 而是使用“逐减”“适量”等模糊词语, 暂不计入不完整项。结论: 目前中成药说明书内容不够完整, 甚至缺项, 应进一步修订。

关键词: [中成药](#) [说明书](#) [缺项](#) [不完整项](#)

DOI: [doi:10.13407/j.cnki.jpp.1672-108X.2019.01.014](#)

基金项目:

## Investigation for Missing and Incomplete Items of Chinese Medicine in A Proprietary

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### Abstract:

Objective: By investigating and analyzing the missing items and incomplete contents in chinese patent medicine package inserts, to facilitate the standardized management and protect the safety of patient treatment of Chinese patient medicine. In addition, to offerion, inepathefor the medical behavior while medical personnel use chinese patent medicine. Methods: 206 package inserts of chinese patent medicines sampled in our hospital were investigated regarding each items in accordance with relevant legal documents especially the items which is he missing items and incomplete contents. Results: Adverse drug reactions, contraindications, pharmacology toxicity, drug interactions and the pregnant women on medication unlabeled rate among 206 package inserts of chinese patent medicines sample were 42.23%, 47.09%, 13.59%, 74.27%, 60.68%, 70.87%, the dosage and administration of special population such as older patients and children were unscientific. Conclusion: The items of package inserts of chinese patent medicines were incomplete, it cannot provide sufficient basis for clinical medication, further revise is needed.

Key words: [Chinese medicine](#) [manual](#) [missing item](#) [incomplete item](#) [investigation](#) [analysis](#)

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