

不同省份医疗机构传统中药制剂备案管理现状及路径优化研究^Δ

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摘 要 **目的** 为医疗机构应用传统工艺配制中药制剂(后文简称“中药制剂”)备案管理政策的完善提供科学参考,进而促进中药制剂研制与备案工作的健康发展。**方法** 采用文献查阅和横断面研究相结合的方式,收集2018—2025年国家及各省份药品监督管理局官网发布的与中药制剂备案相关的政策文件和制剂信息。对各省份中药制剂备案管理核心政策文件的执行与修订情况、备案剂型范围、不予备案情形、备案材料豁免情形等进行比较,通过数据归纳、趋势图绘制等方法对各省份的中药制剂备案品种数量和剂型等进行统计分析,并提出中药制剂备案管理路径的优化建议。**结果与结论** 各省份备案政策存在明显异质性;12个省份细化了备案剂型,15个省份新增了不予备案情形(共16种),9个省份扩大了材料豁免范围;备案品种数量区域不平衡突出,备案品种数量最多的青海(4 269个)与最少的海南(14个)相差300余倍;备案剂型以丸剂(6 928个)、散剂(4 360个)等传统剂型为主;仅12个省份制定了全省中药制剂调剂目录,多数地区仍限于医联体内部使用,制剂成果转化率较低。建议从强化政策标准化与灵活性、优化备案流程和材料要求、加强技术支撑与成果转化3个方面优化制剂备案路径,以缩小区域政策差距,提升备案效率,促进医疗机构中药制剂的规范化发展与临床价值转化。

关键词 医疗机构;传统中药制剂;备案制;管理现状;优化路径

Study on the current status and pathway optimization of traditional Chinese medicine preparations record-filing management in medical institutions across different provinces
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ABSTRACT **OBJECTIVE** To provide scientific reference for perfecting the record-filing management policy of traditional Chinese medicine preparations formulated via traditional processes for medical applications (hereinafter referred to as “TCM preparations”) in medical institutions, and further promote the sound development of the research and record-filing work of such preparations. **METHODS** A literature review combined with cross-sectional research was carried out. We collected policy documents and preparation information related to the record-filing of TCM preparations issued by national and provincial drug administration authorities on official websites during 2018-2025. A comparative analysis was conducted on the implementation and revision of core policy documents for the registration management of TCM preparations across provinces, the scope of record-filing dosage forms, conditions for rejection of record-filing, and exemptions for registration materials. Statistical analysis on the quantity and dosage forms of record-filing preparations in each province was conducted by means of data induction and trend chart plotting, and targeted suggestions were put forward to optimize the management pathway of record-filing. **RESULTS & CONCLUSIONS** There was obvious heterogeneity in record-filing policies among provinces. Twelve provinces refined the applicable dosage forms for record-filing, fifteen provinces supplemented conditions for rejection of record-filing (16 items in total), and nine provinces expanded the scope of material exemptions. The number of recorded preparations presented a striking regional imbalance: Qinghai had the largest quantity of 4 269 varieties, while Hainan only had 14 varieties, with a gap of more than 300 times. The recorded preparations were mainly traditional dosage forms including pills (6 928 varieties) and powders (4 360 varieties). Only 12 provinces formulated the provincial catalog for TCM preparations allocation. In most regions, preparation circulation was only permitted within medical consortia, leading to a low transformation rate of scientific and technological achievements of preparations. It is recommended to optimize the record-filing management pathway from three aspects: strengthening policy standardization while maintaining flexibility, streamlining record-filing procedures and documentary requirements, and reinforcing technical support and achievement transformation. These measures can reduce regional policy differences, improve work efficiency

of record-filing, and advance the standardized development and clinical value transformation of hospital-made TCM preparations.

KEYWORDS medical institutions; traditional Chinese medicine preparations; record-filing system; management status; optimized pathway

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