美国药房临方配制制剂监管政策分析及启示Δ

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摘　要　目的　系统梳理美国药房临方配制制剂的核心监管要点，为完善我国药房临方配制制剂管理制度、保障公众用药安全可及提供参考。**方法**　采用文献研究法，归纳美国《联邦食品、药品和化妆品法案》第503A条款对药房临方配制制剂的监管要点与实践特征；结合美国监管经验，分析我国临方配制制剂发展现状及存在的问题，并提出针对性建议。**结果与结论**　美国依托503A条款构建了系统的临方配制制剂监管体系，覆盖处方管理、原料药管理、已撤市或退市药品清单管理、配制困难药物清单管理、记录保存管理、跨州销售管理等维度，通过全流程规范配制、与专家委员会协同共治，有效平衡了个体化用药需求与药品质量安全。我国临方配制制剂目前局限于中药领域，存在缺乏法律法规支撑、质量管控薄弱、行业标准体系建设滞后、专业人才不足等问题。建议我国应构建分层法规体系、制定全流程技术标准、搭建本土化监管框架、推动技术创新发展并强化专业人才培养，以更好地平衡公众用药合法权益与药品安全性、有效性，促进公众健康。

关键词　临方配制制剂；中药临方制剂；监管政策；药房

Regulatory policy analysis of pharmacy compounding drug products in the United States and its implications

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ABSTRACT　OBJECTIVE To systematically review the key regulatory requirements for pharmacy compounding drug products in the United States, and to provide references for improving the management framework of pharmacy compounding drug products in China, thereby ensuring the safety and accessibility of medication use. **METHODS** A literature review was conducted to summarize the regulatory requirements and practical characteristics of pharmacy compounding drug products under Section 503A of the United States *Federal Food, Drug, and Cosmetic Act*. Based on regulatory experience of the United States, current status and existing deficiencies in pharmacy compounding drug products in China were analyzed, and targeted recommendations were proposed. **RESULTS & CONCLUSIONS** The United States has established a systematic regulatory framework for pharmacy compounding drug products under Section 503A, covering prescription management, active pharmaceutical ingredient management, list management of withdrawn or removed drugs and drugs that present demonstrable difficulties for compounding, recordkeeping management, interstate distribution and so on. Through standardized regulation of the entire compounding process and collaborative governance with expert advisory committees, this framework effectively balances individualized medication needs with drug quality and safety. In contrast, pharmacy compounding drug products in China remain largely confined to traditional Chinese medicine and face several challenges, including the lack of legal and regulatory support, inadequate quality control, lagging development of industry standards, and shortages of specialized personnel. It is recommended that China should establish a tiered regulatory system, develop comprehensive technical standards, build a localized regulatory framework, promote technological innovation, and strengthen professional talent cultivation to better balance the legitimate rights and interests of public medication use with drug safety and efficacy, thereby enhancing public health.

KEYWORDS　compounding drug products; traditional Chinese medicine compounding drug products; regulatory policy; pharmacy

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美国食品药品监督管理局（Food and Drug Administration，FDA）将临方配制制剂定义为由执业药师、执业医师，或在外包机构中受执业药师监督的人员，通过混合、调配或改造药物原料，制备出满足特定患者个体化