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欧盟罕用药管理的成就与经验及其对中国的启示

Achievements and Experience of EU Orphan Drug Administration and Its Implications for China

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英文关键词:orphan drug administration rare diseases

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中文摘要:

目的 提出我国罕用药制度的建议。方法 制度比较分析。结果 欧盟通过颁布《罕用药管理规定》以促进罕用药的研发、投产和上市，取得了较为显著的成绩。这得益于欧盟在管理罕用药领域内采取各项行之有效的政策措施，主要体现在夯实主要立法基础、增强制度可操作性、完善特别审批程序以及大力资助研发投入等方面。这些举措给中国未来罕用药管理政策的制定和完善提供了丰富而又宝贵的经验。结论 我国需要建立罕用药管理制度、完善特殊审批制度、促进罕用药基础研究的成果向应用领域转化。

英文摘要:

OBJECTIVE To put forward suggestions for orphan drug administration in China. METHODS System comparison was used. RESULTS According to issued "Orphan Drug Act" for promoting orphan drug R&D, manufacturing and marketing, European Union achieved quite significant results. It was benefited from that EU taking various effective policy measures to manage orphan drug of this field, mainly in consolidating the key legislative basis and enhancing system operability, improving special approval procedures and financial support to R&D investment, etc.. These measures would confidently benefit China of orphan drug development and improving policies management in the future by providing abundant and valuable experience. CONCLUSION We should better build the orphan drug management in China, complete the orphan drug approval system, promote transformation from the achievement of basic research for orphan drug to application area.

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