

我国临床急需境外已上市药品审评审批制度的优化建议[△]

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摘要 **目的** 为优化我国临床急需境外已上市药品审评审批制度提供参考。**方法** 剖析临床急需境外已上市药品审评审批制度的特点; 运用比较研究法, 对比中国与澳大利亚、瑞士、加拿大三国在临床急需资质认定(即准入资质)、审评方法、批准形式三方面的制度差异。**结果与结论** 我国现行制度中沟通交流会议法律性质模糊, 将资质认定功能嵌入技术咨询程序, 缺乏救济渠道; 药品上市前临床试验豁免与上市后确证义务脱节, 且境外完整审评信息获取不足, 削弱了风险控制效能; 未建立基于获批时序的差异化分流机制, 对全球同步研发激励不足。国际典型监管模式将准入资质、审评方法、批准形式设置为独立模块, 通过药品上市前准入条件放宽与上市后附条件批准机制形成对价关系。建议我国可制定临床急需药品认定技术指导原则以明确客观裁量基准, 明确沟通交流会议的法律性质并配置救济渠道, 强制豁免临床试验的品种纳入附条件批准程序, 并建立负面信号联动机制, 同时实施基于获批时序的差异化分流, 以完善我国审评审批制度。

关键词 境外已上市药品; 药品审评审批; 临床急需; 附条件批准

Optimization suggestions for the review and approval system of clinically urgent overseas-marketed drugs in China

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ABSTRACT **OBJECTIVE** To provide references for optimizing the review and approval system of clinically urgent overseas-marketed drugs in China. **METHODS** The characteristics of the review and approval system for clinically urgent overseas-marketed drugs were analyzed. A comparative research method was employed to examine differences between China and Australia, Switzerland, and Canada in three dimensions: qualification determination for clinical urgency (i.e., access qualification), review methods, and approval modalities. **RESULTS & CONCLUSIONS** In China's current system, the legal nature of communication and consultation meetings is ambiguous, as the qualification determination function is embedded within technical consultation procedures without remedy channels. The pre-marketing clinical trial exemption for drugs is disconnected from the post-marketing confirmation obligation, and insufficient access to complete overseas review information weakens risk control effectiveness. A differentiated triage mechanism based on the timing of global approval has not been established, providing insufficient incentives for global simultaneous research and development. International typical regulatory models set access qualification, review methods, and approval modalities as independent modules, forming a quid pro quo relationship by relaxing pre-marketing access conditions and establishing post-marketing conditional approval mechanisms. It is recommended to formulate technical guidelines for the determination of clinically urgent drugs to clarify objective discretionary benchmarks, clarify the legal nature of communication and consultation meetings and allocate remedy channels, mandatorily include clinical trial-exempted varieties in the conditional approval procedure and establish a negative signal linkage mechanism, and implement differentiated triage based on approval timing, so as

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to improve China's review and approval system.

KEYWORDS overseas-marketed drugs; drug review and approval; clinical urgency; conditional approval