Retrospect and Prospect of Research and Development of Chinese Medicines as New Drugs in China

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Abstract

Background and Purpose: Chinese materia medica is an important part in China's medical system, and the authority has issued a series of regulations and guiding principles to improve the quality of research and development (R&D) of new Chinese drugs. Approach: Investigational new drug (IND) and new drug application (NDA) applications of new Chinese medicines and approval condition were analyzed in 4 categories including number of applications, review conclusions, registration classification and therapeutic area from 2007 to 2022. Key Results:The overall number of IND and NDA acceptance and approval of Chinese materia medica is far less than that of chemical drugs and biological preparations. The 6th classification of traditional Chinese medicine was the most in the INDs and NDAs accepted by drug evaluation authority, with a total number of 889 cases, accounting for 76.6% of all the accepted cases, indicating that the difficulties and risks of R&D of this type were relatively low. Conclusions & Implications: China is still left behind in the aspect of drug R&D by developed countries. The problems about relevant regulations, trial quality, selection of efficacy and safety evaluation indicators and review evidence system should be paid great attention to in the future research on Chinese materia medica.

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