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Abstract:

Title: A Legal Study on the Market Access of Traditional Chinese Medicinal Product in the EU under WTO Legal Framework

The scientificity of traditional Chinese Medicinal Product (TCMP) is widely doubted and uncertain based on the risk assessment system set up by the European Union (EU). The EU has strengthened the authorisation conditions on traditional use herbal medicinal product in which the export of TCMP is seriously influenced. Since then, very rare TCMP has been approved by EU competent authorities. The hardship of the trade of TCMP in practice brings rethinking of the Ph.D study on the rationality of EU pharmaceutical regulations applied on traditional medicine, particularly, taking into account of World Trade Organisation (WTO) rules. The research aims at making the legislative status understandable by medical scientists and raising their attention to the current pharmaceutical legislation relevant to TCMP. On the other hand, it pays attention to use the explicit words to explain the scientific development and knowledge of TCMP for a better understanding of policy makers and law makers on the regulatory status of CAM in the EU. It provides recommendations for improving the regulations relevant to TCMP in the EU based on explicit analysis on the topic.