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# Pharmacovigilance practice and risk control of Traditional Chinese Medicine drugs in China: Current status and future perspective

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## Abstract

Ethnopharmacological relevance

Traditional Chinese Medicine (TCM), including Traditional Chinese Medicine drugs (TCM drugs), has been playing a very important role in health protection and disease control for thousands of years in China. Relying on natural products, mainly of herbal origin, used either as raw materials for decoction, as prepared herbal medicines or as formulated traditional medicines, TCM is still widely accepted by Chinese people, especially for chronic diseases treatment. This extensive use warrants safety measures and so TCM drug safety monitoring and risk management are becoming increasingly important tasks

for the Chinese State Food and Drug Administration (SFDA).

## Methods

The Adverse Drug Reaction (ADR) monitoring system in China was established both for western and TCM drugs in 1989 as a voluntary reporting system with a National Center collecting and compiling reports. Serious or multi-case reports on individual TCM drug or formulated products are detailed in the Chinese ADR Information Bulletin to inform the public and Drug Administrative authorities for risk management.

## Results

About 10–15% of the ADR reports received by the National Center are related to TCM drugs and mainly pertaining to the formulated products. In certain cases, the suspension of a particular TCM preparation is decided by SFDA China.

## Conclusion

The model of safety monitoring and risk management of TCM drugs is still under exploration. Indeed, the characteristics and risk factors associated with these drugs require both proper understanding and control of the risk by strengthening standardization of clinical applications, basic science research, quality control in manufacturing, exploration of the actives monitoring methodology and enhancement of international communication and cooperation.

## Graphical abstract



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## Keywords

Traditional Chinese Medicine drug; Safety monitoring; Pharmacovigilance; Risk management; China

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