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COMMENTARY

Policy Evaluation for Regulating Toxic Traditional Chinese Medicines in Taiwan

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Video abstract

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Abstract: In recent years, growing reports of poisoning and adverse reactions linked to the misuse of traditional Chinese medicine (TCM) have raised increasing concerns about its safety. This article begins with the case of aristolochic acid nephropathy and draws on international regulatory practices to evaluate Taiwan's legal and policy framework governing toxic TCMs. The analysis reveals systemic deficiencies in the *Taiwan Herbal Pharmacopoeia* and related regulations, particularly in the classification of toxic substances, *Paozhi* (processing methods), and dosage safety standards. The article argues that the regulation of toxic TCMs should be grounded in scientific methodology and toxicological principles, incorporating risk assessment to establish rational toxicity classifications, standardized processing protocols, and usage restrictions, thereby enabling clinical practice to achieve the goal of high efficacy with low toxicity. It further advocates for the implementation of adverse event reporting mechanisms to safeguard public health.

Plain Language Summary: In recent years, researchers and regulatory bodies have increasingly focused on the safety of traditional Chinese medicine (TCM), responding to recurrent reports of poisoning and adverse reactions caused by improper usage. To improve the safe administration of TCM, this study conducts a comprehensive evaluation of existing regulatory frameworks.

We investigate the governance of toxic Chinese medicinal substances in Taiwan by examining documented poisoning incidents and analyzing current regulatory policies in comparison with international standards and practices. Our analysis identifies systemic deficiencies in the Taiwan Pharmacopoeia and related regulations, particularly in toxicity classification, processing methods (Paozhi), dosage safety, and adverse reaction reporting mechanisms.

We advocate for a science-based regulatory approach that applies toxicological principles and risk assessment methodologies. We recommend establishing rational usage restrictions and standardized toxicity classifications to ensure the safe and effective use of toxic Chinese herbs.

Keywords: adverse reaction reporting, processing, paozhi, risk assessment, safe dosage

Introduction

Medicine is poison; the line between remedy and toxicity is exceedingly thin. When used appropriately, a substance functions as medicine; when misused, it becomes poison. In recent years, the safety of traditional Chinese medicine (TCM) has received growing attention. Nevertheless, reports of poisoning or adverse reactions resulting from improper use of TCM continue to emerge. The primary distinction between TCM and Western medicine lies in their modes of production and composition. Western pharmaceuticals are predominantly chemically synthesized. Even when derived from natural sources, the active ingredients are extracted and purified, resulting in a final product with a simplified composition that no longer retains the original appearance or nature of the source material. In contrast, Chinese herbal medicine is composed of natural substances with complex and diverse constituents, and its preparations typically preserve the external form and inherent properties of the

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original natural materials. This method of ingesting natural substances to regulate bodily health gives rise to the concept of "medicinal and dietary homology" in Chinese herbal medicine. Accordingly, regulatory approaches differ across jurisdictions. In Western countries such as the United States, TCM products are often classified and regulated as food or dietary supplements. In contrast, East Asian countries such as Taiwan regulate Chinese herbal medicine as pharmaceutical products. These two models reflect divergent regulatory philosophies and cultural understandings of traditional medicine.[1]

In Taiwan, the regulatory framework for TCM categorizes products primarily based on safety considerations, excluding factors such as wildlife conservation, which fall outside the scope of this discussion. Chinese herbal medicine substances are generally classified into three groups: "prohibited medicines" that are completely banned; "poisonous Chinese materia medica" requiring special control—the two categories collectively referred to in this article as "toxic TCMs"; and general medicinal products. The concept of toxic TCMs refers to substances with severe toxicity, where the therapeutic dose closely approximates the toxic dose, and improper use may result in poisoning or death.[2] Regulatory standards governing their use are not only critical to medication safety but also directly impact therapeutic efficacy; thus, a careful balance must be maintained between the two. The primary causes of poisoning from toxic TCMs—specifically those related to regulatory oversight—include improper processing or formulation, excessive dosage, and prolonged use.[3] These factors underscore the importance of precise regulation and professional guidance in the administration of toxic Chinese medicinal substances.

However, Taiwan currently lacks specific legislation dedicated to the regulation of toxic Chinese medicinal materials. Within the category of substances classified as traditional Chinese medicine, the competent authority has only issued public notices prohibiting certain items due to safety concerns. These include materials containing heavy metals, such as cinnabar (*Cinnabaris*),[4] and those containing aristolochic acids (AAs), such as *Guang Fang Ji (Radix Aristolochiae Fangchi), Guan Mu Tong (Aristolochia manshuriensis), Ma Dou Ling (Aristolochia debilis), Bei Ma Dou Ling (Aristolochia contorta)*, and *Tian Xian Teng (Aristolochia debilis* or *Aristolochia contorta)*.[5] The fourth edition of the *Taiwan Herbal Pharmacopoeia* (THP) lists twenty-two poisonous Chinese materia medica. Among them, *Ciandan* (*Plumbum Rubrum*) is restricted to external use and is explicitly prohibited for internal administration.[6] However, the determination of toxicity lacks scientific standards grounded in toxicology and risk assessment. The criteria for inclusion and exclusion are neither specified nor explained, and no grading system has been established. Under such regulatory ambiguity, the safeguarding of TCM safety is subject to considerable doubt, leaving medical and pharmaceutical practitioners without clear guidance. This article focuses on toxic TCMs as defined by safety considerations in Taiwan, draws upon regulatory approaches adopted in other countries, and analyzes discrepancies between dosage recommendations in the literature and those prescribed in the THP. On this basis, it proposes principles for the regulation of toxic TCMs, intended to serve as a reference for future revisions.

Raising the Alarm on Aristolochic Acids (AAs) in Taiwan

The use of herbs in the Aristolochiaceae family (referred to as *Ma Dou Ling Ke* in Chinese pinyin) has been recorded for thousands of years in Chinese herbal medicine. We can find herbs in the Aristolochiaceae family recorded in the *Shennong Bencaojing*, such as *Mu Tong* (*Guan Mu-Tong, Aristolochia manshuriensis* Kom*)., Fang Ji (Guang Fang-Chi*, Aristolochia fangchi *Wu*), and *Xi Xin (Asarum sieboldii*).[7]

In 1993, a journal paper published in the Lancet raised the alarm on the toxic and adverse effects of Aristolochic acids (AAs) to the public. Vanherweghem et al discovered that a group of women in their fifties had suffered from rapidly progressive interstitial renal fibrosis or even renal failure in Belgium.[8] After analyzing this abnormal phenomenon, these patients were found to have sought weight loss at the same clinic and consumed Chinese herbal formulations. In a later paper in 1998, this incident was confirmed to be caused by confusing the species of *Han Fang Ji (Stephania tetandra)* with *Guang Fang Ji (Aristolochia Clematis)*; additionally, the presence of carcinogenic compounds in the form of AAs were detected.[9] Thereafter, similar cases in the UK were reported.[10] This newly discovered knowledge immediately spread to academic groups in biomedicine worldwide. Governments across the West implemented new regulations for Chinese herbs in response to a series of studies of AAs. AAs can induce injury to renal tubular epithelial cells and trigger interstitial fibrosis in the kidney. Its integrated mechanisms of nephrotoxicity and carcinogenicity have not yet been fully

elucidated; however, genetic polymorphisms, concomitant medications, smoking habits, and environmental chemicals have been identified as important factors influencing the toxicity of AAs.[11]

AAs became a prominent issue in Taiwan beginning on November 1, 2003, at the "Asia-Pacific Regional Conference on Chinese Herbal Toxicity " held in Taiwan. At the conference, a TCM physician reported that he had developed interstitial nephritis after long-term consumption, since 1996, of the Scientific Chinese Medicine (SCM) formula *Longdan Xiegan Tang*, which had been manufactured by a Good Manufacturing Practice-certified pharmaceutical company. Subsequent testing, however, revealed that this SCM in fact contained AAs. On November 3, 2003, the Taiwanese government announced a complete ban on all herbal materials and preparations containing AAs and revoked the licenses of fifty products found to contain aristolochic acids.[12]

Establishing Scientific Classification Standards for Prohibited and Toxic Chinese Medicinal Substances

Historically, the *Shennong Bencaojing* (The Classic of Herbal Medicine, thought to be written between 200 and 250 CE) is the earliest classical text on Chinese pharmacology. This book classifies medicinal substances based on their toxicity and safety into the following three categories: superior, medium, and inferior medicines. This classification standard was primarily derived from clinical experience and observation in ancient China. From a modern biomedical perspective, this system of toxicity assessment is not entirely accurate. Nonetheless, contemporary pharmaceutical regulation has adopted this safety-oriented approach to classifying medicines in Taiwan, which are generally categorized into three types, namely, prescription drugs, over-the-counter drugs, and proprietary medicines. If such categorization applies even to general pharmaceuticals, then the management of toxic TCMs—which carry higher risks—requires an even more rigorous scientific approach grounded in toxicology and risk assessment. This should involve more detailed classifications based on safety, as well as the establishment of explicit prohibitions and toxicity standards. In countries with double-track regulatory systems, such as Taiwan, China, Malaysia, and Singapore, biomedicine and Chinese medicine are equally recognized. However, *the Pharmacopoeia of the People's Republic of China* classifies toxic TCMs into three levels (ie, highly toxic, toxic, and mildly toxic) according to the severity of their toxicity.[13] Malaysia[14] and Singapore[15] categorize such medicines based on the specific toxic substance. By contrast, the regulation of toxic TCMs in Taiwan is relatively lax. The government merely distinguishes between prohibited substances and extremely toxic TCMs without further subclassification or explicitly defined inclusion criteria.

TCMs have been used for hundreds, if not thousands, of years and are recognized for their clinical efficacy. Decisions regarding whether they should be prohibited involve numerous considerations. This article takes AAs—which are nephrotoxic and carcinogenic, and therefore have been banned in many countries worldwide—as a case study for discussion. The regulatory framework for *Asarum* (*Xi Xin*) highlights the gap between scientific principles and actual regulatory practice. Because *Asarum* is widely used in TCM formulas, its prohibition would simultaneously render many commonly prescribed formulas unusable, thereby severely affecting the clinical efficacy of TCM practice. Consequently, in contrast to the aforementioned "constituent-based" approach, under which all other AA-containing herbs are categorically prohibited, Taiwan issued a specific administrative order on February 27, 2004, entitled "Regulations on the Management of Asarum Chinese Medicinal Materials and Their Preparations." Under this order, for *Asarum* and its preparations, which also contain AAs, the regulation required that

> The whole herb be replaced with the root, and only after passing testing by High-Performance Liquid Chromatography may it be used for manufacturing and dispensing.[16]

Thus, uniquely for *Asarum*, the regulation shifted to a "content-based" determination by specifying medicinal parts and testing methods, resulting in an inconsistent standard.[17]

With respect to the issue of carcinogenicity, drawing upon the regulatory approach applied to carcinogenicity in Western pharmaceuticals, a drug should not be prohibited solely on the basis of its carcinogenic potential; rather, its risks and benefits should be evaluated, and it should be used within a reasonable scope. Moreover, with the evolution of the concept of risk assessment, the determination of carcinogenic risk depends on both dosage and carcinogenic potency. If the intake of a carcinogen is at a sufficiently low level, the carcinogenic risk may be negligible.[17] One study, using the example of the AAs content in *Asarum*, employed LC-MS/MS (liquid chromatography–tandem mass spectrometry) to

measure the level of aristolochic acid I in *Asarum* clinically used in Taiwan and calculated its carcinogenic risk.[11] The study argued that by integrating the concept of scientific risk assessment with practical application, as long as dosage and duration of administration are properly controlled and accompanied by regular monitoring, even toxic TCMs need not be subject to an outright ban, and an optimal balance between therapeutic efficacy and risk can still be achieved. This stands in contrast to the approach of imposing a blanket prohibition on Chinese medicines and their preparations solely on the grounds that they contain certain toxic constituents, without the support of systematic scientific research.[18]

According to current practice, the most commonly used method for toxicity classification is the median lethal dose (LD_{50}) system, although some approaches also rely on the minimum lethal dose (MLD) as a reference.[18] In addition, the study group led by Kim established a regulatory framework for TCMs, drawing upon a literature review and comprehensive evaluation criteria, and employed the LD_{50} in mice as a clinical indicator of the therapeutic window. Based on this, four regulatory classes were proposed: Class one: Prohibited for medicinal usage, which are those with high toxicity and can lead to injury or death, eg, *Aristolochia*; Class two: Restricted for medicinal usage, eg, *Aconite, Asarum*, and *Ephedra*; Class three: Required warning label, eg, *Tussilago farfara*; and Class four: Over-the-counter herbs with a safe toxicity profile.[19] Although some scholars argue that relying solely on LD_{50} as the toxicity classification standard may omit certain toxic Chinese medicinal substances and obscure the distinct characteristics of their toxic effects,[18] it nevertheless remains a scientifically valuable reference.

This section summarizes that the first step in managing toxic TCM is to carry out scientific risk assessments. This step guarantees a proper balance between therapeutic effectiveness and potential dangers under suitable regulatory conditions, such as setting clear standards for prohibition and toxicity classification and developing safety risk management guidelines that are in line with international practices.

Establish Regulatory Standards for the Processing and Preparation of Medicinal Materials

Paozhi, the traditional processing method in TCM, is a historically significant and clinically indispensable technique used to reduce or eliminate toxicity and to modify the pharmacological properties of medicinal substances. Methods of Paozhi include cutting, grinding, boiling, heating, steaming, and other processes. Raw Chinese materia medica must undergo paozhi before they can be prepared as " TCM decoction pieces" suitable for patient use. Toxic TCMs typically require paozhi to decrease the concentration of toxic constituents or to decompose and transform toxic compounds, thereby rendering them appropriate for clinical application.[3]

For example, both *Pinellia ternata* (Banxia) and *Aconitum (*Fuzi) are classified as poisonous Chinese materia medica in their unprocessed form under the THP and the *Pharmacopoeia of the People's Republic of China*. However, in clinical practice, only their processed forms—*Zhi Banxia* and *Zhi Fuzi*—are used, rather than the raw materials. This distinction is critical, as unprocessed Aconitum contains the toxic alkaloid aconitine, which can induce poisoning at doses as low as 0.2 mg and may be fatal at 3 to 5 mg in healthy adults.[20]

During the processing (paozhi) of raw *Aconitum* herbs, hydrolysis transforms the highly toxic alkaloid aconitine into less toxic derivatives such as aconine and benzoylaconine. The toxicity of benzoyl aconine is approximately 1/50 to 1/100 that of aconine, while aconine itself exhibits only 1/1,000 to 1/2,000 the toxicity of aconitine. Nevertheless, both compounds retain significant cardiotonic and analgesic pharmacological effects.[21] A 2013 journal study published by the First Affiliated Hospital of Zhejiang Chinese Medical University demonstrated that the acute toxicity of processed Fuzi (*Aconitum*) in mice gradually decreases with extended decoction time (see Table 1).[22] This finding underscores the critical importance of proper paozhi (processing) in effectively reducing the toxicity of raw Fuzi.[23]

Table 1 The Acute Toxicity of Processed Fuzi in Mice with Longer Decoction Times

Decoction Times	30 min	60 min	120 min
Median lethal dose (LD_{50})	145.1 g/kg	Too large LD_{50}	No LD_{50}
Maximal tolerance dose (MTD)	70 g/kg	160 g/kg	Unlimited
Minimal lethal dose (MLD)	100 g/kg	190 g/kg	Unlimited
No-observed-adverse-effect-level (NOAEL)	70 g/kg	100 g/kg	130 g/kg

It is essential to recognize that the active constituents of many toxic Chinese materia medica are themselves toxic compounds.[3] For example, in Fuzi-based preparations, the paozhi (processing) procedure decomposes the principal toxic component—aconitine. Although this transformation significantly reduces toxicity to humans, it concurrently diminishes therapeutic effects such as cardiotonic activity.[24] Therefore, the processing of Fuzi must not only focus on detoxification but also preserve its pharmacological efficacy. Whether paozhi is properly executed directly impacts both the safety and effectiveness of clinical application.[24]

Traditional methods for paozhi (processing) of toxic TCMs have often relied on observable changes in appearance—such as alterations in shape or color—which can sometimes be questionable. These practices heavily depend on the practitioner's subjective experience. Therefore, relying solely on traditional techniques and sensory evaluation may be insufficient to ensure the quality and safety of clinical application.[3] In contemporary practice, regulatory authorities should adopt biomedical science and standardized methodologies to rigorously govern the processing of toxic TCMs.

These regulatory developments in mainland China reflect a growing emphasis on risk-based governance for toxic TCMs. In 2025, China implemented the *Special Provisions on the Standardized Management of Traditional Chinese Medicines*, which introduced several regulatory measures concerning toxic medicinal materials. Article 22 stipulates that for substances traditionally regarded as toxic, or those confirmed to be toxic through modern toxicological evaluation, enhanced safety risk assessments must be conducted, and scientifically justified quality control items and limits should be established for toxic constituents. Article 27 emphasizes the importance of key factors in the processing (paozhi) stage that affect the quality of TCM decoction pieces, and calls for the development of control parameters and indicators that reflect their quality characteristics. Article 28 further encourages research into the mechanisms of paozhi.[25]

In addition, the *Regulations on the Administration of Toxic Drugs for Medical Use* (State Council Order No. 23, promulgated 1988) serve as a provisional framework for regulating toxic drugs, including toxic TCMs. Under this regulation, twenty-eight types of TCMs are classified as toxic drugs. Article 7 of the Regulations explicitly requires that the paozhi of toxic TCMs must comply with the standards set forth in the *Pharmacopoeia of the People's Republic of China*, or with processing specifications issued by provincial, autonomous regional, or municipal health authorities. Only materials that meet medicinal standards may be supplied, prescribed, or used in the production of proprietary Chinese medicines.[26] This provision clearly mandates that the processing of TCM decoction pieces must follow legally defined procedures to ensure both safety and efficacy, and underscores the need for strengthened oversight of toxic TCMs used in medical practice to prevent poisoning or fatal incidents.

Compared to the increasingly structured regulatory framework for toxic TCMs in mainland China, Taiwan's current oversight remains limited. To date, there is no dedicated legislation governing the use of toxic TCMs in Taiwan. Although Chinese materia medica must undergo traditional processing (paozhi) to become decoction pieces suitable for clinical use, the THP only sets standards for raw materials—such as botanical origin, marker compounds, impurities, and pesticide or heavy metal residues—without regulating processing methods or the final decoction pieces intended for patient administration. Among the twenty-two poisonous Chinese materia medica listed, only eight have defined standards for raw materials, while the remaining fourteen lack any regulatory specifications. As a result, the actual toxicity levels of these substances in clinical use cannot be adequately controlled, posing potential risks to medication safety. These regulatory gaps stand in stark contrast to China's recent emphasis on risk assessment, quality control, and legally mandated paozhi procedures. To ensure the safe and effective clinical application of toxic TCMs, Taiwan should establish standardized processing protocols and implement a comprehensive regulatory strategy for monitoring the toxicity of decoction pieces.

Standards for Safe Dosages are Needed

The active constituents of toxic TCMs are often identical to their toxic components. Although the duality between therapeutic and toxic dosages remains insufficiently defined,[3] dosage itself underlies the dual nature of pharmacological efficacy and toxicological risk. As Paracelsus, the father of toxicology, famously stated: "All things are poison, and nothing is without poison; only the dose makes a thing not a poison." When employing highly toxic TCMs for therapeutic purposes, it is advisable to initiate treatment with a low dose and gradually titrate upward. The maximum dose must not exceed established limits to ensure medication safety.[27] For example, Singapore, like Taiwan, has a double-track system, but its *Poisons Act* imposes strict regulatory limits on the maximum allowable dosage of toxic constituents in TCM products.[28]

Studies indicate that excessive dosage, followed by prolonged use, is the primary cause of adverse reactions linked to TCM products.[2] Accordingly, dosage control is critical when administering toxic TCMs. This is particularly important for patients with chronic diseases who require long-term treatment, which inevitably increases the risk of drug-induced toxicity.[3] In 2015, Taichung Veterans General Hospital reported three cases of aconite poisoning. The administered doses ranged from 1.5 to 2 qian (where one qian is equivalent to 3.75 grams), corresponding to approximately 5.6 to 7.5 grams.[23] Although these fell within the recommended range of 3 to 15 grams as specified in the THP,[6] toxic reactions nonetheless occurred.

Establishing safe dosage standards for toxic TCMs requires rigorous scientific methodology to define both maximum and standard dosages for each substance. For agents intended for long-term use, it is particularly essential to formulate explicit dosage guidelines and to clearly identify potential adverse reactions that may arise during the course of treatment. Such measures are critical to enhancing medication safety.[2]

Post-Market Monitoring and Adverse Reaction Reporting

Beyond pre-market regulatory oversight, post-marketing surveillance is equally critical to ensuring drug safety. This phase typically involves Phase IV clinical trials conducted after a drug has been approved for public use. To prevent adverse reactions associated with long-term administration, routine monitoring of hepatic and renal function is essential. However, TCMs, which are primarily composed of classical herbal ingredients and formulations, are generally exempt from the Phase I to III clinical trial protocols mandated for conventional pharmaceuticals. This regulatory distinction presents significant challenges in Taiwan when attempting to apply Western drug surveillance standards to traditional herbal products and TCM prescriptions.

Moreover, unlike Western pharmaceuticals, which are typically composed of a single chemical entity, Chinese herbal medicine consist of complex mixtures of herbal components. This complexity renders the monitoring of plasma drug concentrations significantly more challenging. Like all other drugs, toxic TCMs undergo oral administration, gastrointestinal absorption, systemic distribution, metabolic transformation, and eventual excretion. The elimination of toxic substances from the body requires time; even low-toxicity compounds may accumulate and induce poisoning if consumed in excessive quantities or over prolonged periods.[27] Such pharmacokinetic characteristics complicate the clinical use of plasma concentration data for dosage adjustment — let alone for minimizing adverse effects or optimizing therapeutic efficacy.

The adverse drug reaction (ADR) reporting system for TCMs plays a pivotal role in mitigating the risks associated with TCM toxicity. In addition to patient monitoring, systematic reporting of ADRs is equally essential. Long-standing ADR surveillance for Western pharmaceuticals has facilitated the development of robust pharmacovigilance databases. Taiwan established its national ADR reporting system for TCMs in 2001.[29] However, due to the inherent complexity of herbal compositions and the relatively unpredictable and ambiguous nature of TCM-related adverse reactions compared to Western drugs, such events are often overlooked, resulting in underreporting. It is imperative that TCM practitioners pay closer attention to patients' medication histories and enhance their awareness of TCM toxicology.[30] It is also possible to link the Taiwan National Health Insurance (NHI) database to strengthen the ADR reporting system and integrate risk assessment mechanisms, thereby further enhancing pharmacovigilance.

Conclusion and Policy Recommendations

In Taiwan, there is currently no dedicated legislation governing the use of toxic TCMs. Existing regulatory oversight is limited to occasional announcements by competent authorities regarding prohibited substances. Although the THP lists poisonous Chinese materia medica, it does not provide a clear classification of toxicity levels. Moreover, the criteria used to determine toxicity are not based on scientific evidence or toxicological dosage principles, and no standardized framework has been established. While toxic TCMs are commonly used in clinical practice only after undergoing traditional processing (paozhi), the THP sets standards only for raw herbal materials, without regulating processing methods or the final processed products. These regulatory deficiencies may significantly compromise both the therapeutic efficacy and safety of toxic TCMs in clinical settings.

This article recommends that the regulation of toxic TCMs should include greater investment in animal and clinical studies, be guided by scientific methodologies and toxicological principles, and incorporate risk assessment frameworks to establish rational restrictions and toxicity classifications. The THP should also include clear standards for traditional processing techniques (paozhi). Specific guidelines should be developed concerning the content of toxic constituents, decoction methods, dosage and duration of use, as well as associated monitoring mechanisms. Alternatively, a dedicated regulatory framework could be established to govern the management of toxic TCMs. Finally, integrating the Taiwan NHI database to strengthen the functionality of the current ADR reporting system for TCMs is essential. Comprehensive regulatory oversight would help strike a balance between therapeutic efficacy and toxicity, enabling clinical practice to achieve the goal of "high efficacy with low toxicity," and aligning Taiwan's governance of herbal medicines with international standards. Achieving this objective requires substantial investment of human and material resources in scientific experimentation, a process that cannot be accomplished within a short timeframe. Accordingly, the government should formulate and implement a phased plan to ensure the successful realization of this goal.

Declaration of Generative AI and AI-Assisted Technologies in the Writing Process

During the preparation of this work the author used Microsoft copilot to improve the readability and language quality of the article. After using this tool/service, the author reviewed and edited the content as needed and take(s) full responsibility for the content of the publication.

Abbreviations

SCM, scientific Chinese medicine; TCM, traditional Chinese medicine; AAs, aristolochic acids; THP, Taiwan Herbal Pharmacopeia; LC-MS/MS, liquid chromatography–tandem mass spectrometry; $LD_{50,}$ lethal dose; MLD, minimum lethal dose; ADR, adverse drug reaction; NHI, National Health Insurance.

Consent for Publication

All authors have read and agreed to the published version of the manuscript.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

References

1. Chen YP. Policy reform on qualification for dispensing Chinese medicine and industry heritage. *Taiwan J Public Health*. 2019;38(6):569–573. doi:10.6288/TJPH.201912_38(6).108104
2. Li X, Zhang Y, Wang J, et al. Current status, rationality, and management of clinical applications of toxic Chinese medicine. *Med J Chin People's Armed Police Forces*. 2017;28(8):841–843. doi:10.3969/j.issn.1004-3594.2017.08.027
3. Zhang C, Liu Y, Wang H, et al. A new exploration of toxic Chinese medicine research. *Inf Tradit Chin Med*. 2002;19(5):23–24. doi:10.3969/j.issn.1002-2406.2002.05.011

4. Ministry of Health and Welfare. Department of Chinese Medicine and Pharmacy. *Prohibition on the manufacture, dispensing, import, export, sale, or display of Chinese medicine containing cinnabar effective*. Taipei: Ministry of Health and Welfare. Available from: https://dep.mohw.gov.tw/DOCMAP/cp-752-5304-108.html. Accessed September 26, 2025.
5. Ministry of Health and Welfare. Department of Chinese Medicine and Pharmacy. *Prohibition on the use of five Chinese medicinal materials including Aristolochia, Qingmuxiang, Guanmutong, Madouling, and Tianxianteng*. Taipei: Ministry of Health and Welfare. Available from: https://dep.mohw.gov.tw/DOCMAP/cp-752-5315-108.html. Accessed September 26, 2025.
6. Ministry of Health and Welfare. *Taiwan Pharmacopoeia*. Taipei: Ministry of Health and Welfare; 2021: Available from: https://dep.mohw.gov.tw/DOCMAP/lp-759-108.html. Accessed September 26, 2025.
7. Wu TS, Lin JG. *The Researches and Literary Reviews of Aristolochiaceae Herbs*. Taipei: National Research Institute of Chinese Medicine, Ministry of Health and Welfare; 2005:179–210.
8. Vanherweghem JL, Depierreux M, Tielemans C, et al. Rapidly progressive interstitial renal fibrosis in young women: association with slimming regimen including Chinese herbs. *Lancet*. 1993;341:387–391. doi:10.1016/0140-6736(93)92984-2
9. Vanherweghem JL. Misuse of herbal remedies: the case of an outbreak of terminal renal failure in Belgium (Chinese herbs nephropathy). *J Altern Complement Med*. 1998;4(1):9–13. doi:10.1089/acm.1998.4.1-9
10. Lord GM, Tagore R, Cook T, et al. Nephropathy caused by Chinese herbs in the UK. *Lancet*. 1999;354(9177):481–482. doi:10.1016/S0140-6736(99)03380-2
11. Lan YS. Application of risk assessment on aristolochic acids in Chinese herbal medicine Asarum – a study of medication safety of traditional Chinese medicine in Taiwan [master's thesis]. Tainan: National Cheng Kung University; 2021.
12. Ministry of Health and Welfare. Department of Chinese Medicine and Pharmacy. *Withdrawal of marketing authorizations for aristolochic acid-containing products*. Taipei: Ministry of Health and Welfare. Available from: https://dep.mohw.gov.tw/DOCMAP/cp-862-5442-108.html. Accessed January 30, 2025.
13. National Medical Products Administration. *Pharmacopoeia of the People's Republic of China*. Beijing: National Medical Products Administration; 2020. Available from: https://ydz.chp.org.cn/#/main. Accessed September 26, 2025.
14. Pharmaceutical Services Programme, Ministry of Health Malaysia. *Poisons Act 1952 and Regulations*. Putrajaya: Ministry of Health Malaysia. Available from: https://pharmacy.moh.gov.my/en/documents/poisons-act-1952-and-regulations.html. Accessed September 26, 2025.
15. Health Sciences Authority, Therapeutic Products Branch. *Guidelines for the application for approval of Chinese proprietary medicines*. Singapore: Health Sciences Authority; 2024 Nov. p. 9–10 Available from: https://www.hsa.gov.sg/docs/default-source/hprg-tmhs/chinese-proprietary-medicines/pl_fsc_guidelines_chi.pdf. Accessed September 26, 2025.
16. Department of Chinese Medicine and Pharmacy, Ministry of Health and Welfare. *Regulations on the management of Asarum herb and its preparations, effective from the date of announcement*. Taipei: Ministry of Health and Welfare. Available from: https://dep.mohw.gov.tw/DOCMAP/cp-752-7105-108.html. Accessed September 26, 2025.
17. Li JH, Liu TY. Probing the management principle for food and drug carcinogenicity via two web rumors. *Taiwan J Public Health*. 2007;26(1):1–5. doi:10.6288/TJPH2007-26-01-01
18. Huang XQ, Cai ZZ. 'Medicine' and 'poison': several reflections on the historical review and narrative mode of the 'toxic' concept in herbalism. *J Chin Med*. 2014;25(Special Issue 2):259–274. doi:10.3966/101764462014122502014
19. Kim EJY, Lee JH, Park SY, et al. Evidence-based toxicity evaluation and scheduling of Chinese herbal medicines. *J Ethnopharmacol*. 2013;146(1):40–61. doi:10.1016/j.jep.2012.12.027
20. Chen CL, Sun-Lung T. Aconite poisoning and torsades de pointes: case report. *J Emerg Crit Care Med*. 1997;8(2):85–88. doi:10.30018/JECCM.199706.0004
21. Chang HC, Tsai KH. *Science of Chinese Herbal Processing*. Taichung: China Medical University Press; 2003:195–199.
22. Tong P, Zhao J, Xu W, et al. Development and assessment of a complete-detoxication strategy for *Fuzi* (lateral root of *Aconitum carmichaeli*) and its application in rheumatoid arthritis therapy. *J Ethnopharmacol*. 2013;146(2):562–571. doi:10.1016/j.jep.2013.01.025
23. Chen WC, Lin YH, Huang CY, et al. Case series analysis and literature review of *Fuzi* poisoning. *Taipei J Tradit Chin Med*. 2017;20(1):103–109. doi:10.6516/TJTCM.2017.20(1)103
24. Chen SH. Historical evolution and development overview of processing techniques for Aconitum-based Chinese medicinal herbs. *Hubei J Tradit Chin Med*. 2017;39(11):58–61.
25. National Medical Products Administration. Central People's Government of the People's Republic of China. *Announcement on the issuance of special provisions for the management of Chinese medicine standards*. Beijing: National Medical Products Administration. Available from: https://www.gov.cn/zhengce/zhengceku/202407/content_6962491.htm. Accessed September 26, 2025.
26. National Health Commission of the People's Republic of China. *Regulations on the management of toxic drugs for medical use*. Beijing: National Health Commission; 1988. Available from: https://www.nhc.gov.cn/fzs/c100048/201808/6effc859f8e54336b9b8560fa8de5386.shtml. Accessed September 26, 2025.
27. Ho GC, Li MY, Chiang YJ. The therapeutic efficacy of highly toxic Chinese medicinal substances should be given due attention. *China Pharm*. 2000;9(1):54–55. doi:10.3969/j.issn.1006-4931.2000.01.059
28. Health Sciences Authority. *Regulatory overview of Chinese Proprietary Medicines*. Singapore: Health Sciences Authority. Available from: https://www.hsa.gov.sg/chinese-proprietary-medicines/overview. Accessed September 26, 2025.
29. Taiwan Food and Drug Administration, Ministry of Health and Welfare. *National Adverse Drug Reaction Reporting System*. Taipei: Taiwan Food and Drug Administration. Available from:: https://adr.fda.gov.tw/Manager/WebLogin.aspx. Accessed September 26, 2025.
30. Yu YT. Adverse event reporting system of traditional Chinese medicine and its clinical application in Taiwan and China. *J Chin Med Hepat Dis*. 2010;6(1):27–39. doi:10.30031/JCMHD.201002.0008