

Protection and sustainable utilization of traditional medicinal biogenetic resources

The report titled *Investing in extinction: How the global financial sector profits from traditional medicine firms using threatened species*^[1] released by a UK environmental agency highlights issues such as the use of threatened animals in traditional medicine and calls on the global financial institutions to invest cautiously in traditional medicine. Traditional Chinese medicine (TCM) is a representative of traditional medicine. Chinese medicinal materials are the material foundation of the TCM industry and belong to biogenetic resources in a broad sense.^[2] China has sound laws and regulations for the protection and utilization of endangered wild animal and plant resources and strictly regulates the traditional medical use of the species included in the appendix of the *Convention on International Trade in Endangered Species of Wild Fauna and Flora* (CITES).^[3] The *International Classification of Diseases, 11th Revision* (ICD-11), which includes traditional medicine for the first time, marks the recognition of the value of traditional medicine by the international public health systems represented by the World Health Organization (WHO). Since then, the protection and sustainable use of biogenetic resources in traditional medicine have received increasing attention. This article introduces the development of traditional medicine, the current status of legislation on the protection of biogenetic resources, and China's successful experience in protecting medicinal biogenetic resources, exploring the relationship between traditional medicine and the protection and sustainable use of biogenetic resources.

1. Development of traditional medicine

1.1. Representatives of traditional medicine

Traditional medicine is the sum total of the knowledge, skills, and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable, used in the maintenance of health as well as in the prevention, diagnosis, improvement, or treatment of physical and mental illness.^[4] It is generally used to treat or prevent diseases including chronic diseases and improve the quality of life,^[5] serving as the pillar of healthcare services.^[4] The widely spread traditional medicine includes TCM, Ayurvedic medicine, Arabic medicine, chiropractic therapy, Unani medicine, Siddha medicine, homeopathy, and naturopathic medicine.^[6] Among them, TCM, Ayurvedic medicine, and Arabic medicine are not only popular domestically but also used globally. After the release of the *WHO Traditional Medicine Strategy 2002–2005*, many countries have made tremendous efforts to promote traditional and complementary medicine. As of 2018, 170 WHO member states have acknowledged their use of traditional and complementary medicine, and the number of countries with legal and regulatory frameworks for traditional and complementary medicine has increased to 109.^[7]

1.2. World Health Organization's strategy and work regarding traditional medicine

At the 55th World Health Assembly held in May 2002, WHO released the *WHO Traditional Medicine Strategy 2002–2005*, pointing out that the role of traditional medicine is gradually being recognized. The 67th World Health Assembly held in May 2014 urged member states to adapt, adopt, and implement, where appropriate, the *WHO Traditional Medicine Strategy 2014–2023* which was updated from the *WHO Traditional Medicine Strategy 2002–2005*. At the 72nd World Health Assembly on June 18, 2018, WHO released the *ICD-11*, which took effect on January 1, 2022. The *ICD-11* for the first time incorporates traditional medicine into its classification system,^[8] which indicated the recognition of traditional medicine. The *WHO Global Report on Traditional and Complementary Medicine 2019* reveals the current status of traditional and complementary medicine worldwide based on 3 WHO surveys and updated data from member states. It includes the national frameworks for traditional and complementary medicine, regulatory status of herbal medicines, practice, providers, education, and health insurance, challenges and the need for WHO support, and summaries of 149 member states.^[9] The *Updates and Future Reporting* about traditional medicine delivered at the 75th World Health Assembly in 2022 requests the director-general to continue to provide policy guidance to member states on how to integrate traditional and complementary medicine services into national and/or subnational healthcare systems, as well as the technical guidance that would ensure the safety, quality, and effectiveness of such traditional and complementary medicine services; and to continue to promote international cooperation and collaboration in the area of traditional and complementary medicine to share evidence-based information. The 76th World Health Assembly held in May 2023 decided to extend the *WHO Traditional Medicine Strategy 2014–2023* to 2025 and develop the *Traditional Medicine Strategy 2025–2034*. The WHO formulated traditional medicine strategy to build a knowledge base for active management of traditional and complementary medicine through appropriate national policies; to strengthen quality assurance, safety, proper use, and effectiveness of traditional and complementary medicine by regulating products, practices, and practitioners; and to promote universal health coverage by integrating traditional and complementary medicine services into healthcare service delivery and self-health care. Moreover, the significant role of TCM in contributing to global health is illustrated further in the control and treatment of Corona Virus Disease 2019 (COVID-19) cases, when the Expert Meeting on Evaluation of Traditional Chinese Medicine in the Treatment of COVID-19 was held virtually in 2022. The WHO expert panel agreed that TCM was beneficial in reducing the risk of progression from mild-to-moderate cases to severe COVID-19 cases.^[10]

2. China promotes the protection and sustainable use of Chinese medicinal resources through legislation and formulation of relevant plans and programs

The Chinese government attaches great importance to the protection and sustainable use of wild medicinal resources to protect wild animal and plant resources and ensure the sustainable development

Science of Traditional Chinese Medicine, (2024) 2, 1, 1–4

Received January 22, 2024; Accepted January 22, 2024.

<http://dx.doi.org/10.1097/st9.0000000000000026>

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of traditional medicine by continuously amending relevant policies and regulations. For example, *Regulations on the Protection and Management of Wild Medicinal Herb Resources*^[11] clarifies the protection and use principles on the wild medicinal resources, and the *Law of the People's Republic of China on Traditional Chinese Medicine* puts forward the requirement of dynamically monitoring and regular surveying wild animal and plant medicinal resources.^[12] In addition, the outline for the compilation of the *Pharmacopeia of the People's Republic of China* (2020 edition) specifies that depleted wild resources will no longer be included.^[13] China has established a sound wildlife protection and management system, which the TCM work can follow.

2.1. The Law of the People's Republic of China on Traditional Chinese Medicine provides an institutional guarantee for the protection and development of Chinese medicinal resources

On December 25, 2016, the 25th session of the Standing Committee of the 12th National People's Congress passed the *Law of the People's Republic of China on Traditional Chinese Medicine*, which became effective on July 1, 2017. The Chapter III (Protection and Development of Traditional Chinese Medicine) points out that the state protects wild animal and plant medicinal resources and should implement dynamic monitoring and regular survey, establish a gene bank, and encourage the artificial planting and breeding of wild animal and plant medicinal resources, as well as support the protection, breeding, and research of endangered wild medicinal animals and plants in accordance with the law.

2.2. The Wildlife Protection Law of the People's Republic of China has clear provisions on the medicinal use of animal resources

On December 30, 2022, the 38th session of the Standing Committee of the 13th National People's Congress revised the *Wildlife Protection Law of the People's Republic of China* for the second time. This revision plays a key role in protecting endangered wild medicinal animals, curbing unreasonable demand, and maintaining species diversity and habitat balance from the protection of wild animals and their habitat and the management of wild animals. This law emphasizes the conservation of wild animals in the *State Key-protected Wild Animals List* and specifies that the acquisition of animal resources for medicinal purposes must comply with the provisions of medicinal product management laws and regulations.

2.3. The Pharmaceutical Administration Law of the People's Republic of China emphasizes the protection of wild medicinal resources

On August 26, 2019, the 12th session of the Standing Committee of the 13th National People's Congress revised *Pharmaceutical Administration Law of the People's Republic of China* for the second time. Two provisions in the law directly specifies the protection of Chinese medicinal materials, including (1) the state protects wild medicinal materials and varieties and encourages the cultivation of Dao-di herbs and (2) the enterprises selling Chinese medicinal materials shall label the place of origin. The National Medical Products Administration has released the *Technical Guidelines for Evaluation of Chinese Medicinal Resources*, which requires that the marketing and postmarketing assessment of Chinese patent medicines should provide the certificate for sustainable use of Chinese medicinal resources.

2.4. Regulations on the Protection and Management of Wild Medicinal Herb Resources has clear provisions for the protection and rational utilization of wild medicinal resources

As early as December 1, 1987, the Chinese government issued *Regulations on the Protection and Management of Wild Medicinal*

Herb Resources, which is a specially formulated to protect wild medicinal resources. The *Regulation* categorizes national key protected wild medicinal materials into 3 levels for management, which is corresponding to the *State Key-protected Wild Medicinal Species List*. It provides clear provisions for the hunting, use, import, and export of national key protected wild medicinal species. At present, China is revising the *Regulation*.

2.5. The Opinions of the CPC Central Committee and the State Council on Facilitating the Inheritance, Innovation, and Development of Traditional Chinese Medicine proposes the use plan for endangered wild animal and plant medicinal materials

The *Opinions of the CPC Central Committee and the State Council on Development of Traditional Chinese Medicine* released in October 2019 proposes the requirement of strengthening the quality and safety supervision of TCM. Specifically, it puts forward the requirements of revising the Good Agricultural Practice for Chinese Crude Drugs to guide and promote the standardized planting and breeding of Chinese medicinal materials; protecting wild medicinal resources by strictly restricting the use of endangered wild animal and plant medicinal materials; strengthening the evaluation of new Chinese medicinal resources to ensure the stable sources and sustainable use of Chinese medicinal resources. The key task division plan of the *Opinions* points out the need to strengthen the protection of rare and endangered wild medicinal plants and animals and support the research and development of substitutes for endangered Chinese medicinal materials.

3. Successful practices and experience in protecting Chinese medicinal resources

3.1. The fourth national survey of Chinese medicinal resources

To promote the protection, development, and rational use of Chinese medicinal resources, the National Administration of Traditional Chinese Medicine organized the national survey of Chinese medicinal resources and completed all the acceptance work in 2022. The fourth national survey of Chinese medicinal resources revealed the wealth of Chinese medicinal resources in China and identified 18,817 species, including 15,227 medicinal plants, 2611 medicinal animals, 153 medicinal minerals, 826 medicinal fungi, among which 464 medicinal germplasm accessions should be protected. At the same time, 28 seed and seedling breeding bases and 31 key species conservation nurseries for medicinal plants have been established, and researchers have broken the breeding bottlenecks of a batch of endangered medicinal materials. More than 3000 commonly used endangered, Dao-di, and new species of medicinal materials in various regions have been taken under protection. Chinese medicinal germplasm resource banks have been established in Sichuan, Hainan, and Daxing in Beijing for the preservation of normal seeds, recalcitrant seeds, genetic samples including DNA, and foreign medicinal germplasm, with more than 150,000 germplasm accessions being preserved.

3.2. Encouraging artificial cultivation of Chinese medicinal materials

The technological progress and the increasing demand have accelerated the artificial cultivation of medicinal materials for the replacement of wild medicinal materials. More than 300 commonly used Chinese medicinal materials in China have achieved artificial cultivation and farming.^[14] The farming technologies have been developed for a number of endangered animals including *Moschus*

berezovskii,^[15] *Cervus nippon*,^[16] and planting technologies have been developed for endangered plants, including *Paris polyphylla*,^[17] *Bletilla striata*,^[18] and *Dendrobium huoshanense*,^[19] which have promoted the sustainable use of endangered animals and plants. At present, artificial cultivation and farming have been realized in more than 50 species of endangered Chinese medicinal animals and plants, and more than 200 of 600 commonly used species of bulk Chinese medicinal materials have been cultivated or bred on a large scale.^[20] The fourth national survey of Chinese medicinal resources has summarized the information on more than 730 species of cultivated Chinese medicinal materials. The planting area of Chinese medicinal plants in China presents an increasing trend (Fig. 1). It reached the first peak of 87.96 million mu (1 mu \approx 667 m²) in 2020 and then slightly decreased. The planting area reached 89.599 5 million mu in 2022.

As of 2023, 71 species of medicinal animals have been artificially cultivated, accounting for 3.03% of the total species of existing medicinal animals. Among them, 18 (0.77%), 26 (1.11%), and 27 (1.15%) species have reached the primary (introduction and domestication), intermediate (introduction, farming, reproduction), and advanced (introduction, farming, reproduction, breeding) levels of artificial cultivation, respectively. The practices have been mature in the production of *Cervi Cornu Pantotrichum* from *C. nippon* and *Cervus elaphus*, the artificial cultivation of pearls, the artificial induction of bovine bezoar (*Bovis Calculus*), and the collection of musk (*Moschus*) from live musk deer.^[21] The large-scale artificial farming of medicinal animals has been realized for the animals with other use purposes, including the insect animals such as ground beetles and earthworms, edible animals such as donkeys, abalone, and cattle, and economic animals such as pearl mussels. Wild animal species that are only used for medicinal purposes are rarely farmed. Although China has established specialized breeding farms and research centers for medicinal animals, breakthroughs have not been achieved in most of the breeding technologies, which makes it challenging to attain large-scale intensive breeding. Nevertheless, as the farming and biosynthesis technologies keep advancing, artificially raised animals and artificial substitutes will be increasingly applied.

3.3. Supporting the research, development, and utilization of artificial substitutes to replace rare and endangered Chinese medicinal materials

To alleviate the shortage of medicinal resources, researchers in the TCM industry and enterprises have been committed to the research and development of alternatives for endangered animal-derived medicinal materials since the 1970s. Breakthrough progress has been

achieved in the replacement of rhinoceros horns with water buffalo horns, replacement of tiger bone with dog bone,^[21] and the research and development of artificially synthesized bear bile powder.^[22,23] Preclinical research has been accomplished for artificially synthesized antelope horns, and artificial musk,^[24] synthetic bovine bezoar, and artificial tiger bone^[25] have been approved for clinical use. By 2021, China has approved the use of 8 kinds of artificial medicinal materials: artificial borneol, artificial musk, synthetic bovine bezoar, *in vitro* cultured bovine bezoar, synthetic bovine bezoar, artificial tiger bone, artificial *Cordyceps sinensis*, and artificial tabasheer. The breakthroughs in the cultivation of medicinal animal and plant resources and the development of artificial substitutes have made significant contributions to the restoration of medicinal resources and the sustainable development of the environment. *The 14th Five-Year Plan for Scientific and Technological Innovation of Traditional Chinese Medicine* and other laws and regulations also propose the requirements of accelerating the development and application of substitutes for endangered Chinese medicinal materials and seeking for the substitutes with mature artificial cultivation techniques or abundant wild resources to reduce the consumption of wild resources.

4. Discussion

As an important component of traditional medicine and a treasure of Chinese traditional culture, TCM has made an indelible contribution to the prosperity of the nation. Before the era of industrial civilization, wild animals, plants, or minerals serve as the medical resources around the world, and thus the development and utilization of wild animal and plant resources complemented with the development of traditional medicine. With the development of Chinese medicine industry, the reserves of wild medicinal resources have sharply declined because of excessive mining, heavy exploitation over protection, and environment degradation. To protect wild animal resources and ensure the sustainable development of traditional medicine, the Chinese government has introduced multiple measures since the 1990s to strengthen the protection of wild medicinal animals and has made tremendous efforts in the protection, breeding, and sustainable use of Chinese medicinal resources, with rich experience being accumulated.

While some wild animal and plant resources in China have been the main raw materials as active ingredients for the production of Chinese patent medicines, such resources became scarce over time and their protection and utilization have attracted international attention.^[3] Thereafter they are listed as species with medicinal values in the appendix of CITES. When using them, China strictly abides by the provisions of the CITES. China firmly fulfills its obligations and actively carries out actions specified in the CITES and has supported the capacity building and research for protection of endangered wild animals and plants and research for over 10 consecutive years. China has collaborated with countries in Asia, Africa, and other regions to combat illegal trade in wild animals and plants, making great contributions to the global protection of endangered wild animals and plants and curbing of illegal trade. Significant breakthroughs in the research, development and utilization of artificial substitutes have been achieved, sustaining the significant contribution of TCM to global health while preserving the rare and endangered wild animal and plant resources.

Acknowledgments

None.

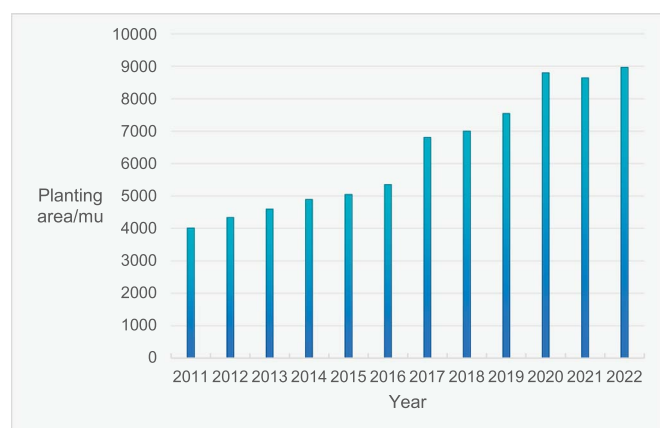


Figure 1. Planting area of Chinese medicinal plants in China during 2011–2022.

Statement of ethics

None.

Conflict of interest statement

No conflict of interest has been declared by the author.

Funding source

None.

Data availability statement

Data sharing not applicable to this article as no datasets were generated or analyzed during the current study.

Author contributions

None.

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How to cite this article: Protection and sustainable utilization of traditional medicinal biogenetic resources. *Sci Tradit Chin Med* 2024;2(1):1–4. doi: 10.1097/st9.0000000000000026