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Review

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Good Agriculture Practice (GAP) and Sustainable Resource Utilization of Chinese Materia Medica

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Abstract

The Good Agriculture Practice (GAP) program, being established in China, is an optimal way for the sustainable utilization of the medicinal plant and animal resources. Most frequently used Chinese materia medica will be mainly produced from the GAP bases in the future. To assure the successful operation of GAP program, standard operating procedure (SOP) should be implemented for specific plants or animals. Both GAP and SOP include the requirements in many aspects from the ecological environment of cultivation place, germplasm and varieties, seedling and transplant, fertilization, irrigation, and field care, to harvest and process, package, transport and storage. As a complex system, GAP demands strong commitment from the pharmaceutical industry, local administrative involvement, long-term R&D support, and years of time of development before a satisfactory result can be achieved.

Introduction

Chinese material medica enjoy an inherent and prominent role in the general health service. It presently accounts for an average of 40% of the total consumption of medicaments in China. The sustainable utilization of CMM resource will be able to guarantee the sustainable supply of the raw material; to preserve the biodiversity of CMM; and to maintain biosphere equilibrium and environmental integrity.

Used in China for thousands of years, traditional Chinese medicine (TCM) has strongly influenced the regional traditional medicine in Asia, such as Japan, Korea, and Singapore. Along with the process that China joins WTO, TCM became recognized by more and more people in the developed countries. An example is that acupuncture has become very popular in the United Kingdom, and other European countries, Australia, etc. CMM is exported to the international market at a high growth rate as TCM is being adopted by more and more people in the world. For instance, Korea imports a large quantity of CMM from China every year, and as a result, about half of the dry material medica in Seoul market came from China. Medicinal plant is the main source of Chinese materia medica (CMM). The wild resources of medicinal plants in China could hardly meet the demand of the market need in terms of quantity. Consequently the over-harvest of wild medicinal plants has been frequently observed, which will lead to the eventual loss of biodiversity of the wild resouces. Hence, Good Agricultural Practice (GAP) is the only way to solve this problem.

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The Medicinal Plant Resources in China

Around 11% of the world plant species can be found in China, including 240 peculiar genera. A national survey for 30 years indicated that China totally has 12,807 species of medicinal materials (Table 1) (Huang et al., 2002a, b). Among them, 11,146 species (9933 taxonomic species and 1,213 taxonomic units under species) are medicinal plants including 10687 species of seed plant, bryophyte, or pteridophyte and 459 species of alga, bacteria, fugi, or lichen (Table 2).

Due to the over-exploitation happening, the reserves and output of wild medicinal plant are decreased generally. For example, *Radix Glycyrrhiza uralensis* was originally produced in Inner Mongolia province, but its reserve and output has been decreasing very quickly. Recently, the total yield of *Radix Glycyrrhiza* reduced by 40% comparing with 1950s and the main harvest place of this plant changes to Xinjiang Province from Inner Mongolia province (Yuan et al., 2000). In case of *Radix Astragalus membranaceus* and *Radix Astragalus mongolicus*, the wild plant output was more than 2,000 tons in 1960s, however, the output decreased to less than 100 tons recently (Wang and Xiao, 2000). The other medicinal plant species whose reserve and output has decreased are listed as follows:

Acanthopanax senticosus;
Atractylodes lancea;
Anemarrhena asphodeloides;
Asarum sieboldii;
Cistanche salsa;
Cynomorium songaricum;
Dichroa febrifuga;
Ephedra sinica;
Gastrodia elata;
Gentiana macrophylla;
Gentiana scabra;
Glycyrrhiza uralensis;
Lithospermum erythrorhizon;
Notopterygium incisum;
Paris polyphylla;
Phellodendron amurense;
Pinellia ternate;
Rheum officinale;
Saposhnikovia divaricata;
Scutellaria baicalensis;
Stellaria gypsophiloides;
Tripterygium wilfordii;
Uncaria rhynchophylla;
Vitex trifolia;
Ziziphus jujuba.

In its narrow sense, to protect the medicinal plant resource means merely to maintain the enough medicinal materials; but in the broader and more accepted sense, it means to conserve the biodiversity. China is one of the countries that have rich bio diversity. Chinese biodiversity lists No. 8 in the world and No. 1 in the Northern Hemisphere. Meanwhile, China is also one of the countries whose biodiversity is threatened (Yuan et al., 2000; Zou, 2001). As shown in Table 3, around 1000 plant species in China are in imminent danger and around 200 species have become extinct. Thus, it is an extremely urgent work to protect the wild plant resources and we have to try our best to conduct this great project. We are happy to see that the Chinese government has recognized the serious situation and began to save the wild resources. Good Agriculture Practice (GAP) should be one of the best ways to protect the medicinal plant resource for sustainable development.

Table 1. The resource of Chinese material medica

Resource	Family	Genus	Species	Percentage (%)
Medicinal plant	383	2,309	11,146	87.03
Medicinal animal	395	862	1,581	12.34
Medicinal mine	-	-	80	0.63
Total			12,807	

Table 2. The medicinal plant resource in China

Resource	Family	Genus	Species
Alga	42	56	115
Bacteria and fugi	40	117	292
Lichen	9	15	52
Bryophyte	21	33	43
Pteridophyte	49	116	456
Seed plant	222	1,972	10,188
Total	382	2,309	11,146

Table 3. The higher plant species in imminent danger in China

Higher plant	Total species	Endangered species	Percentage (%) of endangered species
Bryophyte	2,200	28	1.3
Pteridophyte	2,600	80	3.1
Gymnogen	200	75	37.5
Angiosperm	25,000	826	3.3
Total	30,000	1009	3.4

The Good Agricultural Practice (GAP) in China

In order to accomplish the GMP (good manufacture practice) for Chinese traditional patent medicine, GLP (good laboratory practice) and GCP (good clinic practice) for new drug development from TCM, Chinese government is pushing forward the application of GAP in medicinal plant and animal cultivation. The concept of GAP was first put forward in TCM in 1998, and the GAP work began to be carried out since 2001 after several times of discussion during 1998-2000 organized by the State Administration of Traditional Chinese Medicine of China (SATCM), State Drug Administration of China (SDA), and China National Group Corp. of Traditional & Herbal Medicine (Qin et al., 2001; Zhou, 2001). As summarized in table 4, the application of GAP including the request about the environment and soil in the cultivation place, the germplasm and breeding, the cultivation and process, the transport and storage, the quality control and check, as well as the document management. The key part of GAP is the standard cultivation and quality control.

To make the GAP principles is the task of government, however, how to carry it out is the work of TCM companies. To guarantee the application of GAP principles to different medicinal materials, SOP (standard operating procedure) should be made by different TCM companies for peculiar medicinal plants or animals that they are using as drug material resources. Usually SOP includes the following procedures (Zhang and Lin, 2001a, b; Zhang et al., 2001; Zhou, 2001):

(1) To decide the cultivation place:
   a. The reason why you choose the place;
   b. The ecological environment and soil conditions of the cultivation place.

(2) The SOP about germplasm
   a. The genetic study of germplasm;
   b. The procedure of seed collection, the seed breed and the standard of seed quality.

(3) The SOP about seedling and transplant
   a. The preparation of the cultivation field;
   b. The procedure of seedling;
   c. The procedure of tranlsplant.

(4) The SOP about fertilization, irrigation, and field care
   a. The procedure about the fertilizer used and the time of fertilizing;
   b. The procedure about irrigation;
   c. The procedure about field care such as inter-cultivation, controlling of weeds, etc.;
   d. The procedure about controlling the insect pest and plant diseases, and the utilization of agricultural

Table 4. The main GAP principles for the cultivation of medicinal plant and animal

Chapters	Items	The main contents
Chap 1	General principles	Purpose and significance
Chap 2	The environment of the cultivation area	The detail request for the ecological environment such as air, water, and soil conditions in the cultivation area
Chap 3	The germplasm and breed material	The plant or animal species should be identified correctly and the quality of the germaplasm resource should be controlled.
Chap 4	The management of cultivation	The cultivation process, such as how to use fertilzer, soil, water and how to control the insect pest and plant diseases, should be controlled by SOP (standard operating procedure) principles.
Chap 5	The harvest and process at the harvest place	The optimal harvest time should be studied and fixed. The specific request for process, drying conditions, etc. is clearly written in this chapter.
Chap 6	Package, transport and storage	It should be clearly recorded for each batch of the drug materials. The request for the transport, such as using clean container, for the storage, such as light, temperature, and humidity, is clearly provided in this chapter.
Chap 7	Quality control	The specific request for quality control, such as the items to be checked, the request for the characteristic, foreign matter, water, and ash content, is clearly provided in this chapter.
Chap 8	The equipment and operator	This chapter provides the request for the trained operators, the request about the product and process place, and equipment.
Chap 9	The document management	It should be recorded in every detail and particular for the whole process of cultivation, process, transport and storage, etc. The document should be kept properly at least 5 years.
Chap 10	Supplement	Supplementary explanation

chemicals.

(5) The SOP about harvest and process
   a. The procedure of harvest including the harvest time and harvest methods;
   b. The procedure about the process of drug materials;
   c. The procedure of drying the drug materials.

(6) The SOP about package, transport and storage
   a. The procedure of package including the packing method and packing materials;
   b. The procedure of transport;
   c. The procedure of storage including storage equipment, storage conditions, against insects, mould, color changing, and the loss of volatile active substances.

Around 600 GAP cultivation bases have been established in the whole country and the total cultivation area of medicinal plants has been achieve to 6 million *mu* (Liu et al., 2001; Shang and Zhu, 2000; Wang et al., 2001; Wang et al., 2002). Table 5 listed some GAP cultivation bases in China. To establish a GAP cultivation base, usually a research institute, a TCM company and a culti vation base are the three important and indispensable participators. There are three kinds of GAP models in China. One is the model leading by the TCM companies, *e. g.*, the cultivation base of *Scutellaria baicalensis* in Hebei province and the cultivation base of *Salvia miltiorrhiza* in Shanxii province; One is the model lead ing by the research institutes, e. g., the cultivation base of *Crocus sativus* in Shanghai and the cultivation base of Chrysanthemum morifolium in Jiangsu province; One is the model leading by the cultivation base which is usually managed by the local government, *e. g.*, the cultivation base of *Ginkgo biloba* in Guangxi province and the cultivation base of *Lycium chinensis* in Ningxia province. The GAP cultivation base for each drug material is usually built in its genuine production place.

Table 5. Some GAP bases of Chinese materia medica in China

GAP bases	The cultivated medicinal plants
Anhui province	*Paeonia suffruticosa*
Chongqing	*Pinellia ternata*
Gansu province	*Angelica sinensis*
Guangxi province	*Momordica grosvenorii*
GuiZhou province	*Dendrobium candidum; Eucommia ulmoides; Ginkgo biloba*
Hebei province	*Angelica dahurica; Scutellaria baicalensis*
Heilongjiang province	*Panax ginseng*
Henan province	*Rehmannia glutinosa*
Hubei province	*Lespedeza cyrtobotrya*
Hunan province	*Eucommia ulmoides*
Inner Mongolia	*Glycyrrhiza uralensis*
Jiangsu province	*Chrysanthemum morifolium*
Jiling province	*Panax ginseng; Panax quinquefolium*
Liaoning province	*Panax ginseng*
Ningxia province	*Lycium chinensis*
Shandong province	*Lonicera japonica*
Shanghai	*Crocus sativus*
Shanxii province	*Salvia miltiorrhiza*
Sichuan province	*Crocus sativus; Ligusticum chuanxiong*
Tibet province	*Rhodiola rosea*
Yunnan province	*Dracaena draco; Panax notoginseng*

Conclusion and Prospects

GAP is of fundamental importance for the modernization of TCM. Without the GAP to be carrying out perfectly, GMP, GLP, GCP will be the "water without a source, a tree without roots". The GAP project is being carried out in China, it is an optimal way for the sustainable utilization of the medicinal plant and animal resources. We believe that the main Chinese materia medica will be mainly produced from the GAP bases in future. To assure the GAP to be carried out successfully, SOP should be laid down for different peculiar plants or animals. Both GAP principles and SOP procedures usually include the requirements for the ecological environment of cultivation place, germplasm and varieties, seedling and transplant, fertilization, irrigation, and field care, harvest and process, package, transport and storage.

GAP is a complex system, we still have a long way to go before achieving to the final target. To choose the medicinal plant varieties is the first step and the genuine varieties should be cultivated. The study on medicinal plant breeding is a very weak link that needs more scientists to join and the biotechnology will be applied in this study. In China, we have bred lost of crop varieties but very rare medicinal plant varieties.

The GAP models still need to be perfected. In case of the model leaded by the TCM company, the drug materials will be the unsalable goods if the drug product can not sell very well or is changed in the company. So, an adjustment system should be built among different GAP base and perhaps a GAP association is indispensable. For some provinces, such as Sichuan, Yunnan, and Northeast part of China, which are very rich in drug material resources, they should make their own GAP companies that will not only produce and provide the drug materials, but also produce some prepared Chinese medicine and drug material extracts.

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