Journal of Food and Drug Analysis, Vol. 15, No. 4, 2007, Pages 337-346 藥物食品分析 第十五卷 第四期

Quality Assurance of Chinese Herbal Medicines (CHMs)

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ABSTRACT

As more and more people worldwide are using Chinese Herbal Medicines (CHMs), the safety of their use has raised international concern. Authentication and standardization of CHMs are needed. Authentication of a CHM includes both identifying its botanical origin and evaluating its pharmaceutical quality. In this paper, the important parameters for quality assurance are discussed. Quality control methods such as the examination of taxonomic, morphological and/or microscopic characters, fingerprint chromatography, DNA molecular marker are described and compared. Some topics related to herbal quality control such as contamination, processing as well as the new method MALDI-TOFMS are also introduced. Finally, modernization of Chinese medicine information was brought up.

Key words: Chinese Herbal Medicines (CHMs), authentication, standardization, quality assurance, fingerprint chromatography, DNA molecular marker, MALDI-TOFMS

INTRODUCTION

As an increasing number of people worldwide are using Chinese Herbal Medicines (CHMs), which are often used in health food and dietary supplements, the safety of their use has raised international concern[(1-3)]. Authentication and standardization of CHMs are needed. CHMs differ from both chemical drugs and Western herbs. The multiple sources and unique processing methods are characteristic features of CHMs. While these features give CHMs unique and advantageous properties, they also generate confusion.

Investigation of the current market of CHMs reveals that the reasons for the various types of confusion that occur with regard to CHMs are due to: multiple sources for the herbs, use of regional custom-herbs, confusion in nomenclature, similarity in appearance, and versatility as well as complexity of processing procedures. Counterfeits and CHMs of poor quality degrade the clinical effects of CHMs and may even result in death of patients. Thus, authentication is a critical step for successful and reliable clinical applications and for further experimental studies on CHMs. The therapeutic effect of any CHMs is correlated with its taxonomic authenticity and with its pharmaceutical (biochemical) quality. Authentication of a CHM includes both identifying its botanical origin and evaluating its pharmaceutical quality.

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I. *Important Parameters for Quality Assurance*

According to the *Chinese Pharmacopoeia* (2005 edition) and the "Hong Kong Standard of Chinese Medicines"[(4,5)], certain specific parameters are considered to be generally and commonly important for the assurance of quality in any CHM. The specifications laid down under each parameter will collectively ensure that the CHM:

(I) comes from the correct source, including the designated taxonomic classification, the designated part of the parent plant or animal, etc;
(II) is of the correct physical state, e.g. adequately dried and suitably processed after harvest;
(III) is free from undesirable contaminations and other abnormalities; and
(IV) is suitably verified to contain the necessary ingredients for the realization of efficacy.

II. *Review of Quality Control Methods*

In general, the authentication methods of CHMs are: taxonomy, morphology, microscopy, fingerprint chromatography, and DNA molecular marker technology (used occasionally)[(6)].

(I) *Taxonomic Method*

The botanical origin of a CHM is identified and its scientific Latin binomial (i.e., genus species) is deter-

mined based on this method. It is the first step for CHM authentication[7,8].

(II) *Morphological Method*

Morphological features or characteristics of a CHM are observed, described and quantified as appropriate. They include external characteristics of plant (or animal) parts, such as size, shape, color, texture, smell and taste, as well as internal characteristics (as of the cross-section of plant stems)[9,10].

(III) *Microscopic Method*

Microscopy is used to determine the structural, cellular and internal tissue features of a CHM. It is usually used to identify and differentiate one CHM from other when herbal materials are similar[11-20].

(IV) *Chromatographic Fingerprinting*

This method is generally used for quality assessment as it can provide more precise data of a CHM, both qualitative and quantitative. Thin Layer Chromatography (TLC) and High Performance Liquid Chromatography (HPLC) are the most commonly used techniques. Chromatograms of specific components in CHMs may have unique and characteristic peak patterns that can be used to confirm their presence in samples[5,21-23].

(V) *DNA Molecular Marker*

This method uses tiny amount of sample to perform DNA analysis. It provides specific and accurate data with regard to various plant species. This technique is not used frequently, it is more suitable for extremely valuable and rare CHMs, and is especially useful to distinguish closely related CHMs[24-32].

Aspects of the five commonly used authentication methods, comparing their advantages and limitations, are summarized in Table 1.

Controlling the parameters of quality assurance as a whole will give sufficient assurance that the medicine is of the right quality for safe and efficacious use. The details of each quality assurance parameter are explained below:

(I) *Name/Nomenclature*

Many incidents of confusion and misuse of CHMs are due to the use of different names for the same medicine or the overlapping use of the same name for different medicines. Some cases of poisoning have been reported because of such confusion.

Fangji is a typical example of a CHM with confused nomenclature that has resulted in poisoning. Radix Aristolochiae Fangchi (*Guangfangji*, which contains the toxic substance aristolochic acid) had been mistakenly used as Radix Stephaniae Tetrandrae (*Fangji*) in a slimming drug in Europe[3]. Another similar case concerning the CHM *Baimaoteng*, where Herba Aristolochiae Mollissimae was mistaken as Herba Solani Lyrati, has occurred in Hong Kong. These CHMs share the same Chinese name *Baimaoteng*[33].

Since much confusion is caused by CHMs having similar names, the *Easily Confused Chinese Medicines in Hong Kong* (Chinese and English versions) was published in 2005 and 2007, respectively, to investigate the situation[34,35]. It focuses on the macroscopic characteristics of 90 pairs of CHMs, and thereby clarifies confusion and sets up standards for the naming system.

(II) *Source*

Dao refers to the administrative division of district

Table 1. Comparison of different authentication methods

Methods	Advantages	Limitations
Original plant authentication[7,8]	Specimen can serve as a voucher for research; fundamental for pharmacognosy	Requires long-time accumulated experience Needs a specimen corresponding to its crude CHM
Macroscopic authentication[9,10]	Quick, convenient; a common method	Needs a specimen corresponding to its original plant
Microscopic authentication[11-20]	Quick, convenient; a common method	Requires accumulated experience; lacks quantitative measurement Needs a corresponding microscopic structure standard and histochemical information from the original plant and crude CHM
Fingerprint chromatography (TLC, HPLC)[5,21-23]	Convenient, subjective	Low specificity A reference standard must be present
DNA molecular marker authentication[24-32]	High specificity, small sample size; can distinguish species within the same genus; suitable for some valuable samples	Complicated operation; high cost; not stable enough; not suitable for dried crude CMM and patent CHMs Varies with different CHMs; need to explore new methods

in the Tang Dynasty of China, which is equivalent to a region superordinate to the province, and *Di* refers to origin of production. In history, a great deal of attention was paid to the origin of production. It is because different geographic environments would have certain impact on the quality of CHMs. The term *Daodi* was first recorded in *Bencao Pinhui Jingyao* in 1505. But now, it is a special term that used to describe the best quality supply of CHMs.

The over-harvest of wild medicinal plants threatens the survival of the species and might eventually lead to loss of biodiversity of the wild resources. To reduce, if not prevent, the over-exploitation of wild medicinal plants, cultivation of these wild species has begun with the establishment of Good Agricultural Practice (GAP) farms in China. Many GAP farms, and facilities like them, are needed to solve this problem. As a result, the supply of CHMs has shifted from wild to mainly cultivation-oriented.

During the process of authentication, it is essential to keep voucher specimens of the CHMs for later reference or study, as required by some of the international journals. For this purpose, the HKBU Bank of China (HK) Chinese Medicines Centre located at Hong Kong Baptist University has served as a reference center as it contains a collection of authenticated voucher specimens of source plants[36].

(III) *Description*

Description refers to qualitative and quantitative description of the gross morphology of the CHM. It is the oldest and still most commonly used technique; it is generally the first step in any identification. Standards of description can be found in the *Chinese Pharmacopoeia*. In addition, some monographs have been published with photographs and detailed descriptions for readers' convenience in recent years such as *An Illustrated Chinese Materia Medica in Hong Kong* (Chinese & English versions) published in 2004[37,38]. It is a comprehensive reference book with illustrations of 506 commonly used CHMs.

(IV) *Microscopic Identification*

Microscopic identification is another commonly used technique, which is convenient and quick, and can be applied to prescriptions (i.e., mixtures of herbs) and Chinese proprietary medicines. Microscopic characters are widely included in modern herbal pharmacopoeia, e.g., the *Chinese Pharmacopoeia, British Pharmacopoeia, United States Pharmacopoeia, Japanese Pharmacopoeia, Korean Pharmacopoeia, Indian Pharmacopoeia, etc.*[4,39-44]. A recent monograph published in 2005, *An Illustrated Microscopic Identification of Chinese Materia Medica,* uses microscopic characteristics to describe 126 commonly used CHMs[45].

(V) *Physical and Chemical Identification*

There are two current concerns about physical and chemical identification: heavy metals/pesticide residues and content of active components.

Since heavy metals or pesticide residues are often found in CHMs samples during the process of production, acceptable levels are set up to assure quality of CHMs.

Table 2. Comparison of permitted pesticide levels of CHMs in different countries/regions

No.	Substance	Hong Kong, China (HKCMMS)[5]	Mainland[b], China (CP, 2005)[4]	USA (NSF/ ANSI173-2006)[46]	Europe[b] (EP 5.0)[47]	Japan[b] (JP)[42]	Korea (KFDA/ 2005-624-197)[4]
1	Hexachlorocyclohexane (α,β,δ)	0.30[a]	0.20	0.01	0.30	0.20	0.01
2	Alachlor				0.02		
3	Aldrin	0.05		0.01	0.05		0.01
4	Dieldrin	0.05		0.01	0.05		0.01
5	Azinphos-methyl				1.00		
6	Bromopropylate				3.00		
7	Captan						2.00
8	Chinomethionat						0.30
9	Chlordane (sum of cis-, trans- and oxychlordane)	0.05		0.01	0.05		
10	Chlorfenvinphos				0.50		
11	Chlorpyrifos				0.20		0.10
12	Chlorpyrifos-methyl				0.10		
13	Cypermethrin (and isomers)				1.00		0.05

Table 2. continued

No.	Substance	Hong Kong, China (HKCMMS)[5]	Mainland[b], China (CP, 2005)[4]	USA (NSF/ ANSI173-2006)[46]	Europe[b] (EP 5.0)[47]	Japan[b] (JP)[42]	Korea (KFDA/ 2005-624-197)[4]
14	DDT (sum of p,p'-DDT, o,p'-DDT, p,p'-DDE and p,p'-TDE)	1.00	0.20		1.00	0.02	0.01
15	Deltamethrin				0.50		
16	Diazinon				0.50		
17	Dichlorvos				1.00		
18	Difenoconazole			0.01			
19	Dithiocarbamates (as CS2)				2.00		
20	Endosulfan (sum of isomers and Endosulfan sulphate)				3.00		0.02
21	Endrin	0.05			0.05		0.01
22	Ethion				2.00		
23	Fenitrothion				0.50		
24	Fenvalerate				1.50		
25	Fonofos				0.05		
26	Heptachlor (sum of heptachlor and heptachlor epoxide)	0.05			0.05		
27	Hexachlorobenzene	0.10		0.01	0.10		
28	Lindane (γ-Hexachlorocyclohexane)	0.60		0.01	0.60		
29	Malathion				1.00		
30	Methidathion				0.20		
31	Methoxychlor						1.00
32	Parathion				0.50		
33	Parathion-methyl				0.20		
34	Pentachloroaniline			0.01			
35	Pentachlorobenzene			0.01			
36	Pentachlorothioanisole			0.01			
37	Permethrin				1.00		
38	Phosalone				0.10		
39	Piperonyl butoxide				3.00		
40	Pirimiphos-methyl				4.00		
41	Procymidone						0.10
42	Pyrethrins (sum of)				3.00		
43	Quintozene	1.00	0.10	0.01	1.00		0.10
44	Technazene			0.01			
45	Tetrachloroaniline			0.01			
46	Tolylfluanid						1.00

[a]Units: ppm.
[b]CP: Chinese Pharmacopoeia; EP: European Pharmacopoeia; JP: Japanese Pharmacopoeia.

However, the standards for heavy metals and pesticide residues vary in different countries, some are determined according to dietary standards. Tables 2 and 3 compare the different permitted levels of pesticides and heavy metals in CHMs in China and other countries[4,5,42,46-50]. Therefore, analysis methods should be harmonized, and

Journal of Food and Drug Analysis, Vol. 15, No. 4, 2007

Table 3. Comparison of permitted heavy metal levels of CHMs in different countries/regions

No.	Substance[b]	Hong Kong, China (HKCMMS)[5]	Mainland, China (CP, 2005)[4]	USA (NSF/ANSI173-2006)[46]	WHO (2005)[49]	BP[c][39]	Korea (KFDA/2005-62)[48]
1	As	2.0[a]	2.0	5.0		5.0	5.0
2	Cd	0.3	0.3	0.3	0.3		0.3
3	Pb	5.0	5.0	10.0	10.0	5.0	3.0
4	Hg	0.2	0.2	0.2			0.2
5	Cu		20.0				
6	Cr			2.0			

[a]Units: ppm.
[b]As: Arsenic; Cd: Cadmium; Pb: Lead; Hg: Mercury; Cu: Copper; Cr: Chromium.
[c]BP: British Pharmacopoeia; CP; Chinese Pharmacopoeia.

Table 4. Limits of heavy metals and arsenic by colorimetric method in Japanese Pharmacopoeia

No.	Crude drugs	Heavy metals[a]	Arsenic[b]
		(ppm, as Pb)	(ppm)
1	Achyranthes Root	10	5
2	Alisma Rhizome	20	5
3	Astragalus Root	10	5
4	Atractylodes Lancea Rhizome	10	5
5	Bupleurum Root	10	5
6	Ginger	10	5
7	Ginseng	15	2
8	Glycyrrhiza Root	10	5
9	Gypsum	20	5
10	Japanese Angelica Root	10	5
11	Longgu	20	10
12	Moutan Bark	10	5
13	Ophiopogon Tuber	10	5
14	Peony Root	10	5
15	Pinellia Tuber	10	5
16	Platycodon Root	10	5
17	Poria Sclerotium	10	5
18	Pueraria Root	10	5
19	Red Ginseng	15	2
20	Rehmannia Root	10	5
21	Rhubarb	10	5
22	Scutellaria Root	10	5
23	Trichosanthes Root	10	5

[a]Quantity is expressed in terms of the quantity of lead (Pb).
[a,b]The test is performed by comparison of color between test solutions and control solutions.

limitation level ought to be referred to the import/export country's contemporary standards.

The permitted heavy metal levels of CHMs in Japan are shown in Table 4. They are separately listed because the *Japanese Pharmacopoeia* has different standards for different CHMs[42]. For example, Ginseng has a stricter limitation, and the standards for mineral drugs such as Gypsum and Longgu are undemanding.

Content of active components refers to the concentration of specific active ingredients or marker compounds in a CHM. Such compounds are usually analyzed by methods such as Thin Layer Chromatography (TLC) and High Performance Liquid Chromatography (HPLC).

Marker compounds, however, do not necessarily represent the active ingredients. To assess the quality of Chinese medicine, TLC is also applied to authenticate main ingredients. For example, when identifying Radix Ginseng, its marker compounds, ginsenosides Rb, Re, Rf and Rg_1, are determined and measured. But when assessing its pharmaceutical quality, the content of one of the active or standard ingredients is used for determination. The following table gives examples of content standards for some commonly used CHMs:

In the past, there is no doubt that using the "single ingredient" quality control method was helpful in quality assurance. However, after a great deal of practice, this method has shown its faults. For example, relative content of the marker compounds, ginsenosides Rb_1 and Rg_1 are not correlate with the functionality of Radix Ginseng, Radix Notogingseng or Radix Panacis Quinquefolii; indeed, the contents of these markers are often inversely proportional to a sample's clinical potency. Another example is that the marker compound ginsenoside content in ginseng stem and leaf may be as many as nine times higher than that in the root, but it does not mean that the clinical functions of stem and leaf are better than the root. Another case is Fructus crataegi (*Crataegus pinnatifida* var. *major* or *C. pinnatifida*) and Fructus Corni. Ursolic acid, which is commonly present in most plants, is used as an index when authenticating these drugs by applying the single ingredient method,

Table 5. Standard levels of marker compounds in some commonly used CHMs

Commonly used CHMs	Marker compound levels (based on dried samples)
Radix Ginseng	Ginsenoside Rg_1 and Ginsenoside Re ≥ 0.30%; Ginsenoside Rb ≥ 0.20%
Radix Notogingseng	Ginsenoside Rg_1, Ginsenoside Rb_1 and Notoginsenoside R_1 ≥ 5.0%
Radix et Rhizoma Rhei	Aloe-emodin, Rhein, Emodin, Chrysophanol, and Physion ≥ 1.5 %
Rhizoma Gastrodiae	Gastrodin ≥ 0.20%
Fructus Schisandrae Chinensis	Schisandrin ≥ 0.40%
Rhizoma Cimicifugae	Ferulic acid ≥ 0.10%
Radix Salviae Miltiorrhizae	TanshinoneIIA ≥ 0.20%; Salvianolic acid ≥ 3.0%
Radix Glycyrrhizae	Glycyrrhizic acid ≥ 2.0%; Liquiritin ≥ 1.0%
Radix Gentianae	Gentiopicroside ≥ 1.0%
Rhizoma Scrophulariae	Harpagoside ≥ 0.050%
Radix Rehmanniae	Catalpol ≥ 0.20%
Radix Angelicae Sinensis	Ferulic acid ≥ 0.050%
Rhizoma Corydalis	dl-Tetrahydropalmatine ≥ 0.050%
Radix Polygalae	Polygalacic acid ≥ 0.70%
Radix Paeoniae Rubra	Paeoniforin ≥1.8%
Cortex Eucommiae	Pinoresinol diglucoside ≥ 0.10%
Cortex Moutan	Paeonol ≥ 1.2%
Radix Sophorae Flavescentis	Matrine, Oxy-matrine ≥ 1.2 %
Rhizoma Anemarrhenae	Sarsa-sapogenin ≥ 1.0%
Flos Lonicerae Japonicae	Chlorogenic acid ≥ 1.5%; galuteolin ≥ 0.10%
Fructus Gardeniae	Geniposide ≥ 1.8%
Radix Scutellariae	Baicalin ≥ 9.0%
Radix Astragali	Astragaloside I ≥ 0.040%
Rhizoma Coptidis	Berberine (based on berberine hydrochloride) ≥ 3.6%
Radix Puerariae Lobatae	Puerarin ≥ 2.4%

but the functions and indications of these two drugs are totally different. Therefore, researchers are enthusiastic about finding a chromatographic method that can exclusively indicate the quality of a CHM. It is better to observe the ingredient from "a point" to "a surface" in order to fully indicate the genuineness and quality of the CHM from an objective point of view. One of the representative publications is Chromatographic Fingerprints of Traditional Chinese Medicine Identification (Beijing, People's Health Publishing House, 2005)[23]. Studies of chromatograms obtained from raw material and formulas of *Ginkgo biloba*, *Panax ginseng*, *P. notoginseng*, *Salvia miltiorrhiza*, *Paeonia lactiflora*, and *Pueraria lobata* are mentioned in this book.

The fingerprinting technique (HPLC, TLC) is no doubt an effective way for CHM identification. But, it cannot be denied that this method has its flaws and is still under development. For example, marker is necessary when using this technique, plus it is not applicable in proprietary Chinese medicine because the results vary different in each case. Technical improvement should be made in order to overcome such inadequacy.

The identification and authentication methods mentioned above are steps that are needed in quality assurance. They are summarized as a protocol in the below flow chart, Figure 1.

SOME RELATED ISSUES

I. *Contamination*

Contamination either by the direct use of pesticides or by CHM transfer procedures are measured. Contamination of heavy metals, especially lead (Pb) is also tested. Pb is mainly contained in the soil, and can be gradually absorbed by CHMs. The absorbing process may be accelerated by the use of fertilizers which increase the acidity of the soil. In addition, other heavy metals such as cadmium, copper, and arsenic are determined.

Additionally, concerns have arisen on the issue of sulfur residue in CHMs. Traditionally used for killing insects, sulfur is now often used to sharpen the colors of CHMs for commercial purposes. The acceptable levels of pesticides and heavy metals, as listed in Table 2 and Table 3, are mainly based on the current dietary

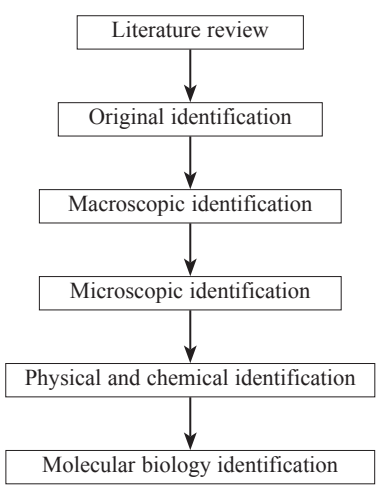

Figure 1. Quality assurance protocol.

standards; thus, specific standards should be set up for CHMs.

Since the levels of contaminants such as arsenic, mercury, cadmium and lead are relatively low in alcohol/water extracted samples, we suggest that different limitations should be applied in two categories: direct oral administration and alcohol/water extract. The *European Pharmacopoeia* can be used as a reference[46]. Under the microbiological experiment section, it has a stricter standard for direct oral administration CHMs; whereas for hot water extracts, it uses a lower standard because hot water can kill some of the micro-organisms.

II. *Processing*

Processing of CHMs is a unique characteristic of Chinese medicine. Processing is primarily used to make the crude drugs into decoction pieces, so as to comply with the requirements of practitioner's prescription, of efficient dispensing and proper decoction and assure the safety and efficacy of the CHMs. Such procedures include cleaning, cutting and stir-baking (roasting).

CHM processing is closely related to the safety and effective use of CHM in clinical application. In recent years, some adverse side effects and toxicities have been found relating to the processing procedures. For example, the poisoning incidents by Radix Aconiti (*Fuzi*) in the past 30 years were 4,755 cases[50]. In 2007, the fact that there was a meeting on "Standardization of Traditional Processing Methodology of Herbal Materials for GMP guideline" (Forum Herbal Harmonization) held by World Health Organization (WHO) in Korea[51], demonstrated in high level of concern there is on this topic throughout Asia. Up to now, standards related to the processing procedures have not been established. It is necessary and urgent to make up the standardization and harmonization of CHM processing.

It is suggested that processing of CHM should be performed in three phases: (I) ancient literature review and market investigation, (II) laboratory experiments, and (III) Good Manufacture Practice (GMP). Phase I studies historical literature record of processing and investigates the processing situation in current market. Phase II mainly focuses on chemical, toxicological and pharmacological experiments of different processed forms. Finally, phase III sets up guidelines for manufacturing standards of GMP and also carries out marketing management on processed CHMs.

The term GMP in some countries is also named as cGMP which means current good manufacture practice. GMP emphasizes all aspects of production, such as facilities, equipment, design and production documentations. Manufacturing of the herbal medicinal products needs to be governed under the GMP. It is also important to setup standardization for additives procedure during processing.

Apart from toxicity that is caused by either heavy metals/contaminants or processing method, it is important to examine possible genetic and carcinogenic effects of CHMs.

III. *A New Authentication Method for Quality Control of Chinese Medicine*

Since there are limitations for each of the current authentication methods, it is necessary to develop a more reliable authentication method. Matrix-assisted laser desorption/ionization-time of flight mass spectrometry (MALDI-TOFMS) is a new method, recently developed and now being applied for direct analysis of small molecular weight pharmaceutical compounds in tissues and plant materials[52-54]. The profiles of the CHM can be obtained without sample extraction and purification. Information such as local molecular composition, relative abundance, and spatial distribution can be found directly from thin tissue sections.

This method allows direct analysis of CHM samples. It avoids damage of components during traditional extraction and purification procedures; and is suitable for study of the differences between the crude and processed CHMs because the toxic components, which may be changed during processing, can be studied both before and after. Thus, it can be applied for toxicological study of original herbs.

IV. *Modernization of Chinese Medicine Information*

Another key problem in quality control of Chinese medicine is the lack of information exchange among countries. Modernization of Chinese medicine information is a very essential step in bringing Chinese medicine to the standardized and international level. In order to address this situation, in 2003, the Hong Kong Jockey Club Institute of Chinese Medicine (HKJCICM), through the Hong Kong Baptist University, began working on the publication of *Encyclopedia on Contemporary Medicinal Plants* (in Traditional and Simplified Chinese, and English version) as part of initiatives to advance the development of Chinese medicine[55].

In 2006, the traditional Chinese version of the Encyclopedia was published and is now circulating in Hong Kong, Taiwan, and Macau. The simplified Chinese version is expected to be published and launched by the end of 2007, and the English version is expected to be published in 2008. In the near future, the electronic version and the web-based version of the Encyclopedia is expected to be prepared by HKJCICM for online subscriptions.

This monograph, comprising four volumes, is the first authoritative, comprehensive and practical encyclopedia on contemporary medicinal plants worldwide, recording the most recent research achievements and findings. It covers about 800 natural medicinal plants that (I) are available in Hong Kong and well known in the international market; (II) have clinical value; (III) have been documented with detailed and accurate scientific data; and (IV) have pros-

pects for further application and development.

The Encyclopaedia has consolidated in a systematic way of numerous useful and updated references, photos, chemical structures, pharmacological uses, clinical applications, and expert comments on medicinal plants from around the world, making it an excellent reference for readers who are either interested or involved in research and development, clinical, education, production, quality control and testing, trading and sales and marketing of herbal, natural or botanical medicines or supplements.

CONCLUSIONS

As Chinese medicines are being increasingly used worldwide, their safe use has become an internationally critical issue. Authentication is fundamental for standardization, and standardization is critical for quality control. Therefore, efforts are needed to authenticate and standardize CHMs in order to ensure their safe and effective use. As an international trading centre for CHM, Hong Kong is the logical place to initiate authentication and quality control. Maintaining the quality of a CHM within a specified level is the basis for ensuring that the medicine is as safe and efficacious as it is expected.

ACKNOWLEDGEMENTS

The authors thank Prof. Yuan-Shiun Chang, Dr. Zhi-Tao Liang, Mr. Takeda Osami, and Shenzhen Tsumura Medicine Co. Ltd. for their support and assistance in this project.

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