Hong Kong Chinese Materia Medica Standards



Department of Health Hong Kong Special Administrative Region The People's Republic of China





PREFACE

Since ancient times when Shen-nong tasted hundreds of herbs to test their medicinal value, Chinese medicine has become a treasure of mankind. With the rapid development of technology, we must, building upon our foundation, face up to the challenges of developing Chinese medicine and demonstrating its potential in health care.

The Government of the Hong Kong Special Administrative Region (HKSAR) formulated the policy for the development of Chinese medicine and enacted the Chinese Medicine Ordinance in July 1999. Since the implementation of the Chinese Medicine Ordinance, Hong Kong has made significant progress in developing Chinese medicine in the areas of regulatory control, education, scientific research and health care.

Chinese medicine has been widely accepted by the Hong Kong community and there is an increasing use of Chinese Materia Medica (CMM) and proprietary Chinese medicines. As CMM are the raw materials for proprietary Chinese medicines, a well-established standard for CMM with international recognition will ensure the safe use of CMM and enhance the quality of proprietary Chinese medicine. It is also the cornerstone of scientific research in Chinese medicine.

In 2001, the Department of Health set up the Hong Kong Chinese Materia Medica (HKCMM) Standards Office under its Chinese Medicine Division to co-ordinate the development of standards for CMM commonly used in Hong Kong. An International Advisory Board (IAB) was established in early 2002 to advise on the principles, methodologies, parameters and analytical methods for the "HKCMM Standards". The IAB is responsible for setting out the contents of the "HKCMM Standards", selecting the CMM and the research institutions to conduct research and laboratory work, as well as evaluating and endorsing the research results. In addition, a Scientific Committee, consisting of visiting IAB members, and representatives of the participating universities and Government departments, was set up to monitor the progress of the research work. The Committee is also tasked to resolve various technical issues encountered in the process and examine the research results.

"HKCMM Standards" Project covers 60 CMM commonly used in the local community and the project is divided into three phases. The standards for 8 CMM covered in phase I were published in "HKCMM Standards Volume 1" in July 2005. Since its publication, the trade has been encouraged to adopt the "HKCMM Standards". In phase II, The University of Hong Kong, The Chinese University of Hong Kong, The Hong Kong University of Science and Technology and Hong Kong Baptist University have already completed the development of standards for 24 CMM. Interlaboratory verification studies have also been conducted by the Government Laboratory of the HKSAR. The findings are now compiled as "HKCMM Standards Volume 2". The research work for phase III is underway.

i



On the development of the "HKCMM Standards", the State Food and Drug Administration and the local universities have rendered assistance in collecting authentic CMM samples from both the Mainland and local market. With the aim of safeguarding the authenticity, safety and quality of CMM, the content of "HKCMM Standards" includes the name, source, description, identification, test, extractive and assay of the CMM.

The "HKCMM Standards" adopts various approaches including macroscopic and microscopic examinations, physicochemical identification and thin-layer chromatography to authenticate the CMM. To enhance user-friendliness of the "HKCMM Standards", the results of macroscopic and microscopic examinations are illustrated with photographs. In phase II, high-performance liquid chromatographic (HPLC) fingerprinting is also established to identify different markers in the CMM for more precise authentication.

On the safety of CMM, the "HKCMM Standards" contains recommended limits for monitoring heavy metals, pesticide residues and mycotoxins (aflatoxins) in the herbs. Specific requirements have also been set for certain CMM covered in phase II to ensure their safety. For example, aristolochic acid I should not be detected in Caulis Clematidis Armandii in order to prevent adulteration with prohibited plant called Caulis Aristolochiae Manshuriensis.

On the quality of CMM, the limits of foreign matter, ash, water content, extractives and assay of CMM are also included in the "HKCMM Standards". Of the 24 CMM covered in this publication, eight have two or more active ingredients or markers analysed quantitatively. The determination of multiple active ingredients or markers in the assay instead of a single one will enhance the quality control of the CMM.

I would like to thank all members of the IAB, the Scientific Committee and the Editorial Board, as well as the research teams of the four participating universities in Hong Kong for their tremendous support and valuable contributions to the project. I am also grateful to the State Food and Drug Administration for their assistance in collecting CMM samples, the State Administration of Traditional Chinese Medicine of the People's Republic of China and many experts in the Mainland for their assistance and professional advice, and the Chinese Pharmacopoeia Commission of the People's Republic of China for allowing us to use the information of the Chinese Pharmacopoeia. We also indebted to the Government Laboratory of the HKSAR for its contribution.

Dr PY LAM
Director of Health
July 2008



Members of the International Advisory Board

Prof. David BRIGGS Director, Office of Complementary Medicines,

Therapeutic Goods Administration, Australia

Prof. Nuntavan Professor in Pharmacognosy, Faculty of Pharmacy,

BUNYAPRAPHATSARA Mahidol University, Thailand

Program co-ordinator (Medicinal Plants for Quality of Life),

Thailand Research Fund

Prof. Kelvin K. C. CHAN Head of Pharmacy Department,

Professor of Pharmacy and Pharmacology, School of Applied Sciences,

University of Wolverhampton, United Kingdom

Dr. Peter CHAN Director General, Health Evaluation Directorate,

Pest Management Regulatory Agency, Ottawa, Ontario, Canada

Prof. Chun-tao CHE Director, School of Chinese Medicine,

The Chinese University of Hong Kong

Prof. Norman R. Research Professor of Pharmacognosy,

FARNSWORTH College of Pharmacy, University of Illinois at Chicago, U.S.A.

Prof. Harry H.S. FONG Professor Emeritus of Pharmacognosy,

Program for Collaborative Research in the Pharmaceutical Sciences, Department of Medicinal Chemistry and Pharmacognosy; and

WHO Collaborating Center for Traditional Medicine;

College of Pharmacy, University of Illinois at Chicago, U.S.A.

Dr. Yukihiro GODA Head of Division of Pharmacognosy,

Phytochemistry and Narcotics,

National Institute of Health Sciences, Japan

Prof. Shiu-ying HU Honorary Professor of Chinese Medicine,

School of Chinese Medicine, The Chinese University of Hong Kong

Dr. Ping-yan LAM Director of Health, Hong Kong SAR

(Chairman of IAB)

Dr. Ting-hung LEUNG Former Deputy Director of Health, Hong Kong SAR

(August 2003 – July 2007)







桔梗 莪朮 la Platycodi Rhizoma Curcum

Prof. Rui-chao LIN Director, Division of Chinese Materia Medica & Natural Products,

National Institute for the Control of Pharmaceutical & Biological Products, State Food and Drug Administration,

The People's Republic of China

Prof. Zhi-xiang SHEN M. D. President of China Association of Research and Development

of Traditional Chinese Medicine, The People's Republic of China

Dr. Gloria TAM Deputy Director of Health, Hong Kong SAR

 $(July\ 2007-)$

Dr. Tai-lun TING Government Chemist, Government Laboratory, Hong Kong SAR

Prof. Hildebert WAGNER Professor, Department of Pharmacy,

Center of Pharma Research, Ludwig-Maximilians-University, Germany

Prof. Pei-gen XIAO Director, Research Centre on Utilization and Conservation of

Chinese Materia Medica, State Administration of TCM,

The People's Republic of China

Prof. Zhong-zhen ZHAO Professor, Course Director-Bachelor of Pharmacy (Hons) in

Chinese Medicine, School of Chinese Medicine,

Hong Kong Baptist University

(Remark: The list is arranged in alphabetical order of last name)

Members of the Scientific Committee

(including those overseas and mainland IAB members who participated in the Scientific Committee meetings during their visits to Hong Kong)

Prof. Kelvin K. C. CHAN Head of Pharmacy Department,

Professor of Pharmacy and Pharmacology, School of Applied Sciences,

University of Wolverhampton, United Kingdom

Prof. Chun-tao CHE Director, School of Chinese Medicine,

The Chinese University of Hong Kong

Prof. Harry H.S. FONG Professor Emeritus of Pharmacognosy,

Program for Collaborative Research in the Pharmaceutical Sciences, Department of Medicinal Chemistry and Pharmacognosy; and

WHO Collaborating Center for Traditional Medicine;

College of Pharmacy, University of Illinois at Chicago, U.S.A.

廣金錢草 Herba Deumodii Styracifullii

牛膝 Ladia Achyrumthis Bidentatae 大香 dix Aucklandiae 赤芍 adix Paeoniae Rubra fugae -#- 16

Dr. Iris M.Y. KWOK

Project Manager (Chinese Medicines),

(June 2006 – September 2007)

Department of Health, Hong Kong SAR

(Former Chairman of Scientific Committee)

Mr. Robert LAW Project Supervisor (Chinese Medicines),
(September 2007 –) Department of Health, Hong Kong SAR
(Current Chairman of Scientific Committee)

Prof. Rui-chao LIN Director, Division of Chinese Materia Medica & Natural Products,

National Institute for the Control of Pharmaceutical & Biological Products, State Food and Drug Administration,

The People's Republic of China

Prof. Ricky MAN Chair Professor, Department of Pharmacology,

The University of Hong Kong

Dr. Wing-wah SY
Project Manager (Chinese Medicines),

(August 2004 – April 2006)
Department of Health, Hong Kong SAR

(Former Chairman of Scientific Committee)

Prof. Karl W.K. TSIM Professor and Acting Head, Department of Biology,

Director, Center for Chinese Medicine R & D,

The Hong Kong University of Science and Technology

Prof. Zhong-zhen ZHAO Professor, Course Director-Bachelor of Pharmacy (Hons) in

Chinese Medicine, School of Chinese Medicine,

Hong Kong Baptist University

Government Chemist and/or

his representatives

Government Laboratory, Hong Kong SAR

(Remark: The list is arranged in alphabetical order of last name)

Members of the Editorial Board

Prof. Chun-tao CHE Director, School of Chinese Medicine,

The Chinese University of Hong Kong



・ 柴胡 。 idia Bupleurl





桔梗 Radix Platycod



Dr. Iris M.Y. KWOK Project Manager (Chinese Medicines), (June 2006 – September 2007) Department of Health, Hong Kong SAR

(Former Chairman)

Mr. Robert LAW Project Supervisor (Chinese Medicines), (September 2007 –) Department of Health, Hong Kong SAR

(Current Chairman)

Prof. Guo-an LUO Director, Modern Research Center of Traditional Chinese Medicine,

Tsinghua University, The People's Republic of China

Chinese Medicine Officer, Department of Health, Hong Kong SAR

Prof. Ricky MAN Chair Professor, Department of Pharmacology,

The University of Hong Kong

Prof. Karl W. K. TSIM Professor and Acting Head, Department of Biology,

Director, Center for Chinese Medicine R & D,

The Hong Kong University of Science and Technology

Prof. Bao-qin WANG Chinese Medicine Officer, Department of Health, Hong Kong SAR

Prof. Zhong-zhen ZHAO Professor, Course Director-Bachelor of Pharmacy (Hons) in

Chinese Medicine, School of Chinese Medicine,

Hong Kong Baptist University

(Remark: The list is arranged in alphabetical order of last name)