Hong Kong Chinese Materia Medica Standards

Department of Health
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PREFACE

The development of Chinese medicine in Hong Kong embarked on a new era in 1997 when the Chief Executive of the Hong Kong Special Administrative Region (HKSAR) Government announced the commitment to establish a sound regulatory framework for Chinese medicine. Two years later, in July 1999, the Chinese Medicine Ordinance (Chapter 549, Law of Hong Kong) was enacted while the Chinese Medicine Council of Hong Kong was established in September of the same year to devise and implement regulatory measures for the practice of Chinese medicine practitioners, the use, trading and manufacture of Chinese medicines. Since then, various regulatory measures including the registration of Chinese medicine practitioners, licensing of Chinese medicines traders, and registration of proprietary Chinese medicines (pCm) have been steadfastly put into implementation.

The increase in the use of herbal medicines, including Chinese herbal medicines, is a global trend. The HKSAR Government, like other regulatory authorities, is concerned about the quality of the Chinese herbal medicines and the safety about their uses. Information on medicines such as sources, characteristics and identification can be found in Pharmacopoeias but the quality aspects and data about safety factors are not always available. To safeguard public health, it is necessary to develop regulatory standards on the commonly used Chinese herbal medicines.

Among the list of over 500 Chinese herbal medicines in the Chinese Medicine Ordinance (Cap. 549), about 200 are commonly used in the local community. Funding was obtained for the development of the standards for the 60 commonly used Chinese herbal medicines. The medicines are selected on the basis that they are commonly used in the local community; of higher economic value and in the list of Schedule 2 medicines of the Chinese Medicine Ordinance (Cap. 549); some medicines of international concern in respect to their safety and quality are also selected for investigation.

As Chinese herbal medicines are the raw material for pCm, the quality of herbs has direct impact on pCm products. The Standards can, therefore, safeguard the quality of pCm. The Standards will also be the corner stone for further research on Chinese materia medica (CMM). In view of the global trend in the use of Chinese medicines, it is important to harmonize with international requirements, such as on the limits of heavy metals and pesticide residues. A well-established standard with international recognition will serve this purpose and help to facilitate the trade.

Hong Kong Chinese Materia Medica (HKCMM) Standards Office was set up under the Chinese Medicine Division in the Department of Health to manage and co-ordinate this project.

An International Advisory Board (IAB) was established in early 2002 to give advice on the principles, methodologies, parameters and analytical methods for the development of HKCMM Standards. The IAB consists of renowned experts from local, Mainland and overseas (including Australia, Canada, Germany, Japan, Thailand and the United States). The Board also helped to decide the contents of the HKCMM Standards, selected the research institutions to take up the research and laboratory work, and determined the target herbs. The board usually meets once a year to examine and endorse the research results.

In order to monitor the progress of the research work, to work out solutions on technical issues and to examine the research results and findings, a Scientific Committee consisting of visiting IAB members, representatives of the participating universities and government officials has been established. The Committee drew up a detailed Technical Guidelines for the research and laboratory work.

Hong Kong Baptist University and The Chinese University of Hong Kong participated in all the research works in phase I of the project, from the characterization, tests, to high-performance liquid chromatographic fingerprinting; their findings are reported to the HKCMM Standards Office, subsequently submitted to the Scientific Committee for examination and finally endorsed by the IAB.

The Government Laboratory of the Hong Kong SAR has actively involved in the development of HKCMM Standards through participating in the inter-laboratory comparison studies of the chemical methods developed by the research institutes and engaging in the trial run studies. It has also developed three analytical methods for the determination of heavy metals, pesticide residues and mycotoxins (aflatoxins) respectively.

The project has received great support from Mainland regulatory body and professionals. While the State Food and Drug Administration (SFDA) is assisting in the collection of representative herb samples and the corresponding herbarium specimens from different parts of Mainland, experts from Mainland also join in the IAB and help the works in the HKCMM Standards Office.

In the development of the HKCMM Standards, adequate representative samples authenticated by experts are obtained from Mainland and Hong Kong for research and data collection. A validation program is set up to ensure the reliability of the methods, which comprises of a within-laboratory validation scheme and a scheme for the verification of method reproducibility. Representative photographs including macroscopic and microscopic examinations of the CMM are included for references. High-performance liquid chromatographic fingerprinting is introduced for the authentication of CMM in addition to the conventional methods such as thin-layer chromatography. For the safety requirements of CMM, the limits of heavy metals, pesticide residues and mycotoxins (aflatoxins) for each CMM are also laid down. The quality of CMM is also safeguarded by the determination of its foreign matter, ash, water content, extractives and assay limits.

The first phase of the HKCMM Standards covering eight herbs, namely, Cortex Moutan, Cortex Phellodendri (Cortex Phellodendri Amurensis and Cortex Phellodendri Chinensis), Radix Angelicae Sinensis, Radix Astragali, Radix Ginseng, Radix Notoginseng, Radix Salviae Miltiorrhizae and Rhizoma Alismatis, has been completed. The consolidated data are complied in this publication. We are confident that these Standards will be a safeguard for the prescribed CMM and will be acceptable in the field of Chinese medicine and the community at large.

Last but not least, we would like to thank all the members of the International Advisory Board, the Scientific Committee and the Editorial Board as well as the research teams of the two participating universities. We are grateful for the SFDA of China for their assistance in collection of representative CMM samples and the State Pharmacopoeia Commission of the People's Republic of China for allowing us to use some of the valuable information of the Chinese Pharmacopoeia. We also owe the Government Laboratory of the Hong Kong SAR for their inter-laboratory work and their contribution to the Scientific Committee.

Dr P Y LAM
Director of Health
June 2005

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