

# 序

中醫中藥是我國傳統文化中的瑰寶，政府向來極為重視，早期於內政部衛生司就設有中醫藥委員會之諮詢單位，民國 60 年行政院衛生署成立後，中醫藥委員會仍負責中醫藥有關之諮詢業務。由於各界對中醫中藥的日益重視，於民國 76 年 7 月 29 日修正「行政院衛生署組織法」第 17 條，明訂中醫藥委員會掌理中醫中藥各項行政事務，依此規定所研擬之「行政院衛生署中醫藥委員會組織條例」草案，則於民國 76 年 11 月 21 日送請立法院審議。在中醫藥界之敦促與關心中醫、中藥之立法委員大力支持下，於民國 83 年 12 月 15 日經立法院三讀通過，同年 12 月 30 日由總統公布實施。歷經 10 個月的籌備，84 年 11 月 1 日正式成立行政院衛生署中醫藥委員會，成為行政院衛生署所屬之獨立附屬機關。

為進一步宣揚我國中醫藥發展之成果，本會積極貢獻臺灣中醫藥發展成果，96 年度更以「中醫藥研發成果擴散年」為施政主軸，訂定 2007 年中醫藥行動要點之八大施政目標，賡續推動相關中醫藥相關政策：(一)賡續推動建構中醫整體臨床教學體系計畫；(二)辦理提昇中醫醫事人員職業素質計畫；(三)建構中藥用藥安全環境，活力產業再躍昇；(四)健全中藥臨床試驗環境，創新產業優質化；(五)推動中醫藥科技發展，促進成果擴散應用；(六)推動中醫藥國際衛生事務，貢獻成果躍進國際；(七)全方位中醫藥資訊服務品質再精進；(八)規劃及推動優質照護，提升中醫醫療服務品質。

目前中醫藥委員會除依法定設有中醫組、中藥組、研究發展組及資訊典籍組 4 個組，另於 91 年度新增設科技政策小組（臨時任務編組），相關工作要項如下：

中醫組業務方面，在中醫行政方面，最近幾年，我們已經陸續完成推動「醫師法」及「醫療法」修法工作、推動提昇中醫醫療服務品質工作、推動提昇中醫護理照護品質工作、處理中醫師考試相關問題、協助推動「全民健保中醫門診總額支付制度」、協調試辦「住院病人使用中藥療效評估計畫」、落實中醫醫政管理工作、宣導民眾正確中醫就醫觀念、建構中醫整體臨床教學體系、訂定中醫醫療院所安全作業參考指引、建立中醫師繼續教育審查認定制度、執行中醫師繼續教育計畫及辦理中醫醫院暨醫院附設中醫部門訪查、評鑑等項工作。

中藥組業務方面，為建構臺灣中藥用藥安全環境，在提昇中藥藥品品質方

面，除重行編修臺灣傳統中藥典籍外，積極推動宣導中藥藥品包裝容器標準標示政策及輔導中藥廠落實全面執行優良藥品製造規範（GMP），並建立亞太中藥標準品供應機制、強化中藥製程安全與建立研發平台、資源管理與建立資訊暨通路網路、研訂完備之中藥新藥查驗登記制度以及強化中藥不良反應通報中心，盡速達成中藥現代化及科學化之目標。在提昇中藥從業人員專業素質方面，建立中醫藥產業科技人才培訓機制，深度培訓多類跨領域之專業人員，另嚴謹審核中藥藥物廣告及不定期進行查緝不法行為之行動，並加強宣導民眾中藥用藥安全觀念，以確保民眾中藥用藥安全。

研究發展組業務方面，為推動中醫藥科技研究，極力爭取研究經費列入政府科技預算，現執行「中醫藥現代化與國際化整合型計畫」及「基因體醫學國家型科技計畫—中醫藥基因體相關研究計畫（挑戰 2008）」二項計畫，另為提昇中醫藥研究水準，訂定計畫審查程序及管考作業流程，並將此作業流程列入 ISO 標準程序書，以提昇行政效能，其管考作業流程大致分為：「徵求計畫」、「計畫審查」、「計畫管考」及「研究成果」等四階段十三步驟。因此，本會「中醫藥現代化與國際化之整合型計畫」已連續 3 年（90-92 年）經行政院衛生署科技類計畫考列甲等。冀藉由有系統之科技研究，將中醫藥推入 21 世紀知識經濟時代新紀元。

資訊典籍組業務方面，係委託進行中醫藥典籍之整理、編纂，編輯出版中醫藥年報，建立中醫藥行政資訊系統，並以「中醫藥資訊網」為中醫藥服務電子化單一窗口，一方面提供中醫藥界及民眾上網查詢相關資訊，落實中醫藥全民化之政策，提升為民服務效率；另一方面建置中醫藥相關之衛生行政管理機構間線上即時的協同作業管道，強化管理機制，提昇行政效率。

科技政策小組業務方面，本會科技業務之統合管理，因應世界衛生組織《2004 年—2007 年全球醫藥策略》中表達希望各國政府應該將傳統醫藥納入國家醫藥政策，所進行之政策規劃，為該小組之主要任務。期望未來在本會各組的配合下，使中醫藥行政與研究能密切配合，加速中藥研發管制、推動中藥臨床療效評估、中醫藥在全民健保發揮應有的功能、中西醫結合與中醫藥國際化。

96 年度中醫藥年報蒐集委託 61 項研究計畫，研擬(1)中醫政策研究；(2)中醫臨床療效評估；(3)中醫證型診斷；(4)中藥療效與藥理；(5)中藥品管；(6)中藥資源；(7)中醫藥基因體研究；(8)中藥材辨識方法研究結果之整合與管理；(9)國際交流；(10)教育訓練等重點。研究計畫內容可概述如下：第一冊--中醫藥療效評估之研究（涵蓋中醫藥療效與藥理研究）；第二冊--中醫藥基因體與免疫學研究（涵蓋利用生物技術研討中醫藥基因體、免疫學研究與人才培訓）；第三冊--中醫藥政策與國際化相關研究（涵蓋中醫藥政策研擬與建立中藥法規資料庫

計畫)；第四冊--中醫藥品質與管理相關研究(涵蓋中藥基原鑑定與中藥有害物質品管面向之研究)；第五冊--中醫證型診斷基準與臨床療效研究(涵蓋重要疾病主要證型之中醫辨證基準與診斷研究)；第六冊--中藥資源與辨識資訊相關研究(涵蓋中藥材辨識與消費者查詢資訊研究)。

為使國人瞭解國內中醫藥研究發展情形，同時也提供國內中醫藥從業人員繼續教育、吸收新知識的機會，每年的研究成果均刊載於行政院衛生署中醫藥年報，並登載在本會中醫藥資訊網頁上，以提供國內外學者專家之參考，自民國70年出版年報第1期，迄今已出版至第26期，未來仍將配合年度研究成果定期出版，以提供各界之參考。

主任委員 **林宜信** 謹識

中華民國97年8月1日



# Preface

Traditional Chinese Medicine and Pharmacy, an invaluable cultural asset to our country, has always received much attention from the government. The Committee on Chinese Medicine and Pharmacy (CCMP), was established under the Department of Health, Ministry of the Interior from the early years, it has been responsible for offering Chinese medicine and pharmacy related consulting services. When the Department of Health (DOH), Executive Yuan was established in 1971, CCMP continues its role. Due to the increasing national emphasis on Chinese medicine and pharmacy, on July 29<sup>th</sup> 1987, Article 17 of the Organic Law of the Department of Health was amended, setting forth that CCMP is in charge of the administrative affairs related to Chinese medicine and pharmacy. In accordance with this, the Organizational Act of the Committee on Chinese Medicine and Pharmacy, Department of Health was drafted and submitted to the Legislative Yuan for deliberation on November 21<sup>st</sup> 1987. With the urging of the Chinese medical and pharmaceutical circle and the support from the legislators concerned, on December 15<sup>th</sup> 1994, the Act was approved by the Legislative Yuan. On December 30<sup>th</sup> of the same year, it was promulgated by the President and was enforced. After 10 months of preparation, on November 1<sup>st</sup> 1995, the Committee on Chinese Medicine and Pharmacy was officially established as an independent institution under the jurisdiction of the DOH, Executive Yuan.

To present the achievement of Taiwan in Chinese medicine and pharmacy, CCMP centered its administration in 2007 on the theme, “Year for extended application of Chinese medicine and pharmacy research findings”, and established its 8 primary goals for implementing Chinese medicine and pharmacy policies in 2007 including: (1) Continued implementation of the Project to Construct Overall Chinese Medicine Clinical Education System. (2) Implementation of the Project to Enhance Professional Competence of Chinese Medicine Practitioners. (3) Constructing medication safety environment for Chinese medicine and revitalizing

the industry for further development. (4) Perfecting Chinese medicine clinical test environment and creating a quality-oriented innovative industry. (5) Promoting technological development for Chinese medicine and pharmacy and encouraging expansive application of the achievement. (6) Extending international outreaches of Chinese medicine and pharmacy and becoming a major contributor making to the international community. (7) Further improvement of the quality of comprehensive Chinese medicine and pharmacy services. (8) Planning and implementation of quality care; enhancement of medical service quality of Chinese medicine.

In addition to the Division of Chinese Medicine, Chinese Pharmacy, Research and Development, and Information and Publications, in 2002, CCMP also established the Technology Policy Unit (task force). Below are the main responsibilities of each division:

In its administrative in recent years, the Chinese Medicine Division has completed amending the Physician Act and the Medical Service Act; carried out tasks that help enhance quality of traditional Chinese medical (TCM) service; implemented projects that help enhance quality of TCM nursing care; handled issues pertaining to Chinese medical doctor's examination; helped with promotion of "sum payment system of National Health Insurance in TCM clinics"; coordinated the "pilot project for evaluating effect of TCM on inpatient"; ensured effective TCM administrations, educated the public of proper idea about TCM clinical visit; constructed the overall TCM clinical education system; formulated TCM clinics operational safety guidelines; established Chinese medical doctor's continuing education review and certification system; carried out Chinese medical doctor's continuing education project; and conducted Accreditation on Chinese Medical Hospitals and Chinese Medical Departments Affiliated with A Western Hospital.

In order to construct a TCM medication safety environment in Taiwan, the Chinese Medicine Division in the area of enhancing Chinese medicine quality compiled and revised books on traditional Taiwanese medicines; actively implemented and promoted Chinese medicine packaging container standard labeling

policy and helped TCM pharmaceutical companies comprehensively follow GMP guidelines; set up Asia –Pacific standard Chinese medicine supply system; reinforced TCM process safety and built researches and developments platform; intensified resource management and established information and channel network; formulated sound TCM new drug inspection and registration system; and strengthened TCM adverse effect notification center for the purpose of accelerating TCM modernization. In the area of enhancing TCM practitioner’s professional ability, it set up a mechanism for training TCM technology talents; offered in-depth programs for training various inter-disciplinary professionals; closely scrutinized TCM medicine advertisements and take intermittent actions to investigate illegal activities; and educated the public of TCM medication safety concept in order to ensure TCM medication safety.

The Division of Research and Development is in charge of promoting the research in Chinese medical and pharmaceutical technologies via the “Integrated Program of Modernization and Internationalization of Chinese Medicine” and “National Research Program for Genomic Medicine – Research Program for Chinese Medical and Pharmaceutical Genomics (Challenge 2008)”. The R&D division is also responsible for setting up program review procedures as well as supervision and evaluation process. To enhance administrative performance this process consists of 13 steps in 4 phases, including “program solicitation”, “program review”, “program supervision and evaluation”, and “research results”. The Integrated Program of Modernization and Internationalization of Chinese Medicine received Grade A Research Award of DOH, Executive Yuan in 3 consecutive years (2001-2003). Hopefully, systematic research will allow Chinese medicine and pharmacy to enter the new knowledge-based economic era of the 21<sup>st</sup> century.

The Division of Information and Publications is responsible for supervising the compiling, editing and publishing of the Chinese Medicinal Yearbook, establishing the Executive Information System for Chinese Medicine and Pharmacy, offering Chinese medical and pharmaceutical information and services on the CCMP website by, on one hand, providing relevant information to the Chinese medical and

pharmaceutical circle as well as the public so as to implement the policy of Chinese medicine and pharmacy for all and improve public service efficiency, and on the other hand, establishing online real-time collaborative channels between health executive management organizations relating to Chinese medicine and pharmacy so as to strengthen the management systems and improve executive efficiency.

In terms of the Technology Policy Unit, it is in charge of the integrated management of the technical affairs of CCMP, and policy planning in response to WHO Medicines Strategy 2004-2007. We hope that the administrative and research functions of the different divisions of CCMP will be closely coordinated to accelerate the management of Chinese pharmaceutical research and development, promote the evaluation of Chinese pharmaceutical clinical efficacy, the functions of Chinese medicine and pharmacy in the National Health Insurance Program, the integration of Western and Chinese medicine and internationalization of Chinese medicine and pharmacy.

In 2007, under the supervision of the Division of Research and Development, 61 research programs were entrusted and conducted, including: (1) studies on the policies of Chinese medicine, (2) evaluation of clinical efficacy of Chinese medicine, (3) Researches on Chinese medicine diagnostic standard, (4) efficacy and pharmacology of Chinese medicine and materia medica, (5) Chinese pharmaceutical quality control, (6) Chinese pharmaceutical resources, (7) studies on Chinese medical and pharmaceutical genomics, (8) Integration and management of Chinese medicine identification researches, (9) international exchange, (10) education.

Contents of the research projects mainly include: volume 1: researches on Chinese medical and pharmaceutical efficacy (TCM effect and pharmacology), volume 2: researches on Chinese medical and pharmaceutical genomics and immunology (employment of biotech for exploration of TCM genomics, immunology study and training) , volume 3: researches related to the policies and internationalization of Chinese medicine and pharmacy (TCM policy formulation and establishing TCM law databank), volume 4: researches related to Chinese medical and pharmaceutical quality



management (authentication of the origin of Chinese herbal medicine (CHM) and quality control pertinent to hazardous CHM ingredients), volume 5: researches on Chinese medicine diagnostic standard and clinical effect (TCM diagnostic standards for the main indications of significant diseases), volume 6: researches on Chinese medicine resources and identification information (CHM material identification and consumer access to information.).

In order to help the public understand the research development of Chinese medicine and pharmacy in Taiwan, CCMP also provides great opportunities of further education and training for Chinese medical and pharmaceutical professionals in our country. The research results of each year are published on the Chinese Medicinal Yearbook by DOH, Executive Yuan as well as on our website to provide references for domestic and international researchers and professionals. Since the released of first volume in 1981, 26 volumes of the Yearbook have been published so far, and in the future, more research results will be released annually.

*I-Hsin Lin*

I-Hsin Lin, MD., Ph.D.

Chairperson

August 1, 2008

