

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。

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，實施「中醫臨床教學訓練計畫(2005-2008)」：透過中醫門診教學、中醫會診教學及中醫住診教學方式，落實中醫臨床教學訓練工作。落實醫療法及醫師繼續教育規定：將參照行政院衛生署新制醫院評鑑基準，研訂中醫醫院暨醫院附設中醫部門評鑑作業程序、評鑑基準及評量表等相關規章，作為辦理該項評鑑之依據。辦理中醫師繼續教育(含經驗傳承)研討會暨中醫護理照護品質計畫，提昇中醫醫事人員執業素質。推動中醫政策及中醫品質相關研究，增進民眾中醫就醫安全，讓全國國民均能得到更好的中醫醫療照護品質。
中藥組業務方面，建構中藥用藥安全環境，提昇專業素質及藥品品質，經由編修中藥典作為品質標準的法典；持續並推動包裝標示並全面落實 GMP 規範，建立完善中藥新藥查驗登記制度，促進中藥現代化；配合貿易便捷化建置通關自動化及其配套措施，暢通中藥流通管道；嚴謹的廣告審核及相關不法行為的監控以確保民眾用藥安全。
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、臨床試驗環境及法規建置、建立 GCP 查核制度，另為因應世界衛生組織《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，所進行之政策規劃等，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。

94 年度共委託進行 75 項研究計畫，研究計畫內容可概分為：(1)中醫政策研究；(2)中醫臨床療效評估；(3)中醫輔助診斷儀器；(4)中醫藥療效與藥理；(5)建立中藥臨床試驗體系相關研究；(6)中藥品管；(7)中藥資源；(8)典籍研究；(9)中醫藥基因體研究；(10)保育藥材替代研究；(11)兩岸中醫藥學術交流；(12)中草藥不良反應通報系統；(13)中醫藥聯合人體試驗醫學倫理委員會；(14)中藥新藥臨床試驗中心 GCP 查核計畫；(15)中醫藥實證醫學研討會等項重點。此外另有補助計畫共計 16 項，重點分別為：(1)教學醫院成立中藥臨床試驗中心，分別由三軍總醫院等 11 家教學醫院執行；(2)中醫藥科技研發暨臨床試驗訓練課程計畫；(3)植物性藥品之研發與臨床試驗國際論壇計畫；(4)中草藥生技法規溝通計畫宣導會議；(5)第 20 屆天然藥物研討會；(6)2005 年生技推動等項重點，合計相關科技總經費約為 69,496,000 元。可見各界對本會之中草藥科技研究之重視。

本會對於中藥種原、本土藥用植物資源調查研究及具有中醫藥專業參考性之研究成果，均規劃出版專籍及電子書籍，以促進中醫藥研究成果增值、擴散及流通。除已編印出版「中藥材品質管制—組織形態學鑑定」、「台灣原住民藥用植物彙編」(榮獲行政院衛生署「91 年優良政府出版品評選」圖書組第 1 名)、「中藥對照用指標成分物理化學資料彙編」及「骨質疏鬆症的中醫治療—近代研究與典籍資訊」(榮獲行政院衛生署「91 及 92 年優良政府出版品評選」圖書組第 3 名)、「台灣常用藥用植物圖鑑(第 1 冊)」(榮獲行政院衛生署「92 年優良政府出版品評選」圖書組第 1 名)、「臺灣藥用植物名錄」(榮獲行政院衛生署 93 年政府出版品圖書組評選優良獎第 2 名)、「台灣原住民藥用植物彙編(英文版)」(榮獲行政院衛生署 93 年政府出版品圖書組評選特別獎—最佳學術獎)、「防治 SARS 教育宣傳影音 DVD 光碟書」(榮獲行政院衛生署 94 年政府出版品電子書優良獎第 1 名)、「中醫藥年報」(榮獲行政院衛生署 94 年政府出版品

期刊組優良獎第 2 名) 等專書，本會連續 3 年 (92、93 及 94 年) 榮獲「政府出版服務獎」第 1 名之殊榮，出版成績斐然，位居行政院衛生署所屬機關之冠。

此外，為強化產學合作機制，促進學術界研究成果結合產業界產值突破，整合國內學術能量轉為台灣中醫藥「創新開發」的競爭力，辦理研究成果下放及授權推廣，二項計畫研究成果獲得專利，並獲得技術授權之權利金，另一項舌診計畫申請專利中，另有一項研發成果辦理技術授權，獲得權利金。本會辦理之前述技術授權案是衛生署所屬單位中第一個成功辦理技術移轉，並有研發成果產生收入之機關。

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 24 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 95 年 10 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), initially established under the Department of Health, Ministry of the Interior, has been responsible for offering Chinese medicine and pharmacy related consulting services since the Department of Health (DOH), Executive Yuan was established in 1971. Due to the increasing national emphasis on Chinese medicine and pharmacy, on July 29th 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 21st 1987. With the urging of the Chinese medical and pharmaceutical circle and the support from the legislators concerned, on December 15th 1994, the Act was approved by the Legislative Yuan. On December 30th of the same year, it was promulgated by the President and was enforced. After 10 months of preparation, on November 1st 1995, the Committee on Chinese Medicine and Pharmacy was officially established as an independent institution under the jurisdiction of the DOH, Executive Yuan. 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: the Division of Chinese Medicine is responsible for carrying out Chinese Medicine Clinical Teaching and Training Program (2005-2008) through clinical teaching in Chinese medicine outpatient clinics, consultations and ward rounds, implementing regulations of the Medical Care Act and continuing medical education: will follow the Hospital Accreditation Standards to draw up the accreditation process, standards and scale for Chinese medicine hospitals and departments, holding continuing education (including experience sharing) symposiums for Chinese medicine practitioners and Chinese medical care quality programs to improve the practice quality of Chinese medical professionals, and promoting relevant research in Chinese medicine policies and quality to enhance patient safety and improve quality

of medical care. The responsibilities of the Division of Chinese Pharmacy are to create a safe pharmaceutical environment of Chinese medicine and to improve professional and pharmaceutical quality by revising Chinese Medicine Pharmacopoeia; to promote package labeling, to completely implement GMP standards, and to establish a complete pharmaceutical inspection and registration system in order to promote the modernization of Chinese medicine; to take advantage of the convenient trade, automatic custom clearance and associated measures to establish smooth Chinese pharmaceutical channels; and to implement strict pharmaceutical advertising review and management so as to ensure pharmaceutical safety of the public. 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 RSD 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 21st 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, establishment of clinical trial environment and regulations and GCP audit system, 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 2005, under the supervision of the Division of Research and Development, 75 research programs were entrusted and conducted, including: (1) studies on the policies of Chinese medicine, (2) evaluation of clinical efficacy of Chinese medicine, (3) auxiliary Chinese medical instruments, (4) efficacy and pharmacology of Chinese medicine and materia medica, (5) studies related to Chinese pharmaceutical clinical trial systems, (6) Chinese pharmaceutical quality control, (7) Chinese pharmaceutical resources, (8) literature reviews, (9) studies on Chinese medical and pharmaceutical genomics, (10) studies on the substitutes for protected medical materials, (11) cross-Strait academic exchange in Chinese medicine and pharmacy, (12) The Taiwan Adverse Drug Reaction Reporting System (TADRRS) for Herbal Medicine, (13) Joint Institutional Review Board for Traditional Chinese Medicine, (14) GCP Inspection of General Clinical Research Center for Chinese Medicine, (15) Key points for The seminar for developing strategy of evidence-based medicine in Chinese medicine. In addition, there are subsidy to plan a total of 16 items, respectively with emphasis on: (1) Clinical Trial Center for Traditional Chinese Medicine, teaching hospital, Separately by Tri-Service General Hospital, and so on 11 teaching hospital execution ; (2) The Chinese medicine science and technology research and development and the clinical test training curriculum plans ; (3) Research and development of and the clinical test international forum the vegetative drugs plan ; (4) Chinese Herbal Medicine and Biotechnology Statute Communication Project ; (5) The 20th Symposium on Natural Products ; (6) Key points of the 2005 biotechnological impetus. The total research funds added up to NT\$69,496,000. It is thus evident that the research on Chinese medicine and pharmacy of CCMP has received enormous attention.

To enhance and promote the value and public awareness of Chinese medical and pharmaceutical research results, CCMP has successfully published many books and digital books of research findings in Chinese pharmaceutical genetic resources, local pharmaceutical plant resources and other related studies, including “Quality

Control of Chinese Medicinal Materials – Tissue Morphological Identification”, “Compendium of Medicinal Plants used by the Indigenous People of Taiwan” (awarded the 1st prize of the Book Group of 2002 Outstanding Government Publications by the Department of Health, Executive Yuan), “Physical & Chemical Data Collection of Chinese Medicine Component Index”, “Treatment of Osteoporosis with Chinese Medicine – Modern Research and Information on Ancient Books and Records” (awarded the 3rd prize of the Book Group of 2002 and 2003 Outstanding Government Publications by the Department of Health, Executive Yuan), “The Illustration of Common Medical Plants in Taiwan (Volume I)” (awarded the 1st prize of the Book Group of 2003 Outstanding Government Publications by the Department of Health, Executive Yuan), “The Directory of Medical Plants in Taiwan” (awarded the 2nd prize of the Book Group of 2004 Outstanding Government Publications by the Department of Health, Executive Yuan), “Compendium of Medicinal Plants used by the Indigenous People of Taiwan (English Edition)” (awarded the Academic Excellence of 2004 Outstanding Government Publications by the Department of Health, Executive Yuan), “SARS Prevention & Cure Education and Publicizing (with DVD)” (awarded the 1st Prize of the Electronic Book Group of 2005 Outstanding Government Publications by the Department of Health, Executive Yuan), “Chinese Medicinal Yearbook” (awarded the 2nd prize of the Periodical Group of 2005 Outstanding Government Publications by the Department of Health, Executive Yuan). CCMP has been awarded the 1st prize of Government Publication Services in three successive years (2003-2005) with its great achievements, topping other institutions under the jurisdiction of the Department of Health, Executive Yuan.

Moreover, to strengthen the collaboration system between industry and academia, to promote breakthroughs in output value of academic research results integrated into industry, and to improve the competitiveness in innovative development of Chinese medicine and pharmacy in Taiwan utilizing national academic strength, CCMP has successfully implemented the sharing and authorized promotion of research results, including patented research results of two projects with royalties for licensing, one of the two being tongue diagnosis project under patent application, and another project under technology licensing. We are the first institution under the jurisdiction of the Department of Health that successfully licensed technology, acquired royalty, and generated revenue from research results.

In order to help the public understand the research development of Chinese

medicine and pharmacy in Taiwan, CCMP also offers 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 1981 when the first volume was released, 24 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

October 1, 2006

