

9 October 2008

Chair, Practitioner Regulation Subcommittee
Email: nraip@dhs.vic.gov.au

Dear Chair

Re: Submission on the Partially Regulated Professions: Addressing the Australian Health Ministers' Advisory Council Criteria for Chinese Medicine Practitioner Regulation

We would like to thank the Australian Health Ministers' Advisory Council for the opportunity to make this submission to address its criteria for the regulation of health professions. Specifically, this submission is made in reference to Chinese medicine, a partially regulated profession in Australia.

Chinese medicine practice has a long history in China and its neighbouring countries such as Japan and Korea. Despite the rapid developments in Western medicine over the last century, Chinese medicine continues to play a significant role in both developing countries (as a form of primary healthcare) and the developed world including Australia (as a form of complementary and alternative medicine). In China, Chinese medicine currently delivers approximately 40% of the total healthcare to its 1.3 billion people. In Australia, Chinese medicine therapies are used by approximately 20% of the population for the treatment of a range of challenging clinical conditions such as acute pain, chronic pain, hay fever, and irritable bowel syndrome. Recent public health studies have demonstrated that the use of acupuncture and herbal medicine in Australia is increasing. It is evident that both acupuncture and Chinese herbal medicine possess considerable therapeutic potential but can also be a source of harm to the public when these therapeutic modalities are not practised by appropriately qualified practitioners.

In 2000, after five years of investigation and preparation, the registration of Chinese Medicine practitioners was introduced in the State of Victoria. Over the last eight years, much has been learned about the complexities of introducing statutory registration to an established profession in which the educational backgrounds of practitioners is diverse. The approach taken in Victoria was very different from those undertaken in Hong Kong and Singapore in recent years. It has adapted itself to the Australian healthcare context and has proven to be an effective, efficient, and fair process that meets the high standards of administrative practice expected in Australia. In all, this process has demonstrated the feasibility of implementing statutory regulation for this profession not only at state level but nationally.

RMIT University is committed to Chinese Medicine education and research that promotes evidence-based Chinese medicine development. Such research activities will provide critical data concerning the efficacy and safety of Chinese medicine interventions in order to further the rational use of Chinese medicine modalities in our community.

This submission addresses the AHMAC's criteria and presents a case for the inclusion of Chinese Medicine, which is currently a partially regulated health care profession, into the National Registration and Accreditation Scheme for the Health Professions, in the interests of protecting public safety and to ensure that only appropriately qualified practitioners provide services in acupuncture and herbal medicine to the Australian community.

On behalf of RMIT University I wish to express my support for this submission. Please feel free to either contact Professor Charlie Xue email charlie.xue@rmit.edu.au or telephone (03) 9925 7745 RMIT University should you require further information.

I wish you all the very best for the implementation of this Scheme.

Yours sincerely

A handwritten signature in cursive script that reads "Margaret Gardner".

Professor Margaret Gardner AO
Vice-Chancellor and President

cc Professor Coloe, Pro Vice-Chancellor (Science, Engineering and Technology),
RMIT University
Profession Greenwood, Head of the School of Health Sciences, RMIT University
Professor Xue, Head of the Division of Chinese Medicine, RMIT University



Division of Chinese Medicine, School of Health Sciences

National Registration of Chinese Medicine Practitioners

**A Submission to the Australian Health Ministers' Advisory Council
Regarding the National Registration and Accreditation Scheme for
Health Professionals: The Partially Regulated Professions**

September 2008

Attention:

Practitioner Regulation Subcommittee

NRAIP@dhs.vic.gov.au

Due: 5.00pm EST on Friday, 3 October 2008.

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1 Executive Summary: Responses to the AHMAC Criteria

1.1 Criterion 1

Is it appropriate for Health Ministers to exercise responsibility for regulating the occupation in question, or does the occupation more appropriately fall within the domain of another Ministry?

Yes. The profession of Chinese medicine (also known as Traditional Chinese Medicine), which uses a range of modalities including acupuncture and herbal medicine to treat a broad range of clinical conditions, clearly falls within the responsibility of the Health Ministers. The report of The Expert Committee on Complementary Medicines in the Health System (2003) and the Australian Government's response to this national report (2004) both took this view.

1.2 Criterion 2

Do the activities of the occupation pose a significant risk of harm to the health and safety of the public?

Yes. There is sufficient evidence to indicate there is significant risk of harm to the health and safety of the public, ranging from pneumothorax and poor infection control (related to acupuncture practice), to renal carcinoma and unfavourable herb-drug interactions due to poor knowledge of herbal medicine and inadequate education in biomedical sciences. It has also been demonstrated that when these modalities are practised by appropriately qualified professionals, such as is the situation in the State of Victoria, the risk of harm to the health and safety of the public can be guarded through the four-step mechanism of program approval (or Board examinations), professional registration, continuing professional education to update practitioners' knowledge and skills, and effective processes for dealing with public complaints about substandard practice and/or professional misconduct. These standards of education and practice can only be achieved through a statutory national registration scheme.

1.3 Criterion 3

Do existing regulatory or other mechanisms fail to address health and safety issues?

Yes. Besides the State of Victoria, the current legislative and non-legislative mechanisms in other States and Territories do not provide adequate protection of public health and safety. Self regulation by professional associations provides a degree of regulation but self regulation is not able to prevent unqualified or inadequately trained practitioners from holding themselves out as qualified Chinese medicine practitioners. Consequently the risks to the public remain. In addition, the fundamental purpose of associations is to protect the interests of their members rather than the public. While practitioners are encouraged to join associations, many choose not to do so. In the case of such practitioners, the public has recourse to the Health Complaints Commissioner or similar body in each state, but this is a reactive or passive approach and the powers of such bodies are generally limited in comparison to those of a registration board. To ensure public safety, the more proactive approach of statutory registration is required.

1.4 Criterion 4

Is regulation possible to implement for the occupation in question?

Yes. Chinese medicine is a well defined healthcare profession with the practices of acupuncture and herbal medicine being guided by a coherent and evolving body of

knowledge underpinned by its unique philosophy, a holistic approach and ongoing scientific endeavour. This profession has over one and a half centuries of development in Australia, with the most rapid period of development being the last three decades culminating in the introduction of statutory registration of Chinese Medicine in the State of Victoria in the year 2000. The achievements of the Chinese Medicine Registration Board of Victoria demonstrate the feasibility of implementing statutory regulation of the profession nationally. What we have learnt through the last eight years of implementation will provide a base for the even more effective and efficient implementation of registration of Chinese Medicine practitioners as part of the national registration scheme.

1.5 Criterion 5

Is regulation practical to implement for the occupation in question?

Yes. Registration was enacted in the State of Victoria in 2000 and the Chinese Medicine Registration Board of Victoria has been functioning effectively since then. Currently, over 1,000 practitioners registered with the Board. The Victorian Board has also developed a range of policies and approaches for dealing with complex issues such as language, ethical conduct and practitioners with a broad range of educational backgrounds. The experience in dealing with over 100 complaints has been extremely beneficial resulting in improved standards of professional practice and conduct. This reflects the importance of effective regulation in protecting public health and safety.

1.6 Criterion 6

Do the benefits to the public clearly outweigh the potential negative impact of such regulation?

Yes. National registration will extend the safety net that has been developed in the State of Victoria to the rest of the country to ensure that only qualified practitioners are approved to provide acupuncture and Chinese herbal services to the public and that a range of mechanisms are in place for dealing with unprofessional conduct and substandard practice. Regulation by a national statutory registration board presents a more efficient and affordable mechanism for minimising risks to public safety and enabling the enforcement of Skin Penetration and Therapeutic Goods legislations while providing equity under the Trade Practices Act. In addition, with the rapidly ageing population, the use of acupuncture and herbal medicine has increased steadily as alternatives or adjunct therapies for the treatment of a range of chronic conditions including those of the elderly. Considering the ongoing expansion of Chinese medicine in Australia and overseas, and the reasonable expectations of consumers that health care providers be both registered and accountable, national registration is timely, and in the public interest. The benefits to the public of registering Chinese medicine practitioners clearly outweigh the potential disadvantages of such regulation.

2 Preamble

The Working Group Advising on Criteria and Process for Assessment of Regulatory Requirements for Unregulated Health Occupations was established by the Australian Health Ministers' Advisory Council (AHMAC). In its 1993 report, a series of six criteria that an unregulated health profession needs to satisfy to warrant occupational registration were determined [1] (see Appendix). In this submission each of the AHMAC criteria are addressed in specific relation to Chinese Medicine.

The primary objective of statutory registration of a healthcare profession is to ensure that the practices undertaken by healthcare professionals are safe to the public. In addition, statutory regulation provides a mechanism for the handling and resolution of complaints about registered practitioners.

Besides these direct benefits to the public, statutory registration also provides a mechanism for:

- Establishing and enforcing minimum educational requirements for entry to the profession;
- Enabling members of the public to identify and locate adequately qualified practitioners;
- Setting enforceable standards of professional practice and ethics;
- Regulating false and misleading advertising; and
- Identifying bona fide practitioners for the purposes of health workforce data collection, professional cooperation, and clinical research.

Each of these aspects confers a direct or indirect benefit on consumers. Chinese medicine is a well defined and well established profession, its practice is associated with significant risks when undertaken by poorly trained individuals, and a successful system of registration is operating in the State of Victoria which has demonstrated effectiveness in protecting public safety over the last eight years.

The RMIT University School of Health Sciences currently offers undergraduate and postgraduate programs in Chinese medicine that provide a professional standard of education and training and are approved by the Chinese Medicine Registration Board of Victoria. In addition, the Division of Chinese Medicine has an active and productive research program that currently involves around thirty post-graduates students and twenty academic staff including three professors. In recognition of its research and educational contributions RMIT University has been designated a World Health Organization Collaborating Centre for Traditional Medicine. In 2008, the contributions of RMIT University were recognised by the World Federation of Chinese Medicine Societies which presented out university with one of the two inaugural International Contribution Awards to Chinese Medicine. .

3 Introduction

3.1 Nomenclature: Traditional Chinese Medicine and Chinese Medicine

There has been ongoing debate within the profession about the appropriateness of using the term "Traditional Chinese Medicine" (TCM) instead of the briefer phrase "Chinese Medicine" (CM). In general, the trend is towards the use of "Chinese Medicine". Firstly, "Chinese Medicine" is a more literal translation of the original Chinese characters. Secondly, in a significant number of diseases the treatment options have been influenced by Western medical investigations and diagnosis as well as the results of experimental and clinical studies employing modern research methods. This is not "traditional" knowledge so it can be

argued that "traditional" is misleading and that current best practice is now "modern" Chinese medicine. On the other hand, the term Traditional Chinese Medicine remains in common use in Australia and internationally, is currently used by the Australian Government and is the English equivalent used by the People's Republic of China in their own translations of titles of governmental organisations. It can also be argued that, retaining the use of TCM is respectful of the origins of the profession and recognises the importance of traditional theory in modern clinical practice. Acupuncture is included in the theory and practice of this profession.

In Victoria, the term used in legislation is Chinese Medicine. This is considered synonymous with Traditional Chinese Medicine and encompasses Chinese herbal medicine and acupuncture as well as a number of other health care practices. In this document, Chinese Medicine (CM) is the preferred term.

3.2 The Usage of Chinese Medicine

In China, CM practice has been fully integrated into the national health care system with traditional herbal therapies reported to represent 30% to 50% of total national medication consumption [2]. Statistics from the Ministry of Health of the People's Republic of China indicated that in 2006, there were 2,665 CM hospitals and over 216,452 registered Chinese medicine practitioners in China [3]. Overall, it has been suggested about 40% of total healthcare in China is provided by CM practitioners [4].

In a nationwide survey conducted in Australia in 2005, Xue and colleagues estimated that nearly 1 in 5 Australians used Chinese medicine over a 12-month period and over 10 million visits were made to acupuncturists nationally each year. Most of the acupuncture users were born in Australia, had completed post-secondary education and, were covered by private health insurance. Approximately 7% Australians used Chinese herbal medicine over a 12-month period and over 2.1 million visits were made to Chinese herbal medicine practitioners nationally in that year [5].

In the past several decades, Chinese medicine has become a formal part of the healthcare systems of a number of Asian countries and, more recently, it has been gaining acceptance in western countries as a therapeutic alternative or adjunct to conventional western medicine. In recent years, the integration of acupuncture into conventional medical settings in the western countries is increasingly common.

In Victoria, more than 1,000 Chinese medicine practitioners are registered with the Chinese Medicine Registration Board. Acupuncture has been widely accepted by Australians as well as general medical doctors. Cohen and colleagues (2005) found that acupuncture was considered one of the three most popular forms of complementary medicine used by medical doctors personally (12%), and nearly one in five (18%) of them practised acupuncture. In addition, over three-quarters (76%) of medical doctors referred their patients to acupuncturists at least once a month [6]. Overall, the evidence suggests that both acupuncture and Chinese herbal medicine have been growing practices and have a considerable degree of community acceptance.

3.3 Evidence for the Efficacy of Chinese Medicine

In the last ten years, at least 30 randomised controlled clinical trials (RCT) on CM have been published in leading medical journals with Science Citation Index (SCI) impact factors higher than 5.0 (based on the 2006 SCI list). These studies included acupuncture for migraine, headache, osteoarthritis of the knee, cocaine addition or dependence, pain due to HIV-related peripheral neuropathy, emesis, fibromyalgia, neck pain, pelvic girdle pain, low back pain, itch, acute stroke, subacute stroke rehabilitation, nicotine withdrawal symptoms and hypertension. Chinese herbal medicine studies have evaluated its effect on hepatitis C, irritable bowel syndrome and moderate to severe allergic asthma. There were also studies

that used acupuncture and Chinese herbal medicine for seasonal allergic rhinitis [7-9], and moxibustion for correction of breech presentation of the foetus [10].

With the ongoing development of evidence-based approaches to Chinese medicine, systematic reviews of the clinical trial literature have become feasible. These include Cochrane reviews on the effectiveness of acupuncture for a number of clinical conditions, such as depression, induction of labour, lateral elbow pain, shoulder pain and fibromyalgia [11-14]. All these reviews are available to the public via the Cochrane Library. Even though the number of clinical studies on one condition remain, in many cases, too small to allow conclusive recommendations, some of the reviews provide promising evidence for the effectiveness of acupuncture for specific conditions, such as pain from neck disorders and idiopathic headache and nausea associated with chemotherapy [15-17]. Reviews on Chinese herbal medicine have found some positive evidence in a number of disorders including type 2 diabetes, acute pancreatitis, hepatitis B, chemotherapy side effects and primary dysmenorrhoea [18-27].

Australian researchers have made considerable contributions to the generation of systematic reviews for acupuncture and Chinese herbal medicine. In 2006, a systematic review by researchers from RMIT concluded, based on a number of well-designed clinical trials, that there is evidence to support the use of acupuncture for the symptomatic treatment of allergic rhinitis [8]. Also in 2006, based on 25 studies with a total of 3,004 patients, Scott and colleagues from the Gold Coast Hospital in Southport, Queensland found that acupuncture was significantly better than waiting list (no treatment) and at least as good as the effect of several routinely used drugs for the treatment and prevention of migraine [28]. Consistent with these findings, Wang and colleagues (2008) conducted a systematic review of 17 studies conducted in China with a total of 2,097 participants, and found that there was moderate evidence that acupuncture was more effective for migraine than western pharmacotherapy [29]. An RCT involving 593 women with nausea and vomiting in early pregnancy showed that women receiving acupuncture had less nausea ($p < 0.01$) throughout the trial and less dry retching ($p < 0.01$) from the second week compared with women who did not receive acupuncture treatment [30]. Recently, this group completed another RCT to evaluate the effects of acupuncture on pregnancy rates for women undergoing embryo transfer [31]. Based on the outcomes of 228 patients, the pregnancy rate was 31% in the acupuncture group, compared with 23% in the control group. In addition, the ongoing pregnancy rate at 18 weeks was higher in the treatment group (28%) than in the control group (18%). A recent review published in the British Medical Journal concluded that acupuncture increased the odds of clinically-confirmed pregnancy by 65% compared with the control groups [32].

There is a growing body of evidence for the clinical benefits of Chinese Medicine therapies. Concurrently, Chinese Medicine is receiving greater acceptance in the community and should be regarded as an important component of the health care system. In order to be able to safely avail themselves of Chinese Medicine services, consumers need to be confident that this profession is properly regulated, its practitioners have received adequate training, and there are effective mechanisms in place to manage the risks associated with unsafe and unethical practice.

3.4 Overview of Reports into the Regulation of Chinese medicine in Australia

Mutual recognition legislation was introduced across all States and Territories in the early 1990s. Consequently a clear policy that provided a rationale for the occupational regulation of the health professions was required. Since 1995 the Australian Health Ministers' Advisory Council (AHMAC) has taken a consensus view that the occupational regulation of an unregulated profession is to proceed only if agreed by a majority of jurisdictions, and only if

the profession meets specific criteria designed to facilitate the process of regulatory assessment.

In 1996, the AHMAC agreed that the Victorian Government should lead a review of the practice of Chinese Medicine to determine whether occupational regulation was required and what, if any, form this should take. The report "Towards a Safer Choice" was published in November 1996 [33]. It addressed the AHMAC criteria for CM, and found that significant risks occurred in practice and that occupational regulation was appropriate for this profession. The Victorian Government established a Ministerial Advisory Committee and called for submissions on what form occupational registration should take. The results of this process, including discussion of various regulatory models, were detailed in the Report on Options for Regulation of Practitioners released in July 1998 [34].

Statutory registration was the recommended model so the Victorian Government passed the Chinese Medicine Registration Act in 2000 with bipartisan support. Since this time the Chinese Medicine Registration Board of Victoria has been registering Chinese herbal medicine practitioners, acupuncturists and dispensers of Chinese herbs and conducting investigations into complaints about registrants' professional conduct or fitness to practice.

In September 2002, the New South Wales (NSW) Department of Health issued a discussion paper on regulation of complementary health practitioners [35]. Comments were invited and submissions were received up to mid-April 2003. In 2005 The Committee on the Health Care Complaints Commission issued a Report into Traditional Chinese Medicine which recommended the registration of Chinese medicine practitioners [36]. In a subsequent report "Review of the 1998 Report into 'Unregistered Health Practitioners: The Adequacy and Appropriateness of Current Mechanisms for Resolving Complaints'" in 2006 [37] the Committee again recommended:

"That legislation be passed in New South Wales to register practitioners of Traditional Chinese Medicine in the divisions of acupuncturist, Chinese herbal practitioner and Chinese herbal dispenser, as recommended in the Committee's November 2005 Report" (Recommendation 3).

In May 2003, the Australian Government established the Expert Committee on Complementary Medicines in the Health System to consider the regulatory, health system and industry structures necessary to ensure that the objectives of the National Medicines Policy (NMP) were met in relation to complementary medicines. The Expert Committee issued its report in September 2003 in which it made recommendations regarding occupational regulation of TCM [38]. The Australian Government issued its response to the report in March 2005 [39].

In 2005 the Western Australian Minister for Health issued a discussion paper as part of a consultation process into the regulation of Chinese medicine practitioners [40]. The purpose of the consultation process was to seek comment on a proposed registration framework for Chinese medicine practitioners in Western Australia. This discussion paper explained the key issues and options, and sought the views of interested groups and individuals. The results of this consultation have yet to be released.

3.5 Key Recommendations of Existing Reports

The reviews of Chinese medicine conducted by governments in two states (Victoria, New South Wales) and by the Australian Government have reached the conclusion that Chinese medicine practitioners should be registered.

The Expert Committee on Complementary Medicines in the Health System (2003) and the Australian Government's response to this national report (2004) both took the same view [38, 39]. The recommendations of the Expert Committee were as follows: