



澳洲全國中醫藥針灸學會聯合會

FCMA

Federation of Chinese Medicine
& Acupuncture Societies of
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21st September 2008

Ms Megan Cahill
Chair, Health Workforce Principal Committee
HWPC Secretariat
Level 12/120 Spencer St
Melbourne, Vic 3000

Dear Ms Cahill

I am writing in relation to the Intergovernmental Agreement for a National Registration and Accreditation Scheme for Health Professions that was signed in March 2008. In this letter, you have stated that there is provision in the Agreement for those partially regulated professions such as Chinese medicine to be considered for inclusion in the national scheme.

On behalf of the Federation of Chinese Medicine and Acupuncture Societies of Australia (FCMA), I strongly advocate the inclusion of Chinese medicine into the new national scheme, which should be implemented as early as possible.

As you are aware, factors that originally led to a decision by the Victoria Government to review the need for statutory regulation of Chinese medicine included a perceived significant increase in demand for and use of Chinese medicine by Victorians and complaints received by the Victorian Department of Human Services (DHS) concerning use of herbal medicines¹. A Working Group of the Australian Health Ministers' Advisory Committee (AHMAC) was reconvened to examine the need for regulation of the practice of Chinese medicine. The AHMAC agreed that no state should agree to register a new health occupation without agreement from the majority of states. A Traditional Chinese Medicine (TCM) Review Committee was formed to oversee and guide a review of Chinese medicine that was ultimately conducted by University of Western Sydney and Southern Cross University in 1995. Extensive consultations with relevant stakeholders were conducted including professional associations representing Chinese medicine practitioners, senior officers of the Victorian DHS and New South Wales and Queensland Health departments, the Commonwealth Therapeutic Goods Administration, Australian Quarantine Inspection Service, importers of Chinese medicine, senior executives from the State

¹ Bensousan A, Myers S (1996), *Towards A Safer Choice*, University of Western Sydney: Macarthur.

Administration of Traditional Chinese Medicine and several overseas experts. This culminated in the publication, *Towards A Safer Choice*¹, that provided detailed information on the workforce, benefits and risks of Chinese medicine, the evidence base of Chinese medicine and Chinese medicine education. The report concluded that some activities within the practice of Chinese medicine pose a significant risk of harm and that existing regulatory mechanisms were inadequate to protect the public. The report recommended that it was appropriate that Health Ministers regulate the practice of Chinese medicine and that the benefits of statutory occupational regulation outweighed the potential negative impacts. The report further recommended that the focus of this statutory regulation be “protection of the public by ensuring practitioners have adequate qualifications for safe and competent practice”². In September 1997, the Victorian Ministerial Advisory Committee on Traditional Chinese Medicine (TCM) published a discussion paper entitled *Traditional Chinese Medicine: Options for Regulation of Practitioners Discussion Paper September 1997*. In July 1998 it was agreed at the Australian Health Ministers’ Conference that Victoria develop legislation for the regulation of Chinese medicine and convene a working group with both state and national (commonwealth) representation to consult with stakeholders. The *Chinese Medicine Registration Act 2000* was ultimately passed.

Thus, there has already been extensive investigation into the need for statutory regulation of Chinese medicine at a national level, via an AHMAC- agreed process. The evidence that lead to a decision to regulate Chinese medicine in the state of Victoria is as valid and relevant today as it was over ten years ago, if not more so. There are more practitioners of Chinese medicine in 2008. Evidence from the Chinese Medicine Registration Board of Victoria strongly supports the role of statutory regulation in protecting the public.

In further arguing why Chinese medicine should be included in the new national Registration scheme, the remainder of this letter will specifically address the six criteria set out in Attachment B of your letter.

Yours sincerely



Professor Tzi Chiang Lin
National President
Federation of Chinese Medicine and Acupuncture Societies of Australia

² Bensousan A, Myers S (1996), *Towards A Safer Choice*, University of Western Sydney: Macarthur, p. 252.

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?

Chinese medicine clearly falls within the domain of the Ministry for Health.

Criterion 2: Do the activities of the occupation pose a significant risk of harm to the health and safety of the public?

The risks associated with Traditional Chinese Medicine practice are set out in Chapter 4 of the publication *Towards A Safer Choice* and include risks associated with acupuncture and those associated with Chinese herbal medicine. Risks associated with acupuncture include: local and systemic infections transferred via unsterile needles, local trauma due to the needle and its location, and patient responses including fainting, nausea and vomiting³. Several reports of infections have been recorded in the literatures with the most concerning being systemic infections including: endocarditis, septicaemia, hepatitis B, HIV, myositis, peritonitis, osteomyelitis, and pleuraempyema. Other trauma-related injuries reported, according to the *Towards a Safer Choice* report include pneumothorax, nerve damage, deep vein thrombosis and auricular chondritis, to name a few. Other more unpredictable reactions include increased pain, hypotension, insomnia and allergic reactions to the needle materials. There have been several Australian cases associated with serious adverse effects of acupuncture including a woman in Perth dying of septicemia and cases of pneumothorax. A survey of Australian Chinese medicine and medical acupuncture practitioners found a reported total of 3177 adverse events related to acupuncture over a life-time of practice which when extrapolated to the total Chinese medicine workforce, was estimated at 11975 adverse events⁴. Obviously acupuncture could also pose a risk to the practitioner who is inadequately trained and who does not follow standard infection control procedures. For example, diseases such as HIV-AIDS and Hepatitis B and C are potentially able to be transmitted through needle-stick injury to a practitioner.

The survey also found that the total number of reported adverse events related to Chinese herbal medicine in a lifetime of practice was 843, which, when extrapolated to the total TCM workforce was 2355 adverse events⁵. There are significant risks associated with the incorrect practice of Chinese herbal medicine. Chinese herbs are typically prescribed in a formula of 2-12 different herbs. Certain herbs should not be prescribed together since they may produce undesirable side effects, and certain herbs are contraindicated concurrently with particular western pharmaceuticals since they may cause serious adverse effects. Adverse events have also been reported in association with overdose of particular herbs. Other adverse events reported in the literature include poisoning due to inherent toxicity of certain herbs.

³ Bensousan A, Myers S (1996), *Towards A Safer Choice*, University of Western Sydney: Macarthur, p. 73.

⁴ Bensousan A, Myers S (1996), *Towards A Safer Choice*, University of Western Sydney: Macarthur, p. 80.

⁵ Bensousan A, Myers S (1996), *Towards A Safer Choice*, University of Western Sydney: Macarthur, p. 77.

In terms of how common risks associated with Chinese medicine are, it was estimated that the number of adverse events per year of full time practice for medical and non-medical TCM practitioners was 1.5 (Std dev 2.7) and 1.1 (Std Dev 1.9) respectively.

Risks to the public associated with clinical practice include those common to other health professions including those associated with unprofessional conduct. The number of complaints about Chinese medicine practitioners received by the Chinese Medicine Registration Board (CMRB) of Victoria over the period of 2202/2003 to 2007/2008 totals 120, averaging 20 per year⁶. In 2007/2008, of the 30 complaints against practitioners, seven resulted in prosecution, one is being investigated by the police, and one resulted in registration suspension or removal⁶. The nature of the complaints has ranged from use of misleading advertising, inappropriate clinical management, to conduct or behaviour issues and more serious misdemeanors including infection control breaches, fraud, sexual misconduct or impropriety⁶. Thus, the CMRB and statutory regulation have played an important role in protection of the public.

Criterion 3: Do existing regulatory or other mechanisms fail to address health and safety issues?

The adverse events relating to acupuncture reported in *Towards A Safer Choice*, occurred within the context of existing state-based infection control legislation including regulations governing skin penetration. Whilst the states and territories have infection control guidelines and regulations in place, the risk of adverse events is likely to relate to standards of practice and standards of education, which are not factors under the control of infection control regulations. Thus, existence of such regulations relating to skin penetration are unlikely to be able to address health and safety issues fully. A body to which professionals are accountable to is necessary.

How safe a practitioner is in practice is likely to depend on quality of education. Whilst there has been a trend in Australian Chinese medicine education towards Bachelor degree level training in Chinese medicine in relatively recent years, undergraduate training varies across Australia. This is likely to be true in particular for medical acupuncture training, which is *substantially* shorter in terms of length of training and substantially less in terms of content, than training undertaken by traditional Chinese medicine practitioners. In Victoria, approval of courses in Chinese medicine for the purposes of registration is a responsibility of the CMRB of Victoria. The CMRB has set a high standard of education, one that is supported by the State Administration of Traditional Chinese Medicine (SATCM) - the government body responsible for Chinese medicine in the P.R. of China. There are several professional associations representing Chinese medicine across Australia, rather than one peak body, with varying interests and abilities to be able to assess education standards in a rigorous and transparent manner. At this point in time, self-regulation of education standards within the profession would be extremely difficult.

⁶ Chinese Medicine Registration Board Annual Report 2007/2008.

It is worth noting that the CMRB has refused over 170 applications for registration, most commonly for inadequate qualifications and training and lack of evidence of competence⁷. Other reasons were related to character issues, in a small number of cases⁷. This is a clear example of the benefit of statutory regulation, in ensuring a high standard of education that in turn helps protect the public.

Victoria is the only state and territory with statutory regulation of Chinese medicine. One result of the passing of the *Chinese Medicine Registration Act 2000* was to provide a mechanism, via changes to the *Drugs Poisons and Controlled Substances Act 1981*, to allow suitably qualified practitioners of Chinese herbal medicine access to established 'tools of their trade', certain potentially toxic Chinese herbs that are commonly used in China but are restricted due to inclusion in the National SUSDP and in Victoria, the Victorian Poisons List. The CMRB have developed monographs of particular herbs to be presented to the Minister for Health for consideration of inclusion in Schedule 1 of the Victorian Poisons List in the near future. However, such a mechanism is only applicable to the state of Victoria. Inclusion of Chinese medicine in the new National Registration Scheme would introduce parity across all states including standards of training required of practitioners to be able to access, sell and supply such Scheduled herbs. This would then contribute to improved public safety.

Criterion 4: Is regulation possible to implement for the occupation in question?

Regulation is possible as the profession of Chinese medicine is well-defined, and has a body of knowledge that can form the basis of its standards of practice which is teachable and testable. In Australia, the majority of training courses in Chinese medicine are Bachelor degree level training, delivered in major Australian universities and within privately operated education institutions. Functional competencies are defined for courses within Universities and privately operated education institutions (which must apply to state-based government higher education departments for accreditation).

Membership of the two major professional associations representing Chinese medicine and acupuncture practitioners in Australia is dependent on demonstrating an adequate level of education in Chinese medicine. The FCMA requires members to have a minimum of a Bachelor degree level training or the equivalent, and has provision for recognition of overseas courses accredited and recognized by relevant government bodies of that country (for example, degrees in Chinese universities) and more traditional modes of training including the master-disciple training. The market has essentially determined that a minimum level of training is now Bachelor degree level in Australia.

Criterion 5: Is regulation practical to implement for the occupation in question?

A form of self-regulation already exists within Chinese medicine, however it is essentially fractionated with several professional associations representing Chinese medicine practitioners across the country. Thus, self-regulation within the Australian Chinese medicine profession context is clearly not as practical as statutory regulation,

⁷ Personal communication Registrar Chinese Medicine Registration Board of Victoria, 18 September 2008.

since standards of practice, ability to assess education qualifications and ability to enforce standards are unlikely to be equivalent across associations. Implementation of statutory regulation has clearly been demonstrated to be practical within the state of Victoria. The next logical step is statutory regulation nation-wide. Regulation under the new National Registration and Accreditation Scheme for Health Professions would be entirely practicable.

Criterion 6 Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?

The experience in Victoria suggests that the benefits of statutory regulation to the public clearly outweigh any potential negative impact of such regulation. There is more than adequate evidence from the *Towards a Safer Choice* report that Chinese medicine (including acupuncture and Chinese herbal medicine) needs to be practiced by competent practitioners, and that in inadequately trained hands, there lies great for harm to the public. In addition, the evidence provided by the Chinese Medicine Registration Board clearly demonstrates the important role of the Board in maintaining standards of practice and ensuring mechanisms by which the public may seek recourse in cases where professional standards have been lacking. Some examples of mechanisms by which standards of practice are guided and ensured include provision of guidelines for educational courses that provide training in Chinese medicine and acupuncture for the purposes of registration, and provision of various guidelines on advertising, the practice of Chinese herbal medicine and acupuncture. It is difficult to argue that there is any real detrimental impact of statutory regulation for the profession of Chinese medicine in Australia.