

National Regulation of Chinese Medicine Practice

October 2008

A Submission to

Australian Health Ministers' Advisory Council for Unregulated Health Occupations

ATTENTION: Practitioner Regulation Subcommittee
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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. It is appropriate for the Health Minister to exercise responsibility for regulating the occupation of Chinese medicine, which includes the practice of Acupuncture and Chinese herbal medicine. The occupation of Chinese medicine falls appropriately within the domain of the Ministry of Health as the practice is to deliver primary health care.

Criterion 2

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

Yes. The activities of the practice of Chinese medicine pose significant risk of harm to the health and safety of the public. Significant risks associated with the practice of Chinese medicine are evidenced by a number of reports, including the Victorian government report, 'Towards a safer choice: the practice of traditional Chinese medicine in Australia' [1].

2.1 The nature and severity of the risk to the client group.

An Australian Workforce Survey Data on adverse events in Chinese herbal medicine and acupuncture was conducted as part of the Victorian report by Bensoussan & Myers [1]. The results were compiled based on three Australian states, which included Victoria, New South Wales and Queensland. Due to no statutory regulation governing the practice of Chinese medicine, except in the State of Victoria, the results from the study cannot provide an accurate account of all adverse events occurring in Australia during this time. However, the study does provide some indication of possible significant harm to the client group.

2.1.1 Risks associated with Chinese herbal medicine

Bensoussan & Myers [1] acknowledge it is impossible to estimate the rate of adverse events for Chinese Herbal Medicine since the total exposure to a particular medicinal substance is unknown. The most common adverse events reported from Chinese herbal medicine by Bensoussan & Myers [1] were severe gastrointestinal symptoms (number (n) =124), fainting and dizziness (n=119) and significant skin reactions (n=110). Serious adverse events reported included central nervous system effects (n=37), hepatotoxicity (n=29), renal toxicity (n=28) and death (n=19).

Furthermore, the Workforce Survey identified practitioners having prescribed a number of scheduled or restricted substances [1]. The data suggested that these identified substances and their frequency of usage in practice are relatively widely used by Chinese herbalists. As existing government regulations are not able to effectively enforce prohibitions on the use of scheduled or restricted Chinese herbal substances at this time, so it may be assumed that significant risk of potential harm from Chinese herbal medicines to the client group remains.

2.1.2 Risks associated with Acupuncture

Bensoussan & Myers [1] further state that accurate numerical estimates of the risks associated with acupuncture is not possible due to the total exposure of the practice being unknown, and therefore associated risks are likely to be under reported. Bensoussan & Myers [1] identify predictable reactions from acupuncture include local and systemic infections transferred via unsterile needles, local trauma due to the needle and its location and adverse patient effects including fainting, nausea and vomiting. Unpredictable reactions are identified as including allergic reactions to the material in the needle, depression, insomnia, convulsions, hypotension, menstrual disturbance and increased pain. Furthermore, it was identified that numerous reports of trauma-related injuries from acupuncture have occurred including, pneumothorax (single and bilateral), spinal cord injuries, fatal and non-fatal cardiac tamponade, pseudoaneurysm, deep vein thrombosis, nerve damage and others. In addition, sustained burns from moxibustion or use of heat lamps, and severe bruising from cupping has also been reported. Other areas of identified risks associated with acupuncture include the use of electrical acupuncture stimulators that are contraindicated in patients who have a pacemaker device, or have epilepsy, or other severe cardiac conditions due to exacerbation of conditions and potential significant harm likely.

Significant adverse events from acupuncture in Australia have been identified by Bensoussan & Myers [1], that warranted coronial or legal examination:

- A patient in NSW in 1984 who is believed to have stopped taking his Western medications after visiting an acupuncturist. The patient later died of status asthmaticus;
- A 34 year women in Perth in 1995 who died of septicaemia arising from necrotising fasciitis after receiving acupuncture for neck pain. The case implied that the acupuncture had introduced infection from the skin into deeper tissues, and the Coroner found that this occurred despite correct sterile technique;
- An acupuncturist in Sydney in 1990 used over 70 cups at one time on a patient, resulting in blistering and reddening over a large proportion of the patient's back;
- A patient in Sydney in 1986 had an acupuncture needle with its top removed inserted and this became lodged in a muscle of her back. Several operations were needed to remove it, and she suffered significant amount of pain and depression; and
- Other Australian cases reported have included pneumothorax, broken needle travelling to the peritoneal cavity, and severe exacerbations of asthma.

A study of adverse event rates for acupuncture practitioners found that the adverse event rates were higher for practitioners with less than 12 months of complementary and alternative medicine (CAM) education compared to those who had between 37 and 60 months of CAM education [2]. This may suggest that level of statutory regulation of education for practice of Chinese medicine, specifically acupuncture, may contribute to minimising adverse events of the practice.

2.2 The nature and severity of the risk to the wider public

Lack of regulatory practices to ensure adequate disposal of materials/ equipment utilised during Chinese medicine practice is a major potential source of risk to the wider public. Used acupuncture needles and infectious waste material including those from Acupuncture practice are a likely source of possible infection and injury. Adequate regulatory standards to ensure an appropriate minimum standard of education and training concerning safe hygiene practices are necessary in order to minimise potential risk to the wider public.

2.3 The nature and severity of the risk to the practitioner

The practice of acupuncture presents as a possible significant risk to the practitioner via exposure to blood and body fluids. Adequate levels of education and training concerning safe and hygienic practice of acupuncture may substantially minimise potential risk to the practitioner.

Criterion 3

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

Yes, existing statutory and non-statutory regulatory mechanisms fail to address the health and safety issues specifically related to Chinese medicine practice. Current regulations in place include:

Acupuncture:

- Skin Penetrations Regulations
- Professional Associations

Chinese herbal medicine:

- Therapeutic Goods Regulations
- Poisons Regulations
- Professional Associations

In each of these cases the degree to which existing regulatory mechanisms can effectively address risks to consumers is limited, since none of these mechanisms ensure a minimum standard of education and training for practitioners.

3.1 Are health and safety issues addressed through other regulations?

The above listed regulations are inadequate based on the inconsistencies between State governments to monitor and regulate the practice of Chinese medicine effectively. Currently, the State of Victoria is the only State to have government statutory regulation of Chinese medicine

practice. All concerns regarding Chinese medicine practice are referred and investigated under the Chinese Medicine Registration Board of Victoria (CMRBV) and actions including prosecutions, if necessary, are sought. Clearly, this highlights the benefit of regulating the practice of Chinese medicine in Australia, as greater regulatory monitoring and enforcement can be achieved that reduces possible harm to individuals, including inappropriate or false advertising that misleads the public. Due to the varying roles and responsibilities of local government to enforce such regulations, adequate regulation of the practice of Chinese medicine is not provided to provide adequate health and safety of the practice.

3.2 Are health and safety issues addressed through supervision by registered practitioners of a related occupation?

Chinese medicine is a unique and highly skilled practice that is not able to be supervised by other registered practitioners of a related occupation.

3.3 Are health and safety issues addressed through self regulation by the occupation?

Self regulation by the occupation does not present an appropriate option that would suitably protect the public from potential risk of harm. At present, there are numerous professional associations, however there is not one organisation that represents the entire profession. Membership of these associations is voluntary, therefore practitioners may choose not to belong to any association. In addition, if a member is non-compliant and hence is expelled from an organisation, they are then able to join another association that will have no prior knowledge of possible misconduct of behaviour or practice that may have caused significant risk or harm to the public.

Criterion 4

Is regulation possible to implement for the occupation in question?

Yes. In the State of Victoria, the CMRBV was enacted through the Chinese Medicine Registration Act (Victoria) 2000. This legislation provides government regulation of the practice of Chinese medicine, including Acupuncture and Chinese herbal medicine. This demonstrates that ability for regulation to be implemented for the practice of Chinese medicine.

4.1 Is the occupation well defined?

Yes. The occupation of Chinese medicine is well defined and documented in numerous texts translated from Chinese into English.

4.2 Does the occupation have a body of knowledge that can form the basis of its standards of practice?

Chinese medicine is premised on philosophy and clear guiding principles that include specific diagnostic and therapeutic interventions that primarily involve Acupuncture and Chinese herbal medicine.

4.3 Is this body of knowledge, with the skills and abilities necessary to apply the knowledge, teachable and testable?

Yes. Various government and non-government funded courses exist in Australia that are teachable and testable, based on both written and practical components.

4.4 Where applicable, have functional competencies been defined?

Yes. Two functional competencies have been developed in Australia, completed by the Acupuncture Steering Committee [3] and the Federation of Natural and Traditional Therapists [4]. In Victoria, all accredited courses are at a Bachelor degree, hence these functional competencies are now incorporated as part of obtaining these qualifications.

4.5 Do the members of the occupation require core and government accredited qualification?

Yes, however this is applicable to Victorian Chinese medicine practitioners only. Victoria has successfully endorsed government accredited qualifications required to practice Chinese medicine, following the introduction of the Chinese Medicine Registration Act (2000), requiring minimum standard of education to ensure safe practice of Chinese medicine. This Act has been developed to reduce the risk of harm to the public.

Criterion 5

Is regulation practical to implement for the occupation in question?

Yes. The CMRBV was enacted in the year 2000 to register Chinese herbal medicine practitioners, acupuncturists and persons dispensing Chinese herbal medicine. This suggests that regulation of Chinese medicine is practical.

5.1 Are self regulation and/ or other alternatives to registration practical to implement in relation to the occupation in question

No. Self regulation of Chinese medicine is a voluntary process, therefore does not require practitioners to become a member, and hence does not ensure that practitioners claiming to be qualified practitioners are in fact appropriately qualified (except State of Victoria). As a consequence, ensuring minimal standards of education and practice that may reduce potential serious risk to public health and safety are not endorsed. In the case of Victoria, there have been 17 formal hearings with 17 prosecutions to date [5] of misconduct of professional practice that may pose significant risk of harm to individuals. Details available from the CMRBV website <http://www.cmr.vic.gov.au>. Furthermore, the CMRBV has the ability to deregister interstate practitioners however, deregistered practitioners have the ability to continue to practice where there is no legislation to prohibit this, hence practice outside the State of Victoria.

5.2 Does the occupation leadership tend to favour the public interest over occupation self-interest?

Yes. The health and safety of the public is paramount in the delivery of Chinese medicine so there is general agreement that the interests of patients/consumers should come first. This is in accordance with the delivery of all primary health care services. However, self regulatory bodies that may hold alliances with educational bodies or other vested interest groups and may not be able to, or be perceived to, prioritise the public interest over the particular interests of specific interest groups/individuals. If statutory regulation of the practice of Chinese medicine were enacted for all States and Territories of Australia, invested interests would not be able to gain precedence and it would be possible to properly prioritise the public interest over self interest.

5.3 Is there a likelihood that members of the occupation will be organised and seek compliance with regulation from their members

Yes. There is likelihood that members of the Chinese medicine profession would be organised and seek compliance with regulation that would ensure the safety of the public, as this would ensure continuation of a unique profession that requires considerable investment on behalf of its practitioners.

5.4 Are there sufficient numbers in the occupation and are those people willing to contribute to their costs of statutory regulation?

Yes. In the case of Victoria, there are 1031 registered practitioners in Acupuncture, Chinese herbal medicine and Chinese herbal dispensary [5]. These practitioners contribute to the self funding of the Chinese medicine Registration Board of Victoria.

5.5 Is there an issue of cost recovery in regulation?

No. The CMRBV utilise annual registration fees as the main source of funding of the board.

5.6 Do all governments agree with the proposal for regulation?

Uncertain. Victoria is currently the only state that has implemented legislation to regulate the practice of Chinese medicine. Western Australia and New South Wales have compiled discussion papers on the regulation of practitioners of Chinese Medicine in Western Australia, however no legislative endorsement of regulation has been enacted to date.

Criterion 6

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

Yes. Significant risk has been identified with the practice of Chinese medicine. Therefore, any reduction in the risk of harm to the public by regulating Chinese medicine practice clearly outweighs any potential negative impact of its regulation. The regulation of Chinese medicine practice would be in accordance with numerous other professions that have been required to be regulated due to significant potential harm. Professions such as chiropractic have been demonstrated to be risky, and are likely to be less risky than Chinese medicine, but following registration and the consequent improvements in education, training and practice, these risks that practitioners present to the public have been greatly reduced.

There are many benefits to the public if registration of Chinese medicine practice be implemented. Appropriate minimal standard of education be obtained by all Chinese medicine practitioners that research has shown (as above) to reduce adverse effects of Chinese medicine practice. Advertising of Chinese medicine practice that may be false or misleading would be effectively controlled with statutory regulation.

Research shows there has been an increasing popularity of the use of complementary and alternative medicine in Australia. Xue et al. [6] study identified that in many cases Western Medical doctors did not appear to be aware that their patients were using CAM. In the study, it was reported that a high proportion of participants used CAM and conventional medicinal services concurrently, and that many CAM users did not inform their medical practitioners (and the doctors did not ask) about their use of CAM. These findings are of concern, given the increasing number of reports of side effects of CAM products. If the practice of Chinese medicine were to be regulated, this may support freedom of choice in health care that minimises potential significant risk of harm.

References

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