

Traditional Chinese Medicine
*Report on Options for
Regulation of Practitioners*

*Victorian Ministerial
Advisory Committee
July 1998*

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Foreword

Traditional Chinese Medicine (TCM) has become increasingly popular throughout Australia over recent years, and its practice now represents a significant component of the total health care industry. The evidence is that this trend will continue, and that more and more Australians will see TCM as playing an important role in maintaining their health. This report completes the second stage of the review of the practice of Traditional Chinese Medicine initiated by the Victorian Department of Human Services in August 1995. The first stage was completed with the launch, in November 1996, of the report *Towards a Safer Choice*.

It is essential that the practice of TCM be safe to the public. This requires that TCM training be of a high standard, that the public and other health care practitioners are easily able to identify practitioners who are well qualified, and that consumers have access to effective mechanisms to deal with any complaints that may arise. Two key models were set out in the Discussion Paper released in September 1997, and were canvassed in the public consultation process that followed. The first is self-regulation through an independent body established cooperatively by professional associations of TCM. The other involves setting up registration boards under State and Territory legislation, similar to those that register medical practitioners, nurses, physiotherapists, chiropractors, and various other health care practitioners.

National Competition Policy requires that any new regulatory measure that might restrict competition must demonstrate that the benefits of the restriction to the community as a whole outweigh the costs, and that the objectives of the legislation can only be achieved by restricting competition. Thus, before adopting the recommendations of this report, State and Territory Health Ministers must be satisfied that self-regulation is not an effective option. The Committee believes that the most effective option for protecting the public is regulation through statutory registration, and the report documents a significant convergence of views on this. Untrained, unregulated practice of TCM poses significant risks to public health, and without regulation, these risks are likely to increase. It is the Committee's view that TCM should be subject to the same standards, models and systems that apply to other health care occupations which require government regulation to protect the public.

While the Committee recognises the limitations in addressing only one of the 'complementary therapies', there is little support for an approach which lumps together all those therapies labelled 'alternative' or 'complementary'. Each should be examined on its merits. In the area of TCM, we believe we have made a significant step forward. This stage of the review has included a lengthy consultation process, and I am confident that all parties with an interest have had ample opportunity to consider the proposals and have their views heard. The cooperation from the TCM profession has been exemplary. I wish to thank all those who have freely given their time and, at their own expense, travelled long distances to participate in the Ministerial Advisory Committee and its sub-committees. There has been enormous support for the review process, with substantial interest from the media. This reflects, I believe, an interest within the community in seeing this form of medicine widely and safely available.

I commend this report and its recommendations to you.

Mr Robert Doyle MP

Parliamentary Secretary to the Victorian Minister for Health

Chair, Victorian Ministerial Advisory Committee on Traditional Chinese Medicine



Executive Summary

Background and Context

This report of the Victorian Ministerial Advisory Committee on Traditional Chinese Medicine completes the second stage of the review of the practice of Traditional Chinese Medicine (TCM). The review, which commenced in August 1995, has been undertaken by the Victorian Department of Human Services on behalf of all States and Territories, in response to a rapid expansion of the practice of and demand for TCM in this country and concerns expressed by consumers, practitioners and professional groups.

The first stage of the review was a major research project to collect information on the risks and benefits of TCM and the nature of the TCM workforce, and to consider the need, if any, for registration of the TCM practitioners and regulation of Chinese herbal medicines. The research was carried out by the University of Western Sydney (Macarthur) and Southern Cross University. It resulted in the report *Towards a Safer Choice: The Practice of Traditional Chinese Medicine* and the recommendation to the Australian Health Ministers Advisory Council (AHMAC) and all State and Territory governments that occupational registration of the profession of TCM proceed as a matter of urgency.

AHMAC accepted the recommendation that Victoria take the lead in exploring the feasibility of occupational registration of TCM, and the Ministerial Advisory Committee was formed. Its report, this document, completes the second stage of the review and contains recommendations to the Victorian Minister for Health on a proposal for regulation of TCM. The Minister will advise AHMAC and the Australian Health Ministers Conference on steps required to achieve a suitable regulatory framework for TCM, and implementation will constitute the third stage.

The review takes place in the context of:

- Mutual Recognition as set out in the Commonwealth *Mutual Recognition Act 1992*. Australian Health Ministers have agreed that mutual recognition is an important first step towards agreed national standards for each health occupation.
- National Competition Policy: Any new regulatory measure that might restrict competition must demonstrate first, that the benefits of the restriction to the community as a whole outweigh the costs and second, that the objectives of the legislation can be achieved only by restricting competition.

Towards a Safer Choice recommended occupational registration by statute. Victoria provides a legislative model for such health practitioner legislation, whereby the main privilege of registration is the right to use the relevant title ("protection of title"). The practice of the profession is not protected in this model. The main purpose of this model is to protect the public rather than to protect and promote professional interests.

The report found that the practice of acupuncture and Chinese herbal medicine carry risks, both inherent in the practice itself and associated with poor practitioner training. A significant number of serious adverse events have been reported, and the risks are likely to increase with the expanding use of TCM. Self-reported adverse incidence rates are linked to length of training in TCM. In Australia, the standard of training varies widely, and the profession has no power to enforce standards. The report concluded that on balance, the benefits of promoting public safety through occupational regulation clearly outweigh its potential negative impacts.

Options for Regulation

Self-Regulation, Co-Regulation, and Statutory Regulation

The Ministerial Advisory Committee on TCM approved the release of a Discussion Paper in August 1997. The first question addressed was: should there be legislative regulation of the occupation of TCM, or should less restrictive self-regulatory approaches be adopted?

Difficulties identified in the discussion paper in applying self-regulation to the TCM profession included fragmentation within the profession, lack of agreement on standards, deregulation of education, and the difficulty of creating incentives for voluntary certification.

An extensive public consultation demonstrated that statutory-based occupational registration of TCM practitioners has widespread support from TCM organisations and others, including universities, government and health care complaints bodies. The only dissent came from AMA Victoria, the Australian Medical Acupuncture Society, and the Australian Traditional Medicine Society.

The Committee is of the view that the most effective method of protecting the public is to apply to the profession of TCM the same models of regulation that apply to medicine, nursing, optometry, physiotherapy, and many other apparently less risky and less intrusive health occupations. (See Recommendation 1).

State Versus National Approaches

Options proposed in *Towards a Safer Choice* for administration of a regulatory scheme for TCM practitioners were: a national registration board, State and Territory based registration boards, or a national accreditation body. That report quoted widespread support for a national approach to setting standards of practice. Public submissions confirmed this, but given the constitutional barriers to formation of a single national board, supported State-and Territory-based registration boards.

To achieve a national approach in conjunction with State-and Territory-based boards, standards might be set by either a group of practitioner representatives from the majority of professional associations, or a Victorian Board with interstate practitioner representation. The Committee recognised the constitutional and political barriers to implementation of occupational regulation at a national level, but supported a national process for standard setting. It believes that responsibility for developing standards rests with the profession, and that any initiative to bring together representatives from a broad cross-section of the profession should be supported. (See Recommendations 2, 3, 4 and 5).

Implementation Issues

Constitution and Powers of a TCM Registration Board

Under the Victorian model, registration boards are established under a statute of Parliament, and have a maximum of twelve members. The Committee and the majority of submissions support this model. Registration board membership of approximately seven was the most popular option, although size should reflect workload. The majority of board members should be practitioners. (See Recommendation 6).

Modalities to be Regulated

Both *Towards a Safer Choice* and submissions identified acupuncture and Chinese herbal medicine as the two key modalities to be regulated, as they present significant risks to the public. The Committee believes that further work is needed to determine whether Chinese orthopaedics and manipulation (which includes traumatology) should be added to this list. While this modality has not been as widely practised in Australia, spinal and joint manipulation carries demonstrated risks and, when carried out by other practitioners such as chiropractors or osteopaths, is regulated by at least protection of title legislation. The Committee does not believe that Chinese therapeutic massage presents sufficient risks to the public to warrant regulation via registration. (See Recommendations 7 and 8).

Protection of Title Versus Protection of Practice

Under "protection of title", recommended for TCM by *Towards a Safer Choice*, use of certain titles is restricted to practitioners who have the accredited qualifications and are registered under the relevant Act. The majority of health practitioner Acts in Victoria (including those for medical practitioners, nurses, osteopaths and chiropractors) are of this nature.

Under this model, practice is not protected, and such protection may be difficult to support under National Competition Policy. In the context of TCM, protection of title only would mean that unqualified practitioners would be able to continue their practice of acupuncture, Chinese herbal medicine and/or Chinese orthopaedics or manipulation, but would not be able to use the titles associated with the profession or lead the public to believe that they were qualified and registered.

The Committee, in agreement with most submissions, believes that protection of title is sufficient for TCM, but it sees no practical difficulties should any State or Territory government decide to implement protection of practice via a core practices model.

Complementing protection of title legislation, the Committee believes that:

- prescribing of identified toxic herbs should be restricted to practitioners qualified in Chinese herbal medicine, and a national process should exist for identifying such herbs
- Skin Penetration Regulations should apply only to unregistered practitioners. (See Recommendations 9, 10 and 11).

Prescribing of Scheduled Herbs

TCM practitioners argue that consumer choice is constrained because prescription of certain herbs traditionally used by TCM practitioners is restricted by the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) and State and Territory legislation. Submissions argued the importance to TCM practitioners of scheduled herbs, and the widespread flouting of the law regarding the use of these herbs; the need to involve those with TCM expertise in identifying and classifying the toxicity of herbal medicines for the purpose of scheduling; the availability of toxic herbs to medical, dental and veterinary practitioners unskilled in their use; and the lack of scientific or policy logic in the way herbs are categorised in the SUSDP. Most supported access to scheduled herbs for suitably trained practitioners; this did not include those trained only in the use of patent medicines and/or acupuncture.

The Committee believes that the current restrictions on access to herbs by trained Chinese herbal medicine practitioners should be reviewed and amended, and that a satisfactory model for regulating limited prescribing rights for

scheduled drugs can be found in the *Victorian Optometrists Registration Act 1996*. The Committee recommended application of that model to TCM and recommended review of the scheduling arrangements as they relate to herbal medicines, with the involvement of suitably qualified Chinese herbal medicine practitioners. (See Recommendations 12 and 13).

Regulation of Dispensing of Raw Herbs

At present, raw herbs (other than scheduled herbs) can be dispensed over the counter with no requirements regarding instructions to the user, labelling, age or source of the prescription, or other related safety issues. While herbs are usually dispensed by the practitioner who prescribes them, dispensing is also emerging as a skilled and independent profession, and the Committee believes this development should not be hindered. A TCM registration board could include a mechanism to ensure that dispensers who dispense scheduled herbs are appropriately trained, and could establish standards for dispensing of Chinese herbal medicines. (See Recommendations 14, 15 and 16).

Which Titles Should be Protected?

There continues to be disagreement as to whether the official descriptor of the profession should be "Traditional Chinese Medicine" or "Chinese Medicine". The Committee's view is that both options should be available, and practitioners seeking TCM registration should be able to nominate which they prefer on their registration certificate.

The Committee believes that sufficient titles should be protected to adequately identify the profession and to ensure that a practitioner qualified in one protected modality but not in another cannot use a title that suggests qualifications in both. (See Recommendations 17, 18, 19 and 20).

Approaches to Standard Setting

If occupational registration proceeds, the registration board will be responsible for determining the standard of training required for registration and accrediting courses that meet this standard. Many submissions favoured degree level training as the minimum standard. The Committee anticipates that the forum and process facilitated by the Australian Acupuncture and Chinese Medicine Association may achieve consensus on draft comprehensive standards that can be used as a basis for the accreditation process. In the absence of consensus, it should be the responsibility of a TCM registration board(s) in cooperation with the profession to determine standards of practice and accredit educational courses. (See Recommendation 5).

Grandparenting Arrangements

Where existing practitioners do not hold the qualifications newly prescribed by the registering authority, recognition could be based on membership of an existing professional association, assessment of qualifications, competency-based assessment, further education and training, or standard examination. The Committee believes that a combination of these is appropriate for TCM. Responsibility for determining and implementing guidelines for grandparenting will rest with the TCM registration board(s). (See Recommendation 21).

Non-English Speaking Practitioners

Arbitrary application of a standard of English fluency in the registration of TCM practitioners could discriminate against the significant proportion of TCM practitioners in Australia from non-English speaking backgrounds. These practitioners have argued their safe practice record and important community service.

It is imperative that clients be able to communicate the history and nature of their complaints, and that practitioners be able to understand the information, question the client, and communicate advice and intentions. The Committee believes that legislation for TCM registration should include the power to refuse registration to an applicant whose competency in English is insufficient, but retain the flexibility to recognise and support to continuing safe practice of NESB practitioners. (See Recommendation 22).

Funding of a Regulatory System

Existing registration boards in Victoria are independently incorporated and self-funding. Submissions and the Committee support self-funding. There is every indication that a sufficient number of practitioners are willing to pay registration fees to support the operation of a registration board. A seeding loan from Government may be required for establishment. (See Recommendation 23).

Regulation of Practitioners Registered with Another Board

Complementary therapies, particularly acupuncture, are being offered by increasing numbers of health care practitioners whose primary form of practice is in a discipline other than TCM and who are registered by another board. There is widespread support among health care professional organisations (other than the AMA and AMAS) for their practitioners who use TCM to be required to register with a TCM board. The Committee's view is that:

- Registered medical practitioners have the necessary skills to use the title "Medical Acupuncturist" without registration with a TCM board, given that an agreement between the AMAS and the Health Insurance Commission can be expected to set a reasonable standard of education for these practitioners.
- Other registered health professionals should be exempted from requirements to register with a TCM board provided that they meet education and practice requirements set down by their own registration board, that these standards have been endorsed by the TCM board, and that where a generalist health practitioner registration board investigates a complaint of unprofessional conduct involving the practice of TCM, it has access to TCM expertise. (See Recommendations 24 and 25).

Regulation of Practitioners of Other Forms of Complementary Therapy

Where modalities of TCM are used by practitioners of other complementary therapies for which practitioner registration is not required, these practitioners may, if TCM registration is introduced, seek registration under the same conditions as all primary TCM practitioners. This view is supported both by submissions and by the Committee.

The Committee believes that further work is required to establish whether there is a need for statutory registration of practitioners of Western herbal medicine, including the need for a mechanisms for access by suitably trained practitioners to certain scheduled Western herbal medicines. (See Recommendations 26 and 27).

Regulation of Other Traditions of Acupuncture

Ayurvedic acupuncture (practised in India, Sri Lanka and Tibet) uses a system different from the Chinese.

The Committee believes that TCM registration should be required for Ayurvedic acupuncturists who wish to use the word 'acupuncturist' as part of their title and that, to assist in regulating this practice, the TCM registration board should have the power to co-opt people with relevant expertise from Ayurvedic medicine associations.

Some veterinary surgeons are trained in, and practise, animal acupuncture. They have proposed that practitioners calling themselves 'veterinary acupuncturists' be exempted from registration requirements where they are registered veterinary surgeons, and the Committee sees no problem in this. (See Recommendations 28 and 29).

The Need for Research

The Committee is of the view that there is a need to develop dialogue between researchers in TCM and in Western medicine, in order to explore opportunities to improve the health status of the Australian community through the application of TCM in concert with Western medicine, to ensure adequate protection of the public, and to determine the place of TCM within the health care system. (See Recommendations 30, 31 and 32).



List of Recommendations

Recommendation 1

That statutory based occupational regulation of the profession of TCM be adopted as the most suitable method of setting educational standards, accrediting training courses and protecting the public from untrained or poorly trained practitioners.

Recommendation 2

That statutory registration via State-and Territory-based registration boards be implemented.

Recommendation 3

That State and Territory Health Ministers agree that Victoria take the lead in developing template legislation for statutory registration of TCM practitioners that can be used as a model by other States and Territories, with an implementation timetable to be determined by each State and Territory.

Recommendation 4

That a national approach to accreditation of training courses and setting of standards be supported as a matter of policy.

Recommendation 5

That a representative group from the profession be encouraged to develop consensus guidelines for an appropriate minimum standard of education in both acupuncture and Chinese herbal medicine.

Recommendation 6

That the Victorian model of health practitioner registration be used as a guide in developing template legislation in Victoria for registration of TCM practitioners.

Recommendation 7

That the modalities of acupuncture and Chinese herbal medicine be regulated via statutory registration.

Recommendation 8

That further work be done to determine the most suitable method of regulation of the practice of Chinese orthopaedics and manipulation.

Recommendation 9

That a model of health practitioner registration based on protection of title be adopted as the minimum requirement for regulation of the TCM profession.

Recommendation 10

That the Federal Department of Health and Family Services convene a national process involving bodies such as the Therapeutic Goods Administration, the National Drugs and Poisons Scheduling Committee (NDPSC), the Complementary Medicines Evaluation Committee (CMEC) and suitably qualified representatives from the TCM profession to revise the scheduling arrangements for Chinese herbal medicines, and identify the list of herbs to be included.

Recommendation 11

That State and Territory Skin Penetration Regulations continue to apply only to those practitioners who use acupuncture and are not registered with either a TCM registration board or other registration board that has set standards of practice for acupuncture in consultation with a TCM registration board.

Recommendation 12

That the Victorian *Optometrists Registration Act 1996* be used as a model for creating powers for within each State and Territory for suitably qualified Chinese herbal medicine practitioners to prescribe scheduled Chinese herbs.

Recommendation 13

That the Commonwealth consider the establishment of a separate schedule of herbs within the SUSDP as one of a number of options for ensuring that herbal substances are more adequately regulated via the scheduling arrangements, and that this review be done in cooperation with those highly trained in Chinese herbal medicine.

Recommendation 14

That the TCM registration board(s) have the power to register suitably qualified dispensers in order to regulate dispensing of scheduled herbal medicines.

Recommendation 15

That the TCM registration board(s), in conjunction with the NDPSC and suitably qualified representatives from the TCM profession, agree on standards that will apply for registration or licensing of those Chinese herbal dispensers who dispense Chinese herbs scheduled under the SUSDP.

Recommendation 16

That the profession be encouraged to establish standards of training and practice and a self-regulatory mechanism for the dispensing of herbal medicines not covered by scheduling arrangements.

Recommendation 17

That the following titles be protected in legislation to register TCM practitioners, and a general clause be included which makes it an offence for unregistered persons to use any other title calculated to induce a belief that the person is registered under a TCM registration Act:

- Chinese Medicine Practitioner or Traditional Chinese Medicine Practitioner
- Traditional Chinese Herbalist or Chinese Herbalist

- Acupuncturist
- Oriental Medicine Practitioner
- Chinese Herbal Dispenser.

Recommendation 18

That the registration certificates issued by a TCM registration board(s) for qualified practitioners should identify which of the following modalities the practitioner is qualified to practice:

- Acupuncture
- Chinese herbal medicine
- Chinese herbal dispensing.

Recommendation 19

That practitioners registered by a TCM registration board be given a choice as to whether 'Practitioner of Traditional Chinese Medicine' or 'Practitioner of Chinese Medicine' is listed in the title on their registration certificate.

Recommendation 20

That further work be done to establish whether there is a need to protect an additional title, that of Practitioner of Chinese Orthopaedics and Manipulation (Gu Shang Tui Na or Zheng Gu).

Recommendation 21

That a representative body from the TCM profession further develop options for consideration by the TCM Registration Board(s) on grandparenting of existing practitioners with the introduction of registration requirements.

Recommendation 22

That a TCM registration board(s) have a range of powers to set standards for the safe practice of NESB practitioners, including powers to:

- Register NESB practitioners under grandparenting arrangements
- Establish English language requirements for newly registering practitioners
- Attach conditions where necessary to the registration certificates of practitioners of NESB who may not meet English language requirements
- Provide exemptions to English language requirements for NESB practitioners over 60 years
- Issue guidelines on what constitutes good practice for treating patients where a language barrier may exist
- Refuse to grant registration where an applicant's competency in speaking or communicating in English is not sufficient for safe practice.

Recommendation 23

That the TCM registration board(s) be self-funding, with access to a seeding loan from government to assist with establishment.

Recommendation 24

That State and Territory Medical Practitioner Registration Boards, in consultation with the AMAS and the Health Insurance Commission, be responsible for establishment of educational standards for those registered medical practitioners who use the title 'Medical Acupuncturist' and/or who make claims under Medicare for acupuncture treatments.

Recommendation 25

That the TCM registration board(s) negotiate with and endorse where appropriate educational standards for other registered health professions to allow exemption from the offence provisions of a TCM registration Act.

Recommendation 26

That unregistered practitioners of complementary therapies other than TCM be required to register with a TCM registration board in order to adopt titles protected under that legislation.

Recommendation 27

That further work be done to establish whether there is a need for statutory registration of practitioners of Western Herbal Medicine and that this include examination of mechanisms to allow prescribing and dispensing of scheduled Western herbal medicines by suitably qualified practitioners.

Recommendation 28

That practitioners of 'Ayurvedic Acupuncture' who wish to include the word 'acupuncturist' in their title be required to register with a TCM registration board.

Recommendation 29

That registered Veterinary surgeons who use the title 'Veterinary Acupuncturist' be exempted from the legislation on the condition that they treat animals only.

Recommendation 30

That the Department encourage dialogue between TCM researchers and Western Medicine researchers in order to establish research priorities for TCM and identify whether there are opportunities for public health intervention.

Recommendation 31

That targeted funding be made available from the Victorian Department of Human Services Health Research Initiatives for research into the risks and benefits associated with the practice of TCM, its effectiveness or lack of in treatment of specific conditions, and the detection and evaluation of opportunities for public health intervention.

Recommendation 32

That the NHMRC consider allocation of targeted funding for research into the risks and benefits associated with the practice of TCM, its effectiveness or lack of in treatment of specific conditions, and the detection and evaluation of opportunities for public health intervention.



1. Background and Context

1.1 Overview

This report of the Victorian Ministerial Advisory Committee on Traditional Chinese Medicine completes the second stage of the review of the practice of Traditional Chinese Medicine (TCM). The review has been undertaken by the Victorian Department of Human Services on behalf of all State and Territory governments. The first stage involved a major research project to collect information on the risks and benefits of TCM and the nature of the TCM work force, and to consider the need, if any, for registration of TCM practitioners and regulation of Chinese herbal medicines. The outcome of this research project was a recommendation to the Australian Health Ministers Advisory Council (AHMAC) and to all State and Territory Governments that occupational regulation of the profession of TCM proceed as a matter of urgency.

The purpose of this report is to make recommendations to the Victorian Minister for Health on a proposal for regulation of TCM. Further to this, the Minister will advise the Australian Health Ministers Advisory Council and the Australian Health Ministers Conference on steps required to achieve a suitable regulatory framework for the TCM profession in Victoria and other States and Territories.

Traditional Chinese Medicine (TCM) has a history of over 2,000 years in China and in recent times it has expanded rapidly in most westernised countries. In Australia in 1996–97, the Commonwealth Health Insurance Commission paid over \$17.7 million in Medicare rebates for 960,000 acupuncture treatments by registered medical practitioners⁽¹⁾. There has been a similar increase in the practice of other aspects of TCM, particularly herbal medicine, but also therapeutic massage, orthopaedics and manipulation, dietary therapy and exercise therapy.

The Victorian Department of Human Services (formerly Department of Health and Community Services) commenced its review of TCM in August 1995. The impetus for the review arose from.

- Recognition of the significant increase in demand for and use of TCM by Victorians of all ethnic origins.
- Consumer complaints dealt with by the Department's Therapeutic Goods Unit concerning herbal preparations, some of which had been adulterated with potent western medicines, along with the difficulties experienced by the Commonwealth Therapeutic Goods Administration in controlling this area.
- Representations from TCM practitioners and professional groups, including delegations from the State Administration of Traditional Chinese Medicine of the Peoples Republic of China.

1.2 The Victorian Model of Health Practitioner Registration

Under the Australian Constitution, statutory registration of health practitioners is a power which rests with State and Territory governments. Over the last ten years, most States and Territories have reviewed the way in which they register health practitioners, and have established common core provisions for legislation governing health practitioner registration. There appear to be few significant differences between jurisdictions as to these legislative provisions.

For example, in 1987, the Victorian Health Department conducted a review of health practitioner registration. The resulting report, entitled *Review of Registration for Health Practitioners*, identified the need to standardise the State Government's approach to regulation of health occupations by applying a consistent and "least restrictive" model that focussed on risk of harm and evaluation of alternatives to regulation^(2, 3). Since that time, six registration Acts have

been passed by the Victorian Parliament. The most recent Acts have undergone an assessment under National Competition Policy and they provide an up to date model for regulation of health professions by statute. They are the Victorian *Chiropractors Registration Act 1996*, the *Osteopaths Registration Act 1996* and the *Podiatrists Registration Act 1997*.

The thrust of the models recommended in *Towards A Safer Choice* is State-and Territory-based occupational registration via statute. In Victoria, each regulated health profession has a registration board established under a State Act of Parliament. These boards are independent of government, and are incorporated so as to avoid personal liability for board members. Membership consists of a majority from the profession being regulated. These Victorian boards are required to consult the Victorian Minister for Health and take notice of their views, but the Minister cannot direct them. Boards are self-funding, and are responsible for setting their own fees and meeting all their expenses such as renting premises, hiring staff, and paying legal counsel.

The key features of the Victorian legislative model of health practitioner registration are as follows:

- The purpose of regulation is to protect the public rather than to protect and promote professional interests.
- The main privilege of registration is the right to use the relevant title; it does not define the practice of the profession.
- It is an offence for non-registered persons to use the relevant title or to hold themselves out as being registered.
- Registration boards must be incorporated as legal entities.
- Board members are appointed by Governor-in-Council on recommendation from the Minister for Health.
- All boards must include legal and community representation.
- Power to make regulations rests with the Governor-in-Council, rather than with individual registration boards.
- Boards have a broad range of disciplinary options, including informal hearings in appropriate cases.
- A standard definition of 'unprofessional conduct' is adopted.
- Legislation includes standard powers of boards to deal with false and misleading advertising.
- Boards have the power, if necessary, to suspend the registration of a practitioner immediately in order to protect the public.
- Hearings are open, but with provision for closed hearings if necessary.
- Complainants have the right to be present at a hearing.
- Appeals from a decision are directed to the Administrative Appeals Tribunal.

Specific issues arising from application of this model for the profession of TCM are raised in Section 5 of this document. Appendix 1 sets out in detail the Victorian model of health practitioner registration that is reflected in the Victorian *Medical Practice Act 1994*, the *Nurses Act 1993*, and more recently, the *Chiropractors Registration Act 1996*, the *Osteopaths Registration Act 1996* and the *Podiatrists Registration Act 1997*.

1.3 Health Practitioner Registration and Mutual Recognition

At a special Heads of Governments meeting in May 1992, the *Mutual Recognition Agreement* was reached between all State and Territory Governments and the Commonwealth. The Commonwealth *Mutual Recognition Act 1992* contains the requirements of mutual recognition. Each State has now passed legislation adopting the provisions of that Act. The legislation is designed to promote freedom of movement of goods and services in an integrated Australian market.

Australian Health Ministers have agreed that mutual recognition is an important first step towards agreed national standards for each health occupation. Mutual recognition helps to ensure that health practitioners registered in one State or Territory are automatically entitled to registration in any other State that registers that occupation. One implication of this is that by default, the minimum standard of education set by one State for registration automatically becomes the standard for registration in all other States.

As part of the application of mutual recognition principles, Australian State and Territory Health Ministers agreed in 1993 that no further action would be taken to regulate any additional health occupations unless the need for doing so had been agreed by the Australian Health Ministers Conference (via the Australian Health Ministers Advisory Council).

1.4 Australian Health Ministers' Advisory Council

The Australian Health Ministers Advisory Council (AHMAC) is made up of the heads of all State and Commonwealth health departments and meets regularly to make recommendations to State, Territory and Federal Health Ministers on matters of common concern.

In 1993, AHMAC agreed that before any State proceeds with a proposal to register a previously unregistered health occupation, a majority of States should agree that such registration was required. AHMAC established a working group with representatives from a number of States, to examine applications from and make recommendations concerning the need for occupational registration of unregistered health practitioner groups⁽⁴⁾. The working group formulated six criteria for assessing the regulatory requirements of unregulated health occupations (see Appendix 2). These criteria addressed questions similar to those addressed under National Competition Policy including:

- Is registration the most direct, effective and least restrictive way of dealing with a significant risk of harm to public health and safety?
- Do the benefits of regulation clearly outweigh the potential negative impact? ⁽⁵⁾

In 1995, the AHMAC Working Group on Criteria and Processes for Assessment of Regulatory Requirements of Unregulated Health Professions was requested to use the criteria to assess applications for registration that had already received from currently unregulated health occupations. All the TCM groups that had made submissions to AHMAC were encouraged to make a single submission addressing the criteria. Acupuncture and Chinese herbal medicine were considered part of the occupation of TCM for the purposes of assessment against the criteria.

In September 1996, the Working Group met to consider a joint submission from the profession, along with the findings of *Towards A Safer Choice*. At its February 1997 meeting, AHMAC received the final report of the Working Group, and accepted its recommendation:

That States/Territories/Commonwealth should determine the efficacy of their legislation and regulation to respond to the public risks identified in *Towards A Safer Choice: The Practice of Traditional Chinese Medicine in Australia*, and take remedial action to resolve any problems which are identified. This efficacy assessment should take into account possible improvements to consumer complaints mechanisms to enable consumers of alternative and/or complementary therapies to make complaints about therapies and therapists.⁽⁶⁾

1.5 National Competition Policy

The review of TCM is being conducted within the context of National Competition Policy. The National Competition Policy Review (the Hilmer Report) was presented to the Council of Australian Governments in August 1993, and Commonwealth, State and Territory Governments agreed to a combined approach to competition policy, to improve Australia's economic competitiveness within the global market.

Complementary arrangements have been put in place at the State and Territory level to give effect to the National Competition Policy. The *Competition Policy Reform (Victoria) Act 1995* came into effect on 21st July 1996, accompanied by complementary *Guidelines for the Review of Existing Legislation* and *Guidelines for the Application of Competition Test to New Legislative Proposals*.

Under the Guidelines in Victoria, regulatory proposals such as occupational registration that have the effect of limiting the number of persons engaged in an occupation and preventing any other party from engaging in certain activities of that occupation, are deemed to be restrictions on competition unless proved otherwise. Such restrictions are seen as tending to promote unwarranted rigidities in the workplace and segmentation in the labour market.

Under National Competition Policy, the 'competition test' must be applied to all new regulatory measures, including Acts of Parliament, ordinances, and regulations. Any regulatory measure which might restrict competition must demonstrate that:

- The benefits of the restriction to the community as a whole outweigh the costs.
- The objectives of the legislation can only be achieved by restricting competition.

In Victoria, when proposed legislation contains competition restrictions, the Victorian Minister for Health must obtain a certificate from the Premier to the effect that the restriction has been justified in the public interest⁽⁷⁾. Any restrictions on competition contained in proposed health practitioner legislation will therefore come under close scrutiny. Similar processes operate in other States and Territories.

1.6 Commonwealth Initiatives

The Commonwealth has taken a significant interest in the practice of TCM. The Commonwealth has established an Alternative Medicines Unit within its Therapeutic Goods Administration, and in October 1996 held an 'Alternative Medicines Summit'. The Summit noted that 'complementary health practitioners who want to be able to prescribe treatments for their patients need to achieve accreditation as a step towards accessing a wider range of medicines'⁽⁸⁾. The Commonwealth statement also confirmed the need for complementary health practitioners to work with State and Territory Governments on accreditation and training.

In mid 1996, the Commonwealth announced a review of its Therapeutic Goods Administration. The report 'Review of Therapeutic Goods Administration' was published by KPMG in January 1997 on behalf of the Department of Health & Family Services. The report contained 18 recommendations on complementary medicines aimed at ensuring that:

- any inappropriate impediments to approval processes for medicines are removed, and

- this significant and rapidly growing area of Australia's medicinal products industry is not inhibited by factors which do not relate to the protection of public health.⁽⁹⁾

The Commonwealth in its response to the report accepted the large majority of these recommendations. In particular, the Commonwealth supported Recommendation 4.9 which addressed the issue of access to scheduled herbs by complementary medicine practitioners qualified in their use.

'A standardised system of training and accreditation is needed, so that the government can feel confident that only those practitioners having undertaken appropriate training will be able to provide these substances to the general public. The government supports the recommendation to pursue the issue of competencies for professional associations through AHMAC. As practitioner accreditation is a State/Territory responsibility, the government encourages State and Territory governments to collaborate on this issue'.⁽¹⁰⁾

1.7 Victorian Review Process

The Victorian review of TCM is being conducted in three stages:

- Stage 1 Research—March 1995–November 1996
- Stage 2 Policy Development and Public Consultation—November 1996–May 1998
- Stage 3 Implementation—Scheduled for August 1998 onwards.

Stage 1: Research

The University of Western Sydney (Macarthur) and Southern Cross University won the tender to conduct the research project. The Departments of Health in New South Wales and Queensland agreed to fund the research jointly with Victoria, resulting in a total research grant of \$125,000 (\$80,000 from Victoria, \$40,000 from New South Wales, and \$5,000 from Queensland).

The resulting research report, *Towards A Safer Choice: The Practice of Traditional Chinese Medicine*, was launched by the Victorian Minister for Health the Hon. Rob Knowles in November 1996. The researchers found that the risks in the practice of TCM relate primarily to the practice of acupuncture and Chinese herbal medicine, which have resulted in at least five documented deaths in Australia. *Towards A Safer Choice* identified a number of factors likely to contribute to increasing public health risks, including:

- Dramatically increasing use of Chinese herbal medicine.
- Increasing demands on TCM practitioners to use Chinese herbal medicine in a wide range of clinical presentations, including in combination with western drugs.
- Difficulty in controlling the importation of Chinese therapeutic goods.
- Varied levels of training among, and available to, TCM practitioners.
- The impact of National Competition Policy in undermining efforts at self-regulation by TCM professional associations.⁽¹¹⁾

Section 2 of this report summarises the findings of *Towards A Safer Choice*, and its Executive Summary is reproduced in Appendix 4. Copies of *Towards A Safer Choice* are available for sale from:

The Faculty Manager, Faculty of Health
University of Western Sydney (Macarthur)
PO Box 55
Campbelltown NSW 2560
Tel: (02) 46 203 347
Fax: (02) 46 254 252

It is also available on the Internet at:

<http://hna.ffh.vic.gov.au/phb/hce/chinese/report/contents.html>

Stage 2: Development of Options for Regulation and Public Consultation

At the launch of the report *Towards A Safer Choice*, the Victorian Minister for Health the Hon. Rob Knowles announced the formation of a Ministerial Advisory Committee on Traditional Chinese Medicine to assess the findings of the report and make recommendations on a regulatory framework for Victoria. The Committee was chaired by the Minister's Parliamentary Secretary, Mr Robert Doyle MP. Appendix 3 contains a list of the membership and terms of reference for the Ministerial Advisory Committee, which included practitioners and academics from TCM, representatives from Western Medicine, as well as consumer representatives. Two sub-committees were set up: Primary TCM Practitioners Sub-Committee and the Generalist TCM Practitioners Sub-Committee.

Primary TCM Practitioners Sub-Committee

This subcommittee was chaired by Dr Vivian Lin, Executive Officer of the National Public Health Partnership, Victorian Department of Human Services. The subcommittee consisted of practitioners whose main form of practice is TCM. All the major TCM professional associations were represented, with representatives from Queensland, NSW and Victoria.

Generalist TCM Practitioners Sub-Committee

This subcommittee was chaired by Dr Graham Rouch, Chief Health Officer, Victorian Department of Human Services. The subcommittee represented generalist health care practitioners who use one or more modalities of TCM as part of their practise in another health care discipline. This included representatives from the professions of Western Medicine, chiropractic, physiotherapy, nursing, naturopathy and shiatsu massage. Membership and terms of reference of these subcommittees is in Appendix 3.

AHMAC, at its February 1996 meeting, endorsed the Victorian review process for TCM and agreed to consider recommendations arising from the review in determining policy matters relating to occupational registration of the profession. In February 1997, Victoria sponsored a paper to AHMAC to provide advice on the outcome of the research, and to propose that further work be undertaken on a framework for regulation of TCM practice. The following recommendations were adopted by AHMAC:

That the TCM report be noted and that Victoria take the lead in exploring the feasibility of occupational regulation of Traditional Chinese Medicine, namely:

1. That Victoria establish a TCM Review Advisory Committee to make recommendations concerning implementation of the report's proposals on occupational regulation.
2. That the attached terms of reference for the committee be noted.
3. That other states nominate an officer to either participate on the committee and/or to provide a point of liaison for the review.
4. That Victoria establish a number of subcommittees of the advisory committee, to address specific issues including:
 - Qualifications, standards.
 - Prescribing, labelling and dispensing of raw Chinese herbs.
 - Standards of practice for practitioners of other health disciplines who also practice modalities of TCM.
5. That Victoria report back to AHMAC on the outcome of the review committee's work.⁽¹²⁾

Section 3 of this report summarises the consultation process conducted as part of the second stage of this review.

Stage 3: Implementation

After consideration of the Victorian Ministerial Advisory Committee report on TCM, State and Territory Health Ministers will decide whether to agree to introduce legislation for the registration of TCM practitioners and regulation of prescribing of herbal preparations. This decision will be informed by data on risks and benefits associated with the practice of TCM and the adequacy of the existing regulatory framework to protect public health. Each State and Territory Health Minister may then consider how to proceed with implementation of this policy on regulation of practitioners and prescribing of herbal preparations within their jurisdiction.

2. The Research Report: Towards a



Safer Choice

2.1 Background

The research project conducted by University of Western Sydney (Macarthur) and Southern Cross University investigated and reported on seven main areas:

- The regulatory frameworks in China, other countries, and all States of Australia.
- The profile of the TCM workforce in Victoria, New South Wales and Queensland, including the organisations that represent practitioners.
- The profile of patients using TCM and patient satisfaction.
- The risks and benefits of TCM.
- The nature of the links and referral networks between practitioners of TCM and other health care practitioners.
- The nature of TCM education in Australia and China.
- The adequacy or otherwise of the current State regulatory frameworks.

The project was directed by Mr Alan Bensoussan, Senior Lecturer, Faculty of Health, University of Western Sydney (Macarthur), and Dr Stephen Myers, Senior Lecturer and Head of the School of Natural and Complementary Therapy, Southern Cross University.

All components of the study were undertaken in Victoria, New South Wales and Queensland, with contributions from a range of institutions including University of Western Sydney (Macarthur), Southern Cross University, Newcastle University, the Victorian Health Issues Centre, the law firms Blake Dawson & Waldron and Philips Fox, and the Centre for the Study of Clinical Practice at St Vincent's Hospital, Melbourne. The report of the project, *Towards A Safer Choice*, provides the first comprehensive view of the practice of TCM in Australia.

2.2 Key Findings

Appendix 4 contains the Executive Summary of *Towards A Safer Choice*.

Key findings were:

- It is estimated that 50% of the Australian population is using some form of 'alternative' medicine. TCM is provided to patients of all ages, including infants. Two in three patients are female, 50% are tertiary educated, and over 80% have English as their first language.
- The practice of acupuncture and Chinese herbal medicine carries both inherent risks and risks associated with poor practitioner training. The project surveyed over 1,000 medically and non-medically trained TCM practitioners practising in Australia, who reported a significant number of adverse events.
- Among these reported adverse events were a number that were serious, mainly related to the practices of Chinese herbal medicine and acupuncture, including 64 pneumothoraxes and 19 deaths. Since many practitioners have had periods of training and practice overseas, it is difficult to estimate what proportion of these events occurred in Australia. However, the rate of adverse events per practitioner is the same, regardless of where the events occurred.
- Cases of injury and death associated with the practice of TCM, in Australia and overseas, have included:
 - Adverse reactions to toxic herbs and herbal combinations, including allergic reactions to some herbs.
 - Contamination of herbal medicines with pesticides, heavy metals, etc.
 - Adulteration of herbal medicines with western pharmaceuticals.

- There is a link between length of training in TCM and self-reported adverse incident rates. Those with less than 12 months of TCM training reported more than double the adverse incident rate in TCM of those with three to five years of TCM training.
- The majority of non-medical professional associations have agreed on the content of TCM courses, and favour a minimum of four years training as the undergraduate primary care TCM qualification. Under a self-regulatory system, however, the profession is not in a position to enforce such a standard.
- There is significant black market activity in the importation of unlisted and/or unregistered patent medicines. Deficiencies exist in the ability of the Federal Therapeutic Goods Administration to address both this problem and that of the importation of raw herbs.
- A review of education programs throughout Australia identified nine fully accredited three to five year undergraduate training programs, including three in universities. The researchers raised concerns regarding the level of training in western medical science in these courses, and that external review of TCM programs and mechanisms to ensure broad professional input are poorly developed in the majority of institutions.
- Twenty-three separate professional associations representing practitioners were identified. The researchers raised concerns about conflict of interest arising from the close affiliations between certain educational institutions and some professional associations, and suggested that, given such fragmentation and vested interests, a self-regulatory approach to standards of practice will continue to be unsuccessful.
- Statutory registration of practitioners of TCM is recommended, as well as tighter regulation of importation of raw herbs and patent medicines, in order to protect the public adequately.

2.3 Risks Inherent in TCM

The report *Towards a Safer Choice* surveyed the risks associated with the practice of TCM.

The risks of acupuncture are associated with the insertion of needles into the body, which is a key aspect of the discipline. An NHMRC Working Party has detailed four possible serious complications:

- Infection
- Puncture of vital organs
- Mental trauma
- Failure to detect serious underlying disease resulting in delayed diagnosis and appropriate treatment. ⁽¹³⁾

The report stated that:

All these risks are potentially catastrophic, and deaths have occurred in Australia associated with the use of acupuncture. The risks of serious infection also affect the broader public through the spread of contagious disease. ⁽¹⁴⁾

Chinese herbal medicine involves the prescription of combinations of herbs for topical application or ingestion. Potential risks include:

- Inherent toxicity of the herbal substances (either alone or in combination) dispensed by practitioners.
- Prescription of herbs that are inappropriate for the condition being treated.
- Contaminants such as heavy metals.
- Adulteration with western pharmaceuticals such as steroids.
- Substitution of herbs by the dispenser without consulting the treating TCM practitioner.

- Poor or non-existent labelling of ingredients, leaving consumers particularly at risk in the event of an adverse reaction.
- Drug interactions in people taking herbal preparations along with prescribed pharmaceuticals.

2.4 Analysis of Risk

Towards A Safer Choice argued that growth in the popularity of TCM and the changing profile, both in terms of training and experience, of those offering TCM modalities is changing the significance of the associated risks, and it points to this changing significance as the basis for its recommendations on the need for occupational registration. The report makes the following points:

- The survey of the TCM workforce carried out as part of the research project made it clear that the risks inherent in the practice of TCM actually occur in practice, and confirmed that the risks of acupuncture are different to those of Chinese herbal medicine, although the adverse effects of each include both predictable and unpredictable reactions, and can be serious and sometimes include fatalities.
- To date, nevertheless, the risk inherent in TCM has been relatively well contained in Australia. The relative risk of adverse events from TCM is less than that from western medicine, although greater than for some other forms of accepted health care practice in the community.
- Adverse events associated with TCM are usually associated with poor training and/or unethical conduct. Potential harm is likely to be minimised if the patient's response to treatment is adequately monitored by an appropriately trained practitioner, who will make appropriate referrals when necessary. Practitioners should have sufficient knowledge of western medicine to know when to refer a patient to a medical practitioner.
- While data before the report suggested a low rate of litigation and complaints to bodies such as the Victorian Health Services Commissioner, this may be partly explained by:
 - The small numbers of primary TCM practitioners in Australia (approximately 2000 compared to over 10,000 medical practitioners) who may be relatively cautious in their practice.
 - A lack of public awareness that the statutory complaints units accept complaints regarding complementary therapies and therapists.
 - Under-reporting of adverse incidents by TCM practitioners and their patients.
- Incidents referred to in the report include:
 - a Coroner's call for accreditation of acupuncturists (1988).
 - a series of serious incidents pre-1982, including acupuncture rendered to persons suffering hepatitis, and broken needles travelling, for example, from the back into the peritoneal cavity.
 - A case in 1986 of an acupuncture needle deliberately broken by a registered medical practitioner which travelled from its point of insertion in a woman's shoulder across her chest.
 - Moxibustion injuries suffered in 1990 at the hands of a practitioner who had previously failed the examinations required for membership of an Australian TCM professional association.
 - Inappropriate response in 1990 by an acupuncturist whose patient became ill whilst undergoing treatment, requiring subsequent hospital attention.⁽¹⁵⁾
- Whilst some associations may be effective in controlling their members, they have no capacity to control those who are not members and particularly those whose training and qualifications do not qualify them for membership in the first place.

- The risks are likely to be increased by the changing demographics of the profession, deregulation of the education sector; and progressive weakening of the existing self-regulatory mechanisms, particularly through the effects of National Competition Policy on health fund provider recognition procedures.
- While there has been a significant increase in overseas-trained practitioners in Australia, particularly since the Tiananmen Square incident in Beijing in 1989⁽¹⁶⁾, there is no uniform, systematic evaluation of the adequacy of overseas courses or the validity of claimed qualifications. Particular concerns relate to whether overseas-trained practitioners have adequate training in western medicine.
- Medical and other practitioners seeking to make referrals that accommodate consumer preference for a wider range of health care options are unable easily to identify appropriately trained practitioners, given the plethora of TCM professional associations. Similar problems are faced by health insurance funds.

2.5 The Need for Regulation: Assessment Against the AHMAC Criteria

Towards A Safer Choice assessed the need for occupational regulation of TCM against the AHMAC criteria. This assessment is reproduced in Appendix 5 of this report.

In answer to Criterion 6, 'Do the benefits to the public clearly outweigh the potential negative impact?', *Towards A Safer Choice* sets out the arguments for and against occupational regulation of TCM as follows.

In brief, some of the concerns are that occupational regulation:

- Restricts entry to a profession
- Increases the costs of entry, in that minimum standards of training and education are set for professional practice and therefore may also narrow the range of persons eligible to practise
- May stifle innovation and interaction between different groups of health practitioners and/or encourage undesirable 'medicalisation' in order to justify TCM practice in western scientific terms
- May increase the cost of TCM services to individuals and the community, through passing on of the increased costs associated with educational requirements, indemnity insurance, and the regulatory mechanism.⁽¹⁷⁾

Major benefits of registration are that it can:

- Help protect the public by promoting the standards established through various national bodies for professionally trained, competent and safe practitioners
- Promote the public's right of access to the health care of their choice, by providing a mechanism for identifying practitioners who should be safe and competent
- Facilitate cross-referral amongst different types of health practitioners and promote the integration of patient care
- Provide enforceable sanctions against practitioners whose practice is incompetent or unethical
- Provide a mechanism for identifying those practitioners who can be safely exempted from the relevant provisions of legislation regulating the provision of therapeutic goods.⁽¹⁸⁾

The report concludes that on balance, the benefits of promoting public safety clearly outweigh the potential negative impacts of occupational regulation, and recommends that State governments proceed to implement occupational regulation of TCM as a matter of urgency.



3. Consultation Process

3.1 Background

The Victorian Ministerial Advisory Committee on TCM approved the release of a discussion paper in August 1997, with a deadline for submissions of Friday 24th October 1997. Availability of the document was advertised in The Australian on Saturday 30th August and through the Internet and various newsletters and journals. Due to the delay in release of the Chinese language version of the document, the deadline for submissions was extended until Wednesday 12th November 1997. Over 2,000 copies of the English language version of the paper have been distributed and approximately 200 copies of the Chinese language version.

3.2 Public Meetings

Public meetings were sponsored by the organisations outlined in Table 1 below. Information on the review process was presented by a panel of speakers from the Ministerial Advisory Committee and Subcommittees. Attendances ranged from 20 to over 120 participants with a total of approximately 400 people attending the meetings.

Table 1: TCM Review Consultation—Public Meetings

| | | |
|---|-----------|---------------------|
| Australian Natural Therapists Association | Sydney | Sunday 31st August |
| Australian Traditional Medicine Society | Melbourne | Mon. 8th September |
| Federation of Chinese Medicine Societies | Melbourne | Thurs 2nd October |
| Australian Acupuncture Association | Brisbane | Sat. 4th October |
| Australian Acupuncture Association | Sydney | Sat. 5th October |
| Australian Acupuncture Association | Melbourne | Sun. 12th October |
| Chronic Illness Alliance | Melbourne | Mon. 6th October |
| Alliance of Traditional Chinese Medicine Associations | Melbourne | Thurs. 6th November |

In addition the two subcommittees of the TCM Ministerial Advisory Committee met on three separate occasions.

The main issues raised at the public meetings were:

- Widespread support for statutory registration and a national process for accreditation of courses.
- Concern about arrangements for grandparenting.
- Concern that non-English speaking practitioners might be disadvantaged by any stringent language requirements.

3.3 Submissions

A total of 78 written submissions were received. They were divided into five main categories:

Category A: Organisations such as the Victorian Health Issues Centre and the Victorian Anti Cancer Council which have no direct interest in the provision of TCM services (14 submissions)

Category B: Organisations which represent practitioners or students of Chinese Medicine.
This includes the universities that operate courses of training (19 submissions)

Category C: Organisations whose members practice TCM as part of other health care practices or who have some other direct interest such as training generic practitioners (10 submissions).

Category D: Individual practitioners of TCM or TCM students (27 submissions).

Category E: Consumers of Chinese Medicine (8 submissions).

A summary of the main findings and recommendations is included in Sections 4 and 5 below.

Appendix 6 contains the list of submissions received, and Appendix 8 provides a summary in table form of the main findings.



4. Options for Regulation

4.1 Self Regulation, Co-regulation and Statutory Regulation Background

The first question the TCM Review has addressed is: should there be legislative regulation of the occupation of TCM, or should less restrictive self-regulatory approaches be adopted?

Self Regulatory Models

The discussion paper identified a number of health occupational groups that have set up or are developing structured programs of self-regulation. The Australian Council for Homoeopathy Inc., for example, has established the Victorian Register of Certified Homoeopathic Practitioners Inc., an independent incorporated body which is intended to regulate the practice of qualified homoeopaths, and protect the public interest in homoeopathic health care. It also serves as a point of contact for complaints and disputes. Board members are drawn from the homoeopathic profession, the medical and health professions, the law, leading university academics, and consumer groups. The Victorian Health Services Commissioner, Ms Beth Wilson, acts as a consultant to the Register. The Victorian Minister for Health, the Hon. Rob Knowles, has endorsed the self-regulatory framework as

a mechanism by which the homoeopathic profession endeavours to promote the highest standard of homoeopathic practice, and to provide avenues for dealing with patient complaints.⁽¹⁹⁾

The Executive of the Australian Traditional Medicine Society Ltd has prepared a proposal for self-regulation of the profession of TCM entitled 'Government Monitored Self Regulation'. The proposal, contained in Appendix 7, includes a structured approach to self-regulation and a suggested process for implementing it.

The discussion paper identified a number of difficulties with applying models of self regulation to the TCM profession. These were:

1. Fragmentation of the Profession and Lack of Agreement on Standards

Within the profession, there are at least 23 associations representing practitioners with varying standards of training. The emergence of a peak body in TCM has been hampered by divergent interests within the profession and historical factors associated with the introduction of acupuncture to the western world. With such fragmentation, it has not been possible to achieve support from all associations for a process to establish a self-regulatory mechanism, or to reach agreement on what standards should be applied for registration. In addition, while educational standards have been agreed to by a majority of the profession, there is no compulsion for providers to comply with these standards.

2. Deregulation of Education

Government-accredited TCM courses exist at certificate, diploma, advanced diploma and degree levels; however accreditation addresses structure and delivery of courses, and may not determine whether course content meets the standard the profession considers acceptable. Many of these courses are not recognised by the leading professional associations as being of an acceptable standard. In the absence of statutory registration, even a well organised profession may be unable to prevent accreditation of a course that is of a standard below that considered desirable by that profession.

3. Difficulties in Creating Incentives for Voluntary Certification:

In the past, eligibility for rebates from private health funds was the main incentive for TCM practitioners to seek membership of associations with higher educational standards. With the introduction of laws against un-competitive practices, private health funds are reluctant to use a practitioner's membership of a given professional association as the criterion for payment of rebates, and are now assessing qualifications on an individual basis. This undermines the ability of associations to impose standards and discipline their members. Under a self-regulatory model, The Register of Certified Homoeopathic Practitioners has experienced considerable difficulties in creating incentives for practitioners to seek certification with the Register. Practitioners can continue to practice without being included on the Register and can continue to hold themselves out to the public as qualified even if they do not meet the standards set by the Register for certification.

4. Lack of Access to Scheduled Herbs

A number of herbs considered toxic have been scheduled under the Standard for the Uniform Scheduling of Drugs and Poisons (see Section 5.4), so that they can be prescribed legally only by registered medical practitioners. In China, practitioners are trained in prescribing these substances safely and preventing undesirable side-effects, and the herbs are widely prescribed, but similarly trained practitioners in Australia are denied access to these herbs. The Federal Therapeutic Goods Administration recognises the difficulties with the current scheduling arrangements, but states that any change is dependent on State and Territory Governments putting in place arrangements to identify, via accreditation or registration, those practitioners who have training in Chinese herbal medicine that equips them to prescribe these substances safely. A self-regulatory scheme is unlikely to be able to incorporate a mechanism to allow access by trained practitioners to scheduled herbs.

Towards A Safer Choice Recommendations

Towards A Safer Choice made a series of recommendations regarding regulation of the profession of TCM and the prescribing, labelling and dispensing of Chinese herbal medicines. The recommendations were based on the premise that any regulatory model must be the minimum necessary to protect the public.

The report recommended statutory regulation of the profession using a model based on protection of title rather than licensing for protection of practice. It argued that such a model would:

- Promote uniform standards of education and training for safe practice.
- Enable the public and other practitioners to identify appropriately qualified, safe TCM practitioners.
- Provide protection from false/exaggerated claims.
- Promote appropriate referrals to medical or other practitioners.
- Promote accountability to the public.
- Provide a mechanism for safe exemption of practitioners from restrictions imposed by legislation regulating therapeutic goods.
- Focus on competence to use therapeutic tools, in addition to maintaining such tools in an appropriate manner
- Enhance effectiveness of the national framework for therapeutic goods administration.⁽²⁰⁾

Submissions

Appendix 8 provides a list of the main findings from the submissions received. There was widespread support for statutory based occupational registration of TCM practitioners, from both TCM organisations and from other organisations. Those non-TCM organisations which support the introduction of statutory registration include:

- AMA Queensland Branch
- Anti-Cancer Council
- Australian Complementary Health Association
- Australian Physiotherapy Association (Victorian Branch)
- Health Complaints Commissioner of NSW
- Health Issues Centre
- Health Services Commissioner of Victoria
- Nurses Board of Victoria
- RMIT University
- The Victorian Workcover Authority
- Mr John Thwaites, MP, Victorian Shadow Minister for Health
- University of Sydney
- University of Technology Sydney
- Victoria University of Technology

The **Victorian Health Services Commissioner** (HSC), Ms Beth Wilson submitted that where there are complaints about non-registered practitioners, there is very little action that the HSC can take. Ms Wilson stated that self regulation has as its primary purpose protection of the practitioner rather than protection of the public. The HSC considered that without registration, there is an unacceptable risk to public health, and supported a registration board model similar to that of the Medical Practice Board of Victoria.

The **NSW Health Care Complaints Commission** submission stated that self regulation cannot work. The Commission submitted that self regulation does not have the public interest as its prime focus, rather protection of the profession is often the driving force. It cannot adequately protect the public.

The **Victorian Workcover Authority** submission stated that it would welcome state or national registration as a better system of setting appropriate standards than the Authority's own administrative processes for approval of practitioners. The Authority expressed concerns about a self regulatory approach given its contact with the range of professional associations which claim to represent high educational and professional standards. It believed that these professions have not already found unity, accord and substantial common ground without government registration, and that self regulation is unlikely to change the situation.

The **Victorian Nurses Board** submission stated that self regulation cannot be implemented and is unlikely to adequately protect the public. The Nurses Board agreed that acupuncture and Chinese herbal medicine should be regulated for the protection of public health and safety. It stated that nurses wishing to practice as both TCM practitioners and registered nurses must practice in a manner that is consistent with the standards of both professional groups.

The Victorian **Health Issues Centre** stated that the community is currently inadequately protected given the burgeoning use of these health care providers by Australian consumers. The Centre submitted:

It is essential that a mechanism exists which can assist not only consumers but also other health care practitioners to identify appropriate TCM practitioners for referral purposes. The adoption of a self regulatory approach to these issues is clearly no longer an adequate mechanism to protect the public particularly given the lack of cohesion amongst practitioner groups in this field.⁽²¹⁾

The **Anti-Cancer Council** submission endorsed the recommendation for the constitution of a TCM registration board, the establishment of recognised qualification levels for practitioners and standards of practice.

Those opposed to introduction of statutory registration of TCM practitioners were:

- AMA Victorian Branch.
- Australian Medical Acupuncture Society—AMAS (Registered Medical Practitioners).
- Australian Traditional Medicine Society—ATMS (Executive consists primarily of private college owners).

The **AMA Victorian Branch** submitted that the profession does not meet the AHMAC criteria, and that to register practitioners would provide a government imprimatur to an 'occupation' which is so fragmented that it cannot agree on minimum standards of practice, qualifications or experience. Consequently, it argued, statutory regulation would be premature as it would give the public false confidence in the safety and competence of TCM practitioners.

The **AMAS** stated that before Government considers establishing a TCM registration board, a body should be set up to establish standards. It argued that unless there is uniform agreement about standards and 'bodies of knowledge', registration is premature. It also stated that if Government is to choose registration, practitioners should be trained sufficiently in Western medicine. The AMAS was also vigorously opposed to any requirement for its members to register with a TCM registration board as a condition of their use of the title 'Medical Acupuncturist'.

It was interesting to note that although the AMA Victorian Branch was opposed to statutory registration, the AMA Queensland Branch was in support. The AMA Victorian Branch stated in its submission that if registration proceeds, then protection of title should be sufficient. The AMA Queensland Branch supported restrictions on practice in addition to protection of title.

The **ATMS** submitted that the risks to the public as identified in *Towards A Safer Choice* did not warrant government regulation of the profession, and that self regulation via the model it proposed should be sufficient. However, there was considerable criticism of the ATMS proposal by all other TCM organisations. The ATMS has recognised the limited support from the profession for its proposal and has expressed its intention not to oppose registration if that is the outcome of this process.

With the exception of the AMA (Victoria), the ATMS and the AMAS, all other submissions which commented on the question of self regulation stated that self regulation would not be effective in protecting the public and that the model proposed by the ATMS could not be implemented. Reasons included those listed above (fragmentation of the profession, deregulation of education, lack of incentives for voluntary certification, and lack of access to scheduled herbs) as well as those detailed in the Queensland Health Department submission below. These organisations supported

statutory based occupational regulation as the best method of adequately protecting the public, and generally support the Victorian model of health practitioner registration as suitable.

The **Australian Acupuncture and Chinese Medicine Association** provided details of cases where they had experienced difficulties in enforcing standards of practice and ensuring adequate protection of the public through a self-regulatory system. See Appendix 9.

Government Submissions

Submissions were received from:

- NSW Health Department
- Department of Community and Health Services Tasmania
- Queensland Health Department
- South Australian Health Commission

The **NSW Health Department** submission identified a number of alternatives to statutory regulation but did not recommend any particular model. Options suggested for consideration were:

- Regulation of practices that present health risks, via for example the *Public Health Act (NSW)*, the *Poisons and Therapeutic Goods Act 1996 (NSW)* and *Skin Penetration Regulations*.
- Establishment of a generic Health Professionals Registration Board to register a range of complementary health practitioners such as acupuncturists, traditional Chinese herbalists, homoeopathic practitioners and naturopathic practitioners.
- Development of co-regulatory approaches where Government accredits self regulatory systems, similar to the NSW Professional Standards Council.

The NSW Health Department submission is attached in Appendix 10 .

The **Department of Community and Health Services Tasmania** submission listed a similar range of options but stated that the most effective of these options in providing some degree of protection of the public is a full registration process which both prevents unregistered persons using protected titles and prevents unregistered persons from providing services of a defined type—dispensing, acupuncture, etc.

Tasmania would support a registration system based on a titles only approach as a first step towards controlling the risks associated with TCM but would reserve the right should the practices of unregistered persons continue to present an unacceptable risk to move to a core practice/scope of practice approach under which activities are only to be performed by registered persons.⁽²²⁾

The **Queensland Health Department** submission made detailed comments on the model of health practitioner registration outlined in the Discussion Paper but stated that:

This Department's recommendations to Government will not be settled until careful consideration has been given to all stakeholder submissions on the Discussion Paper. However, the Department considers *Towards A Safer Choice* (and the Discussion Paper at page 10) fairly identifies the costs and benefits of regulation.⁽²³⁾

The Queensland Health submission identified a number of concerns with a non-statutory model of occupational regulation:

- The model will not restrict the use of a professional title to accredited practitioners (although it is acknowledged that use of the Government Monitored Self-Regulation (GMSR) logo will be restricted)—there will be potential for consumer confusion regarding the credentials of any person calling themselves a TCM practitioner.
- While health complaints bodies (such as the Health Services Commissioner or the Health Rights Commissioner) already have the power to deal with complaints regarding TCM practitioners, the capacity of the GMSR model to effectively discipline practitioners is doubtful. Statutory disciplinary processes have the advantage of appropriate coercive powers and protections.
- The model does not address appellate or review processes—to the detriment of the rights of practitioners and other aggrieved parties.
- The model does not provide for adequate public input into the regulation of the profession—a single consumer member on a council of 29 is unlikely to be effective and will be perceived as ‘tokenism’.
- The effectiveness of the model will depend upon the extent to which it is embraced by the profession and publicised within the community. In view of the risks of TCM, it could be argued that it is inappropriate to rely upon cooperation alone. ⁽²⁴⁾

The **South Australian Health Commission** stated that:

The current lack of control over the practice of TCM, which includes therapies such as acupuncture, and the use of herbal medicines, exposes the public to practitioners whose training may be very limited. In the absence of recognised registration standards, the public has no reference point to make a judgement on the competence of the practitioners. We therefore submit it would be in the public interest to consider regulation of the practice of TCM through registration of practitioners. ⁽²⁵⁾

View of Committee

The Committee accepts that before adopting the recommendations of *Towards A Safer Choice*, State and Territory Health Ministers must satisfy themselves that self-regulation is not an effective option.

There is considerable evidence from a variety of sources both in Australia and overseas to support the conclusion that there are significant risks to the public from unskilled and unregulated practice of TCM, both Chinese herbal medicine and acupuncture. The Committee accepts the view that these risks are likely to increase over time as more practitioners, some with limited training offer their services to the public, and that the most effective method of minimising these risks is by a requirement for statutory registration of suitably qualified practitioners.

The Committee examined each of the options outlined in the NSW submission, as well as the ATMS proposal. These proposals were considered unsuitable for a number of reasons including:

- The Committee shares the concerns of the Health Services Commissioner and others that under a self regulatory model, there is significant potential for conflict of interest on the part of those professional associations placed in the position of registering practitioners, particularly where the associations have close links with the teaching institutions that graduate those same applicants for registration.
- Despite over 20 years of efforts, the TCM profession has been unable to establish a self regulatory system that has the wide support of the majority of groups within the profession. There is no reason to believe that efforts at self regulation will be any more successful in the future.

- Existing provisions such as Skin Penetration Regulations are not considered to provide sufficient protection to the public, nor to address the difficulties with setting educational standards in training institutions.
- The Committee notes submissions to the current Victorian Review of the Physiotherapists Act 1978 which have argued that under a self regulatory system, there is no method of enforcing compliance by training institutions with educational standards determined by the profession.
- Co-regulatory models may be attractive in theory, but in practice present complex and resource intensive options to protect the public when compared with well established models for regulation of health professions. Alternative approaches are not likely to resolve the inter-association disputes that dominate the profession.
- A co-regulatory model where government endorses certain professional associations is contrary to recent trends in Victoria for example with efforts by the Victorian Government to separate the Law Institute's disciplinary functions from its other roles. Where participants are elected rather than appointed by Government, the same problems of conflict of interest can arise.

The Committee's view is that the most effective method of protecting the public is to apply to the profession of TCM the same models of regulation that apply to medicine, nursing, optometry, physiotherapy, and many other apparently less risky and less intrusive health occupations.

Recommendation 1

That statutory based occupational regulation of the profession of TCM be adopted as the most suitable method of setting educational standards, accrediting training courses and protecting the public from untrained or poorly trained practitioners.

4.2 State Versus National Approaches

Background

Towards A Safer Choice proposed that administration of a regulatory scheme for TCM practitioners could be based on one of three options:

- A **national registration board** under Federal jurisdiction with power to delegate investigation of complaints to State and Territory health complaints bodies and to appoint committees at the State/Territory level to hear disciplinary or complaints matters;
- **State and Territory based registration boards** under the jurisdiction of the relevant State or Territory Health Minister. States or Territories where the TCM constituency is not large enough to warrant a separate board could legislate to recognise statutory regulation in another State or Territory;
- A **national accreditation body** made up of delegates from State-and Territory-based registration boards, to accredit education programs and set out the qualifications that should be accepted by the boards for registration. States with fewer practitioners might choose simply to issue registration certificates through a relevant government department on proof that the practitioner has met the qualification standards required by the national accreditation body, or to deem practitioners to be registered if they meet standards prescribed by that body.

While there is widespread support for a national approach to setting standards of practice in TCM, statutory registration of health occupations is not one of the powers given to the Federal Government by the Commonwealth Constitu-

tion, and there is no precedent for occupational regulation at a federal level. There are, therefore, constitutional and political barriers to achieving a federal system of occupational registration for TCM. It is unlikely, at least in the immediate future that States, Territories and the Commonwealth will reach agreement on the ceding of powers required to enable the establishment of a national scheme.

Models of health practitioner registration exist which incorporate a national approach to setting standards and accreditation of training courses:

- In **medicine** and **optometry**, for instance, State-based registration boards operate alongside national bodies whose role is to accredit training courses and conduct, or commission the conduct of, examinations for applicants. In optometry, establishment of national accreditation body has arisen out of a strong State-based regulatory system, with support from the States. The newly constituted Optometry Council is funded by pro rata contributions from State registration boards, based on the number of registered practitioners in each State.
- In **nursing**, the Australian Nursing Council accredits overseas courses and assesses overseas trained nurses, but State boards continue to have responsibility for accrediting nursing courses within their States.

There are a number of options for achieving a national approach to standard setting:

- One State could develop template occupational registration legislation for use across other States and Territories. The responsibility for setting the educational standards and establishing the course accreditation procedures required for registration would fall to the first registration board set up under State or Territory legislation.
- A single State registration board could be established initially, with powers to register applicants from other States and to appoint interstate members to inquiry panels for complaints and disciplinary proceedings. Other States may set up their own registration boards at a later date.
- Where the number of practitioners in a State or Territory is too small to support a registration board, that State could recognise 'by reference' a registration Act in another State, and practitioners would be legally required to seek registration with the interstate board.
- State registration boards could be established, with agreement sought to set up at a later date a national body to accredit courses and set standards (as has occurred in medicine, nursing and optometry).

Submissions

The majority of submissions recognised the constitutional barriers to the formation of a single national registration board, and, therefore, supported State and Territory based registration boards (See Appendix 8). However, there was strong support for a national approach to setting of standards for practitioner training and registration.

The **Tasmanian Department of Community and Health Services** supported the establishment of separate State based registration Acts with a nationally operating body to accredit courses and/or examine overseas trained practitioners not holding approved qualifications. They stated that:

The option of establishing legislation which relies on practitioners being registered in another State, for example Victoria, has some attraction but would entail the practitioners dealing with a remote board, involve some inspection/investigation activity in Tasmania which would put significant extra costs on the mainland based authority and would still involve the passing of legislation similar to the other registration Acts to put the controls in place. ⁽²⁶⁾

The **Queensland Health Department** submission stated that if the Queensland Government decides to regulate TCM, the Department will recommend that a Traditional Chinese Medicine Practitioners Board be established. The enabling legislation would be based on the legislative model developed by Queensland Health's *Review of Medical and Health Practitioners Registration Acts* with appropriate amendments. In particular, the Department would provide the Board with the capacity to make or adopt a Code of Practice regarding appropriate infection control procedures. The Queensland Health Department submission stated that:

A consistent national approach to the educational standards for entry into the profession, grandparenting and accreditation of courses (including the establishment of a national accreditation body) and the titles to be protected is supported in principle. Ideally, a collaborative approach would be used to develop model provisions in respect of these issues.⁽²⁷⁾

The Australian Acupuncture and Chinese Medicine Association Ltd is the largest professional association for TCM in Australia, with over 1000 members. It has offered to convene a National Academic Standards Committee and has invited representation from all identified TCM Associations and teaching institutions. The purpose of the Committee is to develop a document that has the general support of the majority of the profession and course providers on minimum requirements for courses of training in acupuncture and Chinese herbal medicine, as well as a set of assessment criteria for courses. The AACMA has invited observers from State and Territory Government Departments. The role of the National Academic Standards Committee is to:

1. Reach agreement across the association and education sectors of the profession on academic standards for entry level courses in TCM (Acupuncture and Chinese Herbal Medicine).
2. Develop a set of core requirements that training courses should meet (or have as a prerequisite for entry).
3. Develop a set of assessment criteria for training courses that the profession and government recognised accrediting and regulatory bodies may adopt.

Committee's View

The Committee recognised the constitutional and political barriers to implementation of occupational regulation at a national level, but supported a national process for standard setting. Two options were considered:

- The profession could convene a group with practitioner representatives from the majority of professional associations, to work towards a consensus within the profession on standards of training and education for new practitioners. If successful, these standards would then be available to State and Territory registration boards when established, to use as a basis for the accreditation process.
- A Victorian Board (if established first) would have the power to coopt interstate practitioner representatives onto an accreditation subcommittee to establish standards of training, manage the process of accreditation of training schools, and develop guidelines for practitioner standards of practice.

Responsibility for developing standards rests with the profession. Any initiative to bring together representatives from a broad cross section of the profession should be supported.

Options for State and Territory Governments

There are a number of options available for State and Territory Governments in relation to implementation of statutory registration. They include:

1. Participation in joint project led by Victoria to develop template legislation with each State/Territory to determine its own timetable for implementation.

2. Await the outcome of the Victorian work and adopt the Victorian model legislation with or without modifications within time frames determined by each State/Territory.
3. Adopt by reference any Victorian registration legislation.
4. Pass legislation that requires practitioners to register with a Victorian TCM registration board if and when established.
5. Adopt no formal statutory regulation at this point, until practitioner numbers are sufficient to support a registration system.
6. Adopt one of the options outlined in the NSW Health Department's submission. (See Appendix 10).

Options 3, 4, 5 or 6 may be the most suitable options for those States and Territories with very small practitioner numbers.

Time Lines

If State and Territory Health Ministers agree to proceed with statutory registration, or agree for Victoria to develop template legislation that other States may use as a model in the future, then the following is the most optimistic time frame for implementation of statutory registration of TCM practitioners in Victoria:

1. Health Ministers Conference approval to proceed—July 1998.
2. Victorian Cabinet Approval In Principle and preparation of drafting instructions—October 1998.
3. Drafting a Bill—Dec 1998.
4. Earliest possible session of Victorian Parliament for introduction and passage—Autumn 1999.
5. Proclamation date 6–12 months from passage to allow the administrative machinery to be set up—May 2000.
Some sections might not be proclaimed until later, if they required work at a national level by the National Drugs and Poisons Schedule Committee (NDPSC) and the Complementary Medicines Evaluation Committee (CMEC), for example the list of toxic herbs that qualified practitioners might be eligible to prescribe.

Such a time line allows for the three years that the AMAS believes is necessary for standards to be developed (See section 5.7). During this time, the National Academic Standards Committee or a similar group representative of the profession, should have completed its work.

Recommendation 2

That statutory registration via State and Territory based registration boards be implemented.

Recommendation 3

That State and Territory Health Ministers agree for Victoria to take the lead in developing template legislation for statutory registration of TCM practitioners that can be used as a model by other States and Territories, with an implementation timetable to be determined by each State and Territory.

Recommendation 4

That a national approach to accreditation of training courses and setting of standards be supported as a matter of policy.

Recommendation 5

That a representative group from the profession be encouraged to develop consensus guidelines for an appropriate minimum standard of education in both acupuncture and Chinese herbal medicine.



5. Implementation Issues

5.1 Constitution and Powers of a TCM Registration Board

Background

Under the Victorian model for the constitution and powers of health practitioner registration boards, discussed in section 1.2 and outlined in detail in Appendix 1, registration boards are established under a statute of Parliament. Victorian health practitioner registration boards have a maximum of twelve members, and for smaller professional groups, around seven members is considered satisfactory, comprising a majority of practitioners from the profession, as well as a qualified lawyer, and two lay persons with no professional qualifications or pecuniary interest in the profession.

Members are appointed by Governor-in-Council on recommendation of the Minister for Health. The normal procedure is for advertisements to be placed in newspapers inviting interested parties to apply for appointment to practitioner, lay or lawyer positions on the board. President and Deputy President are also appointed from practitioner members. Practitioner members of a TCM board would require expertise in one or more of the key TCM modalities that are to be regulated, that is, Chinese herbal medicine, acupuncture and Chinese orthopaedics/manipulation if it is also to be regulated.

Appendix 1 outlines the powers and functions of a health practitioner registration board in Victoria. These include the power to:

- Register suitably qualified persons and/or persons meeting approved competency standards so that they may practice in Victoria;
- Accredit courses that provide qualifications recognized as acceptable for registration purposes;
- Establish standards for the conduct of examinations for the purposes of registration;
- Investigate complaints about, and inquire into, the conduct of persons registered under the Act.

Submissions

The majority of submissions supported the Victorian model of health practitioner registration with powers as outlined in the Discussion Paper. Membership of approximately seven was the most popular option, although size should reflect workload. The Tasmanian Department of Community and Health Services stated that the Victorian model for a Registration Act is generally in line with that used in Tasmania, although the composition of the Board does not fit in with Tasmanian practice. The Queensland Health Department stated that there should be discretion to include a larger number of public members. "Adequate public involvement is essential if the Board is to have substantial influence over the level of qualifications for registration".

Committee View:

The size of a registration board will depend on the number of modalities to be regulated and on whether its functions include registration of TCM practitioners in other States (in the absence of interstate boards). A larger board of up to 12 might then be required with suitable representation from lay persons and lawyers. Otherwise seven to nine members may be sufficient (four to six practitioners, two lay persons, and one lawyer). The board should be made up of a majority of practitioners. Its powers should be consistent with the standard model in Victoria, or for other States/Territories, the model that applies in that State.

It would be desirable for some registration board members to be bilingual (Mandarin/Cantonese and English). This would facilitate administration of Board activities, dealing with practitioners of non-English speaking background (NESB) and establishment of links with the Chinese State Administration of TCM, visiting experts, etc.

Recommendation 6

That the Victorian model of health practitioner registration be used as a guide in developing template legislation in Victoria for registration of TCM practitioners.

5.2 Modalities to be Regulated

Background

Towards A Safer Choice noted that TCM is as diverse in its practice as is western medicine. It is employed in both acute and chronic illnesses and it includes:

- Chinese herbal medicine, including the use of plant, animal and mineral substances (Zhong Yao).
- Acupuncture and moxibustion (Zhen Jiu).
- Chinese therapeutic massage (Tui Na).
- Dietary and lifestyle advice (Zhong Yi Shi Liao).
- Breathing, movement and meditation (Yun Dong Liao Fa).
- Chinese orthopaedics and manipulation (Gu Shang Tui Na or Zheng Gu).
- Surgery (Zhong Yi Wai Ke).
- Specific techniques associated with acupuncture and moxibustion, including cupping, scraping and point injection therapy.

The majority of TCM practitioners in Australia are trained primarily as acupuncturists, and a significant number have knowledge of Chinese herbal medicine. *Towards A Safer Choice* identified that these are the two practices that present significant risks to the public and therefore require regulation. Other traditional therapeutic approaches such as acupressure, Chinese therapeutic massage, exercise and diet therapy, which are used considerably less in Australia than in China, are unlikely to pose a serious risk to the public and therefore may not warrant government regulation.

Submissions

All submissions supported acupuncture and Chinese herbal medicine as the two key modalities that should be regulated. There was some support for additional modalities, particularly Chinese Therapeutic Massage (TuiNa) and Chinese orthopaedics and manipulation (Gu Shang Tui Na or Zheng Gu).

The Queensland Health Department's position on this issue will be determined following consideration of submissions on the Discussion Paper. 'At this point, the conclusion that acupuncture and Chinese herbal medicine are the TCM modalities which pose the greatest risk to public health and safety is accepted'.

Committee View

There are two modalities of TCM that require regulation at this point. They are acupuncture and Chinese herbal medicine. Further work is required to determine whether Chinese orthopaedics and manipulation, which includes traumatol-

ogy should be regulated via statute. There is documented evidence of risks associated with the practice of acupuncture and Chinese herbal medicine and the need for regulation (See *Towards A Safer Choice*). The case is not so clear in Australia in relation to Chinese orthopaedics and manipulation (Gu Shang Tui Na) partly because it does not appear, to date, to have been widely practised here.

It is understood that Tui Na is the study of all types of basic manipulation and massage techniques, whereas Chinese orthopaedics and manipulation is the clinical specialty area which uses Tui Na techniques. The Committee considers that there may be a sufficient case for statutory regulation of this additional specialty via protection of title only. The arguments are as follows:

- The practice of spinal manipulation is already regulated in all States and Territories via protection of title legislation (and in some States restrictions on practice also apply) for chiropractors, osteopaths, medical practitioners and physiotherapists.
- Many of the techniques adopted in Gu Shang Tui Na or Zheng Gu are similar to the spinal and joint manipulation techniques used by chiropractors, osteopaths and physiotherapists. This area of practice is regulated when carried out by other practitioners because it has demonstrated risks to the public. These risks have been documented recently with the 1996–97 reviews in Victoria of the legislation governing these professions.
- If this area is left unregulated, then in those States/Territories where there are no restrictions on the practise of spinal manipulation (that is, where only protection of title legislation is in place), untrained persons may represent themselves as being qualified in Chinese orthopaedics and manipulation (but not acupuncture or Chinese herbal medicine). They may then avoid meeting standards of practise set by either a TCM registration board(s) or other registration boards such as the Chiropractors, Osteopaths and Physiotherapists Registration Boards. Such a situation may present unacceptable risks to the public.

The Committee is of the view that there are not sufficient risks to the public to warrant the regulation via registration of Chinese therapeutic massage where it does not include more risky practices such as orthopaedics, manipulation and traumatology. Self regulation by professional associations is the preferred approach for massage therapies. This is consistent with the position adopted for other forms of therapeutic massage in Victoria and other States and Territories. It may be possible to regulate via protection of title the practise of Chinese orthopaedics and manipulation while allowing continued self regulation of Chinese therapeutic massage.

Any other TCM specialties can be identified via the membership and rules of professional associations with setting of standards via a model similar to that of the medical profession's Royal Colleges, rather than via a statutory registration system.

Further work is required to determine the most suitable method of regulation of Chinese orthopaedics and manipulation. This should include consultation with the professions and registration boards for physiotherapy, chiropractic, osteopathy and medical practice concerning standards of practice.

Recommendation 7

That the modalities of acupuncture and Chinese herbal medicine be regulated via statutory registration.

Recommendation 8

That further work be done to determine the most suitable method of regulation of the practice of Chinese orthopaedics and manipulation.

5.3 Protection of Title Versus Protection of Practice

Background

The Victorian *Medical Practice Act 1994* is a typical registration Act. Section 1(a) states that the Act's main purposes include:

to protect the public by providing for the registration of medical practitioners, investigations into the professional conduct and fitness to practise of registered medical practitioners.

Section 62 prohibits a non-registered person from representing himself or herself to be a registered practitioner of medicine. The Act does not prohibit an unregistered person practising medicine per se: provisions in other legislation achieve this through restricting to legally qualified medical practitioners the right, for instance, to prescribe various medications, issue various medical certificates, recommend involuntary admission to psychiatric facilities, and receive reimbursement for Medicare services under the Commonwealth *Health Insurance Act 1973*.⁽²⁸⁾ *Towards A Safer Choice* summarises the situation:

The registration of medical practitioners is based only on their achievement of qualifications considered to indicate competence to practise. The registration board's role in ensuring that practitioners maintain standards is enforced only in the breach through the disciplinary process. Ensuring that practitioners maintain annually certified levels of competence is left up other mechanisms such as the activities of the professional colleges. Maintaining theoretical and practical standards is thus the task of continuing medical education, peer review and quality assurance activities. However, this approach is complemented by expanded disciplinary capacities. For example, the board has the capacity to make orders requiring participation in such activities as an outcome of a disciplinary hearing.⁽²⁹⁾

The Victorian model and that recommended for TCM by *Towards A Safer Choice* is based on 'protection of title'. This means that use of certain titles is restricted to those who have the accredited qualifications and are registered practitioners under the relevant registration Act. The Victorian model does not provide for a definition and restriction of practice, leaving unregistered people free to undertake the practices associated with the registered occupation. However, if unregistered people use the protected title or lead members of the public to believe they are registered, they may be prosecuted under the registration Act.

In some professions, such as optometry and dentistry, the legislation prohibits unregistered people from practising certain procedures. This is known as 'protection of practice'. There are differing views on whether occupational regulation for TCM should include restrictions on the use of certain procedures known to carry risk. Some parties, for example, believe that only trained and registered practitioners should be able to use acupuncture. Others believe that certain procedures, such as direct needling of children, or needling certain areas of the body such as the chest or around sensory organs, should be restricted to trained and registered practitioners. In Chinese herbal medicine, prescribing of certain herbs known to be toxic has been restricted to registered medical practitioners, via State and Commonwealth drugs and poisons legislation (see section 5.4).

The majority of health practitioner registration Acts in Victoria, including those for medical practitioners, nurses, osteopaths and chiropractors, incorporate 'protection of title' only. While 'protection of practice' would prevent unqualified practitioners from offering TCM services to the public and prevent untrained practitioners from entering the profession, *Towards A Safer Choice* suggests that, given that the risks of TCM are not more significant than those encountered in the practice of western medicine, the same level of regulation is appropriate. Restrictions on practice may be difficult to support in the current deregulatory environment, especially given the obligations imposed by National Competition Policy.

With the application of protection of title legislation to TCM, unqualified practitioners would be able to continue their practice of acupuncture, Chinese herbal medicine, and Chinese orthopaedics/manipulation (if regulated), but they would not be able to use certain titles associated with the profession, or to lead the public to believe that they were qualified and registered. If additional restrictions on practice are required, for example on the use of acupuncture or certain toxic herbs, then other forms of regulation, for example skin penetration regulations or provisions within State and Commonwealth drugs and poisons legislation, may provide a more suitable mechanism.

Submissions

Most submissions stated that protection of title legislation was sufficient to adequately protect consumers of TCM. A small number of submissions stated that protection of title was insufficient and that restrictions on who can practice acupuncture, Chinese herbal medicine and/or Chinese orthopaedics and manipulation are also required.

If the Queensland Government decides to regulate TCM via occupational regulation, the Queensland Health Department is likely to recommend that this be achieved by way of protection of title and the core practices model put forward in the *Draft Policy Paper on the Review of Medical and Health Practitioner Registration Acts (September 1996)*. Under this approach, the core practice of acupuncture would be restricted to TCM practitioners and other registered health practitioners authorized by their registration board. (Authorisation would only be granted where the Board satisfied itself that the practitioner had the appropriate training). The practice of Chinese herbal medicine will not be restricted through the core practices model.

Committee View

The Committee believes that initially, protection of title only should apply, with no restrictions on practice included in a registration Act. However, the Committee sees no practical difficulties with Queensland or other State or Territory Governments proceeding to adopt a core practices model under which the practice of acupuncture is restricted to registered health practitioners from one or a number of disciplines, as outlined in the Queensland Health Department submission above.

Prescribing of identified toxic herbal medicines should be restricted to practitioners trained and qualified in Chinese herbal medicine (as opposed to acupuncture only). The process for identifying the list of toxic or dangerous herbal medicines should be a national one, involving bodies such as the TGA, the NDPSAC and CMEC (See recommendations 12–16).

Skin Penetration Regulations should apply only to unregistered practitioners as is the case at present in Victoria. That is, registered health practitioners including those registered with a TCM board should continue to be exempt from these regulations by virtue of the fact that:

- Their registration boards have a responsibility to ensure they meet acceptable standards of practice, which include standards concerning skin penetration and infection control;
- Breaches of these standards can be pursued by boards under powers to investigate and discipline practitioners for unprofessional conduct.

Recommendation 9

That a model of health practitioner registration based on protection of title be adopted as the minimum requirement for regulation of the TCM profession.

Recommendation 10

That the Federal Department of Health and Family Services convene a national process involving bodies such as the Therapeutic Goods Administration, the National Drugs and Poisons Scheduling Committee (NDPSC), the Complementary Medicines Evaluation Committee (CMEC) and suitably qualified representatives from the TCM profession to revise the scheduling arrangements for Chinese herbal medicines, and identify the list of herbs to be included.

Recommendation 11

That State and Territory Skin Penetration Regulations continue to apply only to those practitioners who use acupuncture and are not registered with either a TCM registration board or other registration board that has set standards of practice for acupuncture in consultation with a TCM registration board.

5.4 Prescribing of Scheduled Herbs

Background

There is considerable variation in the extent of toxicity of different Chinese herbs. TCM practitioners argue that consumer choice is constrained because prescription of certain herbs traditionally used by TCM practitioners is restricted by the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). The SUSDP is administered by the National Drugs and Poisons Schedule Committee of the Commonwealth's Therapeutic Goods Administration (TGA), and implemented by adoption in State and Territory legislation. Herbs listed in Schedules four and eight of the SUSDP may only be prescribed by registered medical practitioners, dentists or veterinarians and may be dispensed only by registered pharmacists. Herbs listed in Schedules two and three are available through pharmacies only. The SUSDP does not provide for prescribing rights. Rather, it is the State and Territory drugs and poisons legislation which confers this right.

There may be a need to classify herbs according to the extent to which they can be used safely by the general population, untrained practitioners, and trained herbalists. One function of a registration board, in consultation with the TCM profession, the National Drugs and Poisons Schedule Committee, and CMEC might be the classification of Chinese herbs and the determination of regulations regarding their use.

Six categories of herbs have been identified:

1. Poisons for which internal use is prohibited but which should be available for external use upon prescription by a registered practitioner.
2. Substances derived from endangered species the use of which is prohibited under the *Wildlife Protection (Regulation of Exports and Imports) Act 1982*.
3. Substances that are currently classified as drugs of dependence under Australian law but have been used traditionally in herbal practice.
4. Substances requiring special care in prescribing, and requiring a high degree of herbal medicine training.
5. Substances which can be prescribed with relative safety by a TCM practitioner.
6. Substances which are used in food and are freely available to the public.⁽³⁰⁾

Guidelines for prescription and dispensing need to be developed for substances in categories 1, 3 and 4. Similar guidelines and schedules for prepared herbal medicines may also need to be developed.

With the passage of the Victorian *Optometrists Registration Act 1996*, a model has been established which:

- Creates a power for the Victorian Minister for Health to approve a list of scheduled drugs that are appropriately prescribed by suitably trained optometrists.
- Creates a power for the Optometrists Registration Board to endorse the registration certificate of optometrists who have completed the required post-graduate qualifications so that they are trained to prescribe a restricted list of drugs approved for the purpose by the Minister.
- Includes amendments to the Victorian *Drugs Poisons and Controlled Substances Act* and Regulations to allow optometrists limited prescribing rights.

This model may be applicable to TCM, where a list of toxic herbs and herbal preparations might be included on a Schedule or Schedules under drugs and poisons legislation, and suitably trained practitioners might be eligible to seek an endorsement of their registration certificate to allow them legally to prescribe this approved list of substances.

Submissions

A number of submissions raised concerns about the current scheduling arrangements for herbal medicines. These concerns fall into the following areas:

1. The Importance to TCM Practitioners of Scheduled Herbs

There are only a relatively small number of herbs that have been scheduled and therefore removed from use by non-medically trained herbal medicine practitioners. However, it is not the number of herbs that is of concern, it is their importance in the practice of TCM. Two herbs in particular are regularly referred to: *Ma Huang* which is *Ephedra sinica*, is scheduled under ephedrine and pseudo-ephedrine, and *aconite*, several species of which are used in different ways by Chinese Medicine practitioners. One Chinese herbal medicine practitioner writes:

It is in fact ironic that an anti-asthmatic drug (*Ma Huang*) which we pioneered and used successfully on humans for twenty centuries, should—after only three quarters of a century of appropriation by Western medicine—be denied us.⁽³¹⁾

2. Difficulties With How Herbs are Dealt with in the SUSDP

There is perceived to be little scientific or policy logic in the way herbs are categorised in the SUSDP. The SUSDP contains a mixture of specific entries which name a particular chemical compound and specify allowable amounts, and entries which include all species of a particular plant genus with no amounts specified. The SUSDP appears to treat chemical compounds and plant species in the same manner thereby failing to distinguish between isolated compounds and complex mixtures. If plant material is to be included on the SUSDP it should be listed separately from chemical compounds. These are different substances and the allowable amounts also differ. In the case of herbs, the allowable amounts should be specified in terms of dry weight of the herbs per dose for extemporaneously dispensed prescriptions. For prepared medicines, the allowable amounts should be specified in terms of weight of extract per dose.⁽³²⁾

A number of submissions stressed the need to involve those with TCM expertise in identifying and classifying the toxicity of herbal medicines for the purposes of scheduling. One submission drew attention to the recently published English version of the Pharmacopoeia of The People's Republic of China in Chinese Herbal Medicine, and requested that this be used as a basis for drafting scheduling arrangements.

3. Availability of Toxic Herbs to Medical, Dental and Veterinary Practitioners

Aconite is a very toxic herb, especially in its raw state before processing as per the Chinese Pharmacopoeia. Three species of aconite, each with distinctly described actions and applications, have a long history of use in Chinese medicine, dating from at least 210AD. Over 30 traditional formulae include Fu Zi (*Aconiti Carmichaeli Praeparata, Radix*) as the primary herb in their titles, and many times this number include it as an adjunct herb in the constituents of the formula. It is particularly deadly when used by those untrained in its use. Yet the SUSDP by scheduling the drug S4, allows medical, dental or veterinary prescription. Few if any of these practitioners are likely to have ever studied, handled or even seen aconite. One submission states that:

The only possible explanation is that these groups can be identified as medically trained, and therefore presumably able to exercise a modicum of sense in handling the poison. How much better if the training of 'an identifiable group' actually taught the proper employment of aconite. How this training, traditional and modern, can be designed and combined to best ensure the safety of the public should be the subject of negotiation between the proposed TCM Registration Board and the NDPS, and access to aconite should be delayed until acceptable safeguards are agreed upon.⁽³³⁾

4. Illegality of Current Prescribing Practices

Inappropriate scheduling arrangements for certain popularly and widely used Chinese herbs and medicinal formulae have led to widespread flouting of the law as practitioners continue to prescribe these traditional formulae and prescriptions that they have been trained to use.

To not allow access to trained practitioners whilst increasing the number of scheduled herbs is a method of increasing regulation and restricting trade. It only leads to a black market trade and the flouting of regulations. Such outcomes can hardly be considered the product of good policy.⁽³⁴⁾

Most submissions supported access to scheduled herbs for suitably trained practitioners. This did **not** include those trained only in acupuncture. There was general support for the model outlined in the Discussion Paper based on that adopted for optometrists in Victoria.

The Tasmanian Department of Community Services and Health submission makes the point that 'if accreditation were to be a mechanism of gaining access to Scheduled Drugs, then a system not dissimilar to a health professional registration Act would be the most practical method of identifying properly qualified practitioners.'⁽³⁵⁾

Committee View

The Committee acknowledges the desire of practitioners suitably trained in the safe use Chinese herbal medicines to have access within the law to their tools of trade. The Committee believes that the current restrictions on access to herbs under the SUSDP by trained Chinese herbal medicine practitioners are inappropriate and should be reviewed and amended. However, it is accepted that no changes can be made to the SUSDP to support prescribing rights for Chinese Medicine practitioners until a registration system is implemented by States and Territories. Creating a separate schedule of herbs restricted to Chinese medicine practitioners who are trained specifically in the use of raw and/or prepared herbs is one possible option. There may be other options. This work should be done in consultation with those highly qualified in Chinese herbal medicine.

There is considerable work required to review the scheduling arrangements for herbs to determine:

- Which raw herbs should be scheduled under the SUSDP;
- What schedules they should fall into and how they should be labelled when prescribed;
- How prepared medicines that contain scheduled herbs should be regulated;
- Whether a separate schedule is the most suitable method of dealing with herbal medicines.

In addition to a review of the scheduling arrangements at a national level, the Committee favours inclusion in State and Territory TCM practitioner registration legislation of the model that has been applied in Victoria under the *Optometrists Registration Act 1996*. This legislation creates powers for Victorian optometrists to prescribe a limited range of Schedule 4 drugs. Such a mechanism, if applied to TCM would allow controlled access by suitably trained TCM practitioners to the few herbs considered most important. It would also give power for a State or Territory Minister for Health to approve the list of herbs and substances to be legally prescribed by qualified practitioners. Such an approach a relatively straightforward mechanism with inbuilt safeguards.

Further work is required to identify standards of training that should apply to prescribing and dispensing of patent medicines as opposed to raw herbs, particularly where those patent medicines contain scheduled herbs.

See Recommendation 9.

Recommendation 12

That the Victorian *Optometrists Registration Act 1996* be used as a model for creating powers for within each State and Territory for suitably qualified Chinese herbal medicine practitioners to prescribe scheduled Chinese herbs.

Recommendation 13

That the Commonwealth consider the establishment of a separate Schedule of herbs within the SUSDP as one of a number of options for ensuring that herbal substances are more adequately regulated via the scheduling arrangements, and that this review be done in cooperation with those highly trained in Chinese herbal medicine.

5.5 Regulation of Dispensing of Raw Herbs

Background

The Register of Acupuncture and Traditional Chinese Medicine Inc. has identified the following problems with the current unregulated dispensing of raw herbs:

1. At present, any herb (except those scheduled under drugs and poisons legislation) can be sold over the counter without prescription, and there is no requirement for dispensers to:
 - instruct the recipient in its proper use;
 - ensure the herb is properly labelled when sold alone or properly identified when sold as part of a prescription;
 - ensure the herb is safe enough for free use by the public.
2. Prescriptions can be filled by a retail shop without any restriction on the number of repeats, the age of the prescription, the provision of proper instructions, or whether the prescription was provided by a qualified TCM practitioner or copied from a book.
3. There is no requirement for dispensers of herbs in retail outlets to have the ability to:
 - identify the herbs accurately.
 - identify errors in labelling.
 - identify errors in prescriptions.
 - give accurate instructions regarding the use and preparation of herbs.⁽³⁶⁾

Options for regulation range from no change to the current situation for dispensing, through to requirements for licensing of all dispensers of raw herbs, including wholesalers, practitioners and retailers. In the current deregulatory environment, it may be difficult to achieve support for the regulation of dispensing as a separate activity or profession, particularly where a cost/benefit analysis of the impact of regulation of this area has not yet been undertaken.

Some have advocated a role for registered pharmacists in dispensing Chinese herbs. However, pharmacy training is inadequate to ensure safety in this area.

Submissions

There was general recognition of the dangers associated with untrained dispensing of raw herbs. Many submissions supported regulation of dispensing via licensing of wholesale as well as retail outlets. The Register of Acupuncture and TCM Inc. provided a detailed submission on the merits of registering both TCM practitioners and dispensers, particularly where the prescribing and dispensing of scheduled herbs is involved. One submission referred to work being done in Hong Kong where a list of 31 types of Chinese herbal medicine with mild or potent toxicity has been drafted, and recommendations made to wholesalers and retailers concerning dispensing of these substances.

Committee View

The majority of qualified Chinese herbal medicine practitioners in Australia also provide a herbal dispensary on site in their clinic. Registration of these practitioners and regulation via a TCM registration board is a suitable mechanism to ensure standards of training and practice for both prescribing and dispensing of scheduled herbs in these circum-

stances. However, in China, dispensing of raw herbs is a well established and separate profession. With the increasing use of TCM in Australia, dispensing is emerging as a skilled profession, and increasing numbers of practitioners may choose simply to write a prescription that can be filled by the patient at an independent Chinese herbal dispensary located elsewhere.

It is the Committee's view that introduction of regulation of TCM practitioners should in no way stifle the development and evolution of Chinese herbal medicine dispensing as a separate profession. Even where the herbs themselves are not toxic, there are risks associated with combining of certain herbs, contamination, substitution etc. To have a qualified and well trained dispensing profession is expected to minimise these risks. Given these risks, self regulation should be encouraged and should provide sufficient protection to the public by supporting the development of a strong dispensing profession and establishing standards for safe dispensing.

However, where dispensers are dispensing scheduled herbs that have been prescribed by a qualified herbal medicine practitioner who is legally entitled to prescribe these potentially toxic substances, then the community and government must be satisfied that there are adequate safeguards in place as there is with dispensing of scheduled pharmaceuticals by registered pharmacists.

There will therefore need to be a mechanism to ensure that dispensers who dispense scheduled herbs are fit and proper persons and that they have the required training to handle and dispense safely these restricted substances. Regulation of dispensing of scheduled herbs may be achieved via a number of mechanisms:

- Requiring dispensers to register with a TCM Registration Board.
- Licensing of dispensers by State Health Department Drugs and Poisons Units.
- Licensing and inspection by local government health authorities, for example, by Environmental Health officers.

Under any of the above arrangements, dispensers who do not dispense scheduled herbs would not need to be registered or licenced. At this point in time, a single TCM registration board with powers to register both TCM herbal practitioners as well as dispensers handling scheduled herbs is considered the most suitable model, although further work is required particularly in relation to the overlap between medicines and food and what standards should be applied to dispensing of herbs that are not covered by scheduling arrangements.

Recommendation 14

That the TCM registration board(s) have the power to register suitably qualified dispensers in order to regulate dispensing of scheduled herbal medicines.

Recommendation 15

That the TCM registration board(s) in conjunction with the NDPSC and suitably qualified representatives from the TCM profession agree on standards that will apply for registration or licencing of those Chinese herbal dispensers who dispense Chinese herbs scheduled under the SUSDP.

Recommendation 16

That the profession be encouraged to establish standards of training and practice and a self regulatory mechanism for the dispensing of herbal medicines not covered by scheduling arrangements.

5.6 Which Titles Should be Protected?

Background

When a title is protected, no practitioner, unless registered or exempted under the legislation, is able to use that title on their publications, shopfront, advertising, etc. If 'protection of title' legislation is adopted, it is necessary to determine which titles should be protected; that is, which titles would be identified in the legislation to be used only by registered practitioners. The Discussion Paper listed a number of options as follows:

- The term 'Traditional Chinese Medicine' has been adopted to refer to the body of knowledge in the area in Australia. It appears to be the term that is most widely used and therefore least likely to cause confusion. Many organisations representing practitioners prefer the term 'Chinese Medicine'. Other legislatures, for example some States in the United States, have adopted terms such as 'Oriental Medical Doctor' and 'Registered Acupuncturist'. One option is for all these titles to be protected.
- *Towards A Safer Choice* recommended that the following titles be protected:⁽³⁷⁾
 - Registered Chinese Medicine Practitioner
 - Registered TCM Practitioner
 - Registered Traditional Chinese Herbalist
 - Registered Acupuncturist
 - Registered Oriental Medicine Practitioner
 - Registered Traditional Chinese Herbalist and Acupuncturist
- Some sub-specialist practitioners have expressed concerns about protecting individual sub-specialties. They have suggested that the title Chinese Medicine Practitioner (Orthopaedics/Manipulative Therapy) also be protected.
- Another option is for practitioners to be registered as follows:
 - Chinese Medicine Practitioner (Herbal Medicine)
 - Chinese Medicine Practitioner (Acupuncture)
 - Chinese Medicine Practitioner (Herbal Medicine and Acupuncture).

The last approach would distinguish between those qualified in acupuncture only and those with a qualification in Chinese herbal medicine sufficient to qualify them to prescribe certain scheduled herbs. Those acupuncture practitioners without such training might continue to prescribe unscheduled prepared medicines, but would be unwise to go beyond their level of competence and training in prescribing of other herbal medicines. A registration board might issue guidelines for practitioners to assist in clarifying what constitutes safe practice for practitioners with varying levels of training in herbal medicine.

Submissions

A range of titles were proposed for protection, most favouring the options outlined in the Discussion Paper with modalities identified and titles restricted accordingly depending on the level and type of training. There continues to be division within the profession as to whether the term 'Chinese Medicine' or 'Traditional Chinese Medicine' should be used as the main descriptor for the profession.

A number of verbal and written submissions addressed a concern that has been expressed widely in the profession. This relates to the increasing use of the title 'Professor' by practitioners who do not hold such positions within Australian universities or who do not hold the qualifications which would normally be required of a person using that title in Australia. One submission argued that the assumption of titles by members of the Chinese Medicine profession for commercial purposes does great harm to the image of the profession in the eyes of the academic and scientific communities and with a well informed public. That submission recommended that a TCM registration board(s) issue guidelines for use of courtesy titles to prevent, for example practitioners using the title 'Professor' unless holding such an appointment from an Australian University, or on short term secondment from overseas institutions, or in the case of visiting professors only when the person visits the institution that has conferred the title.

Committee View

The Committee recognised that there are four main issues that concern the profession in relation to use of titles. A distinction must be made between:

- Titles that practitioners choose to use in their everyday practice to describe and advertise the service that they offer.
- Titles that might be protected under a TCM registration Act and therefore restricted to use only by qualified and registered practitioners.
- Titles that appear on an official registration certificate issued by a TCM registration board.
- Use of courtesy titles such as 'Dr' or 'Professor'.

Each of these areas is dealt with below.

1. 'Traditional Chinese Medicine' Versus 'Chinese Medicine'

There continues to be considerable disagreement as to whether the title 'Traditional Chinese Medicine' should be adopted as the official descriptor of the profession, or whether the title 'Chinese Medicine' only should be used.

It is the view of the Committee that practitioners who are registered by a TCM registration board should be free to adopt and advertise whatever titles they believe best describe their practice, on condition that:

- The practitioner has the required qualifications and **is in fact registered** with a TCM registration board; and
- The practitioner **does not** assume any title that is protected under other registration legislation for which they do not have the qualifications and are not registered, for example 'medical practitioner'.

Titles that are widely used by registered practitioners can include terms such as TCM, Traditional Chinese Medicine, Chinese Medicine or Oriental Medicine, etc.

2. Which Titles Should be Protected in Legislation?

In recent legislative reviews conducted in Victoria, the approach taken has been to restrict only one, or two titles at most, and to include a clause in the legislation which makes it an offence for an unregistered person to use 'any other title calculated to induce a belief that the person is registered under the Act'. This approach has some attraction. However, due to the range of titles in use in the community by practitioners of TCM, the Committee's view is that unless

the legislation makes explicit the titles that are protected, a new registration board may be exposed to significant and unnecessary court costs in order to establish the boundaries of the offence provisions relating to use of titles.

Practitioners who are qualified in acupuncture but have not met the standards of education and practice required by a registration board(s) in relation to Chinese herbal medicine, should not be able to use titles that lead the public to believe that they are qualified in both acupuncture and Chinese herbal medicine. Similarly, for practitioners qualified in Chinese herbal medicine but who have not met the standards required of acupuncturists. A registration board(s) should issue guidelines on what constitutes safe prescribing of non-scheduled herbs and patent formulae for those practitioners with acupuncture qualifications only. Separate standards may apply to patent formulae that contained scheduled herbs.

3. Which Titles Should be Used on Official Registration Certificates?

With respect to the titles that might appear on a registration certificate issued by a TCM registration board, it is unlikely that the profession will reach consensus on the issue of 'TCM' versus 'Chinese Medicine' outlined above. One option that should cause the least conflict is that each practitioner accepted as eligible for registration should be able to nominate whether they want the title 'Practitioner of Traditional Chinese Medicine' or 'Practitioner of Chinese Medicine' to appear on their registration certificate.

Any approach must distinguish between those practitioners who are trained mainly in acupuncture but who may use prepared medicines and some (unscheduled) raw herbs, and those who have sufficient Chinese herbal medicine training to be eligible to prescribe herbs that have been scheduled under the SUSDP and State and Territory drugs and poisons legislation.

4. Use of Courtesy Titles

Under the Victorian model of health practitioner registration, registration boards do not have specific powers to regulate the use of courtesy titles. For example, there is no legislative restriction on use of the title 'Doctor'. However, under the Victorian *Medical Practice Act 1994* there are restrictions on the use of titles such as 'registered medical practitioner' or any other title which is 'calculated to induce a belief that the person is registered under that Act'. Therefore, if a practitioner in Victoria wishes to use the title 'Doctor', they must identify the relevant discipline in that title to avoid an action by the Victorian Medical Practitioners Board, that is:

Dr Smith (Chinese Medicine)

Dr Wang (Chiropractic)

Dr Chen (Osteopathy).

Restrictions on the use of the title 'Professor' are sometimes applied as a condition of accreditation and approval of higher education private provider courses by State and Territory Education authorities. Any guidelines issued by a TCM registration board on use of other courtesy titles including 'Professor' may be desirable but difficult to enforce.

Recommendation 17

That the following titles be protected in legislation to register TCM practitioners, and a general clause be included which makes it an offence for unregistered persons to use any other title calculated to induce a belief that the person is registered under a TCM registration Act:

- Chinese Medicine Practitioner or Traditional Chinese Medicine Practitioner.
- Traditional Chinese Herbalist or Chinese Herbalist.
- Acupuncturist.
- Oriental Medicine Practitioner.
and
- Chinese Herbal Dispenser.

Recommendation 18

That the registration certificates issued by the TCM registration board(s) for qualified practitioners should identify which of the following modalities the practitioner is qualified to practice:

- Acupuncture
- Chinese herbal medicine.
- Chinese herbal dispensing.

Recommendation 19

That practitioners registered by a TCM registration board be given a choice as to whether 'Practitioner of Traditional Chinese Medicine' or 'Practitioner of Chinese Medicine' is listed in the title on their registration certificate.

Recommendation 20

That further work be done to establish whether there is a need to protect an additional title, that of Practitioner of Chinese Orthopaedics and Manipulation (Gu Shang Tui or Zheng Gu).

5.7 Approaches to Standard Setting

Background

Towards A Safer Choice outlines a range of approaches through which accreditation of courses and standards for professional practice might be established and enforced, from self-regulation to statutory approaches. All States and Territories have legislated to protect higher education award titles such as 'degree' and 'graduate diploma', and procedures have been prescribed for accreditation and approval of courses at these levels. Any TCM education provider wishing to offer courses leading to higher education awards needs to have such approval. In this way academic standards of equivalence to university level are ensured. However, Education authorities rely on input from professional associations or statutory regulation bodies for advice on standards associated with professional practice of TCM. Regardless of whether occupational regulation via statute proceeds, it is important for the profession to formalise and achieve consensus on standards of training for primary care practitioners of TCM.

If occupational registration proceeds, then it becomes the role of the registration board to accredit courses and determine the standard of training required for the purposes of registration. To assist registration boards in this process, it would be valuable to have available standards that have broad support from the majority of professional associations.

Automatic registration might be granted to graduates of educational courses that meet the required standard and have been accredited by a registration board. Graduates of courses which have not achieved accreditation might have their qualifications formally assessed or sit examinations set by a registration board. Standards set by a registration board would provide incentives to administrators of unaccredited courses to upgrade the courses they offer.

The existence of occupational regulation via statute does not diminish the need for ongoing self-regulatory activities by professional groups.

Submissions

Many submissions favour degree level training as the minimum standard. There is an understanding of the process for standard setting via a TCM registration board's role in accreditation of courses, and that this should include structured arrangements for consultation with the key professional associations. The AMAS has proposed that before registration of non-medically qualified TCM practitioners is introduced, the profession reach a consensus on standards of education and practice.

Committee View

There is already considerable work that has been done within the TCM profession to establish standards of education and practice, by organisations such as the FCMA, the Register and AACMA. The various documents produced can be used as a basis for the current task.

It is unlikely that all sectors of the profession will support such standards since there are educational institutions offering training courses at a considerably lower level than that considered acceptable by the majority of professional associations. However, it is hoped that facilitation by the Australian Acupuncture and Chinese Medicine Association of a forum and process will assist the profession to achieve a reasonable level of consensus and draft a comprehensive set of standards. These can then be used as a basis for a TCM registration board(s) to develop and apply its accreditation process (see section 4.2).

AACMA's primary role in the past has been to represent practitioners of acupuncture. It is expected that the standards will address both acupuncture and Chinese herbal medicine training and therefore, must draw on the expertise of practitioners with recognised expertise in each of these modalities. In the absence of consensus, it should be the responsibility of a TCM registration board(s) in cooperation with the TCM profession to determine standards of practice and to accredit educational courses. See Recommendation 5

5.8 Grandparenting arrangements

Background

'Grandfather' or 'grandparent' practitioners are defined as those existing practitioners in a professional discipline which is unregistered and unregulated who do not hold qualifications newly prescribed by a regulatory authority, be this a statutory board or professional self-regulating body. Grandparent practitioners tend to have diverse backgrounds and levels of competence.

The workforce survey published in *Towards A Safer Choice* identified that among primary TCM practitioners, 15% had received an apprenticeship in TCM and approximately two thirds of these had received no further formal TCM education. The report concluded that almost 10% of primary TCM practitioners practise on the basis of apprenticeship training alone. Apprenticeship took various forms, but in some cases consisted of up to six years full time work.⁽³⁸⁾ Among non-primary TCM practitioners, about 9% received an apprenticeship, with the majority receiving no other formal TCM training. In some cases this apprenticeship was reported as training at national or international conferences.

If occupational regulation is to be introduced, a process is needed from the point of introduction of registration for determining which practitioners are eligible for registration. The following models proposed by Prof. Andries Kleynhans from RMIT are based on experience with grandparenting of practitioners with the introduction of first Victorian *Chiropractors and Osteopaths Act 1978*. One or a combination of these approaches might be considered for admission of grandparent practitioners for registration purposes:

1. Recognition of Professional Membership

Membership of a particular professional association at a specific point in time might be used as the requirement for initial registration. This should only apply in case of professional organisations which can demonstrate a long history of adherence to minimum professional standards and codes of conduct, evidence of having policed their own membership, requirements for continuing education and professional development, and importantly, a history of carefully assessing the qualifications for entry to membership through activities such as examination or assessment of prior learning. A potential difficulty is the possibility of a significant increase in membership of an association immediately before submission of the membership register to a registration board. This is of concern particularly where sound protocols for admission to membership have not been followed.

2. Assessment of Qualifications

A registration board or regulatory authority might establish a 'Credentials Assessment Committee' which should include knowledgeable lay members and persons with knowledge of the qualifications that may come before the Committee for validation. Such a Committee would need to establish criteria, acceptable to the relevant board, for evaluation of documents. While it might not be expected that grandparent registrants who enter the regulated profession through this mechanism be at the same level as registrants who hold prescribed qualifications, they would be expected to meet minimum qualifications for safe practice at a basic level, and could be required to undergo additional education and training prescribed by the board in order to obtain a higher level of registration should this be mandatory for the privilege of being able to prescribe therapeutic substances on a 'restricted' or 'poisons' list.

3. Competency-Based Assessment of Grandparent Practitioners

Grandparent practitioners could be assessed against pre-determined competency-based professional standards and performance indicators. This process can be very difficult and has potential for litigation. However, it is possible to implement and might be considerably more effective if linked to a program of education and training approved by a registration board for the purposes of registration.

4. Education and Training of Grandparent Registrants

To qualify for registration, registrants might be required to undertake a program of training including assessment. This could be based on pre-determined criteria, and use a range of innovative, self-paced learning packs and practical-tutorial workshops. It may be the preferable way of standardising grandparent training for registration.

5. Standard Examination

Those seeking registration whose qualifications are not accepted under other criteria outlined above, might be required to sit a formal examination to assess their skills and knowledge in TCM. For example, the State Administration of TCM from the Peoples Republic of China has set up 'The Chinese International Examination Centre for Acupuncture and Moxibustion' and 'The Chinese International Examination Centre for Traditional Chinese Medicine'. The function of these centres is to provide objective examinations to judge the academic quality of the practitioners of TCM. The examination is available to those who have studied TCM at private and public institutions, as well as via apprenticeship. Exams are held in March and October each year and can be sat in either China or Australia.

Submissions

A range of approaches were supported, from competency based examination for all applicants through to membership of reputable professional associations as the sole criteria. There was strong opposition from some quarters to the use of the Chinese International Examination Centre's examinations without modification for Australian conditions.

A number of comprehensive approaches to grandparenting were submitted for consideration. These are contained in Appendix 11.

Committee View

There are a range of approaches for grandparenting. The approach adopted should be a combination of the options outlined above, including professional membership, qualifications assessment, competency based assessment and standard exam, with different requirements applying to different groups of practitioners depending on their level of training and experience.

It is not necessary for the Committee to make specific recommendations at this time as to the exact arrangements. It will be the responsibility of the TCM registration board(s) to determine and implement procedures for grandparenting. However, it may be appropriate for a representative group from the profession to consider submissions from professional associations etc and make recommendations on a suitable approach to grandparenting.

Recommendation 21

That representative body from the TCM profession further develop options for consideration by the TCM Registration Board(s) on grandparenting of existing practitioners with the introduction of registration requirements.

5.9 Non-English Speaking Practitioners

Background

All Victorian health practitioner registration boards set up since 1993 have the power to refuse to register applicants if their competency in speaking or communicating in English is not sufficient for that person to practise as a registered practitioner. Arbitrary application of a standard of English fluency, however, could discriminate against a significant proportion of TCM practitioners in Australia from non-English speaking (usually Chinese) backgrounds. Options include the following:

- Registration standards could include a standard of English language competence sufficient, for example, to be able to read and comprehend western medical prescriptions.
- Registration standards could include a standard of English language proficiency and fluency comparable to that required by already-registered health care practitioners, with discretion for exemption for senior members of the profession (for example those over 60 years of age or those with more than 20 years of safe practice experience), and/or with provisional registration conditional on upgrading English language skills within a defined period for practitioners who do not meet the registration standard for English.
- Where a language barrier exists, practitioners could be required to ensure patient access to a person with sufficient competence to enable response in an emergency situation and to ensure that patients are able to understand the instructions relating to their treatment and administration of any medications.
- A registration body could issue practice guidelines on how to ensure adequate communication between patient and practitioner where language barriers exist.

Submissions

A range of approaches were suggested, from requiring competency in English for all registered practitioners, to allowing a range of exemptions for practitioners over 60 and attaching conditions of practice to registration certificates. There was considerable anxiety expressed by practitioners of NESB that their practice would be disadvantaged by stringent application of English language requirements. They referred to safe practice records and the need for Australian trained practitioners to learn Chinese in order to access classical texts and practice TCM to a satisfactory standard.

The Register of Acupuncture and TCM Inc. stated that

in a therapeutic encounter, it is paramount that the client be able to communicate the history and nature of their complaint, and that the practitioner be able to comprehend the information communicated, be it verbal or written, and be able to question the client and communicate advice and intentions.⁽³⁹⁾

The Register maintains that application of a specified standard of general English as a prerequisite for registration would effectively exclude a large proportion of existing practitioners from the registration process. It would also shift the focus away from safety issues towards issues of ethnicity.

They recommend that during the grandparenting phase, eligibility for registration should be independent of language ability and based purely on TCM training and experience. Language related safety issues would be covered in the standards of practice and continuing education policies developed by committees under the supervision of the Board. Standards of practice for registered practitioners should include requirements of:

1. Effective communication in client-practitioner interactions.
2. The establishment of effective procedures for emergency situations, and
3. Effective access to biomedical information.

Such requirements would apply to all practitioners. Practitioners would need to establish effective communication prior to treating a client and those practitioners whose English ability is insufficient to manage emergency situations would need access to an English speaker during clinical hours. Following the grandparenting phase, training in health and safety issues would become a component of registration and would require specific English language competencies.

Committee View

The TCM registration board(s) should have the power to refuse to grant registration to an applicant whose competency in speaking or communicating in English is not sufficient for that person to practise safely as a registered practitioner. However, in order to ensure protection of the public while at the same time recognising the contribution to the health of the community by practitioners of NESB, a TCM registration board(s) should have the flexibility to recognise and support the continuing safe practice of NESB practitioners. A registration board should, therefore, have powers to:

- Register under grandparenting arrangements those NESB practitioners with a safe record of practice.
- Attach conditions to the registration certificates of practitioners of NESB, as well as provide exemptions from language requirements for NESB practitioners for example, those over 60 years or with more than 20 years of safe practice experience.
- Issue guidelines on what constitutes good practice for treating patients where a language barrier may exist.

Recommendation 22

That a TCM registration board(s) have a range of powers to set standards for the safe practice of NESB practitioners, including powers to:

- Register NESB practitioners under grandparenting arrangements.
- Establish English language requirements for newly registering practitioners.
- Attach conditions where necessary to the registration certificates of practitioners of NESB who may not meet English language requirements.
- Provide exemptions from English language requirements for NESB practitioners over 60 years, or with more than 20 years of safe practice experience.
- Issue guidelines on what constitutes good practice for treating patients where a language barrier may exist.
- Refuse to grant registration where an applicant's competency in speaking or communicating in English is not sufficient for safe practice.

5.10 Funding of a Regulatory System

Background

In Victoria, registration boards are independent incorporated bodies that are self-funding via registration fees. They receive no funds from Government. The range of costs of registration of health care practitioners in Victoria is given in the Table 2 below.

The most significant costs facing a registration board relate to legal fees for the conduct of inquiries and appeals arising from inquiries. These costs vary considerably from profession to profession.

Based on findings from the workforce survey, *Towards A Safer Choice* concluded that:

- TCM practitioners believed that occupational regulation would have a positive effect on TCM practice, and are likely to be compliant with any statutory requirements of regulation.
- There are sufficient numbers in the occupation to fund occupational regulation in the three States reviewed.
- It is uncertain whether there are sufficient numbers in States and Territories other than Queensland, NSW and Victoria to fund registration boards in each State, however a number of regulatory options are available that could disperse these costs.⁽⁴⁰⁾

Table 2: Cost of Registration in Victoria by Profession (1996–97)

| Profession | Registration fee per annum | Numbers registered |
|------------------------------|----------------------------|--------------------|
| Nurses | \$35 | 72,000 |
| Medical practitioners | \$95 | 14,500 |
| Physiotherapists | \$29 | 3,600 |
| Optometrists | \$208 | 700 |
| Chiropractors and Osteopaths | \$352 | 720 |

Submissions

Those submissions which addressed the question of cost of registration supported self funding of a registration board via annual registration fees. Practitioners supported fees in the range of \$150–\$500 p.a.

The Tasmanian Department of Community Services and Health supports the establishment of separate State based registration Acts with a nationally operating body to accredit courses and/or examine overseas trained practitioners not holding approved qualifications. The numbers of registrants in Tasmania would be low and may make the establishment of a practitioner funded registration authority potentially onerous on participants. However, there are already four health professional registration bodies with between fifty and seventy registrants, and while the registration/annual fee levels are not as low as those where the numbers registered are much larger, the costs amount only to a few dollars per registrant per week.

Committee View

In Victoria, there is no government subsidy of registration boards. There is every indication from professional associations that there are sufficient practitioners who are willing to pay registration fees to enable the operation of a TCM

registration board. Initial fees may be in the order of \$200–400 depending on whether interstate functions are required. A detailed costing will be required. It may be possible for a seeding loan with specific repayment terms to be made available by Government to assist with the establishment of the board.

Recommendation 23

That the TCM registration board(s) be self funding, with access to a seeding loan from Government to assist with establishment.

5.11 Regulation of Practitioners Registered with Another Board

Background

Increasing numbers of generalist health care practitioners are offering complementary medicines, particularly acupuncture. Generalist health care practitioners are defined as those whose primary form of practice is in another discipline (registered or unregistered). They include medical practitioners, nurses, physiotherapists, osteopaths, chiropractors, massage therapists and naturopaths.

Towards A Safer Choice documented concerns that practitioners registered to practice in other health care disciplines may not necessarily have adequate training or expertise in TCM, particularly where acupuncture or Chinese herbal medicine has been learned in isolation, without a sound education in the broader principles of TCM, and may be practised part-time:

- The Workforce Survey suggests that in Australia, the rate of adverse events associated with TCM is higher for registered than unregistered health practitioners. It seems likely that this disparity is related to a combination of factors.
- Shorter education courses in TCM were correlated with higher adverse event rates (Chapter Four), and registered health practitioners were identified as undertaking substantially shorter training programs in TCM (Chapter Five).
- Severity of conditions treated and the frequency of practice in TCM may also influence the rate of adverse events.

Willingness to report adverse events in a self-administered questionnaire may be greater amongst registered practitioners, although there is no evidence to support this.⁽⁴¹⁾

The British Medical Association's policy is that medical practitioners who wish to offer therapies outside western medicine should first ensure they are fully trained in the relevant discipline⁽⁴²⁾. Some Australian registration bodies and professional associations are in the process of addressing issues of standards of practice for their members who practise acupuncture and TCM:

- The **Australian Medical Acupuncture Society (AMAS)** represents registered medical practitioners who practice acupuncture. There are over 600 members, and 200 Fellows. Fellows have completed a minimum of 250 hours of training and passed written, practical and oral examinations. Medical practitioners generally use the title 'Medical Acupuncturist'. The Health Insurance Commission and the Royal Australia College of General Practitioners recognise the AMAS as the peak body for registered medical practitioners who practice acupuncture. The Association is in the process of negotiating with the Health Insurance Commission to establish standards of training which must be met in order for medical practitioners to access the Medicare rebate for acupuncture treatments.

- Work is currently underway by Dr Robert English from RMIT, in cooperation with the **Chiropractors Association of Australia**, to survey those chiropractors using acupuncture, with a view to establishing minimum standards of education and training for the profession.
- The **Nurses Board of Victoria** has issued Guidelines for Use of Complementary Therapies in Nursing Practice.

The guidelines caution that nurses are responsible for ensuring that they practice only within the limits of their skills and refer on where necessary and provide advice regarding the selection of appropriate courses, suggesting that nurses look for courses that are accredited or approved by 'the professional organisation'. Unfortunately no advice is provided as to how to identify this organisation(s).⁽⁴³⁾

The main thrust of registration is to protect the public by establishing standards of practice for registered practitioners, and to provide an avenue for aggrieved consumers to have their complaints addressed. Where practitioners are already registered, complaints mechanisms exist via the registration board, regardless of the type of treatment the individual practitioner provides.

There are concerns, however, about whether a generalist health practitioner registration board without access to appropriate TCM expertise will adopt and enforce suitable standards of practice in relation to this form of complementary therapy. Options to ensure that generalist health care practitioners practice to an acceptable standard include the following:

- Generalist health care practitioners might be required to register with a TCM registration body regardless of whether they are already registered with another registration board.
- Practitioners who are already registered with another registration board might be able to continue practising without seeking registration with a TCM registration body. Their registration board would retain responsibility for receiving and dealing with complaints concerning their TCM practice.
- Registered medical practitioners who use the title 'Medical Acupuncturist' might be exempted from the offence provisions of TCM registration legislation, where they have reached the standards of training set by the Health Insurance Commission and the Australian Medical Acupuncture Association, or some other suitable body.
- A TCM registration board(s) might reach agreement with other practitioner registration boards as to a suitable standard of education that the generalist health practitioner registration board will require their registrants to meet if they wish to practice TCM modalities. A TCM registration board could also provide advice and assistance in dealing with complaints that involve TCM.

In Victoria, where a registered practitioner's activities falls within the domain of a number of registration boards, the respective boards have been encouraged to meet and develop mutually accepted guidelines for practice, and cooperate concerning investigation of complaints and imposition of sanctions for unprofessional conduct.

Submissions

With the exception of the AMA Victorian Branch and AMAS, there was widespread support, including from the Nurses Board and the Australian Physiotherapy Association for their members who use TCM modalities to be required to register with a TCM registration board in order to use certain protected titles. There was strong criticism from primary TCM practitioners of the standard of training in acupuncture of 'Medical Acupuncturists' and a belief that they should be prevented from using such a title unless registered with a TCM registration board. The AMAS was vigorously

opposed to any requirement for its members to register with a TCM Registration Board as a condition of their use of the title 'Medical Acupuncturist'.

Committee View

The Committee was of the view that Registered Medical Practitioners possess the required clinical and diagnostic skills that would allow exemption from the requirement to register with a TCM registration board in order to use the title 'Medical Acupuncturist'. This view was based on the expectation that the AMAS will successfully negotiate an agreement with the Health Insurance Commission that will set a reasonable standard of education required by medical practitioners for reimbursement under the Commonwealth Medical Benefits Schedule and that the Medical Practitioners Board will continue to have the power to investigate and discipline registered medical practitioners for unprofessional conduct.

Other registered health professions should be exempted from requirements to register with a TCM registration board under three conditions:

- First, that they have met the requirements for education and clinical practice set by their own registration board.
- Second, that these standards have been endorsed by the TCM registration board in consultation with the practitioner's registration board.
- Third, that where a generalist health practitioner registration board investigates a complaint of unprofessional conduct that involves the practice of TCM, that it has access to suitable expertise in TCM on which to base its findings.

Recommendation 24

That State and Territory Medical Practitioner Registration Boards in consultation with the AMAS and the Health Insurance Commission be responsible for establishment of educational standards for those registered medical practitioners who use the title 'Medical Acupuncturist' and/or who make claims under Medicare for acupuncture treatments.

Recommendation 25:

That the TCM registration board(s) negotiate with and endorse where appropriate educational standards for other registered health professions to allow exemption from the offence provisions of a TCM registration Act.

5.12 Regulation of Practitioners of Other Forms of Complementary Therapies

Background

Questions have been raised concerning the scope of the current review and whether occupational groups practising other forms of complementary medicine should be registered. Given the imperatives created by National Competition Policy and AHMAC agreements, any occupational group pursuing statutory-based registration must satisfy rigorous criteria concerning the need for regulation and the costs and benefits to the public. This involves a comprehensive analysis of risks and benefits such as the one undertaken in *Towards A Safer Choice*.

There is no doubt that risks exist with the practice of most forms of complementary therapy. However, the most significant risks that arise with the majority of complementary therapies appear arise where practitioners:

- recommend to patients that they defer or withdraw from appropriate medical therapy.
and/or
- fail to detect serious underlying disease and/or fail to refer on, resulting in delay of diagnosis and appropriate treatment.

Apart from western herbal medicine, which involves ingestion of potentially toxic substances, it appears unlikely that other forms of currently unregistered complementary therapy present the same range and scale of risks to the public as those posed by TCM. A self-regulatory approach may therefore be sufficient to protect the public.

The focus of this review is TCM, and any recommendations arising from it will apply only to practitioners who use TCM modalities, that is, acupuncture and Chinese herbal medicine. There is no intention at this stage to examine the need for regulation or registration of other forms of complementary therapy, such as naturopathy and western herbal medicine. However, there are practitioners of other forms of complementary therapy, such as massage therapy, naturopathy, and shiatsu, who use modalities of TCM, particularly acupuncture, as part of their practice. If registration of TCM practitioners is introduced, other complementary therapy practitioners may seek registration under the same conditions as all primary TCM practitioners. If their qualifications are considered unsatisfactory for registration, they would have similar options to those outlined under the grandparenting section.

If unsuccessful in achieving registration, then under a restriction of practice model (where the practice of acupuncture would be restricted to practitioners registered with either a TCM registration board or some other health practitioner registration board), they would be unable to practice acupuncture. If protection of title only applied, then these practitioners would be able to continue to use acupuncture but would not be able to use the title 'Registered Acupuncturist' or advertise themselves as qualified to practice acupuncture.

Submissions

There is general agreement that unregistered complementary health practitioners who use TCM modalities should meet the standards set by a TCM registration board in order to use certain protected titles.

The National Herbalists Association has requested that Commonwealth, State and Territory Governments establish an appropriate form of regulatory recognition for the profession of Western herbal medicine, including a mechanism for trained Western herbal medicine practitioners to legally prescribe scheduled herbs.

Committee View

Protection of title only will allow unregistered complementary health practitioners to continue to use TCM modalities within their practice (with the exception of scheduled herbs) as long as they do not use protected titles or hold themselves out to the public as being qualified and registered in TCM. If they wish to use titles protected under TCM registration legislation, they would have to seek registration under the same criteria as other practitioners, and upgrade their qualifications if these were not of an acceptable standard to a TCM registration board(s).

Further work is required to establish whether there is a need for statutory registration of practitioners of Western herbal medicine, including establishment of mechanisms for access by suitably trained practitioners to certain scheduled Western herbal medicines.

Recommendation 26

That unregistered practitioners of complementary therapies other than TCM be required to register with a TCM registration board in order to adopt titles protected under that legislation.

Recommendation 27

That further work be done to establish whether there is a need for statutory registration of practitioners of Western Herbal Medicine and that this include examination of mechanisms to allow prescribing and dispensing of scheduled Western herbal medicines by suitably qualified practitioners.

5.13 Regulation of other Traditions of Acupuncture

Background

Forms of traditional medicine other than TCM use acupuncture as part of their practice. One such form is Ayurvedic Medicine. The International Association of Suchi Karma Inc. has expressed concerns as to how their practice of acupuncture might be affected by statutory regulation of TCM, particularly if legislation prevents them from using the title 'Acupuncturist'. They state that their system of acupuncture is different to the Chinese system and has been practised in India, Sri Lanka and Tibet for over 3000 years. A registration board consisting of practitioners trained in Chinese acupuncture may not be sufficiently qualified to regulate practitioners of 'Ayurvedic Acupuncture'.

Options under a protection of title system of registration include the following:

- Practitioners of Ayurvedic Medicine could be prevented from using the title 'Acupuncturist' but be able to continue practising acupuncture as part of their treatment. They would not be able to advertise themselves or hold themselves out to the public as being a qualified 'Acupuncturist' unless registered with a TCM registration board.
- Practitioners using the title 'Ayurvedic Acupuncturist' could be specifically exempted from the offence provisions of a registration Act where they meet certain standards for safe practice, and are certified by a suitable self-regulatory body.

The Australian Veterinary Acupuncture Association (AVAA) has also raised issues affecting their members. The Association represents qualified veterinary surgeons who are registered under the Veterinary Surgeons Acts in each State and have undergone further training in animal acupuncture. The AVAA is proposing that if registration of TCM Acupuncturists proceeds, then veterinarians with post-graduate training in veterinary acupuncture to a standard set by the AVAA be granted an exemption under the legislation and therefore continue to have the right to use the titles 'Veterinary Acupuncturist' or 'Veterinary Acupuncturer'.

Submissions

There was a range of views submitted on whether Ayurvedic acupuncture practitioners should be required to register with a TCM registration board in order to incorporate the word 'acupuncture' into their title. The organisation representing these practitioners supported their inclusion in a registration system.

Committee View

If a practitioner of 'Ayurvedic Acupuncture' wishes to use the word 'Acupuncturist' as part of their title, then they should be required to apply to the registration board. A TCM Registration Board would have the power to coopt relevant expertise from Ayurvedic Medicine Associations to assist in considering such applications, and may require a minimum standard of safe practice without requiring knowledge of the full body of TCM diagnostic and treatment systems for use of this specific title. These arrangements may or may not be recognised in the provisions of the legislation.

Recommendation 28

That practitioners of 'Ayurvedic Acupuncture' who wish to include the word 'acupuncturist' in their title be required to register with a TCM registration board.

Recommendation 29:

That Registered Veterinary Surgeons who use the title 'Veterinary Acupuncturist' be exempted from the legislation on the condition that they treat animals only.

5.14 The Need for Research

Committee View

The Committee was of the view that there may be opportunities to improve the health status of the Australian community through application of TCM in concert with Western Medicine to address a range of health issues. However, there is a need to develop a dialogue between TCM and Western Medicine researchers and a collaborative approach with established research institutions.

Specifically, there is a need to confirm whether TCM can contribute to improved public health and to establish priorities for joint research initiatives, in particular:

- Clinical trials which compare the effectiveness of TCM with other interventions/treatments for specific conditions;
- Epidemiological studies to validate the effectiveness of alternative approaches to health maintenance and health enhancement.
- An economic evaluation to assess potential savings to the health care system of alternative approaches to health maintenance.

The Committee identified initial research priorities as:

- To assess the efficacy of acupuncture and Chinese herbal medicine in the treatment of a range of conditions.
- To identify and quantify the side effects and adverse reactions to treatments, including in particular interactions between Western medicines and Chinese herbal medicines.

- To investigate and evaluate opportunities for public health intervention using TCM, and estimate the potential public health gain that may be achieved, with a view to developing and evaluating public health interventions.

Such research is essential to ensure adequate protection of the public and to determine the place of TCM within the health care system.

Recommendation 30

That the Department encourage dialogue between TCM researchers and Western Medicine researchers in order to establish research priorities for TCM and identify whether there are opportunities for public health intervention.

Recommendation 31

That targeted funding be made available from the Victorian Department of Human Services Health Research Initiatives for research into the risks and benefits associated with the practice of TCM, its effectiveness or lack of in treatment of specific conditions, and the detection and evaluation of opportunities for public health intervention.

Recommendation 32

That the NHMRC consider allocation of targeted funding for research into the risks and benefits associated with the practice of TCM, its effectiveness or lack of in treatment of specific conditions, and the detection and evaluation of opportunities for public health intervention.



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Appendix 1: Victorian Model of Health Practitioner Registration

This appendix sets out in detail the Victorian model of health practitioner registration that has been adopted with the passage of the *Victorian Medical Practice Act 1994*, the *Nurses Act 1993*, the *Chiropractors Registration Act 1996*, *Osteopaths Registration Act 1996* and the *Podiatrists Registration Act 1997*.

Since the legislation relating to chiropractors, osteopaths and podiatrists is most the most recent in Victoria and has been assessed under National Competition Policy, it is considered the most suitable precedent for the current review. Those interested in these issues are encouraged to examine either the *Osteopaths Registration Act* or the *Chiropractors Registration Act* in detail.

1. Purpose of Registration

The Victorian model of health practitioner registration makes it clear that the purpose of registration is to protect the public rather than to protect the professional group. Practitioners are required to be registered in those professions where the absence of statutory regulation would be likely to result in significant harm to individuals or endanger public health. Under the model, the aim of legislation is to protect use of the relevant title. It does not attempt to define what is and is not included in the practice of TCM and therefore will not limit the practice of certain techniques.

No definition of a TCM practitioner would be included in the legislation. This is because it is difficult to achieve a consensus concerning definitions, and to find definitions that do not encroach on other related professions such as chiropractors, osteopaths, medical practitioners, etc. Use of the titles such as Acupuncturist or TCM practitioner etc would be, however, protected by restricting the use of those titles to those who have the accredited qualifications and are registered as practitioners under the Act.

2. Composition of and Appointments to the Board

As discussed in section 5 of this report , Victorian health practitioner registration boards have a maximum of twelve members, but may have around seven members for smaller professional groups. The members must comprise a majority of practitioners from the profession, plus a qualified lawyer, and two lay persons with no professional qualifications or pecuniary interest in the profession.

The Victorian model provides for the Minister for Health to recommend members to be appointed to the board to the Governor-in-Council, and for the Governor-in-Council to appoint them. In practice, an advertisement is placed in the newspaper seeking applications for appointments, and the Minister seeks advice from interested parties such as the professional associations before making recommendations to the Governor in Council. The president and deputy president of the board are nominated by the Minister from among members of the board and appointed by the Governor-in-Council.

Appointments are generally made for terms of three years. Initial appointments would be for terms of one, two or three years to provide for staggered reappointments. A board member may resign or may be removed by the Governor-in-Council.

3. Relationship between the Board and Government

Victorian health practitioner registration boards are independent of Government but are obliged to consult the Minister for Health and take notice of his/her views. Boards must be incorporated so as to avoid personal liability for board members. Boards must be self-funding, and are responsible for setting their own fees, and meeting all expenses such as renting premises, hiring staff and paying legal counsel. Under the Victorian model, registration boards do not have the power to make regulations. This power rests with the Governor-in-Council.

4. Powers and Functions of the Board

Under the Victorian model, the main powers of a health practitioner registration board are as follows:

- To regulate the standards of practice of the profession in the public interest.
- To register suitably qualified persons and/or persons meeting approved competency standards so that they may practise in Victoria.
- To accredit courses which provide qualifications for registration purposes.
- To establish standards for the conduct of examinations for the purposes of registration.
- To issue guidelines about appropriate standards of practice.
- To investigate complaints about, and inquire into, the conduct of persons registered under the Act; and
- To carry out such other functions as are vested in the Board by or under its Act.

5. Registration

Under the Victorian model, the main powers of registration boards are as follows:

A health practitioner registration board has the power to register a practitioner if the practitioner:

- Possesses or is entitled to receive an accredited qualification; or
- Has attained a level of skill or competence (including those established by the appropriate professional associations, the National Office of Overseas Skills Recognition or the National Training Board); or
- Has passed a prescribed examination.

A registration board has the power to temporarily, provisionally, or conditionally register a practitioner or to grant a restricted registration. This allows additional flexibility in registration, for example with short term registration of visiting overseas lecturers.

It is proposed that registration will be annual.

6. Fees

Annual registration is conditional on payment of a fee set by the respective board.

Registration boards do not have the power to recover the costs of a hearing from the practitioner found guilty of an offence under the relevant Act. Boards must finance these cost and any appeals that may arise, via registration fees.

7. Recency of Practice

Under some registration Acts in Victoria, registration boards have the power to refuse to register an applicant who is otherwise qualified to be registered if he/she has not been registered for the preceding five years either in Victoria or elsewhere, and/or the board is not satisfied that he/she is, therefore, professionally competent to be registered. These provisions are not part of the standard model of health practitioner registration in Victoria but are currently being considered for inclusion in those Acts under review at present.

8. Discipline, Complaints Handling and Relationship with the Health Services Commissioner (HSC)

The Victorian model proposed to be adopted is that set out in Parts 3, 4, and 5 (Sections 20 - 60) of the *Osteopaths Registration Act 1996*. Those interested in these issues are encouraged to examine the *Osteopaths Registration Act 1996*, the *Chiropractors Registration Act 1996* or the *Podiatrists Registration Act 1997* in detail.

8.1 Definition of ‘Unprofessional Conduct’

The model provides a standard definition of ‘unprofessional conduct’. The definition is contained in the *Osteopaths Registration Act 1996* and has been adopted by the Victorian Government’s Scrutiny of Acts and Regulations Committee as the standard to be included in all health practitioner legislation. Unprofessional conduct is defined as any or all of the following:

- (a) professional conduct which is of a lesser standard than that which the public might reasonably expect of a registered practitioner.
- (b) professional conduct which is of a lesser standard than that which might reasonably be expected of a registered practitioner by his or her peers.
- (c) professional misconduct.
- (d) infamous conduct in a professional respect.
- (e) providing a person with health services of a kind that is excessive, unnecessary or not reasonably required for that person’s well-being.
- (f) influencing or attempting to influence the conduct of practice in such a way that patient care may be compromised.
- (g) the failure to act as a practitioner when required under an Act or regulations to do so.
- (h) a finding of guilt of—
 - (i) an indictable offence in Victoria, or an equivalent offence in another jurisdiction; or
 - (ii) an offence where the practitioner’s ability to continue to practise is likely to be affected because of the finding of guilt or where it is not in the public interest to allow the practitioner to continue to practise be cause of the finding of guilt; or
 - (iii) an offence under this Act or the regulations; or
 - (iv) an offence as a practitioner under any other Act regulations.

8.2 Investigation of Complaints

Under the model, registration boards are required to investigate all complaints that are not vexatious or frivolous. The main impact of these provisions is to formalise procedures relating to the conduct of investigations and inquiries, and to provide a broader range of determinations and findings.

Under the model, the relationship between the Board and the Health Services Commissioner (HSC) under the *Health Services (Conciliation & Review) Act 1987* is formalised as follows:

- The Board is required to forward a copy of a complaint to the HSC prior to dealing with it.
- If the complaint is suitable for conciliation the HSC will deal with it.
- If the complaint is not suitable for conciliation or is referred back, the Board will deal with it.

Investigations are undertaken by the Registrar or the Board, or the Board's delegate, or referred to an investigator. If the investigator is a Board member that member must not later sit as an inquiry panel member.

The Board will have the power to inquire into:

- The capacity of a person to carry out the functions of a practitioner; and
- The professional conduct of a practitioner.

An inquiry may be held by the Board at the request of:

- The HSC.
- A complainant.
- When requested to do so by an applicant who is refused registration
or
- On its own motion.

The Board must appoint a panel to undertake the inquiry.

8.3 Formal and Informal Inquiries

Where an inquiry is informal:

- A panel of up to three board members may be appointed;
- There is no entitlement to representation but the practitioner may be accompanied by an adviser;
- It is closed to the public; and
- There is a right of appeal to a formal inquiry.

Where an inquiry is formal:

- There is a panel of up to five Board members of which one must be a lawyer.
- There is an entitlement to legal representation.
- The panel has all the powers of a board of inquiry under the *Evidence Act 1958*.
- It is open to the public but there is a power to close all or part of the hearing.
and
- The avenue of appeal is to the Administrative Appeals Tribunal (A.A.T.).

A decision of an inquiry panel is a decision of the Board.

8.4 Warrant Provisions

Under the model, a person appointed by the registration board may apply to a magistrate for the issue of a search warrant, in order to investigate complaints. A warrant issued in accordance with the Magistrates' Courts Act 1989 may give the power for an appointee of the board to:

- Enter the premises, or the part of the premises, named or described in the warrant; and
- Search for and seize a thing named or described in the warrant; and
- Bring the thing before the Court so that the matter may be dealt with according to law.

Copies or receipts for seized items must be provided to the occupier.

8.5 Penalties

Under the model, registration boards have the power to make various determinations as a result of disciplinary or complaint proceedings including:

Where an informal inquiry is conducted:

- Require the practitioner to undertake counselling
- Caution the practitioner
- Reprimand the practitioner.

Where a formal inquiry is conducted:

- Require counselling
- Caution the practitioner
- Reprimand the practitioner
- Order remedial education
- Impose fines
- Impose restrictions on practice
- Suspend registration
- Cancel registration.

The Board must write to the complainant to tell him/her what action has been taken within fourteen days of the lodgement of the complaint and inform the complainant of the outcome of any inquiry within seven days.

9. Appeal against Board Decisions

Under the model, appeal against Board decisions is to the Administrative Appeals Tribunal rather than directly to the Supreme Court of Victoria. This is designed to streamline the process of review and reduce the costs associated with such action.

10. Professional indemnity Insurance

The Law Reform Committee of the Parliament of Victoria has recently published a report titled *Legal Liability of Health Service Providers*. Recommendation 5 of the report states:

Statutorily recognised health service providers should be required to obtain compulsory professional indemnity insurance cover with respect to privately funded patients, in order to become and remain registered. The minimum level of cover should be specified by the appropriate registration board, in consultation with relevant professional associations. Runoff cover should be provided for those who are currently insured on a different basis to the mandatory requirement.

The Victorian Minister for Health is currently considering any changes that should be made to the Victorian model of health practitioner registration to give effect to this recommendation.

11. Advertising

Under the model, provisions regulating advertising are incorporated into the Act rather than contained in regulations. As in the *Osteopaths Registration Act 1996* provisions prohibit advertising which:

- Is false, misleading or deceptive;
- Offers a discount, gift or other inducement to attract patients unless the advertisement also set out the terms and conditions of the offer;
- Refers to, uses or quotes from testimonials or purported testimonials; or
- Unfavourably contrasts medical or surgical services provided by one practitioner with services provided by another.

Penalties vary depending on whether the practitioner is an individual or part of a body corporate. These provisions supersede any existing or proposed regulations relating to advertising.



Appendix 2: AHMAC Criteria for Assessing the Need for Statutory Regulation of Unregulated Health Occupations

(Towards a Safer Choice p. 260)

Criterion 1: It is 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?

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

The following should be considered when assessing whether there is significant risk of harm to the health and safety of the public:

- The nature and severity of the risk to the client group.
- The nature and severity of the risk to the wider public.
- The nature and severity of the risk to the practitioner.

Areas which could be explored to identify a risk to public health and safety are:

- To what extent does the practice of the occupation involve the use of equipment, materials or processes which could cause a serious threat to public health and safety?
- To what extent may the failure of a practitioner to practice in particular ways (i.e. follow certain procedures, observe certain standards, or attend to certain matters), result in a serious threat to public health and safety?
- Are intrusive techniques used in the practice of the occupation which can cause a serious or life threatening danger?
- To what extent are certain substances used in the practice of the occupation, with particular emphasis on pharmacological compounds, dangerous chemicals or radioactive substances?
- Is there significant potential for practitioners to cause damage to the environment or to cause substantial public health and safety risk?

Epidemiological or other data, (e.g. coroners' cases, trend analysis, complaints), will be the basis for determining the demonstration of risk/harm.

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

Once the particular health and safety issues have been identified, are they addressed through:

- Other regulations, e.g. risk due to skin penetration addressed via regulations governing skin penetration and/or the regulation of the use of certain equipment, or industrial awards?
- Supervised by registered practitioners of a related occupation?
- Self regulation by the occupation?

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

When considering whether regulation of the occupation is possible, the following need to be considered:

- Is the occupation well defined?
- Does the occupation have a body of knowledge that can form the basis of its standards of practice?

- Is this body of knowledge, with the skills and abilities necessary to apply the knowledge, teachable and testable?
- Do the members of the occupation require core and government accredited qualifications?

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

When considering whether regulation of the occupation is practical the following should be considered:

- Are self regulation and/or other alternatives to registration practical to implement in relation to the occupation in question?
- Does the occupational leadership tend to favour the public interest over occupational self-interest?
- Is there a likelihood that members of the occupation will be organised and seek compliance with regulation from their members?
- Are there sufficient numbers in the occupation and are those people willing to contribute to the costs of statutory regulation?
- Do all Governments agree with the proposal for regulation?

Criterion 6: Do the benefits to the public clearly outweigh the potential negative impact?



Appendix 3: Membership and Terms of Reference for TCM Ministerial Advisory Committee and Subcommittees

Ministerial Advisory Committee

Chair:

Mr Robert Doyle, MP Parliamentary Secretary to the Minister for Health

Non-TCM Members:

Ms Jocelyn Bennett

Ms Meredith Carter

Mr Max Pettelin

A/ Professor Rob Moulds

Dr Stephen Myers

Professor Richard Smallwood

A/ Professor Evan Willis

TCM:

Mr Alan Bensoussan

Dr Bing-Zhong Chen

Mr Steven Clavey

Dr Choong Khean Foo

Prof. Andy Kleynhans

Prof. T. Chiang Lin

Mr Brian May

Prof. Jerry Zhang

Departmental Representatives:

Dr Heather Buchan Manager, Health Care Evaluation Section,
Public Health Division

Ms Anne-Louise Carlton Project Manager, Health Care Evaluation Section,
(Executive Officer to Committee)

Dr Vivian Lin Executive Officer, National Public Health Partnership

Terms of Reference:

1. To advise the Victorian Minister for Health on the suitability of alternative models for regulation of Traditional Chinese Medicine practice in Victoria.
2. To assist with the development of a proposal for regulation of Traditional Chinese Medicine in Victoria, including providing advice on standards, qualifications, grandparenting, protection of titles, and accreditation processes.
3. To advise on regulations required for prescription, labelling and dispensing of raw Chinese herbal medicines, and access to scheduled herbs.
4. To advise on issues associated with the standards, training and regulation of practitioners who use acupuncture and/or Chinese medicine as an adjunct to another type of health care practice.
5. To advise on strategies to overcome any language barriers associated with the regulation and delivery of Traditional Chinese Medicine in Victoria.

6. To advise on strategies to ensure the public is adequately informed and protected and consumer choice in health care is supported.
7. To assist with the conduct of a consultation process with the general public and key stakeholders on the proposed model for regulation of Traditional Chinese Medicine in Victoria.
8. To advise the Victorian Minister for Health on a suitable response to the recommendations in the Report *Towards a Safer Choice: The Practice of Traditional Chinese Medicine in Australia* and recommendations arising from the consultation process.

Primary TCM Practitioners Subcommittee

Chair:

Dr Vivian Lin, Executive Officer, National Public Health Partnership

Members:

| | |
|----------------------|---|
| Ms Shelley Beer | (Herbal Medicine, Victoria University) |
| Ms Jocelyn Bennett | (Aust. Complementary Health Association) |
| Ms Christine Berle | (Aust. Natural Therapies Association) |
| Ms Ying Chen | (Chinese Medicine Unit, RMIT) |
| Ms Judy James | (Australian Acupuncture and Chinese Medicine Association) |
| Prof. Kai Zhu Li | (Aust-Sino Acupuncture & Chinese Medicine Centre) |
| Ms Sue Li | (Aust-China Acupuncture and Chinese Medicine Assn) |
| Prof. Yoland Lim | (Victorian Traditional Acupuncture Society) |
| Prof. Wong Lun | (Academy of Traditional Chinese Medicine) |
| Ms Glenys Savage | (Academy of Traditional Chinese Medicine) |
| Prof. Peter Sherwood | (Melbourne College of Natural Medicine) |
| Dr Deyuan Wang | (Federation of Chinese Medicine Societies) |
| Dr Kerry Watson | (Acupuncture, Victoria University) |
| Dr Charlie Xue | (Chinese Medicine Unit, RMIT) |
| Dr Samuel Zheng | (College of Traditional Chinese Medicine) |

Generalist Health Care Practitioners Subcommittee

Chair:

Dr Graham Rouch, Chief Health Officer, Department of Human Services Victoria.

Members:

| | |
|---|---|
| Ms Jocelyn Bennett (Aust. Complementary Health Association) | |
| Ms Christine Berle | (Naturopathy, Aust. Natural Therapists Association) |
| Dr Paul Ghaie | (Medical, Australian Medical Acupuncture Association) |
| Mr Peter Gigante | (Shiatsu Massage) |
| Ms Judy James | (Aust. Acupuncture and Chinese Medicine Association) |

| | |
|----------------------|--|
| Mr Raymond Khoury | (Naturopathy, Aust. Traditional Medicine Society) |
| Prof. Kleynhans | (RMIT - Chiropractic/Osteopathy) |
| Mr Brian May | (Register of Acupuncture & TCM) |
| Mr Peter Richardson | (Aust. Physiotherapy Association) |
| Prof. Yuri Sawenko | (Nursing, Australian Nurses Acupuncture Association) |
| Dr Yuntian Sun | (Medical, Monash Medical Centre) |
| Ms Grace Tham | (Nursing, RMIT) |
| Dr C.T. Tsiang | (Medical, Aust Medical Acupuncture Society) |
| Ms Vivienne Williams | (Victoria University) |



Appendix 4: Towards a Safer Choice Executive Summary

Why a Review?

In December 1995, the Victorian Department of Human Services commissioned a report into the practice of Traditional Chinese Medicine (TCM). The New South Wales and Queensland health departments subsequently contributed funding to the study. The research was directed and undertaken by Mr Alan Bensoussan of the University of Western Sydney Macarthur, with Dr Stephen Myers of Southern Cross University.

The aim was to form a national picture of the practice of Traditional Chinese Medicine, to identify benefits and risks, and make recommendations to help governments decide policy on regulation.

This booklet presents the key findings and recommendations.

What is Traditional Chinese Medicine?

Traditional Chinese Medicine includes a wide range of therapies.

It is best known for the practices of acupuncture and Chinese herbal medicine, but also includes techniques such as massage, moxibustion, dietary advice and breathing exercises. Traditional Chinese Medicine consists of a large body of knowledge which includes a long history of clinical use.

The first recorded material on Traditional Chinese Medicine is traced back to the third century BC. It is used extensively in public hospitals in China for both inpatients and outpatients, and in acute and chronic care.

An Australian Snapshot

Popularity

Traditional Chinese Medicine has existed in Australia since the influx of Chinese migrants to the Australian goldfields in the 19th century. By 1911, Chinese herbal remedies were available with English labels and directions.

Traditional Chinese Medicine accounts for an increasing percentage of total health care services. It is estimated there are at least 2.8 million consultations each year, representing an annual turnover of over \$84 million.

Its popularity is growing strongly, as reflected in the fourfold increase in the importation of Chinese herbal medicines since 1992, and the proliferation of Traditional Chinese Medicine practitioners, training courses and professional associations during the last decade.

The Profession

Traditional Chinese Medicine is practised as a principal health occupation and as an adjunct to other health care practices.

Currently, there are over 1,500 primary practitioners (whose principal health occupation is Traditional Chinese Medicine), and 3,000 non-primary practitioners, (who practise other disciplines such as medicine, nursing, osteopathy, and

physiotherapy). By the year 2000, the number of primary practitioners is forecast to almost double, when over 1,100 students will graduate from Traditional Chinese Medicine qualifying programs.

There are now 23 professional associations representing different segments of the profession. However, there is no peak body covering the entire profession, and the proliferation of groups makes it difficult to achieve uniform practice standards.

Regulation of the Profession

No provisions directly govern the practice of Traditional Chinese Medicine, although practitioners are regulated in part by provisions in various State and/or Federal legislations and guidelines. The dispensing of raw Chinese medicinal substances is not adequately regulated by current legislation.

Education

There has been a recent expansion of Traditional Chinese Medicine education in universities and private colleges. However, there is significant variation in the delivery of education with award and non-award course lengths ranging from 50 hours to over 3000 hours. This results in a very unevenly qualified workforce. Traditional Chinese Medicine courses for qualified medical practitioners range from 50 to 250 hours.

The academic component of education (which includes both acupuncture and Chinese herbal medicine) offered at some institutions appears similar to that in China, but clinical training in Australia is less substantial due to the lack of access to public hospitals for clinical experience.

The Patients

Traditional Chinese Medicine is provided to patients of all ages, including infants. Two in three patients are female, 50% are tertiary educated, and over 80% have English as their first language.

A wide range of illnesses is treated, with 44% of cases being rheumatological or neurological in origin. Over 75% of patients are being treated for a recurrent complaint of at least three months' duration.

On average, the cost of a consultation is \$30, with the cost of a full course of treatment about \$670, including Chinese herbs.

Overseas Trends

A number of overseas administrations have recently reviewed regulations concerning Traditional Chinese Medicine practice, with the result that some have introduced occupational regulation.

Regulatory approaches vary from country to country, from a high degree of regulation where practitioners are licensed and supervising boards are established to maintain standards and oversee qualifications, to a virtual absence of regulation.

For example, in the United States, 27 states have specific legislation to regulate the practice of acupuncture. A small number of states have adopted regulation similar to that applied to medical practitioners in Australia, restricting use of

title to those with full Traditional Chinese Medicine qualifications. In these states, medical and other health practitioners are required to obtain full Traditional Chinese Medicine qualifications in order to be able to call themselves Traditional Chinese Medicine practitioners or acupuncturists.

Does Traditional Chinese Medicine work?

The report reviews international trials and studies the efficacy of Traditional Chinese Medicine.

There is a sufficiently strong case for the use of acupuncture to manage pain, nausea and vomiting. Acupuncture also shows significant promise in other clinical areas, such as in hypertension and other cardiovascular disorders, digestive disorders, neurological problems, and drug addiction.

There are hundreds of clinical trials on Chinese herbal medicine, the majority of which have been undertaken in China. While these generally report favourable outcomes, they do not meet a sufficiently high methodological standard for broad acceptance in the west. However, there is some limited evidence in western countries for the efficacy of Chinese herbal medicine in a small number of clinical disorders.

What are the Risks?

Although Traditional Chinese Medicine may be relatively safe compared to western medicine, it is not risk-free, and fatalities have occurred. Interestingly, it appears to pose greater risks than some regulated health care practices, like chiropractic and osteopathy. On average, practitioners experience one adverse event every eight months. These arise from:

- The consumption of Chinese herbal medicines, leading to toxicity and allergic reactions.
- The application of acupuncture, leading to infection, physical injury, fainting and convulsions.

A key finding is that the risk of adverse events is linked to the length of education of the practitioner. Practitioners graduating from extended Traditional Chinese Medicine education programs experience about half the adverse events experienced by practitioners graduating from short programs.

Key Recommendations

The study recommends an integrated reform package across the industry, with the key aim being the need to minimise risks to the public that may arise from inadequate education and unsafe practice.

The main recommendation is to introduce appropriate regulation to ensure adequate public safety, while minimising any restriction on competition in the health care marketplace.

The need for Regulation

The study found that existing regulatory mechanisms are inadequate to protect the public, and that statutory occupational regulation be introduced in the form of a restriction of title.

Regulation could be based on one of three options, consisting of State and Territory-based registration, or a National Accreditation Board with State and Territory registration, or a National Registration Board.

Regardless of the option adopted, the regulations should provide for:

- Protection of the public by ensuring practitioners have adequate qualifications for safe and competent practice.
- Accreditation of education courses that meet a satisfactory standard.
- Effective disciplinary policies and procedures to enable appropriate responses to consumer complaints.

Recommendations for Education

- Review of Traditional Chinese Medicine education to set an acceptable minimum standard for practice.
- Educational institutions to review their course content and ensure adequate training is available to minimise specific adverse events and promote the ability of practitioners to deal with adverse events.
- Review and upgrade, where necessary, basic medical and clinical sciences for non-medical practitioners.

Recommendations for Herbal Medicines

- Introduce education of importers and/or monitoring of imported raw Chinese herbs to ensure protection against the risk of contamination.
- Improve labelling of raw herbal medicines which are mixed by practitioners.
- Reassess controls on Chinese medicinal substances and identify those substances that are too toxic for use in Australia, those that are safe and appropriate for wide use, and those that should be available for use only by adequately educated practitioners.

Other Recommendations to Minimise Risk

- Professional associations and relevant government agencies to identify and promote a centralised location for reporting and recording adverse events.
- Relevant funding bodies to allocate funds for new research, and the translation of Chinese research, on the interactions between Chinese herbal medicines and western pharmaceutical drugs.

Recommendations for Professional Associations

- Strengthen the self-regulatory mechanisms of professional associations, whether or not State-based occupational regulation proceeds.
- Professional associations to cooperate to standardise course requirements, continuing education requirements, codes of conduct, disciplinary procedures and other matters related to standards of clinical practice.

What Would These Changes Mean?

Members of the public will be assured that the practitioners they choose will have adequate education. This will ensure that health care choices remain as wide as possible while delivery remains as safe as possible.

For the Traditional Chinese Medicine profession there will be legislation within which the profession can set and enforce standards of practice. This will mean increased responsibility for the improved delivery of TCM.



Appendix 5: Assessment of TCM Against AHMAC Criteria—Towards a Safer Choice

(**Towards a Safer Choice:** pp 242-246)

Criterion 1: It is 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?

Both acupuncture and Chinese herbal medicine have a primary clinical care focus, including preventive health care. Chinese herbalism involves the use of internally administered therapeutic substances and acupuncture employs the use of therapeutic devices including needles for skin penetration.

Some relevant TCM professional associations are listed in Schedule 1 of the Regulations under the *Therapeutic Goods Act 1989* (Commonwealth). Complaints against TCM practitioners are within the jurisdiction of the independent complaints units now established in most States and Territories.

Conclusion: It is clearly appropriate for Health Ministers to exercise responsibility for regulating TCM.

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

There is clear evidence that TCM has inherent risks of adverse outcomes, both predictable and unpredictable, which can in extreme cases be life-threatening. Acupuncture is an invasive procedure carrying risks of injury and infection. Chinese herbal medicine involves the topical application or ingestion of herbal medications which can result in toxicity or allergic reactions.

These inherent risks are containable but significant, and have resulted in a number of serious injuries and deaths in Australia. Injuries resulting from TCM are also likely to be under-reported (see Chapter 4). The inherent risks may be exacerbated by:

- Use of TCM treatments in combination with western clinical care and/or a failure of TCM practitioners to refer to western clinicians as necessary, for example in cases of diabetes or epilepsy. Thus, recognition of the limits of a TCM practitioner's scope of practice and adequate training in western medicine are vital.
- Practitioners who are untrained or poorly trained in TCM. There is evidence that practitioners who have not adhered to adequate standards and appropriate procedures have presented a threat to public health and safety (as reviewed in Chapter Four, the NHMRC Working Party Report on Acupuncture, and case studies in submissions). These complications have included deaths in Australia.
- Where contaminated or adulterated herbal preparations are used in patient treatment.

These factors together with the increasing patronage of TCM practitioners for primary care purposes or in combination with western treatments, and the increasing numbers of practitioners with widely variable training offering TCM, are likely to result in an increased propensity for realisation of these risks.

The risks are likely to be reduced by professional monitoring of patient treatment and progress by appropriately trained and qualified practitioners. However, the proliferation of courses and standard setting bodies renders it extremely difficult for consumers seeking to identify competent practitioners.

Medical and other practitioners seeking to make referrals for patients seeking a wider range of health care options, are also inhibited by the difficulties of reliably identifying appropriately trained practitioners. This problem has particular ramifications for attempts to promote co-ordinated care options in Australia.

Conclusion: The activities of the practice of Traditional Chinese Medicine clearly pose a significant risk of harm to the health and safety of the public.

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

Current regulatory measures do not provide the level of protection the public is entitled to expect given the very real risks of harm identified. Accreditation of education and training courses by government and self regulation by the profession both have a bearing on the safe practice of TCM in Australia. However, educational standards amongst Australian trained TCM practitioners are extremely variable and there is a plethora of professional associations. The result is that neither the public nor other health care practitioners have a reliable way of assessing who is adequately qualified for safe, competent practice.

Avenues of legal redress through the criminal law or common law actions for negligence and notifications to health complaints agencies are relatively underutilised given the rate of injury noted by practitioners themselves. Significant gaps have been identified in the regulatory scheme relating to herbal preparations, provided by the Therapeutic Goods Administration and the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). Similarly concerns exist regarding the adequacy of the Skin Penetration Regulations/Guidelines to deal with the risks of acupuncture. In particular, these mechanisms focus on the environment in which acupuncture is carried out and do not address the competence of the practitioner.

Conclusion: Existing regulatory mechanisms are inadequate in safeguarding and protecting the public as consumers of Traditional Chinese Medicine (acupuncture and Chinese herbal medicine).

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

The occupation is well defined by both its body of knowledge and methods of practice. Practitioners of Traditional Chinese Medicine are well recognised and regulated in China and some other international jurisdictions. Traditional Chinese Medicine has been offered as a tertiary education course in Australia for over two decades. Three courses are currently offered in Australian universities which lead to a primary qualification in TCM. Appropriate standards of training are identified with broad professional agreement on core competency and curriculum documents.

Conclusion: There is a defined profession for which regulation is possible to implement.

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

A number of factors outlined in this chapter and elsewhere demonstrate that self-regulation is not a practical alternative to occupational regulation of TCM practitioners. These factors include the increasing proliferation of professional associations representing TCM practitioners, and concern that current standards of education may decline as opportunistic education providers move into the market area.

Of the 18 professional associations (89%) that responded to the TCM associations survey, 16 were in favour of occupational regulation. Whilst some associations acknowledged that there are negative aspects to occupational regulation, they also acknowledged the broad public benefit from its introduction.

TCM practitioners responding to the workforce survey identified significant benefits from the introduction of occupational regulation. In response to the question on potential government regulation of TCM practice, the majority believed it would have a positive effect on professional status, standards of practice, standards of education, access to research infrastructure and postgraduate education (see Table 11.1). Practitioners were more uncertain when it came to the effect of government regulation on practitioner income, possible litigation, patient costs, quality of herbal medicines, access to herbal medicines or definition of occupational boundaries. In balance, however, TCM practitioners believed that occupational regulation would have a positive effect on TCM practice, and are likely to be compliant with any statutory requirements of regulation.

There are sufficient numbers in the occupation to fund occupational regulation in the three states reviewed. It is uncertain whether there are sufficient numbers in other Australian States and Territories to fund registration boards in each State, however a number of regulatory options are available that could disperse these costs.

Conclusion: Occupational regulation is practical to implement for currently unregulated TCM practitioners.

Criterion 6: Do the benefits to the public clearly outweigh the potential negative impact?

The potential negative impact of occupational regulation is discussed in Chapter 10, under Competition Policy, mutual recognition and occupational regulation. In brief, some of the concerns are that occupational regulation:

- Restricts entry to a profession;
- Increases the costs of entry in that minimum standards of training and education are set for professional practice and therefore may also narrow the range of persons eligible to practise;
- May stifle innovation and interaction between different groups of health practitioners and/or encourage undesirable 'medicalisation' in order to justify TCM practice in western scientific terms;
- May increase the cost of TCM services to individuals and the community, through passing on of the increased costs associated educational requirements, indemnity insurance, and the regulatory mechanism.

Major benefits of registration are that it can:

- Help protect the public by promoting the standards established through various national bodies for professionally trained, competent and safe practitioners;
- Promote the public's right of access to the health care of their choice, by providing a mechanism for identifying practitioners who should be safe and competent;
- Facilitate cross-referral amongst different types of health practitioners and promote the integration of patient care;
- Provide enforceable sanctions against practitioners whose practice is incompetent or unethical;
- Provide a mechanism for identifying those practitioners who can be safely exempted from the relevant provisions of the TGA.

Conclusion: The benefits of promoting public safety clearly outweigh the potential negative impacts of occupational regulation.



Appendix 6: List of Submissions Received—Public Consultation

Key

A—Organisations with no direct interest in provision of TCM services

B—Organisations that represent practitioners or students of TCM

C—Organisations whose members practice TCM as part of other health care practices

D—Individual practitioners and students of TCM

E—Consumers of TCM

| | | |
|-----|-----------------------|---|
| A1 | Ms Merrilyn Walton | Commissioner Health Care Complaints Commission, NSW |
| A2 | Mr Robert C. Burton | Director Anti-Cancer Council of Victoria |
| A3 | Lady Lois Woodward | Chair Health Issues Centre (Victoria) |
| A4 | Ms Leanne Raven | Chief Executive Nurses Board of Victoria |
| A5 | Mr Noel Cranswick | The Australian College of Paediatrics |
| A6 | Ms Jocelyn Bennett | Convenor Australian Complementary Health Association (ACHA) |
| A7 | Ms Debbie Shaw | Leader-Traditional Medicines Programme, Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust |
| A8 | Mr L.R. Armsby | Manager, Legislation Project Tasmania Department of Community and Health Services |
| A9 | Mr John Thwaites | Member for Albert Park Shadow Minister for Health (Victoria) |
| A10 | Mr Eric Chalmers | Director, Operations Management Victorian Workcover Authority |
| A11 | Dr R.L. Stable | Director-General Queensland Health |
| A12 | Ms Beth Wilson | Victorian Health Services Commissioner |
| A13 | Dr Andrew Wilson | Deputy Director-General, Public Health NSW Health Department |
| A14 | Dr Andrew Langley | A/Director, Environmental Health South Australian Health Commission |
| B1 | Ms Judy James | Executive Officer Australian Acupuncture Association Ltd. |
| B2 | Mr S.R. Turnbull-Mack | Director National Institute of Health Sciences |
| B3 | Prof. Yuri Sawenko | President Australian Nurses Acupuncture Association |
| B4 | Mr Ross Mack | Academy of Natural Therapies Queensland TAFE |
| B5 | Dr Kerry Watson | TCM Coordinator Department of Health Sciences Victoria University of Technology |
| B6 | Mr Cameron J. Philips | RMIT 1st year students B.Appl.Sci(CM) (12 students) |

| | | |
|-----|---------------------------------|--|
| B7 | Mr Mou Ly | President The Australian Traditional Chinese Medicine Association Inc. |
| B8 | Mr Thomas Cheung | RMIT 4th Year Students (22 students), B. Appl. Sci. (Chinese Medicine), RMIT University |
| B9 | Ms Beverly J. Coats | Dean of Oriental Medicine South Australian College of Natural Therapies and Traditional Chinese Medicine |
| B10 | Prof.Yuri Sawenko | Secretary Acupuncture Association of Victoria |
| B11 | Ms Sharyn Martin | The Allergy, Sensitivity and Environmental Health Association Qld (ASEHA) |
| B12 | Ms Glenys Savage | Vice President Traditional Medicine of China Society, Australia |
| B13 | Prof. T. Chiang Lin | President Federation of Chinese Medicine & Acupuncture Societies of Australia Inc. (FCMA) |
| B14 | Mr Geoff Henry | National President Australian Natural Therapists Association Ltd |
| B15 | Ms Glenys Savage | Vice President Alliance of Traditional Chinese Medicine Associations Australia |
| B16 | Mr Brian May | The Register of Acupuncture and Traditional Chinese Medicine Inc. |
| B17 | Dr Charlie Xue | Head, The Chinese Medicine Unit Department of Chiropractic, Osteopathy and Complementary Medicine RMIT University |
| B18 | University of Technology Sydney | University of Technology Sydney Department of Health Sciences (Acupuncture & Chinese Herbal Medicine), Faculty of Science |
| B19 | Mr Yau Yee Kay | Secretary The Victorian Traditional Acupuncture Society Inc. Chinese Medicine Association Inc. |
| C1 | Dr E Robyn Mason | Executive Director Australian Medical Association (Vic. Branch) |
| C2 | Dr John Jogoda | Federal President The Australian Medical Acupuncture Society (AMAS) |
| C3 | Dr R Brown | AMAQ Queensland Branch of Australian Medical Assn. |
| C4 | Mr Nick Burgess | Vice President National Herbalists Association of Australia |
| C5 | Ms Marie Fawcett | Secretary The Australian Traditional-Medicine Society Ltd (ATMS) |
| C6 | Dr Frank Ros | President International Association of Suchi Karma Inc. (Ayuvedic Acupuncture) |
| C7 | Prof. Jia Qia Niu | Chinese Community Health Advisory of Australia Inc. |
| C8 | Prof. Basil Roufogalos | Executive Director The University of Sydney, Herbal Medicines Research and Education Centre |
| C9 | Ms Megan Davison | President Australian Physiotherapy Association (Vic Branch) |
| C10 | Prof. A. M. Kleynhans | Deputy President The Chiropractors Registration Board of Victoria |

| | | |
|-----|--------------------------------------|---|
| D1 | Five TCM Practitioners | A Group of Qualified Chinese Medicine and Acupuncture Practitioners |
| D2 | Dr Arthur Hsuan (Dr. Xuan Ren Da) | |
| D3 | Mr Study | |
| D4 | Dr Sharyn Martin | |
| D5 | Mr Scott Moir | |
| D6 | Ms Anna M. Walsh | |
| D7 | Not Provided | |
| D8 | Ms Anita Binnington | Nowra Acupuncture |
| D9 | Mr K. Walter | |
| D10 | Ms Grace Tham | |
| D11 | Mr Ngoc Pham | FCMA member |
| D12 | Mr Garry Seifert | |
| D13 | Ms A. Roach | |
| D14 | K C Tang | |
| D15 | Mr Mauro Caputo | |
| D16 | Mr Edwin Y Miao | M. Modern Traditional Chinese Medical Clinic |
| D17 | Ms Celia Huang | Aust-Sino Chinese Medicine & Medical Centre |
| D18 | Dr C. T. Tsiang | |
| D19 | Mr Michael Joubert | Strathmore T.C.M. |
| D20 | Mr Robert Zindler | |
| D21 | Ms Wendy Custance | |
| D22 | M. A. Roach | |
| D23 | Prof. Xiao De-Xin | Beijing Chinese Medicine Specialists Centre |
| D24 | Ms M. Oliver-Berg | |
| D25 | Mr David Kelly | |
| D26 | Dr Nyrie Dodd | Director, Newtown Chinese Medicine |
| D27 | Dr Choong Khean Foo | Hawthorn West Medical Centre |
| E1 | Ms Elva Glarclona | |
| E2 | Ms Teresa Miraglia | |
| E3 | Mr Frank Gagliardi | |
| E4 | Mrs Bronwyn West | |
| E5 | Ms Judith Pollock | |
| E6 | Ms Marion Moore | |
| E7 | Ms Gayle Higgins | |
| E8 | Ms Jeanette Rudd | |



Appendix 7: Australian Traditional-Medicine Society Proposal: Government Monitored Self Regulation



Appendix 8: Submissions—Summary of Main Findings

Summary of Submissions—TCM Review Public Consultation

| Groups | Organisation Individuals | Statute Reg'n | ATMS GMSR | Regulatory Models | Modalities to be Regulated | Restrictions on Practice | Titles Protected |
|--------|---|------------------|--------------|-------------------------------------|---|---|--|
| A1 | Health Care Complaints Commission | Yes | No. | National | Chinese herbal medicine (CHM); Acupuncture | Yes (a lesser degree) | Registered TCM Practitioner Registered Traditional Chinese Herbalist, Registered Acupuncturist, |
| A2 | Anti-Cancer Council of Victoria | Yes | No | | CHM; Acupuncture | No | Yes (Not specified) |
| A3 | Health Issues Centre Victoria | Yes | No | | CHM; Acupuncture | No | |
| A4 | Nurses Board of Victoria | Yes | No | | CHM; Acupuncture. | | Various—see discussion paper |
| A5 | The Australian College of Paediatrics | Yes | No | | | | |
| A6 | ACHA | Yes | No | State | | | |
| A7 | Guy's & St Thomas' Hospital Trust | Yes | No | | | No | Practitioner of Chinese Herbal Medicine |
| A8 | Tasmanian Dept Community & Health Services | Yes | No | State | CHM; Acupuncture | First step: titles only | |
| A9 | Mr John Thwaites MLA Shadow Minister for Health, Member for Albert Park | Yes | | | | | |
| A10 | Victorian Workcover Authority | Yes | No | State or National | | | |
| A11 | Queensland Health | Undec- ided | No | State with national standards | To be determined, most likely CHM & Acupuncture | Yes-core practices model-acupuncture only | As few titles as possible TCM practitioner Chinese Herbalist |
| A12 | Victorian Health Services Commissioner | Yes | No | State with national standards | CHM; Acupuncture | | |

| Groups | Organisation | Statute | ATMS | Regulatory | Modalities to be Regulated | Restrictions on Practice | Titles Protected |
|---------------|---|----------------|----------------------------------|-------------------------------|---|--|--|
| | Individuals | Reg'n | GMSR | Models | | | |
| A13 | NSW Health Dept. | One option | Other models | State with national standards | CHM; Acupuncture | None in reg'n leg'n. Restrictions in scheduling of drugs & poisons | Minimum necessary |
| A14 | South Aust. Health Commission | Yes | Limited effect. Other options | | | | |
| B1 | Aust. Acupuncture Association Ltd | Yes | No | State | CHM; Acupuncture. | No | Various-see discussion paper |
| B2 | National Institute of Health Sciences | Yes | No | | | | |
| B3 | Australian Nurses Acupuncture Association | Yes | No | State | CHM; Acupuncture | | All titles as listed and Registered Laser Acupuncturist |
| B4 | Academy of Natural Therapies, Queensland TAFE | Yes | No | | CHM; Acupuncture | | |
| B5 | Victoria University of Technology | Yes | No | State | CHM; Acupuncture. | No | Various - discussion paper |
| B6 | RMIT 1st year student group B.Appl.Sci(CM) | Yes | No | | CHM; Acupuncture; Moxibustion & Cupping; Chinese Remedial Massage, others | No | Various-see discussion paper |
| B7 | Aust.TCM Association Ltd. | Yes | No | Victorian Model | Various | No | Various-see discussion paper |
| B8 | RMIT University Yr 4 students B. Appl. Sci. (CM) | Yes | No | | Include manual therapy | | Concerns about the abuse of academic titles eg 'Professor' |
| B9 | South Australian College of Natural Therapies and TCM | Yes | No | | | | Reg.TCM Practitioner; Reg. Acupuncturist (incl. moxibustion); Reg. Chinese Herbalist |

| Groups | Organisation Individuals | Statute Reg'n | ATMS GMSR | Regulatory Models | Modalities to be Regulated | Restrictions on Practice | Titles Protected |
|---------------|--|----------------------|------------------|-------------------------------|---|---------------------------------|---|
| B10 | Acupuncture Association of Victoria | Yes | No | State | CHM; Acupuncture & "dry needle" insertion | | |
| B11 | ASEHA | Yes | No | | | | |
| B12 | Traditional Medicine of China Society Australia Inc. | Yes | No | National | CHM; Acupuncture & Moxibustion; therapeutic massage; Food/diet/lifestyle therapy; Physical therapeutic arts | No | Various-see discussion paper |
| B13 | FCMA | Yes | No | Yes | CHM; Acupuncture; Chinese Therapeutic Massage | No | Various-see discussion paper |
| B14 | ANTA | Yes | No | State | CHM; Acupuncture. | No | Various-see discussion paper |
| B15 | Alliance of TCM Assns. Australia | Yes | No | National | | | Traditional Chinese Medicine Practitioner with options to add modalities |
| B16 | The Register of Acupuncture and TCM Inc. | Yes | No | National | CHM; Acupuncture; Herbal dispensing; Tui Na; TCM Orthopaedics; | No | Practitioner of TCM (modalities in brackets) Dispenser of CHMs |
| B17 | RMIT University Chinese Medicine Unit | Yes | No | | CHM; Acupuncture; Chinese remedial massage | No | Restrictions on use of potent herbs in drugs & poisons leg'n. Reg. Chinese Medicine practitioner (CHM)/ (Acupuncture and Moxibustion)/or both. |
| B18 | University of Technology Sydney | Yes | No | State with national standards | CHM; Acupuncture/ Moxibustion; Point injection therapy | No | Wide range Refer discussion paper |
| B19 | Vic. Trad. Acupuncture Society. Chinese Medicine Association | Yes with conditions | | | | | Dr of TCM or Dr of Acupuncture |

| Groups | Organisation Individuals | Statute Reg'n | ATMS GMSR | Regulatory Models | Modalities to be Regulated | Restrictions on Practice | Titles Protected |
|--------|--|-------------------------------|-------------------------|--|--|---------------------------------------|--|
| C1 | AMA (Vic. Branch) | No | | Self reg'n | | No, protection of title sufficient | |
| C2 | The Australian Medical Acupuncture Society (AMAS) | Not until standards set | | | | | |
| C3 | AMA Qld. Branch | Yes | No | National | CHM; Acupuncture; Specific techniques Orthopaedic manipulation Surgery | Yes | Reg. Chinese Med. Practi- tioner Reg. TCM Practitioner Reg.Oriental Med. Practitioner -should not be protected |
| C4 | National Herbalists Association of Australia | Yes | Or coregula- tion | Herbalism dietary and lifestyle advice | No. Protection of Title only | | Medical herbalist; Herbal physician; herbalist; or Registered/licensed herbalist (if herbalists' reg'n board) |
| C5 | ATMS | No | Yes | | | No | Registered Acupuncturist; Registered Traditional Chinese Herbalist |
| C6 | International Association of Suchi Karma Inc. | Yes | No | | | | |
| C7 | Chinese Community Health Advisory of Australia Inc. | Yes | No | | | | |
| C8 | University of Sydney, HMREC | Yes | No | | | | |
| C9 | Australian Physiotherapy Association (Vic Branch) | Yes | No | State reg'n. National standard setting | CHM; Acupuncture | No | Various-see discussion paper |
| C10 | The Chiroprac- tors Registration Board of Victoria | Yes | No | | | | Chiropractic Acupuncturist in relation to chiropractors practising acupuncture |

| Groups | Organisation Individuals | Statute Reg'n | ATMS GMSR | Regulatory Models | Modalities to be Regulated | Restrictions on Practice | Titles Protected |
|--------|--------------------------------------|------------------|--|---|--|-----------------------------|---|
| D1 | 5 TCM Practitioners | Yes | No | State | CHM; Acupuncture; Tuina-Manipulation | No | Various-see discussion paper |
| D2 | Dr Arthur Hsuan (Dr. Xuan Ren Da) | Yes | No | | | | Yes. (Not specified) |
| D3 | Mr Study | Yes | No | | | | |
| D4 | Dr Sharyn Martin | Yes | No | Regulate Practice | All modalities | Yes | Registered TCM practitioners |
| D5 | Mr Scott Moir | Yes | No | | | | |
| D6 | Ms Anna M. Walsh | Yes | No | | Various | No | Various-see discussion paper |
| D7 | Not supplied | Yes | No | | Include herbal medicine | | |
| D8 | Ms Anita Binnington | Yes | No | | CHM; Acupuncture. | No | |
| D9 | Mr K. Walter | Yes | No | State | CHM; Acupuncture (incl. moxibustion, laser, electro-acupun- ture, point injection therapy) | No | Chinese Herbal Medicine Acupuncture |
| D10 | Ms Grace Tham | Yes | TCM practit- ioners to decide | All modalities & Specialist areas | herbalists acupuncturists | | General TCM (all modalities); |
| D11 | Mr Ngoc Pham | Yes | No | No comment | All TCM modalities | No | Oriental Medical Doctor (6 years TCM training) Oriental Medicine Practi- tioner (4 years training) |
| D12 | Mr Garry Seifert | Yes | No | National | CHM; Acupuncture; Tuina; orthopaedic manipulation. | | See Register submission |
| D13 | Ms Allison Roach | Yes | No | | Various | No | Various-see discussion paper |
| D14 | K C Tang | No | No | | | | |
| D15 | Mr Mauro Caputo | Yes | No | | Acupuncture (Western & Chinese models) | No | Separate titles for Western and Chinese acupuncture |

| Groups | Organisation Individuals | Statute Reg'n | ATMS GMSR | Regulatory Models | Modalities to be Regulated | Restrictions on Practice | Titles Protected |
|--------|-----------------------------|------------------|--------------|----------------------|---|-----------------------------|---|
| D16 | Mr Edwin Y Miao | Yes | No | State | CHM; Acupuncture; Tuina-Manipulation; | No | Various-see discussion paper |
| D17 | Ms Celia Huang | Yes | No | | CHM; Acupuncture | Yes | |
| D18 | Dr C. T. Tsiang | Wait 3-5 yrs | | | | | Herbal Medicine and/or Acupuncture practitioner |
| D19 | Mr Michael Joubert | Yes | No | State | Various | No | Various-see discussion paper |
| D20 | Mr Robert Zindler | Yes | No | State | CHM; Acupuncture. | No | Various-see discussion paper |
| D21 | Ms Wendy Custance | Yes | No | | | | |
| D22 | M.A. Roach | Yes | No | | CHM; Acupuncture; Moxibustion & Cupping; Chinese remedial massage, others | | Chinese Herbal Med. Practit. Chinese Acupuncture Practit. CM Practitioner (Herbal Medicine & Acupuncture) |
| D23 | Prof. Xiao De-xin | Yes | No | | | | |
| D24 | Ms M.Oliver-Berg | Yes | No | State | CHM including dietetics; Acupuncture /Moxibustion; Massage /manipulation | Yes | Registered TCM practitioner |
| D25 | Mr David Kelly | Yes | | | | Yes | Various-see discussion paper |
| D26 | Dr Nyrie Dodd | Yes | No | National | | No | Chinese Medicine Practitioner Modality in brackets Chinese Medicine Dispenser |
| D27 | Dr Choong Khean Foo | Wait 3-5 yrs | No | | CHM; Acupuncture | | Primary TCM Practitioner (Herbalist and/or Acupuncturist) Restrict title 'professor'. |
| E1 | Ms Elva Glarclona | Yes | No | | | | |
| E2 | Ms Teresa Miraglia | Yes | No | | Acupuncture (Western & Chinese models) | No | Separate titles for Western and Chinese acupuncture |
| E3 | Mr Frank | Yes | No | | | | |

| Gagliardi | | | | | | | |
|-----------|-----------------------------|------------------|--------------|----------------------|-------------------------------|-----------------------------|---------------------|
| Groups | Organisation Individuals | Statute Reg'n | ATMS GMSR | Regulatory Models | Modalities to be Regulated | Restrictions on Practice | Titles Protected |
| E4 | Ms Bronwyn West | Yes | | No | | | |
| E5 | Ms Judith Pollock | | Yes | | | | |
| E6 | Ms Marion Moore | | Yes | | | | |
| E7 | Ms Gayle Higgins | | | | | | |
| E8 | Ms Jeanette Rudd | | | | | | |



Appendix 9: Australian Acupuncture and Chinese Medicine Association—Difficulties with Self Regulation
Appendix 10: NSW Health Department Submission to



TCM Review

Mr Robert Doyle, MP

Parliamentary Secretary to the
Minister for Health (Victoria)
Chair, Ministerial Advisory Committee
on Traditional Chinese Medicine
Department of Human Services
GPO Box 4057
MELBOURNE VIC 3001

Attention: Ms Anne-Louise Carlton

Dear Mr Doyle

***Traditional Chinese Medicine: Options for Regulation of Practitioners, Discussion Paper,
September 1997***

Thank you for the opportunity to comment on this Discussion Paper, and may I congratulate the Committee on its work thus far.

NSW notes the contents of the Discussion Paper and supports the general direction of the Paper, but has some concerns about the lack of alternatives proposed for the regulation of Traditional Chinese Medicine Practitioners outlined in the paper.

General Comments

It is not disputed that *Towards a Safer Choice* disclosed evidence of risks to consumers from the practice of traditional Chinese medicine. While that Report noted that risks are both avoidable and unavoidable, and that there is evidence to suggest that the incidence of risks could be reduced through additional training, there is little analysis of the frequency of serious complications or death. Although the adverse event rate for each practitioner (one every eight months) may be considered high - the number of significant adverse events would appear to be minor with few serious and lasting side effects.

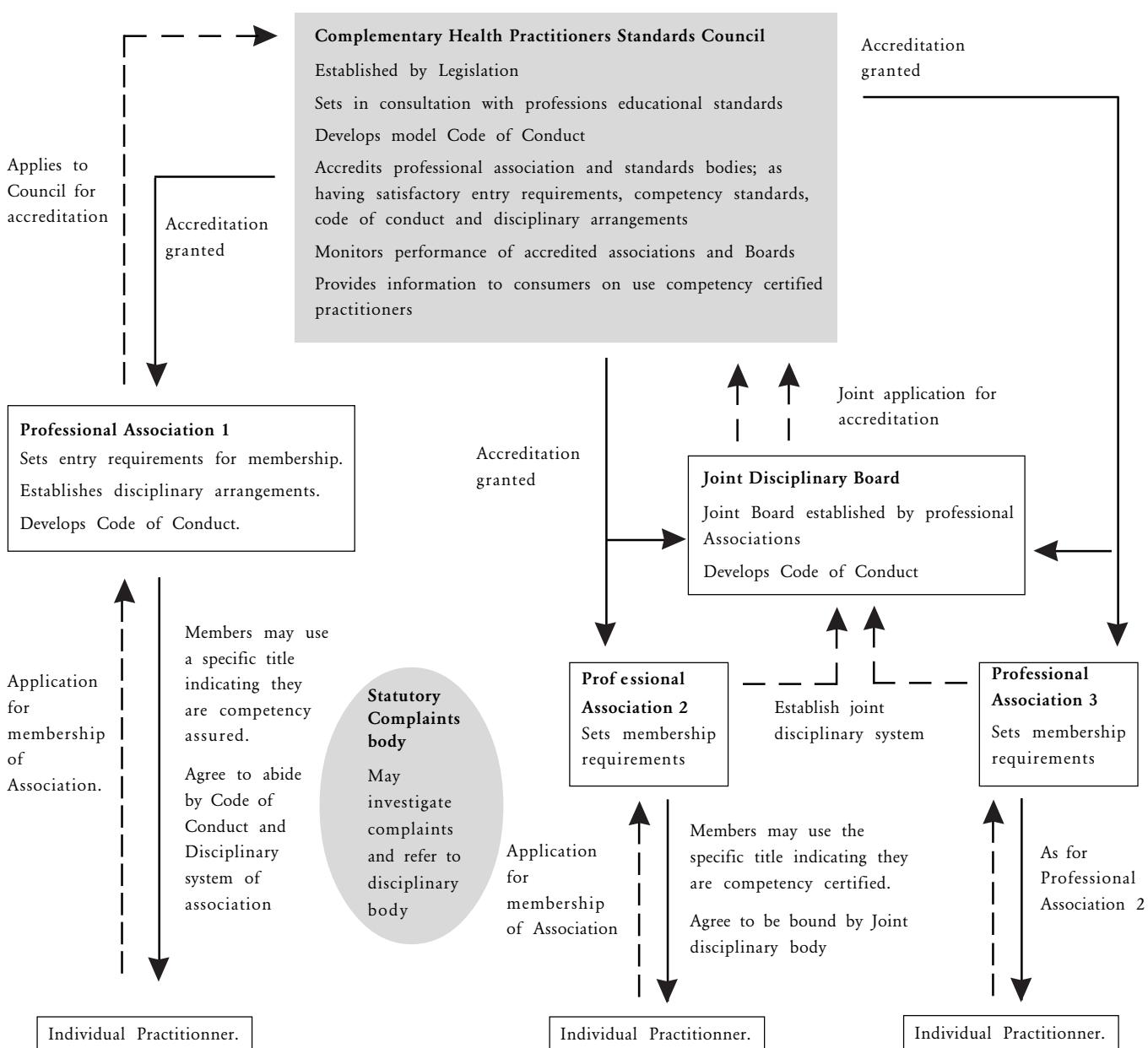
Further, *Towards a Safer Choice* does not consider in detail whether serious risks were avoidable or unavoidable and whether occupational regulation would be effective in minimising these risks. The need for occupational registration can only be considered once existing regulatory controls are demonstrated to be ineffective.

The Department does not however, consider that occupational registration should be ruled out as an option. Indeed the rate of adverse events identified in the Report and the ability to significantly minimise such occurrences through training suggests that more should be done to inform consumers which practitioners have sufficient training to engage in safe and competent practice. Occupational registration is not the only means through which this can be done. A combination of information and regulatory strategies may be effective in reducing the incidence of adverse events.

It is our view that three other options for regulation not canvassed in the Discussion Paper, may provide useful alternatives when AHMAC develops a view on this issue. These are:

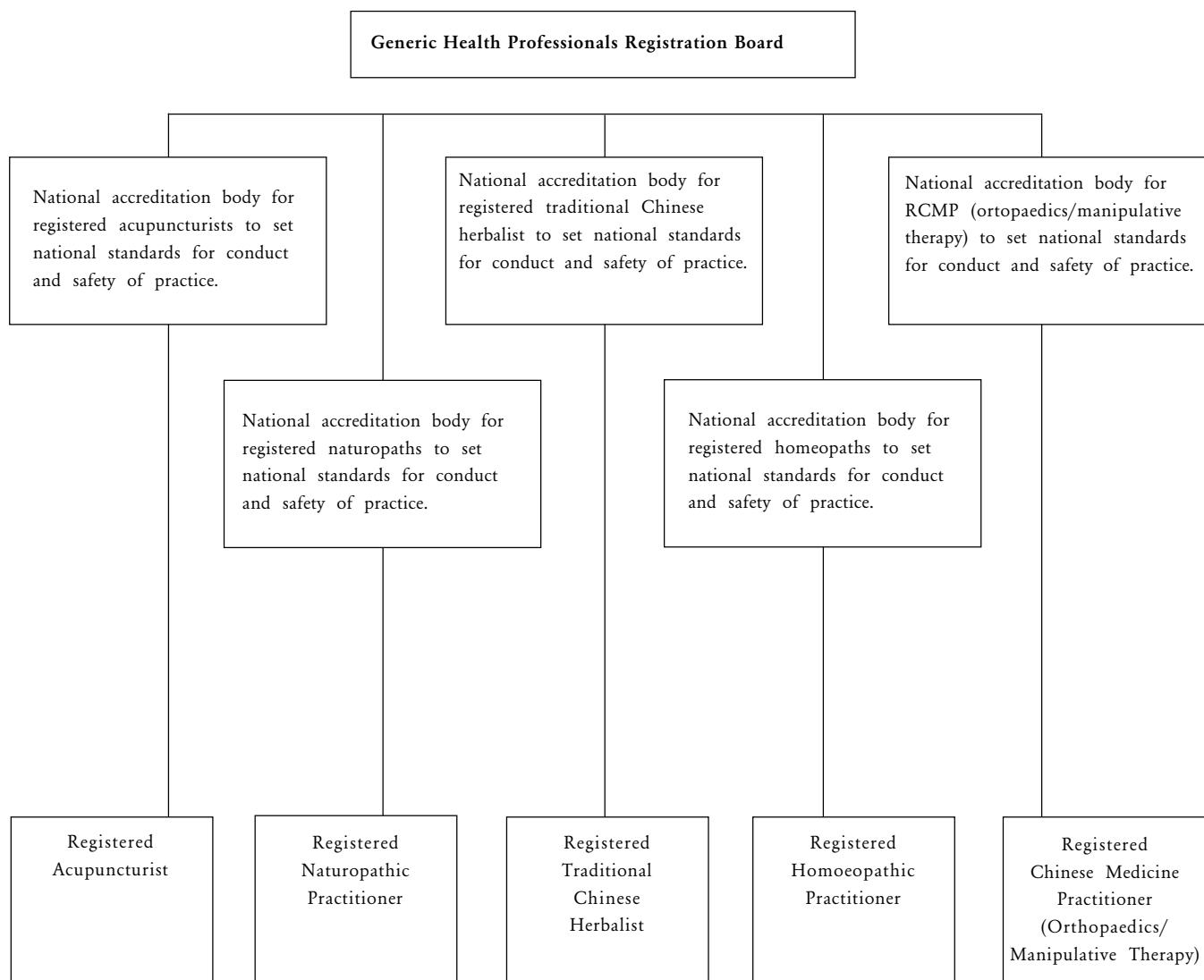
1. Health regulation by statutes such as the *Public Health Act 1991 (NSW)*, or those specific to the individual safety issue of concern such as the *Poisons and Therapeutic Goods Act 1996 (NSW)* or the Skin Penetration Regulation. The effect here is to focus upon the regulation of potentially hazardous aspects of practice. For example, serious adverse risks associated with acetone would appear to relate more to inconsistencies in preparation or illegal prescribing. This drug is already regulated through the NUSDP schedule and therapeutic goods legislation. Increased enforcement and monitoring in these areas may reduce the risks associated with this substance.

Government Supervised Self Regulation



Similarly, the transmission of infectious diseases may be more effectively regulated through improvements to skin penetration regulations;

2. The development under statute of a more generic Health Professionals Registration Board where individual groups of practitioners who identify as a homogeneous group (perhaps eg acupuncturists, traditional Chinese herbalists, homeopathic practitioners, naturopathic practitioners): develop minimum standards of conduct and safety for their practice (preferably at a national level to ensure consistency); and are registered under the statute to practice according to this code, with protection of their specific titles; or



3. The development of co-regulatory approaches where Government accredits self regulatory systems, similar to the NSW Professional Standards Council.

Below is an more extensive outline of these options as well as comments on the specific questions that the Discussion Paper poses.

3.1 Models for Self-Regulation:

Total Self Regulation

The difficulties with self regulation are noted. Indeed an argument can be made that the public values more highly government backed or statutory accreditation systems as opposed to complete industry self regulation. Nonetheless, industry self-regulation can be effective in ensuring that consumers have access to information regarding the competency of practitioners.

The discussion paper overstates the disadvantages of self-regulation. For example, self-regulatory approaches both inside and outside the health sector have operated for many years without necessarily conflicting with the Commonwealth *Trade Practices Act 1974*. Discussions with the Australian Competition and Consumer Commission should be held to identify potential points of conflict.

Similarly, "fragmentation of the profession" which is identified as a problem for self-regulation will continue to be a problem under a system of titles registration. Such disputes will be internalised in the Board, with the possibility that segments of the profession will be disenfranchised.

Access to scheduled substances can still occur under a self-regulatory model. For example, orthoptists are not registered in NSW but access to diagnostic therapeutics in limited circumstances as has been provided for under the *Poisons and Therapeutic Goods Act 1996*. This profession has a self-regulatory scheme established in co-operation with the Royal Australian College of Ophthalmologists.

The most significant problem with industry self-regulation is the difficulty in creating incentives for practitioners to seek accreditation. Large professional associations have the resources available to inform the community of the advantages of dealing with certified practitioners, thus creating an incentive for registration. However, in view of the limited number of TCM practitioners, large scale advertising campaigns would be unlikely to occur.

The Australian Traditional Medicine Society proposal would appear to go some way to addressing this problem in its proposal to develop an identifiable logo for use by certified professionals (as an easily recognised symbol may be more effective in ensuring consumers make informed choices). While the ability of the ATMS to market the symbol remains at issue, there is significant potential for such a system. Other professional associations could establish similar systems.

Although consumers may face difficulties in identifying reputable associations, a co-regulatory model may overcome this problem.

Co-Regulatory Approaches

A model for Government oversight of self-regulatory arrangements can be found in the *Professional Standards Act 1994*. Under this Act the Professional Standards Council does not assess competence of individual practitioners. Instead it assesses proposals for 'limited liability' schemes put forward by professional associations. In short, members of professional associations which can demonstrate to the Council they have effective strategies in place to minimise risks associated with professional practice (such as entry requirements, disciplinary arrangements, compulsory insurance and codes of conduct) can have their liability for damages limited under the Act. The Act has no application to health professionals because liability for personal injury is excluded. Nonetheless it provides a useful model for further consideration.

A co-regulatory model based on the Professional Standards Council is outlined below. The incentive for associations to apply for accreditation from the Complementary Therapies Standards Council would be that its members would gain the right to use an identifiable symbol or description indicating the practitioner has obtained a certain level of competence. Further incentive could be provided if the Council assumed a role in marketing the benefits of dealing with practitioners accredited under the scheme.

The Council would have a role in setting standards for the accreditation of professional associations. This could include setting requirements for consumer participation, the monitoring of disciplinary systems and entry requirements.

This approach has the following advantages:

- (i) It can be extended to apply to other complementary therapies;
- (ii) Professional associations can establish joint accreditation systems while maintaining their separate identities, overcoming problems of fragmentation;
- (iii) Consumers are provided with appropriate information to enable them to make informed choices.
- (iv) The scheme need not be confined to professional disciplines. It could be further modified to accredit practitioners that engage in specific practices which carry risks for consumers. For example, a non TCM profession that utilises acupuncture could gain accreditation for its members.

The main disadvantage of this approach is that it may not be effective in addressing risks of serious harm and death from unregistered persons as they may continue to practice. However there is no guarantee that such risks will be addressed by title registration as unregistered persons can continue to practice.

The Department does not endorse this model as appropriate. It is simply outlined for the purpose of further discussion. However it should be given consideration, along with other possible regulatory strategies, before a decision is made on an appropriate means to address the risks associated with practice.

3.2 Occupation Regulation via Statute

Certainly the Victorian health professional registration process with individual Registration Boards for each of the professional groups is one option. However, there is a second option for statutory regulation that may also be appropriate to consider. That is, the development under statute of a more generic Health Professionals Registration Board where individual groups of practitioners who identify as a homogeneous group (perhaps eg acupuncturists, traditional

Chinese herbalists, homoeopathic practitioners, naturopathic practitioners): develop minimum standards of conduct and safety for their practice (preferably at a national level to ensure consistency); and are registered under the statute to practice according to this code, with protection of their specific titles. See diagram below.

3.5 State Versus National Approaches

Constitutional limitations would make the creation of a national registration board unlikely. However, there is nothing to preclude the development of a national approach to the development of standards of practice for each of the branches of TCM and other modalities of complementary therapies. This model already exists in Medicine, Optometry and Nursing.

4.1 Constitution of the Registration Board

The composition of a registration Board will be dependent upon the type of regulatory system adopted. As the Department's position is that all options for Regulation should be explored, a final position cannot be adopted.

However, the seven member Board adopted in Victoria for other professions would appear to be adequate if registration by title is recommended. It should be noted that the composition of professional registration Boards is varied in NSW. The more recent professional registration Acts for smaller professions (*Psychologists Act 1989* (NSW), *Chiropractors and Osteopaths Act 1991* (NSW), *Optometrists Bill 1993—Exposure Draft*) are generally comprised of 9 members - 5 professionals from the profession being regulated (often one from an educational institution), a lawyer, a medical practitioner, a departmental representative and a consumer/community representative.

The 9 member Board adopted in NSW allows a more diverse range of views to be represented. However, the Department is currently considering the following as part of the review of the *Psychologists Act 1989*:

- (i) representation of the medical profession on other professional registration Boards; and
- (ii) options for increased consumer representation for psychologists.

4.2 What Powers Might a Board Have?

The role and function of the Board cannot be determined until such time as a decision to regulate through statutory registration of practitioners is made. However, functions or powers that might be considered appropriate if registration by title is considered appropriate include:

- The promotion of high standards of practice through education, training and consultation with the profession;
- The provision of advice to the Minister on matters relating to registration and standards;
- The education of consumers through the distribution of information concerning the legislation;
- The power to discipline members for professional misconduct or unsatisfactory professional conduct based upon the established standards; and
- The development of an approach to managing impaired members of that professional group.

4.3 Modalities of TCM to be Regulated

Clearly, the 2 modalities of TCM that would lend themselves to regulation in the first instance would be acupuncture and Chinese herbal medicine because of the risks to consumers identified in those practices. The two additional regulatory models suggested in this paper would enable other modalities to be regulated with minimal difficulty.

4.4 Protection of Title Versus Protection of Practice

If a decision to regulate through statutory occupational registration is made, the least restrictive option, having regard to the nature of the risks involved with the profession, should be adopted. Although there is a need to consider more fully other regulatory options to minimise the risks associated with TCM, *Towards a Safer Choice* does not establish a case for practice restrictions other than through scheduling of individual preparations under poisons and therapeutic goods legislation.

4.5 Titles to be Protected

This depends upon the regulation methodology and upon the modalities that may be selected to regulate via statute. In order that current competition policy is satisfied and so that confusion for the community is minimised, it is recommended that a minimum of titles be protected in this way, should it be the regulatory method of choice.

See comments at **4.14**

4.6 Setting of Standards

The point raised in the Discussion Paper, that the existence of occupational regulation via statute does not diminish the need for complementary self-regulatory activities by professional groups, is strongly supported.

Formal accreditation processes for courses should be established - either by individual professional associations or co-operatively - along the lines outlined in the Higher Education Council's recent discussion document Professional Education and Credentialism. This should include periodic review of courses and external review. *Towards a Safer Choice* noted initiatives in this regard.

Towards a Safer Choice notes that four years academic study is widely considered necessary for safe practice. However, reliance on an academic "years of study" standard in establishing an occupational registration system may impose unnecessary costs and restrict innovative approaches to the education of practitioners (for example - accelerated courses or combined vocational/formal education programmes). In particular, individuals with extensive prior experience in other related disciplines may require less formal academic training.

Decisions to reject certain degrees, diplomas or training programmes need to be made by reference to clear and objective criteria with due regard to the nature of risks involved with practice and the skills needed and the level of training required for initial practice to avoid these risks.

Competency-based standards provide an appropriate means for assessing individual professionals. The process adopted for the development of such standards should ensure that there is extensive consultation with both practitioners and academics, and other independent individuals organisations, to ensure that the standards set are appropriate for initial practice. Individual courses should also be assessed to determine whether graduates meet the competency standard. Individuals seeking registration that have not completed an accredited course should be assessed against these standards.

4.7 Grandfathering

NSW would only support 'grandparenting' on a competency based approach.

4.8 Non-English Speaking Practitioners:

We would argue that this issue should not be the basis for refusing registration, however it may be an issue that needs to be considered by the registration board (if that regulatory approach is taken) as a policy matter or via conditions on registration.

4.9 Prescribing of Scheduled Herbs

Access to prescribing rights for substances listed in the poisons list in the Poisons and Therapeutic Goods Act in NSW should be considered where practitioners can demonstrate they have the competence to use these substances safely. It should not be separately provided for in an occupational registration Act, but dealt with through existing Pharmaceutical Legislation.

4.11 How Might a Regulatory System be Funded

Submissions are sought primarily from the profession on this issue. However, it should be noted that it is the Department's policy that where statutory occupational registration is provided by legislation, regulatory Board's should be established on a self-funding basis.

4.12 Already Registered Practitioners:

There seems to be no necessity to require already regulated health care practitioners to be further regulated by another registering authority. Consultation should occur on the development of standards where there are shared practices or practices which may cross over into areas of specific expertise. There may however, be a need for some process for noting joint practice modalities where a person may be registered under one of the professional groups.

4.13 Practitioners of Other Complementary Therapies

These could be accommodated under either of the 2 additional models of regulation that we have proposed in this paper.

4.14 Other Traditions of Acupuncture

It is inappropriate to restrict the practice of other professions that have sufficient skill and experience to provide services. While this generally only occurs with practice restrictions, title registration legislation can disadvantage other practitioners that are able to provide such services in a safe and effective manner by limiting their ability to claim to be able to provide such services. Any titular restriction should be confined to the title and not the provision of services.

The model proposed in *Towards a Safer Choice* would not prevent unregistered persons from assuming the title 'acupuncturist' if only 'registered acupuncturist' is restricted by legislation because they would not be claiming to be registered. (Editorial note: the title 'acupuncturist' would be restricted in Victoria along with the title 'registered acupuncturist').

In conclusion NSW Health strongly recommends that the development of any regulation for practitioners of Traditional Chinese Medicine must include representatives of the summary stakeholders and representatives of the Chinese Community.

I hope our comments are useful in preparing a position on this matter and I will look forward to hearing of the outcome of this Project through AHMAC. Should you require any further information or have any questions, please do not hesitate to contact Ms Amanda Adrian, Acting Director, Centre for Clinical Policy and Practice on (02) 9391 9211.

Yours sincerely

A handwritten signature in black ink, appearing to read "Andrew Wilson".

Andrew Wilson

Deputy Director-General, Public Health

Chief Health Officer



Appendix 11: Approaches to Grandparenting —Two Models

Proposal 1:

Principles for Grandparenting

Any system of grandparenting should have as its basis the following principles:

- Ease of administration and implementation by a TCM registration board(s).
- Draws on executive strengths of professional associations. It is important that the executive take some responsibility now for the bona fide of each member.
- Process is inclusive rather than exclusive within reasonable safety margins.
- Rather than reviewing standards of associations, the focus is more appropriately on standards of individual members.

Method:

Two lists could be generated by professional associations, one for acupuncture and one for herbs. Professional associations could ensure the lists they provide include practitioners who have met any one of the criteria outlined in Table 1 below.

Table 1:

| Criteria | For acupuncture list | For herbalist list |
|--|--|---|
| 1. At least 10 years practice consisting on average of at least 10 consultations per week, current to within the last three years | 10 acupuncture treatments/week | 10 herb treatments/week |
| 2. Three years effective FT training (min 12hrs/wk contact) plus 2 years clinical experience current to within the last 18 months | Acupuncture or TCM diploma or equivalent. 10 acupuncture treatments/week | Chinese herb diploma or four year TCM diploma or equivalent. 10 herb treatments/week |
| 3. 3.5 years effective FT training (min 12hrs/wk contact) | Acupuncture or TCM diploma or equivalent | Chinese herb diploma or 4 year TCM diploma or equivalent |
| 4. By national examination. Applicants to be currently in TCM practice (currency to within the last 18 months) and to have some claim of training and clinical experience. | | |

A national exam could be run by a TCM registration board(s) with assistance of State Administration of TCM & could be offered in both Sydney and Melbourne with separate exams for acupuncture and Chinese herbal medicine.

If the Chinese herbalist list is to be the method for determining access to some currently scheduled substances then the relevant criteria should refer to raw herb prescribing experience of at least 10 treatments per week for at least 3 years (currency within 18 months in all cases). The title 'Chinese herbal medicine practitioner' and all directly related titles may need to be restricted to practitioners that meet this criterion.

The TCM registration board(s) should be capable of considering special circumstances of individual practitioners through representative associations. However, it may be inappropriate to 'grandparent' as experienced practitioners recent graduates of 3 year diploma courses. Their study is recent and an examination would be a reasonable expectation.

Proposal 2: (The Register of Acupuncture & TCM Inc.)

From the date of registration, there should be a one year period in which practitioners who do not have qualifications that are recognised by the board(s) can apply for registration under grandparenting arrangements. To be eligible under these arrangements, practitioners would need to demonstrate:

1. Five years membership of a recognised TCM association or associations in Australia prior to registration.

or

2. Five years practice in TCM

- practitioners who have not been members of TCM associations
- practitioners who have been members for less than five years
- practitioners from overseas

or

3. Accrual of sufficient number of points under a points system which takes into account a wide range of activities in clinical practice, training and education. The points system would apply to existing practitioners who do not satisfy the standards of formal education set by the TCM registration board(s) and who do not or cannot elect to sit the examinations/competencies set by the board(s).