



REGULATION OF
PRACTITIONERS OF
CHINESE MEDICINE
IN WESTERN
AUSTRALIA

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MINISTER FOR HEALTH

ATTORNEY GENERAL: ELECTORAL AFFAIRS

FOR WESTERN AUSTRALIA

REGULATION OF PRACTITIONERS OF CHINESE MEDICINE IN WESTERN AUSTRALIA

The State Government is committed to enhancing health services throughout the State. Regulation of practitioners of Chinese medicine is being considered given the potential for serious risks arising from the practice of Chinese medicine. Regulation will ensure that registered practitioners have the required level of qualifications and training, ensuring that the public is adequately protected.

This paper, *Regulation of Practitioners of Chinese Medicine in Western Australia – Discussion Paper June 2005* explains the key issues and options for the regulation of Chinese medicine practitioners, and describes the law and practice in other relevant jurisdictions.

Groups and individuals with an interest in this area are invited to respond to the issues raised in the discussion paper. Information regarding comments and submissions is provided on the Consultation Process page in the discussion paper. The closing date for submissions is **Friday 2 September 2005**.

I welcome the comments of all interested groups and individuals.

Yours faithfully

A handwritten signature in black ink, appearing to read 'Sue Ellery'.

Sue Ellery MLC
PARLIAMENTARY SECRETARY
TO THE MINISTER FOR HEALTH

6 July 2005

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PART 1



FOREWORD

Complementary and alternative medicine has experienced a growing acceptance with the Australian public over the past twenty years. It has been estimated that close to 60% of Australians access some form of complementary or alternative health services, indicating a widespread acceptance of complementary and alternative medicines and therapies.¹

In 2000, 52% of the population were estimated to use at least one non-medically prescribed complementary medicine while 23% visited at least one complementary health care practitioner. Annual retail turnover of complementary medicines is estimated at \$800 million with an additional 20% of Australian output being exported.² The use of complementary medicines and therapies is expected to increase as more people come to view complementary health as an important contributor to personal health and well-being.¹

With an increasing number of Australian consumers using a combination of mainstream healthcare and complementary medicines to meet health needs, complementary and alternative medicines and therapies are becoming a significant component of the health services industry.²

The growing popularity of complementary and alternative health services has been attributed to:

- a rising discontentment with conventional, western medicine;
- a preference for natural (or gentler) alternatives to pharmaceutical drugs or surgery;
- a desire for greater control over personal health care; and
- the low success rate of conventional, western medicine in treating conditions, such as chronic pain, for some individuals.

Largely, it appears that consumers who shop around for healthcare services are targeting the most effective way to get better.³

A much wider range of health care services are available in Australia as a result of an increase in immigration and the associated transmission of established medicines and therapies from outside of Australia. Success stories of complementary and alternative medicine in the media, the abundance of information available on the Internet and the high value placed on consumer choice has also contributed to the growth in complementary and alternative medicine in Australia.⁴

Complementary and alternative medicine is widely available to the public in Western Australia (WA). Minimum standards should apply to the education, training and conduct of complementary health practitioners in order to ensure public safety. Regulation of practitioners is being considered in WA as the most appropriate means for establishing such standards, and providing consumers with effective complaint handling and dispute resolution mechanisms.

This discussion paper outlines the movement in Australia to regulate Chinese medicine practitioners. Regulating Chinese medicine practitioners in WA is important given the potential for serious adverse effects arising from the practice of the profession. Descriptions of the three modalities being considered for regulation are given and the models of regulation being consideration for WA Chinese medicine practitioners are explained. Protection of title is recommended as the form of regulation, with controls on prescribing and dispensing rights for restricted herbs. One section reviews potential registration criteria that practitioners would be subject to, including options for an initial grandparenting arrangement to assist with registering existing practitioners. Information is also provided on the impact of the State Administrative Tribunal and the National Competition Policy on regulating the Chinese medicine profession.



BACKGROUND

In August 1995 the Victorian Department of Human Services (DHS) commenced a review of traditional Chinese medicine (TCM), on behalf of all States and Territories. The review was undertaken in response to a rapid expansion in the practice of and demand for TCM in Australia and concerns expressed by consumers, practitioners and professional groups.⁵

With joint funding from Victoria, New South Wales (NSW) and Queensland (Qld), the Southern Cross University (Qld) and the University of Western Sydney (NSW) undertook the major national research project on the practice of TCM. The research project collected information on the risks and benefits of TCM and the nature of the TCM workforce. The project also examined the need for registration of TCM practitioners and regulation of Chinese herbal medicines.⁵ In addressing the criteria set by the Australian Health Ministers Advisory Council for regulation of professions, it became apparent that the practice of TCM involved potential significant risks and therefore occupational regulation would be appropriate.

The review resulted in a major report in November 1996 entitled *Towards a Safer Choice: the practice of traditional Chinese medicine in Australia*.⁸ The report recommended the regulation of practitioners of TCM with the primary purpose of protecting the public.

In September 1997 the Victorian DHS released a discussion paper entitled *Review of Traditional Chinese Medicine*.⁶ This paper presented the options for regulation of the profession of TCM. In July 1998, the Victorian DHS published recommendations on a proposal for regulation in the *Traditional Chinese Medicine: Report on Options for Regulation of Practitioners*.⁵

On completion of their public consultation, the Victorian Government developed a model for occupational regulation and passed the *Chinese Medicine Registration Act 2000*. The Chinese

Medicine Registration Board (CMRB) of Victoria⁷ established under the Act, registers Chinese herbal medicine practitioners, acupuncturists and Chinese herbal dispensers. The CMRB of Victoria is also empowered to investigate complaints about registrants' professional conduct and fitness to practice.

In September 2003 the Therapeutic Goods Administration (TGA) published a report entitled *Complementary Medicines in the Australian Health System*.² The report made the following finding:

Governments should move more quickly to nationally consistent, statutory regulation (where appropriate) of complementary healthcare professions

(Finding 5.1.1).

The report also made recommendations that:

- all jurisdictions introduce legislation to regulate practitioners of traditional Chinese medicine and dispensers of Chinese herbs, based on existing Victorian legislation, as soon as possible (Recommendation 27); and
- Health Ministers review the findings of the New South Wales and Victorian reviews concerning regulation of complementary healthcare practitioners and move quickly to implement statutory regulation where appropriate (Recommendation 28).

In March 2005 the Commonwealth Government released the *Government Response to the Recommendations of the Expert Committee on Complementary Medicines in the Health System*.²⁹

The Commonwealth Government noted the recommendations for regulation of practitioners and proposed to notify the States and Territories, through the Australian Health Ministers' Conference, of their responsibilities in regulating professions.



CONSULTATION PROCESS

SCOPE & AIM

This discussion paper forms part of the consultation process into the regulation of Chinese medicine practitioners. The purpose of the consultation process is to seek comment on a proposed registration framework for Chinese medicine practitioners in WA. This discussion paper explains the key issues and options, and seeks the views of interested groups and individuals regarding the regulation of Chinese medicine practitioners in WA.

It is proposed that registration in WA will initially be limited to three modalities, being acupuncturist, Chinese herbal medicine practitioner and Chinese herbal dispenser. These three modalities were identified as those that should be subject to registration based on the research and consultation undertaken by the Victorian Government, on behalf of all States and Territories. The Victorian Government based their registration system on these three modalities in the *Chinese Medicine Registration Act 2000* (Vic).

The consultation period will be approximately two months and will result in a framework for developing a draft Chinese Medicine Registration Bill. An advertisement will also be placed in the West Australian calling for submissions. Further consultation will be undertaken on a draft Bill when it has been prepared.

This discussion paper has been prepared by Legal and Legislative Services at the Department of Health, Western Australia.

Further copies of this discussion paper can be obtained by contacting:

Ms Rose-Marie Garcia

Tel: 08 9222 4038

Fax: 08 9222 4355

Email: Legal.Services@health.wa.gov.au

The discussion paper is also available on the Department of Health's Internet site at <http://www.health.wa.gov.au/publications/>

HOW TO HAVE YOUR SAY

Annexure 2 provides a reference list of the questions on which your views are sought.

Written submissions should be made to:

Legal and Legislative Services

Department of Health

PO Box 8172

PERTH BC WA 6849

Alternatively, submissions may be emailed to:

Legal.Services@health.wa.gov.au

The final date for receiving written submissions is 5pm, 2 September 2005.

Please indicate whether an individual or an organisation is making the submission. Your name, address and telephone number should be included. Anonymous submissions will not be considered. Individuals or organisations that wish their comments to be treated confidentially should indicate this by marking correspondence *private and confidential*. However, submissions may be subject to release under the *Freedom of Information Act 1992*.



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CHINESE
MEDICINE

WHAT IS COMPLEMENTARY AND ALTERNATIVE MEDICINE?

Complementary and alternative medicine (CAM) refers to a heterogeneous collection of medical and health care systems, therapeutic substances and practices and techniques based on theory and explanatory mechanisms that are not consistent with the western clinical model of medicine.^{8,9}

Complementary therapies include a diverse group of health-related therapies and disciplines that are not considered to be part of mainstream medical care in Australia² such as acupuncture, naturopathy, meditation, and aromatherapy.¹⁰ Chiropractic and osteopathy have been considered both as complementary therapies and allied health practices. These professions are regulated in WA under the *Chiropractors Act 1964* and the *Osteopaths Act 1997* respectively.

The Commonwealth *Therapeutic Goods Act 1989* defines *complementary medicines* as therapeutic goods consisting wholly or principally of one or more active ingredients, each of which has a clearly established identity and either a traditional use or any other use prescribed in the regulations.¹¹ This includes herbal medicines, homoeopathic medicines, and nutritional and other supplements.¹⁰ The regulatory controls for medicines are primarily the responsibility of Australia's national regulator, the TGA, in cooperation with State and Territory governments and the medicines industry.²

The Cochrane Collaboration¹² defined CAM as a 'broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health systems of a particular society or culture in a given historical period. CAM includes all such practices and ideas self-defined by their

users as preventing or treating illness or promoting health and well-being.'¹²

It is interesting to note that in many countries CAM is considered to be traditional medicine, and forms the dominant health system or is at least employed alongside western-type conventional health practices. For instance, African and western Pacific nations consider that traditional medicine is a priority for health care in their regions, but in other regions the role of traditional medicine is treated as complementary or alternative medicine.¹³

CHINESE MEDICINE MODALITIES

For the purposes of this discussion paper Chinese medicine will refer to the three modalities being considered for regulation: acupuncture, Chinese herbal medicine and Chinese herbal dispensing. Importantly, it is the practitioners of these modalities that are being considered for regulation, and not the controls relating to the quality and safety of the medicines or herbs employed within these modalities. Regulation of practitioners will include tight controls on the prescribing and dispensing of restricted herbs. The role of regulating medicines, including many herbal products, is undertaken by the TGA.

WHAT IS ACUPUNCTURE, CHINESE HERBAL MEDICINE AND CHINESE HERBAL DISPENSING?

Descriptions of the modalities being considered for regulation in Western Australia are given below and are taken primarily from the Expert Committee on *Complementary Medicines in the Australian Health System*² report. For the purposes of this discussion paper the Department of Health

has attempted to capture the most appropriate description of acupuncture, Chinese herbal medicine and Chinese herbal dispensing. It is acknowledged that there are varying practices and descriptions available for these modalities, particularly for acupuncture, which could also have been included.

CHINESE HERBAL MEDICINE

Traditional Chinese medicine is best known for the practices of acupuncture and Chinese herbal medicine, in addition to a wide range of therapies such as Chinese massage, dietary and lifestyle advice, orthopaedic manipulations and surgery, breathing, movement and meditation, and specific techniques including moxibustion, cupping, scraping and point injection therapy.⁸ Traditional Chinese medicine is a complete diagnostic and treatment system dating back thousands of years and is based on an understanding of health and illness that differs substantially from that in western medicine. Clinical symptoms are interpreted by reference to theories of bodily operation that are foreign to the western-trained scientific eye.

Chinese herbalism is the most prevalent of the ancient herbal traditions. Chinese herbs are used according to their ascribed qualities such as cooling (yin) or stimulating (yang). Herbalists generally use unpurified plant extracts containing different constituents and often use several different herbs together.

Chinese herbs can be toxic as they contain active principles. Herbal extracts contain plant material with pharmacologically active constituents. The active principle(s) of an extract, which is in many cases unknown, may exert its effects at the molecular level. For example, an extract may have an enzyme-inhibiting effect. When used in conjunction with Western medicine, it is important to be aware of the interactions of Chinese herbs with Western prescription and non-prescription pharmaceuticals. It is also important that practitioners have an understanding of the herbs' indications and contraindications.

ACUPUNCTURE

Acupuncture involves the stimulation of specific points on the skin, usually by the insertion of needles, for therapeutic or preventative purposes. The original form of acupuncture was based on the principles of traditional Chinese medicine

that state that the workings of the human body are controlled by a vital force or energy called 'qi', which circulates between the organs along channels called meridians.

Traditional acupuncturists use an Oriental medicine framework for referring to disturbances believed to cause symptoms, and may use various adjunctive therapies including moxibustion and cupping.

Conventional healthcare professionals who practice acupuncture use acupuncture points thought to correspond to physiological and anatomical features.

Japanese and Ayurvedic acupuncture are amongst other forms of acupuncture practiced in Australia.

CHINESE HERBAL DISPENSING

Chinese herbal dispensers fill prescriptions from Chinese herbal medicine practitioners or dispense medicinal substances for health enhancement and/or treatment purposes.¹⁴ Chinese herbal dispensing is an established profession in China, whilst in Australia most Chinese herbal medicine practitioners carry out their own dispensing.

In Victoria, under section 8(2) of the *Chinese Medicine Registration Act 2000 (Vic)*, registered Chinese herbal dispensers are qualified to obtain and to have in their possession and to use, sell or supply Schedule 1 poisons within the meaning of the *Drugs Poisons and Controlled Substances Act 1981 (Vic)*.

In Victoria, registered Chinese herbal medicine practitioners may dispense over-the-counter medicines to their patients without being a registered Chinese herbal dispenser, as long as they do not use the title 'Chinese herbal dispenser', or mislead members of the public into believing that they are a registered Chinese herbal dispenser. Medicines must be either listed or registered on the Therapeutic Goods Register (manufactured medicines) or extemporaneously dispensed (made up on site to a prescription for an individual patient). However, to prescribe or dispense herbs that are restricted under the Poisons List of the *Drugs Poisons and Controlled Substances Act 1981 (Vic)* a Chinese herbal medicine practitioner must have their registration endorsed and be legally authorised to prescribe and dispense these herbs.¹⁵



REGULATION OF CHINESE MEDICINE PRACTITIONERS IN AUSTRALIA & INTERNATIONALLY

In Australia, regulation of Chinese medicine practitioners is a responsibility of States and Territories.

VICTORIA

The only State in Australia with registration legislation for Chinese medicine practitioners is Victoria. The *Chinese Medicine Registration Act 2000 (Vic)* (CMR Act) provides for the statutory regulation of Chinese herbal medicine practitioners, acupuncturists and Chinese herbal dispensers. The Chinese Medicine Registration Board (CMRB) of Victoria administers this Act.

As at June 2005, the CMRB of Victoria had 779 registered practitioners with 435 registered as both acupuncturists and Chinese herbal medicine practitioners, 309 practitioners for acupuncture only and 35 registered Chinese herbal medicine practitioners only.¹⁶ There were no registered Chinese herbal dispensers.

Overview of Chinese Medicine Registration Act 2000 Victoria

The provisions of the CMR Act establish the CMRB of Victoria and provide for the statutory regulation of Chinese herbal medicine practitioners, acupuncturists and Chinese herbal dispensers.

The main purposes of the CMR Act are:

- to protect the public by providing for the registration of practitioners of Chinese medicine and dispensers of Chinese herbs and investigations into the professional conduct and fitness to practise of registered practitioners of Chinese medicine and dispensers of Chinese herbs;
- to regulate the advertising of Chinese medicine and Chinese herbal dispensing services;
- to establish the CMRB of Victoria and the Chinese Medicine Registration Board Fund;
- to amend the *Drugs Poisons and Controlled Substances Act 1981 (Vic)*;

- to make amendments to other Acts regulating health practitioners; and
- to provide for other related matters.

Section 68 of the CMR Act sets out the powers, functions and consultation requirements of the CMRB of Victoria, and includes:

- registering persons who comply with the requirements of the CMR Act so that they may hold themselves out as registered Chinese medicine practitioners or registered Chinese herbal dispensers;
- approving courses of study which provide qualifications for registration as Chinese medicine practitioners and Chinese herbal dispensers;
- approving courses of study or training which provide qualification for endorsement of registration under section 8;
- regulating the standards of practice of Chinese medicine and the dispensing of Chinese herbs in the public interest;
- investigating the professional conduct or fitness to practise of registered practitioners and impose sanctions where necessary;
- issuing and publishing guidelines about the minimum terms and conditions of professional indemnity insurance in connection with the practice of Chinese medicine and the dispensing of Chinese herbs;
- recognising post graduate courses in Chinese medicine and the dispensing of Chinese herbs in addition to those required for registration;
- issuing and publishing Codes for the guidance of registered practitioners about standards recommended by the Board relating to the practise of Chinese medicine and the prescribing, labelling, storage, dispensing and supply of Chinese herbs including Schedule 1 poisons within the meaning of the *Drugs, Poisons and Controlled Substances Act 1981 (Vic)*;

- initiating, promoting or participating in programs that the Board considers will protect the public from practitioners whose ability to practise medicine may be affected by any matter referred to in section 28;
- advising the Minister on any matters relating to its functions, providing information when requested to the Minister, consulting with the Minister and have regard to the Minister's advice in carrying out its functions and exercising powers; and
- consulting with registered practitioners before formulating any Codes referred to in sub-section (1)(h).

The CMR Act comprehensively outlines what constitutes unprofessional conduct and contains wide-ranging disciplinary powers for the protection of the public. The CMR Act makes it a disciplinary matter for anyone who is not a registered Chinese medicine practitioner or Chinese herbal dispenser to use titles which suggest that they are registered in any of the divisions of the register when they are not. The CMR Act includes stringent advertising provisions and enables the Board to prepare guidelines for minimum acceptable standards for advertising Chinese medicine services.

A person may apply to the Victorian Civil and Administrative Tribunal (VCAT) for a review of decisions made by the CMRB of Victoria where the decision has been made to refuse that person's application for registration, to impose conditions, limitations or restrictions on the person's registration or to suspend their registration. Appeals against findings/determinations made by formal hearing panels may also be taken to the VCAT.

The CMR Act also amended the *Drugs, Poisons and Controlled Substances Act 1981* (Vic) to establish a new list of Chinese herbs. These provisions control access by qualified Chinese herbal medicine practitioners and dispensers to potentially toxic and dangerous herbs that otherwise are restricted.

Practitioners of other forms of acupuncture such as Japanese and Ayurvedic acupuncture are enabled through the CMR Act to register without requiring an understanding of the full body of Chinese medicine knowledge.

The Second Reading Speech for the CMR Act during its passage through the Parliament of Victoria is available at <http://www.cmr.vic.gov.au/about/secondreadingspeech.pdf>

Other registered health practitioners who practice Chinese medicine in Victoria

The *Health Legislation (Further Amendment) Act 2003* (Vic) amended the registration Acts for medical practitioners, nurses, optometrists, dentists, chiropractors, osteopaths, pharmacists and physiotherapists. These practitioners, except pharmacists, who wish to practice acupuncture alongside their usual professional practices, do not have to be registered with the CMRB of Victoria. Instead they may apply for endorsement or notation of registration from their own registration boards, effectively exempting the practitioner from restrictions on using the protected title of 'acupuncturist'.

Pharmacists are the only other health profession able to apply to their registration board for endorsement of registration effectively exempting the pharmacist from restrictions on using the protected title of 'Chinese herbal dispenser'.

The registration boards for these practitioners are responsible for assessing the qualifications and training of the practitioners. However, many registration boards have officially requested that the CMRB of Victoria assess the qualifications of their registered practitioners before an endorsement or notation of registration is granted to allow use of the title 'acupuncturist' or 'Chinese herbal dispenser'. This ensures that the standards for other health practitioners wishing to practice acupuncture or Chinese herbal dispensing are consistent as far as possible with the standards established by the CMRB of Victoria.

Other registered health practitioners who have obtained the required endorsement or notation of their registration from their own registration board are allowed to use the title 'acupuncturist' and advertise that they are qualified to provide acupuncture services to the public, without being registered with the CMRB of Victoria. This endorsement does not, however, legally enable them to use the title 'Registered Acupuncturist'. These titles are reserved for those registered under the CMR Act in the Division of Acupuncture.

Other unregistered health practitioners who practice Chinese medicine in Victoria

Unregistered health practitioners in Victoria, such as massage therapists, homoeopaths, naturopaths etc are not entitled to advertise that they provide acupuncture services unless they first register with the CMRB of Victoria.

Other modalities in Victoria

The 1998 Victorian *Traditional Chinese Medicine Report on Options for Regulation of Practitioners*⁵ recommended that other modalities of complementary therapies be examined. Research is being undertaken to identify the risks and benefits of the practice of western herbal medicine and naturopathy, and assess the need for further regulation of practitioners and the prescribing and dispensing of herbal medicines. A report on the research is due to be released soon. More information is available at: <http://www.dhs.vic.gov.au/pdpcd/workforce/pracreg/naturopathy.htm>

NEW SOUTH WALES

In September 2002, the New South Wales (NSW) Department of Health released a discussion paper on the regulation of complementary health practitioners. The discussion paper was entitled *Regulation of Complementary Health Practitioners – Discussion Paper, September 2002*.¹

Following the close of the consultation period, an expert advisory group prepared a report for the NSW Minister for Health in relation to regulation of Chinese medicine practitioners. The Minister is currently considering the options presented in the report.

ACT, NORTHERN TERRITORY, QUEENSLAND, SOUTH AUSTRALIA & TASMANIA

The Western Australian Department of Health has been advised that there are no immediate plans to regulate complementary health practitioners in these States and Territories.

NEW ZEALAND

A Ministerial Advisory Committee on Complementary and Alternative Health (Committee) was established in June 2001. The Committee has released the *Complementary and Alternative Medicine: Current Policies and Policy Issues in New Zealand and Selected Countries – A Discussion Document 2003 and the resulting Summary of Submissions in response to the discussion document*. The Committee provided its final advice to the New Zealand Minister of Health in June 2004.

The response of the New Zealand Government¹⁷ to the Committee's report, supported recommendations for regulation of practitioners of complementary and alternative health, according to level of inherent risk and consistent with the *Health Practitioners Competence Assurance Act 2003* (New Zealand).

A key feature of the New Zealand approach is the national basis of regulation. This differs from the Australian State-by-State basis. A single route to statutory regulation in New Zealand would be achieved through a 'single, overarching act containing a framework for the governance and functions of registering authorities'.²

UNITED KINGDOM

In November 2000 the House of Lords Select Committee on Science and Technology recommended in its report on *Complementary and Alternative Medicine* that herbal medicine and acupuncture should be regulated by statute.¹⁸ The UK Government endorsed the concept of statutory regulation.

In March 2004 the UK Department of Health released a paper entitled *Regulation of herbal medicine and acupuncture – Proposals for statutory regulation*.¹⁹ This paper proposes the establishment of a statutory registration authority for traditional Chinese medicine and acupuncture, the setting of standards for entry into the profession and protection of a range of titles for practitioners.

UNITED STATES

In 2002 the *White House Commission on Complementary and Alternative Medicine Policy Final Report*²⁰ recommended that public accountability for complementary and alternative medicine (CAM) practitioners was required. The report urged states to consider whether a regulatory infrastructure for CAM practitioners was required in order to promote quality of care and patient safety.¹

Each state decides its own independent policy on the regulation of practitioners within its jurisdiction. Some states have developed regulatory or licensing arrangements for some CAM practitioners. For example, many regulate acupuncture and require practitioners to be trained to a specified standard. The National Certification Commission for Acupuncture and Oriental

Medicine²¹ plays a role in setting standards in individual states. Some states limit the practice of acupuncture to medical practitioners or to those under a medical practitioner's supervision. Naturopathic medicine is also recognised and licensed in several states.

SINGAPORE

Health care in Singapore is based on Western medical science. However, it is common practice among the various ethnic groups to occasionally consult traditional medicine practitioners for general ailments. Chinese medicine is particularly popular among the Chinese residing in Singapore.

The *Traditional Chinese Medicine (TCM) Practitioners Act* was passed on 14 November 2000. The Act requires TCM Practitioners who practice the prescribed practice of acupuncture and/or TCM to be registered and issued with a licence to practice. A TCM Practitioners Board was established as the licensing body for the registration of TCM practitioners, accreditation of TCM schools and courses for TCM, and regulating the professional conduct and ethics of registered acupuncturists and TCM practitioners.²²

CHINA

China relied entirely on TCM until Western medicine was introduced at the end of the 17th century. Efforts by the Chinese Government kept TCM from being displaced by western, conventional medicine in the mid 20th Century.²⁵ Western, conventional medicine and TCM are now practiced alongside each other at every level of the health care system, indicating the integration of both forms of medicine into primary care and hospital settings. Dual systems of traditional Chinese and western medical education exist in China, and the integrated training of health practitioners is formalised. The Government of China promotes equality in policies on traditional and western conventional medicine.²³ The State Administration of Traditional Chinese Medicine was established in 1986 and regulates TCM practitioners.

WORLD HEALTH ORGANISATION

In 2002 the World Health Organisation (WHO) published a *WHO Traditional Medicine Strategy 2002 – 2005*.¹³ The strategy acknowledges the regional diversity in the use and role of traditional, complementary and alternative medicine. It was developed to address the issues of policy, safety, efficacy, quality, availability, preservation and further development of traditional, complementary and alternative medicine.

WHO has also developed guidelines and standards relating to the use of herbal medicine and acupuncture and the training and research into these practices. A couple of these publications are *Guidelines for the Appropriate Use of Herbal Medicine 1998* and *the Guidelines on Basic Training and Safety in Acupuncture 1999*.²⁴



PART 2



WHAT IS STATUTORY REGULATION?

Regulation of practitioners can occur through statutory regulation, co-regulation or voluntary self-regulation. These forms of regulation have similar functions and potential positive outcomes, however only statutory regulation is upheld by law.^{25,19}

SELF-REGULATION

Self-regulation typically develops in a profession where the peak body establishes and maintains standards and codes of practice, education and training and formulates a process for complaint resolution and disciplinary action. For many professional groups, the typical process has been for a widely recognised and accepted peak body to emerge, resulting in the formation of self-regulation. This form of regulation occurs where there is no legal requirement for practitioners of a particular profession to register with a regulatory body. With minimal barriers to entry in the profession, self-regulation enables a wide range of practitioners to practice in the profession. This provides greater choice to consumers.

There are difficulties with self-regulation. Self-regulation relies on voluntary compliance by members. Its effectiveness depends on the ability of the professional association to enforce disciplinary measures. A practitioner's voluntary membership of a professional association may be the only indicator for consumers that a practitioner is suitably qualified and safe to practice, and subject to a disciplinary scheme.²⁶ Self-regulation makes it difficult to monitor and maintain standards of training and practice, resulting in widely varying standards of practice and levels of qualification. There is potential for conflict of interest in the setting and enforcing of standards as some professional associations have close links with or have been established specifically to recognise graduates of particular training institutions.²⁶

Professional associations have generally existed to protect and promote the interests of members. This may have the potential to compromise open, transparent and accountable complaints handling and disciplinary processes. The voluntary nature of membership means that the suspension or cancellation of the membership of a practitioner may have little or no real effect as a disciplinary action. Furthermore, self-regulation does not hinder unqualified practitioners from practising in the profession.

There are many complementary and alternative medicine practitioner associations that vary in size and quality in Australia. Membership of an association is voluntary. Some associations may only accept practitioners with particular training and qualifications, and set their own standards and codes of conduct. The typical process for the emergence of a peak body has not occurred in the Chinese medicine profession. There are a large number of associations in Australia and this has led to fragmentation of the profession. There is no single association that is widely recognised and accepted as the peak body.

Self-regulation is not suitable where there are potentially serious risks to patients arising from the practice of a profession.

CO-REGULATION

Co-regulation is where the government and professional associations share the regulatory role. Practitioners would be required to take up membership with an accredited professional association. Professional associations would establish and maintain professional standards, and administer a disciplinary system to ensure professional standards. The government would undertake accreditation and monitoring of the professional associations in order to promote public safety.

As with self-regulation, co-regulation would most likely lack the legislative capacity to respond satisfactorily to complaints and grievances from the public. Most importantly, there would be no legal underpinning for a scheme controlling the prescribing and dispensing of restricted herbs. Practitioners who are not members of a co-regulated professional association would not be legally prevented from practicing or using the titles of the profession.

STATUTORY REGULATION

Statutory regulation primarily aims to protect the consumers of particular professional services, by ensuring that registered practitioners meet agreed standards of qualifications, practice and competence.¹⁹

A statutory regulatory system involves the establishment of a register of practitioners who are qualified and competent to practice. The existence of a register enables the public to identify registered practitioners who meet the standards prescribed by the regulatory body.

Regulatory bodies are responsible for the setting, monitoring and enforcing of minimum practitioner

education standards and ongoing professional development requirements.²⁷ The system also provides a mechanism for complaint and dispute resolution, such as sanctions, suspension or removal of the practitioner from the register.

Statutory regulation is most often applied to higher-risk modalities. These include modalities that use interventions such as spinal manipulation (eg chiropractic, osteopathy), invasive techniques (eg acupuncture) or ingested substances (eg herbal medicine).²⁵

Advantages of statutory regulation for patients, the public and practitioners are:¹⁹

- ensures protection of title: only practitioners who are registered with the statutory body are legally entitled to use a particular title;
- ensures that practitioners have an appropriate level of skill and training;
- establishes a single register of practitioners, making it easier for the public to find an appropriately qualified and trained practitioner; and
- provides a legislative underpinning of the regulatory body's disciplinary procedures: a practitioner who has been removed from the Register can no longer use the protected title.



2A

What do you consider are/should be important features for statutory regulation of Chinese medicine practitioners in Western Australia?

A review of Western Australian health practitioner legislation was conducted in October 1998. The review sought comments and submissions on the *Osteopaths Act 1997* (the Act), which was referred to as the template legislation. This Act was identified as the model legislation for the regulation of other health professions in Western Australia. One of the aims of this review was to provide the health consumers of Western Australia with effective, modern, readily understandable and, so far as possible, uniform health practitioner legislation.²⁸

The template legislation will be used as the model for all new health practitioner legislation, including the regulation of Chinese medicine practitioners. The template will be adjusted as necessary to take account of particular issues affecting Chinese medicine practitioners. Competition policy review of the draft legislation for Chinese medicine practitioners may involve a more comprehensive analysis of particular provisions.

OVERVIEW OF THE TEMPLATE LEGISLATION

The template legislation has eight parts. Part 1 contains the definitions and interpretation of terms used in the Act. Part 2 establishes the registration board, its membership, functions, and the establishment of committees. Part 3 deals with finance and reports.

Part 4 governs the registration of practitioners, setting out the registration requirements, and providing for conditional and provisional registration. The assessment of complaints, disciplinary proceedings and the role of the State Administrative Tribunal are set out in Part 5, with offences provided for in Part 6. Part 7 provides for the making of codes of practice, rules and regulations. Miscellaneous items are included in Part 8.

OVERVIEW OF THE OSTEOPATHS ACT 1997

The Act closely resembles the framework of the template legislation. The main purpose of the Act is to regulate the practice of osteopathy and to provide a system of registration for osteopaths. The Act provides for a system of regulation that facilitates the maintenance of appropriate levels of knowledge and experience and ensure that osteopaths provide safe standards of care.

Part 1 provides a definition of osteopathy. Part 2 establishes the registration board. Members of the board are appointed by the Minister for Health. The functions of the board are to administer the registration scheme established by the Act; perform disciplinary functions; promote public education and research relating to the practice of osteopathy; provide advice on osteopathy issues to the Minister; and to monitor education in osteopathy. Part 3 governs the registration of osteopaths.

Part 4 provides that the board's funds will consist of registration fees, grants, gifts and donations, pecuniary penalties and other money or property lawfully received by the board in connection with the performance of its functions. These funds are available to the board to administer and enforce the Act, for education purposes and for any other purpose approved by the Minister.

Part 5 relates to disciplinary and impairment matters. Disciplinary matters relate to a person acting carelessly, incompetently and improperly, breaching the Act, failing to comply with instructions by the Board, and providing services that were excessive or not necessary for the recipient's well-being. Impairment matters occur where a person is affected by his or her dependence on alcohol or drugs to the extent that it affects their ability to practice as an osteopath. This part provides for the lodging of complaints

in respect to disciplinary and impairment matters, investigations, the role of the board and review committees, and conciliations. The powers of the State Administrative Tribunal (see 2C State Administrative Tribunal) for dealing with a disciplinary or impairment matter are set out in Part 5.

Part 6 provides a range of offences under the Act. Offences include practising as an osteopath when not registered, using the title 'osteopath' or pretending to be registered as an osteopath when not registered, failing to comply with a disciplinary order, providing false information, failing to attend or take oath, and obstructing an investigator. Part 7 deals with miscellaneous provisions such as appeals and legal proceedings.

The Act is designed to protect members of the community through the establishment of a competent and effective authority to control and regulate the practice of osteopathy in WA.

All Western Australian state legislation, including the *Osteopaths Act 1997*, can be found on the State Law Publisher's website www.slp.wa.gov.au, or contact the State Law Publisher by telephone on 08 9321 7688.



STATE ADMINISTRATIVE TRIBUNAL

The State Administrative Tribunal is a dedicated independent authority, created to handle the resolution of appeals from a range of administrative decisions made by the courts, Government Ministers and public officials. It deals with a number of appeal matters previously dealt with by various boards and tribunals including:

- disciplinary proceedings affecting a number of statutory regulated trades and professions, including lawyers, architects, motor vehicle dealers, plumbers, electricians, finance brokers, real estate agents and all registered health professionals; and
- civil complaints ranging from equal opportunity matters to disputes about strata titles, and disputes lodged with the Commercial Tribunal.

The State Administrative Tribunal has two jurisdictions:

1. Original
 - a) makes original/primary decisions to determine civil, commercial or personal matters; and
 - b) decides matters from regulatory bodies regarding the disciplining of people in various industries, occupations and professions.
2. Review
 - a) reviews administrative decisions made by primary decision makers (eg other tribunals, ministers and public officials who can, by statute, make administrative decisions on a range of personal and commercial activities); and
 - b) reviews decisions made by regulatory bodies regarding licences to operate in an industry or profession.

Health practitioner boards have the power to receive and investigate complaints and deal with minor disciplinary matters. More serious disciplinary matters, such as possible suspension and cancellation of registration, are referred by the relevant board to the State Administrative Tribunal.



NATIONAL COMPETITION POLICY

In 1995 all States and Territories entered into a group of agreements known as the National Competition Policy (NCP). NCP requires that the impact of new and existing legislation on competition must be assessed. The Competition Principles Agreement is one element of NCP and sets out principles to be applied when implementing reform. Clause 5.1 of this Agreement states that:

- 1) legislation should not restrict competition unless it can be demonstrated that the benefits of the restriction to the community as a whole outweigh the costs; and
- 2) the objectives of the legislation can only be achieved by restricting competition.

Regulatory requirements establish title and practice protection for health practitioners. These requirements have been identified as possible restrictions on competition. However, the intent of the health practitioner legislation is the protection of the public. Protection of the public aims to reduce the potential for risk of harm that may result from the provision of health practitioner services by persons who do not possess the knowledge, skill or competence to provide these services safely and competently.

The benefits of restricting competition through regulation include:

- formal establishment and maintenance of education and training standards and practices;
- public access to complaints mechanism for alleged unprofessional conduct by Chinese medicine practitioners; and
- sanctions and disciplinary measures for individuals engaging in unprofessional conduct.

The costs of restricting competition through regulation include:

- financial costs of administration and enforcement by the regulatory body;
- only those practitioners that have undergone a recognised training course will be able to register as a Chinese medicine practitioner. Many practitioners that otherwise would be considered competent in Chinese medicine may not be able to register, effectively reducing the number of practitioners that can advertise their services in the regulated professions. This cost may be overcome through grandparenting arrangements which would be as inclusive of practitioners as possible, while maintaining safety for the public in the practice of Chinese medicine; and
- where protection of title is implemented, unregistered complementary medicine practitioners will not be able to advertise their services using the protected titles, or mislead the public into believing that the practitioner is registered, unless they first register with the Chinese medicine registration board.



WHY REGULATE?

The safety of consumers of Chinese medicine is the primary issue in the discussion about regulation of practitioners. The widespread use and increasing popularity of Chinese medicine and other alternative health services has heightened concern about the level of risk inherent with some practices and therapies. A significant risk is the potential for adverse interactions between Chinese herbs and western pharmaceuticals.

It has been recognised in Australia that there is a need for a structure that reduces the risk faced by consumers of Chinese medicine. Regulation is considered, both in Australia and internationally, to be the most effective measure to ensure practitioners have appropriate education and training, and facilitate controls on the prescribing and dispensing of restricted herbs. Furthermore, the potential risks to the public associated with the practice of Chinese medicine and the current absence of complaint and disciplinary mechanisms would be addressed by statutory regulation.

The development of regulation legislation for Chinese medicine practitioners in Western Australia is supported by recommendations from national government committees and research studies recommending statutory regulation.

EXPERT COMMITTEE ON COMPLEMENTARY MEDICINES

In 2003 the TGA established the Expert Committee on Complementary Medicines in the Australian Health System (Expert Committee). The Expert Committee produced a report entitled *Complementary Medicine in the Australian Health System*.²

While the focus of the Expert Committee was on actual medicines, a section of the report was

dedicated to the regulation of practitioners. The Expert Committee was, in its terms of reference, asked to examine and provide advice on the education, training, and regulation requirements for healthcare practitioners who are supplying complementary medicines and providing advice or delivering care to consumers of complementary medicines.

The findings of the Expert Committee strongly recommended that all jurisdictions introduce legislation to regulate practitioners of traditional Chinese medicine and dispensers of Chinese herbs, based on existing Victorian legislation, as soon as possible (Recommendation 27). The Expert Committee also recommended that Health Ministers should review the findings of the New South Wales and Victorian reviews concerning regulation of complementary healthcare practitioners and move quickly to implement statutory regulation where appropriate (Recommendation 28).

Finding 5.1.1

Governments should move more quickly to nationally consistent statutory regulation (where appropriate) of complementary healthcare professions.²

In March 2005, the Commonwealth Government released the *Government Response to the Recommendations of the Expert Committee on Complementary Medicines in the Health System*.²⁹ The Government noted Recommendations 27 and 28, identifying that occupational regulation is a State and Territory responsibility. In response to the recommendations, the Australian Government proposed to bring the matter to the attention of the States and Territories through the Australian Health Ministers' Conference.

AUSTRALIAN HEALTH MINISTERS' ADVISORY COUNCIL

The Australian Health Ministers' Advisory Council (AHMAC) has established a nationally agreed process for the occupational regulation of health professions. Included in this process is the requirement that regulation should only occur with a majority of jurisdictions agreeing to regulation, and where the profession meets specific criteria. In 1995 AHMAC adopted six criteria that are to be applied when assessing the need for statutory regulation of unregulated health occupations. These criteria are:

1. Is it appropriate for Health Ministers to exercise responsibility for regulating the occupation in question, or does the occupation more appropriately fall within the domain of another Ministry?
2. Do the activities of the occupation pose a significant risk of harm to the health and safety of the public?
3. Do existing regulatory or other mechanisms fail to address health and safety issues?
4. Is regulation possible to implement for the occupation in question?
5. Is regulation practical to implement for the occupation in question?

The 1996 Victorian report, *Towards a Safer Choice: The Practice of Traditional Chinese Medicine in Australia* addressed the AHMAC criteria with the following findings:

1. It is clearly appropriate for Health Ministers to exercise responsibility for regulating TCM.
2. The activities of the practice of TCM clearly pose a significant risk of harm to the health and safety of the public.
3. Existing regulatory mechanisms are inadequate in safeguarding and protecting the public as consumers of TCM.
4. There is a defined profession for which regulation is possible to implement.
5. Occupational regulation is practical to implement for currently unregulated TCM practitioners.

Following its comprehensive review into traditional Chinese medicine, Victoria concluded that statutory regulation of the profession was necessary for the health and safety of the public.

Towards a Safer Choice recommended the introduction of statutory occupational regulation in the form of a restriction of title. The aim was to introduce a minimal, yet sufficient, regulation to ensure adequate public safety and to cause the least anti-competitive effect in the health care marketplace.⁸

POTENTIAL RISKS TO PUBLIC HEALTH AND SAFETY

A number of consumers of complementary health services believe that the practice of Chinese medicine poses minimal risk to the public. This perception may have arisen from the absence or low level of competency standards, regulation and surveillance of the industry.¹ The availability of ingredients from health food stores may also have contributed to this view, as has the belief that Chinese herbal medicine is safe because it is 'natural'.³⁰

There are likely to be some risks associated with any health care practice. Adverse effects are possible with any pharmacologically active ingredients that have the capacity to change physiological function. While Chinese medicine may be considered less risky than western medicine, it is not free from risk. This has been demonstrated by the occurrence of fatalities associated with the practice of Chinese medicine. Chinese medicine appears to pose greater risks than some regulated health care practices such as osteopathy and chiropractic.²

Towards a Safer Choice classifies risks of TCM to the public as:

- risks associated with the clinical judgement of the TCM practitioner;
- risks related directly to the effects of acupuncture needling; and
- risks related directly to the consumption of Chinese herbal medicines.

The following section outlining the risks associated with TCM has been predominantly taken from *Towards a Safer Choice*⁸, Chapter 4.

Risks associated with the clinical judgement of the TCM practitioner

These risks are further grouped into risks of commission or risks of omission. Risks of commission relate to direct and inappropriate acts undertaken by a practitioner during treatment. They include:

- recommendations from practitioners that patients defer or withdraw from appropriate conventional medical treatment. This may result in loss of the benefit of that treatment, increased morbidity and possibly death;
- incorrect prescribing. This includes poor prescribing, failure to observe contraindications, inappropriate dosage, inappropriate duration of therapy and failure to avoid known interactions with pharmaceutical drugs; and
- negligent practice, such as the use of non-sterile acupuncture needles. Serious infection resulting from acupuncture may also affect the broader public through the spread of contagious diseases.

Risks of omission occur when practitioners have inadequate skills or are unaware of the limits of their practice:

- misdiagnoses, or failure to detect serious underlying disease or abnormality;
- failure to refer on, resulting in delay of diagnosis and appropriate treatment; and
- failure to explain precautions. This equates to a failure to obtain informed consent and could result in direct and serious consequences for a patient not aware of possible risks.

Other general risks include:

- Mental trauma;
- Unsubstantiated claims of therapeutic benefit;
- Sexual misconduct; and
- Financial exploitation.

Risks of commission and omission are considered to be related to educational standards of practitioners.

Risks related directly to the effects of acupuncture needling

Predictable adverse reactions to acupuncture include:

- Infections: the use of unsterile needles may cause local infections at the site of needle entry. Of greater concern are systemic infections such as endocarditis, septicaemia,

hepatitis B, HIV, osteomyelitis, myositis, peritonitis and pleuraempyema.

- Local trauma: due to the needle, its location and broken needles. Possible conditions include pneumothorax, spinal cord injuries, factitial panniculitis, auricular chondritis, fatal and non-fatal cardiac tamponade, pseudoaneurysm, deep vein thrombosis, nerve damage, burns (from moxibustion) and severe bruising (from cupping).
- Patient responses such as fainting, nausea and vomiting.

Unpredictable adverse reactions to acupuncture include:

- Allergic reactions to the material in the needle
- Depression
- Insomnia
- Convulsions
- Hypotension
- Increased pain
- Menstrual disturbance

The Workforce Survey undertaken during research for *Towards a Safer Choice* found that the most common adverse events reported were fainting during treatment, increased pain and nausea/vomiting. Serious adverse events included pneumothorax and convulsions.

A study of adverse event rates for primarily acupuncture practitioners found that adverse event rates were higher for practitioners with 0-12 months of CAM education than for those with 37-60 months education.³⁰ This indicates that education standards are a potential contributing factor for adverse events.

Risks related directly to the consumption of Chinese herbal medicines

Chinese herbal medicines are most often used in combinations that follow traditional prescribing guidelines where one ingredient is included to 'counteract' the toxicity of another. Preparation methods may alter the toxicity of ingredients.

Intrinsic adverse reactions are directly related to the active medicine itself. Similar to western pharmaceutical medicines, Chinese herbal medicines have predictable and idiosyncratic (unpredictable) reactions. Predictable reactions are extensions of the pharmacological effects of the medicines, are generally dose-dependent and can be less severe than unpredictable, idiosyncratic reactions.

Some ingredients used in Chinese herbal medicine have direct toxicity and predictable adverse effects, and are considered sufficiently toxic to be included under the Standard for the Uniform Scheduling of Drugs and Poisons³¹. Predictable adverse effects include:

- Aconite poisoning
- Anticholinergic side effects
- Mineralocorticoid effects
- Ginseng abuse syndrome
- Significant allergic reaction
- Overdose
- Interactions with western pharmaceuticals

Idiosyncratic, unpredictable adverse reactions to Chinese herbal medicines are reactions that are not predicted by pharmacology, occur infrequently, are not related to dose and can cause significant morbidity or death.

Extrinsic risks of Chinese herbal medicine arise from the failure of good handling and manufacture procedures, such as incorrect identification of materials, contamination, substitution of ingredients, incorrect preparation, inappropriate labelling, adulteration with western pharmaceutical products and lack of standardisation.

The most common adverse events associated with Chinese herbal medicines, reported during research for *Towards A Safer Choice*, were severe gastrointestinal symptoms, fainting, dizziness and significant skin reactions. Serious adverse events included central nervous system effects, hepatotoxicity, renal toxicity and death.

Furthermore, this research asked practitioners whether they prescribed any of a range of specified Chinese herbs either in raw form or proprietary Chinese medicines, including a number of scheduled or restricted substances. Alarming, a number of restricted or prohibited substances were used relatively widely by Chinese herbalists, indicating either a lack of awareness by practitioners of the restrictions on these substances or a lack of willingness to abide by them.

While complementary and alternative medicine products are regulated by the TGA, the practitioners prescribing and dispensing many of these products are not regulated. Regulation of Chinese medicine practitioners will reduce the likelihood of adverse incidents by ensuring practitioners have a minimum level of education and training, and by enforcing appropriate practice standards. Furthermore, effective education of both practitioners and the public will help minimise risks and maximise safety.³⁰

With growing public use of Chinese medicine and the profession not effectively self-regulating, statutory regulation is seen as the key means to ensuring adequate mechanisms are in place for consumers to access Chinese medicine safely.⁸

COMPLAINTS RESOLUTION MECHANISMS AND DISCIPLINARY MEASURES

Currently in WA there are limited complaint handling and resolution mechanisms available for people who believe they have a grievance with a practitioner of Chinese medicine.

Consumers may lodge a complaint with the Office of Health Review (OHR).³² OHR is a State Government body that provides a readily accessible means of having complaints about health and disability services reviewed, conciliated and dealt with impartially and in confidence. OHR will work towards the resolution of complaints and will recommend remedies where appropriate. OHR may also refer complaints to a statutory registration board.

Statutory regulation would enable disciplining of practitioners, with suspension or removal of a practitioner from the register as a possible action that can be taken by the State Administrative Tribunal. A registration board will be able to make an allegation about a complaint or a matter to the State Administrative Tribunal. See 2C State Administrative Tribunal regarding the functions of the Tribunal on dealing with a disciplinary matter.



2 €

The key reasons for regulating practitioners of Chinese medicine have been given above.

What is your response to the reasons given in this section for regulating Chinese medicine practitioners? Do you have other comments to make regarding these reasons? Are there any other reasons for supporting statutory regulation?



OPTIONS FOR STATUTORY REGULATION

Currently, Chinese medicine practitioners are not regulated in Western Australia. They are free to practice and advertise their services in the same way as any of the unregulated health professions. Membership of a professional association is the main indicator that a practitioner is suitably qualified and subject to professional standards measures, however membership is voluntary and not always dependent on qualifications.

The Victorian report *Towards A Safer Choice* based its recommendations on the premise that any regulatory model is the minimum necessary to protect the public.⁸ These recommendations included:

- both acupuncturists and traditional Chinese herbalists be registered under one registration board, recognising their shared philosophical base in Chinese medicine;
- the register records whether the practitioner is qualified to practice Chinese medicine as an acupuncturist, a Chinese herbal medicine practitioner, or both;
- the model adopted should be sufficiently flexible to allow extension to other related occupational groups, if appropriate in the future;
- the regulatory statute should provide for the protection of the public by ensuring practitioners have adequate qualifications for safe and competent practice;
- the regulatory statute should provide for accreditation of Chinese medicine education courses that meet a satisfactory standard; and
- the regulatory statute should provide effective disciplinary powers.

There are a number of models of regulation relevant for regulation of Chinese medicine practitioners in Western Australia. The cost and potential size of the register (number of practitioners) is an important factor for consideration when assessing suitable models.

ESTABLISHMENT OF A REGULATORY AUTHORITY FOR CHINESE MEDICINE IN WA

This model would involve establishing a dedicated regulatory body for the registration of Chinese medicine practitioners in Western Australia. It is likely that the regulatory body would be based on the CMRB of Victoria, which is made up of three divisions for each of the three registered modalities, and is administered by one board.

This model is potentially costly with expenses occurring from establishment of the regulatory body, including the board, staff, development of the register, development of guidelines and the contingency fund and other associated expenses.

The regulatory body is intended to be self-sufficient, with all costs of the regulatory body funded by registration fees. The potentially low number of practitioners seeking to be registered in Western Australia would result in registration fees being set quite high in order to recover costs. This in turn would raise the cost of Chinese medicine to the public, as practitioners raise prices to reflect their higher operating costs.

JOINT ARRANGEMENT WITH ANOTHER REGISTRATION BOARD

A joint arrangement with other States' registration boards is a possible model for consideration. The relatively small number of applicants for registration in Western Australia means that this model would enable fees to be kept to a reasonable level. Additionally, a joint arrangement would reduce unnecessary duplication of policies, guidelines and research and would align with aims for nationally consistent registration arrangements

for Chinese medicine practitioners. A number of administrative and legal considerations would need to be further considered before this model could be adopted.

For example, there are constitutional barriers to jointly regulating with another State's board because statutory registration of health occupations is a function of State governments. However appropriate arrangements could be made to facilitate a joint arrangement. For example, each State would have their own board and regulation body, but the board would be comprised of the same people across the states. WA would nominate representatives to the board in the other State(s), to be appointed by the Minister for Health in that other State(s), and the other State(s) would nominate representatives to the WA board to be appointed by the WA Minister for Health. Legislation between States would be

comparable to reduce complexity and facilitate effective carrying out of the powers and functions of the board.

At present, Victoria is the only other State with an established registration board for Chinese medicine practitioners. If a joint arrangement is the preferred model for regulation of WA Chinese medicine practitioners, then a joint arrangement with Victoria would come under consideration. This would also be subject to Victoria's approval. Other States may also be interested in such an arrangement in the future.

As it is understood that proposing a joint arrangement may be controversial, further consultation will be undertaken with key stakeholders, on receipt of submissions, before a preferred option for statutory regulation can be recommended.



2F

Two options for a registration board have been described in this section.

Which option is best suited to registering Chinese medicine practitioners in Western Australia? Please provide reasons for your answer.



LEVELS OF PROTECTION PROVIDED BY REGULATION

PROTECTION OF TITLE

Protection of title means that only practitioners who are registered with the statutory regulatory body can legally use a particular title.

The aim of protection of title is to protect the public by ensuring that consumers are able to identify qualified, competent practitioners. Protection of title restricts the use of specified titles to practitioners who have been assessed as competent to deliver the services associated with that title.

A common mechanism for protection of title is to provide that it would be an offence for an unregistered person to falsely represent him or herself by using a protected title or lead the public to believe they are registered. Protection of title would prevent unqualified practitioners from advertising Chinese medicine services to the public. The public's use of registered and therefore suitably qualified practitioners may reduce the costs to the community from injuries incurred through inappropriate or unsafe practices.¹

A competitive advantage is given to registered practitioners over other related health practitioners by preventing unregistered people from using the title. Unregistered persons and other registered health care professionals would not be prevented from using the techniques of the profession, and competing for business in the marketplace. They are just prevented from using the restricted titles.

Protection of title is the model adopted by a number of health professional registration Acts in WA including the *Nurses Act 1992*, *Occupational Therapists Registration Act 1980* and *Psychologists Registration Act 1976*.

The Victorian CMR Act incorporates protection of title for registering practitioners.

PROTECTION OF PRACTICE

Protection of practice places restrictions on the actual techniques and procedures that may be performed, and includes protection of title. In addition to enabling consumers to identify competent professionals, protection of practice prohibits the practice of activities that have been identified as carrying significant risks if performed by unqualified persons. It is not necessary that all techniques or procedures used by the profession would be restricted.

The public is provided with a maximum level of protection by prohibiting unregistered and unqualified persons from practising certain procedures. Consumers would be sure that potentially harmful practices are only undertaken by adequately trained practitioners. Untrained practitioners would be prevented from entering the profession.

Despite the apparent benefits, protection of practice is the most anti-competitive form of regulation. It bestows a competitive advantage for registered practitioners who are deemed to have the training/education to safely undertake restricted practices. Any restriction of practice would need to be considered in the context of the National Competition Policy.

The enforcement of the restrictions may also be difficult for disciplinary purposes. For example it may be difficult to prove that a person has practiced a restricted activity. The restriction of practice has limited effect where registered practitioners practice beyond their level of competence.

It would be difficult to draft workable definitions for prescribed practices that only registered practitioners may provide, without affecting the legitimate scope of other professions. This type of protection may hinder innovation and improvement of techniques within the registered group and by other professional groups with closely related areas of practice.¹



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Do you support protection of title? Why?



WHO WILL BE REGISTERED?

The modalities being considered for registration in Western Australia are:

- Chinese herbal medicine practitioner
- Acupuncturist
- Chinese herbal dispenser

This is consistent with regulation of Chinese medicine practitioners in Victoria. The CMR Act is based on the position that, at present, only these three modalities of Chinese medicine have the potential to be so hazardous to public health and safety as to require statutory regulation.

Other modes of complementary medicine treatment, such as dietary therapy, physical/exercise therapy, and massage therapy are not considered to pose such a risk to the public that they should be subject to registration requirements. Other modalities remain regulated under general law (including consumer protection and public health legislation) and practitioners practising in these areas may choose to self-regulate.¹



2H.1

There are three modalities being considered for regulation in Western Australia.

Do you support the regulation of Chinese herbal medicine practitioners, acupuncturists and Chinese herbal dispensers? Please explain your answer.

OTHER REGISTERED HEALTH PRACTITIONERS IN WA

Section 1E, page 7, provides information on how other registered health practitioners in Victoria are being authorised by their own registration boards to use protected titles. Chiropractors, dentists, medical practitioners, nurses, optometrists, osteopaths and physiotherapists may apply to be registered as acupuncturists, and pharmacists are able to register to dispense Chinese herbs.

Any standards to be determined by other registration boards in relation to qualifications and training required of practitioners for acupuncture and Chinese herbal dispensing, would need to be examined. An option would be to require that the standards of qualifications and training required by other registration boards are similar to the level required by the Chinese medicine registration board.



2H.2

Would a system similar to Victoria be suitable for Western Australian health practitioners?

What measures could be implemented to ensure that other registered health practitioners have sufficient level of education and training to ensure public safety?

Please provide the reasons for your answer.



HOW WILL REGISTRATION OCCUR?

The registration Act will authorise the regulatory board to grant registration to a practitioner. This authority will enable the regulatory board to attach conditions, limitations and restrictions and to refuse registration on the grounds set out in the registration Act.

WHAT REGISTRATION CRITERIA WOULD BE APPLIED?

It is proposed that registration requirements for acupuncturists, Chinese herbal medicine practitioners and Chinese herbal dispensers would be consistent with the registration requirements set out in the Western Australian health practitioner template legislation. The applicant must:

- be a fit and proper person;
- have adequate knowledge of the English language, written and oral;
- possess sufficient physical and mental capacity, and skill to practice;
- have the knowledge and practical experience in the particular profession being registered;
- be qualified; and
- have made adequate arrangements for professional indemnity insurance.

There is considerable overlap between these requirements and the key assessment areas for all applicants for general registration to the CMRB of Victoria which are:

- adequacy of qualification (minimum requirements);
- recency of practice;
- competence;
- good character;
- fitness to practice;
- having the required professional indemnity insurance;

- first aid; and
- effective communication arrangements and English language proficiency.

Some of these assessment areas are considered in more detail below.

Qualifications

Victoria

A person is qualified under section 5 of the CMR Act for general registration with the CMRB of Victoria if they;

- a) have successfully completed an approved course of study; or
- b) have a qualification that is substantially equivalent to an approved course of study; or
- c) have passed an examination set by the Board: or
- d) hold a qualification that is recognised in another State or Territory.

Currently the courses approved by the CMRB of Victoria are:

RMIT University, Division of Chinese Medicine

- Bachelor of Applied Science (Chinese Medicine) & Bachelor of Applied Science (Human Biology) *double bachelor undergraduate program*
- Master of Applied Science (Acupuncture)
- Master of Applied Science (Chinese Herbal Medicine)
- Bachelor of Health Science (Chinese Medicine)
- Bachelor of Applied Science (Human Biology-Chinese Medicine major) & Bachelor of Applied Science (Chinese Medicine) *double bachelor undergraduate program*
- Bachelor of Applied Science (Chinese Medicine)

Australian College of Natural Medicine

- Bachelor of Health Science (Acupuncture)
- Advanced Diploma of Acupuncture

Southern School of Natural Therapies

- Advanced Diploma of Traditional Chinese Medicine

Other courses are under consideration by the CMRB of Victoria. More information is available at the CMRB of Victoria website (<http://www.cmrb.vic.gov.au/registration/approvedcourseintro.html>).

The CMRB of Victoria registers Chinese medicine practitioners for specific registration where the applicant holds qualifications in Chinese medicine which do not qualify that applicant for general registration. Specific registration would enable an applicant to undertake further study or fill a teaching or research position in Chinese medicine at a tertiary institution as approved by the Board.

Western Australia

In Western Australia, there is currently no tertiary level (university) course for Chinese medicine. Independent organisations throughout the Perth metropolitan area offer a range of courses in Chinese medicine.

Practitioners who have completed courses and training that are not approved, would be required to demonstrate their knowledge and competence to practice, in order to register as a Chinese medicine practitioner in Western Australia. This could be achieved through the grandparenting arrangements established by the board (see section 2J *What grandparenting arrangements would be made?* page 29).

Recency of Practice

Recency of practice refers to the experience and competency of practitioners. Practitioners have the responsibility of ensuring they maintain their knowledge and skills. The CMR Act empowers the CMRB of Victoria to refuse renewal if the CMRB of Victoria believes the applicant has not had sufficient experience in the practice in the preceding 5 years.

Where the practitioner cannot demonstrate recency of practice, the CMRB of Victoria requires the practitioner to complete one clinical practice unit from within a CMRB-approved course with a minimum of 200 hours.

The WA health practitioner template legislation requires applicants to have practiced in the profession within the 5 years preceding the

application or have acquired sufficient knowledge and practical experience in the profession. This requirement does not apply to recently qualified applicants registering for their first time.

Professional Indemnity

It is proposed that all practitioners registered for Chinese medicine will be required to be covered by a level of professional indemnity insurance as approved by the Board, prior to commencing practice as a registered practitioner and maintained at all times during practice.

Good Character / Fit and Proper Person

People with convictions of crimes relating to dishonesty or violence, where there is concern that the offence is such that they are considered unfit to practice, should be excluded from registration. The intent for including the requirement of good character in the registration criteria is foremost to support the aim of the legislation in protecting the public, by ensuring people of disreputable nature are not able to gain credibility by registering.

Competency in the English Language

It is proposed that practitioners would be required to be competent in the English language to be allowed to register. Competency in the English language would ensure that Chinese medicine practitioners are able to read and comprehend conventional western medical prescriptions, are able to communicate with the growing number of Australian's using Chinese medicine, and are able to contact emergency services in the event of an adverse reaction to treatment by a patient.

The health practitioner template legislation contains a requirement for 'adequate knowledge of the English language both written and oral' (Section 22(2)(b)). Knowledge of English is also a criteria included in other WA registration legislation such as the *Nurses Act 1992* and the *Medical Act 1894*.

It is recognised that a large proportion of Chinese medicine practitioners have non-English speaking backgrounds (NESB). A 'competency in English' criteria could hinder the regulation of these otherwise competent practitioners. To accommodate such practitioners the following measures have been identified:⁵

- Special provision in 'grandparenting arrangements' to enable NESB practitioners to register based on age and years of safe practice;

- Development of guidelines for practitioners on how to ensure adequate communication between patient and practitioner where language barriers exist, particularly to ensure that patients are able to understand the instructions relating to their treatment and administration of Chinese medicine; and
- Development of standards so the practitioner ensures that the patient has access to a person with sufficient competence in the English language to respond to an emergency situation.

First Aid

The CMRB of Victoria requires registered practitioners to hold a current First Aid Certificate Level 2 or have another person present at the clinic that holds a current First Aid Certificate Level 2.

Chinese medicine does have the potential for complications, and practitioners are responsible for being aware of potentially dangerous situations and possible adverse effects arising from the provision of their services. It is essential that practitioners be able to administer first aid and refer patients to appropriate conventional medical treatment when necessary.



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All applications for registration will be assessed against the registration criteria by the board.

What registration criteria should be adopted? Please explain your answer.

WHAT GRANDPARENTING ARRANGEMENTS WOULD BE MADE?

Grandparenting involves the assessment and registration of existing practitioners where the qualifications of these existing practitioners do not meet the standards set by a newly established regulatory body, but who may otherwise be professionally competent. Grandparenting arrangements would need to be established to determine which practitioners are eligible for registration when regulation is introduced.

Various grandparenting arrangements recognise that practitioners currently in practice have a wide range of training, skills and experience. The arrangements aim to ensure a standard of practice that will provide the necessary protection for the public while aiming to be as inclusive as possible.

Factors taken into consideration under grandparenting schemes could include:⁶

- **Recognition of professional membership:**

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

- **Assessment of qualifications:** The regulatory board would establish criteria for the evaluation of qualifications. While it would not be expected that those applying for registration through the grandparenting arrangements would be at the same level as registrants who hold the prescribed qualifications, they would be expected to meet minimum qualifications for safe practice at a basic level. They 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.
- **Competency-based assessment:** Practitioners could be assessed against pre-determined competency-based professional standards and performance indicators. However, it might be more effective to link the assessment to a program of education and training.
- **Education and training:** To qualify for registration, registrants might be required to undertake a program of training, using a range of methods, and assessment.
- **A standard examination:** Those seeking registration whose qualifications are not accepted under other criteria might be required to sit a formal examination to assess their skills and knowledge in Chinese medicine.

Practitioners may be registered based on a combination of their qualifications and experience in Chinese medicine practice. This type of arrangement would enable practitioners with overseas qualifications and/or long standing practices to be registered. Applications would be considered on a case-by-case basis by the regulatory body.

The grandparenting arrangement would be available for a set time period from the commencement of the register. In Victoria the transition period was three years, while the New South Wales discussion paper¹ indicated that the proposed period for grandparenting provisions is typically one to two years. A person could not use the protected titles until they were registered, and risked disciplinary proceedings if they chose to use the protected titles when they were not registered.

Registration of practitioners who may be professionally competent, yet do not comply with the criteria for registration, could be granted registration for a limited period while they gain further qualifications to assist them meet the criteria.

Following a transitional period, the grandparenting provisions would cease to exist and practitioners wishing to register after that time would be required to apply for registration in the same manner as other applicants.

VICTORIA'S GRANDPARENTING POLICY

Victoria developed a Grandparenting Policy following the establishment of the Chinese Medicine Registration Board (CMRB) of Victoria.³³ Following the commencement of the register, the CMRB of Victoria allowed the registration of practitioners under the grandparenting arrangements for a three-year transitional period from 1 January 2002 to 31 December 2004.

For a person to qualify under the grandparenting policy, the CMRB of Victoria had to be satisfied that the person:

1. was professionally competent; AND

2. had either:
- obtained a qualification or undergone training in Chinese herbal medicine, acupuncture or herbal dispensing that was considered by the CMRB of Victoria to be adequate; or
 - obtained a qualification or undergone training that was not, by itself considered to be adequate, but had also successfully undergone any further study, training or supervised practice required by the CMRB of Victoria; or
 - carried on the practice of Chinese herbal medicine, acupuncture or herbal dispensing for a total of five years out of the last ten years prior to the Chinese Medicine Registration Act (2002) coming into effect; AND
3. if required, had successfully completed an examination set by the CMRB of Victoria.

Professional competence was determined by, for example, a minimum of ten years professional practice or five years professional practice and Australian or international qualifications meeting CMRB of Victoria requirements, or recent graduation from an accredited course in Australia.

The CMRB of Victoria also took into consideration other relevant matters such as the grounds for refusing registration as set out in the Victorian *Chinese Medicine Registration Act 2000*. These mostly referred to the applicant's character, their professional competence, physical and mental capacity to practice and whether they had been guilty of an offence.

While the Board had the authority to refuse registration where the applicant was not sufficiently competent in English, under grandparenting arrangements, the Board was unlikely to refuse registration to existing practitioners, on the sole basis of their lack of competence in English.



2J

Grandparenting arrangements provide for the registration of existing competent practitioners that do not have the formal qualifications for registration.

What factors or combination of factors for grandparenting arrangements for Chinese medicine practitioners in Western Australia would be fair and equitable while ensuring the safety of the public?

OTHER
RELEVANT
LEGISLATION

- *Trade Practices Act 1974 (Cth), Fair Trading Act 1987 (WA)*³⁴
Provides for consumer protection laws that prohibit health practitioners from engaging in false and misleading conduct.
- *Health Services (Conciliation and Review) Act 1995 (WA)*
Establishes the Office of Health Review. The Office is empowered to investigate complaints about a provider of a health service.
- *Therapeutic Goods Act 1989 (Cth)*
Sets out the legal requirements for the import, export, manufacture and supply of medicines in Australia, and their quality, safety, efficacy and timely availability. This Act also covers requirements for listing or registering goods on the Australian Register of Therapeutic Goods, along with advertising, packaging and labelling. Furthermore, it provides a substantially uniform national system of controls over therapeutic goods, facilitating trade between States and Territories and benefiting both consumers and industry.²
- *Health (Skin Penetration Procedure) Regulations 1998 (WA)*
Provides that no person (with the exception of medical practitioners, dentists, podiatrists and nurses) may carry out any procedures that penetrate the skin unless certain requirements are met. Currently, owners of establishments where acupuncture and other skin penetration procedures are carried out must notify the local government of the name and address of the establishment.
- *Mutual Recognition Act 1992 (Cth), Mutual Recognition (WA) Act 2001*
Under the provisions of the Mutual Recognition Act 1992 health practitioners registered in one State or Territory are automatically entitled to registration in any other State that registers that occupation. Conditions may exist for automatic registration, such as lodgement of a statutory declaration. The mutual recognition scheme overrides the provisions of health practitioner legislation dealing with reciprocal recognition of health registration bodies and health practitioners.
- *Poisons Act 1964 (WA)*
Sets out the controls for the regulation of drugs, medicines and other controlled substances in Western Australia. This Act controls the manufacture, packaging, labelling and storage of poisons. The prescription of certain types of drugs for diagnostic or therapeutic use in humans is limited to registered medical practitioners, dentists, veterinarians and pharmaceutical chemists (dispensing only).
- *State Administrative Tribunal Act 2004 (WA)*
Creates the authority and the framework for the resolution of a wide range of disputes and appeals and will work towards achieving resolution of questions, complaints or disputes and make or review decisions within its area of authority. The Tribunal has the authority to review licensing decisions for a range of areas and a wide range of disciplinary functions over professions, occupations and businesses. Furthermore, the Tribunal will enable the separation of the licensing and registration functions carried out by occupational boards from the disciplinary function.
- **Taxation Legislation**
Following the introduction of the national Goods & Services Tax, services provided by acupuncturists, naturopaths and herbalists were GST-free for three years from 1 July 2000. At 1 July 2003, only practitioners who were 'recognised professionals' were entitled to provide GST-free services. Status of 'recognised professional' was seen as being established through some kind of national or state regulatory system either statutory imposed or self-regulation through national professional associations.



ANNEX 2 YOUR VIEWS

The following is a summary of the issues about which we are seeking your views. Further discussion is provided in the text of the discussion paper.

2A What do you consider are/should be important features for statutory regulation of Chinese medicine practitioners in Western Australia?

2E What is your response to the reasons given in this section for regulating Chinese medicine practitioners?

Do you have other comments to make regarding these reasons?

Are there any other reasons for supporting statutory regulation?

2F Which option is best suited to registering Chinese medicine practitioners in Western Australia?

Please provide reasons for your answer.

2G Do you support protection of title? Why?

2H- 1 Do you support the regulation of Chinese herbal medicine practitioners, acupuncturists and Chinese herbal dispensers?

Please explain your answer.

2H- 2 Would a system similar to Victoria be suitable for Western Australian health practitioners?

What measures could be implemented to ensure that other registered health practitioners have sufficient level of education and training to ensure public safety?

Please provide the reasons for your answer.

2I What registration criteria should be adopted? Please explain your answer.

2J What factors or combination of factors for grandparenting arrangements for Chinese medicine practitioners in Western Australia would be fair and equitable while ensuring the safety of the public?



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