Regulation of Complementary Health Practitioners – Discussion Paper

September 2002

NSW HEALTH
Working as a Team

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Foreword

In recent years it has been observed that complementary health usage has been increasing. It is estimated that close to 60% of Australians access some form of complementary health.

For the purposes of this paper the term 'complementary health' encompasses a wide range of disciplines of alternative practises including herbal, homoeopathic, essential oils, nutritional and some health food supplements.

Reasons for the growing popularity of complementary health in Australia include:

- the public's growing dissatisfaction with conventional medicine
- preference for 'natural alternatives'
- a desire for more control over health care
- the lack of success of conventional western medicine in dealing with some individuals and conditions.

The NSW Department of Health is conscious of the need to ensure safety in the practice of traditional Chinese medicine and complementary health practises generally. The Department recognises the need for minimum standards for the conduct and safety of complementary health that address issues such as risks to public health and safety, and includes an effective complaint handling mechanism.

The main complementary health practises currently offered in Australia are traditional Chinese medicine (includes acupuncture), naturopathy, western herbal medicine, and various forms of massage.

This document has been developed by the NSW Department of Health to canvas opinion regarding the need to regulate those parts of the complementary health sector that pose actual risk to the public.

1 Introduction

1.1 Background

The Australian Health Minister's Conference agreed in July 1998 that there is a need to develop a set of minimum standards for the conduct and safety of complimentary health. The Victorian Department of Health and Human Services conducted a review of the practise of traditional Chinese medicine on behalf of all states and territories and was directed to develop model legislation.

The NSW Department of Health has, in the past, released a number of issues papers that have included the regulation of particular professions. This discussion paper is consistent with these previous publications.

1.2 Aim

The aim of this discussion paper is to seek comments from relevant opinion leaders, organisations and members of the public regarding the need to regulate the complementary health sector in NSW.

This discussion paper seeks comments not only on whether regulation is required but also includes suggestions on various models that may be used should regulation be supported.

Submissions should, as a minimum, address the issues as highlighted in the issues boxes throughout the document.

1.3 Process

The consultation phase for this discussion paper is three months. Comments are due by **15th January 2003** and should be forwarded to:

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This consultation process will result in the development of a departmental position paper regarding the regulation of complementary health practitioners in NSW.

The practise of complementary health 2

2.1 **Definition**

'Complementary health' refers to a heterogeneous collection of therapeutic substances and techniques based on theory and explanatory mechanisms that are not consistent with the western clinical model of medicine[1]. Examples of complementary medical practises include herbal remedies, and such ancient skills and traditional techniques as traditional Chinese medicine[2].

The main complementary health practices currently offered in Australia are traditional Chinese medicine (includes acupuncture), naturopathy, western herbal medicine and various forms of massage (see section 2.2).

Examples of the range of practices classified as 'complementary' are provided in Table 1 below.

The use of a single classification to refer to such disparate practices, diagnostic tools and modalities is problematic. At the very least, there seems an obvious distinction between such complementary health 'disciplines' as traditional Chinese medicine, naturopathy / herbalism and homoeopathy with established bodies of knowledge and incorporating a range of diagnostic and treatment techniques, and the individual techniques and modalities themselves (eg acupuncture and therapeutic massage).

Broad classification	Examples
Eastern systems of health	• Traditional Chinese medicine (includes Acupuncture, Chinese herbal medicine, Tui Na, Qi Gong) • Ayurvedic medicine
Western systems of complementary health	• Naturopathy • Homeopathic medicines

Table 1 Examples of 'complementary health' practices

2.2 Types of complementary health practised in Australia

2.2.1 Traditional Chinese medicine

Traditional Chinese medicine is diverse and is used to treat both acute and chronic illness. Modalities used in practice include Chinese herbal medicine (including plant, animal and mineral substances), acupuncture, Chinese massage, dietary and lifestyle advice, specific techniques such as moxibustion and cupping, breathing, movement, meditation, orthopaedic manipulations and surgery.

2.2.2 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 which states that the workings of the human body are controlled by a vial 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 thought to cause symptoms, however many conventional health care professionals who practice acupuncture have dispensed with such concepts, with acupuncture points thought to correspond to physiological and anatomical features.

Traditional acupuncturists may use various adjunctive therapies including:

a. Moxibustion

Moxibustion is a technique used in traditional Chinese medicine in which a stick or cone of burning mugwort (artemesia vulgaris) is placed over an inflamed or affected area on the body. The cone is placed on an acupuncture point and burned. The cone is removed before burning the skin. The purpose is to stimulate and strengthen the blood and the life energy, or qi, of the body.

b. Cupping

Cupping is a technique used in traditional Chinese medicine for certain health conditions. Glass or bamboo cups are placed on the skin with suction, which is believed to influence the flow of energy and blood in the body.

c. Herbal medicine

Chinese herbalism is the most prevalent of the ancient herbal traditions. Chinese herbs are ascribed qualities such as cooling (yin) or stimulating (yang) and used, according to these qualities in the patient.

Herbalists generally use unpurified plant extracts containing different constituents. Often several different herbs are used together. Diagnostic principles are different from conventional practitioners.

Chinese herbs can be toxic as they contain active principles. Herbal extracts contain plant material with pharmacologically active constituents. The active principle(s) of the extract, which is in many cases unknown, may exert its effects on the molecular level and may have, for instance, enzyme-inhibiting effects.

When used in conjunction with western medicine it is important to be aware of their interactions, including interactions with western prescription and non-prescription pharmaceuticals. It is also important that practitioners have an understanding of the herbs' indications and contraindications

2.2.3 Naturopathy

Naturopathy includes the use of homoeopathic remedies, herbal medicine, massage, dietary therapy, and western herbal medicine to help a patient obtain a healthy state. By strengthening and enhancing the patient's immune system, naturopaths aim to help the body to heal itself, believing synthetic pharmaceutical agents contradict the principle of 'do no harm' and can inhibit the healing process.

2.2.4 Homoeopathy

Homeopathy is a system of treating patients using very low dose preparations according to the principle 'like should be cured by like', that is, a therapeutic method using preparations of substances whose effects when administered to healthy subjects correspond to the manifestations of the disorder (symptoms, clinical signs and pathological states) in the unwell patient.

Homoeopaths believe that minute doses of a substance can stimulate the body to fight back against disease (that is 'like cures like'). The theory is that if an overdose of a substance causes a particular set of symptoms, a greatly watered-down dose of the same substance will strengthen the body's immune system sufficiently for the body to heal itself. There are around 2,000 homoeopathic remedies with recorded therapeutic effects. These remedies can be prescribed in a number of forms, but tablets and liquid preparations are most common.

2.2.5 Western herbal medicine

Western herbal medicine is a form of botanical medicine, using herbs that have been studied mostly in Europe or North America. These herbs are not necessarily found in the 'west', but may come from other countries as well.

2.2.6 Ayurvedic medicine

Ayuredic medicine is a traditional Indian style of medicine, although incorporating lifestyle advice and physical therapies, is principally practised in Australia as a form of herbal medicine. Some similarities can be seen between this Indian form of therapy and traditional Chinese methods in the way diagnosis is made by questioning the patient as well as examination of the pulse and tongue.

Ayurvedic medicine is concerned with physical, mental, and emotional aspects of well-being, and with our interaction with our environment. Prescriptions consist of herbal and mineral mixtures.

2.2.7 Massage therapy

Massage therapy is the manipulation of the soft tissue of whole body areas to bring about generalised improvement in health, such as relaxation, improved sleep, or specific physical benefits such as relief of muscular pain.

2.2.8 Shiatsu

Shiatsu is a form of massage therapy. Slow, downwards applications of pressure are generally used by shiatsu practitioners to correct the circulation of energy, or ki, around the body. Shiatsu often stands out from other forms of massage through its use of not only thumbs and hands to apply pressure, but also elbows, knees, and even feet. Very gentle stretching is often involved, especially in zen shiatsu which is almost a cooperative routine between patient and therapist. As with acupressure, shiatsu is performed on a fully clothed patient, with all skin to skin contact kept to an absolute minimum. A treatment is often preceded by a hara (abdominal) diagnosis to allow the practitioner to concentrate on the most important areas for the patient's health.

2.2.9 Reiki

An Eastern massage technique is reiki. This therapy involves lightly placing the hands on the patient to direct healing energies. Many schools of philosophy exist within the reiki paradigm, from those which concentrate on the physical aspect of the therapy, to those with strong esoteric foundations. The five goals of a reiki treatment are the relaxation and removal of physical and emotional tension, the dispersion of stagnant or obstructed energy, detoxification, the endowment of healing energy, and the regulation of the natural vibrational frequency of the body.

2.2.10 Chelation therapy

Chelation therapy consists of slow-drip IV injections of EDTA (ethylenediamine tetraacetic acid), a synthetic amino acid, combined with aerobic exercise, special diet and no smoking. EDTA treatment has been around since the 1940's, when it was developed to treat lead poisoning. The word 'chelate' is derived from the Greek word for claw and apparently refers to the alleged removal of plaque and calcium deposits from arteries and veins by EDTA. Advocates claim that there is evidence to support the claim that chelation can prevent and cure heart disease, stroke, senility, diabetic gangrene and many other vascular diseases.

2.2.11 Chiropractic

Chiropractic therapy is primarily concerned with relationship between the spine, nervous system, and muscular system. The chiropractic technique of manipulating the vertebrae of the spine back into optimum position is well-known. Less well-known is the practice of manipulating muscular tissue and joints elsewhere in the body, a mode of treatment used alongside massage and spinal manipulations to correct functional problems and eliminate pain (see also section 3.4).

2.2.12 Osteopathy

A consultation with an osteopath typically involves a detailed musculo-skeletal examination, as well as some discussion of lifestyle factors. The physical examination will include an analysis of posture, spinal alignment, and soft tissue tone. An osteopath may require you to obtain x-ray or similar diagnostic evaluations as well to assist with making a diagnosis. Treatment may include manipulations of joints and/or massage of muscular tissue.

Osteopathy is a commonly sought for therapy for the alleviation of muscular and skeletal complaints, such as headache, neck pain, back ache, joint pain, carpal tunnel syndrome and other repetitive strain injuries, and instances of compression of nervous structures as in sciatica (see also section 3.4).

2.3 **Who provides complementary health services?**

The following groups provide complementary health services:

- *Registered health professionals working within the western clinical model of medicine* who have a formal qualification and a registration mechanism, for example medical practitioners, pharmacists and physiotherapists.
- *Unregistered health professionals working within the western clinical model of medicine* who have a formal qualification but no formal registration mechanism; for example occupational therapists, dieticians and psychotherapists.
- *Practitioners working outside the western clinical model of medicine* referred to as 'alternative' or 'complementary' health practitioners.

Context

3

3.1 World Health Organisation

The World Health Organisation (WHO) has recently released the first *WHO Traditional Medicine Strategy 2002-2005*. This strategy acknowledges the regional diversity in the use and role of traditional, complementary and alternative medicine. WHO developed this strategy as a way of addressing the issues of policy, safety, efficacy, quality, availability, preservation and further development in relation to the use of these three categories of medicine.

WHO has also published *Guidelines for the Appropriate Use of Herbal Medicines 1998*. Herbal medicines are not necessarily always safe just because they are natural. Some herbal medicines have given rise to serious adverse reactions. Some herbal medicines also contain chemicals that may produce long-term effects such as carcinogenicity and hepatotoxicity.

3.2 International context

In the last two years the international arena has seen the issue of regulation of complementary health practitioners come to the fore.

In 2000 the United Kingdom Parliament, House of Lords Select Committee on Science and Technology, recommended that in the interests of public safety the complementary health sector should be properly regulated and more research into its effectiveness conducted. Also recommended were standardised training courses and accreditation by professional bodies.

In 2001 the Irish Minister of Health announced plans to regulate complementary therapies in Ireland. A robust system of registration and regulation is to be put in place to afford protection to the public when accessing services from the complementary sector.

In 2002 the *United States of America White House Commission on Complementary and Alternative Medicine Policy Final Report* recommends that public accountability for complementary and alternative health practitioners is required. The report urges states to consider whether a regulatory infrastructure for complementary and alternative health practitioners is required in order to promote quality of care and patient safety.

3.3 National context

To date, the majority of work has centred on traditional Chinese medicine. In 1995 the governments of New South Wales, Victoria and Queensland provided funding for a national research project on the practise of traditional Chinese medicine. This project was a response to the proliferation of traditional Chinese medicine practitioners, training courses, professional associations and increase in the use of Chinese herbal medicines.

In November 1996, the project report was issued titled *Towards a Safer Choice: The Practise of Traditional Chinese Medicine in Australia*[3]. The preparation of the report was through close collaboration between the Victorian Department of Human Services, the Southern Cross University and the University of Western Sydney.

In 1998 the Australian Health Ministers' Conference (AHMC) noted that the Victorian Government would develop legislation to provide for statutory registration of traditional Chinese medicine practitioners for the consideration of Ministers. Victoria was also to convene a Working Group with representation from the Commonwealth, states and territories. This group was required to consult with stakeholders and make recommendations to AHMC for controls over prescribing and dispensing of traditional Chinese medicines containing herbs and poisons which are restricted under drug and poisons legislation.

The AHMC also noted that there was a need to develop a set of minimum standards for the conduct safety of alternative health practitioners and recommended that officials should compile a paper for further consideration. The NSW Department of Health was nominated to consult with the Commonwealth, states and territories towards the development of this paper, proposing a national approach to establishing minimum standards for the conduct and safety of complementary health.

Pursuant to the 1998 AHMC requirement the Victorian Government drafted a Chinese Medicine Registration Bill. The Victorian Government proceeded to introduce the Bill in the Autumn 1999 parliamentary session. In May 2000, the *Chinese Medicine Registration Act* was passed by the Victorian Parliament. The *Act* establishes a statutory incorporated Chinese Medicine Registration Board, the powers and functions of which include:

- to regulate standards of practise of the profession in the public interest
- to register suitably qualified persons and/or persons meeting approved competency standards so that they may practise in that jurisdiction
- to accredit courses which provide qualifications for registration purposes.

In April 1999 the NSW Department of Health produced a discussion paper to the Australian Health Minister's Advisory Council (AHMAC) entitled *Development of a National Framework for Establishing Minimum Standards for the Conduct and Safety of Alternative / Complementary Medicine.*

AHMAC considered the paper which recommended the establishment of a working party to consider options for the development of a national framework, consistent with national mechanisms affecting regulation of unregulated health care practitioners, including National Competition Policy and AHMAC guidelines for regulation of unregulated health occupations. This document was supported out of session by AHMAC.

3.3.1 Goods and Services Tax

Under the Commonwealth tax reform package, services provided by acupuncturists, naturopaths and herbalists are GST-free for three years since 1 July 2000. However, from 1 July 2003 only practitioners who are 'recognised professionals' will be entitled to provide GST-free services. 'Recognised professional' is defined by section 195-1 of the *A New Tax System (Goods and Services Tax) Act 1999* as:

- **recognised professional:** a person is a recognised professional, in relation to the supply of a service of a kind specified in the table in subsection 38-10(1), if:

a. The service is supplied in a state or territory in which the person has a permission or approval, or is registered, under a state law or a territory law prohibiting the supply of services of that kind without such permission, approval or registration; or

b. The service is supplied in a state or territory in which there is no state law or territory law requiring such permission, approval or registration, and the person is a member of a professional association that has uniform national registration requirements relating to the supply of services of that kind; or

c. In the case of services covered by item 3 in the table – the service is supplied by an accredited service provider within the meaning of section 4 of the *Hearing Services Administration Act 1997.*

The services specified in the table to section 38-10 are:

- Aboriginal or Torres Strait Islander health
- acupuncture
- audiology, audiometry
- chiropody
- chiropractic
- dental
- dietary
- herbal medicine (including traditional Chinese herbal medicine)
- naturopathy
- nursing
- occupational therapy
- optometry
- osteopathy
- paramedical
- pharmacy
- psychology
- physiotherapy
- podiatry
- speech pathology
- speech therapy
- social work.

3.3.2 Complementary medicines reform package

In 1999 the Commonwealth introduced the Complementary Medicines Reform Package. The reform package resulted in:

a. Establishment of the Office of Complementary Medicine, located in the Therapeutic Goods Administration, to focus on the regulation of complementary healthcare products.

b. Enhancement of the Complementary Medicines Evaluation Committee, also located in the Therapeutic Goods Administration.

c. Establishment of an industry/government Complementary Healthcare Consultative Forum comprised of members from the practitioner, research, academic, industry, consumer and regulatory sectors of the complementary healthcare arena. The aim of the forum is to promote government and industry dialogue regarding complementary healthcare policy, trade, research and related issues.

In 2000, the Commonwealth Department of Health and Aged Care (now the Department of Health and Ageing) released the National Medicines Policy. This policy aims to meet medication and related service needs, so that optimal health outcomes and economic objectives are achieved. The policy refers to the term 'medicine' as including prescription and non-prescription medicines, including complementary healthcare products[4].

3.3.3 National professional registration systems for acupuncture, naturopathy and herbal medicine practitioners

The Commonwealth Government has provided $500,000 to assist five professional associations to form national professional registration systems for acupuncture, naturopathy and herbal medicine practitioners. This registration scheme is linked to the introduction of the GST.

The Commonwealth Government stated that this initiative was to assist practitioners meet the requirements of the GST legislation by establishing national professional registration systems for qualified practitioners. However, the government also stated that this initiative was not anticipated to replace the role of state and territory governments in the regulation of health practitioners.

In April 2002, the organisations to be funded from this initiative were announced. Each organisation will receive a one-off grant of $100,000 towards the development of national uniform registration systems for suitably qualified practitioners in acupuncture, naturopathy and herbal medicine:

- National Herbalists Association of Australia
- Australian Traditional Medicine Society
- Australian Natural Therapists Association
- Federation of Natural and Traditional Therapists
- Australian Acupuncture and Chinese Medicine Association.

3.4 **NSW context**

The NSW Government understands that traditional Chinese medicine is, historically, a well-established therapy and is aware of increasing public use of traditional Chinese medicine and a growing acceptance of the practise among non-Chinese practitioners.

In recognition of the growing use of complimentary health, such as traditional Chinese medicine, the NSW Department of Health released an Information Bulletin in October 1999 to assist public hospitals in formulating local policy in the use of complementary medicines in public hospitals, *Complementary Medicines in Public Hospitals* – Information Bulletin 99/18, which may be found on the NSW HealthWeb site at: www.health.nsw.gov.au/fcsd/rmc/cib/information-bulletins/1999/ib99-18.pdf

The NSW Department of Health is conscious of the need to ensure safety in the practise of traditional Chinese medicine and complementary health practices generally. The Department recognises the need for minimum standards for the conduct and safety of complementary health that address issues such as risks to public health and safety, and includes an effective complaint handling mechanism.

Registration is required where there are clear competencies and judgements that effect the public good. In the public interest registration is set up to ensure that minimum standards are applied across a particular profession.

It should be noted that the literature consistently includes chiropractic and osteopathy in the nomenclature of 'complementary therapy'. In NSW both these professions have legislated registration through the *Chiropractors Act 2001* and the *Osteopaths Act 2001*.

Is there a need to regulate complementary health practitioners? 4

4.1 Overview

The practise of alternative or complementary health has widespread acceptance in Australia. The popularity of complementary health is attributed largely to the public's growing dissatisfaction with conventional medicine (including the sense of not being valued as people within the health system), consumer preference for 'natural alternatives', individuals' desire for more control over their health and the lack of success of conventional medicine in dealing with some individuals and some conditions[2].

Recent estimates suggest that each year almost half of the Australian population uses at least one form of complementary health, close to 20 per cent visit a complementary health practitioner, and over $900 million is spent on complementary medicinal/health substances and techniques[5]. It is expected that these rates will increase as more and more people come to view complementary health as an important contributor to personal health and well being[6].

The need for national structures and/or mechanisms that acknowledge the widespread use and increasing popularity of complementary health, and for health systems to take an interest in the development of strategies to ensure the safe use of these substances and techniques, has been recognised in Australia[2].

The *Victorian Chinese Medicine Registration Act 2000* considers that there are only three modalities of Chinese medicine that are considered to have the potential to be so hazardous to public health and safety as to require statutory regulation. These are acupuncture, Chinese herbal medicine and Chinese herbal dispensing. The practice of Chinese medicine does however include other modes of treatment that are not considered to be as hazardous: dietary therapy, physical/exercise therapy, and massage therapy. In Victoria these other modalities remain regulated under general law (including consumer protection and public health legislation) and unregistered practitioners practising in only those areas will remain self-regulated.

4.2 The impact of legislation on competition

In 1995 the Commonwealth and all state and territory governments signed the Competition Principles Agreement. The agreement states that 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***
- ***the objectives of the legislation can only be achieved by restricting competition[7].***

The goal of any restriction in competition by complementary health practitioners is to ensure that consumers are protected from the risk of harm.

There are a number of national mechanisms that relate to unregistered health professionals, namely:

- ***AHMAC*** *Criteria for Assessing the Need for Statutory Regulation of Unregulated Health Occupations (see Section 4.7)*
- ***Council of Australian Governments (COAG)*** *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies*
- ***Council of Australian Governments (COAG)*** *Competition Principles Agreement.*

These mechanisms require that a need for regulatory intervention be demonstrated prior to implementation of measures that *"would encourage or force businesses or individuals to pursue their interests in ways they would not otherwise have done"*[8].

COAG Principals and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard Setting Bodies describe the "best processes to follow" (p. 3) in the development of regulatory approaches. These processes include demonstration of the need for regulation and consideration of the costs and benefits of alternative regulatory approaches.

The *Principals and Guidelines* aim to ensure that the chosen approach is the least restrictive or minimum necessary when economic, environmental, health, and safety concerns are considered[8]. As endorsed by COAG, and consistent with the objectives of national competition policy (NCP):

> ***"Proposals for new regulation that have the potential to restrict competition should include evidence that the competitive effects of the regulation have been considered; that the benefits outweigh the likely costs; and that the restriction is no more restrictive than necessary in the public interest."***[8]

Compliance with NCP and COAG principles requires that the development of a NSW regulatory approach, which establishes minimum standards for the conduct and safety of complementary health practices, is informed by:

- analyses of the risks posed by the practices to public health and safety
- effectiveness of the proposed framework for reducing these risks
- costs and benefits to public health and safety of the proposed framework as opposed to alternative regulatory mechanisms.

4.3 AHMAC criteria for the regulation of unregulated health occupations

In 1995 AHMAC adopted six criteria that are to be applied when examining the case for 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?
6. Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?

4.4 The role of professional associations

Some professional associations have a role in the monitoring of standards among complementary health practitioners through codes of conduct that include aspects such as continuing professional education.

It should be noted however, that there are many complementary practitioner associations that vary in size and quality. Membership to such organisations is currently voluntary.

As there are many such associations it is usually dependent on the professional background of a practitioner as to which organisation the practitioner may join (if any), for example a general practitioner that practices acupuncture may join the Australian Medical Acupuncture College rather than the Australian Acupuncture & Chinese Medicine Association.

4.5 Demand for information about complementary health

The growth in public interest in various forms of complementary health has paralleled increased demands on state health departments for information and advice about complementary health. Since Victoria commenced its review of traditional Chinese medicine[3], requests for advice from departments of health on traditional Chinese medicine, naturopathy, homoeopathy, western herbal medicine, shiatsu, ayurvedic medicine, massage therapy, reike, chelation therapy, chiropractic, osteopathy and complementary health generally, have increased and are likely to continue to do so.

There is a need for state health departments to have access to and be able to provide consumers with information about the practice of complementary health and/or where accurate information may be sought. This includes information about the range and availability of complementary substances and techniques, the nature and extent of risks to public health and safety of certain practices (when the relevant evidence exists) and the training standards and qualifications of practitioner groups.

4.6 Potential risks to public health and safety

The absence of any competency standards, regulation and/or surveillance of the practice of complementary health may foster the perception that it poses minimal risk to the public[9]. Nevertheless, there are risks involved with various forms of complementary health. These risks fall into two broad categories.

a. Risks associated with specific practices and/or modalities

These include the use of herbal medicines, which may involve the ingestion of potentially toxic substances[10] and the practice of acupuncture. In 1989, the *National Health and Medical Research Council (NHMRC) Working Party Report on the Practice of Acupuncture* detailed risks associated with infection, and puncture of vital organs. Serious infection resulting from acupuncture may also affect the broader public through the spread of contagious disease[11].

b. Risks that are generic.

These may include:

- recommendation from practitioners that patients defer or withdraw from appropriate medical therapy
- failure to detect serious underlying disease and/or failure to refer on resulting in delay of diagnosis and appropriate treatment
- mental trauma
- unsubstantiated claims of therapeutic benefit
- sexual misconduct
- financial exploitation.

With the exception of traditional Chinese medicine and associated techniques, evidence supporting the significance of such risks to public health and safety is largely anecdotal. While the importance of anecdotal evidence should not be undermined[12] (conventional medicine also relies on anecdotes[13]), there is clearly a need for further identification and systematic evaluation of the public health risks posed by complementary health, as well as the mechanisms in place to deal with these.

These processes need not occur independently of attempts to establish minimum standards for the conduct and safety of complementary health, but should form an integral part of the process that seeks to determine these standards.

4.7 Absence of effective complaints handling and resolutions mechanisms

The various legislative instruments establishing statutory health professional registration authorities incorporate mechanisms for receiving and investigating complaints about registered practitioners. These mechanisms include disciplinary committees and tribunals to adjudicate formal complaints.

In NSW, a complaint to a health registration board constitutes a complaint to the NSW Health Care Complaints Commission (the Commission). Complaints may also be made directly to the Commission under the *Health Care Complaints Act 1993*. The Commission investigates and when appropriate, prosecutes complaints before disciplinary bodies. Such disciplinary action may lead to deregistration and the loss of the right to practise.

In contrast to the complaint mechanisms available for registered health professionals, there are currently no entirely satisfactory or effective measures to deal with complaints against unregistered health care practitioners.

When a complaint has been substantiated, the Commission cannot disclose the name of the practitioner and its findings, nor can it undertake disciplinary activity against the practitioner to prevent the behaviour, treatment or service, which was found to depart from an acceptable standard from recurring. Where the Commission makes adverse comment to the practitioner, there is no capacity to publicise the comments to members of the public who may seek to avail themselves of these services in future. The practitioner may also ignore these comments, including any substantive recommendations.

The NSW Joint Parliamentary Committee on the Health Care Complaints Commission published a report in 1999 that makes a number of recommendations to improve the complaint and disciplinary processes for unregistered practitioners. These recommendations include the development of a naming power similar to the one available to the NSW Department of Fair Trading and the establishment of a body with the power to issue court-enforceable orders to allow health consumers to obtain refunds of fees paid to practitioners. The ability to name a practitioner publicly or to issue orders for refunds would occur once a complaint had been substantiated against the practitioner.

The committee further recommended that consideration be given to the introduction of umbrella legislation to cover unregistered health practitioners, which would establish a generic form of registration, generic complaint and disciplinary mechanisms, a uniform code of conduct, entry criteria, and a Ministerial Advisory Board.

4.8 Difficulties confronting existing registration boards

The various health professional registration boards in NSW are responsible for registering relevant health practitioners. The boards also receive complaints about practitioners and in some cases investigate those complaints. In most cases, it is the Health Care Complaints Commission that investigates, and prosecutes complaints relating to allegations of unprofessional conduct.

Registration boards also receive and investigate complaints relating to unregistered practitioners using restricted professional titles (such as medical practitioner, surgeon and registered nurse) and providing treatment in areas where legislative restrictions apply eg spinal manipulation. In appropriate cases complaints about unregistered people are prosecuted as criminal offences in the courts.

Registration boards also investigate complaints against registered practitioners for unprofessional conduct, including cases where adverse events have resulted from unorthodox practices.

Issue 1

Does public health and safety require the statutory regulation of complementary health practitioners in NSW? If so which practitioners should be regulated?

Note

All submissions arguing in support of statutory regulation should clearly demonstrate the need for regulation by addressing each of the AHMAC Criteria in Section 4.3.

Convincing and substantiated arguments will need to be made and examples of instances where the current non-statutory regulatory framework has resulted in serious injury or death should be given, this should include detail of how a statutory regulatory framework would have prevented such an incident from occurring.

5 Models of regulation

If it is determined that the public interest requires statutory regulation of complementary health practitioners there are a number of potential models that can be used to effect that regulation. The different systems of regulation deliver different costs and benefits to the community and these are considered below.

5.1 No regulation (current system)

This is the current arrangement and allows any person to practise and advertise themselves as capable of practising in any of the unregulated complementary health fields. The only assurance consumers may have that practitioners are suitably qualified and subject to a disciplinary scheme is membership of a professional association, which not all practitioners, irrespective of their qualifications, may choose to hold.

Under this model the following legal framework applies:

- The Fair Trading and Trade Practices Acts prevent practitioners and associations (eg a professional association established under the *Associations Incorporation Act)* from engaging in false, misleading or deceptive conduct (eg claiming false or non-existent qualifications or membership of a professional association or making a false or misleading representation concerning the need for services). These Acts would also prevent individual practitioners and incorporated associations from engaging in anti-competitive conduct such as price fixing and exclusionary dealing.
- Employers have a role in maintaining professional standards, as would the bringing of civil claims in negligence or for breach of contract against unethical or incompetent practitioners.
- Practitioners who engage in grossly incompetent or unethical conduct that constitutes a criminal offence are subject to criminal prosecution.
- The Health Care Complaints Commission can investigate complaints and their findings may assist any of the legal remedies contemplated above.

The premise of the no regulation / self regulation model is that statutory intervention is unnecessary because either there are no significant risks to public health from complementary health, or any risks that do exist can be addressed through the mechanisms outlined above and other means. These other means include legislative approaches, such as the skin penetration regulations under the *Public Health Act*, and information campaigns that assist consumers to identify competent practitioners.

The advantages conferred by not imposing regulation are:

- there are no barriers to entry to the profession and no competitive advantage is conferred on any particular professional group providing services
- any person is able to use unregulated titles
- there are no regulatory costs.

The disadvantages are:

- there is no guarantee that professional associations give sufficient emphasis to consumer safety issues and not all practitioners choose to join a professional association
- the consumer protection legislation identified above does not address all disparities in market information
- court action by a consumer against an unethical or incompetent practitioner is difficult, costly and slow
- only that conduct which is criminal in nature is subject to prosecution and sanction.

5.2 Co-regulation

Co-regulation is the title given to those models in which the regulatory role is shared between government and industry (the profession). Such models can include compulsory membership of an accredited professional association or voluntary certification by a statutory authority. Professional associations would administer the disciplinary system to ensure the maintenance of professional standards. The government would accredit professional associations as regulators and monitor the associations to ensure they act in such a way as to protect members of the public. Co-regulation could be achieved by the government publishing a list of accredited associations and promoting the benefits of dealing with a practitioner who is a member of one of those associations.

5.2.1 Co-regulation with voluntary membership of a professional association

Under this model membership of a professional association is not a prerequisite for practice and any person is able to practice. The role of the government is to accredit associations that meet certain defined standards.

Co-regulation with non-compulsory membership of a professional association shares many of the advantages and disadvantages of the no-regulation models but also involves the following:

- it provides a slightly better assurance that members of accredited professional associations are competent to practise
- the government will incur costs in establishing and maintaining an accreditation system
- a disciplinary system administered by a professional association may lack transparency notwithstanding accreditation.

5.2.2 Co-regulation with compulsory membership of a professional association

Under this model membership of an accredited professional association would be a prerequisite for use of certain restricted titles. This form of co-regulation addresses many of the disadvantages of the no-regulation model and introduces a number of additional advantages and disadvantages.

The additional advantages of this type of co-regulation are:

- it provides consumers with an assurance that persons who use the restricted titles are competent to practise
- practitioners who are not members of an accredited association can continue to practise and compete for business in the market although they cannot use the restricted titles.

The additional disadvantages of this type of co-regulation are:

- a competitive advantage is provided for those practitioners who are members of an accredited association
- those practitioners who join an accredited association will incur membership costs
- the government will incur costs in establishing and maintaining an accreditation and enforcement system.

In addition to the disadvantages outlined above all forms of co-regulation involve the government accrediting particular professional associations and this may be considered to be inappropriate. However, this concern can be ameliorated by the government publishing clear and transparent criteria for accreditation.

5.3 Title regulation only

Title regulation means that only registered practitioners (that is, those who can demonstrate that they hold certain statutorily defined qualifications) are able to use certain restricted titles, such as Chinese medicine practitioner. Unregistered people, and other registered health care professionals, would not be prevented from using the techniques of the profession.

Title regulation is similar in effect to co-regulation with compulsory membership of a professional association except that the government, through a statutory board, is responsible for regulating the profession. This model avoids those concerns associated with the government accrediting particular professional associations and potentially provides a more transparent and accessible mechanism for handling complaints from the public.

The objective of title regulation is to protect the public by ensuring that consumers are able to identify appropriately qualified persons. This is achieved by restricting the title so consumers can easily identify practitioners who meet minimum legislated requirements. The public's use of registered and therefore suitably qualified practitioners may reduce the cost to the community of injuries incurred through inappropriate treatments. However, by preventing unregistered people from using the title a competitive advantage is conferred on registrants over other related health practitioners.

Advantages and disadvantages of this approach are essentially the same as for the co-regulation models outlined above. However, an argument can be made that a government administered disciplinary scheme will promote the interests of consumers more than a professional association administered system.

Title regulation is the model adopted by a number of health professional registration Acts in NSW including the *Medical Practice Act* and the *Nurses Act*.

5.4 Title and practice restriction

Commonly title and practice restriction is the most anti-competitive form of professional regulation. This form of regulation involves title restriction, as outlined above, so that consumers can identify competent professionals as well as the restriction of practices which have been identified as carrying significant risks if performed by unqualified persons. It is not necessary that all techniques used by the profession would be restricted.

The advantages of this approach are:

- consumers can be sure that potentially harmful practices are only undertaken by practitioners who are considered to have adequate training.

The disadvantages of this approach are:

- it provides a competitive advantage for those registered groups who are deemed to have the training to safely employ the restricted practices
- previous experience with practice restrictions has been that more regulatory concern surrounds other registered groups entering into the restricted practice area than lay persons undertaking restricted practices
- practice restrictions are of limited effect in that they do not apply to those cases where members of the registered group practise beyond their level of competence.

A further disadvantage with practice restrictions is the difficulty of drafting workable definitions of those prescribed practices that only registered practitioners may provide so that the legitimate scope of practice of other professions is not affected. The enforcement of such restrictions, which involves satisfying a court that a restricted activity has occurred, can be onerous. It may also be argued that practice restrictions hinder innovation and improved techniques both within the registered group and by other professional groups with closely related areas of practice.

Issue 2

Section 5 covers a number of models that potentially may be used in the registration of complementary health practitioners. If statutory regulation is supported which model should be the preferred model in NSW and why?

Submissions that support regulation, which includes restrictions on the use of certain titles, should indicate the titles that should be restricted and why the public interest requires that they be restricted.

6 Initial registration

6.1 **Registration criteria**

The methodology for assessing a practitioner's competence for registration must be transparent, and exclude both commercial considerations and pressures that affect the particular profession.

6.1.1 Qualifications

There are a number of mechanisms that can be used for recognising qualifications. These include prescribing recognised qualifications by regulation; requiring the Board to publish accreditation guidelines against which the Board is to assess educational courses for accreditation; and allowing the Board to recognise accreditation granted by another organisation, such as an intestate registration board. In the case of published guidelines educational institutions may apply to the Board for accreditation of their courses, with a right of appeal to the Administrative Decisions Tribunal.

In the case of traditional Chinese medicine the Board may be assisted by the recently released education guidelines. In 2001 the first *Australian Guidelines for Traditional Chinese Medicine Education* were published by the National Academic Standards Committee for Traditional Chinese Medicine. These guidelines outline the broad principles and minimum requirements for Australian primary qualifying courses in traditional Chinese medicine and treatment systems.

6.1.2 Other criteria

a. Good character

The inclusion of a requirement for 'good character' in the registration criteria is to ensure that disreputable people are excluded from practicing. Such people may include those who have been convicted of crimes relating to dishonesty or violence, where there is concern that the offence is such that they are rendered unfit to practise.

b. Proficiency in the English language

The inclusion of this criterion in the registration criteria would result in a practitioner that cannot prove to the Board's satisfaction that they have an adequate knowledge of the English language, being excluded from registration.

This criterion is also included in other NSW registration legislation such as the *Medical Practice Act* and the *Nurses Act*.

Issue 3

What registration criteria should be adopted and why?

6.2 Grand parenting arrangements

Grand parenting arrangements may take two forms. The first form is the initial registration of practitioners who, whilst they may be professionally competent, do not currently fit the criteria for registration and are granted registration for a limited period while they upgrade their qualifications. The second form provides for the registration of practitioners based on a mix of qualifications and experience in practice. It is clear that there may be practitioners of complementary health with overseas qualifications and/or long standing practices who should be granted registration under such arrangements. Grand parenting provisions are typically available for a limited period of time (one to two years) after which they cease to operate, any practitioner who fails to take advantage of grand parenting provisions whilst they are in operation must then establish their entitlement to registration in the same manner as all other applicants.

Issue 4

If registration of complementary health practitioners is adopted what grand parenting arrangements should be included and why?

7 Other issues

7.1 Dispensing of raw herbs

In the last few years a number of herbs have been identified by the Therapeutic Goods Administration (TGA) as being toxic or having interactions with prescribed medicines. The TGA has issued alerts regarding these herbs as appropriate. The alerts related to aristolochia, kava, and hypericum perforatum (commonly known as St John's Wort).

Apart from those herbs that are listed in the *NSW Poisons and Therapeutic Goods Act*, eg belladonna, there is no current restriction on the ability of herbs to be sold over the counter. Prescriptions are not required, nor are the instructions on the correct use of herbs required. There remain issues relating to combinations of specific herbs and subsequent interactions, contamination and substitution.

Issue 5

What mechanisms should be put in place for practitioners to either prescribe and/or dispense restricted herbs and to which practitioners would this apply?

7.2 Emergency services, provision of first aid treatment and appropriate referral

Given the potential complications of some forms of complementary therapy it is expected that complementary health practitioners have in place adequate emergency procedures. This would include procedures regarding the contact of both medical and non-medical emergency services. The English-speaking requirement would be a key aspect of these procedures.

It is also expected that the practitioner know basic first aid. Therapies such as acupuncture are known to be associated with fainting, nausea, vomiting, whilst herbal medicine has been associated with allergic reactions and direct toxic effects.

Complementary health practitioners should be aware of potentially dangerous situations and know the consequences for their practise, possible adverse effects and appropriate mechanisms of referral to medical treatment.

Issue 6

It is proposed that complementary medicine practitioners should have qualifications that include first aid training or undertake separate approved first aid training. This not a requirement of other registered health professions. Should this be implemented for complementary health practitioners, which professions should be included, why or why not?

Appendix 1 – Legislation

A

1. Taxation legislation

Under the tax reform package negotiated with the Democrats, the Federal Government announced that services provided by acupuncturists, naturopaths and herbalists will be GST-free for three years from 1 July 2000. From 1 July 2003, only practitioners recognised under state law or a national registration scheme will be entitled to provide GST-free services. This will bring the treatment of appropriately qualified naturopaths, acupuncturists and herbalists in line with that of other health service providers.

2. *Therapeutic Goods Act 1989*

Within the Therapeutic Goods Administration, the Commonwealth has established the Office of Complementary Medicine. For a complementary medicine to be registered, independent clinical trials must show evidence of its efficacy and safety. For a complementary medicine to be listed, evidence of safety rather than efficacy, must be provided. This registration process does not relate to preparations that are made by individual practitioners.

This office also oversees the Complementary Medicines Evaluation Committee, who provide scientific and policy advice relating to controls on the supply and use of complementary medicines.

The *Therapeutic Goods Act 1989* includes the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) which contains the decisions from the National Drugs and Poisons Schedule Committee, regarding the classification of drugs and poisons into schedules for inclusion into relevant legislation of states and territories. Also included are model provisions regarding containers and labels, product list recommended for exemptions to provisions, and recommendations regarding other controls for drugs and poisons. This also includes herbs that are considered to have toxic effects.

The inclusion of substances in the SUSDP results in some restriction of prescribing, such as, in Schedules 1-4 substances listed may only be prescribed by medical practitioners, dentists or veterinarians. Dispensing of these substances is also restricted, that is, only pharmacists may dispense items in Schedules 1-4.

3. *Mutual Recognition Act 1992*

Under the provisions of the *Mutual Recognition Act 1992* a person who has a current authority to practise in one state/territory in an occupation recognised as equivalent to an occupation in another state/territory, is eligible to be registered and to carry on that equivalent occupation in that second state/territory. This right may be exercised provided that certain conditions, including lodgement of a statutory declaration, are met[14].

4. *NSW Public Health Act 1991*

The *Public Health Act 1991* and the *Public Health (Skin Penetration) Regulation 2000* control various skin penetration industries which are not carried out as a medical procedure under the control of a doctor, dentist or other registered practitioner. This applies to those complementary health procedures that involve skin penetration such as acupuncture.

In September 2001 the NSW Department of Health released the *Skin Penetration Guidelines* (SPHN EH 010149) and the *Skin Penetration Code of Best Practise* (EHU 010150). These guidelines give specific direction regarding the most common forms of skin penetration, including acupuncture.

5. *NSW Poisons and Therapeutic Goods Act 1966*

This *Act* has provision for the labelling and dispensing of prescribed substances through the Poisons and Therapeutic Goods Regulation 1994. It also includes the recommendations made in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP), which in turn contain the decisions from the National Drugs and Poisons Schedule Committee.

Appendix 2 – The regulation of complementary health practitioners in other jurisdictions

In Victoria the *Chinese Medicine Registration Act* was passed by the Victorian Parliament and enacted in 2000.

This *Act* establishes a statutory incorporated Chinese Medicine Registration Board, which will monitor the activities of practitioners to ensure that they maintain a satisfactory standard of professional performance.

Other states and territories are yet to pass such legislation.

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