



Submission
to the
Health Workforce
Principal Committee

September 2008

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Executive Summary

The Australian Traditional-Medicine Society (ATMS) is Australia's largest professional association of complementary medicine practitioners, representing approximately 65% of the total complementary medicine profession.

Complementary medicine and traditional Chinese medicine (TCM) practices do not pose a significant risk of harm to the health and safety of the public. These practitioners are not permitted to use any substance which is in either Schedule 1, 2, 3 or 4 of the *Standard for the Uniform Scheduling of Drugs and Poisons*. All therapeutic goods utilised by these practitioners are either listed or registered on the Australian Register of Therapeutic Goods. This ensures that the quality and safety of therapeutic goods have been assessed by Commonwealth Health regulators in the pre-marketing stage.

Of the 4,259 complaints against health practitioners received by the Health Care Complaints Commission between 1998–2006, 110 were against complementary medicine practitioners, representing 0.7% of all complaints. Of the 23,484 complaints received by the Victorian Health Services Commissioner in the 1996–2006 period, only 0.8% were against complementary medicine practitioners. The medicines and devices used by these practitioners do not involve intrusive techniques, radioactive substances or harmful chemicals.

The 1995 TCM review did not conclusively find that a significant risk of harm resulted from its practice. Indeed, not one case of supposed deaths was investigated by the Review, nor was academic rigour applied to prove causality. Even though Victoria registered TCM practitioners on the premise of causation of harm, no other jurisdiction has enacted statutory registration, thereby querying the veracity of significant risk of harm from TCM practice. Moreover, a key finding of the Review was the positive relationship between risk of adverse events and short training courses. Registered medical practitioners were identified as the group with the shortest training courses, but were exempted from the *Chinese Medicine Registration Act 2000* (Vic).

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A. About The Australian Traditional-Medicine Society

The Australian Traditional-Medicine Society (ATMS) is Australia's largest professional association of complementary medicine practitioners, representing approximately 65% of the total complementary medicine profession. It is the largest professional association for naturopathy, massage therapy, herbal medicine, homœopathy and nutrition practitioners. It is the second largest professional association for traditional Chinese medicine practitioners. At September 2008, the membership of ATMS was 11,153 practitioners.

ATMS was founded in 1984 and is a not-for-profit company incorporated with the Australian Securities and Investments Commission (ABN 046 002 844 233).

1. Executive and Administration

ATMS is governed by the Executive Board of Directors. The Society's administration consists of 9 fulltime and one part-time staff. The Departments of massage therapy, traditional Chinese medicine, naturopathic nutrition, naturopathy, homeopathy and western herbal medicine were established within ATMS to address the specific needs of members.

2. Committees

ATMS has four main national committees:

- *Academic Review Committee*: reviews current standards for all disciplines, conducts college inspections and assesses individual membership applications.
- *Complaints Committee*: handles complaints made by consumers against members and colleges.
- *Executive Management Committee*: handles day-to-day operational matters.
- *Regulatory Policy Committee*: monitors, assesses and formulates policy.
- *Seminar and Conference Committee*.

3. Representation on Commonwealth Statutory Bodies

ATMS is the only complementary medicine professional association represented on two Commonwealth statutory bodies ie the Therapeutic Goods Advertising Code

Council and the Complaints Resolution Panel. Both these statutory committees have their legal authority underpinned in the *Therapeutic Goods Regulations 1990*.

4. Publications

ATMS publishes the:

- *Journal of the Australian Traditional-Medicine Society* (ISSN 1326-3390), a quarterly peer reviewed publication. The Journal is indexed in the following international bibliographic indexes: Alt Healthwatch (USA), Cumulative Index of Nursing and Allied Health (CINAHL) (USA) and CAB International (UK).
- *Qualified Natural Therapists Membership Directory* which lists practitioner members.
- *ATMS Annual Report*.
- *Code of Conduct*.

5. Continuing Professional Education Program

ATMS is committed to a high quality Continuing Professional Education (CPE) program. The ATMS CPE program draws upon accomplished practitioners to discuss clinical experiences, as well as theoretical and philosophical perspectives. The CPE program is committed to quality education. It is mandatory that ATMS practising members participate in the CPE program.

6. ATMS Code of Conduct

The ATMS Code of Conduct sets the standard for adequate professional conduct for ATMS members. The Code deals with duty of care, professional conduct, confidentiality, patients records, advertising and stationery. It is ATMS policy that members must adhere to the Code. A wide range of sanctions are imposed on members who breach the Code, with a serious breach of the Code resulting in removal from the Society.

7. Criteria for a College to Gain ATMS Recognised Status

The ATMS Criteria for Recognised College requires that a teaching institution must meet the ATMS requirements for advertising, refunds policy, student information, student grievances, recruitment procedures, general standards as well as a college inspection. If the requirement is met, a teaching institution is granted provisional

status for a three year period. At the end of the provisional period another inspection of the teaching institution is conducted. When all criteria have been met, full Recognised College status is then granted.

8. Professional Indemnity Insurance

Practising members must have professional indemnity insurance of at least \$1 million, and the Society has a master policy scheme with an insurer.

9. First Aid Certificate

Practising members must hold a current Level II Senior First Aid Certificate.

10. Website

The ATMS website address is www.atms.com.au.

11. Disciplines Accredited by ATMS

ATMS accredits the following complementary medicine practices:

- Acupuncture
- Alexander Technique
- Aromatherapy
- Chinese Herbal Medicine
- Chinese Massage
- Counselling
- Herbal Medicine
- Homœopathy
- Hypnotherapy
- Integration Therapy
- Ka-Tone (Deep Tissue Muscle Therapy)
- Kinesiology
- Myofascial Release
- Naturopathy
- Nutrition and Modern Dietetics
- Osteopathy and Chiropractic
- Reflexology
- Reflexognosy
- Remedial Massage
- Remedial Therapies
- Rolfing
- Shiatsu
- Sports Therapies
- Rolfing
- Myofascial Release
- Traditional Thai Massage.

B. Recognition Of The Australian Traditional-Medicine Society By The Australian Taxation Office For GST-free Status

ATMS gained a Private Ruling from the ATO on 27 November 2002 that allows its acupuncture, herbal medicine and naturopathy practitioners to have GST-free status. ATO Private Ruling 21937 consists of two decisions.

The first decision is that:

ATMS is a professional association that has uniform national registration requirements for practitioners of natural and traditional medicine. Consequently practitioners (acupuncturists, herbalists and naturopaths) who are members of ATMS will be considered to be recognised professionals for the purposes of paragraph 38-10(1)(b) of the GST Act.

The second decision is that:

Acupuncture, herbal medicine and naturopathy services will continue to be GST-free where the services are provided by:

- a practitioner that satisfies the ‘recognised professional’ criteria; and
- the services provided are considered by the profession as necessary for the appropriate treatment of the recipient.

The term ‘appropriate treatment’, for the purpose of GST legislation, refers to the process when the practitioner:

...assesses the patient’s state of health and determines a process to pursue, in an attempt to preserve, restore or improve the physical or psychological wellbeing of that patient insofar as that recognised professional’s particular area of training allows.

C. Purpose Of This Submission

On 26 March 2008, the Council of Australian Governments (COAG) signed an Intergovernmental Agreement for a National Registration and Accreditation Scheme for the healthcare occupations.

The Intergovernmental Agreement made provision for partially regulated occupations for inclusion in the new Scheme. The purpose of this submission is the expression of ATMS's view to the Health Workforce Principal Committee as to whether traditional Chinese medicine practitioners should be regulated nationally, and therefore included in the Scheme.

The Health Workforce Principal Committee requires that submissions must be based on the six criteria of the Australian Health Ministers Advisory Council (AHMAC) *Working Group Advising on Criteria and Process for Assessment of Regulatory Requirements for Unregulated Health Occupations*. The six criteria of the Working Group 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?

The AHMAC criteria have adopted two principles. The first is whether the sole purpose of occupational regulation is to protect the public interest, and the second is that the purpose of regulation is not to protect the self-interests of the occupation.

ATMS is of the view that healthcare occupations that meet the AHMAC criteria be subject to a co-regulatory framework.

D. Response To The AHMAC Six Point Criteria For Unregulated Health Occupations

Criterion 1: Is It Appropriate For Health Ministers To Exercise Responsibility For Regulating The Occupation In Question, Or Does The Occupation More Appropriately Fall Within The Domain Of Another Ministry?

Traditional Chinese medicine and all of the complementary medicine occupations are directly related to health services:

- The occupations have a primary clinical focus and are involved with preventative medicine.
- Naturopathy, western herbal medicine, Chinese herbal medicine, homoeopathy and nutrition involve the use of internally administered therapeutic goods.
- Acupuncture practice uses a therapeutic device in the form of needles.
- Many massage therapies use essential oils topically as part of the therapeutic treatment.
- Many of the occupational practices are eligible for rebates from a large number of health funds.
- The education of all of the occupations involve training in the medical and health sciences.
- Complementary medicine professionals associations that accredit practitioners of herbal medicine, acupuncture, naturopathy and/or homoeopathy are listed in Schedule 1 of the *Therapeutic Goods Regulations 1990* (Cth). The Regulations are administered by the Therapeutic Goods Administration, Commonwealth Department of Health and Ageing.
- In New South Wales the professional conduct of complementary medicine practitioners is within the terms of reference of the Health Care Complaints Commission. In Victoria the Health Services Commissioner covers

complementary medicine practitioners. In Queensland complementary medicine practitioners can be investigated by the Health Rights Commission.

- All therapeutic goods and devices used by complementary medicine practitioners must be either listed or registered on the Australian Register of Therapeutic Goods, which is administered by the Therapeutic Goods Administration (TGA). The Parliamentary Secretary to the Commonwealth Minister of Health and Ageing is responsible for the activities of the TGA.

Therefore the activities of complementary medicine occupations fall directly within the domain of the Health Minister.

Criterion 2: Do The Activities Of The Occupation Pose A Significant Risk Of Harm To The Health And Safety Of The Public?

The practice of traditional Chinese medicine and complementary medicine does not pose a significant risk to either its users, the wider public or to its practitioners. In healthcare practice, an element of risk to the client is always present. However the crucial point is whether this risk is significant or not. Traditional Chinese medicine and complementary medicine practice does not pose a significant risk of harm to the health and safety of the public for the following reasons:

- Practitioners do not use any equipment, materials or processes which pose a significant risk to the public.
- Practitioners are not permitted to use any substance which is in either Schedule 1, 2, 3 or 4 of the *Standard for the Uniform Scheduling of Drugs and Poisons*.
- All therapeutic goods utilised by practitioners are either listed or registered on the Australian Register of Therapeutic Goods. This ensures that the quality and safety of therapeutic goods have been assessed by Commonwealth Health regulators in the pre-marketing stage.
- Equipment used by traditional Chinese medicine and complementary medicine practitioners does not contain or emit radioactive or dangerous substances.
- Equipment used by traditional Chinese medicine and complementary medicine practitioners must be listed on the Australian Register of Therapeutic Devices.

- No intrusive techniques are used by traditional Chinese medicine and complementary medicine practitioners. Acupuncture, although penetrating the skin, is gentle, soft and safe when used by a qualified practitioner.
- There is no potential for the work of traditional Chinese medicine and complementary medicine practitioners to cause damage to the environment.
- Over the last 30 years in Australia, death of consumers involving traditional Chinese medicine and complementary medicine practitioners is rare. In comparison it is estimated that the Australian medical and hospital system are implicated with the deaths of 15,000 Australians annually.
- On an international level, death from the practice of traditional Chinese medicine and complementary medicine practice is also rare.

Parliament of Victoria Social Development Committee Inquiry

In 1984 the Victorian Parliament commenced the Social Development Committee *Inquiry into Alternative Medicine and the Health Food Industry*¹.

The terms of reference of the Inquiry were to ‘inquire into, consider and report to the Parliament on the practice of alternative medicine in Victoria and on the health food industry’. Alternative medicine was defined as naturopathy, homoeopathy, herbalism, iridology and orthomolecular medicine and related practices. The terms of reference of significance to this submission included:

- whether such services, methods and therapies are effective, beneficial or harmful.’

The Inquiry found:

Evidence presented to the Committee indicated that there is very little public concern over the active harm caused by alternative medical practitioners at the present time. The Committee therefore does not consider that there is a case established for registration based on this aspect of public protection.

¹ Parliament of Victoria. Social Development Committee Inquiry into Alternative Medicine and the Health Food Industry. 2 Volumes. December 1986.

Health Care Complaints Commission

The Health Care Complaints Commission (HCCC) is a statutory body established by the *Health Care Complaints Act 1993* (NSW). Section 3 of the Act specifies the functions of the HCCC:

- (a) to facilitate the maintenance of standards of health services in New South Wales,
- (b) to promote the rights of clients in the New South Wales health system by providing clear and easily accessible mechanisms for the resolution of complaints,
- (c) to facilitate the dissemination of information about clients' rights throughout the health system,
- (d) to provide an independent mechanism for assessing whether the prosecution of disciplinary action should be taken against health practitioners who are registered under health registration Acts.

Complaints Against Complementary Medicine Services

The number of complaints received by the HCCC against complementary medicine services for the period 1998–2006 was very low:

Year	Total Number of Complaints to HCCC	Number of Complaints Against Complementary Medicine Services	% of Complementary Medicine Complaints Compared to Total Complaints
1998-1999 ²	642	2	0.3%
1999-2000 ³	742	8	1.1%
2000-2001 ⁴	899	0	0%
2001-2002 ⁵	918	1	0.1%

² Health Care Complaints Commission. HCCC Annual Report 2000-2001. Table 8, p 32.

³ Health Care Complaints Commission. HCCC Annual Report 2000-2001. Table 8, p 32.

⁴ Health Care Complaints Commission. HCCC Annual Report 2000-2001. Table 8, p 32.

⁵ Health Care Complaints Commission. HCCC Annual Report 2001-2002. Table 8, p 32.

2002-2003 ⁶	902	2	0.2%
2003-2004 ⁷	942	2	0.2%
2004-2005 ⁸	1,133	2	0.2%
2005-2006 ⁹	1,239	1	0.1%
Total	7,417	18	0.2%

Of the total number of 7,417 complaints against health services for the period 1998–2006, only 18 were against complementary medicine services representing 0.2% of complaints received by the HCCC.

Complaints Against Complementary Medicine Practitioners

The number of complaints received by the HCCC against traditional Chinese medicine and complementary medicine practitioners for the period 1998–2006 was also very low:

Year	Total Number of Complaints to HCCC	Number of Complaints Against Complementary Medicine Practitioners	% of Complementary Medicine Complaints Compared to Total Complaints
1998-1999 ¹⁰	1,360	11	0.8%
1999-2000 ¹¹	1,678	7	0.4%
2000-2001 ¹²	1,989	6	0.3%

⁶ Health Care Complaints Commission. HCCC Annual Report 2002-2003. Table 8, p 27.

⁷ Health Care Complaints Commission. HCCC Annual Report 2003-2004. Table 32, p 66.

⁸ Health Care Complaints Commission. HCCC Annual Report 2004-2005. Table 51, p 86.

⁹ Health Care Complaints Commission. Annual Report 2005-2006. Appendix B, Table 14.7, p113.

¹⁰ Health Care Complaints Commission. HCCC Annual Report 2000-2001. Table 11, p 35.

¹¹ Health Care Complaints Commission. HCCC Annual Report 2000-2001. Table 11, p 35.

¹² Health Care Complaints Commission. HCCC Annual Report 2000-2001. Table 11, p 35.

2001-2002 ¹³	1,755	9	0.5%
2002-2003 ¹⁴	1,814	10	0.5%
2003-2004 ¹⁵	1,873	22	1.2%
2004-2005 ¹⁶	2,002	13	0.6%
2005-2006 ¹⁷	1,788	32	1.8%
Total	14,259	110	0.7%

Of the total number of 14,259 complaints against health practitioners for the period 1998–2006, only 110 were against traditional Chinese medicine and complementary medicine practitioners representing 0.7% of all complaints received by the HCCC.

Complaints Received by Victorian Health Services Commissioner

The low number of complaints against traditional Chinese medicine and complementary medicine practitioners is not confined to NSW. In Victoria the number of complaints to the Victorian Health Services Commissioner (HSC) is also very low as the following table shows:

Year	Total Number of Complaints to HSC	Number of Complaints Against Complementary Medicine Practitioners	% of Complementary Medicine Complaints Compared to Total Complaints
1996-1997 ¹⁸	1,871	13	0.7%
1997-1998 ¹⁹	2,481	15	0.6%

¹³ Health Care Complaints Commission. HCCC Annual Report 2001-2002. Table 11, p35.

¹⁴ Health Care Complaints Commission. HCCC Annual Report 2002-2003. Table 11, p 30.

¹⁵ Health Care Complaints Commission. HCCC Annual Report 2003-2004. Table 35, p 68.

¹⁶ Health Care Complaints Commission. HCCC Annual Report 2004-2005. Table 53, p 88.

¹⁷ Health Care Complaints Commission. Annual Report 2005-2006. Appendix B, Table 14.3, p 110.

¹⁸ Office of the Health Services Commissioner. Health Services Commissioner Annual Report 1998/1999. Appendix 1.

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1998-1999 ²⁰	2,261	24	1.1%
1999-2000 ²¹	2,354	23	1.0%
2000-2001 ²²	2,796	27	1.0%
2001-2002 ²³	2,366	9	0.4%
2002-2003 ²⁴	2,373	12	0.5%
2003-2004 ²⁵	2,450	12	0.5%
2004-2005 ²⁶	2,357	23	0.9%
2005-2006 ²⁷	2,175	25	1.1%
Total	23,484	183	0.8%

Of the total number of 23,484 complaints received by the Victorian Health Services Commissioner in the 1996–2006 period, only 183 were against traditional Chinese medicine and complementary medicine practitioners, representing 0.8% of all complaints.

¹⁹ Office of the Health Services Commissioner. Health Services Commissioner Annual Report 1998/1999. Appendix 1.

²⁰ Office of the Health Services Commissioner. Health Services Commissioner Annual Report 1998/1999. Appendix 1.

²¹ Office of the Health Services Commissioner. Health Services Commissioner Annual Report 1999/2000. Appendix 1.

²² Office of the Health Services Commissioner. Health Services Commissioner Annual Report 2000/2001. Appendix 1.

²³ Office of the Health Services Commissioner. Health Services Commissioner Annual Report 2001/2002. Appendix 1.

²⁴ Office of the Health Services Commissioner. Health Services Commissioner Annual Report. 2002/2003. Appendix 1, p 51.

²⁵ Office of the Health Services Commissioner. Health Services Commissioner Annual Report. 2003/2004. Appendix 1, p 50.

²⁶ Office of the Health Services Commissioner. Health Services Commissioner Annual Report. 2004/2005. Appendix 1.

²⁷ Office of the Health Services Commissioner. 2006 Annual Report. Here For All Victorians. Appendix 1, p 37.

Data from both NSW and Victorian health care complaints regulatory agencies shows very low number of complaints against traditional Chinese medicine and complementary medicine services and practitioners.

Complaints Received by the Office of Health Review, WA

The low number of complaints against traditional Chinese medicine and complementary medicine practitioners is not confined to NSW and Victoria. In Western Australia the number of complaints to the Office of Health Review is also very low as the following table shows:

Year	Total Number of Complaints to Office of Health Review	Number of Complaints Against Complementary Medicine Practitioners	% of Complementary Medicine Complaints Compared to Total Complaints
2003-2004 ²⁸	1,718	14	0.8%
2004-2005 ²⁹	1,802	15	0.8%
2005-2006 ³⁰	1,502	7	0.5%
Total	5,022	36	0.7%

Complaints Received by ATMS Professional Indemnity Insurer

In the period 2000 to 2005 Marsh Ltd, the professional indemnity master policy insurer of ATMS, settled 17 claims requiring a payment ie an average of 3 claims per year.

Department of Fair Trading

Part 5 of the *Fair Trading Act 1987* (NSW) provides general consumer protection by prohibiting deceptive and misleading conduct, unconscionable conduct, making false representations and accepting payment without intending to supply. Part 6 of the Act

²⁸ Office of Health Review. Annual Report 2003/2004. Appendix B, p 70.

²⁹ Office of Health Review. Annual Report 2004/2005. Appendix A, p 87.

³⁰ Office of Health Review. Annual Report 2005/2006. Appendix A, p 72.

provides a range of remedies including fines, injunctions, orders and payment of damages.

The Department of Fair Trading handles a small number of complaints against unregistered health service providers. On 2 April 2008, under section 65(1) of the *Fair Trading Act 1987* (NSW), Justice McCallum issued an injunction that Jeremiah Hunter be permanently restrained from carrying on the practices of naturopathy, herbalism, iridology, hydrotherapy, nutrition, sports medicine, osteopathy or blood analysis. Justice McCallum also ordered that Hunter not use the title of PhD, which was obtained from the Open International University for Complementary Medicines. The permanent injunction was ordered as a result of Hunter's misleading and deceptive advertising, in which he used the title of Dr and claimed that he could cure illnesses.

The Department of Fair Trading also successfully prosecuted Paul Perrett. On 12 October 2007, Justice Ian Harrison prohibited Perrett from selling or prescribing therapeutic goods for cancer, multiple sclerosis and Huntington's disease. The Supreme Court also restrained Perrett from telling patients that he could cure, alleviate symptoms of, prevent or delay the onset or progression of diseases, including various forms of cancer, multiple sclerosis and Huntington's disease. Perrett was ordered to pay the Department of Fair Trading court costs.

Therapeutic Goods Administration

The *Therapeutic Goods Act (1989)* (Cth) and the *Therapeutic Goods Regulations (1990)* (Cth) is Commonwealth legislation that covers the quality, safety, efficacy and advertising of therapeutic goods and medical devices used or exported from Australia.

Police and Director of Public Prosecutions

Police investigations will be conducted if the complaint appears to contravene the *Crimes Act 1900* (NSW), which usually means matters of a sexual misconduct nature. Over the last 10 years, ATMS has worked with the police as a peer reviewer on at least 15 occasions. During this period, an ATMS representative was subpoenaed to give evidence in court on about 6 occasions. The ATMS policy is one of co-operation with the police.

The Director of Public Prosecutions will proceed an investigation to prosecution if in the opinion of the Director a jury will make a conviction. The strength of the Director prosecuting serious complaints against healthcare practitioners, whether registered or not, is that the criminal sanctions sends a loud and clear message to the health care community about legal expectations of standards of professional conduct.

NSW Medical Board

Section 105(3) of the *Medical Practice Act 1992* (NSW) has an impact on complementary medicine practice in that unregistered health service providers cannot use the title of Doctor:

a person who is not a registered medical practitioner must not hold himself or herself out to be a registered medical practitioner, doctor of medicine, physician or surgeon, or be entitled, qualified, able or willing to practise medicine or surgery in any of its branches or to give or perform any medical or surgical advice, service, attendance or operation.

In the matter of the NSW Medical Board v Dummett (Lismore Local Court, 16 November 2001), the Board successful prosecuted Dummett for the use of the title of Dr, resulting in a \$34,000 fine.

Does The Use Of Equipment, Materials or Processes Pose A Threat To Public Safety?

Herbal medicines are used in the practice of western and Chinese herbal medicine and naturopathy. The majority of herbal medicines are manufactured in Australia from dried plant material. The manufacture of herbal medicines must conform to the Code of Good Manufacturing Practice (GMP) which is administered by the Therapeutic Goods Administration (TGA).

GMP requires standards of manufacture of herbal medicine comparable to pharmaceutical drugs. GMP requires regular inspection of manufacturing companies. The solvents used in the extraction process from the crude herb material into the liquid herbal medicine are water and ethanol (alcohol). No technique or equipment used in the manufacture of herbal medicines is hazardous or threatening to the environment.

Nutritional supplements and homoeopathic medicines, like herbal medicines, whether imported or manufactured locally must conform to GMP, and must be either listed or registered on the Australian Register of Therapeutic Goods thus ensuring that their safety and quality have been assessed by the TGA before entering the marketplace.

The labelling of herbal medicines, nutritional supplements and homoeopathic medicines conform to the standards determined by the TGA. Advertising of therapeutic goods to consumers in mainstream media is regulated by the Therapeutic Goods Advertising Code Council, a statutory body established under the *Therapeutic Goods Regulations 1990* (Cth).

Some massage therapies incorporate the topical use of essential oils. Essential oils must conform to GMP and must be listed or registered on the Australian Register of Therapeutic Goods. The raw material suppliers, manufacturers and distributors of herbal medicines, nutritional supplements and homoeopathic medicines to complementary medicine practitioners operate in a regulatory framework administered by the TGA.

In addition to TGA standards, each jurisdiction has its own legislative requirements for the supply of therapeutic goods to complementary medicine practitioners, as well as to consumers. The NSW therapeutic goods legislation is now linked with the Commonwealth *Therapeutic Goods Act 1989*, with the other states yet to introduce similar harmonisation.

Acupuncturists use needles, moxabustion or laser machines. Acupuncture needles and laser machines are controlled by the Therapeutic Devices section of the Therapeutic Goods Administration. Laser machines operate at such low intensity that they are not hazardous. All therapeutic devices must be listed on the *Australian Register of Therapeutic Devices*.

Does Faulty Practise Result in Serious Threat to Public Health and Safety?

A serious threat to public health and safety does not arise from the faulty practice of complementary medicine. Herbal medicines, nutritional supplements and

homoeopathic medicines used in the practice of complementary medicine are of low toxicity ie most have the same LD₅₀ as fruit and vegetables. They do not have the same potential for adverse reactions as pharmaceutical drugs.

The therapeutic goods of complementary medicine practitioners:

- are not listed in the first four schedules of the *Standard for the Uniform Scheduling of Drugs and Poisons*
- are either listed or registered on the *Australian Register of Therapeutic Goods*, thereby satisfying the criteria of safety and quality for listed therapeutic goods, and safety, quality and efficacy for registered therapeutic goods.
- figures from the Commonwealth Department of Health and Ageing show that 61% of the Australian population are using complementary medicines. As most of these complementary medicines are self-prescribed, this indicates that these therapeutic goods have a low toxicity and are regarded as being generally safe by the TGA.

Some exponents of statutory registration for acupuncture practitioners argue that a chief reason for favouring statutory registration is contamination of acupuncture needles between patients. Such exponents falsely argue that statutory registration will correct the problem of acupuncture needle contamination. While it is correct that Sydney City Council inspectors have expressed concerns in policing skin penetration legislation, the fact is that Council inspectors have found that both registered medical practitioners and lay acupuncturists engage in faulty acupuncture needle practise. Clearly statutory registration of medical practitioners has done nothing to address acupuncture needle contamination issues. Furthermore, Council inspectors have been frustrated in performing their duties as they have no jurisdiction over statutory regulated medical practitioners.

The Council inspectors believe the solution to this problem is educating both medical and lay acupuncturists to either use disposable needles once or to utilise appropriate sterilisation equipment. Clearly statutory registration is not the answer to acupuncture needle contamination, but rather an education program for all practitioners of acupuncture, including statutory regulated medical practitioners.

Acupuncture needle contamination is an example that illustrates how statutory registration does not offer the guarantee of public health and safety that an average consumer would expect. In fact, the consumer becomes more vulnerable through the creation of a false sense of security, as consumers tend not to be as vigilant. The limitation of jurisdiction by Council inspectors highlights the inverse relationship between statutory registration and public health and safety.

The practice of massage therapy must be performed to certain procedures in order to produce maximum therapeutic effect. Bruising has been the worse reported consequence from the practice of massage therapy which does not constitute a serious threat to public health and safety.

Do Intrusive Techniques Cause Serious or Life Threatening Danger?

The practice of complementary medicine does not involve intrusive techniques. Therefore there is no threat to public health and safety, and statutory registration is not the appropriate regulatory model for the practice of complementary medicine.

Are Dangerous Chemicals or Radioactive Substances Used?

The practice of complementary medicine does not involve dangerous chemicals or radioactive substances. Therefore there is no threat to public health and safety, and statutory registration is not the appropriate regulatory model for the practice of complementary medicine.

Is There Significant Potential to Cause Environmental Damage?

The practice of complementary medicine does not have the potential to cause environmental damage. Therefore there is no threat to public health and safety, and statutory registration is not the appropriate regulatory model for the practice of complementary medicine.

Reports of Adverse Reactions

The majority of reports of adverse reactions to herbal medicines and nutritional supplements are based on anecdotal evidence. In many instances, reports of adverse reactions have failed to be clearly substantiated when properly investigated.

There are four main types of adverse reaction to therapeutic goods: side effect, allergic response, misuse/abuse and contamination. The majority of adverse reaction reports to herbal medicines and nutritional supplements do not specify the type of adverse reaction. This has falsely created the impression that herbal medicines and nutritional supplements have wide ranging side effects, where in fact the adverse event could have been allergic hypersensitivity, misuse/abuse or contamination.

Advocates of statutory registration frequently use the adverse reaction argument to promote their case. This deliberately creates a false impression that herbal medicines and nutritional supplements pose a significant threat to the community. Such advocates argue that the solution to this significant threat is statutory regulation of complementary medicine practitioners. If statutory registration is the solution to prevent adverse reactions to therapeutic goods, then it is perplexing that 15,000 deaths occur in Australia annually from the practices of statutory regulated medical practitioners, nurses, pharmacists etc.

Death from Kava

The death of a Sydney female in late 2002 was implicated with the self-administration of the herb kava (*Piper methysticum*). The kava preparation also contained other herbal medicines, and it is unclear as to whether kava was solely responsible for the death or another herb in the preparation. Consequently, in the interests of public safety, the TGA issued a voluntary recall of kava products for consumers. However kava preparations used by complementary medicine practitioners were not recalled, indicating the TGA's lack of concern with practitioner-administered kava.

During 2001–2002, kava was implicated in European countries with the deaths of at least 80 consumers. It is believed that the problem lies with the way in which European companies manufacture kava herbal medicine, and not with the herb itself, as there have been no deaths reported in the Pacific Islands where kava is consumed on a daily basis. This death is clearly a manufacturing issue, and nothing to do with complementary medicine practitioners. Statutory registration of complementary medicine practitioners would have been irrelevant in the prevention of this death.

Herb-Drug Interactions

Advocates of statutory registration often cite herb-drug interactions as a reason for the statutory registration of complementary medicine practitioners. This argument lacks rationality. Even though the biomedical literature still lacks comprehensive information on herb-drug interactions, what is currently understood is that some herbal medicines and pharmaceutical drugs interact in a positive synergistic manner, while a few herbal medicines and pharmaceutical drugs have an adverse interaction.

The main herbal medicine that is currently known to adversely interact with a range of pharmaceutical drugs is St John's wort (*Hypericum perforatum*)³¹. Reports in the biomedical literature suggest that *Hypericum* may interact with some pharmaceutical medicines by either:

- a) affecting drug metabolism, or
- b) altering levels of neurotransmitters.

Drug metabolism may be affected by *Hypericum* inducing certain cytochrome P450 enzymes in the liver. P450 enzymes are responsible for the detoxification of compounds such as pesticides, herbicides, petroleum products, food additives as well as pharmaceutical medicines.

Statutory registration of traditional Chinese medicine and complementary medicine practitioners is an irrelevant consideration in the debate of herb-drug interactions. The TGA's Office of Complementary Medicines is the appropriate regulatory authority to handle herb-drug interaction issues. This was witnessed when in March 2000 the TGA issued an alert via its website to all health care professionals on the emerging evidence of the interaction between *Hypericum* preparations and some pharmaceutical medicines.

Review of Traditional Chinese Medicine Practice In Australia

In 1995 the Victorian Department of Human Services, the NSW and Queensland Health Departments commissioned a review of the practice of traditional Chinese

³¹ Khoury R. TGA Issues *Hypericum* Warning. Journal of the Australian Traditional-Medicine Society 2000;6(1):47.

medicine (TCM) in Australia. The review's report, *Towards a Safer Choice*³² was released in 1996.

The Review concluded that there was some risk to consumers associated with the practice of TCM. A national survey of TCM practitioners supposedly found that eight deaths had occurred from TCM practice, and written communication with coroners nationally found that three deaths were associated with TCM practice. Consequently *Towards a Safer Choice* recommended:

- That TCM practitioners be subject to statutory occupational regulation and that the focus of this regulation be the protection of the public by ensuring practitioners have adequate qualifications for safe and competent practice (p 252)
- That the model of regulation adopted be registration with protection of title rather than licensing for protection of practice (p 252).

On 16 May 2000, the Victorian government passed the *Chinese Medicine Registration Act 2000*, thereby making Chinese herbal medicine practitioners, Chinese herbal dispensers and acupuncturists regulated by statute. Three of the main purposes of the Act were:

- (a) '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';
- (b) 'to regulate the advertising of Chinese medicine and Chinese herbal dispensing services';
- (c) 'to establish the Chinese Medicine Registration Board of Victoria and the Chinese Medicine Registration Board Fund'.

The impetus for the introduction of statutory registration for TCM practitioners was the report of deaths, and the finding of the Review that TCM practice has the potential of harm in the community. The following facts query whether TCM practice really has the potential to cause harm in the Australian community:

³² Bensoussan A, Myers S. *Towards a Safer Choice: The Practice of Traditional Chinese Medicine in Australia*. University of Western Sydney, Macarthur, 1996.

- NSW and Queensland have not yet enacted statutory registration, thereby indicating a preference for the current self-regulation of TCM practitioners. If Victorian TCM practitioners have the potential to cause harm, then it is perplexing as to why NSW and Queensland TCM practitioners do not have the same potential to harm.
- Not one case of supposed deaths was investigated by the Review, nor was academic rigour applied to prove causality.
- Medical practitioners usually undertake short training TCM courses. A key finding of the Review was that the risk of adverse events is linked to the length of education of the practitioner, with practitioners graduating from extended TCM education programs experiencing about half the adverse event rate of those practitioners who have graduated from short training programs ie medical practitioners. Yet section 111 of the *Chinese Medicine Registration Act 2000* (Vic) exempts medical practitioners who practise Chinese medicine from having to be registered with the Chinese Medicine Registration Board.

Sydney University Survey Of Workforce

In June 2002, ATMS conducted a national survey of its members, which was funded by the Commonwealth Department of Health and Ageing. The survey was conducted by the School of Behavioural and Community Health Sciences, Faculty of Health Sciences, University of Sydney. The report of the survey for acupuncture, herbal medicine and naturopathy practitioners was published in December 2002³³.

Question 30 of the survey asked about adverse reactions. Those who reported adverse reactions were asked to supply information about the type of adverse reaction, the number of times the adverse reaction occurred, in what years, and whether the adverse reaction had required a consultation with a medical practitioner. Of the 1,415 acupuncture, herbal medicine and naturopathy practitioners who responded to the survey, only 17% (243 practitioners) reported an adverse reaction, while 83% of survey respondents did not report an adverse reaction. The following table shows the main groupings of adverse reactions reported:

³³ Hale A. Survey Data of the Australian Traditional-Medicine Society as Part of the Uniform National Registration Systems Project for Suitably Qualified Practitioners in Naturopathy, Herbal Medicine and Acupuncture. Meadowbank, Sydney: Australian Traditional-Medicine Society, 2002.

	Frequency	Percent
Skin reaction	59	24.3
Headache/dizziness/ nausea/digestive	98	40.3
Respiratory	1	.4
Emotional	3	1.2
Muscular distress	6	2.5
Bruising	9	3.7
Exacerbation of symptoms	18	7.4
Burn	1	.4
Two of the above	47	19.3
Three of the above	1	.4
Total	243	100.0
No adverse reaction	1208	
Total	1451	

The majority of adverse reactions were of a minor nature. Of a more serious nature were reports of breathing difficulties, one broken acupuncture needle that required minor surgery, an anaphylactic response and thrombosis of the left leg. Survey respondents did not report a single death. This may indicate that the reports of death in the survey conducted as part of the review of TCM and published in *Towards a Safer Choice* may have occurred overseas rather than in Australia³⁴.

Of the 243 survey respondents that reported an adverse reaction, only 34 reported that the adverse reaction resulted in a consultation with a medical practitioner. The types of reactions that were referred to a medical practitioner included:

- skin reactions and allergies
- stomach upsets
- pain in liver
- increased urination
- intestinal pain
- headaches
- vomiting and diarrhoea
- existing conditions that became exaggerated or intensified.

³⁴ Bensoussan A, Myers S. *Towards a Safer Choice: The Practice of Traditional Chinese Medicine in Australia*. University of Western Sydney, Macarthur, 1996.

Of the survey respondents who reported adverse reactions in the years 1999–2002, 70.6% completed their education after 1996, indicating that these respondents were more recent graduates. It is noteworthy that 12.7% of these practitioners had a Bachelor degree, as opposed to 9.1% of all those who reported adverse reactions. The survey report noted that:

...differences in reporting adverse reactions between these groups may indicate that more recent graduates are more inclined to medicalise client reactions, thus indicating changing perceptions about what constitutes an adverse reaction, and changing attitudes to reporting conditions as adverse reactions.

Criterion 3: Do Existing Regulatory Or Other Mechanisms Fail To Address Health And Safety Issues?

Current regulatory agencies adequately cover the health and safety issues of complementary medicine practice.

Commonwealth Therapeutic Goods Legislation

The control of therapeutic goods and devices is under the control of the Therapeutic Goods Administration (TGA), which was established by the *Therapeutic Goods Act 1989* (Cth) and the *Therapeutic Goods Regulations 1990* (Cth). The TGA is part of the Commonwealth Department of Health and Ageing.

All therapeutic goods and devices cannot enter the Australian market unless they are either listed or registered on the Australian Register of Therapeutic Goods. Listed goods must fulfil the criteria of quality and safety, while registered goods must fulfil quality, safety and efficacy. All of the therapeutic goods and devices used by complementary medicine practitioners are covered by the Therapeutic Goods Administration.

NSW Therapeutic Goods Legislation

In NSW the *Poisons and Therapeutic Goods Act 1966* (NSW) regulates the supply of therapeutic goods.

Section 31 of the *Poisons and Therapeutic Goods Act 1966* (NSW) provides that Commonwealth therapeutic goods laws (ie the *Therapeutic Goods Act 1989* and all

regulations, orders and manufacturing principles in force under that Act) apply as a law of NSW as if they extended to intra-State conduct and to the conduct of individuals ie

- (1) The Commonwealth therapeutic goods laws, as in force for the time being and as modified by or under this Part, apply as a law of New South Wales.
- (2) Those Commonwealth therapeutic goods laws so apply as if they extended to:
 - (a) things done or omitted to be done by persons who are not corporations, and
 - (b) things done or omitted to be done in the course of trade or commerce within the limits of New South Wales.
- (3) The regulations under this Act may modify the Commonwealth therapeutic goods laws for the purposes of this section.

The *Poisons and Therapeutic Goods Act 1966* (NSW) adequately covers all of the therapeutic goods used by complementary medicine practitioners in NSW.

Complementary Medicines Evaluation Committee

The Office of Complementary Medicines (OCM) was launched by Senator Grant Tambling, Parliamentary Secretary to the Minister for Health and Aged Care, on 28 April 1999. The OCM specifically deals with complementary medicines and is located within the TGA.

Within OCM is the Complementary Medicines Evaluation Committee (CMEC). CMEC is a statutory committee established by section 52G of the *Therapeutic Goods Act 1989* (Cth). The functions of CMEC are defined by Regulation 42ZE of the *Therapeutic Goods Regulations 1990* (Cth) which include the evaluation of:

- a complementary medicine;
- an ingredient in a complementary medicine;
- a kind of ingredient in a complementary medicine;
- therapeutic goods referred to CMEC by the Minister of Health or the Secretary of the Department of Health and Ageing.

CMEC may make recommendations as to:

- whether or not a complementary medicine should remain in the Australian Register of Therapeutic Goods;
- whether or not a complementary medicine should be included in the Australian Register of Therapeutic Goods;
- whether or not an ingredient or kind of ingredient should be included in [Schedule 14](#) of the *Therapeutic Goods Regulations 1990* (Cth).

Standard for the Uniform Scheduling of Drugs and Poisons

The National Drugs and Poisons Schedule Committee (NDPSC) is responsible for the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). The NDPSC has its authority underpinned in section 52B of the *Therapeutic Goods Act 1989* (Cth).

The SUSDP classifies drugs and poisons into Schedules for inclusion into the relevant legislation of the States and Territories. It also includes model provisions about containers and labels, a list of products recommended to be exempt from those provisions, and recommendations about other controls on drugs and poisons. Herbal medicines, nutritional supplements, essential oils and homœopathic medicines which are considered to be unsafe for general use are listed in one of the Schedules or Appendices of the SUSDP.

Schedules 1–4 are restricted in prescribing to only medical practitioners, dentists or veterinarians. Pharmacists can only dispense goods in Schedules 1–4.

Complementary medicine practitioners do not prescribe or dispense any therapeutic goods in Schedules 1–4 of the SUSDP, or any good in listed in Appendix C.

Criterion 4: Is Regulation Possible To Implement For The Occupation In Question?

Regulation of the complementary medicine occupation is possible for the following reasons:

- The complementary medicine occupation is a defined discipline of healthcare practice.

- Each of the complementary medicine disciplines have, to one extent or another, a body of knowledge which forms the basis of the principles and practice of that discipline.
- Government established competencies are required by each of the complementary medicine disciplines. These qualifications are determined through a collaborative process by the professional associations and teaching institutions.

Criterion 5: Is Regulation Practical To Implement For The Occupation In Question?

Co-regulation with compulsory membership of a professional association is practical to implement for the complementary medicine occupation:

ATMS represents about 65% of complementary medicine practitioners nationally. This makes implementation of co-regulation practical, as the target occupation has already been defined. For individual complementary medicine disciplines, ATMS is the:

- largest professional association of massage therapists, naturopaths, western herbalists, homœopaths and nutritionists.
- second largest professional association of acupuncturists and Chinese herbalists.

ATMS has a mandatory Code of Conduct. The financial costs of running a co-regulatory model does not pose a financial problem, for ATMS as it is able to operate with surplus of funds each year.

Can Practitioners be Organised to Comply with Co-Regulation?

ATMS already represents about 65% of all complementary medicine practitioners nationally. ATMS already has in place:

- a Code of Conduct
- an effective complaints mechanism
- a professional peer reviewed journal covering all disciplines

- a mandatory continuing professional education program
- permanent administrative staff
- acceptance by 42 health funds for rebates
- professional indemnity master insurance policy.

Criterion 6: Do The Benefits To The Public Of Regulation Clearly Outweigh The Potential Negative Impact Of Such Regulation?

An appropriate regulatory model needs to:

- advance unregistered health service providers, but not be solely for the self interest of these providers
- be in the best interests of consumers without limiting consumer choice
- focus on education, clinical standards and the complaints resolution mechanism
- not inhibit the safe practice of unregistered health service providers so as to limit its effectiveness in health care.

Given these considerations, ATMS believes that co-regulation between the complementary medicine profession and government is the most appropriate form of regulation for the complementary medicine occupation. ATMS has proposed a co-regulatory model, entitled Government Monitored Self Regulation (GMSR).

The essential features of a co-regulatory model are:

- impartiality
- independence, and
- accountability to the community.

Co-regulation must not:

- restrict competition in any way
- involve harsh penalties out of proportion to the infringement involve contravention of state or federal law

- deny access to legal remedies in any way.

During the review of the practice of traditional Chinese medicine in Australia, the NSW Health Department suggested three regulatory models for Chinese medicine practitioners³⁵:

- 1) Health regulation by statutes such as the *Public Health Act 1991* (NSW), or those specific to individual safety issue of concern such as the *Poisons and Therapeutic Goods Act 1996* (NSW) or the Skin Penetration Regulations.
- 2) The development under statute of a generic Health Professionals Registration Board with standards of conduct and safety of practice, and protection of specific titles.
- 3) The development of a co-regulatory model where Government accredits self-regulatory systems similar to the NSW Professional Standards Council. This model is similar to the Government Monitored Self Regulation co-regulatory model advocated by ATMS. The NSW Health Department called its model Government Supervised Self Regulation (GSSR).

The NSW Health Department related its co-regulatory model for Chinese medicine practitioners to that found in the *Professional Standards Act 1994*. Under this Act the Professional Standards Council does not assess individual practitioners, but rather assesses proposals for limited liability schemes put forward by professional associations. Where professional associations can demonstrate to the Council that they have strategies in place to minimise risks associated with professional practice, the members of the association can have their liability for damages limited under the Act. Such practitioners could be identified to consumers through the right to use a specified logo indicating that the practitioner has obtained a certain level of competence. The identification strategy is similar to that proposed by ATMS.

Policy makers have argued that the potential disadvantages of a statutory regulatory model are:

³⁵ Victorian Ministerial Advisory Committee. Traditional Chinese medicine. Report on Options for Regulation of Practitioners. July 1998. Melbourne: Victorian Government Department of Human Services, 1998.

- The major benefactor from statutory registration of title is not the public, but the regulated health practitioners themselves
- Restriction of entry into the profession resulting in shortages of practitioners especially in public institutions, rural areas and amongst particular ethnic groups
- Higher fees by practitioners to support the Registration Board
- The pre-conditions for monopoly can well be established by the controls of competition and on information to the public
- By confining the health care service to a particular group of providers, developments and innovation in the training of that group can be stifled
- Controls on competence are focused when the practitioner is entering the profession, rather than those who are already in practice
- The costs of administration of the registration system may not be recouped in total from the registration fees, which means that the part of the cost is borne by the community
- Statutory registration implies official endorsement of the professional status and methods of practice of the registered group
- Statutory registration can lead to undue emphasis being placed on academic qualifications, rather than on practical clinical ability.