

CAM Regulation

National Working Group on the Regulation of Complementary Therapists

August 2005

The information below is supplementary to the 2002 O'Sullivan report which describes in detail how complementary and alternative therapies are regulated in each country. Detailed below is an update to the 2002 report and a description of recent legislative changes internationally.

Issues surrounding regulation

Trends in Regulation

Europe

Updated status on regulation internationally

Denmark

Italy

Holland

Norway

Belgium

Portugal

Sweden

UK regulation since 2000

United States

Canada

Australia

New Zealand

Issues surrounding regulation

In the past few years, the rise in the use of complementary therapies, the improved quality of research on efficacy and successful models of integrated healthcare have prompted much analysis of the best way to regulate therapists in the sector. This has led to many countries conducting systematic reviews of their regulatory systems, with several publishing reports arising from the findings of advisory committees and working groups commissioned by governments. It has been a useful process internationally in helping countries gather facts on the issue and to set their regulation agenda.

In terms of regulation, there are unique challenges affecting complementary and alternative practitioners which have been noted by many of the advisory documents and government reports arising from this examination. Some of these challenges of regulating practitioners were identified in the 2002 report of the United States White House Commission on Complementary and Alternative Medicine Policy.⁽¹⁾ They found the chief challenges to be:-

- disagreement surrounding the nature and scope of some professions

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- confusion and potential legal consequences arising from the overlap of approaches and techniques used by practitioners.
- the variation in the views of practitioners about how much training is needed to attain regulation status in a given field.

There are also those points recognised by the New Zealand Commission on Complementary and Alternative Health in terms of regulation of practitioners by statutory regulations.⁽²⁾

- Statutory regulation can be seen as a means to gain legitimacy with consumers and biomedical practitioners, facilitate integration and access public health funds.
- The costs of statutory regulation are not warranted for low risk modalities.

Trends in Regulation

Many countries, including New Zealand, favour strong self-regulation with statutory regulation of those therapies that are understood to have potential risk to the consumer. The model of self-regulation is also preferred in Canada, where the advantages of using the therapists themselves to self-govern have been examined by their health services.⁽³⁾

- The therapists act as “gate-keepers” to the therapy, typically by establishing and enforcing entrance standards for the therapy.
- They establish standards of practice for the therapy providing guidance to their members on the performance of their duties.
- They establish continuing education or continuing competence requirements which members must follow to maintain their competence throughout their career.
- They administer a professional disciplinary process designed to protect the public from incompetent or unethical professionals. Members of the profession found to have engaged in unprofessional conduct or unskilled practice can face a range of sanctions from a directive to take remedial training to the expulsion from the profession in extremely serious cases.

Self-regulation through professional bodies seems to be a desirable option in many countries. This is particularly the case where the level of perceived risk to the consumer as one of the main forces driving the need to statutorily regulate some professions while leaving other to police themselves. Increasingly, organisations and professional associations of complementary therapists are formulating frameworks for self-regulatory possibilities. A 2005 report by the European Council for Classical Homeopathy (an NGO with participatory status with the Council of Europe)⁽⁴⁾ gives an example of agreed minimum criteria for voluntary self-regulation.

1. A single national professional body, where appropriate, established according to common high standards of education, registration and practice agreed across Europe.

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2. Patient representation on all standard committees – particularly for complaints and professional conduct procedures.
3. An accreditation process for institutions providing education.
4. Continuing professional development required for all practitioners.
5. Professional indemnity insurance for all practitioners.
6. Code of ethics and practice.
7. Complaints and disciplinary procedures.

The reports published by Canada, New Zealand and the House of Lords recommendations in the UK all favour a degree of self-regulation combined with statutory regulation for certain therapists as a possible regulatory framework. In both the UK and New Zealand, recent legislation (The 2003 Health Practitioners Competence Assurance Act and the Health Act 1999) allow for the possibility of the therapy to become statutorily regulated without separate lengthy legislation having to be formed. All Government Advisory Groups reporting in the last seven years point out that statutory regulation is not suitable or necessary for all modalities. In most cases, solid self-regulation, preceded by a strong degree of uniformity in the sector, is seen as a useful way forward.

Europe

Following the 1997 Lannoye report, the Collins resolution⁽⁵⁾ was passed by the European Parliament in 1997 which called on the Commission to “launch a process of recognising non-conventional medicine” and to carry out a study of its effectiveness, areas of application, and legal models to which it was subject. Two years later the 1999 COST report⁽⁶⁾ (Cooperation in Science and Technology) was published. It identified two legal issues in relation to licensing therapies, licensing a therapist to practise complementary medicine and the reimbursement by social security systems of the costs for the client.

In relation to licensing, COST developed three categories of models of regulatory frameworks; the

- monopolistic systems where only the practice of modern, scientific medicine is recognised as lawful, with the exclusion of, and sanctions against, all other forms of healing and practitioners.
- tolerant systems where only the system based on modern, scientific medicine is recognised, although the practitioners of various forms of complementary medicines are tolerated, at least to some extent, by law.
- mixed systems where there are some monopolistic and some tolerant characteristics.

Ireland, Germany and Britain fell into the “tolerant” category while countries like France and Spain were seen as monopolistic and Denmark, Finland and Sweden were examples of mixed systems. Since the COST report and the Collins resolution, there have been no legislative

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procedures made concerning complementary and alternative medicine by the EU. Nuala Ahern, former MEP, led a working group on the sector in the last parliamentary session. Since the new term began in June 2004, the position regarding the basis on which the sector is regulated remains unchanged.

To this end, a Brussels based NGO, the European Forum for Complementary and Alternative Medicine (EFCAM) was formed in 2004 in response to the EU Commission's call for single umbrella bodies to represent the various stakeholders sharing broad areas of interest and concern in the EU. Its aim is to represent the collective views and promote the interests of professional practitioners, patients and users of complementary and alternative medicine in Europe. Together with lobbying groups such as the European Public Health Alliance (EPHA), EFCAM hopes to keep the issue on the agenda.

The EPHA represents over 100 non-governmental and other not-for-profit organisations working in support of health in Europe. The platform was founded in 1994 in Brussels. Their aim is to create a permanent forum for exchange of views and information and to act as a point of reference for the EU institutions on policy and regulatory issues for CAM.

Updated status on regulation internationally

Denmark

The Danish parliament has passed a resolution to establish a register effective from June 2004 for CAM practitioners. The register is voluntary and practitioners will be self-regulated through their member associations. It includes practitioners who have well defined criteria for education and are members of an organisation for practitioners that will take on the necessary tasks for registration and maintaining the register. Politicians hope that the resolution will result in bridge building between alternative practitioners and healthcare practitioners. The register is voluntary and practitioners are self-regulated through their member associations.⁽⁸⁾

Italy

The Government of Northern Italy (Piedmont region) issued a new regional law in 2002 which legally recognises the practice of Complementary and Alternative Medicine.⁽⁹⁾ There is no national policy on CAM other than that in the Piedmont region.

Holland

Holland has regulated CAM therapies since 1993. The Individual Health Care Professions Act came into force in 1997. In relation to alternative practitioners, the focus has been on voluntary self-regulation and on the development of systems to ensure quality. A quality framework has been established for alternative practitioners. It includes 36 criteria developed in agreement with patient organisations, health insurers and the health inspectorate.

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CAM Regulation.doc 30th March 2007.

The areas covered include education, vocational training and continuing education; the register of qualified members; the application of alternative treatments; guidelines on practice organisations; codes of conduct; relationships with other healthcare providers; disciplinary rules and complaints procedures; and quality assurance. An independent research organisation is monitoring the progress which organisations are making in the implementation of this quality policy.

Norway

A new law for alternative therapies was enacted from 1 January 2004. The law lays out regulation for the legal practice of therapies by someone who is not a medical doctor.

The law states that the practitioner:

- must follow the same regulations for confidentiality as health care personnel.
- may not treat dangerous contagious diseases or serious diseases, but may treat when the purpose of the treatment exclusively is to palliate or reduce symptoms of, or consequences of, the disease or side-effects of treatment given, or when the purpose is to enhance the body's immune system or ability to heal itself.
- may treat serious diseases in co-operation or understanding with the patient's doctor and when the patient is over 18 years of age and has the ability to give consent.
- may treat serious diseases when the healthcare service cannot offer the patient healing and can only offer palliative treatment.

In June 2004 a register for practitioners was also established by the Norwegian Government and is open to practitioners to join voluntarily. To qualify for registration they must be a member of a professional organisation that has been approved in accordance with the nine recommended points that the register requires for approving professional organisations. The register is run by the Bronnøysund Register in conjunction with the Directorate for Health and Social Affairs. The register is voluntary and the professions are self-regulated.

Belgium

In Belgium, before 29 August 1999, anyone who practised medicine – complementary or orthodox – without being enrolled with the Belgian General Medical Council was committing a criminal offence. Registered doctors have had clinical and diagnostic freedom to carry out whatever treatments they think fit. However, those who chose complementary medicine found themselves in conflict with their professional organisation, which requires them to treat patients 'taking all reasonable care given the current state of scientific knowledge'. This discrimination led to Colla's law, named after Minister Colla (29 April 1999).

Colla foresees the installation of four 'commissions' (homeopathy, acupuncture, osteopathy and chiropractic) and for the first time in Belgium, regulation concerning complementary and alternative therapies.

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CAM Regulation.doc 30th March 2007.

Work is now in progress to establish committees and procedures under the new legislation that will establish the legal right to practice under a new national register.

Portugal

In July 2003, the Portuguese Parliament voted in a new law that recognises the practice of acupuncture, homeopathy, osteopathy, naturopathy, phytotherapy and chiropractic. Under this law, the practice of these therapies will be controlled and accredited by the Health Ministry while the education and certification of qualifications will be controlled by the Ministry of Education.

Sweden

The Government has proposed the establishment of a register of complementary and alternative practitioners. Funding for the process was included in the budget of 2004.

UK regulation since 2000

In the United Kingdom, the House of Lords Science and Technology Committee report on complementary and alternative medicine, published in 2000, is the chief blueprint for regulatory policy. The inquiry was mounted because of the increased use of complementary and alternative therapies not only in the United Kingdom but across the developed world. This rise in its popularity and use raised several questions of substantial significance in relation to public health policy. The inquiry lasted for 15 months. It received more than 180 written submissions and took evidence from 46 different bodies. To understand its recommendations on regulation we must first look at the report's subdivision of therapies into three groups.

- *The first group* embraces what may be called the principal disciplines, two of which, osteopathy and chiropractic, are already regulated in their professional activity and education by Acts of Parliament. The others are acupuncture, herbal medicine and homeopathy. Each of these therapies claims to have an individual diagnostic approach and are seen as the 'Big 5'.
- *The second group* contains therapies which are most often used to complement conventional medicine and do not purpose to embrace diagnostic skills. It includes aromatherapy; the Alexander Technique; body work therapies (including massage); counselling; stress therapy; hypnotherapy; reflexology and probably shiatsu, meditation and healing.
- *The third group* embraces those other disciplines which purport to offer diagnostic information as well as treatment and which, in general, favour a philosophical approach and are indifferent to the scientific principles of conventional medicine, and through which various and disparate frameworks of disease causation and its

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CAM Regulation.doc 30th March 2007.

management are proposed. These therapies can be split into two sub-groups: Group 3a includes long-established and traditional systems of healthcare such as Ayurvedic medicine and Traditional Chinese medicine. Group 3b covers other alternative disciplines which lack any credible evidence base such as crystal therapy, iridology, radionics, dowsing and kinesiography.

Group 1 includes the most organised professions and Group 2 contains those therapies that most clearly complement conventional medicine. While the question of efficacy was not included in their initial terms of reference, in the absence of a credible evidence base it was seen that Group 3 cannot be supported unless and until convincing research evidence of efficacy, based upon the results of well designed trials, can be produced.

Their chief recommendations were:

- In order to protect the public, professions with more than one regulatory body should make a concerted effort to bring their various bodies together and to develop a clear professional structure (para 5.12).
- Each of the therapies in Group 2 should organise themselves under a single professional body for each therapy. These bodies should be well promoted so that the public who access these therapies are aware of them. Each should comply with core professional principles, and relevant information about each body should be made known to medical practitioners and other healthcare professionals. Patients could then have a single, reliable point of reference for standards, and would be protected against the risk of poorly-trained practitioners and have redress for poor service (para 5.23).
- Acupuncture and herbal medicine are the two therapies which are at a stage where it would be of benefit to them and their patients if the practitioners strive for statutory regulation under the Health Act 1999, and it was recommended that they should do so. Statutory regulation may also be appropriate eventually for the non-medical homeopaths. Other professions must strive to come together under one voluntary self-regulating body with the appropriate features outlined in Box 5, and some may wish ultimately to aim to move towards regulation under the Health act once they are unified with a single voice (paras 5.53 and 5.55).
- Each existing regulatory body in the healthcare professions should develop clear guidelines on competency and training for their members on the position they take in relation to their members' activities in well organised CAM disciplines; as well as guidelines on appropriate training course and other relevant issues. In drawing up such guidelines, the conventional regulatory bodies should communicate with the relevant complementary regulatory bodies and the Foundation for Integrated Medicine to obtain advice on training and best practice and to encourage integrated practice (para 5.79).
- The report encourages the bodies representing medical and non-medical CAM therapists, particularly those in Groups 1 and 2, to collaborate more closely, especially on developing reliable public information sources. They recommended that if CAM is to be practised by any conventional healthcare practitioners, they should be trained to

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CAM Regulation.doc 30th March 2007.

standards comparable to those set out for that particular therapy by the appropriate (single) CAM regulatory body (para 5.83).

Following on from these recommendations, between March and June 2004 the Department of Health began a period of consultation on proposals to proceed with the regulation of herbal medicine and acupuncture practitioners. Over 1000 copies of the consultation were distributed to interested individuals and organisations and a total of 698 responses were received to the consultation. The majority of the responses indicated strong support for the introduction of statutory regulation, in order to ensure patient and public protection. Key areas of debate included the type and name of the proposed regulatory council, protected titles, collaborative regulation and the composition of the council.

The Department analysed the responses received and in February 2005 launched a report on the consultation titled "Statutory regulation of herbal medicine and acupuncture: Report on the consultation". The Department of Health planned to publish draft legislation for further consultation in autumn 2005.

However, pace on the statutory regulation of herbal medicine and acupuncture has slowed as a result of the UK Government's current scrutiny of the entire area of statutory regulation. Since the enquiry into the deaths caused by Dr Harold Shipman, two major reviews of statutory regulation of healthcare workers are now taking place as part of the Government's response to the Shipman enquiry. At present there are nine different regulators in what is regarded by some as an unwieldy and time consuming process. This has resulted in the regulation of herbal medicine and acupuncture being put on hold until the Government reacts to the findings of these enquiries.

Many people who are expert in the field of complementary therapies in the UK and their regulation feel that voluntary regulation through a federal structure could be the way forward for most groups. This would mean the establishment of agreed umbrella organisations with bodies structured beneath them through each (or related) therapies, a route which is in line with the recommendations of the House of Lords report.

Also, further regulatory change is about to occur in the UK; regulation of healthcare workers such as social workers, domiciliary workers etc allows for further registration and tracking of those who work with potentially vulnerable adults and children. This process has raised questions for the alternative and complementary sector in terms of registration. Could registration and a rigorous framework of voluntary regulation act just as effectively as statutory regulation? It is felt that for some groups, the economics of statutory regulation (and perhaps factors based on lack of perceived risk) could result involuntary regulation being a more effective choice.

The Foundation for Integrated Health is currently examining these issues and looking at the various possibilities for non-statutory regulated therapies. It is felt that there are many issues to be examined such as incentive for practitioners to belong to a federated structure and quality assurance criteria but that voluntary self-regulation could be the most suitable way forward for many groups.

The Foundation receives Government funding to support the setting up of effective voluntary self-regulation schemes for therapies such as homeopathy, aromatherapy and reflexology.

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CAM Regulation.doc 30th March 2007.

The Foundation's focus is to help establish a single regulatory body for each of the main complementary health therapies and then to facilitate the development of robust forms of voluntary or statutory self-regulation.

United States

In the USA, every state has its own licensing scheme, with different laws and regulations and courts and judicial documents that interpret these rules. The primary means by which states regulate healthcare practitioners are: (1) mandatory licensure, the most common; (2) title licensure, where a licence is needed to use a particular professional title; (3) registration, with the designated state agency; and (4) exemption from licensure requirements. In general, state regulatory boards establish educational and licensure requirements such as requiring the passing of a specific exam and minimum number of training hours.

Regulation for certain therapies is also moving faster than for others. For example, South Dakota passed a law in February of this year to regulate the state's massage therapy profession. According to the American Massage Therapy Association (AMTA), South Dakota is now the 34th state to regulate massage therapy. The first state to regulate massage therapy was Arkansas, which passed its law in 1951. Fifty-four years later, there are still 16 states with no specific regulation and in many states, massage is still regulated by individual town ordinances. This situation is one familiar to many complementary and alternative therapies in the USA.

Minnesota is a state where there is almost unlimited freedom to practise a therapy. Unlicensed practitioners must inform clients of their education, experience and intended treatments, as well as possible side effects or known risks of the treatment. Clients must sign an informed consent form acknowledging the practitioner is unlicensed, that complaints may be filed with the Minnesota Department of Health if the treatment is unsatisfactory, and that they have the right to seek licensed care at any time. Requirements for practice are minimal, but practitioners are not exempted from liability for untoward outcomes.

In a contrasting example, Washington provides licensure, registration, or exemption for various categories of therapists, based on their education and the extent to which their profession prepares practitioners to assume responsibility for the total healthcare of clients. Regulations delineate standards of practice, the scope of practice allowable, education and training requirements for licensure, registration or exemption and required professional oversight. Four therapy groups (naturopaths, acupuncturists, massage therapists and chiropractors) are licensed and regulated.

While accepting the view that the US has a multiplicity of regulatory and educational requirements for therapists, in order to facilitate future uniformity the Federation of State Medical Boards Special Committee for the Study of Unconventional Health Care Practises has begun to develop guidelines for the use of complementary therapies. These guidelines address training and education with a focus on the scientific basis of treatment methods. The American Board of Holistic Medicine has administered a board certification examination covering 13 areas of holistic medicine including nutritional medicine, environmental medicine, bio-molecular medicine, homeopathic medicine, manual medicine, ethno-medicine including acupuncture and conventional medicine.

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December 2005

CAM Regulation.doc 30th March 2007.

Chiropractic is the most developed in terms of national standards for education and training in the USA of any complementary profession. Traditional Chinese acupuncture, therapeutic massage and naturopathic medicine have moved closer than other CAM professionals to having national education and training standards. Because of this progression, these professions are appropriate candidates for conferences convened by the Department of Health and Human Services and other agencies where the leaders of the sector, conventional medicine, health professional groups, the public and other organisation will meet to facilitate the establishment of education and training guidelines. Establishing agreed levels of training, education and standards of continuing education and scope of practice is necessary if legal authority to practise a therapy is to be recognised in a wider context across the states.

As the US regulatory framework is framed by its federal nature, one of the recommendations of the report of the White House Commission on Complementary and Alternative Medicine Policy is to establish a centralised office for the sector in order to facilitate policy formulation and implementation.

It was also a recommendation of the White House Commission on Complementary and Alternative Medicine Policy that the Department of Health and Human Services should assist the states in evaluating the impact of legislation enacted in various states in terms of regulation of practitioners and ensure accountability to the public, with periodic review. It was also recommended that the Secretary of Health and Human Sciences, in collaboration with states, should assist CAM organisations that wish to develop consensus within the field of practice regarding standards of practice including education and training.⁽¹⁾

These conclusions could then be considered by states in terms of regulatory options such as registration licensure or exemption. In conclusion, it is evident that the United States is endeavouring to establish a more cohesive framework for regulation across the country and facilitate better communication, evaluation, and review of regulation between states, regulatory bodies and practitioners.

Canada

Canada, along with many other nations, is examining policy issues relating to the safety, efficacy, cost effectiveness and regulation of complementary and alternative healthcare. In the next few years, the policy choices that will be made with respect to the recognition and regulation of complementary and alternative healthcare practitioners will have a great impact on the continuing development of complementary and alternative healthcare in Canada.⁽¹³⁾

The predominant mode of regulation for health professions in Canada is self-regulation. Historically, this has been achieved after certain acceptance or recognition by the political and economic players and institutions in the health sector. Regulatory precursors to such self-regulation include direct government regulation through mechanisms such as the Acupuncture Committee in Alberta. Legislation in Canada has established three primary regulatory structures for the self-regulation of health professions.

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CAM Regulation.doc 30th March 2007.

The provinces and territories have the constitutional jurisdiction to regulate healthcare professionals, including complementary and alternative practitioners. While the national health service (Health Canada) does not have a direct role in regulation health professionals, the significant impact of complementary and alternative health practices on the health system has necessitated policy analysis in this area.

The 2001 report commissioned by Health Canada recommended four primary themes for further regulation of the sector.⁽¹⁴⁾

- The importance of government to remain cognisant of the consumer driven nature of complementary and alternative healthcare. The potential lack of an “evidence-based” approach should not necessarily be a barrier to regulation.
- Consideration of potential regulatory mechanisms should focus primarily on the identification of risk and the meaningful reduction of risk.
- Consider carefully the implications of championing complementary over alternative healthcare, or over-emphasising the concept of integration of Complementary and Alternative Health Care with conventional healthcare. Many practitioners worry that complete integration of Complementary and Alternative Health care with conventional healthcare would lead to an undermining of the holistic nature of complementary therapies which is perceived by consumers to be of great value.
- Consider the pace and extent to which governments consider regulating CAM practitioners, given the dearth of evidence about harm done to the public because of the level of current professional regulation. Government should advise for *appropriate regulation*, rather than over-regulation or under-regulation. In some cases, no regulation of practitioners of certain CAM modalities may be appropriate. Where some form of regulation is necessary, it cannot be assumed that the same type of regulation is necessary for all CAM modalities.

Australia

Regulation of practitioners in Australia is the responsibility of various state governments. Currently, Victoria is the only Australian jurisdiction to formally regulate therapists, requiring practitioners who use the title “Acupuncturist”, “Chinese Herbal Medicine Practitioner”, and “Chinese Medicine Practitioner” to register with the Chinese Medicine Registration Board. However, all state jurisdictions have legislation (with varying requirements) for the registration of chiropractors and osteopaths. Most therapists are therefore subject only to varying forms of professional self-regulation.

However, the federal Government is getting involved in funding some groups of practitioners to explore avenues for self-regulation. Under A New Tax System (Goods and Services Tax) Act 1999, complementary and alternative practitioners had to satisfy the definition of being a recognised professional in order to continue to supply their services GST-free beyond 30 June 2003. To this end, the Australian Government has provided AUS\$500,000 to help professional associations form national professional registration systems for acupuncture, naturopathy and herbal medicine practitioners. The funding was spread between the

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December 2005

following groups: National Herbalists Association of Australia; Australian Traditional Medicine Society Ltd; Australian Natural Therapists Association Ltd; Federation of Natural and Traditional Therapists; and Australian Acupuncture and Chinese Medicine Association Ltd. ⁽¹⁵⁾

New Zealand

New Zealand has taken a risk-based approach to the statutory regulation of health practitioners and to date has provided for the statutory regulation of two therapies; chiropractic and osteopathy. Other therapies are at various stages of self-regulation through a range of therapy-based professional bodies and/or through the multi-therapy body, the New Zealand Charter of Health Practitioners.

The 2003 Health Practitioners Competence Assurance Act stresses the importance of the health and safety of the public and an accountability regime for practitioners. Most importantly for the professions under discussion, it also provides an opportunity for additional complementary modalities to be covered under the Act. Again, the risk-based approach is primary here and chiropractic and osteopathy were regulated under this act as they were felt to have appropriate level of risk for consumers.

In 2004, the Ministerial Advisory Committee on Complementary and Alternative Health (MACCAH) published its report into the sector with advice to the Minister for Health on policy.⁽²⁾ The MACCAH report examined the issue of statutory regulation for therapies while favouring the risk-based approach. The report also notes that other countries are at a similar stage of considering statutory regulation but that no country has yet provided a best practice model for New Zealand.

For future policy, the report concludes that an increased level of regulation of practitioners is needed to effectively protect New Zealand consumers from the risks involved with complementary and alternative healthcare. On the basis of the information available to them, the report recommends that strong self-regulation through professional bodies is the best way to protect consumers and that a strong regulatory framework, including such elements as those set out in the House of Lords Report, is the most desirable basis for regulation.

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Complementary Therapists to the Minister for Health and Children
December 2005

CAM Regulation.doc 30th March 2007.

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CAM Regulation.doc 30th March 2007.