

Ministerial Advisory Committee on
Complementary and Alternative Health

Te Kōmiti Tohutohu Minita mō te Hauora Whakahāngai

Complementary and Alternative Health Care in New Zealand

Advice to the Minister of Health

From the
Ministerial Advisory Committee
on
Complementary and Alternative Health

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Terms of Reference

The Ministerial Advisory Committee on Complementary and Alternative Health (MACCAH) was established in July 2001 under Section 11 of the New Zealand Public Health and Disability Act 2000 to provide independent advice to the Minister of Health on matters related to complementary and alternative medicine in New Zealand.

The key tasks for the Committee to address during its three-year term were to:

- (a) provide information and advice to the Minister on complementary and alternative health care
- (b) provide advice on the need, or otherwise, to regulate complementary and alternative health care practitioners in order to protect consumers who use complementary and alternative health care
- (c) provide advice on consumer information needs and, in particular, advice on the benefits, risks and costs of complementary and alternative therapies
- (d) review overseas evidence-based research, identify priorities for the development of New Zealand evidence-based research on the safety and efficacy of specific complementary and alternative therapies and support the development of guidelines
- (e) provide advice on whether, and how, specified complementary and alternative health practitioners should be integrated into the mainstream system
- (f) provide advice on how complementary and alternative health care can improve outcomes in the priority areas signalled in the New Zealand Health Strategy.

This document presents the Committee's final advice to the Minister of Health, Hon Annette King.

Committee Foreword

The Ministerial Advisory Committee on Complementary and Alternative Health (MACCAH) met regularly throughout its term, to discuss issues relating to each Term of Reference. It began by undertaking an environmental scan of relevant national and international information. This scan highlighted the need to develop a common terminology for use by the Committee that would be relevant to the New Zealand situation.

In November 2002, MACCAH published on-line its *Terminology in Complementary and Alternative Health* that spelt out the terminology MACCAH would use to discuss both complementary and conventional forms of health care. It also listed some of the therapies included within MACCAH's definition of 'complementary and alternative medicine', and outlined the model that MACCAH had developed to categorise such therapies.

MACCAH used this initial work to identify issues in its discussion document, *Complementary and Alternative Medicine: Current Policies and Policy Issues in New Zealand and Selected Countries*, which was released, along with a Submission Booklet containing questions for public response, in April 2003. These questions sought views on MACCAH's Terms of Reference: regulation; consumer information needs; research; evidence and efficacy; and integration. The views of the public were sought through written submissions, public presentations held in three centres, and the hearing of oral submissions in May and June 2003.

By the closing date, the Committee had received 315 written submissions from individuals and organisations, and heard 13 oral submissions as well as the views of those who spoke at the public meetings. The Committee read and discussed the views that were presented in submissions and prepared a Summary of Submissions (see Appendix A8 for the Executive Summary).

Of the 315 submissions received, approximately two thirds (212) were from individuals and 103 from organisations. The majority of submissions (145) were from a CAM perspective, 68 had a predominantly biomedical perspective (those submitting included doctors, nurses/ midwives and physiotherapists), 65 were from individual members of the public, and 42 submissions included an educational perspective. Smaller numbers of submissions brought other perspectives (see Appendix A8 for further details).

Taking into account the submissions it received, MACCAH continued to research questions relevant to the Terms of Reference, through further searches of the international literature, the activities of other countries and New Zealand experiences.

During MACCAH's term, other health sector developments impacted on areas relating to its Terms of Reference. These included the Government's decision to form a Trans-Tasman Therapeutic Goods Agency to regulate therapeutic products, and the introduction of the Health Practitioners Competence Assurance Act during 2003. In addition, in March 2004, the Ministry of Health launched an on-line Complementary and Alternative Medicine (CAM) database.

In developing its advice, MACCAH has been mindful of other health sector initiatives, in particular the ongoing implementation of the New Zealand Health Strategy, the Primary Health Care Strategy and other population based strategies.

Throughout its term, MACCAH drew on member's expertise in:

- CAM education, practice and professional bodies (including the modalities of Aromatherapy, Homeopathy, Iridology, Massage, Naturopathy, Nutritional Medicine, Sclerology, Traditional Chinese Medicine and Acupuncture)
- medical education and practice (General Practice, Nursing, Public Health Medicine, Māori Health, Pacific Health)
- consumer advocacy
- provision of advice to government and the World Health Organization
- Rongoa Māori
- tertiary education in New Zealand
- health policy
- research and research methodologies in the areas of social science, medicine and statistics.

Members of the Ministerial Advisory Committee on Complementary and Alternative Health have had a very interesting and busy three years and are pleased to offer this advice as the output of their activities. The Committee's term finishes on 30 June 2004, and each member is looking forward to further developments in the Government's consideration of the place of complementary and alternative medicine in health care.

A handwritten signature in black ink, appearing to read 'P. Koopman-Boyden', is written over a long, thin horizontal line that extends to the left and right of the signature.

Prof Peggy G Koopman-Boyden CNZM
Chair
Ministerial Advisory Committee on Complementary and Alternative Health

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Chapter 1: Setting the Scene

1.1 What is Complementary and Alternative Medicine (CAM)?

The Ministerial Advisory Committee on Complementary and Alternative Health (MACCAH), has adopted the definition of complementary and alternative medicine developed at a 1997 conference of the United States' Office for Alternative Medicine of the National Institutes of Health (and subsequently adopted by the National Center for Complementary and Alternative Medicine):

Complementary and alternative medicine (CAM) is a broad domain of healing resources that encompasses all health systems, modalities, and practices, and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period. CAM includes all such practices and ideas self-identified by their users as preventing or treating illness or promoting health and well being (O'Connor et al, 1997).

It is important to realise that CAM is an 'umbrella' term used to describe a range of health systems, modalities and practices that may have little in common other than that they are practised alongside or as an alternative to mainstream medicine. There can be great variation in the nature and degree of training required to become competent in the practice of individual CAM forms. There may however be similarities in philosophy and approach – for example, the need to take a holistic approach to health care, including the interactions between physical, spiritual, social and psychological aspects. CAM may also involve practitioners working and supporting a person to determine what they themselves can do to maintain or improve their health, reduce the likelihood of illness, illness or disease, or maximise the effectiveness of treatments or other forms of relief.

With this in mind, MACCAH reviewed existing systems of classifying CAM modalities, and agreed to adapt the United States National Centre for Complementary and Alternative Medicine model to fit the New Zealand context. This model categorises forms of complementary and alternative health care into categories based on the characteristics of the different therapies: Alternative Medical Systems; Mind, Body, Spirit Interventions; Biological Based therapies; Manipulative and body-based therapies; and Energy Therapies (Appendix A2 provides details).

In this document, MACCAH has chosen to use the term 'modality' to describe a form of complementary and alternative medicine (such as acupuncture or reflexology), and the more neutral term of 'biomedicine' to refer to mainstream medical practice.

1.2 The context and focus of MACCAH's deliberations

Provision of most complementary and alternative health care occurs outside the publicly funded health system in New Zealand, and outside a specific legislative framework. Only chiropractors are statutorily regulated, though they will be joined shortly by osteopaths who will also be regulated under the Health Practitioners Competence Assurance Act 2003.

This means that information is not readily available about the dynamics of the CAM sector. Furthermore, there is no statutory requirement for any organisation to collect information about:

- the numbers of practitioners and the modalities practised
- the similarities and differences between practitioners in terms of nature and extent of training
- the nature, function and power of professional and self-regulatory bodies
- the extent of formal and informal interactions with biomedical practitioners, organisations or systems.

Towards the end of its term MACCAH was able to obtain provisional results from the 2002/03 New Zealand Health Survey about the number and nature of visits made to complementary and alternative health practitioners. Such data (which can be generalised to the New Zealand adult population) show nearly one in four adults had seen a complementary and alternative health practitioner in the previous 12-month period (further details are in Appendix A3).

Key elements of MACCAH's discussion and communications under each Term of Reference include:

Regulation – MACCAH members identified and discussed the regulatory framework needed to protect consumers and decided that a risk-based approach was appropriate. The Committee also discussed the role of regulation in developing professionalism within a modality and the respective roles of the Government, CAM and biomedical regulatory bodies and education and training bodies in achieving this. MACCAH recognised the role that a strong system of regulation may play in moves towards the integration of CAM with biomedicine, and noted concerns about the potential effect of regulation in conferring unwarranted legitimacy on a practice, and also the effect, through compliance costs, on the numbers of practitioners and eventual consumer choice.

Consumer information – MACCAH members agreed on the need for more information and discussed what the nature of this information should be. The importance of providing consumers with balanced and neutral information on the role, safety and effectiveness of CAM was emphasised in discussions along with the means by which this might occur. The development of the Ministry of Health CAM database was of great interest to members, and there was much discussion about the levels of evidence for safety and efficacy that should be used in the summaries being prepared. Members were pleased to be able to convey their concerns to the

developers of the database about discrepancies in the levels of evidence being used for proof of efficacy and the levels of evidence for potential harm (safety). There was also concern about the limitation of such a database to locate unpublished research, particularly that undertaken in non-English cultural contexts. In addition, MACCAH noted consumers' needs for information about practitioners, including how to locate and assess the quality of practitioners, and about what to do if something went wrong.

Research and evidence – MACCAH members saw the increased availability of research findings about safety and efficacy as the key to a greater role for CAM within the New Zealand health system. This would involve the development of an infrastructure making better use of existing findings and identifying priority areas for New Zealand research. The Committee also grappled with issues about the levels of evidence required to prove specific CAM practices as safe and effective for the health care functions they may perform. MACCAH concluded that consensus on the methods and levels of evidence necessary for researching CAM is vital, along with ensuring that the existing research funding infrastructure is aware of this. MACCAH also considered that alongside research on specific modalities, there is a need for more research on the characteristics of CAM practice and regulation in New Zealand.

Integration – MACCAH members considered the various meanings of integration, what is known about current interactions between CAM and biomedicine in New Zealand, and the factors that need to be looked at if any further integration is to take place. The Committee discussed the desirability and challenges of different types of practitioners working together and also considered health consumer perspectives. From its deliberations, MACCAH concluded that a robust regulatory system and an evidence base which is strong or has potential (yet to be defined) should form the basis of further integration in New Zealand. However, MACCAH also recognised that for many consumers integrating different forms of health care is a reality, and it is in the interests of consumer safety that both biomedical and CAM practitioners work with each other in sympathetic ways. This is likely to involve further initial and ongoing education of biomedical practitioners about CAM modalities and New Zealand based regulation. It may equally require ongoing education of CAM practitioners about referrals and relevant minimum levels of understanding of anatomy, physiology and first aid.

New Zealand Health Strategy – MACCAH members acknowledge that there is potential for complementary and alternative health care to contribute to outcomes specified in the New Zealand Health Strategy. Key considerations are the orientation of complementary and alternative health care towards a holistic approach to health, and an emphasis on support for consumers making lifestyle changes. MACCAH also recognises that those funding health care need to be making sound and population appropriate decisions and that a dual approach is required. The first is the development of an infrastructure to ensure that information about safety and efficacy is available to decision makers as it emerges; the second approach requires that, where there is sufficient potential (according to the criteria to be developed), pilot studies should be established to enable the systematic collection of relevant information in these areas.

1.3 Guiding principles

The Committee applied the following principles in developing its advice:

- (a) a holistic concept of health that combines the definition of health developed by the World Health Organisation and 'Whare tapa wha', the four-sided house concept of health developed by Professor Mason Durie:

Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. (World Health Organisation, 1948)

Whare tapa wha incorporates taha wairua, a spiritual focus; taha hinengaro, mental focus; taha tinana, physical focus; and taha whanau, extended family. (Mason Durie, 1998)

- (b) recognition that health care may involve the maintenance of health and well being, the prevention or treatment of illness, disease and injury and/or relief from the effect of illness, disease, injury or treatment
- (c) patient satisfaction is an important health outcome (together with any reduction in symptoms)
- (d) participation and shared responsibility by both patients and practitioners
- (e) balancing health consumers' needs for health care options with those of safety and efficacy
- (f) maximisation of public health gains within the constraints of limited health resources
- (g) reduction of disparities both in access to effective health care and in health outcomes
- (h) acknowledgement of the special relationship between Māori and the Crown under the Treaty of Waitangi
- (j) recognition of the growing ethnic diversity within New Zealand and implications for the demand and provision of health care
- (k) consistency with the goals of the New Zealand Health Strategy.

Traditional Māori healing

It should be noted that the development of policy advice in the area of traditional Māori healing is being led by the Ministry of Health's Māori Health Directorate in the context of implementing He Korowai Oranga, the Māori Health Strategy. As a result, MACCAH has not included this area in its advice.

1.4 Recommendations

Regulation

Term of reference – to provide advice on the need, or otherwise, to regulate complementary and alternative health care practitioners in order to protect consumers who use complementary and alternative health care.

MACCAH Recommendations:

1. Practitioners of complementary and alternative health should be regulated according to the level of inherent risk involved in the modalities they practise.
2. The process of regulating practitioners of high-risk CAM modalities should continue under the Health Practitioners Competence Assurance Act 2003.
3. Practitioners of lower-risk CAM modalities should be encouraged to self-regulate through their professional body.
4. Practitioners (either biomedical or CAM) who practise one or more CAM modalities should undertake training and monitoring that is appropriate to the risk of each CAM modality.

Consumer information

Term of reference – to provide advice on consumer information needs and, in particular, advice on the benefits, risks and costs of complementary and alternative therapies.

MACCAH Recommendations:

5. Consumers should have ongoing access to evidence-based information on the efficacy and safety of CAM therapies. As one way of achieving this, MACCAH recommends that the Ministry of Health continue to fund research summaries from the Complementary and Alternative Medicine Database (CAM Database).
6. The Ministry of Health should fund research on the needs of consumers for CAM information.

Evidence and research

Term of reference – To review overseas evidence-based research, identify priorities for the development of New Zealand evidence-based research on the safety and efficacy of specific complementary and alternative therapies and support the development of guidelines.

MACCAH Recommendations:

7. The Ministry of Health should encourage research-funding bodies to facilitate further research on complementary and alternative medicine.
8. The wide range of methodologies appropriate for researching the safety and efficacy of CAM should be used and recognised by CAM researchers and research funding bodies.
9. Recognition should be given, by research funding bodies, healthcare professional organisations and educational institutions, to the relevance and importance of research at different levels of evidence for the efficacy and safety of CAM.

Integration

Term of reference – to provide advice on whether, and how, specified complementary and alternative health practitioners should be integrated into the mainstream system.

MACCAH Recommendations:

10. Where there is evidence of safety, efficacy and cost effectiveness, specified CAM modalities should be considered for public funding.
11. Health care education and training bodies should be encouraged to include elements of CAM and biomedicine in each other's curriculum. A national curriculum committee should be established to develop policy on this.
12. Research should be undertaken to establish best practice for the integration of the approved CAM modalities with biomedicine.
13. District Health Boards should be provided with guidance on the appropriateness of integration initiatives.
14. The Ministry of Health should encourage the District Health Boards to establish pilot studies to identify the practicalities, costs, benefits and health outcomes that would accompany CAM and biomedical practitioners working together.

New Zealand Health Strategy

Term of reference – to provide advice on how complementary and alternative health care can improve outcomes in the priority areas signalled in the New Zealand Health Strategy.

MACCAH Recommendations:

15. Where there is evidence of safety, efficacy and cost-effectiveness in contributing to the New Zealand Health Strategy, use of specific CAM modalities should be encouraged.
16. Where evidence of safety, efficacy and cost-effectiveness of a CAM is inconclusive but has potential, research should be undertaken into the contribution that the CAM may make to the New Zealand Health Strategy outcomes.
17. Further information about the contribution of CAM towards the New Zealand Health Strategy priorities should be developed and distributed for use by health care decision makers, health professionals and consumers.

Where to Next?

18. The Minister of Health should develop a framework (or unit) to coordinate the existing expertise and build a CAM capacity to better evaluate the safety and efficacy of CAM in the interests of further integration of biomedicine and CAM.

1.5 Chapter 1 references

Durie M. 1998. *Whaiora: Māori Health Development*. 2nd edition. Auckland: Auckland University Press.

New Zealand Public Health and Disability Act 2000.

O'Connor B, Calabrese C, Cardena E, et al. 1997. Defining and describing complementary and alternative therapies. *Alternative Therapies* 3(2): 49.

Preamble to the Constitution of the World Health Organisation as adopted by the International Health Conference, New York, 19–22 June 1946 signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organisation, no 2, p 100) and entered into force on 7 April 1948.

Chapter 2: The Regulation of Complementary and Alternative Health Practitioners

2.1 Term of reference

To provide advice on the need or otherwise to regulate complementary and alternative health practitioners in order to protect consumers who use complementary and alternative health care.

2.2 Context of recommendations

The Ministerial Advisory Committee on Complementary and Alternative Health has considered:

- international approaches to the regulation of complementary and alternative health practitioners
- current New Zealand approaches, both in terms of regulating health practitioners generally and the regulation of CAM practitioners specifically
- how consumers might be protected through the identification and management of risks associated with CAM practice
- the role of regulation in managing risks
- the benefits, costs and risks of regulation, including their effect on consumer choice and practitioner costs.

MACCAH has concluded that:

- an increased level of regulation of CAM practitioners is needed to effectively protect New Zealand consumers from the risks involved with CAM practice
- more information is needed about existing forms of regulation.

Risks can be broadly categorised into two types. Common risks are shared by all health professionals and include the making of misleading claims, possibilities of professional misconduct, and environmental risks. Inherent risks are specific to the practice of a particular modality and include risks involved with the nature and the intensity of the techniques used and the potential for side effects or interactions with other forms of treatment.

To better protect New Zealand consumers, MACCAH suggests that practitioners of modalities with a greater inherent risk should be required to meet a higher degree of regulation. In addition, consideration may need to be given to the number of consumers being treated by a practice. However practitioners of lower risk modalities should also be encouraged to form, or continue to belong to, modality-based or profession-based regulatory bodies.

At the same time, MACCAH recognises that many complementary and alternative health practitioners practise more than one modality, and that some biomedically trained practitioners practise one or more CAM modalities. For this reason, MACCAH suggests that practitioners of all modalities should meet minimum standards of training and be monitored in their practice in each modality.

MACCAH Recommendations:

1. Practitioners of complementary and alternative health should be regulated according to the level of inherent risk involved in the modalities they practise.
2. The process of regulating practitioners of high-risk CAM modalities should continue under the Health Practitioners Competence Assurance Act 2003.
3. Practitioners of lower-risk CAM modalities should be encouraged to self-regulate through their professional body.
4. Practitioners (either biomedical or CAM) who practise one or more CAM modalities should undertake training and monitoring that is appropriate to the risk of each CAM modality.

2.3 What are the issues?

MACCAH has investigated the rules and directives that might be required to optimise the safety of CAM consumers. The Committee has also considered the type of authority that is best placed to make and maintain these rules and directives. Finally, MACCAH has taken into account the extent to which such mechanisms already exist or need further developing in New Zealand.

MACCAH has looked at these matters by asking the following questions:

- Do consumers need protecting from complementary and alternative health practitioners? (Section 2.4)
- How can regulation protect consumers? (Section 2.5)
- To what extent are consumers protected already? (Section 2.6)
- What further regulation is required? (Section 2.7)
- How should multiple modality CAM practitioners be regulated? (Section 2.8)
- How should biomedical practitioners of CAM be regulated? (Section 2.9)

2.4 Do consumers need protecting from complementary and alternative health practitioners?

The practice of complementary and alternative health care, like the practice of biomedicine, involves two broad categories of risk that may result in harm: the first relates to causes of potential harm that could be associated with any health care practitioner; the second involves potential harm that might result from modality-specific risks.

General risks consumers may face from all health practitioners:

- misleading claims leading to financial and other losses
- unsafe or unsanitary environment
- lack of appropriate referral, resulting in delays in receiving effective treatment
- lack of first aid knowledge in dealing with emergencies.

Inherent risks consumers may face from the nature of particular CAM modalities include:

- tissue, nerve, organ damage
- aggravation of injuries
- infections
- poisoning, allergic reaction or interactions with other forms of treatment
- psychological, cultural and spiritual harm.

Some groups may face additional risks because of their vulnerability under a regulatory system. Examples include children who tend not to make their own choice of health care practitioner, and those coping with a severe disability or terminal illness.

2.5 How can regulation protect consumers?

The containment of the risks involved with complementary and alternative health practitioners can be managed in a number of ways, some of which are identified in the United Kingdom House of Lords' Report:

Risks addressed	Strategies for containing the risk
<ul style="list-style-type: none"> • Unprofessional or unethical behaviour • Lack of monitoring of practice • Unsafe or unsanitary environment • Financial loss • Lack of redress if something goes wrong 	A code of conduct, a disciplinary procedure and a complaints procedure
<ul style="list-style-type: none"> • Lack of training or competency in relation to each modality practised • Lack of professional development • Unprofessional or unethical behaviour • Lack of first aid knowledge 	Minimum standards of training, supervision of training courses, and accreditation
<ul style="list-style-type: none"> • Misleading claims leading to financial and other losses • Lack of appropriate referral 	Provision and publication of information on CAM Better understanding and advertising of areas of competence, including the limits of competence within each therapy
<ul style="list-style-type: none"> • Lack of monitoring of practice 	An up-to-date register of qualified practitioners.

Adapted from the British Medical Association model cited in House of Lords Science and Technology, Sixth Report 2000: 5:14.

Forms of regulation

Regulation is a key means of containing the risks involved with CAM. The main forms of practitioner regulation relate to authority setting and maintaining the rules and directives. They are:

- self-regulation, where a professional body sets and maintains regulations. This body can have either a modality-specific or multi-modality focus
- statutory regulation, where a statutory body is responsible for setting regulations and ensuring that practitioners comply. Because statutory regulation is enforceable by law, this is generally regarded as a stronger form of regulation.

In addition to these specific forms of regulation, CAM practitioners must also operate within a broader legislative framework that includes legislation and regulations applying to those in business and/or specifically in the health sector.

2.6 To what extent are consumers protected already?

As in other countries, 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 CAM professions – Chiropractic (from 1982) and Osteopathy (the regulatory authority is currently being established). Other CAM modalities are at various stages of self-regulation through a range of modality-based professional bodies and/or through the multi-modality body, the New Zealand Charter of Health Practitioners.

In their documentation, many of these bodies appear to have adopted a regulatory system with features that would comply with best practice (for example see Appendix A4).

To date there has not been a systematic review of the coverage and actual operation of CAM practitioners associations and their processes in New Zealand. Such a review appears to have been useful internationally in helping countries set their regulation agenda. For example, the United Kingdom House of Lords' Report (2000), which provided a brief review of the function and operation of regulatory bodies in the United Kingdom and Ireland, is planning a similar review as it moves towards statutory regime for all complementary and alternative health practitioners.

In New Zealand, the Health Practitioners Competence Assurance Act 2003 Section 3(1) states that:

The principal purpose of the Act is to protect the health and safety of members of the public by providing for mechanisms to ensure that health practitioners are competent and fit to practice their professions.

Subsection (2) lists the provisions within the Act that facilitate:

- a consistent accountability regime for all health professionals
- the determining of a scope of practice that individual practitioners are competent to practise within, and systems to ensure practitioners do not do so beyond that scope
- powers to restrict specific activities to particular classes of health practitioner in order to prevent members of the public from risk of serious or permanent harm
- protections for practitioners who take part in protected quality assurance activities
- additional health professions becoming subject to the Act.

This last point provides an opportunity for additional CAM modalities to be covered under the Act.

The threshold for inclusion under this Act is based on the Government's overall framework for statutory regulation of occupations. In 1998, Cabinet (CO(99)6) agreed to a policy framework on occupational regulation to be used by all government agencies and departments that become involved in regulating new occupations or reviewing existing occupational regulation. This framework identifies the steps to be taken in considering whether Government should take a role in occupational regulation.

In deciding whether to regulate, the Cabinet framework considers the severity of potential harm and whether the problem is unlikely to be solved in any other way. If statutory regulation is required, the framework establishes the principle that the degree of intervention should be the minimum required to solve the problem, and that the benefits of such intervention must exceed the costs (Ministry of Commerce, 1999).

Examples of New Zealand statutes and regulations that relate to the New Zealand CAM practitioners are provided in the Appendix (see Appendix A5).

2.7 What further regulation is required?

MACCAH deems a risk based approach to statutory regulation to be appropriate, and that regulation of chiropractic and identification of osteopathy under the HPCA Act 2003 is appropriate in terms of the inherent risks involved and the training needed for the safe practice of each of these modalities.

Provisional data from the 2002/03 New Zealand Health Survey indicates that 6.1 percent of New Zealand adults visited a chiropractor at least once during a 12-month period and 4.9 percent visited an osteopath. The only practitioners visited by more New Zealand adults during that period were massage therapists (9.1 percent).

As to whether other modalities should work towards statutory regulation, MACCAH has noted that several other countries are at a similar stage in considering further statutory regulation of CAM practitioners or currently investigating implementation issues and that no country as yet provides a best practice model.

The United States White House report recommended that the effects of different regulatory regimes be investigated in terms of consumer choice and consumer protection (White House, 2000). Ireland has decided on the statutory regulation of complementary and alternative health practitioners. In surveying a number of European countries, O'Sullivan (2002) describes how these countries are moving 'very cautiously' towards regulation.

In particular, consideration is being given to the statutory regulation of:

- herbal medicine (by United Kingdom). In New Zealand, 1.8 percent of all adults had visited a herbalist at least once during the previous 12 months according to Provisional Results of the 2002/03 New Zealand Health Survey.
- acupuncture (by United Kingdom). 2.6 percent of all New Zealand adults visited an acupuncturist at least once during the previous 12 month period.
- traditional Chinese Medicine (by Australia). 1.4 percent of all New Zealand adults and 4.8 percent of Asian New Zealand adults visited a TCM practitioner at least once during the previous 12 month period.
- massage therapists (by United States). As indicated earlier, 9.1 percent of all New Zealand adults visited a massage therapist at least once during the previous 12 months (Ministry of Health, unpublished, see Appendix A3).

MACCAH also considered the views of submissions made in response to its 2003 discussion document *Complementary and Alternative Medicine: Current Policies and Policy Issues in New Zealand and Selected Countries*. The majority of submissions favoured some form of regulation. A few did not support regulation because they thought it would restrict access to practitioners and products. Others thought that regulation would confer an unwarranted status on CAM practitioners and would run

counter to achieving consumer or public safety (particularly if consumers sought ineffective treatments and delayed seeking proper medical attention).

Of those in favour of regulation, views were divided about whether statutory or voluntary regulation would be more effective in addressing consumer and public safety issues. Those who favoured statutory regulation suggested voluntary schemes would not have the necessary status to enforce standards and disciplinary processes. Those who favoured a voluntary approach thought that a process managed by professional organisations (rather than the Government) would encourage a greater ownership of regulation and thus be more effective in achieving safety. Whatever the style of regulation favoured, an approach based on risk to consumers was advocated by many of the submissions.

On the basis of information available to date, MACCAH believes consumers will be adequately protected from the risks involved with CAM practice through strong self-regulation by the professional bodies of each modality or by multi-modality organisations. In MACCAH's view a strong regulatory framework would include elements such as those set out in the United Kingdom House of Lords' Report *Modern Principles of Statutory Self Regulation in the Health Field* (see Appendix A4).

MACCAH has also identified specific issues associated with multiple modality practitioners and the practice of CAM by biomedical practitioners. These are discussed below.

2.8 How should multiple CAM modality practitioners be regulated?

Many practitioners practise several CAM modalities. The risk is that consumers may not be able to identify the level of competency a practitioner has in each modality. MACCAH suggests therefore that all practitioners be required to complete minimum standards of training specific to each of the modalities they practise. This approach would need to accommodate the possibility of cross-crediting for training that is general to all health care practice (for example, dealing with emergencies, referral practices and so on) or where there is a common philosophical base to the modalities practised (for example, acupuncture and Chinese herbal medicine).

Applying a risk based approach to the regulation of multiple CAM modality practitioners

Example 1: Combining two higher risk CAM modalities – herbalist/massage therapist

- The inherent risks involved with herbal medicine include poisoning, allergic reactions and injury.
- The inherent risks involved with massage include tissue or nerve damage or exacerbation of injury.

MACCAH suggests that:

- basic anatomy/physiology be cross-credited
- basic standards of training be met in the use of herbs/massage techniques as specified by relevant regulatory bodies
- each form of practice should be monitored by the respective regulatory organisation.

2.9 How should biomedical practitioners of CAM be regulated?

Biomedical practitioners of CAM refers, in this instance, to health professionals including doctors, physiotherapists, nurses (and soon midwives) who are already regulated by statute under the Health Practitioners Competency Assurance Act 2003 (HPCA 2003).

The risk is that consumers might well assume that, because a practitioner is regulated by statute, they are competent in the practice of the CAM they offer. This is not necessarily the case. They may, for example, have only attended an introductory training session on the modality.

Again, MACCAH suggests that dual practitioners be required to complete minimum standards of training specific to each of the modalities they practise. This approach also accommodates the possibility of cross-crediting for training that is general to all health care practice (for example, dealing with emergencies and referral practices).

The HPCA Act 2003 sets out how the scope of each health practitioner's practice is to be determined. Section 11 of the Act details the requirements for professional regulatory authorities to describe the contents of the profession in terms of one or more scopes of practice. These scopes of practice can be described by reference to:

- a name or form of words that is commonly understood by those working in the health sector
- areas of science or learning
- tasks commonly performed
- illnesses or conditions to be diagnosed, treated or managed.

Section 12 of the Act sets out the requirement for authorities to describe the qualification or qualifications required for each scope of practice.

Applying a risk-based approach to the regulation of dual practitioners (biomedical/CAM)

Example 2: Combining two paradigms of health – doctor/acupuncture

- This practitioner's biomedical practice is regulated by statute under HPCA Act 2003. It is not clear whether acupuncture falls within the scope of practice defined by the relevant regulatory authority, the New Zealand Medical Council. We will assume that it does not for the purposes of this example.
- The issue is whether a practitioner should be required to comply with further regulation in order to ensure consumer protection.

Are they sufficiently competent in the practise of acupuncture to manage the inherent risks involved with acupuncture (for example, infection, organ puncture)?

MACCAH suggests that the practitioner should meet minimum standards of training for acupuncture and that the acupuncture practice is monitored.

However this raises a number of issues.

- Traditional Chinese medicine (from which acupuncture originates), is based on a different paradigm of health. Some argue that a practitioner cannot operate effectively from two perspectives of health. Others argue that acupuncture can be practised as a technique.
- There are several bodies regulating acupuncture in New Zealand including a Medical Acupuncture group. Each may have different ideas about the minimum levels of training that need to be met.

2.10 Ongoing issues

Unique issues involved in the regulation of CAM

Unique challenges facing the regulation of CAM were identified in the United States White House Commission on Complementary and Alternative Medicine Policy (2002:94) report as:

- the variation in the views of CAM practitioners about how much training is needed to attain regulation status in a given field, and how education and training can incorporate intuitive skills and individualised approaches to providing health care services. There is a tension between the desire to increase standardisation of CAM education training and practices while at the same time keeping CAM practice flexible, non-standardised and linked to subjective, interpersonal and intuitive aspects of care. Increased regulation may facilitate research, ease referrals, enhance patient access and increase consumer protection, but it may also decrease the individualisation of services, the time spent per patient and the range of patient options. These qualities are valued by both practitioners and patients alike.
- disagreement surrounding the nature and scope of some CAM professions. This can make it difficult to assess what value-added CAM services offer.

- confusion and potential legal consequences arising from the overlap of approaches and techniques used by CAM practitioners.

All of these views were echoed in the submissions received by MACCAH in response to its 2003 discussion document *Complementary and Alternative Medicine: Current Policies and Policy Issues in New Zealand and Selected Countries*.

Statutory regulation confers legitimacy

MACCAH recognises that some groups of practitioners see statutory regulation as a means to gain legitimacy with consumers and biomedical practitioners, facilitate integration and access public health funds. MACCAH suggests that using regulation for these reasons, in contrast to a risk-based approach, is not the best means of achieving these aims.

In MACCAH's view the costs of statutory regulation are not warranted for low risk modalities. Instead MACCAH encourages such groups to consider how these ends might be better achieved through the recommendations made in other chapters.

Relationship between education, training and regulation

MACCAH makes a distinction between the role of regulatory bodies and the role of education or training bodies in practitioner education and professional development. Regulatory bodies are responsible for the setting, monitoring and enforcing of minimum practitioner education standards and of requirements for ongoing professional development whereas education and training bodies are responsible for delivering the training and education that will help practitioners meet these requirements but which may be wider in focus than the achievement of minimum requirements.

MACCAH considered whether it was necessary to make a recommendation directed to education and training bodies to facilitate the protection of consumers of complementary and alternative health care. After discussion, the Committee decided that the recommendation to regulate according to inherent risk was sufficient and in line with the activities of other professional groups. It would be expected that regulatory bodies would alert education/training bodies if they considered standards of education were inappropriate.

Need for more information on current self-regulation

As stated earlier, while not included as a recommendation, MACCAH suggests that consideration be given to funding research into the nature of CAM professional organisations in New Zealand. The purpose of this research would be to determine the extent to which current regulatory practices conform to the best practice suggested in the House of Lords' Report (see Appendix A4) and to identify the ways in which self-regulating bodies can increase their effectiveness and better protect consumers. Such a process has already been undertaken in the United Kingdom, and has recently been recommended in Ireland where O'Sullivan (2002) has suggested that

statistics should be collected on complementary and alternative therapies, including numbers practising, scopes of practice, and information on their representative/regulatory bodies.

2.11 Chapter 2 references

Health Practitioners Competence Assurance Act 2003.

House of Lords' Select Committee on Science and Technology. 2000. *Complementary and Alternative Medicine*. London: The Stationery Office.

Ministry of Commerce. 1999. Booklet: Policy Framework for Occupational Regulation: A guide for Government Agencies Involved in Regulating Occupations. Wellington: Competition and Enterprise Branch, Ministry of Commerce.

http://www.med.govt.nz/buslt/bus_pol/policyframework/index.html.

Ministry of Health. 2004. Unpublished. *Provisional Results of the 2002–03 New Zealand Health Survey*, provided to MACCAH, May 2004.

O'Sullivan T. 2002. *Report on the Regulation of Practitioners of Complementary and Alternative Medicine in Ireland*. Health Services Development Unit, Institute of Public Administration.

Chapter 3: Consumer Information Needs

3.1 Term of reference

To provide advice on consumer information needs and, in particular, advice on the benefits, risks and costs of complementary and alternative therapies.

3.2 Context of recommendations

The Ministerial Advisory Committee on Complementary and Alternative Health has considered:

- international approaches on how best to identify and meet the information needs of consumers regarding the benefits, risks and costs of complementary and alternative therapies
- whether current sources deliver adequate information on the benefits, risks and costs of these therapies to New Zealand consumers
- the lack of information available on what New Zealand consumers themselves want to know about the benefits, risks and costs of complementary and alternative therapies (including their preferred style and content of information, where they would like the information to be located and how that information might be made available – for example, through the Internet or print).

MACCAH recognises that increasing the quality of consumer information on CAM – making the information easy to obtain and understand, more accurate and transparent in terms of its perspective – could go some way towards helping New Zealand consumers make better and more confident decisions about the type of CAM health care provider they choose.

Whether they are looking to maintain good health, prevent or treat illness, injury or disease, or gain relief from the effects of illness, injury, disease or other forms of treatment, better information could help consumers maximise the benefits they gain from health care, minimise risks and be better informed on what to do if things go wrong.

For these reasons, it is MACCAH's view that information on CAM used to improve the match between patient, practitioner and health concern, and also to increase the efficiency of health consultations, will have flow on effects that help meet New Zealand's wider health goals.

MACCAH Recommendations:

5. Consumers should have ongoing access to evidence-based information on the efficacy and safety of CAM therapies. As one way of achieving this, MACCAH recommends that the Ministry of Health continue to fund research summaries from the Complementary and Alternative Medicine Database (CAM Database).
6. The Ministry of Health should fund research on the needs of consumers for CAM information.

3.3 What are the issues?

A consumer seeking further detail on the benefits, risks and costs of complementary and alternative therapies can find information on the Internet from a variety of sources and interest groups. MACCAH has considered the role that consumer information plays in contributing to the safety and efficacy of consumers' choices in health care. The Committee has also taken into account the types, quality and sources of information that are currently available and what further sources might need to be developed. In exploring these issues, MACCAH has looked at the following questions:

- Why do healthcare consumers need CAM information? (Section 3.4)
- What information about CAM do consumers need? (Section 3.5)
- How can CAM information be provided? (Section 3.6)
- What CAM information is already provided in New Zealand? (Section 3.7)
- What else needs to happen? (Section 3.8)

3.4 Why do healthcare consumers need CAM information?

MACCAH has not been able to investigate how much influence CAM information has on consumers' eventual health care choices in New Zealand, but has noted overseas initiatives in this area. There is general acceptance that providing CAM consumers with more information does indeed help them to make better choices about the best source of care.

MACCAH also notes overseas observations that indicate healthcare consumers 'commonly rely on two networks for information about health issues and health care: the informal network of family and friends, and the formal network of professional referral' (De Bruyn, 2001). In effect, this means considering not just how consumers receive information, but also the networks through which that information passes. In practical terms, this requires communicating information to many types of health professionals.

3.5 What information about CAM do consumers need?

Overseas studies of consumers' information needs have identified a number of basic questions that consumers ask about a therapy or product. A Health Canada study (De Bruyn, 2001) identified the following questions as typical of those asked by CAM users:

- What is the CAM therapy or product?
- Will CAM work?
- Where can I get CAM?
- How much will CAM cost?
- Who will pay for CAM?

Consumers also want to know that the answers they receive can be relied upon, and that the information is impartial (in other words, it is not provided by an interested party). Alternatively, consumers need to have the skills to carry out their own evaluation of information. This need has been recognised by the United States' National Center for Complementary and Alternative Medicine (NCCAM) whose website offers a guide to help consumers evaluate online health information. This guide suggests that consumers find out who runs a website and why, about the nature of information on the site, and how the site is managed.

(see <http://nccam.nih.gov/health/webresources>)

Most submissions in response to MACCAH's 2003 discussion document *Complementary and Alternative Medicine: Current Policies and Policy Issues in New Zealand and Selected Countries* stated a need for better quality information on CAM that could be accessed easily. Some were against any information being made available until safety and effectiveness had been clearly established. Submissions suggested further information should be provided on:

- the safety and efficacy of CAM practitioners and modalities (including education, training, regulation and complaints procedures) both generally and in relation to particular ailments or conditions
- the safety and efficacy of CAM products (including side-effects, interactions, reports of adverse reactions, and in comparison to biomedicine)
- how to locate and assess the quality of practitioners
- how to assess information about the safety and effectiveness of modalities and products.

There was an emphasis in the submissions on the need for consumers to have easy access to good quality, non-biased information, with those caring for the severely or terminally ill (especially children) seen as being in particular need of accurate, evidence-based and impartial assistance. This concern was voiced by both biomedical practitioners and voluntary groups involved in this area, because consumers who act on misleading information could face unnecessary emotional and/or financial consequences. Some suggested that those who provide misleading information should face sanction.

There was also a concern that while some websites contain a disclaimer statement or recommend that consumers consult a health professional, this may not happen in practice and could result in consumers spending money on unsafe or ineffective products.

The need to protect the privacy of consumers accessing CAM information from 'subscription only' websites is also mentioned in the international literature (White House Commission on Complementary and Alternative Medicine Policy, 2002:75)

3.6 How can CAM information be provided?

MACCAH is aware that consumers access information on CAM in a variety of ways, including through consultation with health professionals (doctors, pharmacists or CAM), over the Internet, through printed material, the media, advertising information and health education forums. Other potential sources of information include practitioners and practitioner organisations (CAM and biomedical), manufacturers and distributors of CAM products, and Government health bodies (including the Ministry of Health, District Health Boards, Medsafe).

While there is no research on New Zealand consumers' preferences in terms of source and mode of information, MACCAH's view is that easily understood reliable and impartial information should be readily available, along with help on how to evaluate different and potentially conflicting sources of information.

Some understanding of the sources of information used by New Zealanders in choosing to visit a CAM practitioner can be gained from the provisional findings of the 2002/03 New Zealand Health Survey. When the New Zealand adults who had visited a complementary or alternative practitioner were asked about their reasons for doing so, 29.2 percent said that a friend or relative had referred them and 12.0 percent had been referred by their doctor. One in three of the adults (33.4 percent) that had visited a complementary and alternative health practitioner had also seen a general practitioner about the same condition (Provisional Results from 2002/03 New Zealand Health Survey). While the Survey did not investigate other sources of information used by CAM consumers, these figures support the overseas experience that friends, family and biomedical practitioners are the major sources of information about CAM treatments.

MACCAH notes the concerns of some submissions that if the Ministry of Health were to take a role in providing further CAM information it would need to involve CAM practitioner organisations. MACCAH considers that further research is required to identify consumer needs before policy is developed in this area.

3.7 What CAM information is already provided in New Zealand?

(a) Information about the nature of CAM modalities or products – what is CAM?

Consumers may need information that describes the nature of CAM treatments and products, the history of the modality or product, and the philosophy behind its use for different purposes.

Currently, the main sources of information on the nature of CAM modalities and biomedical practitioners and practitioner organisations are printed material and Internet sites (for examples, see end of chapter). Information about some CAM products is available from Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, which is currently responsible for the regulation of therapeutic products in New Zealand.

MACCAH notes that there may be opportunities to incorporate CAM material into existing publications (for example, into District Health Board Toolkits) and suggests that criteria and processes for such inclusion be developed.

(b) Information about the safety and efficacy of CAM modalities or products – does CAM work?

Consumers may need information on the evidence for safety and efficacy and other benefits of CAM practices and products, as well as help with evaluating information on safety and efficacy. In March 2004, the Ministry of Health launched a web-based CAM database (www.cam.org.nz) for consumers and health practitioners. This database has been funded for an initial period of four years and summarises research findings on the use of CAM for specific health conditions. Users can search by type of CAM treatment or by condition. At the end of June 2004, eight summaries had been completed. To date, these summaries have presented the findings of studies that meet the most stringent levels of evidence for the safety and efficacy of CAM.

MACCAH notes the ongoing debate about what level of proof is required to assure the public that a form of health treatment (whether CAM or biomedical) is safe and effective. A detailed discussion of these issues is provided in Chapters 5 and 6 (Evidence and Research, and The New Zealand Health Strategy).

(c) Information on where to find a particular kind of CAM practitioner or product

Consumers may need information on those trained in the modality, the types of qualification and training needed for safe practice, and contact details of practitioners.

MACCAH is aware that CAM professional organisations provide contact details for their members by location, and some information about the types of training practitioners receive and the codes of practice they adhere to. There is currently no singular source of information for this.

(d) Information on how much a particular kind of CAM practitioner or product will cost

Consumers may need information on the schedules of fees, the expected frequency and duration of treatment, and the likely costs of products or diagnostic tests associated with treatment.

Overseas experience suggests that this information should be provided by professional organisations and that regulatory frameworks should ensure practitioners are forthcoming about the full costs that may be involved with the treatment.

(e) Information on who will pay for CAM treatment

Consumers may want to better understand the circumstances in which government organisations and private health insurers will pay for treatment (for example, ACC and Work and Income New Zealand). MACCAH suggests that information about this is fragmented and, while it is provided by the individual organisations, it is not easy to locate.

3.8 What else needs to happen?

MACCAH believes that further development of the CAM database must meet the consumers' needs for different levels of evidence-based information on the safety and efficacy of CAM therapies.

There may also be a need to co-ordinate the provision of other information for consumers. However, before such co-ordination occurs, MACCAH suggests that further research is required to determine the exact nature, preferred mode and sources of information for different consumer groups.

3.9 Chapter 3 references

De Bruyn T. 2001. Invitational seminar on information and informed choice in the use of complementary and alternative health care with respect to practitioners, users and the health system. Seminar report in Health Canada. *Perspectives on Complementary and Alternative Health Care: A collection of paper prepared for Health Canada*. Ottawa: Health Canada.

National Center for Complementary and Alternative Medicine website <http://nccam.nih.gov>

White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP). 2002. Final Report. Washington DC:WHCCAMP.

Sources of New Zealand based information on CAM products and practitioners

LandCare Nga Tipu Whakaoranga. Site developed by LandCare detailing traditional uses of New Zealand native plants. The database is searchable by condition and plant name, and is referenced – www.lawsite.co.nz/landcare/index.cfm?option=searchtemplate.

Medsafe – www.medsafe.govt.nz.

Ministry of Health and New Zealand Health Technology Assessment CAM database – www.cam.org.nz.

New Zealand Food Safety Authority - www.nzfsa.govt.nz.

New Zealand Guidelines Group – www.nzgg.org.nz.

The New Zealand Charter of Health Practitioners – www.healthcharter.org.nz.

Chapter 4: Evidence and Research

4.1 Term of reference

To review overseas evidence-based research, identify priorities for the development of New Zealand evidence-based research on the safety and efficacy of specific complementary and alternative therapies, and support the development of guidelines.

4.2 Context of recommendations

The Ministerial Advisory Committee on Complementary and Alternative Health has considered the following:

- international approaches to researching the safety and efficacy of CAM
- New Zealand's need for research on the safety and efficacy of CAM, and the appropriateness of overseas research
- the need for New Zealand based research and the current infrastructure available in New Zealand.

MACCAH recognises New Zealand's need for relevant and reliable information on the safety and efficacy of CAM therapies for both providers and consumers of health care.

In reviewing the overseas research on complementary and alternative health care, MACCAH has concluded that New Zealand would benefit from more information on the safety and efficacy of complementary and alternative therapies. In particular, New Zealand could do with more information on the safety and efficacy of the many roles that complementary and alternative therapies may play in health care. Some information on these roles can be obtained from overseas evidence-based research (for example through the summaries from the Ministry of Health CAM database discussed previously). Other information would be more appropriately sourced from New Zealand based research.

At the same time, MACCAH suggests that New Zealand needs to develop its own infrastructure for researching complementary and alternative therapies – specifically, an infrastructure for the funding of research and developing of the necessary research skill bases, networks for collaboration, and the dissemination of research findings.

It is important to note at this point that in the wider context of health care, there is an historical focus on evidence-based research and clinical outcomes, with corresponding importance attributed to research based on evidence from randomised controlled trials. Such evidence may not be present in all instances of CAM research. The issue is whether different levels of research evidence are appropriate, given efficacy and safety requirements.

MACCAH Recommendations:

7. The Ministry of Health should encourage research-funding bodies to facilitate further research on complementary and alternative medicine.
8. The wide range of methodologies appropriate for researching the safety and efficacy of CAM should be used and recognised by CAM researchers and research funding bodies.
9. Recognition should be given, by research funding bodies, healthcare professional organisations and educational institutions, to the relevance and importance of research at different levels of evidence for the efficacy and safety of CAM.

4.3 What are the issues?

Research on the safety and efficacy of specific CAM therapies addresses two broad questions:

- Does a specific CAM therapy work?
- Is the specific CAM therapy safe?

Diverse parties may be interested in resolving these issues:

- consumers making a choice about health care
- practitioners of a modality wanting to make or substantiate claims, those looking to improve practice, those contemplating a therapy, and those who provide training in the specific CAM therapy
- other practitioners (biomedical or CAM) wanting to make sound referrals
- manufacturers, distributors and retailers of CAM products and equipment
- health-care funding and policy bodies making decisions on the provision of health care according to a range of criteria including cost-effectiveness.

MACCAH recognises that each party may have specific expectations about the degree of reliance they should place on research findings in making decisions. In addition, the need for proof of safety and efficacy of a CAM treatment may vary according to whether the purpose of treatment is primarily that of maintenance, prevention, treatment, or relief. For example, if a person finds something provides relief, as long as it is safe, they may not have as strong a need for evidence of its efficacy. In contrast, a person who is wanting to prevent a particular condition may be more concerned about having accurate information about a treatment's effectiveness.

While many approaches can be taken to investigate these questions and to substantiate findings, MACCAH suggests that the central issue is agreeing on the appropriate use of research findings, i.e. that claims being made are based on research adopting appropriate methodologies to investigate a particular research question.

In its Term of Reference MACCAH has been asked to review overseas evidence-based research and to consider New Zealand's priorities for such research. By evidence-based research, MACCAH includes research findings which have been assessed in terms of whether a specific CAM therapy works or is safe in a given situation.

To this end, MACCAH has explored the following questions:

- What are the issues? (Section 4.3)
- Who has an interest in using research on specific CAM therapies, and why? (Section 4.4)
- How do we know what is appropriate research? What types of research evidence are there? (Section 4.5)
- What evidence is needed to prove the efficacy of specific CAM therapies? (Section 4.6)
- What kind of evidence is needed to prove the safety of specific CAM therapies? (Section 4.7)
- What is the nature of overseas-based research and how are priorities set? (Section 4.8)
- What are New Zealand's CAM research needs? (Section 4.9)
- What needs to happen next? (Section 4.10)

4.4 Who has an interest in using research on specific CAM therapies and why?

A number of groups have a research interest in CAM for various reasons. They include:

User of research	Research information required, and why
Health care consumers	To compare the relative safety and efficacy of different forms of treatment in choosing between health care options
CAM practitioners	To substantiate the claims they can make about the safety and efficacy of the treatment they provide To improve their practice through modifying their techniques or other skills To better target treatments to patients
Prospective health care students / training and education establishments	To evaluate the overall effectiveness and safety of a specific therapy and the likely duration and intensity of training needed to become proficient and safe in a particular practice
Biomedical practitioners	To have confidence in referring patients to other forms of health care, or in making their own choices about further training
Health care funders and policy makers	To have the means of distinguishing among different providers on the basis of safety and efficacy
CAM manufacturers distributors and retailers	To identify which CAM products and equipment to develop, manufacture and supply, and to improve the accuracy of marketing strategies.

4.5 How do we know what is appropriate research? What types of research evidence are there?

Individual patients making medical decisions about their choice of treatment or risk management options and policy makers making such decisions on behalf of groups require confidence in the information they receive. In the context of healthcare, such information arises from evidence based on clinical experience or on systematic programmed research with appropriate populations (Donald, 2002). This evidence-based research is then assessed according to three key criteria: validity; clinical importance; and applicability.

‘Validity’ refers to the degree to which the methods used in the research clearly establish a relationship between the specific treatment (be it CAM or biomedicine) and the safety and efficacy of the health outcome. In other words, does the treatment or therapy have a direct positive health outcome? In some cases, it may be more accurate to say that the treatment appears only to be ‘associated’ with the health outcome – it may or may not be the actual cause of the outcome.

'Clinical importance' refers to the degree to which the findings apply – whether the findings apply to a small or large number of people; or whether the strength of the effect is strong, medium or weak – so that the health outcome may be of greater or lesser clinical importance.

'Applicability' refers to the degree to which the research has been carried out in a way that clearly identifies to whom and in what situations the specific treatment or therapy is effective and safe.

It is this latter criteria, applicability, which often differentiates biomedical research from CAM research. Biomedical decision makers have traditionally accepted randomised controlled trials (RCTs) as the major form of research evidence considered appropriate in healthcare research, whereas CAM researchers include a variety of forms of evidence, such as case studies and comparative studies, and often have difficulty in providing evidence from randomised controlled trials.

These different 'levels of evidence' are differentiated by the rigour of the research methods. Some examples are detailed in Table 4.1.

Table 4.1: Ways of gaining evidence in research – 'levels of evidence'

Level of evidence	Evidence is obtained through:
I	Systematic reviews and meta-analyses
II	Randomised controlled trials with definitive results
III	Randomised controlled trials with non-definitive results
IV	Cohort studies
V	Case-control studies
VI	Cross-sectional surveys
VII.	Case reports

Source: Clinical Evidence Online 2002

Systematic reviews and meta-analyses (Level I) are considered the strongest evidence for the effectiveness of medical treatments. However, this has been questioned with regard to CAM as there are often methodological issues, such as the difficulty in forming 'blinded' control groups, that preclude many studies from being undertaken in Levels I and II and thus having wide applicability.

It should be noted that there have been similar difficulties associated with trials on surgery and aspects of general practice, and it has been estimated that less than half of the interventions in these areas of biomedicine appear to have been tested by randomised controlled studies (Gatchel et al, 1998).

Thus, while in no way detracting from the important role played by randomised controlled trials in establishing the wide applicability of a treatment or therapy, it is also important to consider information/research evidence from the other levels when there is insufficient randomised controlled evidence available. There is a huge range and diversity in such research methods.

Despite the diversity of research methods used to establish appropriate evidence, there are still philosophical and practical difficulties associated with applying the RCT methodology to CAM (Fabrega, 2002), and with establishing appropriate research methodologies (Walach, 2001). These include:

- the complexity of measuring the holistic and multivariate nature of many CAM therapies
- the problem of providing an appropriate control for non-ingestive treatments (e.g. massage or acupuncture)
- the likelihood of small sample sizes
- the costs involved in undertaking randomised control trials
- the lack of research resources and infrastructure.

Nevertheless, there is a need to consider what specific evidence is needed to establish the efficacy and safety of CAM therapies, even though a discussion of such evidence raises even further issues, both in the international literature and in the New Zealand submissions.

4.6 What evidence is needed to prove the efficacy of specific CAM therapies?

Those making decisions based on research findings on the effectiveness of a specific CAM therapy are usually interested in evidence that establishes:

- that the specific CAM therapy is responsible for the outcomes claimed
- the applicability of the outcomes to other populations, ie who else could expect a similar outcome from the CAM therapy
- if there are any other factors that are likely to affect the outcome of the intervention.

They may also be interested in information on the theory and method of how a specific CAM therapy works.

The UK House of Lords' report identified the following issues in establishing the efficacy of CAM therapies:

- whether a history of safe and apparently successful traditional use is enough evidence to justify the acceptance or use of a particular therapy, or whether a critical mass of scientifically controlled evidence is needed

- an overall lack of research, because the research findings that have been done may have been given disproportionate weight by re-cycling them in meta-analyses and reviews
- the importance of evidence of efficacy may be less important than the evidence of safety. If a person feels a therapy is helpful, and can be shown not to have been harmed, then it may not be necessary for there to be statistically valid research supporting the therapy's efficacy. This does however raise the question as to whether such treatments should be available at public expense
- that the existence of evidence supporting a therapy's claims may be of secondary importance, where patients are aware of the state of the evidence, and strong measures can be taken against practitioners who make false claims
- whether the demands for a high level of evidence of efficacy for CAM is reasonable given that the evidence base for other forms of health care is weak in some areas
- whether there are other factors operating to prevent an uptake of CAM research findings
- that the evidence for the efficacy of CAM's diagnostic procedures (in terms of reliability and ability to be reproduced) is as important as the efficacy of a treatment (House of Lords' Select Committee on Science and Technology, 2000).

4.7 What evidence is needed to prove the safety of specific CAM therapies?

Those using research findings on the safety of specific CAM therapies are usually interested in evidence that establishes:

- the level of risk in using the therapy
- the level of acceptability of the risk.

The UK House of Lords' report identified the following issues in establishing the safety of CAM therapies:

- in determining the level of safety to be sought, it may be appropriate to use a risk/safety ratio approach. For example if the potential benefits of a therapy are likely to be significant or life-saving, then the level of risk a patient may be willing to accept is likely to be higher than for the benefit of temporary symptom relief
- it may also be appropriate to consider whether the risks are inherent or can be minimised through regulation of practitioners or products (i.e. the level of practitioner skill influences the degree of risk)
- the safety of CAM therapies may be less important than efficacy when there is a proven conventional treatment for serious or potentially lethal situations (House of Lords' Select Committee on Science and Technology, 2000).

4.8 What is the nature of overseas-based research and how are priorities set?

Having reviewed the research activities of a range of countries, MACCAH considers the following approaches to have the most relevance to the setting of New Zealand's CAM research priorities.

United States

The largest single source of CAM research funding is probably the United States National Institutes of Health (NIH), and in particular the National Center for Complementary and Alternative Medicine (NCCAM).

The White House Commission Report (The White House: 2000) reports that NIH funding of CAM research during its 2002 financial year was a total of USD\$247 million. Of this total, NCCAM funded USD\$104.6 million. Such funding enables the ongoing development of a research infrastructure as well as the production of research findings.

NCCAM conducts scientific research on complementary and alternative healing practices, training researchers and disseminating authoritative information. To achieve these aims, it uses a range of funding mechanisms, including centres to support research, training and career development. Research centres provide an opportunity to develop a programme of related research projects that result in a 'whole greater than the sum of its parts'. These also serve as a focal point for the development of additional research and training activity.

The 'Centers of Excellence on Complementary and Alternative Medicine' provide opportunities for accomplished researchers to apply their expertise to address CAM research questions, whereas the 'Developmental Centers for Research' on CAM aim to strengthen collaborations between CAM and conventional institutions and to facilitate exploratory and developmental research projects.

After heavy investment initially in clinical trials, NCCAM is now broadening its research portfolio to study the mechanisms of action underlying those CAM approaches for which there is already evidence of safety and efficacy, and to examine more closely the nature of other interventions showing potential. Priority areas of research include a combination of disorder/disease based conditions (for example, arthritis, asthma/allergy, cardiovascular, digestive, neurological and infectious diseases), general areas of health (immunology, pain, mental health) and some focused on particular kinds of CAM therapies (manual therapies, acupuncture, mind-body medicine) (see www.nccam.nih.gov).

United Kingdom

The United Kingdom's government response to the House of Lords' Report (Department Health [UK], 2002) agreed that research on a particular CAM intervention should focus on:

- establishing therapeutic benefits above the placebo effect (i.e. the efficacy)
- protection of patients from hazardous practices (i.e. the safety)
- comparison of the CAM intervention with other forms of treatment in terms of medical outcome and cost-effectiveness.

However, the UK government has suggested that there is also a need to prioritise across CAM interventions and to focus on those interventions where there is already a research capacity. A further factor is whether the nature of a treatment, the condition being treated, or the scale of use creates an exceptional public health need for evidence of safety and efficacy. As well as this research focus, the government has responded to the practical issues that need to be addressed in order to facilitate research. These include:

- commissioning research comparing the methods used to assess the effectiveness of interventions and quality of care (through the National Health Services, Research and Development Methodology Programme)
- developing databases of research experts familiar with issues raised by CAM research (through the UK Medical Research Council)
- suggesting that research capacity in the CAM field be increased, including the development of high quality researchers (through the Workforce Capacity Implementation Group and Fellowships). However, the Government did not follow the House of Lords' suggestion to develop research centres of excellence, or to develop a separate funding pool for CAM. The UK Government viewed such moves as premature, because of the need to first build up the research capacity
- promoting a research culture in the CAM field to forge links between CAM practitioners and research experts. For example, a new division in the Medical Research Council's Clinical Trials Unit aims to increase opportunities for collaboration with CAM and other areas where expertise trials and other evaluative methodologies are weak. The National Health Service's Research and Development Strategy also includes provision for the development of workforce capacity in health care research, including the therapeutic professions. The Department of Health [UK] agreed to better promote support for research capacity within the CAM community, through research training courses and awards for research leaders.

Overall, the UK government favoured an integrative approach to research involving CAM and research experts working together, instead of the suggestion to establish new University posts dedicated to CAM, made in the House of Lords' report. However, the government did agree with the House of Lords' recommendation that manufacturers of CAM products needed to consider research and development as part of their financial and legal responsibilities to ensure the standardisation, safety and efficacy of their products.

The United Kingdom differs from New Zealand and the United States in that much of the funding of research in the CAM area is through Charitable Trusts including the Research Council into Complementary Medicine and the Prince of Wales Foundation for Integrated Health. The Research Council disseminates research findings and facilitates appropriate research in complementary and alternative medicine. It also aims to improve understanding and co-operation between CAM and biomedical professionals. The Foundation for Integrated Health works towards increasing high quality and appropriate research into CAM and integrated health care (Global Information Hub on Integrated Medicine: 2003).

Canada

In 2003, Health Canada's Natural Health Products Directorate formed a collaboration with other government funded Health Institutes (of Musculoskeletal Health and Arthritis; of Infection and Immunity; and of Health Services and Policy Research) to support research into complementary and alternative medicine in Canada. This collaboration, the CAM Interdisciplinary Capacity Enhancement Teams Grants Programme (ICE) aims to create a self-sustaining, well-connected, highly trained CAM research community that is internationally recognised for excellence in research and contribution to a strong evidence base for CAM. CAM ICE involves medical professionals from a variety of disciplinary backgrounds (including pharmacy, medical sociology, medicine, chiropractic, naturopathic medicine and ethics) and from different Canadian provinces. The team is funded for five years to:

- develop CAM research priorities and a research agenda
- build CAM research capacity
- promote knowledge transfer among researchers, health care practitioners, policy makers, research funders, and the public about CAM
- link with other relevant networks, organisations, and educational institutions to develop partnerships that further objectives (Health Canada, 2003).

Australia

Australia does not have a national level strategy for the researching of CAM interventions. The Therapeutic Goods Administration evaluates complementary medicines and their ingredients. A number of universities have CAM research programmes. The University of Queensland and the Southern Cross University have jointly formed a collaborative research and education centre, the Australian Centre for Complementary Education and Research. This centre aims to provide an independent reference point built on strengths of research innovation and teaching. The University of Western Sydney, Monash University and the Joanna Briggs Institute also undertake CAM related research programmes (Global Information Hub on Integrated Medicine, 2003).

Relevance to the setting of New Zealand's priorities

MACCAH notes that other countries have prioritised investigating the safety, efficacy and the cost-effectiveness of CAM therapies. Other governments have also recognised the need to develop an infrastructure for research on CAM including agreement on appropriate methodologies, the development of research capacity, the means of disseminating existing research findings, and the development of links between research experts and the CAM community. MACCAH also notes the dilemmas of funding CAM research activities – whether a separate stream of funding CAM research activity is more appropriate than activities to facilitate funding through existing channels.

In line with this, and throughout its term, MACCAH debated the relative merits of establishing a separate CAM entity that would have responsibility for facilitating further research and for information dissemination and integration as well. However, instead of addressing the structures that might be required, MACCAH has chosen to focus on the functions that are needed. Thus MACCAH would prefer to see some agreement on the following functions being undertaken by a separate or existing entity or entities:

- the development of a framework for setting priorities such as the extent of use and potential contribution of CAM to the health outcomes in the national health priority areas
- the consolidation and agreement on appropriate methodologies for establishing evidence for the different roles that CAM may play in health care
- the development of research expertise and networks among CAM practitioners and research experts
- the identification and dissemination of existing and future research findings.

4.9 What are New Zealand's CAM research needs?

Submissions received in response to MACCAH's 2003 discussion document *Complementary and Alternative Medicine: Current Policies and Policy Issues in New Zealand and Selected Countries* suggested more research was needed on the efficacy and cost-effectiveness of CAM and that any research findings should be more widely available.

Some submissions identified the limited research funds as an issue in New Zealand and suggested that, rather than replicate overseas research, New Zealand should focus on its own unique areas (for example, population groups, native plants and fauna). Views were varied about the applicability of the 'levels of evidence' model to researching complementary and alternative medicine. Some maintained that the scientific methods used should be the same as those applied to biomedicine. Others suggested that different methodologies needed to be developed that considered a wider set of variables, for example, the spiritual and mental wellbeing aspects emphasised by CAM practitioners.

Existing research in New Zealand

Some research is being undertaken in CAM training institutions by practitioners and by professional bodies. Unfortunately, there is no systematic way of accessing these research efforts and assessing their contribution to the areas of CAM safety/efficacy. This is in contrast to university requirements to lodge post-graduate research in university libraries.

To maximise the gains from existing New Zealand based research and to continue to develop the level of research training, MACCAH considers that a facility for recording past and current research projects would be useful. Again, research should meet agreed methodological requirements.

4.10 What needs to happen next?

A number of issues need to be addressed to allow for high quality research into CAM. These include:

- organisational requirements
- research expertise within CAM
- co-operation among biomedical and academic research sectors
- choosing appropriate research topics and strategies
- funding research and its dissemination.

(a) Organisational requirements

The types of organisation that could help facilitate research include the government through the Ministry of Health, academic institutions such as universities and their medical schools, and non-government organisations such as CAM professional associations, the NZ Charter of Health Practitioners and private groups.

An example of a government sponsored organisation involved in CAM research is the United States National Center for Complementary and Alternative Medicine (NCCAM) which conducts basic and applied research and research training, and disseminates information with respect to identifying, investigating, and validating complementary and alternative therapies (Melchart et al, 1997).

It is noted that a number of submissions on CAM in New Zealand asked that a specialised CAM unit should be formed in New Zealand to co-ordinate research and dissemination of information. Such a unit could be structured along the lines of NCCAM (ie a government sponsored organization), or as a specific department of a university (such as in the United Kingdom or Australia). Alternatively, a co-ordinating framework could be devised to bring together and share existing CAM expertise to build further capacity (for example, to oversee research, regulation and the training of practitioners).

(b) Research expertise within CAM

Although many of the CAM modalities encourage research projects as part of a student's training, the research tends to be either descriptive or case studies. This may be entirely appropriate, but students should have exposure to a wider range of methodologies. This may require a greater level of CAM research expertise, along with more research funding.

(c) Co-operation with biomedical and academic research sectors

In the United Kingdom, United States and Australia, there are university based research centres that aim to bring together both CAM practitioners and academic researchers. In addition, these countries also have CAM training in their undergraduate and postgraduate courses which is likely to foster better co-operation for joint CAM and biomedicine research. New Zealand could well co-operate with these centres and develop similar research networks.

(d) Choosing appropriate research topics and strategies

Various research possibilities need to be considered, including the relevance of research outcomes to the health needs of New Zealand, the cost-effectiveness of CAM in terms of the best use of the health vote, and specific areas of concern in relation to efficacy and safety.

(e) Funding research and its dissemination

Setting funding priorities among research projects for complementary and alternative therapies is especially vulnerable to arbitrary and partisan criteria. A study in the United Kingdom looked at the types of funding available to CAM and found that the National Health Service, the Medical Research Council, Medical Research Charities, and industry and private donations constituted the main potential sources. However, their data suggested that funding was generally very poor. (Ernst, 2001).

New Zealand has dedicated health research funding through the Health Research Council which in the past has been flexible in adopting and accepting methodological frameworks suitable for researching Māori health care. It remains a possible source of funding, although its emphasis to date has been on biomedicine.

In the future, insurance companies could be interested in investing in research on CAM outcomes, as they are beginning to support a variety of CAM therapies.

In assessing the need for New Zealand based CAM research, the following questions need to be asked:

- is there international evidence-based research available already in the area?

- if not, can one identify the funding and expertise available in New Zealand, along with the appropriate research methodology?
- if so, can the findings be applied in New Zealand or are the differences between the findings and New Zealand society sufficiently different to warrant separate research? Such differences might be in the composition of the New Zealand population, the profile of health issues, the nature and practice of therapies or products, or the desired outcomes of the treatment.

4.11 Chapter 4 references

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Chapter 5: Integrating Complementary and Alternative Health Practitioners with the Biomedical Health System

5.1 Term of reference

To provide advice on whether, and how, specified complementary and alternative health practitioners should be integrated into the mainstream health system.

5.2 Context of recommendations

The Ministerial Advisory Committee on Complementary and Alternative Health has considered:

- the different ways in which the integration of practitioners may occur
- overseas approaches to the integration of complementary and alternative medicine practitioners and biomedical practitioners
- the nature of the current integration of complementary and alternative medicine practitioners and biomedical practitioners in New Zealand
- criteria for the further integration of complementary and alternative medicine and biomedicine.

MACCAH recognises that integration involves health-care consumers and practitioners, as well as those funding and developing policy about the provision of health care. It may involve a range of practitioner interactions and occur in a variety of health care settings. The key difference with integration is that there is a relationship between the CAM practitioner and elements of the biomedical health system.

MACCAH notes that currently integration occurs in New Zealand on an ad hoc basis and mainly in the primary health sector. Individual consumers make a choice to seek health care from both CAM and biomedical practitioners and individual biomedical practitioners are choosing to refer patients to CAM providers, to work in co-operative arrangements with them, or to gain training in CAM themselves.

There is some public funding of CAM care for those with injury by the Accident Compensation Corporation, for those receiving income support through Work and Income New Zealand, and more recently, there has been coverage of CAM treatments by a number of private health insurance providers. MACCAH also notes that some District Health Boards are developing policies on CAM use in secondary care settings and that CAM practitioners are providing services to patients by arrangement in some public hospitals. However, these initiatives are occurring on a region-by-region basis and are not nationally co-ordinated.

The New Zealand Health Strategy suggests that multifaceted approaches to the provision of prevention, treatment and relief are required to achieve population health goals. In addition, given New Zealand's ageing population, it is likely that relief from the effects of illness, injury or disease and from other forms of treatment may become an increasingly important part of health care. For these reasons, MACCAH has considered whether integrating specified CAM practitioners with the biomedical health system will assist in meeting New Zealand's health care needs and result in the better access of health care to all New Zealanders.

MACCAH has also considered integration with respect to the structures of the health care delivery system. It has reflected on the implications and practicalities of integration for practitioners delivering health care in primary and secondary health settings, for District Health Boards in making decisions about what services to purchase on behalf of their population base, and for the Ministry of Health in its oversight and policy making roles. MACCAH recognises that all of these bodies are concerned with providing the most appropriate form of health care for consumers and that they need good quality information about the safety and efficacy of different forms of CAM, so that a CAM option can be compared with the other options available. MACCAH also recognises that these parties need a means of identifying practitioners who would best offer such services and the role that increased levels of regulation may play in this.

Where there is evidence of efficacy and safety of CAM use in a particular health priority area, and a means of identifying skilled practitioners, MACCAH suggests that it would be appropriate for the Ministry of Health to establish a number of pilot projects. The information gained from such pilots could be used to further develop the infrastructure and ongoing monitoring systems needed to establish the integrated health care that would further the achievement of health goals.

Currently, nearly one in four New Zealand adults visit a complementary or alternative health practitioner at least once a year (Provisional Results of the 2002/03 New Zealand Health Survey). Given that such a significant number of the population are using CAM, MACCAH considers an open attitude and the availability of information for all health care practitioners (including biomedical and CAM) about a consumer's other forms of treatment will help identify and minimise the risks of undesirable interactions and prolonged use of ineffective forms of treatment.

Integration will require practitioners to have at least a minimum knowledge about the approaches and evidence base for other forms of treatment, forms of regulation and how to identify skilled practitioners. Such a need could be addressed through the initial education of new practitioners, ongoing professional development of existing practitioners, and by ensuring that all health practitioners have access to current information in the areas of integration.

MACCAH Recommendations:

10. Where there is evidence of safety, efficacy and cost effectiveness, specified CAM modalities should be considered for public funding.
11. Health care education and training bodies should be encouraged to include elements of CAM and biomedicine in each other's curriculum. A national curriculum committee should be established to develop policy on this.
12. Research should be undertaken to establish best practice for the integration of the approved CAM modalities with biomedicine.
13. District Health Boards should be provided with guidance on the appropriateness of integration initiatives.
14. The Ministry of Health should encourage the District Health Boards to establish pilot studies to identify the practicalities, costs, benefits and health outcomes that would accompany CAM and biomedical practitioners working together.

5.3 What are the issues?

MACCAH has considered the following issues:

- What is integration? (Section 5.4)
- What are the benefits and drawbacks of integration? (Section 5.5)
- What factors facilitate or obstruct integration? (Section 5.6)
- What criteria should be used to determine whether or not a CAM modality is integrated? (Section 5.7)

5.4 What is integration?

MACCAH defines New Zealand's 'mainstream health system' (as in the Term of Reference) as the 'public funding and provision of personal health services, public health services and disability support services' referred to in the New Zealand Public Health and Disability Act as the provision of privately funded health and disability services with a biomedical orientation. However, given the previous discussion on the use of the word 'mainstream' and the implication that this is the only paradigm of health care, MACCAH uses the alternative term 'biomedicine' to imply that this paradigm is but one of several.

Integration and integrated care are concepts used in the health field to refer to the combining of different forms of health care in general. The World Health Organization (Grone and Garcia-Barbaero, 2001) defines integrated care as:

A concept bringing together inputs, delivery, management and organisation of services related to diagnosis, treatment, care rehabilitation and health promotion. Integration is a means to improve the service in relation to access, quality, user satisfaction and efficiency.

Integration can occur vertically between different levels or forms of delivery of the health system (e.g. primary, secondary and tertiary, or community and institutionalised care) or horizontally, involving different services within primary care (for example, general practice and allied health). Other concepts of integration focus on the interactions between individual practitioners, with co-operative processes and continuity of care seen as the key features of a successful integrated system (Health Services Research Centre and Te Ropu Rangahau Hauora a Eru Pomare, 2001).

To develop an idea of what integration could mean in New Zealand with specific regard to CAM and biomedicine, it is useful to examine some key issues of integration:

- integration of CAM and biomedicine may involve key differences in understandings about health, illness and the purpose of treatment (whereas the above forms of integration occur broadly within a biomedical paradigm). This complicates the relationship between practitioners, particularly concerning the flow of information about a patient's condition
- individual providers, recipients, and funders of health care may have different perspectives on whether it is possible to combine the two into a single 'whole' system of health care, and indeed whether it is desirable
- the question must be asked whether it is possible for CAM and biomedicine practitioners to participate equally given biomedical practitioner dominance in the current health care setting.

Types of integrated health systems

Bodeker (2000) contrasts the parallel and integrative approaches to health system integration of CAM and biomedicine. 'Parallel integration' involves different forms of health care being offered as 'alternative', with consumers able to choose one form or an alternative. 'Integrative integration' by contrast involves blending the forms of care. This may be achieved through referral, or through practitioners practising more than one form of care. In this case, the different forms of treatment tend to be seen as complementary rather than alternative. Bell et al (2002) suggest that integrative medicine is more than blending the best of conventional and CAM; and define integrative medicine as involving 'a comprehensive, primary care system that emphasises wellness and healing of the whole person (bio-psycho-socio-spiritual dimensions) as major goals, above and beyond suppression of a specific somatic disease' (Bell et al, 2002).

5.5 What are the benefits and drawbacks of integration?

A number of overseas countries are at a similar stage as New Zealand in noting the increased role that CAM is playing in the health care of citizens as indicated by utilisation data. These countries have also been considering whether a systematic means of integrating CAM practices with mainstream forms of health delivery may be appropriate.

In reviewing overseas approaches, MACCAH found that the issues involved in developing integration policies are different in those countries where there exist general problems with access to any forms of health care (and where there may be a long history of the use of traditional medicine).

In addition, the provision of CAM treatment by medical doctors is generally treated as a separate issue from the integration of CAM practitioners without biomedical training and regulation. For example, in the United Kingdom, doctors may be funded to provide CAM treatments such as acupuncture and homeopathy through the National Health Service but practitioners only trained in CAM do not generally receive funding.

Of the countries that have similar issues to New Zealand, some are beginning to conduct research into factors affecting the success of integration but are not at the point of reviewing the overall success or otherwise of their healthcare integration policies. New Zealand does not have a system in place for researching and monitoring the success of integration initiatives as exists elsewhere (for example, in the United Kingdom and the United States). However, MACCAH has found it reassuring that those factors which are considered benefits or drawbacks of integration are similar.

The improved outcomes for health consumers through a planned approach to integration include:

- transparent referral systems, sharing of information, better communication and understanding between biomedical and CAM practitioners working with the same patient. Each practitioner has a better understanding of the overall care being received. Patients are able to talk about their overall care, thereby reducing the risk of unanticipated interactions between medicines
- more equitable access to proven CAM therapies across population groups and geographical locations
- the holistic health models of CAM may be able to complement biomedicine in areas such as chronic conditions or where radical changes in lifestyle need to be maintained and supported by a therapist.

Drawbacks of an integrated approach include:

- the risk that there will be a focus on providing a limited number of therapies that are accepted in an integrated system at the expense of efforts to determine whether other therapies can be used, that may be less proven but are have potential
- integration of specified practitioners may lead either to an oversupply of primary health practitioners, or to discontinuation of a practice where integration is not accepted, thereby reducing consumer options
- the burden of continuing education required for both CAM therapies and biomedical therapies could become excessive.

These views were echoed in submissions received in response to MACCAH's 2003 discussion document, *Complementary and Alternative Medicine: Current Policies and Policy Issues in New Zealand and Selected Countries*. A large number of submissions were in favour of increasing integration and provided suggestions of settings or health conditions which would benefit from this. There were however some additional drawbacks identified:

- concerns about the lack of a recognised evidence base for CAM
- the possibility that CAM practitioners would not have equal status in an integrated system
- the incompatibility of different forms of practice.

Some New Zealanders also thought that further integration should only occur after systems of regulation were strengthened and a sound evidence base was established.

5.6 What factors facilitate or obstruct integration?

Consumers, CAM practitioners, biomedical practitioners, and the government are potential participants in the integration process. The development of an integrated health system depends on the perspectives and approaches that each party brings to integration, and whether these approaches facilitate or present challenges to the integration of CAM in the health system.

MACCAH has considered these factors with reference to the New Zealand situation and identified the following factors as facilitating integration:

(a) Consumer demand for CAM practitioners

A measure of consumer demand can be obtained from the provisional results of the 2002/03 New Zealand Health Survey, which records the number of New Zealand adults who made a visit to a CAM practitioner at least once during a 12-month period. By gender, 28.1% of all New Zealand women and 18.4% of all New Zealand men made at least one visit. By ethnicity; 22.7% of Māori adults; 12.3% of Asian New Zealand adults; and 11.7% of Pacific New Zealand adults, and 25.1% of all other New Zealand adults made a visit.

Further understanding for this demand for CAM practitioners can be gleaned from the reasons given for choosing to see a complementary and alternative health practitioner. These reasons were: for help with conditions that other health care providers were unable to treat (50.7% of those that visited a practitioner); through referral by a friend or relative (29.2%); to seek specialist services (12.5%); through referral by their doctor (12.0%); and because the CAM practitioner was able to spend more time discussing their health than a doctor (9.8%). A smaller proportion indicated that complementary and alternative health practitioners were more accessible in terms of cost or location: 6.2% gave the reasons of CAM being cheaper than a medical doctor; 2.7% said the CAM practitioner was closer than a doctor (Ministry of Health, Unpublished, 2004. see Appendix A3).

(b) CAM and biomedical practitioners are already referring patients to each other

The only source of national data MACCAH has located on referral practices by general practitioners are the provisional results of the 2002/03 New Zealand Health Survey, which found that of the 23.4% of New Zealand adults who visited a CAM practitioner during the previous year, 12.0% had been referred by their general practitioner (Ministry of Health, Unpublished, 2004. see Appendix A3).

A number of small regional studies have also been undertaken. For example, in a study of Wanganui general practitioners' and patients' use of, and attitudes towards, CAM, it was found that 92% of general practitioners referred patients to CAM practitioners, and 80% had contact with at least one CAM practitioner (Taylor, 2003). When questioned about their confidence in CAM therapies, acupuncture was rated the most useful, followed by chiropractic, hypnosis, aromatherapy and Rongoa Māori.

In a study of 249 Auckland based general practitioners, 171 (68.7%) of the practitioners had referred patients to CAM treatment (Marshall et al, 1990). 56 (32%) of the practitioners felt that it was necessary for the CAM practitioner to be medically qualified. The study also found that younger doctors were the most likely to refer patients to CAM practitioners.

The most common reason for referral given by general practitioners was the 'failure of conventional medicine'. This is similar to the provisional findings of the 2002/03 New Zealand Health Survey in which the main reason for visiting a CAM practitioner was to provide help with conditions that other health care providers were unable to treat (48.7%).

(c) Practitioners are already undertaking 'cross' training

The Wanganui study found that seven out of the 25 general practitioner respondents had some CAM training and practised some form of CAM therapy (Taylor, 2003).

In the earlier study (Marshall et al, 1990), 75 (30%) of the Auckland practitioners practised one or more forms of CAM, with acupuncture being the most common form of treatment. CAM treatments were most frequently used to treat musculoskeletal and chronic pain syndromes.

(d) Biomedical professional groups are already developing policies on CAM.

(e) CAM professional groups are providing policies on referral.

(f) Medical schools are providing information on CAM.

(g) There are moves within CAM education to provide a basic level of biomedical understanding (for example, in anatomy, physiology, first aid and emergency procedures).

(h) Stronger forms of regulation are being developed, along with the promotion of practitioners who belong to these groups.

(i) The Ministry of Health's CAM database provides more evidence-based information on specific CAM modalities.

The following factors may act as barriers to integration:

- (a) professional resistance to CAM integration by CAM or biomedical practitioners unwilling to refer patients to other forms of treatment
- (b) the practicalities of the additional demands involved with continuing education about other forms of health care in order to make appropriate referrals.

5.7 What criteria should be used to determine whether or not a CAM modality is integrated?

MACCAH has considered the approaches to integration used by overseas countries as a way of establishing the criteria for determining whether a modality should be integrated or not. The three country-based approaches outlined below each emphasise:

- the need for the safety and efficacy of treatments to be established before integration
- the role of strong forms of regulation in providing a measure of practitioner skill and safety
- the wider role that CAM may have in health care (i.e. not just curative treatment)
- the potential value of studying examples of integration, in practice, as a means of streamlining services to targeted groups or to improve delivery mechanisms.

Canada

In a paper prepared for Health Canada, it is acknowledged that integration already occurs in Canada through consumers combining different forms of health care (Tataryn and Verhoef, 2001). Adoption of three key criteria to establish the appropriateness of further integration occurs at the systemic, professional, clinical and practitioner levels. The three key criteria are:

- evidence of the safety and efficacy of a treatment modality
- evidence for improving the quality of life (it is suggested that Canada's ageing population and the growing number of people with chronic diseases mean that quality of life issues are becoming an increasingly important aspect of health care)
- evidence of the potential to prevent disease and illness.

MACCAH notes that these approaches require decision makers to agree as to what level of evidence is necessary to prove that a treatment is safe or effective, or that it improves the quality of life, or that it has the potential to prevent disease. Tataryn and Verhoef (2001) suggest that evidence from well conducted and scrutinised observational studies coupled with the accumulation of knowledge on the medical uses of plants and other practices may be as acceptable as evidence from randomised control trials.

Other factors mentioned as secondary criteria for integration include the extent of present use, the cost and ease of integration, and risk/benefit analysis.

United Kingdom

In its response document to the House of Lords' Select Committee on Technology and Science Report, the UK government (Department of Health: 2001) agreed on an approach towards greater integration with the following key features:

- privately practising CAM therapists should work towards integration between CAM and conventional medicine and should encourage patients to discuss all conditions with their general practitioners
- both CAM and general practitioners should keep an open mind about each other's ability to help their patients, help patients feel comfortable about integrating their health care provision, and exchange information about treatment programmes and perceptions of the health care needs of patients.

The government also agreed that all National Health Service provision of CAM should continue through general practitioner referral and only be available to practitioners of statutorily regulated CAM therapies or to those with a powerful mechanism for self regulation.

United States

With respect to integration the United States' White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP, 2002) recommended that:

- nationally recognised accrediting bodies evaluate how health care organisations within their oversight are using CAM practices and develop strategies for the safe and appropriate use of qualified CAM practitioners and the safe and effective use of products in these organisations (WHCCAMP: Recommendation 21)
- the Federal Government facilitate and support the evaluation and implementation of safe and effective CAM practices to help meet the health needs of special and vulnerable population (WHCCAMP: Recommendation 22). Among the actions recommended was the identification and evaluation of models of health care delivery with safe and effective CAM practices, followed by targeting successful models for use with special and vulnerable populations, including the chronically and terminally ill. Another recommended action was the development and evaluation of demonstration projects that integrate safe and effective CAM services as part of health care programmes in hospices and community health centres.

Relevance to New Zealand

Integration of CAM and biomedical practitioners already occurs in New Zealand on an ad-hoc basis. Health care consumers make choices to combine care, practitioners

choose to work co-operatively or to gain training in both CAM and biomedicine, and health provider and policy bodies are starting to develop policies about CAM (see Appendix A6 for hypothetical scenarios that illustrate some current issues in New Zealand).

Biomedical bodies are also developing or revising existing policies about the practice of CAM, and are acknowledging that many health consumers are choosing to visit CAM practitioners. Many CAM bodies have codes of practice that specify situations in which they are expected to refer to a biomedical doctor.

MACCAH considers increasing the level of integration would be appropriate for the following reasons:

- equity of access to CAM
- the potential to maximise health outcomes through the combining of safe and effective CAM and biomedical treatments
- minimising of risks involved with potential interactions between forms of treatment.

In particular, where there is proof that a CAM treatment is safe and that it is able to make a significant contribution to health care (be it for maintenance, prevention, treatment or relief) it is unfair that only those who can pay should gain access to such treatment. MACCAH considers that effective delivery of treatments is vital and would expect that a robust system for regulating practitioners would help ensure the quality of CAM practitioner care.

MACCAH therefore suggests that further integration along the lines of the criteria being considered elsewhere would be appropriate for New Zealand, i.e. where there is evidence for efficacy and safety of the CAM and statutory regulation or strong self-regulation. As stated in other chapters, defining what constitutes 'sufficient evidence' for a particular use of CAM in a given situation is an area that requires further exploration in the New Zealand setting.

Similarly, there is a need to have more information about the nature of regulation, including the means of monitoring compliance, and managing breaches of regulations. These are issues that MACCAH considers will need to be investigated before any national policies or guidelines on the integration of CAM are developed. However, MACCAH believes that while such guidelines are being developed for use by District Health Boards and other health provision decision makers, there would be value in establishing pilot studies to identify the practicalities, costs, benefits and health outcomes that would accompany CAM and biomedical practitioners working together.

In addition, MACCAH suggests that a mechanism be developed to ensure that both biomedical trainees and practitioners have education and access to up-to-date information about CAM practices, their evidence base and regulatory mechanisms. Equally, CAM practitioners will need accurate and up to date information about appropriate referral practices.

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Chapter 6: The New Zealand Health Strategy

6.1 Term of reference

To provide advice on how complementary and alternative health care can improve outcomes in the priority areas signalled by the New Zealand Health Strategy.

6.2 Context of recommendations

In meeting the Terms of Reference, MACCAH has considered:

- those areas generally in which complementary and alternative health care may contribute to improving outcomes that go some way towards achieving the priority population health objectives of the New Zealand Health Strategy
- issues relating to the information required by consumers (as covered in the Consumer Information chapter)
- issues relating to how the nature and extent of a CAM contribution could be assessed, including the levels of evidence needed for safety, efficacy and cost-effective (as covered in the Research and Evidence chapter)
- the issues around integrating CAM services to form part of an interdisciplinary approach (as covered in the Integration chapter)
- a brief review of evidence for the efficacy of complementary and alternative health care in key areas relating to two of the thirteen population policy objectives.

MACCAH supports the view that a holistic approach to health, involving consideration of the physical, mental, spiritual and family aspects, is required to achieve optimal well-being, and to prevent disease, injury, illness and unwanted side effects. MACCAH recognises that such a view of health is central to many CAM therapies.

MACCAH also recognises that a range of intervention strategies are required to eliminate or minimise the occurrence of disease, injury, illness and any unpleasant side effects of treatment, and to maximise the likelihood of recovery and associated quality of life.

Thus, the main forms of CAM intervention strategies aim to:

- maintain existing good health, or through prevention reduce the likelihood of an initial or further onset of disease, injury, illness, or unwanted side effects
- diagnose and intervene early to minimise or reverse the effects of disease, injury, illness, or unwanted side effects
- treat a disease, injury, illness, or unwanted side effects

- relieve and manage the symptoms of illness, injury or disease or associated side effects of treatment.

MACCAH supports the wider use of complementary and alternative health care practices where there exist appropriate levels of evidence for efficacy, safety and cost-effectiveness in comparison to other forms of intervention for the outcome.

MACCAH recognises this may require a framework to improve co-ordination among different health service providers, to ensure that appropriate information is provided to health consumers and to enable efficient use of New Zealand's resources.

MACCAH Recommendations:

15. Where there is evidence of safety, efficacy and cost-effectiveness in contributing to the New Zealand Health Strategy, use of specific CAM modalities should be encouraged.
16. Where evidence of safety, efficacy and cost-effectiveness of a CAM is inconclusive but has potential, research should be undertaken into the contribution that the CAM may make to the New Zealand Health Strategy outcomes.
17. Further information about the contribution of CAM towards the New Zealand Health Strategy priorities should be developed and distributed for use by health care decision makers, health professionals and consumers.

6.3 What are the issues?

The New Zealand Health Strategy (Ministry of Health 2000) sets out the platform for the Government's action on health, identifying priority areas and aiming to ensure that health services are directed at those areas that will achieve the highest benefits for the population and, at the same time, help to ameliorate inequalities in health.

When reviewing the usefulness and applicability of complementary and alternative medicine (CAM) to the Health Strategy, there are four specific issues to consider:

- How can CAM contribute to achieving the NZ Health Strategy outcomes? (Section 6.4)
- What would be the criteria for using CAM? (Section 6.5)
- What are the difficulties involved? (Section 6.6)
- How can CAM contribute to specific health priorities? (Section 6.7)

6.4 How can CAM contribute to achieving the NZ Health Strategy outcomes?

MACCAH notes that the Government has prioritised the following 13 population health objectives on the basis that any improvement in outcomes in these areas will contribute to the overarching Government initiatives of reducing inequalities, and improving the health status of the population. The objectives are:

- reducing smoking
- improving nutrition
- reducing obesity
- increasing the level of physical activity
- reducing the rates of suicides and suicide attempts
- minimising harm caused by alcohol and illicit and other drug use to individuals and the community
- reducing the incidence and the impact of cancer
- reducing the incidence and the impact of cardiovascular disease
- reducing the incidence and the impact of diabetes
- improving oral health
- reducing violence in interpersonal relationships, families, schools and communities
- improving the health status of people with severe mental illness
- ensuring access to appropriate child health care services, including well child and family care and immunisation (Ministry of Health, 2000).

MACCAH is aware that these priorities are recognised in the Minister's expectations of the Ministry of Health, in the Minister's funding arrangements with the District Health Boards, and in District Health Boards' funding arrangements with providers. MACCAH notes the range of Tool Kits and Action Plans that have been developed to assist District Health Boards in implementing strategies. In particular, a series of toolkits have been developed for use by District Health Boards. These include:

- evidence and 'best practice' for achieving health gains for different population groups
- evidence on action that can be taken by different health providers and agencies outside the health sector
- indicators by which performance on the priority is measured (Ministry of Health, 2000).

MACCAH also notes the availability of *Evidence and Effectiveness: Checklists for DHB Decision Makers* provided to District Health Boards by the New Zealand Guidelines Group to assist in the assessment of the evidence for different forms of treatment.

MACCAH appreciates that in order to receive District Health Board funding, a complementary and alternative health care provider needs to demonstrate that they offer a safe and cost-effective means of addressing the district's population health priorities.

MACCAH also recognises that many individual consumers are already using complementary and alternative health care as part of their overall health care and are funding this treatment themselves. There is however no means of establishing the current contribution that the use of complementary and alternative health care may or may not be making towards all, or specific, Health Strategy goals.

Given this, MACCAH recognises that to improve the outcome in each of the population health areas requires a combination of strategies for:

- prevention – minimising the initial occurrence or further occurrences of a condition (which may be an illness, injury, disease or unwanted side effect) through health care approaches that focus on maintaining good health, on preventative measures, and recognition of early warning signs
- early intervention – diagnosing the onset of a condition or risk factor, and implementing early intervention strategies through health care approaches that require accurate diagnosis, assessment of risk factors relating to the person, and development of an intervention for minimising or reversing the effects of the condition
- treatment – involving diagnosis of the development of a condition, and an assessment of appropriate forms of treatment
- relief – involving minimising unwanted side effects of the condition, or from other forms of treatment. Such health care approaches require knowledge of likely side effects, as well as a means of monitoring the experience of the person.

Such interventions may involve a person making challenging, or severe, lifestyle changes: for example, changes to diet, exercise patterns and stress management practises. These changes sometimes require considerable support to maintain. They may also involve a person experiencing reduced abilities and/or pain or other forms of discomfort for an unknown duration. These factors are not only physical in effect, but also involve a complex interaction of intellectual, psychological, social and family related factors. MACCAH suggests that an approach to health care that considers all factors and provides appropriate support will facilitate achievement of the NZ Health Strategy outcomes.

In an oral submission to the Committee, and in response to MACCAH's 2003 discussion document *Complementary and Alternative Medicine: Current Policies and Policy Issues in New Zealand and Selected Countries*, a cancer patient gave this perspective:

“Health includes our mind and spirit as well as our body. We also need to understand the difference between cure and healing. Cure is a successful medical treatment. Healing is an inner process through which a person becomes whole. In cancer curative treatments may prove impossible. Yet as the disease progresses an inner healing process (emotional, mental and spiritual) can be astonishingly powerful in the patient’s life and in those of their loved ones.”

Submissions on the New Zealand Health Strategy were only sought in the context of discussing how further integration would assist the achievement of the Strategy. However, a number of submissions provided examples of how various forms of CAM may contribute to achieving various objectives of the New Zealand Health Strategy. Overall, the contribution of the holistic approach advocated by many forms of CAM, involving self-responsibility for health and a focus on lifestyle factors and nutrition, was thought to be able to contribute to achieving the goals of the Strategy. In addition, a number of submissions were of the view that CAMs (either in general, or specific modalities) would provide benefit to all the health priorities, and that they do no harm.

MACCAH recognises that a focus on lifestyle factors is inherent in many CAM modalities. For some people, the type of intervention, rationale and support provided by a CAM practitioner may help them to make the necessary changes to prevent an initial or ongoing occurrence of an illness or disease. In suggesting a wider role for CAM, MACCAH recognises that the most efficient form of health care needs to be used in all situations, particularly where a person’s condition is acute, severe or involves likelihood of infection.

6.5 What would be the criteria for using CAM?

MACCAH suggests that the main criteria for deciding whether a particular CAM intervention contributes to achieving the goals of the New Zealand Health Strategy should be whether there is evidence that an intervention is safe, efficacious and cost-effective with respect to the purpose (or outcome sought) from the treatment. Previous chapters have discussed each of these criteria.

6.6 What are the difficulties involved?

As MACCAH has already suggested, further work and agreement is needed in order to determine the level of proof of safety, efficacy and cost-effectiveness required in relation to the functions that a CAM intervention might have in health care (for example, for prevention, treatment or relief). In addition, further identification is needed of the degree of regulation required to assure patients and healthcare funders that the risks have been minimised and the safety and efficacy of individual practitioners maximised. Finally, there is a need for information about CAMs to be in a form that is easily understood by consumers, District Health Boards and others funding health care.

6.7 How can CAM contribute to specific health priorities?

MACCAH suggests that complementary and alternative medicine can contribute to the healthcare of the consumer through an emphasis on general lifestyle factors and diet, taking a holistic approach to health (involving shared emphasis on the physical/spiritual/mental/social/family aspects), and the specific contribution of safe and efficacious modalities. Such modalities may minimise the incidence (i.e. primary or secondary prevention), and the impact (treatment and relief).

However, MACCAH notes that further research is needed to establish whether, and how, CAM actually contributes to this area. The international literature suggests many consumers choose CAM practitioners for particular reasons, and that these reasons often appear to be subsequently emphasised in the philosophies and provision of many CAM modalities. MACCAH recognises that choosing to use and a willingness to provide are not the same as demonstrated effectiveness and safety in an area.

Contribution of CAM to Palliative Care (towards the NZ Health Strategy goal of reducing the incidence and impact of cancer)

To further identify practicalities that may help establish whether and how CAM may contribute to specific outcomes of the New Zealand Health Strategy priorities, MACCAH explored the evidence for safety and efficacy available in one aspect of these priorities – palliative care.

Improving the quality of palliative care is an outcome that contributes to the Health Strategy objective of ‘reducing the incidence and impact of cancer’. ‘Ensuring access to appropriate palliative care services’ is also one of the Government’s population objectives, of medium priority (Ministry of Health, 2000).

Palliative care can be defined as:

‘Palliative care: provides relief from pain and other distressing symptoms; affirms life and regards dying as a normal process; intends neither to hasten nor to postpone death; integrates the psychological and spiritual aspects of patient care; ... will enhance quality of life, and may also positively influence the course of illness; is applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life, such as chemotherapy or radiation therapy, and includes those investigations needed to better understand and manage distressing clinical complications’ (see World Health Organization, 1998).

This is an approach that improves the quality of life for patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering, by means of early identification and impeccable assessment

and treatment of pain and other problems, psycho-social and spiritual (New Zealand Cancer Control Strategy: Minister of Health, 2003).

At present approximately 90 percent of people known to be accessing hospice palliative care services in New Zealand have cancer, and the large majority of these people are aged 60 years and over. This age group accounts for 78.8 percent of cancer deaths.

Existing New Zealand strategies include the Minister of Health's Cancer Control Strategy with the goal of improving the quality of life for those with cancer, their family and whānau, through support, rehabilitation and palliative care (Minister of Health, 2003). As well, Objective 4 of the Strategy is to 'ensure that those with cancer and their family and whānau have access to high quality information on treatment and care, including complementary and alternative medicine'. The Minister of Health's Cancer Control Strategy recognises that a diagnosis of cancer presents a psycho-social as well as a physical burden.

Complementary and alternative health care can contribute to palliative care through recommending and supporting diet and lifestyle changes. These include nutritional advice, dietary supplements and aromatherapy. CAM also fits well with the palliative approach in its holistic emphasis, including social, cultural and spiritual aspects.

In looking at the reasons for the apparent popularity of CAM in cancer and palliative care, some researchers have cited the holistic nature of CAM, the focus on individualised and patient-centred treatment plans, the absence of serious adverse effects, the emphasis on improving the health of cancer patients instead of treating the disease alone, and recognition of the importance of the mind-body connection (see Howells and Maher, 1988; Hess, 1999).

MACCAH's brief review of CAM's contribution to palliative care through specific CAM modalities included studies of effectiveness and safety of: acupuncture (for pain relief, nausea treatment and prevention, dry mouth - xerostomia), herbal therapies (extracts, ointments and ingestives) for pain relief, nausea treatment and prevention; hypnosis for pain relief, nausea treatment and prevention; hypnosis for pain relief, nausea treatment and prevention; and homeopathy for nausea treatment and prevention.

There is evidence that the use of the following CAM modalities is increasing in palliative care: acupuncture, aromatherapy, nutritional medicine, homeopathy, hypnotherapy, massage, reflexology, relaxation techniques, and spiritual healing (for example, Ernst, 2001). CAM has also been used to alleviate symptoms related to chemotherapy and radiotherapy, as well as to provide comfort from the disease itself and increase the quality of life of patients who otherwise may despair through methods that promote relaxation, reduce stress and anxiety, relieve pain and other symptoms, and improve sleep (Howells & Maher, 1988). Each of these approaches may contribute to the enhancement of well-being and the quality of life.

Again MACCAH would acknowledge that choosing to use a CAM is not the same as demonstrated efficacy and safety in the area.

MACCAH has therefore considered some of the research evidence that is now becoming available. For example, a large body of evidence on the efficacy of specific CAM modalities has been summarised as part of the *National Guidelines for Use of Complementary Therapies in Supportive and Palliative Care* [in the United Kingdom] (Tavares, 2003).

In considering the efficacy of hypnosis to palliative care, Tavares documents the research evidence for hypnosis enhancing immune support; as an adjunct to more conventional forms of psychotherapy to enhance coping ability; to enhance recovery from surgery; to reduce chemotherapy related nausea and vomiting; to increase tolerance of scanning and radiotherapy procedures; to reduce pain; in mood disturbance and emotional and psychological distress; to enhance quality of life; and to reduce anxiety and depression (Tavares, 2003). Other research evidence is also available (e.g. Valente, 1991; Lynn et al, 2000; Bejenke, 2000; Leichstein et al).

The United Kingdom review also considers the contribution that acupuncture can make to palliative care and includes the evidence supporting the use of acupuncture and acupressure for chemotherapy induced and post-operative nausea and vomiting with high level evidence for acute pain and dry mouth (xerostamia). It is also suggested that there are data to support the use of acupuncture for other symptoms, for example, breathlessness, musculoskeletal pain, hot flushes and angina (Tavares, 2003, Eshkevari 2003, Vickers 1996, Pan and Morrison et al, 2000)

Thirdly, in reviewing the evidence for the contribution of homeopathy to palliative care, it is suggested that further clinical research is required but that there may be some basis for prescribing homeopathic remedies in the following circumstances: for fatigue and hot flushes, anxiety and stress, and depression, quality of life, including mood disturbance, radiotherapy and skin reactions (Tavares, 2003; Lewith and Kenyon, 2000; Ernst 1999).

In summary, the evidence for the efficacy of CAM modalities in palliative care is often mixed, and scientific research is still in a developmental stage (Lewith & Kenyon, 2001). While there is evidence that patients often find the CAM approach useful, difficulties of involving patients in research trials and ethical issues often preclude the undertaking of replicable research of wider applicability. Such factors, among others, need to be overcome before policy is developed for the wider use of CAM.

In assessing CAM's contribution to palliative care (and other priorities of the New Zealand Health Strategy), MACCAH suggests that decision makers need to consider the questions that have been raised in previous chapters, that is:

1. What evidence is there of the safety, efficacy and cost effectiveness of specific CAM treatments?

2. If evidence is strong, are consumers, health practitioners, and purchasers of health services aware of this (through better information) and is there a way of determining which practitioners can provide the service (for example, through robust regulation)?
3. If evidence is not strong but has potential, is there a need for services in the area, and is there the research capacity to evaluate the potential contribution of a CAM intervention?

This example of palliative care illustrates the current problems in assessing the contribution of CAM. While there is evidence of reasons for use, provision, and some positive benefits, there is not yet the sufficient level of evidence required by decision makers.

MACCAH has been struck by the numerous cases where efficacy is claimed for CAM modalities, but where there does not appear to be systematic documentation. This may be in part because research funding is less available for the investigation of effectiveness of relief. It may also be because this is an area traditionally seen as that of a family responsibility. Yet, as family structures change and with an increasing ageing population, palliative care is likely to become increasingly important.

Therefore MACCAH suggests that both more research, and more documentation of findings are needed on the efficacy and safety of specific CAM modalities before CAM's contribution to the population goals of the New Zealand Health Strategy can be fully assessed.

MACCAH also recognises that there is considerable overlap in the emphasis of both biomedical and CAM approaches to some areas of health care, for example an emphasis on lifestyle and diet and in some cases on taking a holistic approach to health. Nevertheless, CAM practitioners may through their time commitment be able to contribute to making these necessary changes.

CAM may be able to add value, but it is currently very hard for decision makers to interpret the range of studies that exist, or to have confidence in any non-randomised control trial evidence and perhaps even in some randomised control trial evidence. This is the area that needs developing, although once methodologies for getting evidence at the right level for prevention, cure, and treatment have been agreed, there are then the issues of public and professional confidence in the information, and government policies to support integration that respects consumer choice.

Implementation of CAM within the framework of New Zealand Health Strategy

As already suggested, implementation would require a process to identify ways that the CAM professions could work towards fulfilling the directives proposed by government. This could be achieved:

- by developing toolkits to identify the action that different types of organisations or providers can take to address the New Zealand Health Strategy priorities
- by developing more detailed action-oriented strategies for specific health issues, services or population groups
- through performance and/or funding agreements with the Ministry of Health, District Health Boards and providers.

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Chapter 7: Where to Next?

The Ministerial Advisory Committee on Complementary and Alternative Health has deliberated carefully over the recommendations made in relation to each of its Terms of Reference. MACCAH members now look forward to New Zealand's complementary and alternative health consumers being further protected through statutory regulation of high risk CAM modality practitioners, and self-regulation of low risk CAM modality practitioners. The Committee hopes for an on-going provision of quality, unbiased information on the safety and efficacy of CAM modalities, and for further work to be done to identify and address consumers' needs for information about the practice of CAM in New Zealand.

MACCAH suggests that research funding bodies should be better able to meet the need for research on the safety and efficacy of CAM modalities as they are practised and used in New Zealand. In addition, the infrastructure needed for the undertaking of CAM research in New Zealand (including priority setting, agreement on methodologies and development of research expertise and partnerships) should be developed.

MACCAH members hope that further innovative and creative forms of integration are initiated by practitioners in both biomedical and CAM fields. Members also look forward to the development of the means for assisting public health decision makers to assess the benefits of CAM, especially in addressing New Zealand's health strategy priorities. In areas where there is less certainty about the contribution of CAM, but where findings have potential, MACCAH looks forward to the value of CAM approaches being investigated and the information and research findings being carefully evaluated.

MACCAH recognises that responsibility for future activities in all these areas lies not only with CAM modalities and their professional organisations but also with other health practitioners, the Ministry of Health and with District Health Boards working together.

MACCAH suggests that each of the above activities is necessary to further progress the potential of CAM to contribute to the health of New Zealanders.

MACCAH recommendation:

18. The Minister of Health should develop a framework (or unit) to coordinate the existing expertise and build a CAM capacity to better evaluate the safety and efficacy of CAM in the interests of the further integration of biomedicine and CAM.

Appendix A1: Membership of the Ministerial Advisory Committee on Complementary and Alternative Health

Prof Peggy Koopman-Boyden (Chair)

David Holden

Rhys Jones

Melva Martin

James McNeill

Janine Randle

Maika Kinahoi-Veikune

Marilyn Wright

Tim Ewer (Committee Advisor)

Appendix A2: Categorisation of Complementary and Alternative Medicines adopted by the Ministerial Advisory Committee on Complementary and Alternative Health

Group 1: Alternative medical systems	Examples
Involve complete systems of theory and practice that evolved independently of, and often prior to, the biomedical approach. Many are traditional systems of medicine that are practised by individual cultures throughout the world.	Ayurveda Traditional Chinese medicine Pacific traditional healing systems Homoeopathy Naturopathy
Group 2: Mind / body / spirit interventions	
Employ a variety of techniques designed to facilitate healing. Only a subset of mind–body interventions are considered CAM. Those that have now have a well-documented theoretical basis (for example, patient education and cognitive-behavioural approaches) are considered ‘mainstream’.	Hypnotherapy Rebirthing Spiritual healing
Group 3: Biological-based therapies	
Involve natural and biologically based practices, interventions and products, many of which overlap with biomedicine’s use of dietary supplements.	Herbal medicine Homeobotanical therapy Biological therapies
Group 4: Manipulative and body-based therapies	
Involve methods based on manipulation and/or movement of the body.	Chiropractic Osteopathy Massage (therapeutic and remedial) Alexander technique
Group 5: Energy therapies	
Focus on the energy fields originating from within the body (biofields) or those from other sources (electromagnetic fields).	Chi kung Reiki Touch for health Bioelectromagnetic-based therapies

Based on the model developed by the United States’ National Center for Complementary and Alternative Medicine Previously published in MACCAH’s Terminology document (www.newhealth.govt.nz/maccah/publications/terminology).

Appendix A3: Use of Complementary and Alternative Health Care in New Zealand

Source: Ministry of Health. Unpublished. 2004. *Provisional data from the 2002/03 New Zealand Health Survey* provided to MACCAH May 2004. The 2002/03 New Zealand Health Survey included face-to-face interviews with more than 12,000 adults (15 years and over). Key results will be available on 30 July 2004 and further analyses are planned.

Note: differences between gender or ethnic groups may be influenced by differences in the age structure of comparison groups.

Q.102 In the last 12 months, did you see any complementary or alternative health care worker or a traditional healer?

Q.103 Who were these? Please indicate all you may have seen in the past 12 months?

Table A3.1: Percentage of New Zealand adults visiting a complementary and alternative health practitioners during a 12-month period 2002/03

CAM Practitioner visited	Consumers as % of NZers surveyed	Female consumers as % of females surveyed	Male consumers as % of males surveyed	Ethnic group consumers as % of ethnic group surveyed			
				Māori	Pacific	Asian	Other
All CAM practitioners	23.4	28.1	18.4	22.7	10.8	11.7	25.1
Massage therapist	9.1	11.6	6.4	8.4	3.5	4.5	9.8
Chiropractor	6.1	6.3	6.0	4.5	1.5	1.3	7.0
Osteopath	4.9	6.1	3.6	2.2	-	-	5.9
Homeopath or naturopath	4.5	6.8	1.9	2.9	0.7	-	5.2
Acupuncturist	2.6	3.4	1.9	1.7	0.9	2.5	2.9
Spiritual healer	1.9	2.3	1.5	4.7	1.4	-	1.7
Herbalist	1.8	2.5	1.0	1.7	1.0	-	2.0
Traditional Chinese medicine	1.4	1.9	0.7	1.1	1.7	4.8	1.1
Māori healer	0.9	1.0	0.7	6.0	-	-	0.2
Pacific healer	0.2	0.3	0.2	-	4.6	-	-
Feldenkrais or Alexander Technique	0.2	0.2	-	-	-	-	0.2
Aromatherapist	0.7	1.0	0.4	0.9	-	-	0.7
Other practitioners	1.3	1.5	0.9	1.3	-	-	1.4

- Q.105 The last time you saw an alternative or complementary health worker about your own health, what was it for? What types of issues do see them about?
- Q.108 The last time you saw an alternative or complementary health worker, did you also see a GP about the same condition?

Table A3.2: Reasons given for last visit to a complementary and alternative health practitioner (of those that made at least one visit)

Reasons for last visit	Consumers as % of NZers surveyed	Female consumers as % of females surveyed	Male consumers as % of males surveyed	Ethnic group consumers as % of ethnic group surveyed			
				Māori	Pacific	Asian	Other
Disability/long-term illness/chronic condition	32.5	31.4	34.5	22.2	30.8	22.4	34.2
Short-term illness or temporary condition	28.3	29.9	25.7	32.1	35.5	50.8	26.9
Injury or poisoning	23.9	19.2	31.8	24.9	27.7	12.1	24.1
Spiritual well being	12.4	14.2	9.6	33.3	13.7	8.6	9.9
Mental/emotional health	10.7	13.1	6.9	18.3	-	-	10.2
Second opinion to what doctor told me	4.3	4.9	3.3	7.1	-	-	3.9
Maternity care	1.9	3.0	-	3.1	-	-	1.7
Contraception/family planning	0.8	1.3	-	2.8	-	-	-
Immunisation/vaccination	0.4	0.2	-	-	-	-	-
Other reasons	10.6	10.7	10.4	5.7	-	6.2	11.4
Also saw GP about same condition	33.4	33.8	32.7	34.2	42.2	31.4	33.1

Please note that percentage listed is of those who visited a practitioner during the 12-month period and that more than one reason could be given.

Q.106: Why did you choose to see a complementary or alternative health worker?

Table A3.3: Reasons given for choosing a complementary and alternative health practitioner (of those that made at least one visit)

Reasons for choosing a CAM practitioner	Consumers as % of NZers surveyed	Female consumers as % of females surveyed	Male consumers as % of males surveyed	Ethnic group consumers as % of ethnic group surveyed			
				Māori	Pacific	Asian	Other
Can provide help with conditions that other health care providers are unable to treat	50.7	52.7	47.5	46.1	53.2	39.7	51.6
Referred by friend/relative	29.2	28.5	30.5	31.9	30.1	30.5	28.8
Offer specialist services	12.5	11.9	13.6	10.1	17.9	8.4	12.8
Referred by doctor	12.0	10.7	14.1	12.6	12.7	14.1	11.8
Can spend more time discussing health than doctor	9.8	11.0	7.9	14.6	11.3	7.4	9.3
Cheaper than doctor	6.2	4.9	8.3	12.2	13.9	-	5.3
Closer than doctor	2.7	2.1	3.8	5.2	8.3	-	2.3
Other reasons	16.7	18.4	14.0	19.7	11.1	13.0	16.6

Please note that percentage listed is of those who visited a practitioner during the 12-month period and that more than one reason could be given.

Appendix A4: Modern Principles of Statutory Self-Regulation in the Health Field

Adapted from Budd S; Mills S. 2000. *Regulatory Prospects for Complementary and Alternative Medicine: Information pack on behalf of Department of Health, United Kingdom.*

Regulatory bodies:

- must set clearly expressed standards of the knowledge, skills, experience, attitudes and values necessary for continuing practice
- should demonstrate that their activities are conducted in an open and clear manner
- should concern themselves with the competence and conduct of practitioners at all stages in their careers
- should not delay in taking action to protect patients from serious adverse outcomes of care when such circumstances arise
- should demonstrate their objectivity in making assessments and forming judgements about performance
- should show that their procedures are free of racial and other forms of bias and discrimination
- should take proper account of the health service contexts when making interventions
- if involved in education, should produce clearly stated standards for professional education and training by which the providers of education and training can be monitored and held to account
- should operate clear and independent disputes procedures
- should supply appropriate and valid information on their regulatory activities
- should demonstrate an ability to work across different regulatory boundaries to develop consistent standards
- should retain high public confidence and have sufficient lay involvement to make an effective contribution in their governance and operation
- should ensure that those being regulated understand what is expected of them and the role of the regulatory body in relation to their practice and wider health services
- should review and update standards regularly taking account of feedback from patients, practitioners and other interested parties
- should ensure that their procedures are well-defined and transparent, that they are operated in a way that is fair and sensitive, and that their efforts to enforce standards are targeted in a way that is proportionate to the seriousness of the problems involved

- should work in partnership with the National Health Service (NHS) and with other organisations that provide or manage healthcare, thus enabling NHS organisations to achieve high standards of quality care for all those for whom the NHS is responsible.

Appendix A5: Legislation affecting CAM Products and Practitioners

Consumer Guarantees Act 1993

The purpose of the Consumer Guarantees Act 1993 is to 'amend the law relating to:

- the guarantees given, or deemed to be given, to consumers upon the supply of goods or services, and
- the rights of redress against suppliers and manufacturers in respect of any failure of goods or services to comply with any such guarantees'.

The following sections of the Consumer Guarantees Act 1993 are particularly relevant to CAM products:

- Section 6: The guarantee as to acceptable quality (reference to safety)
- Section 7: The meaning of 'acceptable quality'
- Section 8: Guarantees as to fitness for a particular purpose
- Section 9: The guarantee that goods comply with their description.

Fair Trading Act 1986

The main purposes of this Act are to prohibit certain conduct and practices in trade, to provide for the disclosure of consumer information relating to the supply of goods and services, and to promote product safety.

The following sections of the Fair Trading Act 1986 are pertinent to CAM practitioners and products:

- Section 9: Misleading and deceptive conduct generally
- Section 10: Misleading conduct in relation to goods
- Section 11: Misleading conduct in relation to services
- Section 13: False representation.

Food Act 1981 and New Zealand (Australia New Zealand Food Standards Code) Food Standards 2002

The Food Act 1981 was enacted in order to 'consolidate and amend the law relating to the sale of food'. The definition of food is such that it would include some CAM products. Food is defined in the Act as anything that is used or represented for use as food or drink for human beings, and includes:

- (a) any ingredient or nutrient or other constituent of any food or drink, whether that ingredient or nutrient or other constituent is consumed or represented for

- consumption by human beings by itself or when used in the preparation of or mixed with or added to any food or drink, and
- (b) anything that is or is intended to be mixed with or added to any food or drink, and
 - (c) chewing gum, and any ingredient of chewing gum, and anything that is or is intended to be mixed with or added to chewing gum’.

The following sections of the Act are particularly relevant to CAM products:

- Section 9: General prohibition on sales
- Section 10: Misleading labelling and packaging
- Section 11: Restrictions on advertising.

Regulations made under the Food Act 1981 include:

- **Food Regulations 1984** – establish general labelling requirements for food, and general standards for vitamins and minerals. They also establish specific standards and labelling requirements for different food groups. These regulations also cover food additives, and the protection and safety of food.
- **Dietary Supplements Regulations 1985** – establish general requirements, such as maximum daily doses and therapeutic claims. They also establish specific requirements regarding, for example, tableting aids and preservatives. Many complementary and alternative health products are deemed to come under the definition of dietary supplements. The definition of dietary supplement given in these regulations is as follows:

‘any amino acids, edible substances, foodstuffs, herbs, minerals, synthetic nutrients, and vitamins sold singly or in mixtures in controlled dosage forms as cachets, capsules, liquids, lozenges, pastilles, powders, or tablets, which are intended to supplement the intake of those substances normally derived from food’.

- **Food Standards Code**

The New Zealand Food Safety Authority was formed on July 2002 and is responsible for “food safety” for New Zealand consumers and meeting importing country requirements for New Zealand exports. A Food Standards Code implemented in December 2002 is a joint set of food labelling and composition standards for New Zealand and Australia. It provides consumers with information about contents of the food they eat and a common set of food composition and labelling rules between New Zealand and Australia. FSANZ (formerly the Australia New Zealand Food Standards Authority - ANZFA) develops food standards (primarily composition and labelling) for food sold in Australia and New Zealand.

Health and Disability Commissioner Act 1994

This Act may impact on CAM practitioners. The purpose of the Act is to 'promote the rights of health and disability consumers, and, in particular:

- (a) to secure the fair, simple, speedy, and efficient resolution of complaints relating to infringements of those rights, and
- (b) to provide for the appointment of a Health and Disability Commissioner to investigate complaints against persons or bodies who provide health care or disability services; and to define the Commissioner's functions and powers, and
- (c) to provide for the establishment of a Health and Disability Service Consumer Advocacy Service, and
- (d) to provide for the promulgation of a Code of Health and Disability Services Consumers' Rights, and
- (e) to provide for matters incidental thereto'.

- **Code of Health and Disability Consumers' Rights**

The Code confers a number of rights on all consumers of health and disability services in New Zealand. It places corresponding obligations on providers of those services, including those who practise CAM.

The Code covers all registered health professionals. It also brings a level of accountability to all those who might be considered to lie outside the mainstream of medical practice (for example, naturopaths, homoeopaths and acupuncturists). It is the duty and obligation of providers to comply with the Code to ensure that they promote awareness of it to consumers, and to enable consumers to exercise their rights.

Under the Code, the 10 rights of consumers and duties of providers are as follows:

- Consumer right 1: The right to be treated with respect
- Consumer right 2: The right to freedom from discrimination, coercion, harassment and exploitation
- Consumer right 3: The right to dignity and independence
- Consumer right 4: The right to services of an appropriate standard
- Consumer right 5: The right to effective communication
- Consumer right 6: The right to be fully informed
- Consumer right 7: The right to make an informed choice and give informed consent
- Consumer right 8: The right to support
- Consumer right 9: Rights in respect of teaching or research
- Consumer right 10: The right to complain.

Health Practitioners Competency Assurance Act 2003

The Health Practitioners Competence Assurance Act 2003 (HPCA) aims to provide a framework for the regulation of health practitioners in order to protect the public where there is a risk of harm from the practice of the profession.

The framework covers a diverse range of health professional occupational groups and when fully in force in September 2004, the Act will repeal 11 occupational statutes governing 13 professions.

Having one legislative framework will allow for consistent procedures and terminology across the professions. The principal purpose of the Act is to protect the health and safety of the public. The Act includes mechanisms to ensure that practitioners are competent and fit to practise their professions for the duration of their professional lives.

- The HPCA package is about public safety. Its purpose is to protect the health and safety of members of the public by providing mechanisms to ensure the lifelong competence of health practitioners.
- The HPCA builds on the existing framework. All the major concepts of the Medical Practitioners Act 1995 have been carried forward into the HPCA, adjusted where necessary to generic terms to provide a framework that can apply to all health practitioners, not just doctors.
- The basic principles of ongoing competence, separation of the registration process from the disciplinary process, and the declaration of protected quality assurance activities have all been carried through to the new legislation.
- Major deficiencies in the mix of existing occupational legislation (and the difficulties that caused for the existing authorities) will end with this new legislation.
- Important key protections are in place, with provisions that will ensure that:
 - (a) only health practitioners who are registered under the new Act will be able to use the titles protected by the Act or claim to be practising a profession that is regulated by the Act, and
 - (b) registered health practitioners will not be permitted to practise outside their scopes of practice, and
 - (c) registration authorities will be required to certify that a practitioner is competent to practise in their scope of practice when they issue an annual practising certificate, and
 - (d) certain activities will be restricted and will only be able to be performed by registered health practitioners.

Medicines Act 1981

The purpose of the Medicines Act 1981 is to 'consolidate and amend the law relating to the manufacture, sale, and supply of medicines, medical devices, and related products'.

The Act is broadly relevant to CAM products and practitioners. In the Act, the terms 'medicine' and 'therapeutic purpose' are defined. Part II discusses medicines and medical devices. Various sections state that manufacturers, wholesalers and packers of medicines are to be licensed. Part II also discusses the sale of medicines by retail. There are some exemptions that allow natural therapists to provide medicines to individuals, and in respect of herbal remedies administered to particular individuals. There is a section regarding quality and standards for medicines and medical devices. There is also a section on advertising.

The following sections are particularly pertinent to CAM:

- Section 2: Interpretation (defines 'herbal remedy')
- Section 3: The meaning of 'medicine'
- Section 4: The meaning of 'therapeutic purpose'
- Section 28: Exemptions in respect of herbal remedies
- Section 32: Exemptions for natural therapists and others.

A 'herbal remedy' is defined in Section 2 of the Act as:

'a medicine (not being or containing a prescription medicine, or a restricted medicine, or a pharmacy-only medicine) consisting of:

- (a) any substance produced by subjecting a plant to drying, crushing, or any other similar process, or
- (b) a mixture comprising two or more such substances only, or
- (c) a mixture comprising one or more such substances with water or ethyl alcohol or any inert substance'.

A 'medicine' is defined in Section 3 of the Act as:

'any substance or article, other than a medical device, that is manufactured, imported, sold, or supplied wholly or principally:

- (a) for administering to one or more human beings for a therapeutic purpose, or
- (b) for use as an ingredient in the preparation of any substance or article that is to be administered to one or more human beings for a therapeutic purpose, where it is so used:
 - (i) in a pharmacy or a hospital
 - (ii) by a practitioner

(iii) in the course of any business that consists of or includes the retail sale, or the supply in circumstances corresponding to retail sale, of herbal remedies,

(c) for use as a pregnancy test.’

New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods

This code has implications for the manufacture of CAM products. It sets out standards for:

- the manufacture of pharmaceutical products
- the manufacture of blood and blood products
- compounding and dispensing generally, and specifically, compounding and dispensing of pharmaceutical products
- wholesaling of medicines and medical devices
- uniform recall procedure for medicines and medical devices.

Appendix A6: Scenarios of Possible Integration

Example 1: Integration through consumer choice

Over the past year or so, Renee has been getting migraines. She has gone to her general practitioner who has recommended that she take tablets when she feels the start of a migraine. This has usually been effective in stopping the more severe effects of the migraine but a friend has suggested that Renee see her acupuncturist who has recommended acupuncture treatment, along with changes to her diet.

Example 2: Integration through practitioner training in both biomedicine and CAM

Jenny spent the weekend digging up a section of the lawn for a new flowerbed. She felt a bit tired on Sunday night but on Monday morning, found she could barely walk. Something had happened to her back. She phoned her work and her manager suggested a doctor who 'specialised in backs'. Jenny decided to follow up the recommendation. She found the doctor also specialised in Chinese medicine and prescribed her a course of Chinese herbs to help her recover from the injury along with some prescription medicine for pain relief.

Example 3: Integration through practitioner referral

Robyn is the owner/manager of a small health practice in a semi-rural location. She is a physiotherapist. Other members of the practice include a general practitioner, a chiropractor, a naturopath, a massage practitioner/aromatherapist, a podiatrist and a counsellor. An older woman, Mary, visits Robyn who treats her for arthritis in her knee. Mary mentions digestive problems she has been experiencing and Robyn suggests that she take advantage of the 'Two for the price of one' appointments that are currently being offered by the doctor and the naturopath. Visiting the doctor will mean that Mary can get access to subsidised diagnostic tests which will establish if there is a serious underlying condition responsible for her condition. The naturopath will conduct his own diagnoses and with Mary's permission the two practitioners will discuss her case and develop some suggestions before her next appointment.

Example 4: Integration of practitioners in secondary care

Unit 'Ex' is a specialist unit for those that experience severe or chronic pain. Practitioners working in 'Ex' include biomedical specialists with training in various fields of medicine, nursing and psychology. They have found that for many patients effective pain management and relief involves a multi-disciplinary approach. Some staff members have also broadened their skills through undertaking training in therapeutic massage, acupuncture, and art therapy, and they bring in CAM expertise from practitioners on an as-needed basis. To find out who might be appropriately skilled in the area they contact the professional organisations who are generally able to provide names of local practitioners with appropriate training.

Example 5: Integration – a policy and funding issue

For some time, the 'Wai' District Health Board has been aware that in one of the district's hospitals, patients have requested visits from CAM practitioners. This has generally been tolerated on the understanding that in-patients pay for these visits themselves and have received any treatments during visiting hours to avoid interfering with hospital routines. Some patients have requested visits from practitioners outside visiting hours. At another location, both staff and patients have requested the use of aromatherapy atomiser and have forwarded a pile of articles on the benefits of aromatherapy in secondary health care settings. 'Wai' has checked with the Ministry of Health but there are no guidelines in this area.

Appendix A7: List of Publications by the Ministerial Advisory Committee on Complementary and Alternative Health

Ministerial Advisory Committee on Complementary and Alternative Health (MACCAH). 2002. *Terminology in Complementary and Alternative Health*. Wellington. Wellington: Ministry of Health.
www.newhealth.govt.nz/maccah/terminology.htm

Ministerial Advisory Committee on Complementary and Alternative Health (MACCAH). 2002. *First Annual Report to the Minister of Health*. Wellington. June 2002. Wellington: Ministry of Health.
www.newhealth.govt.nz/maccah/maccah-first-annual-report.pdf

Ministerial Advisory Committee on Complementary and Alternative Health (MACCAH). 2003. *Complementary and Alternative Medicine: Current Policies and Policy Issues in New Zealand and Selected Countries. A Discussion Document 2003*. Wellington: Ministry of Health.
www.newhealth.govt.nz/maccah/ComplementaryandAlternativeMedicineDiscussionDocument.pdf

Ministerial Advisory Committee on Complementary and Alternative Health (MACCAH). 2003. *Complementary and Alternative Medicine: Current Policies and Policy Issues in New Zealand and Selected Countries. Submission Booklet 2003*. Wellington: Ministry of Health.
www.newhealth.govt.nz/maccah/CAMSubmissionBooklet.pdf

Ministerial Advisory Committee on Complementary and Alternative Health (MACCAH). 2003. *Second Annual Report to the Minister of Health*. Wellington. December 2003. Wellington: Ministry of Health.

Appendix A8: Summary of Submissions received in Response to the Discussion Document *Complementary and Alternative Medicine: Current policies and policy issues in New Zealand and selected countries*

Executive summary

This document summarises the content and range of views that were received by written and oral submission in response to the discussion document *Complementary and Alternative Medicine: Current policies and policy issues in New Zealand and selected countries: A discussion document 2003*.

The summary of views, in response to the discussion document, represents one of several important sources of information that were considered by the Ministerial Advisory Committee on Complementary and Alternative Health (MACCAH). Along with other sources of information MACCAH used this summary to help form its final advice to the Minister of Health delivered in June 2004.

This document does not represent the views of the Committee nor can it be taken to be indicative of its final advice to the Minister.

The document provides an overview of the nature and range of views contained in the 315 written submissions received by the Committee by the closing date 30 June 2003. It also reflects the substance of the 13 oral submissions heard and the discussions that occurred at each of the three public presentations/oral submissions hearings held in Auckland (Friday 9 May 2003), Christchurch (Friday 6 June 2003) and Wellington (Friday 27 June 2003).

Scope of discussion document

The discussion document sought views on each of MACCAH's Terms of Reference which, when combined, aim to meet the Committee's overall task of providing information and advice to the Minister of Health on complementary and alternative health care. The specific areas and associated Terms of Reference on which information was sought were:

- **Regulation** – to provide advice on the need, or otherwise, to regulate complementary and alternative practitioners in order to protect consumers who use complementary and alternative health care
- **Consumer information** – to provide advice on consumer information needs and, in particular, advice on the benefits, risks and costs of complementary and alternative therapies

- **Research, evidence and efficacy** – to review overseas evidence-based research, identify priorities for the development of New Zealand evidence-based research on the safety and efficacy of specific complementary and alternative therapies, and support the development of guidelines
- **Integration with mainstream medicine** – to provide advice on whether, and how, specified complementary and alternative health practitioners should be integrated into the mainstream health system
- **New Zealand Health Strategy** – to provide advice on how complementary and alternative health care can improve outcomes in the priority areas signalled in the New Zealand Health Strategy.

The development of policy advice in the area of traditional Māori healing is being led by the Ministry of Health's Māori Health Directorate in the context of implementing He Korowai Oranga, the Māori Health Strategy. As a result MACCAH is not including this area in its advice. A small number of submissions stated that they disagreed with this situation.

Context of consultation

This consultation process was a key part of MACCAH's work programme. It occurred towards the end of the second year of its three-year term and provided crucial input into its work programme and delivery on its Terms of Reference. The discussion document was the Committee's third publication. *Current Policies and Policy Issues in New Zealand and Selected Countries* and *Terminology in Complementary and Alternative Health* were both published electronically on the MACCAH website in 2002.

A number of external processes were also occurring at the time of the consultation, which may have impacted on the overall level of interest and focus of response. Two key pieces of legislation – the Health Practitioners Competence Assurance Bill and the Trans-Tasman Therapeutic Goods Agency regulations were in the final stages of being drafted. The Health Practitioners Competence Assurance Act received the Royal Assent in September 2003 (Appendix C provides more details). Products originating from a major Australian pharmaceutical manufacturer (Pan Pharmaceuticals) were recalled and the Ministry of Health let a tender for the development of a CAM database. In addition, a number of Chinese Medicines sold as herbal remedies had recently been withdrawn by Medsafe because they contained 'pharmacy-only medicines'. The proposed legislative changes, the Pan Pharmaceuticals recall and Chinese herbal medicine withdrawal are most likely to have influenced response to the Term of Reference regarding 'Regulation'. The development of a CAM database is most relevant to the Terms of Reference relating to consumer information, research, evidence and efficacy and the New Zealand Health Strategy.

Summary of response and comments to discussion document

Of the 315 written submissions received, over two-thirds were clearly in response to the questions posed in the discussion document. Many respondents used the submission booklet to make their submission or referred directly to the discussion document content and questions. Other submissions were in letter format. Some of these were extremely brief and focused on one or two issues. Other submissions were much more detailed or provided supplementary material with the submission.

There was some evidence that responses to the submission document were circulated. Forty virtually identical submissions were received from hypnotherapist practitioners and organisations. A smaller number (fewer than 10) of very similar submissions were received from natural medicine practitioners and students. These appeared to be based on the submission from the New Zealand Charter of Health Practitioners Incorporated.

A number of submissions stated that it was important for policies on all forms of CAM to be developed in parallel and to be consistent with those being developed for traditional Māori healing. A few submissions were concerned that regulation of traditional Māori healing would lead to it being dominated by mainstream medicine interests. One submission suggested that as with other spiritual healing processes, that there is no need for regulation in the area at all. A few submissions suggested that New Zealand CAM research should focus on the health issues of relevance to Māori and Pacific people, including their physiology and use of native herbs.

Overall, written submissions tended to focus on regulation. This may have been simply because it was the first topic in the booklet or perhaps due to one or more of the contextual factors described above. The discussion at public presentations often focused on levels of evidence and research methods appropriate to CAM modalities. Oral submissions varied in their coverage of the four areas. Comments were also received about the consultation process.

A. Regulation

Views on regulation were mixed, with the majority of submissions favouring some form of regulation. A few did not support regulation because they thought it would restrict access to practitioners and products. Others thought that regulation would confer an unwarranted status on CAM practitioners and would run counter to achieving consumer or public safety (particularly if consumers sought ineffective treatments and delayed seeking proper medical attention). Of those in favour of regulation, views were divided about whether statutory or voluntary regulation would be more effective in addressing consumer and public safety issues. Those who favoured statutory regulation suggested voluntary schemes would not have the necessary status to enforce standards and disciplinary processes. Those who favoured a voluntary approach thought that a process managed by professional organisations (rather than the government) would encourage a greater ownership of

regulation and thus be more effective in achieving safety. Some advocated an approach based on risk to consumers.

B. Consumer information

Most submissions thought that there was a need for more consumer information about CAMs. There was a concern that information provided be accurate, up-to-date (therefore maintained) and unbiased. Views varied about the type of evidence base that should be required before claims about effectiveness and efficacy can be made. Those in favour of increased consumer information being made available generally agreed that there is probably a need for some central body to have responsibility for co-ordinating and overseeing the provision of information. However, there was variation in views about who should have this central role, particularly over whether the Ministry of Health was an appropriate body.

C. Research, evidence and efficacy

Most submissions suggested more research was needed on the efficacy and cost-effectiveness of CAM and that any research findings should be made more widely available. Some identified limited research funds as an issue in New Zealand and suggested that rather than replicating overseas research New Zealand should focus on its own unique areas (for example, population groups, native plants and fauna). Views were varied about applicability of the 'levels of evidence' model to researching complementary and alternative medicine. Some maintained that the scientific methods used should be the same as those applied to mainstream medicine. Others suggested that different methodologies need to be developed that include consideration of a wider set of variables, for example, the spiritual and mental wellbeing aspects emphasised by CAM practitioners.

D. Integration

The majority of submissions were in favour of a greater degree of integration between CAM and mainstream medicine in a variety of settings. Some pointed out that this integration should be 'with' and not 'into' mainstream medicine. Initial and ongoing education of both CAM and mainstream practitioners about other forms of practice was seen as having the potential to achieve a greater level of integration. It was anticipated that consumers of both mainstream medicine and CAM would benefit from a greater flow of information between practitioners of both modalities. Practitioners would also benefit from knowing the full range of medication that a patient was taking.

E. The New Zealand Health Strategy

While views were only sought on this area in the context of discussing integration, a number of submissions provided examples of how various forms of CAM can contribute to achieving various of the objectives of New Zealand Health Strategy. The contribution of the holistic approach advocated by many forms of CAM involving self-responsibility for health and a focus on lifestyle factors and nutrition was thought to be able to make a contribution to achieving the goals of the New Zealand Health Strategy.

F. Comments on the consultation process

Comments about the consultation process were varied and focused mainly on the breadth of content and terminology used in the discussion document, the timeframe and publicity associated with making submissions, and the location of public presentations. Some very favourable reactions to the discussion document were received both in writing and at the presentations and oral submissions. Less favourable comments concerned perceived biases in terminology, overall focus and questioning. A number of people did not feel that enough time had been allowed for the making of submissions and that more publicity about the availability of the document or greater distribution were warranted. The amount of interest raised by the consultation process was apparent in these comments.

Those who made submissions

The majority of written submissions were either from practitioners of complementary and alternative medicine or from organisations representing a wide range of complementary and alternative medicine modalities. Those who identified themselves as members of the public formed the next largest group. The third major group of submissions included biomedical practitioners and organisations involving doctors, nurses, midwives, pharmacists and physiotherapists.

Within these three groups, a number of submissions indicated an education or training sector interest, either as a private training establishment, a professional body or as an individual student.

Three submissions were received from District Health Boards. Small numbers of submissions were received from voluntary or support groups. Some of these had a focus on particular health conditions.

A submission was received from the Accident Compensation Corporation and one from another health related ministerial advisory committee (the Health Workforce Advisory Committee). Three submissions were received from 'watchdog' groups. One of these was United States-based with a particular focus on health issues. The other two had a brief wider than health (consumer issues and investigations into the paranormal). Two submissions were made from a Pacific perspective. One organisation's submission included a Māori perspective.

Perspective of written submissions received in response to the discussion document *Complementary and Alternative Medicine: Current policies and policy issues in New Zealand and selected countries*

	Number of organisations	Number of individuals	Number of mainstream practitioners also practising CAM
CAM practitioner	59	86	
CAM students	–	5	–
Doctors/medical	7	21	5
Educational organisations	20	22	
Private training establishments	13	9	
Nurse/midwife	3	26	16
Physiotherapists	2	6	5
Pharmacists	1	4	–
Manufacturers or distributors of CAM products	4	–	
Members of the public	–	65	
Voluntary organisations	10	–	
Watchdog groups	3	–	
Pacific	1	–	
Māori perspective	1	–	
Medical related organisations (nutrition, dietetics, optometrists)	3	–	
District health boards	3	–	
Accident Compensation Corporation	1	–	
Health Workforce Advisory Council	1	–	