<table>
<thead>
<tr>
<th>S. No.</th>
<th>Submitter</th>
<th>Page no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Name withheld</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>Taranaki District Health Board</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>Arthritis New Zealand</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>Name withheld</td>
<td>6</td>
</tr>
<tr>
<td>5</td>
<td>Name withheld</td>
<td>7</td>
</tr>
<tr>
<td>6</td>
<td>Natural Health Council (NZ) Inc</td>
<td>9</td>
</tr>
<tr>
<td>7</td>
<td>Auckland Medical School</td>
<td>10</td>
</tr>
<tr>
<td>8</td>
<td>Name withheld</td>
<td>11</td>
</tr>
<tr>
<td>9</td>
<td>New Zealand Medical Association</td>
<td>16</td>
</tr>
<tr>
<td>10</td>
<td>Medical Council of New Zealand</td>
<td>18</td>
</tr>
<tr>
<td>11</td>
<td>Royal Australian and New Zealand College of Obstetricians and Gynaecologists</td>
<td>20</td>
</tr>
<tr>
<td>12</td>
<td>Physiotherapy New Zealand</td>
<td>24</td>
</tr>
<tr>
<td>13</td>
<td>Capital and Coast District Health Board</td>
<td>26</td>
</tr>
<tr>
<td>14</td>
<td>Physiotherapy Acupuncture Association of New Zealand</td>
<td>28</td>
</tr>
<tr>
<td>15</td>
<td>The Royal Society of New Zealand</td>
<td>33</td>
</tr>
<tr>
<td>16</td>
<td>Faculty of Health and Environmental Sciences, Auckland University of Technology</td>
<td>36</td>
</tr>
<tr>
<td>17</td>
<td>New Zealand Nurses Organisation</td>
<td>52</td>
</tr>
<tr>
<td>18</td>
<td>New Zealand Chinese Medicine and Acupuncture Society</td>
<td>58</td>
</tr>
<tr>
<td>19</td>
<td>New Zealand College of Chinese Medicine</td>
<td>59</td>
</tr>
<tr>
<td>20</td>
<td>Physiotherapy Board of New Zealand</td>
<td>61</td>
</tr>
<tr>
<td>21</td>
<td>Sport and Recreation New Zealand (SPARC)</td>
<td>63</td>
</tr>
<tr>
<td>22</td>
<td>New Zealand Institute of Acupuncture</td>
<td>64</td>
</tr>
<tr>
<td></td>
<td>Name</td>
<td>Page</td>
</tr>
<tr>
<td>---</td>
<td>------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>23</td>
<td>Royal New Zealand College of General Practitioners</td>
<td>68</td>
</tr>
<tr>
<td>24</td>
<td>New Zealand Register of Acupuncturists</td>
<td>70</td>
</tr>
<tr>
<td>25</td>
<td>New Zealand Acupuncture Standards Authority</td>
<td>76</td>
</tr>
<tr>
<td>26</td>
<td>Pharmacy Council of New Zealand</td>
<td>81</td>
</tr>
<tr>
<td>27</td>
<td>Name withheld</td>
<td>86</td>
</tr>
<tr>
<td>28</td>
<td>New Zealand Skeptics Inc.</td>
<td>95</td>
</tr>
<tr>
<td>29</td>
<td>Accident Compensation Commission (ACC)</td>
<td>108</td>
</tr>
<tr>
<td>30</td>
<td>New Zealand College of Midwives</td>
<td>111</td>
</tr>
<tr>
<td>31</td>
<td>Royal Australasian College of Surgeons</td>
<td>113</td>
</tr>
<tr>
<td>32</td>
<td>Health and Disability Commission</td>
<td>115</td>
</tr>
<tr>
<td>33</td>
<td>Australian Acupuncture and Chinese Medicine Association</td>
<td>119</td>
</tr>
<tr>
<td>34</td>
<td>Nurse Education in the Tertiary Sector</td>
<td>121</td>
</tr>
<tr>
<td>35</td>
<td>Mark Inglis</td>
<td>124</td>
</tr>
</tbody>
</table>
Individual submission

To Whom It May Concern.

Re the proposal to regulate TCM practitioners..

While I have no real objection to the proposal I do hope this not an elitist move to put practitioners in a position where they have to belong to a particular association.

If regulation does come about then all practitioners need to and must retain the right to belong to any association they wish.

Further there has to be a grandfather clause for registration for people who have been in practice all their adult lives.

People like myself who qualified in 1954 probably feel we do not need to conform to any new age philosophy or requirements. I consider myself a fully able practitioner and am probably more qualified than many of the people who have put the proposal forward.
Submission 2

Please see comments on behalf of Taranaki DHB Planning and Funding Dept.

Regards

Vicki Kershaw
Assistant General Manager, Planning & Funding

I've read the proposal and discovered that it is discussing regulating practitioners of the tradition Chinese medicinal disciplines. I support the concept of regulating TCM practitioners but also support the regulation of the medicinal products they use. There have been a number of instances where Chinese herbal medicines have been found to contain prescription medicines and these products have been available for open sale (as they are not currently regulated as medicines). Thus although this proposal is about regulating a profession you will see I have made comments regarding the issue of regulating the medicinal products which TCM practitioners use.

Submission comments follow (NB: this encompasses feedback from myself and Dianne Wright (clinical advisory pharmacist)):

1. Is TCM a health service, as defined by the HPCA Act?
   Yes.

2. Are practitioners of TCM generally agreed on the qualifications required to deliver the health services they provide?
   Not able to comment.

3. Is there a risk of harm to the public from the practice of TCM?
   Yes.

4. If so, what are the nature, frequency, severity and potential impact of risks to the public? What is the likelihood of the harm occurring?
   There is the risk of harm to the public from both the inappropriate practice of TCM (i.e. a practitioner practising at a poor standard) and also from the unregulated and open availability of herbal medicinal products. There have been numerous cases published where Chinese herbal products have been available in NZ and subsequently found to contain prescription medicines, e.g. steroids, tryptophan. This poses a risk to the health of the public.

   If a product makes a therapeutic claim then it should be classified and regulated as a medicine (under the definition of a medicine in the Medicines Act 1981).

   There are also risks associated with the current poor labelling of these products. It is common for these products to be labelled entirely in Chinese thus it is difficult for a non-Chinese-literature reader to ascertain what is actually in the product (and how much of each ingredient is in the product). This has serious implications when a person using TCM herbal products is admitted to hospital. It is often not possible to ascertain what the product actually contains. Thus it is difficult to ascertain how the product could be impacting upon a patient's clinical status (e.g. bleeding risk) or if the product is / could interact with the conventional medicines the patient is being given.

   It is known that every year several deaths in NZ are attributed to the use of TCM products.
5. Other than on the basis of risk of harm, is it in the public interest that the profession of TCM be regulated?

   It would give the public confidence that the particular practitioner they were seeing was of a set standard. It would also put a legal framework around the actions of the practitioner making them legally responsible for their actions.

6. Are practising TCM practitioners generally agreed on the standards that TCM practitioners expected to meet?
   Not able to comment.

7. Are practising TCM practitioners generally agreed on the competencies for scopes of practice for TCM?
   Not able to comment.

8. What qualifications are generally held by member of the profession, and what is the degree of uniformity in qualifications across members?
   Not able to comment.

9. Does your organisation accord any standing or status to the profession of TCM, or to those who practice as TCM practitioners?
   No

kind regards

Claire Barnfather (nee Sheerin)
Pharmacy Operations Manager
Taranaki District Health Board
Private Bag 2016
New Plymouth
Phone 06 7537814 ext 7733 pager 828
27 July 2011

Mary-Louise Hannah
Workforce Intelligence and Planning
Health Workforce New Zealand
National Health Board
Ministry of Health
PO Box 5013
WELLINGTON 6145

Dear Mary

Response to proposal to regulate traditional Chinese medicine (TCM)

Arthritis New Zealand welcomes the opportunity to submit on this issue and acknowledges the challenges in this area. We have read the consultation documents and considered these against the experiences of people with arthritis accessing health services.

We have provided responses to some of the questions raised in the consultation documents.

Arthritis New Zealand supports this application that TCM become a regulated profession under the HPCA Act. This will set standards for required competency to practice TCM competently, capably and ethically. Our main points are listed below.

1. Is TCM a health service, as defined by the HPCA Act?
   We believe that TCM can be defined as a health service with practitioners assessing patients’ health and designing a treatment plan/programme to improve people physical and/or mental health.

2. Is there a risk of harm to the public from the practice of TCM?
   There is a potential risk of TCM practice not being regulated. TCM is very popular with clients. TCM practitioners are educated in New Zealand or overseas, qualifications are not regulated with a variety of degrees, diplomas etc. Regulation of this practice will provide professional standards and registration to highly qualified professionals and will reduce risk to the public.

3. If so, what are the nature, frequency, severity and potential impact of risks to the public? What is the likelihood of the harm occurring?
• Acupuncture – there is a risk of infection and risk of tissue damage. A UK study in 2010 identified 86 reported deaths following acupuncture treatment.¹
• Chinese herbal medicine – there is a risk of herb-drug interaction; toxicity or other side effects.
• Tuina – there is a risk due to manipulation which can cause body injury.

9. Does your organisation accord any standing or status to the profession of TCM, or to those who practise as TCM practitioners?
   No

Arthritis New Zealand
Arthritis New Zealand is the trading name for the Arthritis Foundation of New Zealand, a registered New Zealand charity. We are an incorporated society that has been operating since 1966. Since early 2000 we have provided services to people regardless of membership status. In the 2009/10 year we provided over 70,000 client contacts and have approximately 7,000 current members.

Arthritis New Zealand facilitates the provision of quality services and programmes, supporting those affected by arthritis through education, public awareness, direct support, lobbying and promoting research. Our National Office is based in Featherston St, Wellington with services delivered nationally. The annual operating budget for Arthritis New Zealand is $4.8million. Over 85% of our income is fundraised, less than 15% of our income comes in the form of contracts with the government.

Arthritis affects one in six New Zealanders over the age of 15, estimated to be over 530,000 New Zealanders. Approximately 1,000 New Zealand children have arthritis. The total financial cost of arthritis in New Zealand (2010) was estimated to be $3.2 billion or 1.7 percent of GDP. Health sector costs of arthritis (2010) accounted for 22% of total financial costs².

Further Information
The contact person for all queries related to this submission is:
Dr Natalia Valentino
Service Development Manager
Arthritis New Zealand
PO Box 74-581
Greenland
Auckland 1546
Ph 09 523 8907

Yours sincerely

Sandra Kirby
Chief Executive

² Access Economics Pty Limited. The economic cost of arthritis in New Zealand in 2010. Arthritis New Zealand; April 2010
Submission 4

Tena koe

The existing of TCM training/education provider does not meet the standard as Australia’s university. Most current Chinese TCM practitioners are not fluent in oral/written English without an evidence to prove their English language proficiency, such as IELTS attempt or lower than band 5 etc.

In addition to the cultural awareness, they do not understand the basis of Treaty of Waitangi in their normal practice. In the public interest, the TCM programme should be taught by local university as medical health science programme. In the transitional arrangement, the existing TCM practitioners should be assessed by English and competent examinations in the delegated authority for two years’ temporary licence and then following with public examination for registration.

Thank you for your attention

Mauri ora
Submission 5

Ministry of Health Criteria are inadequate for assessment of admission of practitioners of Traditional Chinese Medicine (TCM) under the Health Practitioners Competence Assurance Act.

This submission is a response to a recent proposal\(^1\) that would have TCM admitted as a regulated profession under the Health Practitioners Competence Assurance Act, 2003 (“the Act”). My submission has three sections. In the first, I summarise proposed Ministry of Health (MoH) criteria for admission of TCM under the Act, and show that TCM appears to meet the criteria fully, as may all other forms of Complementary and Alternative Medicine (CAM). In the second section, I show that MoH criteria for TCM are inadequate, as they concentrate on harm, and do not take into account potential benefits of TCM. In the third and final section I indicate how the criteria might be corrected by appropriate changes.

1. Does TCM meet the proposed criteria?

A “submission booklet”\(^2\) from the Ministry of Health outlines criteria for assessment of TCM, in the application by TCM practitioners for admission as a regulated profession under the Act. This booklet describes several criteria, which I have divided into three:

a) A first criterion (or pre-condition) is that TCM is a “health service”, which the Act defines as intent to assess, improve, protect or manage health. (Note that there is no requirement for efficacy);

b) Diverse criteria related to structure, organisation and accreditation. These criteria include agreement on qualifications, standards and competencies; regulation of TCM in the public interest; and accordance of status to TCM practitioners;

c) Criteria related to the risk of harm, including the “nature, frequency, severity and potential impact of risks to the public”.

It is clear that although these criteria specifically relate to TCM, they might equally be applied to other disciplines that fall under the heading of “Complementary and Alternative Medicine”. All such disciplines easily meet the first criterion, as they explicitly or implicitly advertise intent to meet at least one of the objectives of assessing, improving, protecting or managing health.

Similarly, it should be easy for many or even most CAM disciplines to demonstrate the structural requirements, including qualifications, standards and competencies; many such disciplines have already established themselves in the public eye (so regulation would seem to be in the public interest), and many have been accorded status not only by the public but also by certain health care professionals who practise 'conventional' Medicine under the Act, but also practise aspects of CAM.

Finally we have point c). The MoH criteria do not define harm clearly, but it should be apparent that harm may take two forms:

i. Active harm (injury is actively induced by the treatment);

ii. Passive harm, which is more insidious and difficult to characterise.

TCM definitely causes active harm, for example the practice of acupuncture has resulted in both injury and death.\(^3\) Based on the MoH criteria, TCM would appear eminently suitable for admission under the Act. Passive harm is more difficult to assess. It can occur through delays in seeking treatment, choice of an

---


3 A recent review (Pain 2011;152(4):755–64) identifies ninety five severe adverse events in the literature, including five deaths. The authors conclude “Numerous reviews have produced little convincing evidence that acupuncture is effective in reducing pain. Serious adverse events, including deaths, continue to be reported”. Another review of the Chinese literature (Bull World Health Organ. 2010;88(12):915–21C) found 479 injuries with 14 deaths; an earlier Japanese review found 124 injuries with two deaths (Complement Ther Med 2001;9(2)98–104). These reports may underestimate the problem, as the abstract of one prospective study reports adverse events in 8.6% of 19,726 patients. (Forsch Komplementmed 2009 16(2):91–7, PubMed reference 19420954).
ineffective treatment, or an “opportunity cost” that arises from a sub-optimal choice. Because it often involves not doing something, passive harm may be difficult to measure. As health care resources of both individuals and society are finite quantities, passive harm will result wherever a sub-optimal choice is made.

As nobody can claim that TCM (or other forms of CAM) always represent an optimal choice, it follows that all forms of CAM have significant potential to cause passive harm, and can thus meet the current MoH evaluation criteria for regulation under the Act. This conclusion invites the possibility that literally hundreds of different variants of CAM will ultimately be accepted for regulation under the Act — variants as diverse as iridology, angel healing, chakra balancing, homeopathy, crystal therapy, Ayurvedic administration of 'organometallic' compounds, and ear candling.

2. A substantial deficiency in the Ministry of Health criteria

The argument of the preceding section has led us to the inescapable conclusion that all forms of CAM can easily meet the current MoH criteria (as advertised in the “submission booklet”). In fact, any organisation with an appropriate structure can potentially be included as a “health service”, regardless of whether it confers a health benefit or not. The MoH criteria concentrate on harm and completely exclude potential benefits of therapy.

It seems peculiar to assess the acceptance of a “health service” based on criteria that exclude any demonstration that this service actually improves health.

Modern science has clear methodology for determining with confidence whether a given intervention confers benefit and/or harm. For example, if a particular drug is claimed to work for a specific condition, subjects with that condition can be prospectively randomised to take either the drug or a placebo, and it can then be determined whether the condition being treated is made better or not. (To remove bias, both those who administer the trial and those who receive treatment should be blinded as to whether the drug or placebo is given). This approach is agnostic of whether the intervention is currently classified under the heading of “Medicine” or “CAM”.

3. How and why MoH criteria should be altered

There are two ways that the MoH criteria could be revised to include assessment of the actual health benefits delivered by the “health service” that is applying for regulation under the Act:

1. A requirement that practitioners from this “health service” demonstrate the current balance of risks and benefits that accrue from their service, measured using the methodology of modern science;

2. Mandating that practitioners demonstrate how they have built ongoing measurement of outcomes into the “health service” and how this measurement feeds back to alter practice.

Both of the above are important. The former can be used to assess whether the “health service” actually is one i.e. that it delivers health in excess of the harm done. (Note that as passive harm will likely be underestimated, this assessment will be biased in favour of the “health service”). The latter will ensure that if the “health service” is admitted for regulation under the Act, a process of continuous quality improvement will be in place from the start.

I recommend that both criteria be made mandatory in the assessment of TCM and any other CAM service that applies for regulation under the Act.

---

5 Effective aspects of what was formerly CAM have already been accepted into Medicine. For example, one of the first drugs used in pharmacology — digoxin — originated as a 'herbal' therapy. Clear characterisation of dosing, effects and pharmacokinetics subsequently allowed a very toxic herbal drug to be used with less danger.
Proposal that Traditional Chinese Medicine be regulated under the Health practitioner’s Competency Assurance Act

Submission from the Natural Health Council (NHC)

This submission addresses the following questions:
1. Is TCM a health service, as defined by the HPCA Act? (Note: the Act defines a health service as ‘a service provided for the purpose of assessing, improving, protecting, or managing the physical or mental health of individuals or groups of individuals’.)
2. Are practitioners of TCM generally agreed on the qualifications required to deliver the health services they provide?
3. Is there a risk of harm to the public from the practice of TCM?
4. If so, what are the nature, frequency, severity and potential impact of risks to the public? What is the likelihood of the harm occurring?
5. Other than on the basis of risk of harm, is it in the public interest that the profession of TCM be regulated?
6. Are practising TCM practitioners generally agreed on the standards that TCM practitioners are expected to meet?
7. Are practising TCM practitioners generally agreed on the competencies for scopes of practice for TCM?
8. What qualifications are generally held by members of the profession, and what is the degree of uniformity in qualifications across members?
9. Does your organisation accord any standing or status to the profession of TCM, or to those who practise as TCM practitioners?

Responses to questions

The NHC would like to submit that:

1. TCM is a health service and an important part of health care delivery in New Zealand, not just for Chinese immigrants and those of Chinese descent, but for all New Zealanders. As a traditional health practice, TCM has the appropriate philosophical and knowledge base to deliver effective health services to people with a wide range of conditions. This base gives it an ability to improve and protect health, rather than just manage disease, which makes it an invaluable health service in the New Zealand environment.
2. The NHC is not qualified to answer this question unconditionally, but we believe that the practitioners have a broad agreement on the level of qualification required.

3. ‘Risk of harm’ is a loaded term, but we believe that, in unqualified hands, TCM does pose a risk to the public.

4. Any herbal medicine tradition (such as TCM, Ayurvedic Medicine and Traditional Western Herbal Medicine) contains herbs that, in unqualified hands or sold over the counter, could be harmful to the public. We contend that such herbs (and each profession will have to define and agree on which herbs and/or preparations pose a risk) should be supplied to the public on a prescription only basis, by those who are trained to dispense such herbs safely.

Acupuncture also has a risk. We contend that acupuncture should only be practised by those who have the appropriate qualifications, as defined by the *NZ Register of Acupuncturists* and the *NZ Acupuncture Standards Authority*.

5. It is important that TCM practitioners be regulated for a number of reasons. The public has the right to expect a high standard of health care delivery from all practitioners. Whilst TCM practice remains under *common law or voluntary regulation*, there is a risk that the high standards will be compromised. This is unacceptable to the NHC, which recognises the need for recognition and registration across those health professions where there is a *risk of harm from them being unregulated* as well as a need to maintain high standards of delivery, based on the appropriate level of qualifications.

6. The NHC is not qualified to answer this question unconditionally, but we believe that the practitioners have a broad agreement on the standards required.

7. The NHC is not qualified to answer this question unconditionally, but we believe that the practitioners have a broad agreement on the competencies and scopes of practice required.

8. The NHC is not qualified to answer this question unconditionally, but we believe that the practitioners within the *New Zealand Register of Acupuncturists* and the *NZ Acupuncture Standards Authority* have received 4 years of training at level 7 (NZQA).

9. At present the NHC does not recognise TCM as a modality to be registered. This is because TCM has maintained its own regulatory body. However, if TCM associations were to apply, and they met the criteria of the NHC, they would be eligible for membership of the NHC’s register.
Submission 7

Dear Mary-Louise

I am writing as Dean of the Faculty of Medical and Health Sciences at the University of Auckland. We have discussed this proposal and would like to make a number of points. I would preface this by saying that there exists within the Faculty a number of divergent views on whether it is appropriate to regulate a profession that many felt did not have a sound scientific evidence base. Against this was the clear recognition of the potential for harm and on this basis our view is that given the numbers of practitioners that TCM should be regulated.

Answers to the specific questions are as below

1. Is TCM a health service, as defined by the HPCA Act? (Note: the Act defines a health service as ‘a service provided for the purpose of assessing, improving, protecting, or managing the physical or mental health of individuals or groups of individuals’). YES

2. Are practitioners of TCM generally agreed on the qualifications required to deliver the health services they provide? WE ARE NOT ABLE TO COMMENT

3. Is there a risk of harm to the public from the practice of TCM? YES, BOTH IN TERMS OF FACTS OF COMMISSION AND OMISSION (NOTABLY NOT REFERRING ON OR INVESTIGATING APPROPRIATELY). FURTHER THERE ARE MULTIPLE EXAMPLES OF THE USE OF TCM WHICH HAS BEEN ADULTERATED WITH OTHER PHARMACEUTICALS, WITH POTENT STEROIDS OFTEN QUOTED AS ONE SUCH.

4. If so, what are the nature, frequency, severity and potential impact of risks to the public? What is the likelihood of the harm occurring? WE CANNOT COMMENT ON THE MAGNITUDE OF THIS RISK

5. Other than on the basis of risk of harm, is it in the public interest that the profession of TCM be regulated? IT IS OUR VIEW THAT THE ISSUE OF HARM IS THE ONLY REASON TO REGULATE. A NUMBER OF INDIVIDUALS IN OUR ORGANISATION HOLD STRONGLY TO THE VIEW THAT REGULATING ENDORSES A PRACTICE WITHOUT A STRONG SCIENTIFIC BASE.

6. Are practising TCM practitioners generally agreed on the standards that TCM practitioners are expected to meet? WE CANNOT COMMENT

7. Are practising TCM practitioners generally agreed on the competencies for scopes of practice for TCM? WE CANNOT COMMENT

8. What qualifications are generally held by members of the profession, and what is the degree of uniformity in qualifications across members? WE CANNOT COMMENT
9. Does your organisation accord any standing or status to the profession of TCM, or to those who practise as TCM practitioners? NO WE DO NOT

We hope that these comments help in your deliberations

Iain Martin

=================================

Iain G Martin
Dean
Faculty of Medical and Health Sciences
University of Auckland
Level 6, E-Com House, Ferncroft Street
Grafton, Auckland
New Zealand

Email i.martin@auckland.ac.nz
Mobile: +64 21 451888
Phone: +64 9 9236740
Fax: +64 9 3082308
Skype ID: iain.g.martin

=================================
22/07/2011

Proposal that Traditional Chinese Medicine Become a Regulated Profession under the Health Practitioners Competence Assurance Act 2003

Mary-Louise Hannah
Workforce Intelligence and Planning
Health Workforce New Zealand
National Health Board
Ministry of Health
PO Box 5013
WELLINGTON 6145

Dear Mary-Louise Hannah,

I am an acupuncturist, the member of NZASA and NZCMAS. It is stirring to hear that the government is going to make Traditional Chinese Medicine Become a Regulated Profession under the Health Practitioners Competence Assurance Act 2003. I write this letter directly to you because I am afraid of my voice being vanished.

I am very happy to see that it will come true as soon as possible. And I believe that the Chinese Medicine will get bloomy in NZ and contribute much more to the society. As we all understand that this is a great and very important step in the NZ history, so it is so important to do it carefully.

I agree most parts of the proposal. And I have my own opinions in the following aspects:

1. About the Minimum qualifications to practise as a practitioner of TCM in New Zealand
1.1 The NZ TCM industry is quite complicated and nonstandard at the moment. Anyone can do even without any qualification. That is dangerous. So it is urgent to make a law to ban those who are not qualified. The Proposal should focus on making a law to ban irregularity and helping improving the atmosphere of the industry. So it is also unfair to elevate the Minimum qualifications from Diploma to bachelor’s degree to practise as a practitioner of TCM in New Zealand.

1.2 Most of the practitioners of TCM in NZ are holding the Diploma Degree at the moment. They are doing well and will be better by time of practice. You can't say that they are not good or illegal or valueless. Otherwise all the patients have been treated and still being treating by them should be acknowledged mistaken. As a governor and law maker (enactive organization) should respect the facts and the history. The diploma degree should remain as the benchmark.

1.3 The higher degrees should be the practitioners' self-determining choice for further development and the employer’s selections. All industries like this. Many industries only need a certificate for the benchmark in NZ.

1.4 Many practitioners have higher overseas degrees like from China, Japan, and Korea etc when they came to NZ. And NZ actually accept their qualifications at the government level. They just need a benchmark to start to contribute to the society. The system today should not devalue them. TCM education in NZ is only a few years and even not enough good teachers compare to thousand years practice, thousands of huge TCM hospitals and 55 years formal education even with postdoctoral degree in China. I do not think that NZ’s TCM qualifications are more valuable than overseas’ qualifications like Chinese qualification. So we should accept the valuable overseas qualifications directly to those who already with NZ’s diploma degree especially to those from the grandfathering country.

1.5 At present NZ is still a beginner in TCM industry. There is a long way to go to improve the industry. We should respectfully to work together with the better one. Our arrogance is going to be someone’s gold mine. I strangely remind the law maker not to be the helper of someone's own business. Because someone already
pushed the practitioners to do the higher degrees and said openly that the benchmark will be bachelor's degree. They took over the government's authority to make private business. And we are the lam waiting slaughtering.

1.6 One big question is who will be the big winner of higher benchmark! Another question is who have the stronger influence to make the law. Is it fair to all the practitioners and the patient? Obviously the schools, the organizers and the English speaking people play the most influence to it. But NZ is a multi-culture country. Is the decision adapted to different ethnic groups? Please consult with the ethnic affair department.

1.7 I graduated from Nanjing University of TCM in Aug. 1987(five years course). Then I worked in the Jiangsu Provincial Hospital of TCM (about 3 thousand staffs, 2000 inpatient beds) for 16 years. I was the director of the Acupuncture Department for four years before I came to NZ in 2003. I was the associate professor in China already. I held a Master's degree on medicine science. Then I immigrated here on skill program in 2003 and opened my own clinic in Auckland. As an ACC provider I helped thousands of people. The bachelor's degree can't help me to do anything, only bothers me and wastes the time and resources. Many practitioners have similar experience like me. Please someone could hear our voice. If you insist to do so then I don't like to pay for it and someone should pay my time spent on it.

2. Language standard

I agree with English as an official professional language. But better do not trace back and make the standard so high. Knowledge is more important than language. And the background of their education and work experience seems more valuable. There are millions of documents been written in foreign languages. The foreign language speakers can contribute more to the local industry. Enough to communicate with the client and can write the notes in English should be ok.

That is my opinions on the Proposal. I will be appreciated if my opinions could help in anyway.
15 August 2012

Mary-Louise Hannah
Workforce Intelligence and Planning
Health Workforce New Zealand
National Health Board
Ministry of Health
PO Box 5013
WELLINGTON 6145

Dear Mary-Louise

Proposal that Traditional Chinese Medicine Become a Regulated Profession under the Health Practitioners Competence Assurance Act 2003

Thank you for the opportunity to comment on this proposal.

The principal grounds for regulation in our view must be public safety. The public must have, protection in respect of services provided by health practitioners. On this basis we support the regulation of practitioners of traditional Chinese medicine, although we note that in general the level of harm to be protected against is low.

We are however, reluctant to see traditional Chinese medicine practitioners regulated under the HPCA Act as the end result is likely to give these practitioners and the products and services they provide legitimacy and credence that they otherwise would not have had.

We have always held the view that before an alleged therapeutic product or service is provided its efficacy should be proven by properly verifiable scientific methodology (such as double blind trials etc). Regrettably much of the complementary or alternative medicines offered (such as traditional Chinese medicine) have not been subjected to these standards of evidence.

We note that the government has in the past raised concern about the proliferation of regulatory authorities being created for new health professions seeking registration and regulation under the HPCA Act 2003. In response to this concern the NZMA suggested the possibility of a two tier system of regulation, the first being the current system to cover those professions where there is potential for significant harm and the second being a lesser licensing system that covered those professions where there was the potential for some harm but at a far lower level. We attach a copy of our original submission on this for your information.
In our view, regulating the practice of traditional Chinese medicine under a second tier licensing system would resolve the following issues:

- It would avoid further proliferation of authorities
- It would protect the public from harm without also fostering an interpretation by the public that traditional Chinese medicine is supported by the government as meeting the same standards of efficacy as other health professions which do subject themselves to properly verifiable scientific methodology.

Yours sincerely

Dr Paul Ockelford
Chair, NZMA
Submission 10

LIA04.13

12 August 2011

Ms Mary-Louise Hannah
Workforce Intelligence and Planning
Health Workforce New Zealand
National Health Board
Ministry of Health
PO Box 5013
Wellington 6145

Dear Ms Hannah

Regulation of Traditional Chinese Medicine

Thank you for asking for the Medical Council of New Zealand to comment on your Proposal that Traditional Chinese Medicine become a regulated profession under the Health Practitioners Competence Assurance Act 2003. Council members discussed the paper at their meeting of 9 and 10 August 2011.

The Medical Council of New Zealand
The Council is a statutory body instituted with the primary purpose to protect the health and safety of the public. It has the following key functions:
- Registering doctors
- Setting standards and guidelines
- Recertifying and promoting lifelong learning for doctors
- Reviewing practising doctors if there is a concern about performance, professional conduct or health.

Comment
The Council’s view is that regulation of Traditional Chinese Medicine (TCM) is appropriate because:
- TCM is a health service and, in an unregulated environment, TCM practitioners may present a risk of harm to the public.
- Regulation may provide some protection to the public through the development of a code of ethics for the profession.
- A form of de facto regulation already exists through the NZASA, the NZRA and the provisions of the Injury Prevention, Rehabilitation and Compensation Act 2005. Regulation would formalise these existing mechanisms and provide for a consistent regulatory regime.
However, although regulation of TCM appears appropriate, Council considers that regulation under the Health Practitioners Competence Assurance Act 2003 (HPCAA) might not be the most effective mechanism. This is because:

- Regulation may have little effect on practice. The Ministry of Health has taken a rather narrow view of s.7 in its interpretation of the HPCAA. This interpretation allows practitioners to perform a large number of the functions of their profession without needing to be registered simply by using a different title. This has proven a particular problem in the regulation of dieticians and occupational therapists, and it appears likely that TCM will face similar issues.
- While a number of TCM remedies are of proven benefit, many are not. Regulation may serve to legitimise treatments that have no positive benefit for patients.

Because of these concerns the Council suggests that Health Workforce New Zealand consider alternate regulatory mechanisms for the regulation of TCM, including:

- Reviewing the requirements of the HPCAA and the Health and Disability Commissioner Act 1994 with a view to providing the Commissioner the ability to refer unregistered practitioners to the Health Practitioners Disciplinary Tribunal, and for the Tribunal to consider such cases and to impose appropriate penalties – including suspension and restrictions on practice.
- Introducing a second tier layer of regulation (modelled on a licensing regime) for professions where the risk of harm is lower as proposed in the Council's submission on Health Workforce New Zealand's Proposal for a shared secretariat and office function for all health-related regulatory authorities together with a reduction in the number of regulatory authority board members. A second tier model could also make use of provisions such as those in s.9 of the HPCAA to prevent non-registered practitioners from performing specified restricted activities.
- Regulation of all traditional and complementary modalities under a single umbrella. This would prevent the problem outlined above, whereby practitioners are able to avoid regulation under the HPCAA simply by using an alternate title.

Thank you again for providing the Council with an opportunity to comment. I hope you find these comments useful. If you have any questions please do not hesitate to contact the Council's senior policy adviser and researcher, Michael Thorn, on (04) 381 6793 or at mthorn@mcnz.org.nz.

Yours sincerely,

Philip Pigou
Chief Executive
10 August 2011

Mary-Louise Hannah
Senior Policy Analyst
Workforce Intelligence and Planning
Health Workforce New Zealand
National Health Board
Ministry of Health
PO Box 5013
WELLINGTON 6145

Dear Ms Hannah

Proposal that Traditional Chinese Medicine Become a Regulated Profession under the Health Practitioners Competence Assurance Act 2003

Thank you for the opportunity to provide comment to the proposal that Traditional Chinese Medicine becomes a Regulated Profession under the Health Practitioners Competence Assurance Act 2003.

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) New Zealand Committee support the Medical Council of New Zealand’s (MCNZ) Statement on complementary and alternative medicines dated March 2011. The NZ Committee would suggest that the MCNZ statement (enclosed) covers the areas that should be considered when progressing with this proposal.

Thank you for the opportunity to comment on the proposal and the RANZCOG New Zealand Committee would be happy to be involved in any further discussions on the matter.

Yours sincerely

Mr John Tait
Chair, New Zealand Committee

Encl.
Statement on complementary and alternative medicine

Background

1. This statement has been written to inform doctors of the standards of practice that are expected of them by the Medical Council of New Zealand should they choose to practise complementary or alternative medicine or if they have patients who use complementary or alternative medicine.

2. This statement may be used by the Health Practitioner’s Disciplinary Tribunal, the Council and the Health and Disability Commissioner as a standard by which a doctor’s conduct is measured.

3. When complementary and alternative medicines (CAM) have demonstrated benefits for the patient and have minimal risks, and patients have made an informed choice and given their informed consent, Council does not oppose their use.

4. No person may be found guilty of a disciplinary offence under the Health Practitioners Competence Assurance Act 2003 merely because that person has adopted and practised any theory of medicine or healing if, in doing so, the person has acted honestly and in good faith.

Definition

5. CAM is a widely used term, but it has no commonly accepted definition. 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 Cochrane Collaboration and the Ministerial Advisory Committee on Complementary and Alternative Medicine is:

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-defined by their users as preventing or treating illness or promoting health and well-being.

And the World Health Organisation defines it as follows:

Complementary and alternative medicine (CAM) refers to a broad set of health care practices that are not part of a country’s own tradition and not integrated into the dominant health care system. Other terms sometimes used to describe these health care practices include ‘natural medicine’, ‘non-conventional medicine’ and ‘holistic medicine’.

---

1 Section 100(4) of the Health Practitioners Competence Assurance Act 2003
Doctors whose patients use CAM

6. CAM therapies are often used by patients. You need to acknowledge and be aware of CAM therapies, even if you do not intend to use or recommend them. Some CAM therapies can adversely impact on conventional medical care. Therefore you need to be aware, and where appropriate record, what CAM therapies your patients use so this can be taken into account when providing conventional care.

7. You should also take into account that CAM therapies may be practised within a specific cultural context. You need to be mindful of the cultural beliefs, mores and behaviours of your patients and must respect these.

8. Some patients might be reluctant to tell you about CAM therapies they use. In asking about CAM therapies, you should be respectful and ensure that the patient is aware these treatments may impact on the outcome of care.

9. If a patient expresses an interest in CAM you should indicate the limits of your knowledge and, where appropriate, suggest that further information could be obtained from sources such as the Cochrane Collaboration\(^4\), BMJ Best Treatments\(^5\), a CAM practitioner, or a New Zealand-based professional body.

10. Where a patient is making a choice between conventional medicine or CAM, you should present the patient with the information that a reasonable patient, in that patient’s circumstances, would expect to receive about the options available. This information includes an assessment of the expected risks, side effects, benefits and cost of each option\(^7\). This allows competent patients to make an informed choice.

Doctors who practise CAM or refer patients to CAM practitioners

11. Some doctors do refer patients for CAM therapies or incorporate them into their own practice.

12. In a decision the Medical Practitioners Disciplinary Tribunal (the Tribunal) stated:

   There is an onus on the practitioner to inform the patient not only of the nature of the alternative treatment offered but also the extent to which that is consistent with conventional theories of medicine and has, or does not have, the support of the majority of practitioners…\(^8\)

13. The Council endorses these comments and expects that if you include CAM within your medical practice or refer patients for CAM therapies you inform the patient in the manner suggested by the Tribunal before obtaining consent (and as required by the Code of Health and Disability Services Consumers’ Rights). Careful attention to the process of informed consent is particularly important when the proposed treatment is expensive or in any way innovative, and you should advise patients when scientific support for treatment is lacking.

14. In the same decision, the Tribunal further stated:

   The Tribunal recognises that persons who suffer from chronic complaints or conditions for which no simple cure is available are often willing to undergo any treatment which is proffered as a cure. As such, they are more readily exploited.\(^8\)

15. You must never exploit patients or misrepresent any form of treatment or health service in order to obtain consent.\(^8\)

16. If you are not the patient’s general practitioner, then you should ensure continuity of medical care is being provided elsewhere. When you see a patient whose continuity of care is being provided by another general practitioner, you should be in regular contact with the general practitioner and should fully document CAM and other treatments provided.

\(^4\) Refer to the Statement on cultural competence.
\(^5\) http://www.compmed.umm.edu/Cochrane/index.html, the Cochrane Collaboration is an international organisation that brings together healthcare providers, consumers, and scientists who volunteer to compile up-to-date systematic reviews of evidence regarding the benefits and risks of health care.
\(^6\) www.besttreatments.net/btgeneric/home.jsp, BMJ Best Treatments has been developed by the British Medical Journal to collate the best and most up-to-date medical research into the effectiveness of treatments.
\(^7\) As required by Right 6 of the Code of Health and Disability Services Consumers’ Rights.
\(^8\) Director of Proceedings v Dr R W Gorringe MPDT Decision No: 237/02/89D
\(^9\) As required by Right 2 of the Code of Health and Disability Services Consumers’ Rights.
17. In **assessing** patients you must:
   
   (a) perform a pertinent history and physical examination of patients, sufficient to make, or confirm, a generally recognised diagnosis, and in this meet the standard of practice generally expected of the profession\(^1\)

   (b) reach a diagnosis by using a diagnostic system demonstrated by appropriate research methodologies to have a high level of accuracy and proven benefits to patients

   (c) advise patients of the evidence based and conventional treatment options, their risks, benefits and efficacy, as reflected by current knowledge

   (d) document all of the above in accordance with sound practice.

18. In **treating** patients and in engaging in health promotion, you must:

   (a) ensure that the treatment is efficacious, safe and cost effective

   (b) have current knowledge and skills in your area of practice

   (c) be competent in the practices you employ

   (d) act honestly and in your patient's best interests according to the fundamental ethics of the profession

   (e) provide sufficient information to allow patients to make informed choices, and to refer to, or consult with, others when patients request it, when you require assistance or when the standard of practice requires it. (Where there is no reason to believe such a referral would expose the patient to harm there is no barrier to making a referral to a CAM practitioner or to utilising a CAM treatment)

   (f) not misrepresent information or opinion. Patients must be made aware of the likely effectiveness of a given therapy according to recognised peer-reviewed medical publications, notwithstanding your individual beliefs

   (g) obtain informed consent to any proposed treatment.

19. In **advancing knowledge**, and providing treatments in areas of uncertainty where no treatment has proven efficacy you must:

   (a) ensure that your patients are told the degree to which tests, treatments or remedies have been evaluated, and the degree of certainty and predictability that exists about their efficacy and safety

   (b) be prepared to collaborate in the collection of information that can be appraised qualitatively or quantitatively, so that new knowledge is created, to be shared with, and critically appraised by, the profession.

March 2011

*This statement is scheduled for review by March 2016. Legislative changes may make this statement obsolete before this review date.*

---

\(^1\) In its decision Director of Proceedings v Dr R.W. Gorringe, the MPDT found that Dr Gorringe conducted inadequate clinical examinations of two patients, took inadequate histories, placed undue reliance on one diagnostic technique (peak muscle resistance testing) and “…failed to carry out any other diagnostic tests to confirm or exclude his diagnosis when, plainly, he should have done so.”
Submission on the proposal:

Traditional Chinese Medicine becomes a regulated profession under the HPCA Act.

1. Is TCM a health service, as defined by the HPCA Act? (Note: the Act defines a health service as ‘a service provided for the purpose of assessing, improving, protecting, or managing the physical or mental health of individuals or groups of individuals’.)

Comment: It is the opinion of Physiotherapy New Zealand that TCM meets the definition of a health service as defined by the HPCA Act. It must though be noted that TCM is not well defined and there are other areas of practice that could potentially fall under its umbrella.

2. Are practitioners of TCM generally agreed on the qualifications required to deliver the health services they provide?

Comment: Although there are registered providers of TCM education approved by the NZQA they teach a range of different subjects – Acupuncture, Herbal Medicine, Tuina and Gigong. Only one course, the Bachelor of Chinese Medicine from the NZ College of Chinese Medicine appears to offer a course covering the whole range of topics that make up TCM.

3. Is there a risk of harm to the public from the practice of TCM?

Comment: There is a major risk of harm to the public due to the lack of regulation of TCM. Risks include infection due to lack of sterile techniques and tissue damage due to inappropriate needle placement. There is always an inherent risk of an adverse reaction from acupuncture – the majority of the adverse reactions to physiotherapy relate to acupuncture (mainly fainting, dizziness, nausea). This risk increases if the practitioner has not received adequate training. Adverse reactions to herbal medicines are becoming more common as they frequently react with prescription medicines. Some Chinese medicines imported into New Zealand fail to meet our health and safety regulations and there is minimal evidence supporting their efficacy. Massage and manipulation require an appropriate level of training and understanding of the possible risks and complications. There is always a risk with manipulation of the spine and the risk increases in an unregulated profession. There is also a risk that some providers currently do not speak or have a good understanding of English. This may result in them failing to fully understand a patient’s condition and consequently missing warning signs of more complex conditions. If TCM is regulated English language requirements should match those of other health professionals.

4. If so, what are the nature, frequency, severity and potential impact of risks to the public? What is the likelihood of the harm occurring?
5. Other than on the basis of risk of harm, is it in the public interest that the profession of TCM be regulated?

Comment: Physiotherapy New Zealand believes it is in the public interest for TCM to be regulated. The public would then have the confidence when seeing a TCM provider that they had undergone an appropriate training and had to meet ethical and professional standards.

6. Are practising TCM practitioners generally agreed on the standards that TCM practitioners are expected to meet?

No Comment

7. Are practising TCM practitioners generally agreed on the competencies for scopes of practice for TCM?

Comment: From the range of courses currently offered it would appear there is not yet agreement on the core competencies for TCM practitioners. Training providers have developed a range of courses but few cover the whole range of interventions which currently sits under the umbrella of TCM.

8. What qualifications are generally held by members of the profession, and what is the degree of uniformity in qualifications across members?

Comment: As above. It must be noted that physiotherapists who practise acupuncture have an undergraduate degree in physiotherapy and their practice is regulated by the Physiotherapy Board of New Zealand. Under the HPCA act they are required to meet ongoing continuing professional development standards for re-certification.

9. Does your organisation accord any standing or status to the profession of TCM, or to those who practise as TCM practitioners?

Comment: Acupuncture is already recognised as a scope of practice for physiotherapists in New Zealand (and internationally). We have a strong Special Interest Group (PAANZ) for physiotherapists practicing acupuncture and there is a postgraduate programme of study in acupuncture at AUT University and the University of Otago which cover Western and Traditional Chinese acupuncture. PAANZ have submitted a more detailed paper on the regulation of TCM to support the Physiotherapy New Zealand submission.

Karen McLeay
Executive Director Physiotherapy
Email: Karen.Mcley@physiotherapy.org.nz
Phone 04 801 6500
17 August 2011

Mary-Louise Hannah  
Workforce Intelligence and Planning  
Health Workforce New Zealand  
National Health Board  
Ministry of Health  
PO Box 5013  
WELLINGTON 6145

Dear Ms Hannah


Thank you for the opportunity to comment. We acknowledge that our comments reflect a westernised medical viewpoint, and that the consumer has the right to choose from any alternatives that may be available to them. Of course this choice should be informed as to the benefits and potential for harm when seeking treatment with TCM.

Our first comment is that there is little scientific evidence of the efficacy of Traditional Chinese Medicine.

Of greater concern is the potential for harm. In addition to those listed on page 7 of the consultation document, harm may occur in the following way:

1. There may be treatment of symptoms and not their cause so an underlying medical condition may remain undiagnosed and harm resulting from a delay in instituting more appropriate therapy. Vulnerable groups such as children and the elderly may be at particular risk.

2. Chinese herbal medicines are often compounded in such a way that potentially active ingredients are not accurately quantified, if indeed they are known. This lack of pharmacological detail may result in unexpected side effects and or interactions with other medicines being used. This raises the question of whether it is the practitioner or the traditional medicines, or both, that require regulation.

3. Although of least concern there is the possibility that ‘legitimisation’ of Traditional Chinese Medicine by including it under the HPCA Act may result in resources being misdirected that might otherwise be used for more evidence based treatments

We also note that there are a number of different approved courses at differing levels on the NZQA hierarchy. Of particular concern is the potential for health practitioners currently under the HPCA, e.g. physiotherapists, midwives and nurses having to have dual registration. This is impractical and increases the cost or regulation unnecessarily. For this reason it is suggested that if TCM becomes regulated, that there is the ability for those practitioners within another health profession to continue to be able to practice these skills without dual registration (conditional upon their existing regulatory body accepting ‘traditional medicine’ as part of the practitioner’s scope). They will still be responsible for the standards of the care they provide to their patients.
As we have not provided an extensive analysis of Traditional Chinese Medicine (including among other things its ‘scientific’ basis, efficacy, prevalence and acceptability to the community) it would be inappropriate for us to conclude that TCM does or does not warrant inclusion under the HPCA Act, or if continuation of self regulation is sufficient.

Ultimately if there is any concern of potential harm then regulation under the Act would be beneficial and would likely ensure that there is one professional body in the future and/or one agreed set of minimum criteria for the quality of the provision of the training and qualifications, and therefore of the services provided.

Yours sincerely

Sally Taylor
DIRECTOR OF ALLIED HEALTH, TECHNICAL AND SCIENTIFIC
Should TCM become a regulated profession under the HPCA Act.

The guidelines for interpreting the criteria in Appendix 1 may assist you in answering the questions.

1. Is TCM a health service, as defined by the HPCA Act? (Note: the Act defines a health service as ‘a service provided for the purpose of assessing, improving, protecting, or managing the physical or mental health of individuals or groups of individuals’.)

Traditional Chinese Medicine is a health service in itself. It is a health service that differs in philosophical and theoretical perspectives from orthodox Western medical (OWM) practices, thus is not suitable to be registered under an existing profession under the HPCA Act.

Because of the differences between the philosophical and theoretical perspectives underpinning TCM and OWM, TCM should be registered under the HPCA Act for the safety of the public. The lay public has differing levels of understanding of what OWM is able to provide. However the lay public does comprehend that OWM is a regulated ‘industry’ where measurable standards in regard to: assessment, treatment, documentation, informed consent, pharmaceutical interaction, complaints procedures and English language standards are upheld for the safety of the public.

Furthermore TCM is an umbrella term which is loosely defined as medical practices coming from mainland China. However many other forms of traditional East Asian medical practices should also be encompassed under this umbrella, including all herbal (this includes plant, animal and mineral products), acupuncture, acupuncture needle related, acupuncture point related treatment, massage, manipulation and moxibustion practices practised using an East Asian clinical reasoning methodology.

The submission does not define what TCM should fully include. This is of potential concern in that some practices may be covered under the umbrella term of TCM, yet not be subject to relevant scrutiny to protect the public from possible harm. These practices include:

1. Tuina includes manipulation (high velocity cervical manipulation is a restricted activity in New Zealand).
2. Gua Sha which involves scraping of the skin to reduce fever.
3. Blood letting, which is practiced in conjunction with cupping and is a banned practice in states / countries, such as California, U.S.A. because of the concerns of contamination from blood products.
4. The breaking of or embedding of needles as permanent stimulants in the skin. Literature has demonstrated migration of these needles into heart, kidneys and other bodily organs.

Please note this list is not exhaustive of all potential modalities, thus care must be taken to carefully denote what the profession of TCM does include. When
such practices are scrutinized the issue of TCM being registered under the HPCA Act to protect the health and safety of the New Zealand public becomes more urgent.

A clear definition of TCM and its encompassing practices is required for the safety of the public. They need to be educated as to what a regulated practice is and what is not. Currently much of the populace is poorly informed as to what professions and practices are regulated. There is a general assumption that TCM / all therapeutic practices are regulated by the Government, when this is not the situation.

2. Are practitioners of TCM generally agreed on the qualifications required to deliver the health services they provide?

From the submission document it states that from 2012 all practitioners qualified in New Zealand require a Bachelors degree to practice. However there are differences in the hours required to achieve theoretical and clinical competence. This does infer that there is disagreement between practitioners of TCM and may be complicated by the varying qualifications and competencies of those practitioners who have qualified overseas.

There is no mention of English language standards or qualifications to practice. Many TCM practitioners both trained in New Zealand and from overseas do not speak English as their first language. The ability to effectively communicate with the public is an absolute imperative. The Nursing Council sets a standard a score of seven (7) to be achieved in all areas of the International English Language Testing System (IELTS) for all practitioners seeking Nursing Registration.

3. Is there a risk of harm to the public from the practice of TCM?

Yes. Several points and examples are supplied below.

Currently any person can set up and purport to practice acupuncture etc.

1. They may not have sufficient knowledge of safe practice
   a. Use re-sterilisable needles rather than disposable needles
   b. Not have adequate knowledge of anatomy (therefore increasing the chance of adverse reactions i.e. pneumothorax etc)

2. They may not have an adequate understanding of human disease processes, thus miss red or yellow flags, and treat a patient inappropriately without referring onto a relevant medical professional such as a General Practitioner.

3. A practitioner may not have an adequate command of the English language (many examples can be provided from members of the public
who have been unable to communicate with the acupuncturist, herbalist and tuina practitioner they have consulted with).

4. Practicing high velocity cervical manipulations without relevant prescreening tests, such as vertebral artery tests (example: on a 71 year old gentleman who underwent 30 minutes of manipulation to the cervical and lumbar spine).

5. Not have a clean and inviting premise to provide treatment (note the gentleman reported to the Physiotherapy Board of New Zealand by one of the respondents who was advertising the practice of acupuncture and physiotherapy. He was unable to communicate in English. His premises were a curtained off area at the back of a food hall in Karangahape Road in Auckland. He was not a registered physiotherapist).

6. Herbal remedies are of particular concern.

There is especially concern that some herbal remedies may contain drugs which are restricted in New Zealand. One example of an herbal product is the recent banning of Kronic importation to New Zealand from China because a restricted medication phenazepam was found in the product.

Other concerns include:
   a. Remedies are not labeled in English for full disclosure of the contents.
   b. A TCM practitioner may not be aware of drug interactions with other OWM medications taken by the patient.
   c. Herbal remedies containing restricted drugs, such as phenazepam.
   d. Herbal remedies contain animal and mineral items, these may be unpalatable to conservationists, vegans, vegetarians etc.
   e. Some herbal remedies are known to contain parts of turtles, seahorses, bear bile (the bears are captive), gallstones of cows etc. Penis’s of animals are noted to be considered therapeutic.
   f. Some herbal remedies use items from endangered species, such as tiger penis and rhinoceros horn. Poachers are known to supply the black market for such products.
   g. The decimation of wildlife stocks, such as rhinoceros and seahorses has been linked to the demand for traditional Chinese medicinal supply.
   h. Does importation of some herbal medicines meet New Zealand’s Biosecurity standards?

All herbal remedies should be subjected to the same strictures as imposed by the relevant legislation, such as the Medicines Act 1981, because they are prescribed and used for a therapeutic purpose.
4. If so, what are the nature, frequency, severity and potential impact of risks to the public? What is the likelihood of the harm occurring?

Adverse effects in alternative and complementary medicines such as acupuncture are acknowledged in current medical literature as underreported. It has been reported that the physician treating the adverse effect is far more likely to report the adverse effect than the treating practitioner.

Acupuncture literature in the past three years is reporting an increasing proportion of acupuncture related MRSA infections, particularly into joint spaces. The patients almost always had full joint reconstructive surgery following the MRSA infection. The incidence of MRSA in the New Zealand community is unknown and must not be underestimated. The incidence of MRSA infection can be minimised, following best needling practices with respect to skin preparation.

5. Other than on the basis of risk of harm, is it in the public interest that the profession of TCM be regulated?

Yes. Examples have been cited above.

6. Are practising TCM practitioners generally agreed on the standards that TCM practitioners are expected to meet?

A lack of agreement in terms of standards of TCM practitioners is apparent, particularly in that differing acupuncture groups both made submissions to the MOH for the regulation of TCM, rather than as a unified profession.

7. Are practising TCM practitioners generally agreed on the competencies for scopes of practice for TCM?

From the submission document it appears that consensus in terms of clinical and theoretical hours are not agreed.

8. What qualifications are generally held by members of the profession, and what is the degree of uniformity in qualifications across members?

The qualifications appear varied and a Grandfathering process may be required to be undertaken.

It must be noted that many TCM practitioners have a full Bachelors degree in TCM. Other TCM practitioners, such as Midwives build their TCM knowledge upon their Undergraduate Bachelor of Health Science and study a 26 week Certificate course.
Furthermore other professionals build on their Undergraduate Bachelor of Health Science or similar, to study some acupuncture components adapted and divergent from TCM, such as the PAANZ Introductory Acupuncture course (80 hours) which has now been superceded by the Certificate of Western Acupuncture at AUT or Postgraduate Certificate in Physiotherapy (Acupuncture) at Otago University (both 600 hours).

These acupuncture practitioners practice has been adapted from TCM and is utilised within OWM, using OWM clinical reasoning methodologies to underpin practice. Furthermore these practitioners are regulated by their respective Boards to practice acupuncture under the HPCA Act.

[The British Medical Association acknowledged the difference between traditional Chinese acupuncture and Western acupuncture in 1986 (Payne, 1986).]

9. Does your organisation accord any standing or status to the profession of TCM, or to those who practise as TCM practitioners?

PAANZ (The Physiotherapy Acupuncture Association of New Zealand) currently has 327 members. Most practice OWM or a blend of OWM / TCM acupuncture. Some practice TCM acupuncture, including Chinese, Japanese (Manaka & Toyohari) and other East Asian acupuncture practices. It is the belief of PAANZ that practitioners following ‘pure’ TCM practices must demonstrate a level of education, competency and ongoing continuing professional development.

Your submissions should be addressed to:
Mary-Louise Hannah
Workforce Intelligence and Planning
Health Workforce New Zealand
National Health Board
Ministry of Health
PO Box 5013
WELLINGTON 6145

Proposal that Traditional Chinese Medicine Become a Regulated Profession under the Health Practitioners Competence Assurance Act 2003: Submission to the Ministry of Health

Traditional Chinese Medicine (TCM) refers to a broad range of medicine practices including acupuncture, tuina (massage therapy), tei-da (practice of bone-setting) and the application of herbal medicine. It has been used for around 3000 years, and is commonly used among Asian countries such as China, Japan, Singapore, Korea and Taiwan, for the prevention and treatment of diseases and health maintenance. Western scientific and clinical research on the effectiveness of TCM to treat diseases is in its infancy but on the increase. For example, Taiwan has set up a National Research Institute of Chinese Medicine to carry out basic (molecular) and clinical studies to improve the formulation and potency of certain herbal medicine in treating cancers and inflammations. The American Journal of Chinese Medicine has also been created to publish studies related to TCM. Since the public awareness/experience of the application of TCM in improving personal health has increased in New Zealand, it is an appropriate time to consider whether the New Zealand should classify TCM practitioners as health service providers under the Health Practitioners Competence Assurance (HPCA) Act.

For this submission, a RSNZ Professional member, Dr Marian Mare (a consultant research psychologist) undertook a small survey of Maori, Chinese and European individuals who had: 1) some knowledge of Traditional Medicine and Praxis (Maori, Chinese), and/or; 2) some link with China and TCM, and/or; 3) some link with the health sector in New Zealand. Details of the findings are included in our submission below.

Is TCM a health service, as defined by the HPCA Act?

The general public, especially those from the Asian community, are likely to view TCM as a health service. People consult TCM practitioners regarding their physical or mental symptoms, ranging from the common cold and aches, to severe illnesses such as terminal cancer as a last resort treatment. In Taiwan and Hong Kong, TCM practitioners are also classified as health service providers.

In Dr Mare’s survey of different New Zealand communities, the New Zealand Maori respondents seemed relatively sympathetic to the proposal that TCM become a regulated profession under the HPCA Act, although with specific conditional requirements (robust specifications, monitoring systems and consultancy, cultural appropriateness and continuity). The New Zealand European respondents did not support the proposal that TCM become a regulated profession under the HPCA Act for a range of reasons. These largely related to their perception of the potential for harm and the difficulties relating to lack of compliance with scientific standards concerning medicinal properties, monitoring, supervision, and practitioner qualifications. The New Zealand Chinese respondents, with various reservations, provisos, concerns and recommendations, tended to support the proposal that TCM become a regulated profession under the HPCA Act. They favoured TCM in China and the principle/ideal of TCM in New Zealand but were the group who seemed most conflicted about registration of TCM practitioners in New Zealand.
Overall, since the HPCA Act defines a health service as “a service provided for the purpose of assessing, improving, protecting, or managing the physical or mental health of individuals or groups of individuals”, there is a case to be made that TCM should become a regulated profession under the HPCA Act.

Is there a risk of harm to the public from the practice of TCM?

There is the potential of harm from the practice of TCM. Apart from the risks already outlined in the proposal document, clients consulting TCM practitioners are at risk of delayed diagnosis and treatment of their conditions, which can carry significant consequences. It is possible that an occult fracture is missed in a client consulting a TCM practitioner for foot pain, or early meningococcal disease overlooked in a client with fevers and general malaise.

Regulation of TCM will ensure that all TCM practitioners are aware of the limitation of their service, and to know when to refer clients to another health service if necessary. Improper practice of TCM, such as tuina (massage therapy) and tei-da (practice of bone-setting), has been shown to induce physical damage (e.g. joint dislocation, spindle damage, deep tissue/muscle damage) to the patients and some herbal medicine may also not be suitable for pregnant women. It will therefore be important to ensure that registered TCM practitioners are responsible and clinically well qualified.

What qualifications are generally held by members of the profession, and what is the degree of uniformity in qualifications across members?

Many TCM practitioners have been trained overseas. In Taiwan, in order to qualify as a TCM practitioner, a candidate needs to hold a bachelor degree (with a major in Chinese medicine) issued by one of Taiwan’s accredited universities (both national and overseas), and to have also passed the nationwide examinations for the registration of medical practitioners. If a candidate’s bachelor degree is obtained from an overseas university, legal certification of the candidate’s graduation certificate, academic transcripts and medical practitioner’s registration certificates need to be obtained before they are able to sit the examination to become registered as a medical practitioner in Taiwan.

In Hong Kong, a person is eligible to undertake the Chinese Medicine Practitioners Licensing Examination if they have completed an approved undergraduate degree course in TCM (as approved by the Chinese Medicine Practitioners Board), or they have passed the Chinese Medicine Practitioners Licensing Examination, before they are eligible for registration as TCM practitioners.

In New Zealand, the New Zealand School of Acupuncture and Traditional Chinese Medicine” and “New Zealand College of Chinese Medicine” offer training in TCM. Unlike in Taiwan and Hong Kong, a TCM graduate in New Zealand is not required to register as a medical practitioner before practicing TCM. In regulating the profession, it would be important to create a nationwide standard with a high level of clinical knowledge and competence.

In Dr Mare’s survey of different New Zealand communities, one of the issue for the New Zealand Chinese community was: “How do we [Chinese New Zealanders] know if young NZ-trained TCM doctors have the true skills and knowledge of their counterparts in China?”. 
Additional Information and References

This response was produced by the Royal Society of New Zealand from a range of submissions from its members, and signed off by the Chair of the Academy. Any enquiries about this submission or others should be addressed to the Royal Society’s External Relations Manager, Dr Marc Rands (Email: marc.rands@royalsociety.org.nz). Responses are published on the RSNZ website (www.royalsociety.org.nz/publications/policy).

Details of consultation survey:
The participant groups were comprised of...
- European respondents 10 (5 men, 5 women) aged 20s to 60s
- Chinese respondents 10 (5 men, 5 women) aged 30s and 60+
- Maori respondents 10 (5 men, 5 women) aged 20s to 60+

Maori category: There were 10 lots of responses received from the Maori respondents, but more than 10 people were involved, as an unknown number of people were part of ‘consensus’ (group) returns. The 10 named respondents all had tertiary education qualifications (degrees and/or diplomas). The respondents were all affiliated to Te Arawa iwi mostly from Rotorua, currently living or working or studying where Dr Mare contacted them in Rotorua, Hamilton, Auckland, Australia.

Chinese category: the respondents were mostly working parents in their 30s and 40s and grandparents aged 60-plus, and two people with no children. The older participants’ responses were translated by younger family members. All but 2 older people had tertiary education qualifications. The majority of respondents Dr Mare contacted directly (or indirectly via members of their family) were Waikato or Auckland residents who were working and studying in Hamilton and/or Auckland. One respondent, a colleague’s wife, was contacted in Australia where she was working.

European category: ten independent responses were received from 10 people. Ages ranged from 20s to 60+. All had tertiary education qualifications (degrees and/or post-grad diplomas). All had lived and worked in China. Dr Mare contacted them in Hamilton, Auckland, Wellington, Australia.

August 2011
Submission 16

18.08.11

Mary-Louise Hannah
Workforce Intelligence and Planning
Health Workforce New Zealand
National Health Board
Ministry of Health
PO Box 5013
WELLINGTON 6145

Re: Proposal that Traditional Chinese Medicine Become a Regulated Profession under the Health Practitioners Competence Assurance Act 2003

Dear Ms Hannah

Please find comments in relation to this submission made by two senior academics who teach on the Western Acupuncture Postgraduate Certificate programme at Auckland University of Technology.

1. Is TCM a health service, as defined by the HPCA Act? (Note: the Act defines a health service as ‘a service provided for the purpose of assessing, improving, protecting, or managing the physical or mental health of individuals or groups of individuals’.)

Traditional Chinese Medicine is a health service in itself. It is a health service that differs in philosophical and theoretical perspectives from orthodox Western medical (OWM) practices, thus is not suitable to be registered under an existing profession under the HPCA Act. The principle of statutory regulation of acupuncture and herbal medicine has been investigated and endorsed as in the public interest by the Department of Health Steering Group on the Statutory Regulation of practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems practised in the UK (2008).

The following is enclosed in support of this submission. Sladden (2006) the Chief Legal Advisor of the Health and Disability Commission wrote:

“Acupuncturists are “health care providers” as defined by section 3 of the Act and therefore subject to the Commissioner’s jurisdiction. Section 3 defines “health care providers” as including “any other person who provides, or holds himself out as providing, health services to the public or to any section of the public, whether or not any charge is made for those services”. “Health services” are defined in section 2 of the Act as services to promote and protect health. Based on the definition on page 14 of the consultation document acupuncture is clearly a service that promotes and
protects health (p.2)”... “The HPCAA aims 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. Consequently we fully support the regulation of acupuncturists and consider the proposal that they are registered under the HPCAA a positive step in achieving an acupuncture workforce that provides safe, competent care to consumers (p.1)...You have asked in question one whether “the work undertaken by acupuncturists [is] a health service, as defined by the HPCAA?” Section 5 of the HPCAA defines health service as “a service provided for the purpose of assessing, improving, protecting, or managing the physical or mental health of individuals or groups of individuals”. In my opinion, acupuncture falls within this definition. This is consistent with the definition given...which states that acupuncture “performs diagnostic evaluations [of] physical and mental illnesses and conditions and provides medications and treatments to promote or restore good health”. This clearly includes “assessing”, and “improving” both physical and, sometimes, mental health (p.2).”

This was in response to a previous submission made to the HPCA for Acupuncture to be regulated as a healthcare practice. Acupuncture is one of the more prominent practices of TCM, but other practices of TCM also pose risk of harm to the public.

The lay public understands that OWM is a regulated ‘industry’ where measurable standards in regard to: assessment, treatment, documentation, informed consent, pharmaceutical interaction, complaints procedures and English language standards are upheld for the safety of the public. However the lay public has differing levels of understanding of what TCM can offer and the actual standards that apply to TCM healthcare ‘modalities’. Therefore TCM should be registered under the HPCA Act for the safety of the public. Additionally the public may not know that TCM is currently not a formally regulated industry.

TCM is an umbrella term which is loosely defined as medical practices coming from mainland China. This broad range of therapies needs to be properly defined as to what is included and what is not included before further proceedings can advance. This is further highlighted by literature which notes TCM to have encompassed a diverse range of therapies “under one heading primarily to serve the political and public health needs of China after the 1949 liberation” (Birch & Kaptchuk, 1999, p.13).

All forms of traditional East Asian alternative and medical practices should be encompassed under the ‘TCM’ umbrella, including all herbal (this includes plant, animal and mineral products), acupuncture, acupuncture needle related, acupuncture point related treatment, massage, manipulation and moxibustion practices practised using an East Asian clinical reasoning methodology.

Perhaps in the application the term TCM should be altered to Traditional East Asian Medicine (TEAM) in order to encompass other Asian medical practices (Korean, Japanese, and Vietnamese etc) that include similar forms of acupuncture, moxibustion and herbal therapies etc.
Thus the current submission does not define what health practices TCM should encompass. This broad range of therapies is of potential concern in that some practices may be covered under the umbrella term of TCM, yet not be subject to relevant scrutiny to protect the public from possible harm. These practices include:

1. Tuina which include manipulations (high velocity cervical manipulation is a restricted activity in New Zealand). ‘Bone setting’ is classified within tuina, and tuina is considered to be the Chinese Medicine equivalent to Physical Therapy and a precursor to Osteopathy and Chiropractic (McCarthy, 2003).

2. Gua Sha which involves scraping of the skin to reduce fever etc (Nielsen, Knoblauch, Dobos, Michalsen, & Kaptchuk, 2007).

3. Bloodletting, a cutting of the skin to allow the escape of blood, which is practiced in conjunction with cupping, and is a banned practice in states / countries, such as California, U.S.A. because of the concerns of contamination from blood products (Kavoussi, 2010).

4. The breaking of or embedding of needles as permanent stimulants in the skin. Literature has demonstrated migration of these needles into heart, kidneys and other bodily organs (Chaput & Foster, 2010; Ulloth & Haines, 2007).

Please note this list is not exhaustive of all potential modalities, thus care must be taken to carefully denote what the profession of TCM does include. When such practices are scrutinized the issue of TCM being registered under the HPCA Act to prevent the health and safety of the New Zealand public becomes more urgent.

On page six of the submission document, third paragraph, and line six contemporary practice developments have been listed.

1. The therapies listed (which do not include auriculotherapy, an OWM therapeutic development) have largely emanated from Western medical scientific acupuncture practice and have been assimilated and integrated into acupuncture practice, whether traditional Chinese, other East Asian, or OWM therapy.

2. The statement regarding point injection therapy is misleading. Only specific registered medical professionals can administer injection therapy. Point injection therapy should be listed as trigger point needling as developed by Travell and Simons from 1940 onwards (Travell & Simons, 1992). Trigger point needling has been described by TCM acupuncturists as Ah Shi point needling, however they differ in that Ah Shi point needling is acupuncture needling of tender areas, and not necessarily motor trigger points (Campbell, 1998). Furthermore trigger point needling is an integral component of OWM acupuncture. Please note the practice of trigger point needling has been labeled ‘dry needling’ in some countries such as the United States and Australia where some healthcare professionals who have not studied acupuncture (and are not registered to practice acupuncture) utilise acupuncture needles to practice acupuncture techniques that they call ‘dry needling’ (Federation of State Boards of Physical Therapy, 2010). Dry needling, as a practice in isolation is not a healthcare practice advocated within this submission.
A clear definition of TCM and its encompassing practices is required for the safety of the public. The public needs to be educated as to what a regulated practice is and what is not. Currently much of the populace is poorly informed as to what professions and practices are regulated. There is a general assumption that TCM / all therapeutic practices are regulated by the Government, when this is not the situation.

In addition the public need to have all medical and associated practices ‘spelt out’ to them in clear, non obfuscating language, in order that they clearly understand the treatment being provided, from both its philosophical and theoretical frameworks. This principle has been clearly elucidated with reference to the diversity depicted of the acupuncture profession in the United Kingdom (The Report of the Acupuncture Regulatory Working Group, 2003). Thus all forms of TCM practice require clear delineation and explanation. There are cited criminal cases, such as R v Ibrahim (1998) CA352/98 and R v Fernando [2007] NZCA 485 where the defendant (convicted as guilty) had practised acupuncture and sexually assaulted a client, implying that the touching of breast tissue etc was a part of the TCM practice in terms of locating acupuncture points.

2. Are practitioners of TCM generally agreed on the qualifications required to deliver the health services they provide?

From the submission document it states that from 2012 all practitioners qualified in New Zealand require a Bachelors degree to practice. However there are differences in the hours required to achieve theoretical and clinical competence. This does infer that there is disagreement between practitioners of TCM and may be complicated by the varying qualifications and competencies of those practitioners who have qualified overseas.

There is no mention of English language standards or qualifications to practice. Many TCM practitioners both trained in New Zealand and from overseas do not speak English as their first language. The ability to effectively communicate with the public is an absolute imperative. The Nursing Council and Physiotherapy Board set a standard of a minimum score of seven (7) to be achieved in all areas of the International English Language Testing System (IELTS) or similar for all practitioners seeking Nursing Registration (New Zealand Nurses Organisation, 2011; New Zealand Physiotherapy Board, 2011).

The ability of the patient to give Informed Consent to treatment is another tenant of healthcare practice in New Zealand. Informed consent includes a number of issues as identified under the HPCA Act. Cases where these issues have been allegedly breached have been brought before tribunals such as: Director of Health & Disability Proceedings v DG (2005) Decision No 3-05, HRRT 23-04. This case summary identifies the practitioner, G., as having failed to sufficiently explain treatment, did not provide a private place for undressing, touching the genital region, and not explaining why G. touched that region. G. was noted to not be able to effectively communicate in English and G. was noted to have very little idea of obligations of the Health and Disability Services Code.
3. Is there a risk of harm to the public from the practice of TCM?

Yes. Several points and examples are supplied above. Other issues are in relation to points raised in Criterion C of the Submission document. Many TCM practitioners practice in isolation or in small practices. Are they subject to support and supervision by peers? What ongoing professional development and peer support networks are available to them? Importantly all professionals must be guided by a strong professional code of conduct. This is particularly important because many TCM providers are not New Zealand born or educated and may be used to practice in a country with very different medical and cultural systems to that of New Zealand. It is imperative for the interest of the public that they understand the notions of quality services as perceived by the New Zealand populace and be complicit with the tenants of the Treaty of Waitangi. Furthermore people in New Zealand have high expectations that good access to health care services will be available when they are required, as stated from The Ministry of Health publication: We are Targeting Better Health Services. Whilst the objectives in this publication are primarily targeted to the District Health Board sector it does encompass all practitioners providing healthcare services. It is noted that health targets provide a clear and specific focus for action to ensure that health care provided is of the highest quality and within the best possible time frame. If TCM is not regulated under the HPCA Act then the ability for the Ministry of Health to ensure that the public is receiving high quality appropriate and timely healthcare.

Further forms of regulation that require addressing for the health and safety of the public is the recognition by all healthcare practitioners to work as a ‘healthcare team’ in the best interests of the health of New Zealanders. Many OWM practitioners have knowledge of the benefits of ‘TCM like’ practices, such as acupuncture. Do TCM healthcare professionals have training in the benefits of OWM? Moreover are they encouraged to liaise with OWM practitioners in the patient’s best interest? Particularly are TCM healthcare professionals trained to recognise ‘red and yellow flags’ denoting the need for referral or particular healthcare needs? This raises the notion of the potential to treat a condition with TCM that may mask a more sinister complaint, such as a malignancy etc. Additionally academic literature cites multiple qualitative and quantitative research studies where people from all parts of the world, both Eastern and Western fail to inform their doctor or other OWM practitioners of any alternative and complementary medicines in which they may be participating. Clear pathways of communication must be addressed in order that the general practitioner, nurse, physiotherapist etc as a ‘gatekeeper’ is kept informed of all therapies provided. Regulation of TCM may be one means to open and enforce these lines of communication which are in the best interests of the New Zealand public.

Currently any person can set up and purport to practice acupuncture, herbal medicine, tuina etc. Issues relating to any practitioner practicing TCM that may not be in the best interests of the public are cited below:

1. There are bodies that regulate acupuncture practice, such as the NZRA, NZASA, The Osteopathic Council of New Zealand, The Physiotherapy Board of New Zealand etc. If a
member of one of these bodies was deregulated because of breaching standards of practice the person can still independently set up and practice acupuncture or any other associated TCM practice.

2. Practitioners may not have sufficient knowledge of safe practice
   a. Use re-sterilisable needles rather than disposable needles
   b. Not have adequate knowledge of anatomy (pneumothorax etc)
   c. Not have adequate training in safe acupuncture practice for the immune deficient patient or the patient with other co-morbidities that may require special precautions to acupuncture treatment.

3. They may not have an adequate understanding of human disease processes, thus miss red or yellow flags, and treat a patient inappropriately without referring onto a relevant medical professional.

4. Practitioners may not have an adequate command of the English language (many examples can be provided from members of the public who have been unable to communicate with the acupuncturist, herbalist and tuina practitioner they have consulted with) (personal communications, names withheld for privacy reasons, 2008, 2011).

5. Practicing high velocity cervical manipulations without relevant prescreening tests, such as vertebral artery tests (personal communication, name withheld for privacy reasons, 2011).

6. Recent online websites have made some issues more ‘public’ orientated. See Appendix item two, the Migun Wellness Clinic voucher, as obtained from a public online website. This advertisement for a ‘discounted’ session of spinal decompression and deep tissue massage also promotes treatment including chiropractic style manipulation and acupuncture. One must question the level of assessment the individual members of the public will receive prior to such treatment, particularly when the cost of sessions is advertised as $29 for three sessions. A member of the public attended a similarly advertised ‘clinic’ for a discounted massage. He mentioned headaches and was invited to book in to see their ‘specialist’. This gentleman did return for one treatment with the ‘specialist’. An interpreter was in the room because the specialist did not speak English. The patient received what he described as thirty minutes of firm manipulation to his cervical and lumbar spine. He was told he would need to book for up to twenty more treatments. When later questioned about pre-screening tests prior to cervical manipulation the gentleman in question could only recall being asked to demonstrate cervical range of motion. This gentleman was 71 years of age and takes antihypertensive medications (personal communication, name withheld for privacy reasons, 2011).

7. Not have a clean and inviting premise to provide treatment. For example: the gentleman reported to the Physiotherapy Board of New Zealand who was advertising
the practice of acupuncture and physiotherapy. He was unable to communicate in English. His premises were a curtained off area at the back of a food hall in Karangahape Road in Auckland. He was not a registered physiotherapist (personal communication to New Zealand Physiotherapy Board, 2008).

8. Herbal remedies are of particular concern.
There is particular concern that some herbal remedies may contain drugs which are restricted in New Zealand. One example of an herbal product is the recent banning of Kronic importation to New Zealand from China because a restricted medication Phenazepam was found in the product (TVNZ, 2011).
There are several cited cases of herbal medicine practitioners selling prescription medications, such as Ministry of Health v Zhang [2010] DCR 860. Sibutramine (Reductil), Glibenclamide, Sildenafil (active constituent in Viagra), Paracetamol and Sulphacetamide Sodium Eye Drops were sold within Chinese herbal remedies. Another example is Zheng v Ministry of Health (2008) CRI-2007-404-384; CRI-2007-404-390, who is cited as illegally selling Reductil and Viagra.
Other herbal treatment concerns include:
   a. Remedies are not labeled in English for full disclosure of the contents.
   b. A TCM practitioner may not be aware of drug interactions with other OWM medications taken by the patient
   c. Herbal remedies containing restricted drugs, examples already cited include Phenazepam, Paracetamol, Viagra, Reductil etc.
   d. Herbal remedies contain animal and mineral items, these may be unpalatable to conservationists, vegans, vegetarians etc
   e. Some herbal remedies are known to contain parts of turtles, animal penis’s, seahorses, bear bile (the bears are captive), gallstones of cows etc.
   f. Some herbal remedies use items from endangered species, such as tiger penis and rhinoceros horn. Poachers are known to supply the black market for such products.
   g. The decimation of wildlife stocks, such as rhinoceros and seahorses has been linked to the demand for traditional Chinese medicinal supply.
   h. Does importation of some herbal medicines meet New Zealand’s biosecurity standards?

All herbal remedies should be subjected to the same stricture as imposed by the relevant legislation, such as the Medicines Act 1981, because they are prescribed and used for a therapeutic purpose.

4. If so, what are the nature, frequency, severity and potential impact of risks to the public? What is the likelihood of the harm occurring?

Adverse effects in alternative and complementary medicines such as acupuncture are acknowledged in current medical literature as underreported (Ernst, 2010; Woo, Lin, Lau, &
Yuen, 2010). It has been reported that the physician treating the adverse effect is far more likely to report the adverse effect than the treating practitioner (Rotchford, 2000; Zhang, Shang, Gao & Ernst, 2010).

Acupuncture literature in the past three years is reporting an increasing proportion of acupuncture related MRSA infections, including septic arthritis in joint spaces (Woo, Laua & Yuena 2009). Patients almost always have had full joint reconstructive surgery following the joint MRSA infection. The incidence of MRSA in the New Zealand community is unknown and must not be underestimated. The incidence of MRSA infection can be minimised, following best needling practices with respect to skin preparation.

There is risk of pneumothorax in acupuncture needling in the thoracic and shoulder region (Ernst, 2010; McCutcheon & Yelland, 2011). This has potentially fatal consequences and all cited authors on the subject state that acupuncture should be safe when the practitioner has undertaken adequate training. The incidence of pneumothorax has been investigated by the Health and Disability Commissioner in (2008), case 07HDC12714. In this circumstance it was cited that the acupuncturist failed to provide the patient with sufficient information in regard to the risk of coughing.

5. Other than on the basis of risk of harm, is it in the public interest that the profession of TCM be regulated?

Yes. Examples have been cited above.

Furthermore Sladden (2006) wrote:

Since May 2005 this Office has received two further complaints about acupuncturists. One complainant alleged that the acupuncturist did not look at his x-rays, did not listen to him when he advised that manipulation would aggravate his condition, and asked him to lie in a position which caused him pain. This complaint was not investigated, as a satisfactory response was received by the acupuncturist in question and the complaint did not give rise to an apparent breach of the Code. The second complaint received recently was that the complainant’s acupuncturist inappropriately touched her during a massage, watched while she undressed, pulled her underwear down without asking, and that the complainant was inadequately covered. The complainant expressed concern that the acupuncturist in question had been charged with indecent assault but was still practising. A formal investigation was not commenced by this Office, as action had already been taken by the Police, and commencing an investigation would have duplicated this process. However my Office notified the New Zealand Register of Acupuncturists (‘NZRA’) about the complaint and the potential risk to the public if the acupuncturist in question continued to practice.

Both of these complaints raise serious concerns. They follow-on from the theme of the earlier complaints (with regard to inappropriate touching, and aggravation of an existing condition). This demonstrates the nature, frequency, and severity of potential harm to the public...In question six you ask whether, other than due to risk of harm, it is in the public interest that the profession of acupuncture be regulated. From the perspective of
this Office, regulation of acupuncturists under the HPCAA would significantly improve the range of options available to protect consumers when faced with serious complaints about acupuncturists or concerns about an acupuncturist’s competence or fitness to practice. I refer to the comments in our earlier letter of 18 May 2005, under the headings ‘Current limitations on possible action when we receive serious complaints about acupuncturists’, and ‘Current limitations when we are concerned about an acupuncturist’s competence or fitness to practise’. Powers of suspension, restriction of practice and competence reviews, in particular, are important mechanisms for addressing the public safety issues (p.3).

6. Are practising TCM practitioners generally agreed on the standards that TCM practitioners are expected to meet?

A lack of agreement in terms of standards of TCM practitioners is apparent, particularly in that differing acupuncture groups both made submissions to the MOH for the regulation of TCM, rather than as a unified profession. This difference is exemplified by the case: New Zealand Register of Acupuncturists Inc v Attorney-General [2006] CIV-2003-485-1082. In this circumstance the NZRA sought proceedings for a judicial review of a decision of the Minister following regulations giving members of the NZASA the right to claim Accident Compensation subsidies for acupuncture treatment. This implies that these organisations are competing, rather than co-operating, this being further evidenced by the separate applications made to the HPCA by the respective groups in 2011. Is their common ground for these organisations to proceed?

Another question, raised from Criterion C is the level of evidence-based education provided and continuing professional development. A tenant of OWM education and professional development is that of evidence-based medicine. A question must be raised as to whether TCM education and professional development is based on ‘evidential’ or ‘empirical’ knowledge.

7. Are practising TCM practitioners generally agreed on the competencies for scopes of practice for TCM?

From the submission document, page 7, paragraph 3 it notes that consensus in terms of clinical and theoretical hours are not agreed.

8. What qualifications are generally held by members of the profession and what is the degree of uniformity in qualifications across members?

The qualifications appear varied and a Grandfathering process may require to be undertaken. Any Grandfathering process would require specific education into the relevant requirements as set by the scope of practice for the healthcare practice, for example acupuncture, tuina, herbal
medicine, the Medicines Act 1981 etc. It would also require standards to be acquired with relevance to the Treaty of Waitangi (Ministry of Health, 2000), The Code of Health and Disability Services Consumers’ Rights (Health & Disability Commissioner, 2009) and other relevant documents.

It must be noted that many TCM practitioners have a full Bachelors degree in TCM. Other TCM practitioners, such as Midwives build their TCM knowledge upon their Undergraduate Bachelor of Health Science and study a 26 week Certificate course.

Furthermore other healthcare professionals build on their Undergraduate Bachelor of Health Science or similar, to study some acupuncture components adapted and divergent from TCM. The British Medical Association acknowledged the difference between traditional Chinese acupuncture and Western acupuncture in 1986 (Payne, 1986).

Formal acupuncture courses have been available, such as the PAANZ Introductory Acupuncture course (80 hours study) which has now been superseded by the Certificate of Western Acupuncture at AUT or Postgraduate Certificate in Physiotherapy (Acupuncture) at Otago University (both 600 hours study) since 1992 (Kohut, Larmer & Johnson, 2011). OWM clinical reasoning methodologies underpin acupuncture education and practice. Furthermore these practitioners are regulated by their respective Boards to practice acupuncture under the HPCA Act. The Physiotherapy Board of New Zealand has recognised acupuncture as a scope of physiotherapy modality since 1984 (Scrymgour, 2000).

Some of these practitioners practice TCM or other TEAM acupuncture practices which are not OWM practices. Should their scope of practice not meet their own Registration Board regulations these practitioners may require registration under the proposed TCM HPCA Act registration pathway.

9. Does your organisation accord any standing or status to the profession of TCM, or to those who practise as TCM practitioners?

Criterion 4 makes mention of ‘enshrining’ of professional roles in statute, which can create closed shops’. Please note the definition of acupuncturist in the Statutes of New Zealand between the 01 April 2002 and 10th of May 2005:

“Acupuncturist”: acupuncturist means a member of the New Zealand Register of Acupuncturists Incorporated.

This definition was substituted in 2005 to:

“Acupuncturist means:
(a) a member of the New Zealand Register of Acupuncturists Incorporated; or
(b) a member of the New Zealand Acupuncture Standards Authority Incorporated who—
(i) is a qualified health professional registered to practise in some other medical discipline in New Zealand who holds a recognised postgraduate qualification in acupuncture of a minimum of 120 credits (1 year full time) at Level 8 or above on the New Zealand Register of Quality Assured Qualifications; or
(ii) holds a National Diploma in Acupuncture (Level 7) or equivalent according to the criteria for the New Zealand Register of Quality Assured Qualifications”, as from 11 May 2005, by s 3(1)
Injury Prevention, Rehabilitation, and Compensation Amendment Act (No 2) 2005 (2005 No 45).

OWM acupuncture is a separate entity to TCM and as such should be recognised in New Zealand healthcare. It cannot be emphasised strongly enough that acupuncture has developed since its ‘emergence’ to the Western world, particularly since the 1970’s. OWM acupuncture is heavily researched; there are randomised controlled trials into acupuncture efficacy, scientific studies into mechanisms of acupuncture action, described at molecular levels and quantitative and qualitative studies into acupuncture usage at all levels of society and medicine. Both OWM and TCM / TEAM practices have much to offer the public as evidenced by the discussion paper provided by Cohn, Niemtzow and Jabbour (2011).

OWM is practiced by healthcare professionals with a relevant undergraduate degree. These healthcare professionals are regulated under their own HPCA Act regulated professional Registration Boards. All registered practitioners practicing a ‘TCM related’ practice, such as OWM acupuncture should continue to be regulated and practice within their relevant defined scope of practice. Standards of initial education, continuing practice development and safe practice should be stipulated by the relevant Board.

Thus:

- There should be a clear minimum standard of acupuncture education for TCM providers and a separate clear minimum standard for OWM providers.
- A clear definition of acupuncture must be provided in order that only those who meet set standards of education provided are accorded the right to use acupuncture needles. However, the stimulation of acupuncture points from the skin, i.e. without needle penetration, through acupressure, laser, magnet therapy etc has equivalents in other therapies such as physiotherapy, osteopathy and massage and as such this should not be a regulated activity.
- Clear agreed levels of safety and standards of needling, such as those published by the Physiotherapy Acupuncture Association of New Zealand should be upheld by all practitioners, TCM and OWM. This is in the interests of the safety of the public.

An item of note, the submission makes no mention whatsoever in regard to upholding the tenants of the Treaty of Waitangi. Does the underlying tenant of this submission discriminate against ‘alternative and complementary medicines from cultures other than East Asia? Thus should this application be for the practice of Complementary and Alternative Medicinal (CAM) practices? Then massage, manipulation, herbal and other practices that are not practiced as traditional Chinese medicines should also fall under the encompassing umbrella of CAM.

In summary, the regulation of all medical practices underpinned by a traditional East Asian theoretical and philosophical basis under the HPCA Act is in the public interest as it would provide tools to ensure the competence of practitioners and the safety of health consumers. However does it go far enough? Should this application succeed and TCM be regulated under
the HPCA Act is it in the public interest that all other CAM practitioners be regulated at a later stage under the same Registration authority?

This submission was completed by:

S.H. Kohut, MHSC (Hons), Dip PHTY, MPNZ, Reg PHTY Acu.
Paper Leader Western Acupuncture
Division of Rehabilitation and Occupation Studies
Faculty of Health and Environmental Sciences
Auckland University of Technology
Private Bag 92006
Auckland 1142

Dr P.J. Larmer, DHSc, MPH (Hons), MPNZ, Dip MT, Dip Acup.
Head of Physiotherapy
School of Rehabilitation and Occupation Studies
Faculty of Health and Environmental Sciences
Auckland University of Technology
Private Bag 92006
Auckland 1142

Please address any correspondence to:
Susan Kohut
Division of Rehabilitation and Occupation Studies A-17
Faculty of Health and Environmental Sciences
Auckland University of Technology
Private Bag 92006
Auckland 1142
Tel: 09 921 9999 ext: 7041
References:


Department of Health Steering Group on the Statutory Regulation of practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems practised in the UK (2008). *Report to Ministers from The Department of Health Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK*. Retrieved from https://openair.rgu.ac.uk/handle/10059/176

Director of Health & Disability Proceedings v DG (2005) Decision No 3-05, HRRT 23-04


Health and Disability Commissioner (2008), 07HDC12714.


Ministry of Health v Zhang [2010] DCR 860


R v Fernando [2007] NZCA 485

R v Ibrahim (1998) CA352/98 and


Appendix

2. Migun Wellness Clinic Voucher (2011)
Submission 17

New Zealand Nurses Organisation

Submission to the Ministry of Health

On the

Proposal that Traditional Chinese Medicine Become a Regulated Profession under the Health Practitioners Competence Assurance Act 2003

19 August 2011

Inquiries to: Marilyn Head
Policy Analyst
NZNO
PO Box 2128, Wellington
Phone: 04 494 6372
Email: marilynh@nzno.org.nz
ABOUT NZNO

The New Zealand Nurses Organisation (NZNO) is the leading professional and industrial organisation for nurses in Aotearoa New Zealand, representing over 45,000 nurses, midwives, students, kaimahi hauora and health workers on a range of employment-related and professional issues. Te Runanga o Aotearoa comprises our Māori membership is the arm through which our Te Tiriti o Waitangi partnership is articulated.

NZNO provides leadership, research and support for professional excellence in nursing, negotiates collective employment agreements on behalf of its members and collaborates with government and other agencies throughout the health sector. Nurses are the largest group of health professionals comprising half the health workforce.

The NZNO vision is “Freed to care, Proud to nurse”. Our members enhance the health and wellbeing of all people of Aotearoa New Zealand and are united in their professional and industrial aspirations to achieve a safe, sustainable and accessible system of public health care for all New Zealanders.

INTRODUCTION

1. The New Zealand Nurses Organisation (NZNO) welcomes the opportunity to comment on the proposal to regulate the profession of traditional Chinese Medicine (TCM) under the Health Practitioners Competence Assurance Act 2003 (HPCAA).

2. NZNO has consulted its members and staff in the preparation of this submission, including Te Runanga, Regional Council and Board members and members of our specialist Colleges and Sections, and professional nursing, industrial, policy, research, and legal advisers.

3. NZNO is confident that the criteria for the addition of professions set out in Clause 116 of the HPCAA are robust. With respect to Clause 116 section (a)
NZNO is not aware of substantial evidence suggesting that TCM is posing a risk of harm to the public, and is unable to comment on as matters relating to section (b) standards, qualifications and competencies for TCM are outside our area of expertise.

4. We also note that recent proposals to change the structure of the responsible authorities (RAs) regulating health practitioners in response to the HPCAA Review recommendations, indicate that there are serious concerns with the potential for the proliferation of regulated professions and the costs of sustaining them.

5. However, we acknowledge that there are a range of treatments outside western medicine (WM) which are practised, and that the cultural context is an important aspect of healing.

6. In the brief discussion that follows, we explain how nurses manage the interface with other therapies to ensure the safe delivery of appropriate care, and comment on those issues where we feel we may make a practical contribution.

DISCUSSION

7. In general the nursing profession regards TCM as a complementary therapy, along with the indigenous healing practice of Rongoā. We believe the latter has specific relevance and priority in Aotearoa New Zealand, especially in addressing disparities in health. We draw your attention to the Waitangi Tribunal's recent major report *Ko Aotearoa Tēnei: a report into the claims concerning New Zealand law and policy affecting Māori culture and identity* (Waitangi Tribunal, 2011).

8. Aotearoa New Zealand’s law is bicultural, based on the Treaty of Waitangi and while we may embrace many cultures, our sovereign obligation is to protect Māori culture and identity, and ensure Māori equity. Clearly that is not
the case in health, where significant disparities in access, treatment and outcomes have been consistently identified. Before regulating traditional medicine from another country, we believe it is relevant to consider what contribution that will make to the health status of Māori, considering the costs and status that regulation infers.

9. Nursing is both evidenced based and holistic. We draw your attention to the way in which dimensions of Rongoā Māori are used by some nurses who, as regulated clinicians, practise it within a framework of evidence-based best practice (See for instance Kai Tiaki Nursing New Zealand, 2011).

10. NZNO’s position on the use of complementary therapies, including Rongoā, is that all who practise must be properly trained and competent in each modality.

11. Most issues raised in the consultation document are covered and, indeed, exceeded, by (voluntary) membership of professional bodies, which have training and education, continuing professional development programmes (CPD), codes of conduct, and complaints systems. Public safety could be bolstered by the promotion of selected practitioners on this basis.

12. Similarly, issues of recognition by publically funded health systems, such as ACC, could be addressed by the requirement for registration with recognised professional bodies.

13. Dual registration (for example midwife/acupuncturist, or physiotherapist/acupuncturist) may be a stronger safeguard than WM training alone in conferring approval to practice TCM. A study of serious adverse acupuncture events by Edzard Ernest, Chair of Complementary Studies, Exeter, identified that of the very few events (White et al. 2001, MacPherson et al. 2001) recorded worldwide, the serious ones were due to medically trained practitioners. However, dual registration would infer additional costs and we note that these, and the burden of additional CPD, have been a
significant barrier to nurses maintaining dual registrations, in midwifery for example.

14. We suggest that Medsafe may be an appropriate body to address the safety of Chinese herbal medicines as opposed to their prescription.

15. Regulation would, presumably, carry a requirement for English language competence. A substantial number of non-English speaking practitioners and patients (whose access to their health care system of choice) could be adversely affected by this move.

16. Regulation would imply that practitioners of TCM would be able to access medical funding for research into a western oriented evidence base.

17. We note that Medical doctors in China are usually still trained in WM, TCM and Acupuncture and that some countries like Belgium, forbid acupuncture except by western trained medics. However there are several countries who have opted fo either voluntary or mandatory regulation of TCMs without it being clear that either option is safer than the other. Considering the number of iatrogenic events due to WM, it seems clear that regulation does is not as good a guarantee of public safety as expected.

CONCLUSION

18. In conclusion NZNO reiterates its support for the HPCAA in regulating health professions where there is potential for significant harm, notes that the costs and complexities of regulation are substantial, and that there does not appear to be a high risk of harm from TCM in Aotearoa New Zealand. We recognise the importance of the cultural context in healing and the right of patients to access healing therapies of choice.

19. We recommend that you:

- Agree that Rongoā Māori has priority and relevance as a traditional medicine;
• **Note** that nurses, with appropriate training and in appropriate contexts, are able to utilise aspects of unregulated complementary therapies to deliver safe quality care;

• **Note** that English language requirements for regulations may adversely affect some TCM practitioners and patients; and

• **Note** that voluntary membership of professional bodies offers some public protection and could be promoted to ensure quality without imposing the additional costs of regulation.

Nāku noa, nā

Marilyn Head

**Policy Analyst**

**REFERENCES**


8 July 2011

Virginia Spackman
Workforce Education, Intelligence and Planning
Health Workforce New Zealand
National Health Board
Ministry of Health

Dear Virginia

Re: Proposal to Regulate Traditional Chinese Medicine

We have received your email on 7 July 2011 from NZASA. Thank you for sending us the Proposal for Traditional Chinese Medicine to become a regulated profession and inviting us to provide feedback on it.

We note there are two separate applications you have received and we are one of Joint applicants with NZASA. You have listed the organizations of New Zealand Register of Acupuncturists, New Zealand Register of Traditional Chinese Medicine Practitioners and New Zealand Acupuncture Standards Authority. However, our organisation “The New Zealand Chinese Medicine and Acupuncture Society Inc.” is not on the proposal.

The New Zealand Chinese Medicine and Acupuncture Society Inc. (NZCMAS) is a well-established and the largest TCM Professional Organisation of whom majority of members are Chinese and Korean practitioners in New Zealand since 1988.

NZCMAS has always been involved in the promotion of TCM development in New Zealand. These activities include participating in ACC legislation and amendment, NDA establishment, Acupuncture legislation and Traditional Chinese Medicine legislation. Recently, NZCMAS successfully co-hosted the First Oceania Chinese Medicine Forum which was held at Massey University, Albany Campus on 11 and 12 June 2011. I attach a photo for your information.

Therefore, we request that the MoH amends the 2nd bullet under the Introduction Overview on page 1 by adding our organisation “New Zealand Chinese Medicine and Acupuncture Society Inc.”

We also request that the MoH will copy any correspondence in regards to the application to NZCMAS directly. Our communication addresses are below:

NZCMAS email address: nzmas@chinesemedicine.ac.nz

NZCMAS postal address: PO Box 17318, Greenlane, Auckland 1546

Yours truly,

Roger Guo
President
New Zealand Chinese Medicine and Acupuncture Society Inc.

Cc: NZASA
Re: Submission for Proposal that Traditional Chinese Medicine Become a Regulated Profession under the Health Practitioners Competence Assurance Act 2003.

Thank you for the opportunity to submit the college’s views on the proposal that TCM become a regulated profession under the HPCA Act. While we support the Chinese Medicine to be regulated, we would like to make following comments.

1. Traditional Chinese Medicine (TCM) is a health service; it is alternatively known as Chinese Medicine (Chinese Medicine) to reflect more accurately its research basis and modern application to contemporary conditions.

2. TCM practitioners are generally agreed that the NZ National Diploma of Acupuncture is sufficient to deliver acupuncture services. The TCM professions also agreed in general that the Bachelor degree in Chinese Medicine or Traditional Chinese Medicine should be the primary qualification to competently provide the Services under new regulation.

3. There is a considerable risk of serious harm in the current environment, and it is extremely fortunate that there have not been significant incidents.

4. The risks to the public are from inappropriate or unclean equipment, and/or unsafe practice, and/or lack of skill or knowledge on the part of the practitioner.
   a. The nature of risks include serious infection of contagious diseases including hepatitis and AIDS; physical damage to organs, tendons and other tissues; psychological scarring from trauma.
   b. The frequency of risks is low but depends entirely on the number of practitioners operating outside their competence, and/or entirely untrained, and/or cutting corners in an attempt to cut costs.
   c. The severity of risks is very high, given that organ damage can easily be done and is potentially fatal eg punctured lung, or infection with AIDS virus.
   d. The potential impact of risks is huge, considering that infected needles could be used on dozens of unsuspecting patients, or a practitioner could set themselves up as an expert on something that is totally contraindicated but still gain a large number of patients eg offering acupuncture for cancer.
   e. The likelihood of harm occurring is slight as long as practitioners are vigilant, cautious, collegial and motivated by service rather than greed.

5. It is in the public interest for TCM to be regulated because it is generally regarded as the most effective Complementary and Alternative Medicine. However, public faith and commercial investment in TCM is hampered by its perception as an unregulated
profession. Cleaning up the practice as well as the image of TCM has the potential to result in better health outcomes across the entire community.

6. Practicing TCM practitioners who belong to or engage with professional associations are generally agreed on the standards that TCM practitioners are expected to meet.

7. Practicing TCM practitioners who belong to or engage with professional associations are generally agreed on the competencies for scopes of practice for TCM, but each professional association is likely to have their own very clear practitioner focus, eg physiotherapists who practice acupuncture, or TCM practitioners who can offer Chinese Herbal Medicine treatment as well as acupuncture. However, the acupuncture professions do agree that the NDA and/or Post graduate qualification in Acupuncture are the competency for Acupuncture practice.

8. A significant proportion of the profession have trained in China or Korea and hold international qualifications such as Bachelor and/or Master in TCM that are higher than the standard recognised in New Zealand, namely the Level 7 National Diploma of Acupuncture (NDA). Among that group of practitioners, probably 40% have had their qualification recognised towards the NDA, the main motivation for doing so being that they can become ACC-accredited practitioner. However, given the broad range of qualifications offered across Asia and around the world, the NDA is little uniformity even among this group. Further afield there is less uniformity eg General Practitioners can and no doubt some do practice acupuncture and/or Chinese Medicine without any training in either because they are already licensed to practice as a GP.

There are other qualifications practitioners held are:
- NZ Bachelor of Health Science (Chinese Medicine)
- NZ Bachelor of Health Science (Acupuncture)
- Post graduate Diploma in Acupuncture
- Master of Health Practice in Acupuncture

9. Our organisation does not accord any standing or status to the profession or practitioners of TCM beyond
   a. Employing and/or contracting TCM practitioners to teach TCM, and
   b. Assessing students in TCM.

Please let me know if there is any opportunity to be further involved in this important deliberation.

Yours sincerely,

Stephen Xu
CEO and Managing Director
Submission to the Ministry of Health’s proposal to regulate traditional Chinese medicine

The Physiotherapy Board (the Board) thanks the Ministry of Health for the opportunity to comment on the proposal that traditional Chinese medicine (TCM) become a regulated profession under the Health Practitioners Competence Assurance Act 2003 (HPCA Act).

The purpose of the Board is to set, monitor and promote competence, continuing professional development and proper conduct for the practice of physiotherapy in the interests of public health and safety.

The Board supports the establishment of any regulated authority where a health profession is deemed a risk to the health and safety of the public. Specific comments are as follow:

1. Is TCM a health service, as defined by the HPCA Act?

The Board believes TCM in general could be considered a health service, as health consumers may approach a practitioner of TCM for the purpose of assessing, improving, protecting, or managing the physical or mental health (the definition of health service as defined by the HPCA Act).

2. Are practitioners of TCM generally agreed on the qualifications required to deliver the health services they provide?

While the Board has no profession specific knowledge to provide specific comment on the qualifications, it is pleased to note that there are several three and four year undergraduate programmes that are NZQA approved. This would seem to indicate that there is already significant academic support for the profession.

3. Is there a risk of harm to the public from the practice of TCM?

If a person could hold themselves as a practitioner of TCM without holding the prescribed NZQA approved qualifications, e.g. from the passing on of knowledge or apprenticeship model, then it does appear that there may by risk of harm to the public.

4. If so, what are the nature, frequency, severity and potential impact of risks to the public? What is the likelihood of the harm occurring?

The risk of harm to the public may be better assessed by those with more profession specific knowledge. The Board’s experience is with those that practice acupuncture. This risks identified in acupuncture are fainting and infection.

There may also be a risk in the use of herbal medicines where there is limited clinical trials to support their effectiveness or undocumented side effects.
5. Other than on the basis of risk of harm, is it in the public interest that the profession of TCM be regulated?

Registration of TCM practitioners would assist the public in identifying properly trained and qualified practitioners. Currently practitioners of TCM can advertise holding qualifications that have not assessed against any standard.

6. Are practising TCM practitioners generally agreed on the standards that TCM practitioners are expected to meet?

The Board has no specific comment as to what TCM practitioners agree to as standards, but it would draw attention to professional organisations, such as Physiotherapy Acupuncture Association of New Zealand, who already have established standards for their professional members who may fall under the umbrella of TCM.

7. Are practising TCM practitioners generally agreed on the competencies for scopes of practice for TCM?

No specific comment

8. What qualifications are generally held by members of the profession, and what is the degree of uniformity in qualifications across members?

No specific comment

9. Does your organisation accord any standing or status to the profession of TCM, or to those who practise as TCM practitioners?

No, while there is an overlap in that some registered physiotherapists may also practice acupuncture, it is not recognised in the general scope of practice: Physiotherapist or reflected in any of the Physiotherapy Competencies.

This submission has been prepared on behalf of the Physiotherapy Board. Any enquiries should be addressed to Mrs Susan Beggs, Chief Executive and Registrar, The Physiotherapy Board, P.O. Box 10-734, Wellington New Zealand. Phone +64 04 471 2610
Proposal that traditional Chinese medicine becomes a regulated profession

In response to the Ministry of Health’s call for submissions on the proposal that traditional Chinese medicine becomes a regulated profession, SPARC is in general support of the proposal.

In particular, we are supportive of regulating the profession if this improves the chances that Chinese herbal medicine is properly labelled, to ensure athletes are fully aware of any substances they may take, to avoid problems in relation to sports anti-doping rules.

Andrew Zielinski || Principal Advisor || Research, Policy and Evaluation
Mob. 021 244 2393

SPARC is the crown entity responsible for promoting, encouraging and supporting sport and physical recreation in New Zealand. For more details, visit www.sparc.org.nz

The information contained in this email is confidential and intended for the addressee only. If you are not the intended recipient, you are asked to respect that confidentiality and not disclose, copy or make use of its contents. If received in error, you are asked to destroy this email and contact the sender immediately. Your assistance is appreciated.
Dear Ms Hannah

RE: Proposal that Traditional Chinese Medicine Become a Regulated Profession under the Health Practitioners Competence Assurance Act 2003

NZIA wishes to make the following comments on this proposal.

1. Is TCM a health service, as defined by the HPCA Act? (Note: the Act defines a health service as ‘a service provided for the purpose of assessing, improving, protecting, or managing the physical or mental health of individuals or groups of individuals’.)

Chinese Medicine is a health service as defined by the HPCA Act, and clearly does meet all of the requirements to be considered under Criterion A of the application guidelines.

2. Are practitioners of TCM generally agreed on the qualifications required to deliver the health services they provide?

Previously, the acupuncture profession agreed to the National Diploma of Acupuncture (level 7) being the accredited qualification for entry to the acupuncture profession. The NDA has now been deregistered. The final group of students enrolled will gain this qualification in December 2012.

It is now generally agreed by the TCM profession that the minimum entry requirement to the profession is a Bachelor degree. Whether this undergraduate Bachelor Degree is of a three year or four year duration, is generally determined by the length of the academic year set by the educational provider. This issue was discussed by the Joint Applicant group in their Submission.
The Joint Applicants also agree on a post-graduate entry for practicing health professionals of a minimum of 150 credits, as recommended by the World Health Organisation.

3. Is there a risk of harm to the public from the practice of TCM?

As discussed on pages 7 & 8 of the joint application, acupuncture and herbal medicine do have the potential to cause harm to a client. As the majority of CM practitioners work in sole practice, the risks most probable are those associated with an incompetent practitioner or one who lacks the necessary language and communication skills.

4. If so, what are the nature, frequency, severity and potential impact of risks to the public? What is the likelihood of the harm occurring?

Please refer to pages 9 - 13 of the Joint Application, where the incidences of minor and serious adverse events associated with acupuncture are discussed.

Well-trained practitioners should negate the risks associated with poor clinical techniques, poor standards of hygiene and limited knowledge of western medical science. It would be expected that properly trained practitioners will be acutely aware of the potential interactions and issues associated with prescription of Chinese herbs and would do so with diligence and due caution.

Regulation of Chinese herbs will not change poor manufacturing practice, fraudulent advertising or patterns of inappropriate self-administration of herbs by the public.

5. Other than on the basis of risk of harm, is it in the public interest that the profession of TCM be regulated?

Yes. It in the public interest that the provision of Chinese Medicine health services be regulated as a profession.

See page 18 of the Joint Application.

6. Are practising TCM practitioners generally agreed on the standards that TCM practitioners are expected to meet?

Yes. Chinese Medicine has a defined body of knowledge that forms the basis for agreed standards of practice. All Chinese Medicine practitioners use treatment techniques that are predicated upon a common philosophical, theoretical and diagnostic framework.

While there are no nationally agreed standards, Chinese Medicine organisations have developed and implemented their own standards of conduct, performance, ethics and discipline.
Most Chinese Medicine professional organisations have standards of practice covering the following issues:

- ethics & culture
- history taking, communication, documentation & storage
- NZ law (privacy, confidentiality, HDC etc)
- clinical skills for Chinese Medicine including: history taking and communication, diagnosis, needling skills, hygiene requirements, lifestyle advice, precautions and contraindications, “red flags” in the case of complications or the need for referral

In NZ practitioners who do not belong to any of these groups are not required to meet standards, and may have varying standards. Their numbers are unknown.

See page 21 and 28 of the Joint Application.

**7. Are practising TCM practitioners generally agreed on the competencies for scopes of practice for TCM?**

No – it would appear from the Proposal document that only the Joint Application mentions possible scopes of practice.

The acupuncture profession agreed on functional competencies for acupuncture in 2006 (refer 2.1). This was based on the profession agreeing that the National Diploma in Acupuncture (NDA) was the minimum standard, and these functional competencies have since been expanded into degree programmes.

At a Chinese Medicine profession meeting in September 2010 the Joint Applicants generally agreed that the minimum functional competencies for acupuncture are defined within either a Bachelor’s Degree, or a post-graduate qualification for a practising health professional.

Whilst the functional competencies for Chinese herbal medicine are definable, they have not been formalised by the Chinese Medicine profession in NZ.

See page 23 of the Joint Application.

**8. What qualifications are generally held by members of the profession, and what is the degree of uniformity in qualifications across members?**

NZIA notes that the AUT(Level 8) post graduate qualifications of MHPPr (Acup) 180 credits & MHSc (Acup) 240 credits – in traditional acupuncture have not been listed in the Proposal.

Ultimately, consistency of qualifications and standards will be the responsibility of the Chinese Medicine Council of NZ who will formally approve and moderate qualifications, set ongoing education requirements, and award ongoing education hours to approved courses. It is imperative that the Minister selects future CM Council members who are truly representative of the broadest range of current CM practitioners in NZ. It may be useful to select a number of Council members who have previous experience as a member of a regulated profession.
NZIA understand some groups within the CM profession have concerns regarding how the profession can continue to ensure consistency of knowledge, uniformity of skills and practice at entry level to the profession. We have a number of Private Training Establishments and one University - Tertiary Education provider in NZ, providing learning at differing academic levels & preparing entry level practitioners to CM from a variety of professional backgrounds.

NZIA sees that a nationwide entry level examination set & managed by the CM Council of NZ to be the fairest and most manageable method of ensuring that minimum standards of CM knowledge & written English language are met. This would be applicable to all new graduates following regulation of CM and would be similar to the State final Examination sat by Nurses and by Midwives currently in New Zealand. This examination could also be the entry level standard for practitioners seeking to be registered with an overseas qualification in CM.

9. Does your organisation accord any standing or status to the profession of TCM, or to those who practise as TCM practitioners?

New Zealand Institute of Acupuncture became an Incorporated Society in November 1994 and has a current membership of 74. The great majority of NZIA members are Registered with NZASA or NZRA in addition to membership with NZIA. Many are also registered with other health professions already regulated by the HPCA Act - including The Nursing Council of NZ, The Medical Council of NZ, The Midwifery Council of NZ, The Physiotherapy Board of New Zealand & The Occupational Therapy Board of NZ.

NZIA Members are very committed to maintaining their professionalism, knowledge and skills, and gain continuing education through NZIA on a regular basis. NZIA aims to provide teaching and learning at the highest level for its members, sourcing presenters with international reputations from both within New Zealand and from overseas.

NZIA has until recently had acupuncture as it’s prime focus, but since the 2010 Application for Regulation of Chinese Medicine under the HPCA Act, we have broadened our educational focus to include Chinese Herbal Medicine and other modalities such as Tuina, Qi Gong, Guasha and Moxibustion.

Yours sincerely

Rose-Marie A. Vos,
President NZIA
On behalf of NZIA Membership
Submission 23

Our Ref: JO135-11 JM

19 August 2011

Mary-Louise Hannah
Workforce Intelligence and Planning
Health Workforce New Zealand
National Health Board
Ministry of Health
PO Box 5013
WELLINGTON 6145

TCM@moh.govt.nz

Dear Sir/Madam

Proposal that Traditional Chinese Medicine Become a Regulated Profession under the Health Practitioners Competence Assurance Act 2003

1. The Royal New Zealand College of General Practitioners is the professional body and post-graduate educational institution that sets the standards for general practice, providing research, assessment, post-graduate training and ongoing education and support for general practitioners and general practice. College Fellows provide advice and expertise to government and within the wider health sector. The College aims to improve the health of all New Zealanders by supporting and strengthening high quality care and standards in general practice.

2. The College has a focus on ensuring high quality patient centred clinical care is delivered in CORNERSTONE accredited general practices by vocationally registered general practitioners.

3. Thank you for the opportunity to comment on the proposal that Traditional Chinese Medicine Become a Regulated Profession under the Health Practitioners Competence Assurance (HPCA) Act 2003.

4. The College considers that in order for a profession to be defined as a health service pursuant to the HPCA Act that profession must be able to demonstrate on an evidential and scientific basis that it assesses, improves, protects or manages the physical or mental health of individuals. The College does not consider that the current proposal contains sufficient information or evidence to demonstrate that Traditional Chinese Medicine is a health service such as is defined in the HPCA Act. The College also considers that the large differences and diversity between the different treatment modalities within Traditional Chinese Medicine mean that Traditional Chinese Medicine as a whole does not provide a coherent health service.
5. The College believes that the practitioners of Traditional Chinese Medicine are not agreed on the qualifications, standards or competencies required to practise Traditional Chinese Medicine. This is demonstrated by the plethora of qualifications and levels available within the ambit of Traditional Chinese Medicine. It is unclear what the differing levels of qualification (Bachelor, Diploma, and Certificate) mean with regard to the practice of Traditional Chinese Medicine.

6. The College notes that there is some risk of harm to the public from the practice of Traditional Chinese Medicine. The College does not consider that the proposal has sufficiently quantified that risk of harm, beyond that which might exist for other non-regulated professions. For example is the risk of harm from tattooing, taking synthetic drugs, taking health supplements and receiving a massage any lesser or greater than the risk posed by Traditional Chinese Medicine?

7. The College considers that the risk of harm from Traditional Chinese Medicine must be carefully balanced and weighed against the risk to the public in regulating Traditional Chinese Medicine under the HPCA Act. There is no doubt that regulation provides a profession with a greater level of legitimacy from a public perspective. The College does not consider that the proposal contains sufficient evidence to warrant a greater level of public trust/expectation in the profession of Traditional Chinese Medicine. In fact, regulation of Traditional Chinese Medicine may lead to more harm if greater levels of trust and legitimacy are not backed up by a scientifically credible properly regulated profession.

8. The College does not consider that the proposal provides sufficient evidence to demonstrate that Traditional Chinese Medicine practitioners have the diagnostic skills to perform accurate diagnoses. The diversity of treatment modalities and approach within Traditional Chinese Medicine also leads to concerns that Traditional Chinese Medicine practitioners may practise beyond their scope of practice and may not recognise when to refer patients for diagnostic investigation and treatment.

9. If the risk of harm associated with the practice of Traditional Chinese Medicine is considered to be an unacceptable risk, the College suggests that the Ministry explores other means of negating or mitigating that risk. Options may include utilising the Restricted Activities List pursuant to the HPCA Act (which limits certain activities to registered practitioners) or voluntary registration outside of the HPCA Act.

10. Thank you for again for the opportunity to comment on this proposal. If you have any questions or comments about the content of this submission, please feel free to contact Jeanette McKeogh, Policy Manager on 04 550 2828 or jeanette.mckeogh@nzccp.org.nz

Yours sincerely

Jane O'Hallahan
Acting Chief Executive
19 August 2011

Mary-Louise Hannah
Workforce Intelligence and Planning
Health Workforce New Zealand
National Health Board
Ministry of Health
PO Box 5013
WELLINGTON 6145

By Email

Comments from the New Zealand Register of Acupuncturists on

The Proposal that Traditional Chinese Medicine Become a Regulated Profession under the Health Practitioners Competence Assurance Act 2003

First incorporated in 1977 and with more than 430 members throughout the country, the New Zealand Register of Acupuncturists Inc (NZRA) is the longest established and largest professional body representing practitioners of Acupuncture and Chinese Medicine in New Zealand. Members of NZRA have been recognised by ACC as Treatment Providers since 1990.

This submission was prepared on behalf of the members of the New Zealand Register of Acupuncturists by:

Paddy McBride  
MHSc(TCM)  
President – New Zealand Register of Acupuncturists  
Vice President – World Federation of Acupuncture-Moxibustion Societies
Questions:

1. **Is TCM a health service, as defined by the HPCA Act?** (Note: the Act defines a health service as ‘a service provided for the purpose of assessing, improving, protecting, or managing the physical or mental health of individuals or groups of individuals’.)

As outlined in our original application to the Ministry for Chinese Medicine to be included under the Health Practitioners Competence Assurance Act 2003, Traditional Chinese Medicine (TCM) is most definitely a health service as defined by the HPCA Act. TCM is a complete system of primary health care, encompassing a range of therapeutic interventions (or treatment modalities), including but not limited to Acupuncture and Moxibustion, Chinese Herbal Medicine, *Tui Na* (TCM remedial massage), diet and exercise, as well as contemporary practice developments (such as laser therapy, electro-stimulation, and point injection therapy).

Each TCM modality is predicated upon a common TCM philosophical, theoretical and diagnostic framework. Differences and diversity appear in the therapeutic and clinical applications of its component disciplines. Practitioners of TCM utilise one or more TCM treatment disciplines in clinical practice.

2. **Are practitioners of TCM generally agreed on the qualifications required to deliver the health services they provide?**

The New Zealand Qualifications Authority has approved two New Zealand teaching institutions to deliver the Bachelor of Health Science in either Acupuncture or Chinese Medicine.

The risks associated with TCM practice derive primarily from poor education and training. The Toward a Safer Choice report in Australia identified a direct inverse relationship between the duration of education and training in TCM and the incidence of adverse events from TCM treatments. Practitioners with less than one year of training in TCM reported double the rate of adverse events compared with practitioners with four or more years of education and training in TCM.

The New Zealand Register of Acupuncturists firmly believes that a four year minimum course of study is essential. Those who graduate in three years may well be good technicians but in order to produce competent and confident practitioners, a four year full time course is the minimum requirement.

It is of great concern to us that NZQA have approved one teaching institution to deliver a three year Bachelor programme when the first programme they approved was a four year programme. It is very difficult to understand how such a situation could possibly have arisen and to date we have been unable to obtain any explanation from NZQA regarding this matter. We are aware that many of the students graduating from the three year programme are inadequately prepared for clinical practice and we are in the process of implementing a full Clinical Competence assessment for any such graduates who wish to become members of our organisation. Those who complete the four year course spend the majority of their fourth year in supervised clinical practice and are thus far more prepared when entering the work force.
NZRA does not endorse any short course of acupuncture which is taken on top of a previous qualification such as physiotherapy, nursing, midwifery or osteopathy. The one and two year part time courses available in New Zealand have minimal clinical content and much of the learning is self directed. Graduates from such courses do not meet the entry requirements of NZRA.

Australia currently requires graduates to have completed a four year course of study in either Acupuncture or Chinese Herbal Medicine and four to five years for a combined programme. China requires a five year programme and Korean students undertake a six year programme. It is essential that we here in New Zealand also meet similar standards of education of our students and that our graduates are easily able to travel and have their qualification recognised and accepted by our neighbouring countries.

3. Is there a risk of harm to the public from the practice of TCM?

The risks associated with both the practice of Acupuncture and of Chinese Herbal Medicine were fully outlined in our application to the Ministry for Chinese Medicine to be included under the HPCA Act.

4. If so, what are the nature, frequency, severity and potential impact of risks to the public? What is the likelihood of the harm occurring?

These too were fully outlined in our original application.

5. Other than on the basis of risk of harm, is it in the public interest that the profession of TCM be regulated?

There is currently a substantial degree of confusion in the minds of the general public as to who actually is a practitioner of Chinese Medicine or Acupuncturist. With Physiotherapists actually stating on their website and on individual business cards that they are “Registered Acupuncturists” there is little wonder that people who visit them for treatment really do believe that they are seeing a fully trained and competent practitioner. On the Physiotherapy Acupuncture Association of New Zealand (PAANZ) website, it is stated that physiotherapists are required to complete a minimum of 150 hours of PAANZ approved acupuncture training and have passed a written assessment and a practical acupuncture safety assessment. There is no mention at all of any clinical component or requirement.

More recently Osteopaths have included Acupuncture in their scope of practice, requiring only a minimum of 120 hours training. Understandably those practitioners with their primary qualification in Acupuncture or Chinese Medicine find this to be a very frustrating situation and one which has to be explained on an almost daily basis to those who say they “have tried Acupuncture but it didn’t work” when in fact they have been treated by someone who has completed a short course rather than by a fully qualified practitioner.

It was originally intended that midwives who completed a short course of study of the use of acupuncture in relation to pregnancy and childbirth would treat only their own patients through the period of time they were their Lead Maternity Carer. Unfortunately it has been observed that some of the midwives who have completed the course have set themselves up in individual practice and have been advertising their services broadly. To their credit, the New Zealand College of Midwives have
spoken out strongly against this practice and have made it clear that any midwife operating in such a manner is not covered in terms of professional indemnity insurance under their regular insurance agreements. These midwives, because they have only completed a short course in a very limited field of acupuncture do not meet the entry requirements of the New Zealand Register of Acupuncturists. W

As practitioners of Chinese Medicine are not required to be registered it is difficult for the general public to determine the standard of training of not only other professionals with a limited knowledge of Chinese Medicine but also those persons who remain outside any of the professional bodies. Additionally, many practitioners of Chinese Medicine work in individual practices in rural or remote areas of New Zealand and have little contact with other health practitioners. Regulation of the profession will assist in providing mechanisms to help ensure that all are meeting the required standards of practice as well as support to provide the most effective treatment to those who attend their clinics.

6. Are practising TCM practitioners generally agreed on the standards that TCM practitioners are expected to meet?

As outlined in our original application, protocols for acupuncture and Chinese herbal medicine practice have been developed throughout their long history of use, and are detailed in numerous modern and classical Chinese and English language texts. The World Federation of Acupuncture-Moxibustion Societies (WFAS) and the World Federation of Chinese Medicine Societies (WFCMS), in collaboration with the International Standards Organisation (ISO) are currently working on international standards for a number of different aspects of the practice of Chinese Medicine.

It is estimated that there are approximately 600 TCM practitioners in New Zealand and 430 of these are members of the New Zealand Register of Acupuncturists. A further 130 who are currently members of NZASA were formerly members of NZRA. All these practitioners have met the requirements of our organisation in terms of entry qualifications, clinical practice and ongoing Continued Education. This would strongly indicate that by far the majority of TCM practitioners in New Zealand do agree on the standards they are expected to meet.

7. Are practising TCM practitioners generally agreed on the competencies for scopes of practice for TCM?

In recent years a number of countries have developed or are in the process of developing competency standards in the area of TCM. These competencies outline the scope of practice for acupuncture as well as Traditional Chinese Medicine, and describe the knowledge and skills required for entry-level professional practice.

Whilst the actual development of the Scopes of Practice will be the domain of the new Regulatory Board when it is appointed, NZRA is strongly of the opinion that there must be clear delineation between those who have completed a short course of Acupuncture on top of their primary qualification and those who have completed a full four or more years of full time study in the field of Traditional Chinese Medicine. It is essential that the difference between the two groups be made very apparent to the general public.

The recently announced Chinese Medicine Board of Australia will be modelling their requirements on the documents produced by the Chinese Medicine Board of Victoria. International co-operation ensures that practitioners are more easily able to transfer and utilise their skills should they choose to travel in the future. It is suggested that New Zealand follow the same pathways as our international colleagues.
8. **What qualifications are generally held by members of the profession and what is the degree of uniformity in qualifications across members?**

In 2000 the National Diploma of Acupuncture was adopted as the benchmark for practitioners. The New Zealand schools were obliged to teach the NZQA approved Unit Standards and the professional bodies adopted the NDA as the minimum entry standard.

Practitioners who were already members of the different bodies had to be assessed to ensure their previous qualification met the same standard. In many instances this required practitioners to update their qualification particularly in the areas of Pharmacology and Ethics. Any overseas applicant was required to have their qualification assessed by NZQA to ensure equivalence to the NDA.

NZQA chose to deregister the NDA in 2008 and the final students will graduate with this qualification at the end of 2012. Both teaching institutions now offer a New Zealand Qualifications Authority approved Bachelor degree and the first students graduated with this qualification in 2010.

Many practitioners who completed their training overseas (primarily in China, Korea or Australia) hold Bachelor, Masters or PhD qualifications.

9. **Does your organisation accord any standing or status to the profession of TCM, or to those who practise as TCM practitioners?**

The New Zealand Register of Acupuncturists (NZRA) is an incorporated society, founded in 1977, providing voluntary membership to Practitioners of Acupuncture and Chinese Medicine. NZRA has a policy of active involvement in all aspects of Acupuncture and Chinese Medicine in New Zealand. The history and tradition of Chinese Medicine are honoured and maintained whilst ensuring current information and attitudes are incorporated into all areas of work of the organisation.

The aim of the organisation is -

- To promote the tradition of Acupuncture and Chinese Medicine as a viable form of health care for all New Zealanders
- to establish and maintain appropriate standards of practice in all aspects of the medicine
- to protect the interests of the public in relation to the practice of Acupuncture and Chinese Medicine
- to foster strong relationships with other health organisations both nationally and internationally for the continued growth of the profession.

Should the Minister of Health decide to proceed with bringing Chinese Medicine under the Health Practitioners Competence Assurance Act 2003, the Council and members of NZRA understand that part of our current role would be passed to the new Regulatory Authority. We look forward to working with the Ministry, the new Regulatory Authority, other professional organisations and the teaching institutions to ensure that the public of New Zealand are able to take full advantage of the benefits offered through Acupuncture and Chinese Medicine, whilst at the same time being protected from the risks.
Should any further comment or clarification of any point be required, please contact:

**Paddy McBride**  
MHSc(TCM)  
President – NZ Register of Acupuncturists Inc  
Vice President – World Federation of Acupuncture Societies Inc  
paddynz@paradise.net.nz  
Ph: +64 3 544 0411  
Mob: +64 21 104 3592  

The New Zealand Register of Acupuncturists,  
PO Box 14106. Kilbirnie, Wellington 6241 New Zealand  
nzra@acupuncture.org.nz  
www.acupuncture.org.nz
Submission 25

18th August 2011

Mary-Louise Hannah
Workforce Intelligence and Planning
Health Workforce New Zealand
National Health Board
Ministry of Health
PO Box 5013
WELLINGTON 6145

Dear Ms Hannah

RE: Proposal that Traditional Chinese Medicine Become a Regulated Profession under the Health Practitioners Competence Assurance Act 2003

The NZ Acupuncture Standards Authority (NZASA) Inc wish to make the following comments on this proposal. The Joint Applicants have discussed the proposal and will make independent submissions.

1. Is TCM a health service, as defined by the HPCA Act? (Note: the Act defines a health service as 'a service provided for the purpose of assessing, improving, protecting, or managing the physical or mental health of individuals or groups of individuals'.)

Yes, Chinese Medicine is a health service as defined by the HPCA Act, and as a profession, meets all the requirements to be considered under Criterion A of the application guidelines.

Please refer to page 6 of the Joint Applicant’s application.

2. Are practitioners of TCM generally agreed on the qualifications required to deliver the health services they provide?

In 2006 the acupuncture profession agreed to the NDA (level 7) being the accredited qualification for the acupuncture profession. The NDA has now been deregistered.

It is now generally agreed by the TCM profession that the minimum entry requirement to the profession is a Bachelors degree. The Joint Applicants...
also agree on a post-graduate entry for practicing health professionals of a minimum of 150 credits.

The Joint Applicants clarified the differences between Australian and NZ qualifications, educational standards and tertiary academic years in its application.

Ultimately, consistency of qualifications and standards will be the responsibility of the Chinese Medicine Council of NZ who will formally approve and moderate qualifications, set ongoing education requirements, and award ongoing education hours to approved courses.

The Joint Applicants have made recommendations for the new regulatory authority to consider.

See pages 24 – 25 of the Joint Application.

3. Is there a risk of harm to the public from the practice of TCM?

Acupuncture, Chinese herbal medicine and tuina each involve specialised procedures which have the potential to cause physical or mental harm. Risks for acupuncture and Chinese herbal medicine are detailed in the Joint Application.

The most significant risk to the consumer is an incompetent Chinese Medicine practitioner. Most Chinese Medicine practitioners work autonomously and are therefore unsupervised by other regulated health professionals.

A non-competent practitioner may therefore pose risks to the public and a practitioner with poor language and/or communication skills may also pose a risk to the Public.

See pages 7 – 8 of the Joint Application.

4. If so, what are the nature, frequency, severity and potential impact of risks to the public? What is the likelihood of the harm occurring?

While the incidence of minor adverse events associated with acupuncture treatment may be numerous, serious adverse events are rare. Recent reputable studies in the United Kingdom found a low adverse event rate of between 0 and 1.1 per 10,000 treatments. Of over 66,000 treatments the most common minor transient events reported were local reactions at needle site, such as bruising (1 in 60 treatments), pain (1 in 90 treatments), bleeding (1 in 30 treatments); and the aggravation of symptoms (up to 11%).

See page 9 of the Joint Application.
In general, it would appear that most risks directly associated with acupuncture and allied practices are the result of a poor standard of hygiene, inadequate training in acupuncture, poor clinical judgement, poor clinical techniques and inadequate education in western medical sciences.², ³

See page 12 of the Joint Application.

Well-trained practitioners are aware of the dangers inherent in the use of Chinese herbs and exercise care to ensure that substances are used appropriately and not in excessive amounts.

A small quantity of Chinese herbal medicines which contain some toxic elements have their toxicity reduced or eliminated after being processed or prepared, or used in conjunction with other compatible Chinese herbs. Many western nations have not legislated for Chinese medicines because of their low toxicity.

Regulation of Chinese herbs will not change poor manufacturing practice, fraudulent advertising or patterns of inappropriate self-administration of herbs by the public.

See pages 11 – 13 of the Joint Application.

5. Other than on the basis of risk of harm, is it in the public interest that the profession of TCM be regulated?

Yes. It in the public interest that the provision of Chinese Medicine health services be regulated as a profession.

See page 18 of the Joint Application.

6. Are practising TCM practitioners generally agreed on the standards that TCM practitioners are expected to meet?

Yes. Chinese Medicine has a defined body of knowledge that forms the basis for agreed standards of practice. All Chinese Medicine practitioners use treatment techniques that are predicated upon a common philosophical, theoretical and diagnostic framework.

While there are no nationally agreed standards, Chinese Medicine organisations have developed and implemented their own standards of conduct, performance, ethics and discipline.

Most Chinese Medicine professional organisations have standards of practice covering the following issues:
- ethics & culture
- history taking, communication, documentation & storage
- NZ law (privacy, confidentiality, HDC etc)
• clinical skills for Chinese Medicine including: history taking and communication, diagnosis, needling skills, hygiene requirements, lifestyle advice, precautions and contraindications, “red flags” in the case of complications or the need for referral

In NZ practitioners who do not belong to any of these groups are not required to meet standards, and may have varying standards. Their numbers are unknown.

See page 21 and 28 of the Joint Application.

7. Are practising TCM practitioners generally agreed on the competencies for scopes of practice for TCM?

No – it would appear from the Proposal document that only the Joint Application mentions possible scopes of practice.

The acupuncture profession agreed on functional competencies for acupuncture in 2006 (refer 2.1). This was based on the profession agreeing that the National Diploma in Acupuncture (NDA) was the minimum standard, and these functional competencies have since been expanded into degree programmes.

At a Chinese Medicine profession meeting in September 2010 the Joint Applicants generally agreed that the minimum functional competencies for acupuncture are defined within either a Bachelor’s Degree, or a post-graduate qualification for a practising health professional.

Whilst the functional competencies for Chinese herbal medicine are definable, they have not been formalised by the Chinese Medicine profession in NZ.

See page 23 of the Joint Application.

8. What qualifications are generally held by members of the profession, and what is the degree of uniformity in qualifications across members?

Members of the profession may have obtained their qualifications from NZ or overseas.

Members of the profession may also hold additional certificates, diplomas and degrees in other health professions already regulated under HPCA.

The following qualifications are generally held by members of the profession:
- the NZ National Diploma (NDA) in Acupuncture
- diplomas in Acupuncture, Tuina, Qi Gong
- national and international Bachelor degrees in Health Science (Acupuncture) or Bachelor degrees in TCM or Chinese Herbal Medicine or Oriental Medicine
- Post-graduate Certificates (Acupuncture), Post-Graduate Diplomas (Acupuncture)
- Masters of Health Practice or Health Science (Acupuncture) or Masters of Oriental Medicine or Chinese Medicine

NZASA notes that the post graduate qualifications in traditional acupuncture awarded by AUT have not been listed in the Proposal.

Initially, the NDA was the most commonly held qualification by NZ trained practitioners. Since the introduction of the Bachelor degrees, many practitioners have upgraded their qualifications from the NDA.

9. Does your organisation accord any standing or status to the profession of TCM, or to those who practise as TCM practitioners?

Yes. NZASA was established in 2000 as an Incorporated Society. It is recognised under the Accident Compensation Corporation (ACC) Act 2005 and through that members are able to become ACC Treatment Providers.

Accredited qualifications are only required for those acupuncturists who wish to register and then apply for ACC Treatment Provider status.

NZASA is a standards-based registration and disciplinary body committed to maintaining standards of clinical competency in acupuncture in NZ.

NZASA maintains a Register of more than 200 competency assured practitioners who may also choose to apply for ACC Treatment Provider status in terms of Section 6 (1) of the ACC Act.

NZASA is underpinned by ethical, technical and practice standards, which are implemented through the registration and certification programme and through a code of conduct and disciplinary procedures that apply to all its Registered Acupuncturists. NZASA operates a competency assessment regime that includes workplace evaluation by qualified assessors.

Yours sincerely

Vanessa Morgan
NZASA Executive
Dear Mary-Louise

Pharmacy Council of New Zealand Submission to: Proposal that Traditional Chinese Medicine Become a Regulated Profession under the Health Practitioners Competence Assurance Act 2003

Thank you for the opportunity to respond to the Ministry of Health’s proposal that Traditional Chinese Medicine become a regulated profession under the Health Practitioners Competence Assurance Act 2003.

The Pharmacy Council of New Zealand is established under the Health Practitioners Competence Assurance Act 2003 (HPCAA) and has a duty to protect the public and promote good pharmacist practice. The Pharmacy Council is responsible for registration of pharmacists, the setting of standards for pharmacists’ education, scopes of practice and conduct. The Pharmacy Council’s vision is Safe Effective Pharmacy Practice.

With respect to this consultation, the Pharmacy Council will respond in general terms to the proposal rather than reply to each question specifically.

The Practice of Traditional Chinese Medicine

The Pharmacy Council of New Zealand understands that the practice of Traditional Chinese Medicine (TCM) involves three major activities. These activities are acupuncture, Chinese herbal medicine, and tuina (Chinese Medical Massage). The consultation document states that a TCM practitioner may practice one or more of these activities. The activity the TCM practitioner chooses would be dependent on the training acquired and patient need. The consultation document states that while the majority of concerns for patient safety arises from the practice of acupuncture, the proposal is for the regulation of TCM in its entirety. The Pharmacy Council is of the understanding that the current proposal will subject all TCM practitioners to statutory regulation and, this would be regardless of whether they practised all three activities or just one of the activities in TCM.

Acupuncture and tuina are activities that do not form part the scope of practice of the pharmacy profession. Therefore the Pharmacy Council cannot comment on the practice of acupuncture and tuina, nor comment on the qualifications and standards required to practise these activities.

Mary-Louise Hannah
Workforce Intelligence and Planning
Health Workforce New Zealand
National Health Board
Ministry of Health
PO Box 5013
WELLINGTON 6145
E-mail mary-louise_hannah@moh.govt.nz

19 August 2011
Focus of Pharmacy Council’s submission on the proposal

Part of the scope of practice of a pharmacist includes the custody, preparation and dispensing of medicines and pharmaceutical products; the provision of advice on health and well-being, including health screening, and the selection and provision of non-prescription medicine therapies and therapeutic aids. Therefore in its submission the Pharmacy Council has chosen to restrict its comments on the regulation, sourcing, prescribing, blending and dispensing of Chinese herbal medicines only.

Risk of harm with Chinese herbal medicines

The Pharmacy Council can identify some potential risks of harm associated with the activities of Chinese herbal medicine practitioners. These risks centre on the sourcing, prescribing, blending/formulating and dispensing of Chinese herbal medicines.

The specific factors contributing to the risk of harm are:
1. Absence of regulation of Chinese herbal medicines. This includes the absence of clinical data regarding the potential efficacy and safety of phytochemical constituents in Chinese herbal medicine formulations.
2. Absence of systems to check and add to a patient’s current medication history.
7. Absence of dispensing records for dispensed Chinese herbal medicines.
8. Absence of evidence-based data outlining potential interactions or synergistic effects with western medicines.

The Council’s submission will address the significance of each of the risks identified.

1. Absence of regulation of Chinese herbal medicines. This includes the absence of clinical data regarding the potential efficacy and safety of phytochemical constituents in Chinese herbal medicine formulations.

The Council is not aware of any overarching policy in place that addresses the regulation, procurement, management and use of Chinese herbal medicines in New Zealand.

In New Zealand therapeutic medicines are regulated by Medsafe. The objective of the medicines legislation is to manage the risk of avoidable harm associated with the use of medicines. The legislation is designed to ensure that:
1. medicines meet acceptable standards of safety, quality and efficacy;
2. personnel, premises and practices used to manufacture, store and distribute medicines comply with requirements designed to ensure that products meet acceptable standards right up until they are delivered to the end-user; and
3. information about the selection and safe use of medicines is provided to health professionals and consumers.
It is known that active ingredients found in medicinal herbs have been extracted to produce common pharmaceutical medicines for example aspirin, digoxin and morphine. The absence of regulation of Chinese herbal medicines means that unknown medicinal compounds, from unknown sources and in unknown strengths results in being taken by a patient. It would appear that Chinese herbal medicines are being used for a therapeutic purpose and hence should be subject to the same regulation standards as other therapeutic medicines.

There is also concern over the absence of evidence-based clinical data assessing the efficacy and safety of Chinese herbal medicine formulations. Although there appears to be a growing body of research, the Council supports commentators who recommend that the essential methodological principles of evidence-based medicine should be applied in clinical trials of Chinese herbal medicines in order to evaluate the potential efficacy and safety of Chinese herbal medicines objectively and scientifically.

It is the Pharmacy Council’s view that the system for governing the regulation, procurement, management and use of Chinese herbal medicines should receive an equal if not greater priority than the regulation of Traditional Chinese Medicine practitioners as a profession.

2. Absence of systems to check and add to a patient’s current medication history and patient medical records

Prescribers (doctors, midwives, dentists, optometrists, nurse practitioners) and pharmacists utilise the patient’s current medication history to ensure that new medicines prescribed will not interfere/interact with the medicines the patient is already on. Prescribers have the ability to add newly prescribed medicines to the patient’s medical record. The patient’s medical record is an essential information source whenever a medical intervention is sought by the patient. While the patient medical information sharing systems are not well integrated across all prescribers, it can be easy to access. The TCM practitioner does not have the system in place to check or add to the patient’s medical record. The risk to the patient is that they may be prescribed a Chinese herbal medicine that may interact with their other prescribed medicines or worsen their diagnosed medical condition as result of the interaction. The liver and renal function of a patient is important for the absorption, metabolism, distribution and excretion of any medicine. There are currently no systems in place that would alert the TCM practitioner to this type of information about a patient and only adds to the risk of an adverse event being experienced by the patient.

3. Absence of sourcing and storage standards for Chinese herbal medicines

The standards around sourcing and storage of medicines have been alluded to earlier in the submission. The sourcing regulations ensure the quality of medicine while the storage standards ensure the effectiveness of the medicine is maintained.

Although Chinese herbal medicines are available from Chinese shops or dispensed by TCM practitioners, the patient cannot be assured of the quality or the effectiveness of the dispensed herbs. There is no form of regulation to address sourcing and storage; as a result Chinese herbal medicines are imported from a wide range of unregulated sources and have been subjected to variable storage conditions.
4. Absence of prescribing standards for Chinese herbal medicines

Health practitioners involved in prescribing, dispensing and managing the use of medicines for a patient should be confident that a prescribed medicine is safe and effective for the patient.

The Pharmacy Council has recently developed a scope of practice of prescribing pharmacists. To ensure the safe and effective use of medicines by a patient the Council has deemed that the pharmacist prescriber must demonstrate competence in the following competency areas:

- The Consultation - Demonstrate the clinical and pharmaceutical knowledge required; Establish options for the patients; Communicate effectively with their patients

- Prescribing Effectively – prescribe safely and professionally, maintain the quality of prescribing practice

- Prescribing in Context – working within the context of the NZ Healthcare System; working in collaboration with the collaborative health care team

The Pharmacy Council is not aware of any prescribing standards in place for the prescribing of Chinese herbal medicines. The Pharmacy Council’s view is that there must be prescribing standards in place to mitigate the risks of harm associated with prescribing Chinese herbal medicines.

5. Absence of dispensing standards for Chinese herbal medicines

The Pharmacy Council understands that TCM practitioners prescribe, blend and dispense Chinese herbal medicine for individual patients. Pharmacists are required to dispense medicines according to best practice and quality standards. These standards include:

1. Validating the prescription
2. Assessing the prescription
3. Interpreting the prescription
4. Reviewing the patient’s medicines in relation to their histories
5. Deciding what is safe and appropriate to dispense
6. Filling the prescription
7. Packaging medicines to optimise safety and compliance (includes labelling)
8. Maintaining dispensing records
9. Minimising dispensing errors
10. Counselling patients about their medicines

These standards are in place to ensure the safe and quality use of medicine. The standards also ensure that the right patient receives the right medicine. The Pharmacy Council has not found evidence of dispensing standards that TCM practitioners are required to adhere to when dispensing Chinese herbal medicines.

6. Absence of packaging and labelling standards for Chinese herbal medicines

Medicines dispensed by pharmacist are required to be packaged to optimise safety and patient compliance. Packaging medicines in suitable containers and producing comprehensive and complete labels is part of the packaging standard.

From the consultation document it cannot be ascertained whether packaging or labelling standards exist for the dispensing of Chinese herbal medicines.
7. Absence of dispensing records for Chinese herbal medicines

The practice of pharmacy requires that a record is kept of every Prescription Medicine or Restricted Medicine dispensed. This record includes the name and address of the patient, the name and quantity of the medicine supplied, the name of the prescriber, and a unique identifying number or code. The importance of records for patient safety has been discussed earlier in the submission.

From the consultation document it cannot be ascertained whether dispensing records are a mandatory requirement for Chinese herbal medicine dispensers.

Pharmacy Council Position

The Pharmacy Council of New Zealand agrees that the practice of Traditional Chinese Medicine meets the definition of a health service as defined by the Health Practitioners Competence Assurance Act 2003. This agreement is on the basis that Traditional Chinese Medicine includes the activity of acupuncture, Chinese herbal medicine and tuina.

The Pharmacy Council cannot be certain if statutory regulation of Traditional Chinese Medicine practitioners is being sought based solely on the risk of harm to patients that may arise from the practice of a TCM practitioner. Statutory regulation is the most expensive form of regulation and should be used when the risk to patients cannot be mitigated any other way. Statutory regulation should not be used to recognise a health profession.

The Pharmacy Council is of the view that statutory regulation of Traditional Chinese Medicine as a health profession may be a reasonable consideration given some of the risks to patient safety. However, the Pharmacy Council’s view is drawn only from the identified risk of harm to patient that may arise from the prescribing and dispensing of Chinese herbal medicines.

The Pharmacy Council re-iterates its earlier expressed view that the system for governing the regulation, procurement, management and use of Chinese herbal medicines should receive an equal if not greater priority than the regulation of Traditional Chinese Medicine as a health profession. The regulation of Chinese herbal medicines should be included any proposed scheme to regulate health products in the New Zealand market.

Once again thank you for the opportunity to respond to the proposal to regulate Traditional Chinese Medicine as a health profession under the HPCA Act 2003.

Yours sincerely

[Signature]

Bronwyn Clark, MClinPharm, MPS, RegPharmNZ
Chief Executive & Registrar
Submission to the Ministry of Health on the matter of the proposal that Traditional Chinese Medicine (TCM) become a regulated profession under the Health Practitioners Competency Assurance Act (HPCA Act) 2003.

1. Is TCM a health service, as defined by the HPCA Act?

Statistics New Zealand defines TCM as "the treatment of imbalances of energy flows through the body by assessing the whole person, and using techniques and methods such as acupuncture, Chinese herbal medicine, massage (tuina), diet, exercise and breathing therapy (quigong)." which is an better descriptive of TCM than the applicants' definition. This definition is stated to be "as an occupation with a clear professional identity and an established body of knowledge with standards of practice, and as a system of primary health care, encompassing a range of therapeutic interventions, including but not limited to, acupuncture and moxibustion, Chinese herbal medicine, remedial massage, diet and exercise, as well as contemporary practice developments...". This definition is too broad, concentrates on various interventions rather than defining TCM itself and is written in a way that means that the definition may be added to as the applicant desires.

Either of these definitions may appear to meet Primary Criteria, as the practice of TCM does seem to involve the process of assessing and treating. However, many of those practices are not unique to TCM such as massage and dietary interventions, there is already the profession of Dietician covered under the HPCA Act and whether these practices are valid and evidence based is another matter.

TCM has two main concepts - that of "Five Elements" and "Yin-Yang". Acupuncture is an ancient (but more recently revived) system of medicine which is based on the idea that health relates to the flow of "Chi" or "Qi" through pathways in the body. The aim of needling is to rebalance and unblock Chi/Qi. TCM dietary interventions involve sorting foods into categories such as hot or cold and if the wrong mix of foods are eaten this is thought to create an imbalance in the body. The stomach and spleen are thought to be as a “cauldron” and “fire” which turns food into blood and energy. Herbal medicine characterises by temperature and flavour in a similar way to food which is thought to influence Yin-Yang energy. All of these concepts developed long before modern medicine, biology, chemistry and physics and there is no evidence for the existence of concepts such Yin-Yang or Chi/Qi or that either have a role in modern healthcare. The core principles appear to correlate with Vitalism, a long discarded pre-scientific view of human health. This means that for diagnosis in TCM\(^1\) as one example that there is little to no correlation between practitioners when

diagnosing and treating consumers and no correlation with relevant physiological processes in the body. Where the diagnosis is something like "Liver Qi deficiency" this is impossible to match up with any conventional medical diagnosis which may be made for the consumer seeking care. This means that while the "form" of assessing and treating patients occurs, there is no rational basis to this and no relevance to the body of knowledge of health care as it currently stands. As such, it cannot be accepted that TCM fulfils the criteria of being a health service but rather can be defined as more a culturally based practice.

Regulation and other applicable consumer protection legislation, particularly in the context of health care, need to be robust and have the trust of the public. There are risks to granting the legitimacy of official regulation ahead of the evidence — in this case measurable efficacy and a plausible method of action. This may lead to regulation being ineffective and failing to protect the public by creating the situation where it is difficult for a consumer to determine the best health care provider to treat them and the situation where care can be inappropriate and/or harmful, but the provider cannot be deemed to be acting outside regulations. This also tends to go against legislative changes elsewhere, such as European laws which make it illegal to make claims about treatments where no evidence exists to support the claim.

2. Are practitioners of TCM generally agreed on the qualifications required to deliver the health services they provide?

Two institutions offer degrees, diploma and certificate courses in TCM which are the New Zealand School of Acupuncture and Traditional Chinese Medicine and the New Zealand College of Chinese Medicine. These courses are approved by NZQA. It is noted in the proposal that not all groups agree on hours required to achieve competence and that courses need to be a combination of both to define minimum standards for practice and to determine fitness to practice. The difficulty is that on checking on the sites of the institutions to determine whether there is agreement between the courses and what teaching they deliver it cannot be determined. Also, while there is some agreement there are also differences in schools of thought within TCM with, for example, some acupuncturists working on the basis of 12 meridians, while others support the concept of 14 and additional concepts such as Yin-Yang may be divided into 2 subcategories while others use 4. While the courses may have some science based courses within the qualification they offer, NZQA determinations are more about processes and delivery than content. Given this there are some real issues about the content of the courses when considering there is no evidence for the principles of TCM and therefore anatomy and physiology is not understood in terms of its own reality.

The New Zealand School of acupuncture has their core teaching areas in TCM on their website which include "Channel Theory", "Zang-fu organ theory", "Eight Principles Syndromes" and "Qi-Blood-fluids Syndromes." While it is not possible to comment on detail of the content, it is clear students are being taught in many cases pre-scientific principles that bear no relationship to the current understanding of the human body and as such, much of what is being taught and what is being tested is incorrect.

2 See: http://www.acupuncture.ac.nz/courses/bachelor-of-acupuncture
An examination paper from the University of Salford came available to view online in 2009 and included questions such as:

Q5: What are the four fundamental substances?

- a) Qi.
- b) Blood/Xue.
- c) Spirit/Mind.
- d) Jing/essence.
- e) Jin ye/body fluid.
- f) Organs.

Q23: Explain the meaning of 'liver and kidney have a common source'.

Questions like this are not only difficult to parse, but also it is difficult to understand how teaching students these concepts and having them being able to respond to these questions in any way prepares for having a rational theoretical background in health care and in delivering adequate and competent care to any person that may seek their services.

3. Is there a risk of harm to the public from the practice of TCM?

1. Acupuncture risks may include:
   - Infection risks due to poor sterile technique, not using single use needles and incorrect disposal of used sharps.
   - Risk of harm from needling causing bruising and bleeding, along with forgotten or broken needles and risk of perforation of organs such as the lung or heart. In the proposal it says "the evidence of risk of harm is largely based on practitioners that are inadequately trained or who have inadequate clinical experience". While this may be the case for some areas (i.e. infections) this ignores inherent risk from any insertion of needles. Case decision 07HDC12714 of the Health and Disability Commissioner was a case where pneumothorax (a punctured lung) was experienced as a complication of acupuncture. This was intended to treat asthma. The acupuncturist was said to have breached the standard of care with the opinion of another acupuncturist being "The following points were selected by [Mr B] in the treatment: BL12, BL13, BL23, BL43, DU4, EX-B1, K13, ST36 and SP6. These points are used to treat Asthma or reinforce body energy...[Mr B]'s acupuncture treatments comply with these standards." even though a complication occurred that was the likely result of the positioning of the needles. The "Code of Safe Practice for Acupuncturists" from the New Zealand Acupuncture Standards Authority (NZASA) states that there are "vulnerable points that require skill and care" including Liangmen ST 21 which lies over the gallbladder which demonstrates needles may be inserted in areas posing an increased risk to the consumer if it is deemed necessary for treatment by the acupuncturist.
   - TCM is said to treat many disorders, but there is nothing there that would suggest plausibly that so many disparate conditions could be treated with one or more modality. In particular Acupuncture may be used for conditions for which there is no evidence it may be effective and additionally it may not compare favourably with other treatments in cost or outcomes. Even if there appears to be some benefits, it can be difficult to assess benefit/risk for the patient. For instance non-specific effects could apply for conditions where the consumer experiences pain (such as lower back

---

5 http://www.nzasa.org/files/NZASA%20Codes%20of%20Safe%20Practice%20for%20Acupuncturists.pdf
pain) and possibly there may be some marginal benefit to needling there. The drawback is that for conditions such as lower back pain cheap, relatively simple interventions like NSAIDS and advice to “keep active” can achieve the same benefit without significant risks. Using TCM diagnosis may also mean a treatable medical condition is not properly diagnosed or treated. Many studies are poor quality which can make it difficult to determine reliability. Ernst and Singh in their book “Trick or Treatment” cite the Cochrane Collaboration and state that from their review there is no significant benefit from acupuncture for: smoking, cocaine dependence, induction of labour, Bell’s palsy, chronic asthma, stroke, breech presentation, depression, carpal tunnel syndrome, irritable bowel, schizophrenia, Rheumatoid Arthritis, insomnia, back pain, lateral elbow pain, shoulder pain, soft tissue shoulder injury, morning sickness, egg collection, glaucoma, vascular dementia, period pain, whiplash. Any perceived benefit appears to be from the placebo effect. Some other conditions have been more optimistically reported but not stated to be convincing such as pelvic and back pain in pregnancy, low back pain, headaches, post-operative and chemotherapy induced nausea and vomiting. Later well-designed trials for conditions such as chronic tension headache, migraine prevention, nausea under chemotherapy and post-op nausea and vomiting using sham acupuncture provide no convincing evidence that real acupuncture is more effective than sham acupuncture (placebo with the same theatrical effect). These findings apply as well to any variations of acupuncture such as acupressure.

2. Chinese Herbal Medicine risks:
   - Possible herb-drug interactions, or herb-herb interactions.
   - TCM practitioners may use many different types of herbs in one product which can mean dosage varies. Increasing numbers of herbs taken in one mix gives a greater chance of adverse effects. Herbs may also be misidentified.
   - Significant safety issues including the possibility of toxicity and liver or kidney damage or allergic reactions. Adverse events may be experienced by the consumer such as an allergic reaction and it could be that the risk of this is not communicated to them or the actions that should be taken if they think they are having an adverse reaction. Some herbs may require preparation of some type (i.e. boiling) prior to use, which can increase the risk of toxicity if the consumer isn’t informed.
   - TCM practitioners may fail to assess contraindications for patients i.e. Glycerrhiza species - liquorice root may exacerbate high blood pressure.
   - Contamination of products which may cause poisoning. Adulteration such as with pharmaceuticals may cause adverse effects or interactions with other medications.
   - TCM may use threatened or rare species of plants and animal products in preparations.
   - Herbal preparations may be used inappropriately when there are probable safer and more effective options. This is particularly where evidence is lacking for safety and efficacy of an herb or preparation.
   - Consumers may fail to inform others treating them or abandon medical treatment which may lead indirect harm from their condition not being treated properly or at all. It can be difficult to determine if any herbal preparation is safe to use and there may be a lack of information as to whether many herbs are safe for use in groups such as children or pregnant women.
   - TCM herbal preparations are used to treat a broad range of conditions. There is a plausible mechanism of action but actual evidence for use in any condition may be

---

variable or even non-existent. Many trials are poor and have significant methodological problems. The Cochrane Library (New Zealand) has reviewed Chinese medicines for idiopathic chronic fatigue and chronic fatigue syndrome concluding that "Although studies examining the use of TCM herbal products for chronic fatigue were located, methodologic limitations resulted in the exclusion of all studies. Of note, many of the studies labelled as RCTs and conducted in China did not utilize rigorous randomization procedures. Improvements in methodology in future studies is required for meaningful synthesis of data." In conjunction with lifestyle modification for impaired Glucose tolerance or impaired fasting blood glucose, the review found that "The positive evidence in favour of Chinese herbal medicines for the treatment of IGT or IFG is constrained by the following factors: lack of trials that tested the same herbal medicine, lack of details on co-interventions, unclear methods of randomisation, poor reporting and other risks of bias." The Cochrane Library has other reviews are in their database giving similar variable conclusions.

3. Tuina:
- Tuina is a form of massage and can probably be regarded as being safe. Spinal manipulation that may be part of doing this type of massage may cause harm.
- Little evidence for effectiveness exists. One study which was a systematic review and meta-analysis of the efficacy of tuina for cervical spondylosis found that "based on the results of this systematic review, a definitive conclusion regarding the effects of tuina on cervical spondylosis remains to be determined" with the clinical relevance being that "The efficacy of tuina is not supported by parallel-group comparison studies."

4. Diet:
- Dietary interventions can be considered safe, however there may be some risk with restrictions of certain foods that could cause harm or inconvenience to the consumer. The advice may conflict with other advice given by health professionals.

5. General:
- Using Chinese diagnosis may mean a medical condition is not properly diagnosed or treated.
- TCM practitioners may make claims that exceed the available evidence and/or give advice contrary to other health practitioners which may dissuade them from appropriate care. It can be common to make an artificial division between "Western" and "Eastern" medicine which does not exist. This can include anti-vaccination advice and/or giving information that otherwise may deter people from medical care. On one site, an "immune system package" is offered along with stating acupuncture is effective for colds/flu. The article on the page states "The flu shot does not work for babies...the flu shot does not work in children with asthma...adults are also not protected by flu vaccine...for elderly living in nursing homes, flu shots were nonsignificant for preventing the flu..."for elderly living in the community, vaccines were not significantly effective."

---

8 http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006690.pub2/abstract;jsessionid=0A137B9FE5F72D15553B7D8719E901E.d0104
10 http://elementalacupuncture.co.nz/resources-articles/movies/
11 http://www.aac.net.nz/794/155901.html
• Traditional Chinese Medicine may be used in inappropriate groups such as the very young who may have different health needs to adult consumers which may cause harm to them, often by delaying access to appropriate treatments. There are websites that promote use in children for conditions such as jaundice, colic, cerebral palsy, eczema and epilepsy. This website has material on it such as "children may avoid disease altogether if introduced to acupuncture at an early age."

• Treatments such as acupuncture may be recommended where there is no evidence of needing treatment, increasing risk without benefit to the consumer.

• There may be failure to refer on to medical care or inform other health professionals appropriately. The practitioner may not recognise their limits or incorrectly think they can treat a condition. An example of this is in the NZASA Code of Safe Practice for Acupuncturists which for unstable epilepsy says "care should be taken with needling. If a seizure is triggered then appropriate resuscitation techniques apply including the use of Rhenzong CV26 or/and Yongquan KI 1." This seems to be inappropriate.

• General contraindications such as avoiding acupuncture and other therapies in consumers with pacemakers, bleeding disorders, high blood pressure, diabetes, unstable epilepsy etc.

• Financial harms are possible as a result of using inappropriate treatments.

4. If so, what are the nature, frequency, severity and potential impact of risks to the public? What is the likelihood of the harm occurring?

There are some studies available that try and measure harms from the use of TCM. It appears that it is likely that there is significant under-reporting of adverse events so it is difficult to assess likely impacts other than to factor this in when taking into account the figures. It is likely that if the use of TCM becomes more widespread, that adverse events would occur more frequently as well.

Ernst (2005) has published safety data stating that "Acupuncture has occasionally been associated with several serious adverse effects, in particular, trauma to internal organs (e.g. pneumothorax or cardiac tamponade) and infections, such as hepatitis C or HIV. Several large prospective studies have shown that such adverse events are extreme rarities, provided acupuncture is carried out by well trained practitioners. These studies also show that mild, transient adverse effects, e.g. needling pain or bleeding at the site of needling, occur in about 7–11% of all cases. The largest study included 190,924 chronic pain patients. The data revealed 2.4 serious adverse events per 10,000 patients. However, the authors suspect this figure to be distorted through under-reporting.

In their series, only 5% of the average death rate in the German population was reported. Assuming therefore that under-reporting of acupuncture-unrelated death (and by implication serious acupuncture-related adverse events) was 95%, the true incidence of serious adverse events after acupuncture could be as high as 48 per 10,000 patients. A recent UK survey suggested that, in 3% of all cases, non-medically qualified acupuncturists interfere with the prescribed medications of their patients, which could therefore constitute an indirect risk of acupuncture. The totality of this evidence nevertheless suggests that acupuncture, as used by well-trained professionals is probably a reasonably safe therapy. Serious adverse effects may be a consequence of poor training and the large number of paramedics exercising the technique."

32 http://www.naturaltherapypages.co.nz/article/Acupuncture_for_Infants_and_Children
33 Ernst E, Acupuncture – a critical analysis Journal of Internal Medicine 2006; 259: 125–137
White, Hayhoe, Hart and Ernst\textsuperscript{14} (2001) attempted to ascertain the incidence related to acupuncture treatment finding that along with some avoidable adverse events occurring that "...a total of 2135 minor events was reported, giving an incidence of 671 per 10 000 (42/10 000 to 1013/10 000) consultations. The most common events were bleeding (310 (160 to 590) per 10 000 consultations) and needling pain (110 (49-247) per 10 000 consultations). Aggravation of symptoms occurred in 96 (43-178) per 10 000 consultations; in 70% of these cases, there was a subsequent improvement in the presenting complaint. The highest rates reported by individual acupuncturists, expressed as a percentage of consultations, were 53% for bleeding, 24% for pain, and 11% for aggravation of symptoms."...."Doctors and physiotherapists who performed acupuncture reported no serious adverse events and 671 minor adverse events per 10 000 acupuncture consultations. These rates are classified as minimal; however, 14 per 10 000 of these minor events were reported as significant. These event rates are per consultation, and they do not give the risk per individual patient."

Bensoussan, Myers and Carlton\textsuperscript{15} (2000) Australian study stated it is extremely difficult to estimate the rate of adverse events for Chinese Herbal Medicines as the total exposure is unknown and it is likely that there is significant under-reporting. The study stated "the most common adverse events reported were severe gastrointestinal symptoms (n=124), fainting and dizziness (n=119), and significant skin reactions (n=110). Serious adverse events reported included central nervous system effects (n=37), hepatotoxicity (n=29), renal toxicity (n=28), and death (n=19). The number of deaths reported is consistent with literature reviews, which cite deaths associated with specific Chinese herbal preparations, notably those containing aconite...." Practitioners were also identified as having prescribed a number of scheduled/restricted substances.

When discussing acupuncture the paper stated that "...Practitioners reported that more than 3000 adverse events occurred during their practice lifetimes. The most common adverse events reported were fainting during treatment (n=1169), increased pain (n=1069), and nausea/vomiting (n=534). Serious adverse events reported included pneumothorax (n = 64) and convulsions (n=80)." In addition the authors noted "Instances of local and systemic infections have been reported in the literature such as endocarditis, septicemia, hepatitis B, human immunodeficiency virus infection, osteomyelitis, myositis, peritonitis, and pleural empyema, allegedly contracted as a result of acupuncture. Causality had not been confirmed in many of these cases. Numerous reports of trauma-related injuries from acupuncture have been published in the last 15 years, including pneumothorax, spinal cord injuries, auricular chondritis, fatal and nonfatal cardiac tamponade, pseudoaneurysm, deep-vein thrombosis, nerve damage, burns (from moxa), and severe bruising (from cupping). Published reports have also referred to psychiatric changes (such as depression), insomnia, convulsions, hypotension, menstrual disturbance, increased pain, and allergies to certain needle compositions."

"...A variety of treatment techniques, many of which fall under the umbrella of acupuncture, were administered to patients. Some of the more traditional techniques such as bleeding, scoring moxibustion, and scraping were used only by nonmedical practitioners, and carried their own distinct risks. It is unknown how many of the adverse events reported by practitioners could be accounted for by any one technique....Adverse events due to acupuncture accounted for 79% of all adverse events reported. This reflects the substantially larger cohort of practitioners who principally use acupuncture..."\textsuperscript{14,15}

\textsuperscript{14} White A, Hayhoe S, Hart A and Ernst E, Adverse events following acupuncture: prospective survey of 32000 consultations with doctors and physiotherapists BMJ 323 : 485 doi: 10.1136/bmj.323.7311.485 (Published 1 September 2001)
\textsuperscript{15} Bensoussan A, Myers SP, Carlton A Risks Associated With the Practice of Traditional Chinese Medicine: An Australian Study Arch Fam Med. 2000;9:1071-1078.
The paper had the conclusion that "We determined that each practitioner had encountered an average of 1.38 adverse events during each year of equivalent full-time TCM practice. Hence, approximately 1 adverse event occurred every 8 to 9 months of full-time practice, or for every 633 consultations."

5. Other than on the basis of risk of harm, is it in the public interest that the profession of TCM be regulated?

The New Zealand Register of Acupuncturists Incorporated and the NZASA offer voluntary membership which allows members to become ACC acupuncture providers. Regulation also occurs through the practice of TCM being subject to the Code of Health and Disability Services Consumers' Rights. The Ministry of Health provides "Guidelines for Skin Piercing" and local Councils have regulations and licensing which cover skin piercing. TCM is also be impacted by various provisions in other acts such as the Medicines Act as well as general consumer legislation such as the Fair Trading Act and Consumer Guarantees Act.

This current regulation regime appears to provide protection for the public but could be strengthened. It would have been preferable to see more TCM practitioners comply with general requirements as regards advertising and claims whilst in the process of applying for recognition under the HPCA Act. As stated earlier, there are concerns about granting official legitimacy ahead of the evidence being present for the practice and this can risk that regulation may fail to achieve its aims. It would be preferable to review the current system and/or look at other means such as accreditation or third party oversight to strengthen the current practice environment and ensure that safety guidelines and evidence based practice are complied with. Practitioners of TCM have an incentive to join with the NZASA or the New Zealand Register of Acupuncturists Incorporated to become ACC providers (with acupuncture being the majority of treatment provided). With rigorous and open standards of practice that are enforced by the organisations concerned with additional external oversight from a third party this could have the desired effect in both maintaining adequate standards and protecting the public harm.

6. Are practising TCM practitioners generally agreed on the standards that TCM practitioners are expected to meet?

Within TCM there is an rather wide spread in the workforce consisting of some that hold voluntary membership with organisations involved in TCM and still others that work independently so it is difficult to work out whether any agreement on standards exist with practising TCM practitioners. It may be that practitioners may agree, however, it also appears that at least in some cases that standards under the current regulatory system may not be fully complied with which may indicate that practitioners can hold different views and/or may not feel that standards are applicable to them such as where claims are made about the conditions treated by TCM which outstrip the available evidence. The proposal document states that although the applicants have developed policies this will not necessarily be the same as those put in place in the event the practice of TCM is regulated under the HPCA Act. Some practitioners may face changes to how they currently practice, and it is possible that some may resist more regulation and having to comply with a new set of rules.

7. Are practising TCM practitioners generally agreed on the competencies for scopes of practice for TCM?

It may be that practitioners may feel they have agreement or that they can achieve it however it also appears that at least in some cases that requirements under the current regulatory system may not be fully complied with. This may indicate that TCM
practitioners can hold differing views of any competencies and standards of practice that apply at the present time and/or may not feel that they are applicable to them. The proposal says that although the applicants have developed policies this will not necessarily be the same as those put in place in the event the practice of TCM is regulated. In the event of regulation some practitioners may not end up agreeing with what the competencies should be or any restrictions or limits that may be set on competencies.

8. What qualifications are generally held by members of the profession, and what is the degree of uniformity in qualifications across members?

Given that there is inconsistency in possible qualifications that may apply to individual practitioners it could be that there is a distinct lack of uniformity in what qualifications are generally held by members of the profession. The educational spread may be quite broad, with some having qualified with Diplomas, others Degrees as well as another subset of TCM practitioners having trained overseas to different standards. Yet others may have only done short courses, although these practitioners may be more likely to have health related qualifications prior to taking these courses. In the proposal it states that although the applicants have developed policies this will not necessarily be the same as those put in place in the event the practice of TCM is regulated under the HPCA Act and this makes the task even more difficult of trying to homogenise what is a rather disparate workforce into some kind of uniformity as regards qualifications.

9. Does your organisation accord any standing or status to the profession of TCM, or to those who practise as TCM practitioners?

No. It is more important to assess the benefits and risks of any particular health care practice by assessing whether the treatment(s) provided offer therapeutic benefits greater than placebo, safety of the treatments and how it compares in outcomes and cost effectiveness with comparable treatments prior to using a treatment rather than according status based on the claims made by any individual practitioner. Most other regulated health professions provide similar, evidence based services and the public generally understands the educational level and standards they base their practice on and they would be recognised on that basis.
Submission 28

New Zealand Skeptics Society Inc.

Submission to the Ministry of Health on the matter of the proposal that Traditional Chinese Medicine (TCM) become a regulated profession under the Health Practitioners Competency Assurance Act (HPCAA) 2003.

1. Is TCM a health service, as defined by the HPC Act?

In the proposal, the applicants have defined TCM “as an occupation with a clear professional identity and an established body of knowledge with standards of practice, and as a system of primary health care, encompassing a range of therapeutic interventions, including but not limited to, acupuncture and moxibustion, Chinese herbal medicine, remedial massage, diet and exercise, as well as contemporary practice developments...”.

Statistics New Zealand defines TCM as “the treatment of imbalances of energy flows through the body by assessing the whole person, and using techniques and methods such as acupuncture, Chinese herbal medicine, massage (tuina), diet, exercise and breathing therapy (quigong).”

We consider that Statistics New Zealand provides a better descriptive definition of TCM, as the applicants’ definition focuses on the interventions that are part of TCM rather than defining TCM as a whole. The former definition also tends to be overly broad, with the term “including but not limited to” allowing the definition to be arbitrarily added to and any products and services appended. The alternative health industry is well known for taking a scatter-gun approach to include a vast range of modalities based, it seems, on marketing and consumer wishes, rather than on evidence of efficacy.

As well, some interventions are defined as unique to TCM but are in fact used by many other health practices, such as diet, exercise and massage in providing health care services. In the case of dietary approaches, there already is a health profession adequately covered by the HPCAA of Dieticians, and based on evidence and independent verification.

In many respects either of these definitions appears to meet Primary Criteria, as the practice of TCM does appear to involve the process of assessing and treating the physical or mental health of individuals or groups of individuals. Whether the assessment or treatment is acceptable health practice is another matter, and we maintain that it should not be accepted as such based on current evidence.

Measures to protect the public such as regulation and other applicable consumer protection legislation, particularly in the context of health care, need to be robust and have the trust of the public. It is particularly important to support the process of regulation of health care practice and delivery where appropriate to ensure that people seeking care can be confident that the person they seek care from is qualified and competent to practice safely and that, should they fail to meet identified standards, there is a system in place to deal with this.
There is, however, significant risk in granting the legitimacy of official regulation ahead of adequate evidence of efficacy and a plausible method of action (Secondary criteria: Criterion 2). Such presumption can lead to regulation being ineffective in protecting the public.

An example is where the ability for informed consent is diminished as the person seeking care must make an assessment based on the beliefs of the provider rather than proper assessment of their clinical condition and choice of evidence-based therapies. It is also possible that such a person can receive treatment that is not only ineffective for their condition, but which also has the potential to cause harm.

This has been demonstrated in many of the core practices of TCM such as acupuncture, energy medicines, cupping/moxibustion and the like (example case studies from the media are monitored by WhatsTheHarm.net; others are available via professional medical groups and monitoring organisations).

In such cases, regulation may fail in its aims by creating the situation where it is difficult for a health care consumer to determine the best health care provider to treat them and provide apparent support for situations where care can be inappropriate or even harmful but where the provider is not deemed to be acting outside the regulations that cover their practice. This also tends to go against a growing number of legislative developments worldwide where jurisdictions have determined that it is illegal to make claims about treatments where no evidence exists to support that claim.

TCM uses two major concepts – that of Yin-Yang and Five Elements. Diagnosis involves looking, listening, smelling, asking and touching. It includes acupuncture, which is based on the idea that health relates to the flow of the claimed Chi/Qi (life force) through pathways in the body. The goal of needling is to rebalance and unblock Chi, under the belief that such imbalance and blockages cause illness. TCM also involves dietary management by categorising foods into set characteristics of "hot" or "cold" (NB: not actually based on temperature, but on esoteric qualities) and by flavour. Imbalances in such characteristics are believed to be a root cause of illness. As an example, the stomach and spleen are conceptualised as a cauldron, with internal fire transforming the food into energy and blood. Herbal medicine in TCM again involves categorising by temperature and flavour that is considered to influence Yin-Yang energy patterns.

All of these concepts developed long before modern medicine, biology, chemistry and physics, which are evidence-based, cross-cultural bodies of knowledge that exist independently of a practitioner's or client's beliefs, supported by independent verification and monitored practice. With TCM, there is no evidence for the existence of concepts such as Yin-Yang or its role in health care.

The highly fluid nature of such beliefs means that there is little correlation between practitioners when diagnosing and treating patients and no correlation with relevant physiological processes in the body. Where the diagnosis may be cited as something like "kidney Qi deficiency", this has no relationship to any conventional medical diagnosis. Thus while TCM practitioners may appear to be undertaking assessments, diagnosis and treatment using similar-sounding terms and practices to evidence-based medicine, there is no accepted medical body of knowledge or health practice at work.
TCM does not fulfil the criteria of being a health service, but is more in the nature of an applied cultural practice or belief system. Much of its current system, in fact, owes a great deal to the political and social context of China in the 1950s and 60s rather than to the claimed long-established traditional practices. The same can be said for a great deal of its apparent pharmacopoeia, where materials have been added, often on an ad hoc basis, over the past 50 years. There are many reports of the problems that this lack of consistency and independent oversight has caused, ranging from animal welfare issues (eg the use of bear bile or tiger parts) to negative health outcomes from unmonitored and unacceptable production process (eg heavy metal poisoning or inclusion of drugs such as Viagra).

As such, to provide TCM with apparent legitimacy of health regulation would be misleading to those seeking such services, doing a disservice to the general public, particularly if this were used to justify the expenditure of public monies for the provision thereof. The only way in which this could be accepted would be if there were to be established an independent assessment and monitoring body prepared to:

- Examine all current and proposed practices for both safety and efficacy.
- Check claims relating to practices, services and products.
- Provide in-depth, freely accessible advice to allow informed consent on the part of the general public with regard to the relative claims, successes and appropriate applicability of such practices, services and products.

2. Are practitioners of TCM generally agreed on the qualifications required to deliver the health services they provide?

It is typical of such cultural practices that there is a wide, divergent range of beliefs and applications throughout those operating within such a system. This has proved a major problem for much in the way of complementary and alternative health practices where very little agreement has been possible in defining such practices, the nature, role or extent of qualifications required; the responsibilities of those involved etc (New Zealand’s MACCAAH group serves as one example of the industry’s lack of capability in this regard).

In the proposal it is noted that currently there are two institutions offering bachelor degrees and diploma and certificate courses in TCM which are the New Zealand School of Acupuncture and Traditional Chinese Medicine and the New Zealand College of Chinese Medicine. These courses are approved by NZQA. The proposal notes not all groups agree on hours required to achieve both theoretical and clinical competence, and that courses need to be a combination of both to define minimum standards for practice and to determine a practitioners fitness to practice.

On checking information provided by these institutions, it is extremely difficult to determine whether there is any agreement between the courses and what teaching they deliver. In addition, while there is some agreement, there are significant differences in schools of thought within TCM with, for example, some acupuncturists working on the basis of 14 meridians, while many support the idea of 12 and with additional concepts such as Yin-Yang some schools may divide this into 2 subcategories while others may divide into 4. This does not provide any confidence that there is any recognised basis for acceptable health care practice or meaningful education related to these practices. Rather than suggesting that these practices are
acceptable health care, such disparity indicates that they are based on highly variable cultural beliefs with significant variation from practitioner to practitioner.

The currently provided courses may have some science-based material within the qualification they offer, but it is well known that NZQA determinations are more about processes and quality of delivery than actual content of courses. Mere acceptance in to the NZQA framework says little to nothing about the validity, scholarship, research, safety and the like of approved courses.

This does not engender any confidence in the ability of the industry to define, monitor or regulate its practices. This is exacerbated by those practices being fully embedded in a culturally determined context, rather than in any evidence-based, cross-cultural body of knowledge.

An example may help indicate the problems that this approach causes for any attempt to provide industry-wide regulation for such a non-defined culturally based approach to health.

The New Zealand School of Acupuncture provides the following information on TCM core teaching areas:

**Core Teaching Areas in TCM:** Traditional Chinese Medicine is a vast area of study with many and varied concepts concerning sickness and health. Of that body of information there are certain core concepts that underpin this system of medicine. Listed below are those concepts that can be taken as the 'core teachings' of TCM.

- Yin-Yang / The Five Phases
- Zang-fu organ theory
- Qi-Blood-Body Fluid Inter-relationships
- Channel Theory
- Acupoint Classification/Nomenclature
- Therapeutic Properties the Points
- Etiology and Pathogenesis
- The Four Diagnostic Methods
- Eight Principles Syndromes
- Qi-Blood-fluids Syndromes
- Differential Diagnosis
- Principles of Treatment
- Treatment Methods
- Basic Prescription Principles
- Selection of Points
- Selection of Herbs and Formulas

While it is not possible here to comment on detailed content, it is clear students are being taught pre-scientific concepts that bear no relationship to the current understanding of the human body, anatomy, physiology, the germ theory of disease etc, etc.

---

1 http://www.acupuncture.ac.nz/courses/bachelor-of-acupuncture
It may be that they would be the first to admit that—and perhaps even claim it as a strong point of differentiation for their practices—but it does mean that there are definite vulnerabilities for their target client market who may not be aware of the lack of evidence for the practices, the cultural context for TCM and the variability of training in potential practitioners.

In another example, which raises concerns regarding the nature of research and teaching within the TCM industry, a University of Salford examination paper (2009) included questions such as:

Q1: Which of the following explain(s) the physiological relationships between qi and blood/xue:

a. Qi is the source of all material in the body and blood carries the energy.
b. Blood is the source of all material in the body including Qi.
c. Qi drives blood moving and blood carries Qi.
d. Qi flows in the channels and blood is stored in the organs.
e. Qi produce blood and blood is the mother of Qi.

Q24: In Chinese Medicine, anger is associated with liver and the suppression of of anger causes Liver Qi stagnation. Explain your understanding of the statement in 100 words.

As with other alternative health approaches, proponents of TCM do not question the underlying assumptions of their industry, treating their authorities as having perfect knowledge that does not need testing. In many cases, any external calls for such testing is met with resistance, if not outright hostility. Providing a faux legitimisation of such a authoritarian approach will make the would-be consumer much more vulnerable to negative health outcomes, and with very little in the way of any avenue for protection or redress.

3. Is there a risk of harm to the public from the practice of TCM?

Yes.

There is the risk of physical harm from:

- The use of unnecessary and inappropriate invasive practices (such as acupuncture).
- The distribution of unmonitored substances which may contain harmful substances that are not disclosed to the consumer (or even the practitioner if they are supplied by a third party, as is common practice).
- The tendency for this type of industry to discourage (whether actively or passively) their clientele from seeking conventional medical treatment.

There is the risk of financial harm from:

- the long-term reliance encouraged by this industry on its products and services; dependency relationships are a common factor in alternative health practices, which raise both financial and ethical issues.

2 http://www.dcsociety.net/SalfordChineseMedicine.pdf
the diversion of public monies (whether ACC payments, insurance coverage or outright funding support) into a health industry based on cultural beliefs.

There are many examples of specific examples of actual and potential harm related to core TCM practices. The alternative health industry is well-known for poor record-keeping and a lack of patient redress, but many cases and concerns can be found in publications such as The Journal of Alternative and Complementary Medicine; websites such as Quackwatch.com; health analytics such as the Cochrane Collaboration and so on.

For a core practices such as acupuncture, there are risks of:

- Infection due to not using sterile techniques, including not using single use needles and incorrect disposal of used sharps.

- Tissue damage from bruising and bleeding, forgotten or broken needles and perforation of vital organs such as the lung or heart. The proposal states that “the evidence of risk of harm is largely based on practitioners that are inadequately trained or who have inadequate clinical experience”. While this may be the case for such areas as prevention of infection, this tends to ignore risks inherent in the insertion of needles. The “Code of Safe Practice for Acupuncturists” from the New Zealand Acupuncture Standards Authority (NZASA) states that there are vulnerable points that require skill and care including Zhongfu LU1, Jiangjing GB21 and Dazhu BL11 which are points over lung tissue unprotected by bone or cartilage. This indicates that acupuncturists may insert needles in areas with an increased risk to the patient if it is deemed necessary for treatment. In addition, in case decision 07HDC12714 of the Health and Disability Commissioner, pneumothorax was experienced as a complication of using acupuncture to treat asthma. The acupuncturist was not deemed to have not breached the standard of care with the opinion of another acupuncturist being “The following points were selected by [Mr B] in the treatment: BL12, BL13, BL23, BL43, DU4, EX-B1, K13, ST36 and SP6. These points are used to treat Asthma or reinforce body energy...[Mr B] acupuncture treatments comply with these standards.” despite the complication occurring.

TCM is claimed to treat many disorders, from acne to vertigo, but with little to no actual proof beyond placebo and marketing testimonials for many such claims. It is a common attribute of the alternative health industry to maximise its clientele and profits by keeping its alleged coverage as broad as possible.

The fact that acupuncture is accepted by ACC is already used to legitimise use of the practice far beyond any clinically accepted areas, with a consequent risk to patient care and waste of public funds.

As an example, acupuncture has been shown to have minimal use in almost all its applications, with only some success in a very limited context (ie it may provide some pain relief). Its effects have been replicated using sham acupuncture and other non-invasive techniques, which makes its use ethically

---

questionable, particularly given the cases of infection and other negative outcomes associated with its use.

Acupuncture is widely used for conditions for which there is no evidence that it has any efficacy. Acupuncture additionally may not compare well in outcomes or cost-effectiveness for the patient in comparison with other comparable treatments. Even if there appears to be some efficacy, it can be difficult to assess benefit/risk for the patient. Non-specific effects may apply for pain-related conditions and there may be some benefit to needling in those cases. However, for conditions such as lower back pain simple and cheap interventions like regular pain relief and advice to keep active can achieve the same benefit for the person seeking care without the risks of needling being incurred. Using Chinese diagnosis may also mean a medical condition is not properly diagnosed or treated.

That many studies are of poor quality can make it difficult to determine whether any evidence is reliable. According to Edzard Ernst and Simon Singh⁵, (citing the Cochrane Collaboration) there is no significant benefit from acupuncture for the following conditions: smoking, cocaine dependence, induction of labour, Bell's palsy, chronic asthma, stroke, breech presentation, depression, carpal tunnel syndrome, irritable bowel, schizophrenia, Rheumatoid Arthritis, insomnia, back pain, lateral elbow pain, shoulder pain, soft tissue shoulder injury, morning sickness, egg collection, glaucoma, vascular dementia, period pain, whiplash. Any perceived benefit appears to be from the placebo effect. Some other conditions have been more optimistically reported, but not stated to be convincing, such as pelvic and back pain in pregnancy, low back pain, headaches, post-operative and chemotherapy induced nausea and vomiting. Later well-designed trials for conditions such as chronic tension headache, migraine prevention, nausea under chemotherapy and post-operative nausea and vomiting using sham acupuncture provide no convincing evidence that real acupuncture is much more effective than sham acupuncture. These finding apply also to any variations of acupuncture, such as laser acupuncture or acupressure.

2. Chinese Herbal Medicine risks:

- Interactions between herb and drugs, or herb-herb interactions.

- Failure to assess contraindications of herbs for patients i.e. liquorice root (Glycyrrhiza species) may cause problems for those with high blood pressure, exacerabating the condition.

- Safety issues such as the possibility of toxicity and liver or kidney damage or allergic reactions. Some herbs may require specific preparation such as boiling before use, which may fail to be communicated and therefore increase the risk of toxicity. It may also fail to be communicated to the patient that they may have an adverse event, and what to do if they have any possible reaction to a herbal medicine they are taking.

- Contamination or adulteration of products which may cause poisoning or if adulterated with pharmaceuticals, adverse effects or interactions with other medications that may be being taken.

• Labelling or identification issues that mean an herb may be misidentified.

• The use of several types of herbs in a mix as made by TCM practitioners can mean dosage varies and increasing numbers of herbs taken in the mixture gives a greater chance of adverse effects.

• TCM may use rare or threatened species of plants or animal products in preparations.

• Inappropriate use such as the use of herbal preparations where there is a safer and more effective pharmaceutical option can be risky where evidence is lacking for the safety and efficacy of an herb or herbal preparation. Using Chinese diagnosis may mean a medical condition is not properly diagnosed or treated. Patients may also fail to inform their doctor or abandon current treatment which may lead indirect harm from their condition not being treated properly or at all. It can be very difficult to determine if any particular preparation is safe to use and there may be a lack of information as to whether many herbs are safe for use while pregnant or breastfeeding, in children or with current medication being taken.

• TCM herbal preparations are used to treat many disorders and while there is a plausible mechanism of action due to active ingredients, the evidence for efficacy may be variable and many trials are poor and have methodological problems. This means that these may be used for conditions for which there is no evidence it may be effective which can be considered an indirect harm as it may delay uptake of effective treatment, interfere with other treatments being used by the patient or make it difficult to assess benefit/risk in using the treatment. This may also not compare well in outcomes or cost-effectiveness for the patient in comparison with other comparable treatments due to the lack of evidence of efficacy and safety issues. The Cochrane Library in New Zealand has assessed Chinese herbal medicines in conjunction with lifestyle modification for impaired Glucose tolerance or impaired fasting blood glucose6, finding that “The positive evidence in favour of Chinese herbal medicines for the treatment of IGT or IFG is constrained by the following factors: lack of trials that tested the same herbal medicine, lack of details on co-interventions, unclear methods of randomisation, poor reporting and other risks of bias,” and for idiopathic chronic fatigue and chronic fatigue syndrome7 finding that “Although studies examining the use of TCM herbal products for chronic fatigue were located, methodologic limitations resulted in the exclusion of all studies. Of note, many of the studies labelled as RCTs and conducted in China did not utilize rigorous randomization procedures. Improvements in methodology in future studies is required for meaningful synthesis of data.” Other Cochrane reviews are in their database and it would be relevant to consider that if regulating, that this is limited to preparations where evidence of efficacy and safety for a condition are present.

6 http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006990.pub2/abstract;jsessionid=0A13759FE5FD72D1555B7D8719F901E.d01104
3. **Tui na:**

- Tui na is a form of massage and can be generally regarded as being safe, however spinal manipulation may cause harm particularly when a practitioner is inadequately trained.

- There appears to be little evidence for effectiveness in treating any condition, and one study which was a systematic review and meta-analysis of the efficacy of tui na for cervical spondylosis[^8] found that "based on the results of this systematic review, a definitive conclusion regarding the effects of tui na on cervical spondylosis remains to be determined" with the clinical relevance being that "The efficacy of tui na is not supported by parallel-group comparison studies."

4. **Diet:**

- Dietary interventions can be considered generally low risk, however there may be some risk that a proposed diet and restrictions of certain foods could cause harm or inconvenience to the patient. The advice given as it does not follow current human nutritional rationales may conflict with other advice given by health professionals, such as diet recommendations for diabetics.

5. **General:**

- Traditional Chinese Medicine may be used inappropriately, as in treating very young children, pregnant or lactating women or the elderly who may have different health needs to the rest of the population and/or for conditions it is not effective for. It is not difficult to find websites[^9] that promote its use for children for conditions such as colic, cerebral palsy, new born jaundice, myopia, eczema and epilepsy which have material on them such as "children may avoid disease altogether if introduced to acupuncture at an early age." This also may indicate that treatments such as acupuncture may be recommended where there is no evidence of needing treatment, increasing risk without benefit to the person. It is important for these groups to be properly assessed, as they may not display symptoms of illness the same or have specific health care needs and it is important that they have appropriate assessment and treatment with minimal delay.

- Failure to refer on to medical or other care or inform other health professionals appropriately may occur as the practitioner may not recognise the limits of their expertise or may incorrectly think they can treat a diagnosed condition.

- TCM practitioners may make claims that outstrip the evidence and give advice contrary to other health practitioners such as displaying or giving anti-vaccination[^10] advice or giving information that otherwise may deter people from medical care. Many may make an artificial division between so-called

[^10]: http://www.naturaltherapypages.co.nz/article/Acupuncture_for_Infants_and_Children
[^10]: http://elementalacupuncture.co.nz/resources-articles/movies/
"Western" and "Eastern" medicine which does not in fact exist. In one case\textsuperscript{11}, an immune system package is offered along with information stating acupuncture is effective for colds and flu and an article stating "The flu shot does not work for babies"..."the flu shot does not work in children with asthma"..."adults are also not protected by flu vaccine"..."for elderly living in nursing homes, flu shots were non-significant for preventing the flu"..."for elderly living in the community, vaccines were not significantly effective..."

This may discourage people seeking appropriate interventions, particularly in groups vaccines are recommended for.

... General contraindications such as need for caution or not using acupuncture and other therapies with those with bleeding disorders, pacemakers (use of electroacupuncture), high blood pressure, diabetes and unstable epilepsy. (Note: with unstable epilepsy the NZASA Code of Safe Practice for Acupuncturists states "care should be taken with needleling. If a seizure is triggered then appropriate resuscitation techniques apply including the use of Rhenzong CV26 or/and Yongquan KI 1." It could be suggested that basic first aid, including keeping the person safe, would be the most appropriate intervention rather than needleling a seizing person.)

4. If so, what are the nature, frequency, severity and potential impact of risks to the public? What is the likelihood of the harm occurring?

According to the 2000 paper by Bensoussan, Myers and Carlton\textsuperscript{12} "Risks Associated With the Practice of Traditional Chinese Medicine: An Australian Study" it is extremely difficult to estimate the rate of adverse events for Chinese Herbal Medicines (CHM) as the total exposure to any particular substance is unknown and there is likely to be significant under-reporting.

The study stated "the most common adverse events reported were severe gastrointestinal symptoms (n=124), fainting and dizziness (n=119), and significant skin reactions (n=110). Serious adverse events reported included central nervous system effects (n=37), hepatotoxicity (n=29), renal toxicity (n=28), and death (n=19). The number of deaths reported is consistent with literature reviews, which cite deaths associated with specific Chinese herbal preparations, notably those containing aconite..."

For acupuncture the paper stated "Medical practitioners used predominantly acupuncture, while nonmedical practitioners frequently combined acupuncture and CHM...Mean length of full-time TCM practice was 7.7 years. Practitioners reported that more than 3000 adverse events occurred during their practice lifetimes. The most common adverse events reported were fainting during treatment (n=1169), increased pain (n=1069), and nausea/vomiting (n=534). Serious adverse events reported included pneumothorax (n = 64) and convulsions (n=80)." In addition the authors noted "Instances of local and systemic infections have been reported in the literature such as endocarditis, sepsis, hepatitis B, human immunodeficiency virus infection, osteomyelitis, myositis, peritonitis, and pleural empyema, allegedly contracted as a result of acupuncture. Causality had not been confirmed in many of these cases. Numerous reports of trauma-related injuries from acupuncture have

\textsuperscript{11} http://www.aac.net.nz/794/158901.html
\textsuperscript{12} Bensoussan A, Myers SP, Carlton A Risks Associated With the Practice of Traditional Chinese Medicine: An Australian Study Arch Fam Med. 2000;9:1071-1078
been published in the last 15 years, including pneumothorax, spinal cord injuries, auricular chondritis, fatal and nonfatal cardiac tamponade, pseudoaneurysm, deep-vein thrombosis, nerve damage, burns (from moxa), and severe bruising (from cupping). Published reports have also referred to psychiatric changes (such as depression), insomnia, convulsions, hypotension, menstrual disturbance, increased pain, and allergies to certain needle compositions."

"The majority of acupuncture practitioners stated that they always used single-use disposable needles (93%) and adhered to government skin penetration guidelines (63%). Of the small number (n=69) who did not always use disposable needles, autoclaving was the preferred method of sterilization (68%). A variety of treatment techniques, many of which fell under the umbrella of acupuncture, were administered to patients. Some of the more traditional techniques such as bleeding, scarring moxibustion, and scraping were used only by nonmedical practitioners, and carried their own distinct risks. It is unknown how many of the adverse events reported by practitioners could be accounted for by any one technique. Adverse events due to acupuncture accounted for 79% of all adverse events reported. This reflects the substantially larger cohort of practitioners who principally use acupuncture..."

The paper stated "We determined that each practitioner had encountered an average of 1.38 adverse events during each year of equivalent full-time TCM practice. Hence, approximately 1 adverse event occurred every 8 to 9 months of full-time practice, or for every 633 consultations." Practitioners were also identified as having prescribed a number of scheduled or restricted substances.

Another paper by White, Hayhoe, Hart and Ernst attempted to ascertain the incidence related to acupuncture treatment finding that "a total of 2135 minor events was reported, giving an incidence of 671 per 10 000 (42/10 000 to 1013/10 000) consultations. The most common events were bleeding (310 (160 to 590) per 10 000 consultations) and needling pain (110 (49-247) per 10 000 consultations). Aggravation of symptoms occurred in 96 (43-178) per 10 000 consultations; in 70% of these cases, there was a subsequent improvement in the presenting complaint. The highest rates reported by individual acupuncturists, expressed as a percentage of consultations, were 53% for bleeding, 24% for pain, and 11% for aggravation of symptoms."..."Doctors and physiotherapists who performed acupuncture reported no serious adverse events and 671 minor adverse events per 10 000 acupuncture consultations. These rates are classified as minimal; however, 14 per 10 000 of these minor events were reported as significant. These event rates are per consultation, and they do not give the risk per individual patient. The researchers noted that some avoidable adverse events occurred.

Ernst has also published safety data in an 2005 paper "Acupuncture a critical analysis" stating that "Acupuncture has occasionally been associated with several serious adverse effects, in particular, trauma to internal organs (e.g. pneumothorax or cardiac tamponade) and infections, such as hepatitis C or HIV. Several large prospective studies have shown that such adverse events are extreme rarities, provided acupuncture is carried out by well trained practitioners. These studies also show that mild, transient adverse effects, e.g. needling pain or bleeding at the site of needling, occur in about 7-11% of all cases. The largest study included 190,924 chronic pain patients. The data revealed 2.4 serious adverse events per 10 000

---

13 White A, Hayhoe S, Hart A and Ernst E, Adverse events following acupuncture: prospective survey of 32000 consultations with doctors and physiotherapists BMJ 323 : 485 doi: 10.1136/bmj.323.7311.485 (Published 1 September 2001)
14 Ernst E, Acupuncture – a critical analysis Journal of Internal Medicine 2005; 259; 125-137
patients. However, the authors suspect this figure to be distorted through under-reporting. In their series, only 5% of the average death rate in the German population was reported. Assuming therefore that under-reporting of acupuncture-unrelated death (and by implication serious acupuncture-related adverse events) was 95%, the true incidence of serious adverse events after acupuncture could be as high as 48 per 10 000 patients. A recent UK survey suggested that, in 3% of all cases, non-medically qualified acupuncturists interfere with the prescribed medications of their patients, which could therefore constitute an indirect risk of acupuncture. The totality of this evidence nevertheless suggests that acupuncture, as used by well-trained professionals is probably a reasonably safe therapy. Serious adverse effects may be a consequence of poor training and the large number of paramedics exercising the technique."

We are concerned that any move to legitimate TCM as an accepted health practice alongside evidence-based medicine will see a rise in negative patient outcome through encouraging public uptake of inappropriate practices and the use of unmonitored substances.

5. Other than on the basis of risk of harm, is it in the public interest that the profession of TCM be regulated?

The only public interest that it would appear to serve is that of the industry itself. We already have a number of medically dubious practices covered by our regulations, and this legitimisation has been used as a marketing tool by them to justify public funding, expand their clientele base and gain credibility without requiring to provide evidence as to the safety and efficacy of their practices. The public of New Zealand will not be better served by adding to this.

Currently there are a few organisations offering voluntary membership for members of this industry, including the New Zealand Register of Acupuncture Incorporated and the New Zealand Acupuncture Standards Authority Incorporated. Membership in either organisation allows its members to become ACC acupuncture providers. Currently neither has the authority to register an acupuncture practitioner as a health care provider under the HPCA Act.

Regulation also occurs through the practice of TCM being subject to the Code of Health and Disability Services Consumers’ Rights. The Code has ten rights covering being treated with respect and dignity; being given information in a way that is clear; being given quality care and having the right to make a complaint if there is the belief that these rights have been breached in any way. Members of the public have rights to ask any health practitioner what qualifications they have. Members of the public also have the right to contact professional associations to ask what is required of their members, in terms of qualifications, professional development and code of practice. Members of the public can also contact a professional association to ask if a particular practitioner is a member of that association.

The Ministry of Health provides Guidelines for Skin Piercing and local Councils have regulations and licensing processes covering areas such as skin piercing and tattooing which includes acupuncture practice. Local authorities are required to appoint Environmental Health Officers under Section 28 of the Health Act 1956 and under Section 128 have rights of inspection and to execute works under the Act in order to promote and protect the health of the public by ensuring minimum standards of hygiene and health are practised. TCM may also be impacted by provisions in the
Medicines Act and Medsafe guidelines as well as general consumer legislation such as the Fair Trading Act and Consumer Guarantees Act and bodies such as the Advertising Standards Authority.

This current self-regulation regime with external regulations broadly applicable to practicing TCM appear to cover most health and safety issues, but should be strengthened. It would be preferable to see more TCM practitioners comply with general requirements as regards advertising and claims whilst in the process of applying for recognition under the HPACAA.

As stated earlier, there are concerns about granting official legitimacy ahead of there being adequate evidence for TCM. If such is granted, scopes of practice would need to be strictly limited to areas where sufficient evidence is supportive of the treatment being effective and for risks to be managed. Otherwise, regulation may fall in its aims by creating the situation where it is difficult for a health care consumer to determine the best provider and, additionally, the situation where care can be inappropriate or even harmful for the condition, but the provider cannot be deemed to be acting outside the regulations that cover their practice.

Given this, it would be preferable to improve the current self-regulatory regime or look at other means such as accreditation to strengthen the current regulatory environment and ensure compliance with safety guidelines and evidence based practice. Currently, there is encouragement for practitioners of TCM to gain membership with the NZASA or the New Zealand Register of Acupuncture Incorporated to become ACC Acupuncture providers, the majority of treatment provided by TCM practitioners. If the organisations were required to develop and maintain rigorous and open standards of practice under third-party independent scrutiny, this could have the desired effect in maintaining standards within the practice of TCM and protecting the public from harm.

6. Are practising TCM practitioners generally agreed on the standards that TCM practitioners are expected to meet?

With a disparate workforce consisting of some who are voluntary members of an organisation and others who work independently, it is difficult to ascertain whether there is any agreement between practitioners outside of the general standards set by the current self and external regulatory environment.

It appears that, in some cases, the codes and standards as set out by various bodies may not be fully complied with in such areas as claims in advertising of their services. This suggests that TCM practitioners themselves may hold differing views of these codes and standards of practice or not feel that they are fully applicable to their practice as it is currently. The proposal document states that although the applicants have developed policies on qualifications and scopes of practices this will not necessarily be the same as those put in place in the event the practice of TCM is regulated under the HPACAA and that this will happen may be an issue for some practitioners that may face a number of changes to how they currently practice.
23 August 2011

Mary-Louise Hannah
Workforce Intelligence and Planning
Health Workforce of New Zealand
National Health Board
Ministry of Health
PO Box 5013
WELLINGTON 6145

Dear Mary-Louise

**Regulation of Traditional Chinese Medicine under the Health Practitioners Competence Assurance Act 2003 - ACC Submission**

Thank you for the opportunity to comment on the regulation of Traditional Chinese Medicine (TCM) under the Health Practitioners Competence Assurance (HPCA) Act 2003.

The Accident Compensation Corporation (ACC) broadly supports the regulation of any profession under the HPCA Act whose practices present a risk to public safety.

ACC cannot comment on any element of the application concerning Chinese herbal medicine as it does not ordinarily fund the provision of services such as liniments and herbal plasters, herbs and nutritional supplements. This submission will concentrate solely on acupuncture as a modality of TCM.

**ACC relationship with acupuncturists**

Acupuncturists are recognised by ACC as treatment providers for ACC covered personal injuries. ACC contributed to costs by registered acupuncturists for 47,244 clients in financial year 2010-2011. As a treatment provider acupuncturists are able to provide up to 16 treatments to injured clients without prior approval.

ACC understands many acupuncturists registered as treatment providers also provide Chinese herbal medicine services.

ACC considers that acupuncture meets the definition of ‘health service’ under the HPCA Act. Additionally, acupuncturists are defined under section 6(1) of the Accident Compensation Act 2001 as being:

(a) a member of the New Zealand Register of Acupuncturists Incorporated; or

(b) a member of the New Zealand Acupuncture Standards Authority who –

(i) is a qualified health professional registered to practice in some other medical discipline in New Zealand who holds a recognised postgraduate qualification in acupuncture of a minimum of 120 credits (1 year full time)
at Level 8 or above on the New Zealand register of Quality Assured Qualifications; or

(ii) holds a National Diploma in Acupuncture (Level 7) or equivalent according to the criteria for the New Zealand Register of Quality Assured Qualifications

**ACC's purchasing strategy**

ACC funds services on behalf of clients based on effectiveness of treatment. ACC does not fund services based on whether the profession that performs the treatment is regulated under the HPCA Act.

**Injury diagnosis**

ACC determines cover for a personal injury based on a diagnosis by a health professional approved to diagnose under ACC's treatment provider claim lodgement framework. ACC is not confident that claims submitted by acupuncturists on behalf of their clients would result in an accurate diagnosis, or that a causal link between accident and injury would be made with accuracy. As a result acupuncturists are not permitted to confirm a diagnosis or determine a causal link to an injury.

**Scopes of practice**

If TCM is regulated under the HPCA Act, ACC would advocate that there are separate scopes of practice for acupuncture and Chinese herbal medicine. ACC recognises acupuncture as a modality of treatment but does not recognise or ordinarily contribute towards the treatment costs of TCM services such as herbs liniments and herbal plasters, herbs and nutritional supplements.

**Public safety**

ACC considers that the services provided by acupuncturists pose a potential risk of harm to the public. Although the potential risk of harm is low (eg surface bruising, bleeding from incorrect insertion, infection) ACC has received 28 claims for treatment injury in relation to acupuncture since 1 July 2005. Of these, 18 were accepted as treatment injury. The most common accepted injuries are cellulitis and pneumothorax. Two claims were notified to the Director General of Health as serious events.

Note that only claims relating to acupuncture provided by a registered health professional are included (eg medical practitioner, physiotherapist, osteopath) in the figures. Treatment by acupuncturists is not included as acupuncturists are not registered health professionals; as treatment injury legislation only covers treatment provided by registered health professionals.

ACC anticipates an increased number of acupuncture related treatment injury claims if this application for regulation is successful, and cost of operation for ACC is likely to increase.

It is not possible to identify claims related to Chinese herbal medicine.
Injury prevention

ACC is one of a number of government and non-government agencies with a mandate to reduce the incidence and severity of injury in New Zealand. ACC welcomes any move which has the potential to improve the practices of healthcare professionals and may reduce injury.

Acupuncture qualifications

The two voluntary acupuncture regulatory bodies recognised by ACC (the New Zealand Register of Acupuncture and the New Zealand Acupuncture Standards Authority) have differing standards for the qualifications necessary for registration. The two organisations have not been able to agree what the minimum requirements for registration should be. ACC is concerned that, should TCM become a registered profession under the HPCA, they will not be able to agree on the standards of education or clinical experience necessary for practitioner registration. Without consistent defined pathways into the profession, the public may be given a false sense of reliability and credibility about the skills of registered practitioners.

Language

One criteria of the HPCA Act is that all new registrants communicate in and comprehend English sufficiently well to protect the health and safety of the public. It is also the requirement of ACC that all clinical records relating to a covered injury are in English. ACC is concerned that some acupuncture practitioner’s expression and comprehension skills in verbal and written English are sub-optimal. If TCM is registered under the HPCA Act, adequate steps should be taken to ensure all registrants’ English is of a satisfactory level. This may mean that some practitioners currently registered with either the New Zealand Register of Acupuncture or the New Zealand Acupuncture Standards Authority may not achieve the required standards for registration with the new regulatory authority.

Acupuncture as a modality of treatment

ACC understands that this application will only encompass TCM based treatments and not Western medical acupuncture. ACC is concerned that other registered health professionals carry out needling with varying levels of training and skill. ACC recommends other regulatory authorities follow the lead of the Osteopathic Council of New Zealand and introduce an extended scope of practice for acupuncture.

Thank you for this opportunity to comment on the regulation of TCM under the HPCA Act. If you have any queries regarding this submission please contact my by email russell.elleswei@acc.co.nz or on 04 816 4649.

Yours sincerely

[Signature]

Russell Elleswei
Policy Analyst
19 August 2011

Mary-Louise Hannah
Workforce Intelligence and Planning
Health Workforce New Zealand
National Health Board
Ministry of Health
PO Box 5013
WELLINGTON 6145

Dear Mary-Louise

**Re: Proposal that Traditional Chinese Medicine Become a Regulated Profession under the Health Practitioners Competence Assurance Act 2003**

Thank you for the opportunity to provide feedback on this consultation document which seeks stakeholder views regarding the regulation of Traditional Chinese Medicine (TCM). TCM encompasses a number of different modalities including acupuncture.

The New Zealand College of Midwives (NZCOM) is the professional organisation for midwifery. Our members are employed and self-employed and collectively represent 90% of the practising midwives in this country. The College encourages consumer membership and involvement, and makes places on all of its national and regional committees for consumer membership. The College works in partnership with Maori membership, which has representation on the College’s National Executive.

There are around 3000 midwives who hold an Annual Practising Certificate (APC). These midwives provide maternity care to on average 64,000 women and babies each year. The New Zealand model of maternity care is unique. It provides the opportunity for women to receive continuity of care throughout their maternity experience. For the majority of women in New Zealand this means having the same midwife Lead Maternity Carer (LMC), or her back up, providing the majority of their care. This care is provided at home or in a variety of community settings with the majority of labour and birth care provided within hospital settings. The midwife therefore works within the community providing primary care but also is an integrated member of the maternity team working in close collaboration with specialised services, and other health professionals across primary, secondary and tertiary hospital service environments.

When considering your proposal that TCM becomes a regulated health profession we would like to make the following points. Firstly, midwives often provide elements of Traditional Chinese Medicine to women as part of their existing role. For example many midwives provide acupuncture as part of their role and scope of practice. Midwives, who have
undertaken additional education in acupuncture specific to pregnancy, may provide acupuncture to their clients, to treat a range of pregnancy related conditions. These midwives are not fully qualified as an acupuncturists as such but have undertaken additional education to support them to provide certain techniques as part of their scope of practice as a midwife. The Midwifery Council (which regulates midwives) states that it is within a midwife’s scope of practice to provide such treatments if the midwife is suitably educated, remains competent in the skill and is providing the service to their own clients. The New Zealand College of Midwives has a consensus statement which provides the professions agreed position on the issue and can be seen at: http://www.midwife.org.nz/index.cfm/3,108,559/complementary-therapies-2004-refs-updated-2009.pdf

We understand that there are many other professions who utilise elements of TCM such as acupuncture within their scope of practice in order to provide specific treatments (for example physiotherapists and medicine). We are therefore concerned that if TCM does become a regulated profession under the HPCA Act, it is possible that the ensuing regulatory authority may apply to have acupuncture listed as a restricted activity. This would have a considerable impact on the practice of these professions whose own regulatory authorities consider acupuncture to be within the respective scopes of practice. Such a move would therefore be likely to create considerable opposition from midwives and a number of other professional groups.

Secondly, we consider that regulation of any group has the potential to improve safety for the consumer, but this comes at a cost to the professional group itself. Regulation requires additional administration and monitoring responsibilities and often requires that ongoing education is undertaken to ensure continued competence. As an organisation that advocates for consumers, we are concerned that these additional costs may be passed onto the consumer resulting in potential increased costs for pregnant women (who may be significant users of TCM). Therefore, there is a need to balance improvements in the benefits of public safety that may occur as a result of regulation against a potential increase in costs for the profession, as we assume that these costs will be passed onto the consumer.

In summary, the New Zealand College of Midwives does not object to the regulation of TCM. However, we would like to be reassured that there would be no plans to make certain elements of TCM restricted activities. If we cannot be assured of this we would object to TCM becoming a regulated profession.

Yours sincerely

Alison Eddy
Professional Projects Advisor
NZCOM
19 August 2011

Mary Louise Hannah
Senior Policy Analyst
Workforce Intelligence & Planning
Health workforce New Zealand
National Health Board
Ministry of Health
PO Box 5013
WELLINGTON 6145

Dear Ms Hannah

The New Zealand National Board of the Royal Australasian College of Surgeons has considered the information provided on the application by traditional Chinese medicine (TCM) practitioners for regulation under the HPCA Act. Our responses to some of the questions posed are as follows:

1. Is TCM a health service, as defined by the HPCA Act? (Note: the Act defines a health service as ‘a service provided for the purpose of assessing, improving, protecting, or managing the physical or mental health of individuals or groups of individuals’.)

Traditional Chinese Medicine, as defined by the HPCA Act 2003, might be accepted as a health service. However, it is important to have some confidence that there is a significant patient benefit to be derived from Traditional Chinese Medicine prior to consideration of regulation. The act of regulation provides a measure of assurance to the public in respect to efficacy and there should be evidence to confirm that the majority of people attending Traditional Chinese Medicine practitioners achieve benefit.

2. Are practitioners of TCM generally agreed on the qualifications required to deliver the health services they provide?

The information provided suggests that there is some inconsistency between the New Zealand School of Acupuncture and the New Zealand College of Chinese Medicine in respect to the training necessary to achieve qualifications. This suggests that there is not agreement in respect to the required qualifications.

3. Is there a risk of harm to the public from the practice of TCM?

The stated risks are –

a) In the use of acupuncture the potential for infection,

b) In the use of Chinese herbal medicine the potential for interaction with prescribed medications or the development of hypersensitivity reaction

c) In the use of Chinese massage therapy a risk of injury

No information has been provided in respect to the level of risk with each of these, but the incidence must be low or this would likely to have been common public knowledge.
Infection through the use of acupuncture has been raised as a specific concern, but acupuncture has been widely practiced in New Zealand for more than 30 years with extensive use by medical practitioners and physiotherapists beside traditional Chinese medicine practitioners. Infection appears to be a rare event. If penetration of skin was seen to be the specific procedure which should be regulated, then it would be necessary to consider extension of the same concept to the registration of tattooists and the variety of skin piercing therapists in the appearance and cosmetic industry.

Recognising that many herbal medicines (not necessarily solely Chinese) are widely available in pharmacies and supermarkets these appear to carry little significant risk.

Manipulation has been recognised as carrying some risk, particularly where serious underlying structure spinal disorders present as a sore back or neck. However this risk is not confined to Chinese massage therapy, but exists for all who undertake manipulation as an extension of massage therapy. While physiotherapists and chiropractors are regulated, masseurs and similar therapists are not.

4. If so, what are the nature, frequency, severity and potential impact of risks to the public? What is the likelihood of the harm occurring?

This question can be best answered by the Ministry of Health through its collection of data in respect to health care injury over the past 20 years. Serious events may have been recorded by the Health and Disability Commissioner Office, ACC or the Coroner’s office. If this has not occurred then the risks associated may be slight and not warrant the costs that flow from regulation.

5. Other than on the basis of risk of harm, is it in the public interest that the profession of TCM be regulated?

Regulation on the basis of risk of harm is the key issue and should be dependent upon the level of the risk. Every human activity carries an element of risk and it is necessary to consider the risk-benefit analysis. In this particular situation it must be asked what the real or perceived risk is, whether regulation significantly mitigates against it and if so are the continuing imposed costs of that regulation justified?

9. Does your organisation accord any standing or status to the profession of TCM, or to those who practise as TCM practitioners?

The Royal Australasian College of Surgeons does not have any specific interaction with Traditional Chinese Medicine practitioners and does not at this time accord them any "standing or status".

Yours sincerely

Scott Stevenson FRACS
Chair, New Zealand national Board
Submission 32

24 August 2011

Mary-Louise Hannah
Senior Policy Analyst
Workforce Intelligence and Planning
Health Workforce New Zealand
National Health Board
Ministry of Health
PO Box 5013
WELLINGTON 6145

By email: TCM@moh.govt.nz

Dear Ms Hannah

Proposal to regulate Traditional Chinese Medicine Practitioners

Thank you for the opportunity to comment on the proposal that traditional Chinese medicine becomes a regulated profession under the Health Practitioners Competence Assurance Act 2003 (the HPCA).

Traditional Chinese medicine covers a range of therapeutic interventions including acupuncture, Chinese herbal medicine, and contemporary practice developments such as electro-stimulation and point injection therapy. Both the New Zealand School of Acupuncture and Traditional Chinese Medicine and the New Zealand College of Chinese Medicine offer NZQA-approved degrees in Chinese medicine.

Role of the Health and Disability Commissioner

My role under the Health and Disability Commissioner Act 1994 (the Act) is to promote and protect the rights of health and disability services consumers. Pursuant to section 14(1)(d) of the Act, one of my functions is to make public statements in relation to any matter affecting the rights of health and disability consumers. In my view, the regulation of practitioners of Chinese medicine under the HPCA is a matter affecting the rights of health and disability consumers.

Regulation of Chinese medicine in Australia

Chinese medicine has been regulated in Victoria, Australia since December 2000 by the Chinese Medicine Registration Board of Victoria (CMRB). The CMRB operates under the same model as other health profession registration boards. It registers Chinese herbal medicine practitioners, acupuncturists, and dispensers of Chinese herbs, and conducts investigations into notifications about registrants’ professional conduct and/or fitness to practise.
In March 2008 the Council of Australian Governments signed an Intergovernmental Agreement to create a single national registration and accreditation system. The scheme, regulated by the Health Practitioner Regulation National Law Act 2009 and overseen by the Australian Health Practitioner Regulation Agency, came into force on 1 July 2010. Similar to the New Zealand scheme under the HPCA, a profession must meet certain criteria before it meets the threshold for national regulation. Chinese medicine has been found to meet this threshold in Australia, and is due to be included in the Australian national scheme from 1 July 2012 with the establishment of the Chinese Medical Board of Australia.

**New Zealand proposal to regulate Chinese medicine**

I support the regulation of traditional Chinese medicine in New Zealand under the HPCA. As recognised in Australia, it is advantageous for there to be authoritative systems in place to address competence, fitness to practice, and learning initiatives for this growing profession. I would specifically like to address three of the nine questions in the invitation for submissions.

1. *Is there a risk of harm to the public from the practice of traditional Chinese medicine?*
2. *What is the nature, frequency, severity and potential impact of risks to the public, and the likelihood of harm occurring?*

The primary and overriding objective of the regulation of health professionals is to protect public health and safety. In my view there is a risk of harm to the public from the practice of traditional Chinese medicine.

As noted by the CMRB in its submission on the inclusion of Chinese medicine in the Australian national scheme for registration of health professions, Chinese medicine is growing in popularity and consumer usage is increasing. Most practitioners of Chinese medicine practice as primary contact practitioners, and treat a wide range of health conditions. Risks associated with the consumption of Chinese herbal medicines and the effects of acupuncture needling include unpredictable reactions, predictable reactions, issues relating to the clinical judgment and/or conduct of practitioners, infection control, and the parallel use of complementary and mainstream treatments.

The risks identified by the CMRB are echoed in complaints to my Office about practitioners of Chinese medicine. Complaints to my Office demonstrate that therapeutic procedures performed by practitioners of Chinese medicine often involve invasive interventions that can result in significant harm to patients. For example, in one complaint investigated by this Office, acupuncture treatment resulted in a pneumothorax to the patient, who then required admission to hospital and emergency surgery. Two other recent complaints to this Office have highlighted concerns with the preparation of herbal remedies, and the quality of imported products, which had serious outcomes for the consumers involved.

---


2. For example: removal of appropriate therapy; incorrect diagnosis; incorrect prescribing; inappropriate duration of therapy; failure to refer on where appropriate; failure to explain risks and precautions associated with treatment options; inappropriate dosage, and failure to observe contraindications and interactions with pharmaceuticals.

3. Complaint 07HDC12714.

4. While the Natural Health Products Bill, when enacted, will address concerns about quality of imported remedies used in natural health, there is the outstanding issue of the competency of the preparation of medicines by practitioners of Chinese medicine. In one complaint to my Office a consumer consulted a practitioner of Chinese medicine for treatment of a form of arthritis. The consumer complained that the practitioner instructed
Other themes in complaints to my Office about practitioners of Chinese medicine have been inappropriate touching, acupuncture needles left in too long, provision of treatment without adequate examination or assessment, inadequate response to side-effects of treatment, poor communication, and the inappropriate advertising of acupuncturists as “doctors”.

The complaints received show that the risk to consumers from traditional Chinese medicine can be significant. Despite the increasing role of Chinese medicine in primary health care, and the level of risk associated with Chinese medicine, there are highly varied standards for the education of practitioners of Chinese medicine. Regulation and clearly defined scopes of practice provide benchmarking for qualifications, standards, and competency. With regulation, the public can easily identify practitioners with adequate training and competence, and can make better informed choices about their care and treatment.

In Australia, the CMRB has noted that registration has contributed to reducing or managing risks associated with unqualified practice and varying standards.\(^5\) As at October 2008, the CMRB had processed 1566 applicants for registration. The CMRB refused more than 170 of those applications and imposed conditions on registration in more than 30 other cases. The most common reason for refusal was inadequate qualifications and training, or lack of evidence of competence.\(^6\) As at June 2010, the number of applications for registration with the CMRB from the time of its inception was 1717.\(^7\) While the number of applicants in New Zealand is likely to be lower, the safety and competence issues are still of significance.

3. Does your organization accord any standing or status to the profession of traditional Chinese medicine, or to those who practise as traditional Chinese medicine practitioners?

The Code of Health and Disability Services Consumers’ Rights (the Code) sets out the rights of health and disability services consumers, and places corresponding obligations on the providers of those services. All health and disability services providers must comply with the rights and duties in the Code.

“Health care provider” is broadly defined in section 3 of the Act. It includes health practitioners, as defined in section 5(1) of the HPCA, and also any person who provides or holds himself or herself out as providing health services to the public or a section of the public, whether or not any charge is made for those services. In this respect, practitioners of traditional Chinese medicine are health care providers for the purposes of the Act, and must comply with the rights and obligations set out in the Code.

Currently, if a practitioner of Chinese medicine seriously breaches the Code, the Commissioner can refer the matter to the Director of Proceedings to consider laying charges

---

5 See footnote one.
6 See footnote one.
against the provider involved. Because practitioners of Chinese medicine are currently unregistered, proceedings can only be brought against them before the Human Rights Review Tribunal (HRRT). The remedies available in the HRRT are a declaration that there has been a breach of the Code, an order restraining the practitioner from continuing to engage in conduct that was the subject of the breach, and damages. Following complaints to my Office, two providers of Chinese medicine have been referred to the Director of Proceedings and successful charges were laid against those practitioners in the Human Rights Review Tribunal.

The focus of the HRRT is the rights of the individual, rather than issues of public safety. The HRRT has no power to impose conditions on the practice of a practitioner to protect patients, and there is no remedy in the HRRT for responding to issues of public safety posed by practitioners who are not competent to practise.

If practitioners of Chinese medicine are brought under the scheme of the HPCA, proceedings against practitioners of Chinese medicine who seriously breach the Code will be able to be brought in the Health Practitioners Disciplinary Tribunal (HPDT). The HPDT has much greater powers to impose conditions on practice, suspend a practitioner from practice, or even remove a practitioner from practice altogether. In addition, I would be able to refer practitioners of Chinese medicine to their responsible authority for competence reviews, should complaints to my Office raise serious concerns about a practitioner’s competence to practice.

These mechanisms provide positive measures to protect the health and safety of members of the public, and would be a benefit of regulating Chinese medicine under the HPCA.

Conclusion
In conclusion, I welcome the inclusion of Chinese medicine as a regulated profession under the HPCA. In my view, the risks of harm to the public posed by the practice of Chinese medicine are such that regulation is in the public interest.

Yours sincerely

Anthony Hill
Health and Disability Commissioner

---

8 The Director of Proceedings is a lawyer appointed under the Health and Disability Commissioner Act. On referral of a breach finding by the Commissioner, the Director of Proceedings makes an independent decision whether to lay a disciplinary charge before the Health Practitioners Disciplinary Tribunal, issue proceedings before the Human Rights Review Tribunal, or both.

26 August 2011

Mary-Louise Hannah
Workforce Intelligence and Planning
Health Workforce New Zealand
National Health Board
Ministry of Health
PO Box 5013
WELLINGTON 6145

Dear Ms Hannah

Re: Proposal that Traditional Chinese Medicine Become a Regulated Profession under the Health Practitioners Competence Assurance Act 2003

Please accept this late short submission on the above.

The Australian Acupuncture and Chinese Medicine Association Ltd (AACMA) is the peak national professional association of qualified practitioners of Acupuncture and Chinese Herbal Medicine in Australia. We represent over 2140 members, including 1780 qualified practitioners and over 360 students.

In Australia, the state of Victoria introduced statutory registration of the Chinese medicine profession in 2000. On 1 July 2012, the profession will become part of the National Registration and Accreditation Scheme (NRAS) for the Health Professions. The inaugural Chinese Medicine Board of Australia (CMBA) has been appointed and is responsible for setting mandatory registration standards and the transition (grandparenting) standards to apply for the first three years (up to 30 June 2015) of the scheme.

As the peak professional body for the Traditional Chinese Medicine (TCM) profession in Australia, AACMA is keen to see the New Zealand profession become a regulated profession under the Act. This will enable the process of mutual recognition of registered practitioners to commence which, in turn, will enable movement of bona fide registered TCM practitioners between our two jurisdictions. This will benefit the development of the profession in both countries and ensure minimum standards of education and practice will apply once the initial transition period has ended.
We support the submission by the New Zealand Register of Acupuncturists Inc with whom AACMA has a long-standing relationship of cooperation, support and academic exchange.

Our comments, therefore, are mainly in the area of minimum educational standards (Chapter Three in the proposal) to apply to new entrants to the profession once regulation is in place.

**Minimum educational standard (Chapter 3)**

In Victoria, the minimum educational standard for new applicants that has applied since the end of the initial transition period has been a four to five year bachelor degree majoring in acupuncture and/or Chinese herbal medicine or an equivalent standard in post-graduate or graduate-entry programs. These standards can be found at [http://www.cmrb.vic.gov.au/information/p&c/registration.html](http://www.cmrb.vic.gov.au/information/p&c/registration.html).

It is unlikely that the CMBA will adopt a lesser standard when it comes to TCM course approval.

AACMA recognises four to five year full-time bachelor degree programs majoring in acupuncture and/or Chinese herbal medicine as a basis for membership and accreditation in these two modalities of TCM. AACMA will not approve programs delivered under four years full-time duration nor will we recognise programs delivered by correspondence/distance mode or substantially via on-line methods. Our view is that development of the full range of knowledge skills and attributes necessary for safe, ethical and competent unsupervised practice of acupuncture and Chinese herbal medicine requires substantial face-to-face interactive learning.

Program duration is also a factor in developing a well-rounded practitioner able to effectively operate in the mainstream health system. Our experience is that graduates of three year programs, in general, have not developed the full range of knowledge, skills and attributes to enable them to operate safely, competently and ethically as unsupervised practitioners. Our experience is that at least four years is required to prepare them for the challenges of commencing practice.

We strongly recommend that, when considering the minimum educational standard to apply to new entrants to the TCM profession in New Zealand, a bachelor degree program majoring in acupuncture and/or Chinese herbal medicine of at least four years full-time duration be the base-line.

I may be contacted at the AACMA national office on +61 7 3324 2599 ext 13 or via email at [ceo@acupuncture.org.au](mailto:ceo@acupuncture.org.au) if you wish to discuss this submission.

Yours sincerely

[Signature]

**Judy James**

AACMA CEO
Nurse Education in the Tertiary Sector (NETS)
Submission in response to

Ministry of Health Consultation document

Proposal that Traditional Chinese Medicine Become a Regulated Profession under the Health Practitioners Competence Assurance Act 2003

July 2011

Contact person Kathy Holloway, National Co-ordinator kathryn.holloway@whitireia.ac.nz
We appreciate the opportunity to be involved in the consultation process regarding the proposed regulation of Traditional Chinese Medicine practitioners. Our comments are provided in response to the questions raised in the consultation document.

1. Is TCM a health service, as defined by the HPCA Act? (Note: the Act defines a health service as ‘a service provided for the purpose of assessing, improving, protecting, or managing the physical or mental health of individuals or groups of individuals’.)

Response: It is not clear if Acupuncture is considered part of TCM. If it includes acupuncture then it is worth noting that ACC approved acupuncturists as service providers. However, TCM as a discipline on its own appears to involve assessing and managing/treating individuals from an Eastern Medicine perspective, thus it could be seen as a health service in terms of the HPCA Act.

2. Are practitioners of TCM generally agreed on the qualifications required to deliver the health services they provide?

Response: Whilst there is competition between two societies for “control”, discussions with members of both seems to indicate a philosophical support of the need for this step. Some are simply pragmatic and see it as a means to obtain subsidised care

3. Is there a risk of harm to the public from the practice of TCM?

Response: All forms of therapeutic interventions have elements of risk and in the interest of public safety, health professions such as medicine, nursing etc are regulated, TCM should be no different. There is more risk from the lack of regulation. In New Zealand, TCM is being practiced anyway and the risk remains irrespective of regulation.

4. If so, what are the nature, frequency, severity and potential impact of risks to the public? What is the likelihood of the harm occurring?

Response: It is difficult to ascertain what the current situation is. However an informed public will have a voice and be more prepared to seek help/report bad practice as per “mainstream” medicine

5. Other than on the basis of risk of harm, is it in the public interest that the profession of TCM be regulated?

Response: Regulation leads to minimum standards in education and training which should be in the general interest of the public.

6. Are practising TCM practitioners generally agreed on the standards that TCM practitioners are expected to meet?

Response: Surely that needs to be asked of the industry. If there is no consistency, then legislation can direct and ensure the establishment of standards for practice and education. In our interactions with TCM practitioners it is clear that there are different schools of thought on TCM in China and that they influence what is happening in New Zealand.
7. Are practising TCM practitioners generally agreed on the competencies for scopes of practice for TCM?

Response: We doubt if they are as this will be embedded in the schools of thought behind the practice. It is an area for further development

8. What qualifications are generally held by members of the profession, and what is the degree of uniformity in qualifications across members?

Response: Generally, both in China and in developed countries, there has been a concerted effort to raise the qualification for entry to practice to a degree level. In New Zealand TCM is part of the BHSc degree offered by the New Zealand College of Chinese Medicine

9. Does your organisation accord any standing or status to the profession of TCM, or to those who practise as TCM practitioners?

Response: NETS offers a collegial response and recognition that TCM offers choice and hence elements of TCM are supported in discussion around health choices in some undergraduate nursing programmes.

We trust you find our comments constructive, and thank you again for the opportunity to comment.
Dear Mary-Louise

We would like to respond to the 9 questions you have outlined in relation to TCM being possibly regulated.

1. TCM is definitely a health service. In Mainland China it has equal health status with Western medicine and contributes greatly to both peoples physical and mental health.

2. The qualifications for TCM health providers is not agreed on as most TCM herbalists etc are small family businesses in which the knowledge has been passed down from generation to generation. If they have been practising TCM for 5-10 years then they are usually considered competent.
   In the hospital situation, then qualification is necessary.

3. The risk of public harm of TCM is very minimal. Herbs are mild and pose no greater risk than going for a curry at the local Indian restaurant. The current legislation bans any dangerous herbs or any illegal products.
   Tuina has a very small risk, no greater than a Chiropractor or massage therapist.
   Acupuncture has a minor risk, not so much in its usage, but by its sterilization process if using the same needles.
   This has now been negated as most acupuncture is done by disposable needles, so risk is very minimal.

4. The potential risks to the public is minor, if prescribed the wrong herbs, Acupuncture, qigong, they may get mild discomfort like diarrhoea, stomach ache, sweating, in general no greater than reactions which occur from eating different foods or not being suitably clothed for the elements. Tunia may have a higher risk due to bone manipulation, but in general it is no more than minor.

5. We can see no reason why the public would be interested in TCM being regulated as it is a service which is not funded or subsidised by the government (other than acupuncture), however if that status changed then it would more likely be in the publics interest.

6. There is no current standards in NZ required for TCM as most practitioners are small businesses. Regulation of these could be perceived as being unduly harsh unless they were able to gain equal status with other approved providers and gain government subsidies to absorb the costs of regulation.

7. Competence is not agreed currently as there is no regulatory body to determine this. From a small practice perspective we would be more happy if a regulatory body was independant from its members, rather than a few organisations which could be viewed as possibly having their own objectives.

8. As previously mentioned little qualifications are required for TCM at present due to the nature of TCM training being individual in nature. Some have diplomas or degrees but most do not have any formal qualifications.

9. Our organisation only has 2 members, myself with 11 years experience and my partners with 18 years. We believe we have a very high standard and a good reputation which has enabled us to provide acupressure, Herbal remedies, Qigong training and practice, short courses of learning etc for more than 16 years.
For further information about our organisation please refer to our website www.thewayofnature.co.nz

Thank you for giving us the opportunity to express our views and we would be most interested on being kept informed on the Ministry of Health's approach to the possible changes to regulating the industry.

Yours Sincerely

Mark Inglis  (04) 4721515  027 2580071