Coversheet: Regulation of the Chinese medicine profession under the Health Practitioners Competence Assurance Act 2003

Advising agencies	Ministry of Health
Decision sought	Regulate the Chinese medicine profession under the Health Practitioners Competence Assurance Act 2003 (the Act) and establish a new responsible authority, the Chinese Medicine Council of New Zealand, to regulate the profession.
Proposing Ministers	Minister of Health

Summary: Problem and proposed approach

Problem definition

What problem or opportunity does this proposal seek to address? Why is Government intervention required?

1. The practice of Chinese medicine (including acupuncture, Chinese herbal medicine, tui na, and other modalities) poses a risk of harm to the public. Risks include tissue and vital organ injury, spinal injury, serious infections, and toxic reactions.

Proposed approach

How will Government intervention work to bring about the desired change? How is this the best option?

2. Regulation under the Act is a long-term intervention that will protect the public by ensuring that only practitioners who meet qualification, competency, and ethical standards requirements are able to hold themselves out to be registered members of the profession. The Act provides mechanisms to ensure ongoing competence and fitness to practise, as well as disciplinary and complaints procedures. Establishing a new authority to regulate the profession, supported by an existing authority, will minimise the costs of regulation.

Section B: Summary impacts: benefits and costs

Who are the main expected beneficiaries and what is the nature of the expected benefit?
3. Members of the public who use the services of Chinese medicine practitioners will benefit by having confidence that registered members of that workforce are qualified, competent, and fit to practise their professions. Chinese medicine practitioners will benefit from enhanced credibility, increased status and professional identification, protected title(s), and opportunities and mechanisms to increase and maintain competence.
Where do the costs fall?
4. Costs are borne by the profession and may be passed on to clients and/or to third-party payers (eg ACC).
What are the likely risks and unintended impacts, how significant are they and how will they be minimised or mitigated?
5. There is a risk that practitioners who do not meet the required standards will continue to practise using different titles. This could be mitigated by the new Council educating the public about the benefits of ensuring they are consulting a registered health practitioner. There is also a risk that the public may interpret regulation as government endorsement of the profession and its activities (including those with little or no scientific evidence of efficacy). This is, however, already the case with some other professions regulated under the Act and can be mitigated by profession- and/or government-led public education regarding the rationale for regulation.
Identify any significant incompatibility with the Government's "Expectations for the design of regulatory systems".
6. The proposal is consistent with the Government's expectations.

Section C: Evidence certainty and quality assurance

Agency rating of evidence certainty?
7. The evidence of risk of harm is clear and comes from a range of journal articles and Health and Disability Commissioner records. The risks were assessed by an expert panel who recommended regulation. Public consultation found overall support for regulation, based on the risk of harm.

Quality Assurance Reviewing Agency:
A Quality Assurance Panel with representatives from the Ministry of Health and the Regulatory Quality Team at the Treasury has reviewed this Impact Statement, produced by the Ministry of Health.
Quality Assurance Assessment:
The panel considers that the Impact Statement meets the Cabinet requirements to support its decision.
Reviewer Comments and Recommendations:
A range of options has been assessed using well-developed criteria. Establishing a new responsible authority meets the objective of reducing risks of harm to the public by ensuring practitioners are competent and fit to practise Chinese medicine while minimising costs to the profession. It is preferred by the Chinese medicine profession and the Ministry of Health.

Impact Statement: Regulation of the Chinese medicine profession under the Health Practitioners Competence Assurance Act 2003

Section 1: General information

Purpose

8. The Ministry of Health is solely responsible for the analysis and advice set out in this Regulatory Impact Statement, except as otherwise explicitly indicated. This analysis and advice have been produced for the purpose of informing key policy decisions to be taken by Cabinet.

Key Limitations or Constraints on Analysis

9. The exact number of Chinese medicine practitioners is not known, as not all practitioners register with one of the existing self-regulating bodies. It is not known whether those practitioners who are not associated with an existing professional body are supportive of the proposal.

10. The number of patients of Chinese medicine practitioners has been estimated by using ACC data and data supplied by Acupuncture New Zealand and the New Zealand Acupuncture Standards Authority. ACC data capture an estimated 80 - 90 percent of Chinese medicine practitioners in New Zealand.

11. No other options (refer paragraph 47) have been costed. The 'status quo' options do not meet policy objectives and the 'complementary medicines' authority option is beyond the scope of current consideration (but could be considered in the medium-term future). The cost of adding the Chinese medicine profession to an existing responsible authority is assumed to be higher because:

    - The existing authority would need to establish an advisory body to advise it on clinical aspects of the profession and operating costs of such a body would likely cost a similar amount to establishing a new authority.
    - New members would need to be added to the board or council of the existing authority and meeting times extended to encompass Chinese medicine, and this would result in higher costs.

Responsible Manager (signature and date):

amclark

Anna Clark
DDG, Health Workforce
Ministry of Health

Date: 11/06/20

Section 2: Problem definition and objectives

2.1 What is the context within which action is proposed?

12. The objective of this proposal is to protect the health and safety of members of the public by providing mechanisms to ensure that practitioners of Chinese medicine are competent and fit to practise their profession.

13. There are an estimated 1,100 Chinese medicine practitioners in New Zealand, usually operating in sole practices. This figure does not include other health practitioners (such as midwives, osteopaths, and medical practitioners) who use acupuncture or other forms of Chinese medicine as part of their practice. There is evidence that the Chinese medicine profession is growing, alongside the growing Chinese population in New Zealand. Statistics New Zealand projects that the total Chinese population in New Zealand will increase from 263,300 in 2018 to 438,900 in 2038, representing growth of 67 percent.

14. Chinese medicine is currently a self-regulating profession. There are several professional organisations involved, each with different (but overlapping) membership and criteria. These include the New Zealand Acupuncture Standards Authority (NZASA), Acupuncture New Zealand (AcNZ, previously the New Zealand Register of Acupuncturists), the New Zealand Register of Traditional Chinese Medicine Practitioners Inc (NZRCMP), and the New Zealand Chinese Medicine and Acupuncture Society (NZCMAS).

15. The applicants (two groups comprising Acupuncture NZ, the New Zealand Register of Traditional Chinese Medicine Practitioners, the New Zealand Acupuncture Standards Authority, the New Zealand Association of Traditional Chinese Medicine, the New Zealand Chinese and Acupuncture Society Inc, the New Zealand Council of Traditional Chinese Medicine, and the New Zealand Institute of Acupuncture Inc) have identified a number of reasons for wanting the profession to be regulated. In particular, they stress that "the only reason for supporting regulation is public health and safety". They see regulation under the Act as imperative and view the current (voluntary registration) approach as inadequate. The original application documents (2010) also mention wanting access to funding beyond ACC, and fuller engagement with the wider health system.

16. ACC recognises acupuncturists as treatment providers, but only if they are registered with Acupuncture New Zealand or the New Zealand Acupuncture Standards Authority.

17. ACC has advised that there were 941 active providers of acupuncture over the 2018/19 financial year. A total of 789,157 acupuncture treatments were funded in 2018/19, for 83,486 clients. Total expenditure from ACC in 2018/19 was $44 million, an increase from $39 million spent in 2017/18, $30 million in 2015/16, and $26 million in 2014/15. (An average increase of 19 percent per year.)

18. The profession has indicated it wishes to have a single scope of practice that covers all aspects of the practice of Chinese medicine. However, this could be revisited by the new responsible authority if it identified a need for additional scopes.

19. Certain activities are restricted under the Act where it has been shown that there is a serious risk of serious or permanent harm. Restricted activities may only be performed by a registered health practitioner whose scope of practice includes the activity, or by any person in an emergency. The Ministry has noted on its website that acupuncture is not intended to be captured by any of the current restricted activities. The Ministry does not propose adding any restricted activities in respect of Chinese medicine at this time.

20. Therapeutic products used by Chinese medicine practitioners are currently not regulated and are likely to be exempted under legislation (eg, the Therapeutic Products Bill) currently being drafted. The residual risk can be mitigated by regulation of the profession.

21. Chinese medicine practitioners will be required to demonstrate ongoing competence to gain and to renew their practising certificate. Practitioners must hold a current practising certificate in order to practise the profession.

2.2 What regulatory system, or systems, are already in place?

22. Chinese medicine is currently a self-regulating profession. There are several professional organisations involved (see list in paragraph 14 above).

23. There are currently two registered private training establishments delivering approved programmes in Chinese medicine:
    - New Zealand College of Chinese Medicine Limited.
    - New Zealand School of Acupuncture and Traditional Chinese Medicine.

24. All health practitioners, whether regulated or not, must comply with the Code of Rights, which is a regulation under the Health and Disability Commissioner Act 1994. The Code of Rights establishes the rights of consumers and the obligations and duties of providers of health services. Complaints about practitioners (including Chinese medicine practitioners) can be taken to the Health and Disability Commissioner.

2.3 What is the policy problem or opportunity?

25. The current self-regulatory system for Chinese medicine is fragmented and difficult for the public to navigate. There are multiple Registers and it is not easy for members of the public to check that a practitioner is appropriately qualified.

26. There is no ability for a registration body to place conditions on a practitioner's practice or to require them to undertake further (or remedial) training.

27. There is no dedicated regulatory organisation to accredit educational institutions and courses to ensure initial competency and subsequent safe practice. Some Chinese medicine education providers are registered with NZQA. However, NZQA National Qualifications Services is no longer involved in setting educational standards nor qualifications in Chinese medicine (or other natural and traditional health and healing practices).

28. There is no ability to formally and effectively assess, investigate, suspend, and/or discipline or remediate a practitioner if they are alleged to be practising unsafely.

Risk of harm

29. The evidence of the risk of harm to the public derives from Health and Disability Commissioner records, information supplied by the applicants, public submissions, and journal articles. For example, in 2000 an Australian study reported numerous adverse events arising from acupuncture (including fainting, nausea and vomiting, and increased pain), and from the consumption of Chinese herbal medicines (including direct toxic effects and allergic reactions).

30. An expert panel convened by the Ministry met in January 2011 to assess the Chinese medicine professions' applications against the criteria for regulation under the Act.

The panel comprised:

a. Dr Stewart Jessamine, formerly of Medsafe, a public health physician with an extensive knowledge of pharmaceuticals and their regulation.
b. Dr Susan Martindale, formerly of Medsafe, an expert in pharmacology and medicine regulation.
c. Professor Charlie Xue of the Royal Melbourne Institute of Technology (RMIT) an international expert in Chinese medicine.
d. Wei Zhang, a research fellow at the Department of Primary Health Care and General Practice at Wellington Medical School, University of Otago.

31. A key part of the panel's assessment process was determining the degree of potential risk of harm to the public from the practice of Chinese medicine. A rating system was developed to guide that assessment. The expert panel assessed Chinese medicine's score as 27 points out of a possible 35.

32. The expert panel identified a range of risks, noting that the strongest body of evidence of risk of harm relates to acupuncture. Risks are summarised below:

Acupuncture

- Tissue and vital organ injuries can occur.
- If sterile techniques are not used for needle insertion, serious infections may occur.
- If lasers or electrostimulation are not used competently, tissue damage can be caused.
- Sharps disposal can be a problem, causing the spread of infections.
- If moxibustion (burning of mugwort or common wormwood on particular points on the body) is used with an incorrect technique, burns may be suffered.
- If treatments cause serious infections, these could be transmitted to others.
- Patients can be required to undress/ expose body surfaces, so privacy considerations are common.

Chinese herbal medicine

- Inappropriate herbal remedies (type and/or amount) can result in allergic or toxic reactions.
- A number of the herbs used interact adversely with other medications when administered incompetently or inappropriately.
- Contaminated/adulterated products can present safety issues.

Tui na

- The main risk in New Zealand is unprofessional practice.
- Inadequate training for application of massage may result in spinal injury.
- As with acupuncture the patient may be required to undress for therapy, so there are privacy issues and a need for understanding of and respect for professional boundaries.

General

- Overseas information indicates that it is those Chinese medicine practitioners with inadequate training that are most likely to cause harm.
- Delays in diagnosis and timely referral to another health practitioner where required could result from limited clinical experience, and this could ultimately increase the cost of health care.
- Since these services have been widely offered (for example in shopping malls) in Australia there has been an increasing number of complaints. (Complaints in Victoria increased once the profession was regulated.)

33. Among the public submissions, there was strong agreement (twenty-six submitters, or 74 percent) that Chinese medicine carries a risk of harm to the public, with some submitters emphasising the risk of traditional Chinese herbal medicine and others the risks of acupuncture. The issue of Chinese medicine practitioners not making referrals when there were health issues that could not be managed purely through Chinese medicine was also mentioned in several submissions, along with the need for assurances around the competence of practitioners and concerns about the adequacy of training.

34. In 2013, Britain's Medicines and Healthcare Products Regulatory Agency issued a warning that extreme caution should be used with a number of traditional Chinese medicines because they could contain dangerously high levels of toxins including lead, mercury, and arsenic.

2.4 Are there any constraints on the scope for decision making?

35. There are no constraints on the scope for decision making.

2.5 What do stakeholders think?

36. The profession (through its main associations) initiated discussions and made formal application for regulation.

37. A broad consultation was conducted in 2011. Organisations consulted included ACC, the Ministry of Business, Innovation and Employment, the Treasury, district health boards, responsible authorities, health professional bodies, and health services consumer associations. The consultation was also posted on the Ministry of Health's website and invitations to comment were emailed to key stakeholder organisations (eg Chinese medicine associations and education providers). The Department of Prime Minister and Cabinet was informed.

38. Thirty-five submissions were received on the discussion document. Respondents included professional organisations, individual practitioners, education organisations, responsible authorities, government organisations, and others.

39. Most of the submissions received supported regulating the practice of Chinese medicine under the Act, based on the risk of harm.

40. Twenty-five submitters (71 percent) thought that Chinese medicine should be regulated because of safety issues, but a quarter (six) of these had reservations about regulating. Some considered that the criteria for regulation should be revised to include effectiveness and several were concerned that regulating Chinese medicine practitioners would change how the public viewed their professional status because regulation would grant formal recognition. Several suggested that the Chinese medicine profession should be regulated but that it should be a "second tier" regulation. (There is currently no facility for this under the Act.)

41. Seven submitters did not take a definite position about whether Chinese medicine practitioners should be regulated, two submitters said that Chinese medicine practitioners should not be regulated, and one was neutral as to whether or not to regulate.

42. Several submissions mentioned that English-language requirements could be an issue for some practitioners and raised the need for a grandparenting clause to allow practitioners with lesser qualifications to either be registered or to undertake further training so that they could subsequently become registered.

43. Several submitters believed that the criteria for regulating should include consideration of whether Chinese medicine practice is effective and the need to consider if health practitioners rely on scientific evidence.

44. It was proposed by several submitters that regulation would be useful as it would allow for disciplinary procedures under the HPCA Act to be implemented.

45. The Ministry has also had several meetings with the Chinese medicine profession to discuss the practical details of how regulation could work and to confirm that there was no need, from their perspective, to update the 2011 consultation. (That is, that there had been no major changes in the proposal, the risks of harm identified, or in the wider policy environment.)

46. ACC advises that regulation will likely impact how they purchase acupuncture and that costs will "likely be impacted by potential pressure":

    - to broaden current policy and purchasing guidance to reflect the new scope of services
    - for equity with other regulated practitioners in regard to lodgement of claims and status within other contracted services
    - to recognise diagnoses under the Chinese medicine paradigm as physical injuries and treatment injuries under the Accident Compensation Act 2001
    - from provider-induced demand for services due to the above.

Section 3: Options identification

3.1 What options are available to address the problem?

47. The principal options for ensuring public safety in respect of the Chinese medicine profession are:
    a. Status quo (self-regulation by multiple professional bodies).
    b. Enhanced status quo (strengthen self-regulation).
    c. Establishing a new responsible authority.
    d. Amalgamating the profession with an existing responsible authority.
    e. Establishing a single responsible authority to regulate a range of complementary medicine professions (which could include osteopathy, chiropractic, and potentially Western medical herbalism should the herbalists become regulated in future) and/or a range of allied health professions (which could include physiotherapy, occupational therapy, and other allied health professions).

Status quo

48. The status quo (self-regulation by a range of different bodies with differing standards and qualifications) is, in the Ministry's view, inadequate to protect the public from the risk of harm.
49. Acupuncture is an invasive technique which can result in serious injury if used incorrectly, the use of herbal medicines carries the risk of toxicity, and incorrect use of tui na can result in spinal injury. The use of Chinese medicine is growing in New Zealand and it is important to protect the public from poor practice.
50. Currently, members of the public cannot readily identify whether the Chinese medicine practitioners they consult have relevant qualifications and are competent and fit to practise. While some of the professional bodies maintain Registers of practitioners, there is no single, reliable source of information that can be referred to by the public.
51. The ability of the voluntary registration bodies to enforce minimum standards is limited. There are no disciplinary procedures available to these organisations (beyond a complaint to the Health and Disability Commissioner) and a practitioner who is removed from one of their Registers may continue to practise.
52. The Ministry's and the profession's view are that regulation under the Act is the only way to assure the public of the quality of the practice of Chinese medicine, and to minimise the risk of harm from unqualified or incompetent practice.

Enhanced status quo

53. Steps could be taken to address the shortcomings noted above, such as accrediting an existing voluntary registration body which would develop a central register of all Chinese medicine practitioners, prescribe minimum standards, and develop mechanisms (such as suspension or removal from the accredited register) to enforce those standards. A framework for accrediting voluntary registers of health professionals would need to be established, with the Crown likely to shoulder significant costs.
54. This is not recommended because the monitoring and accountability mechanisms under the Act would not apply and risks would therefore not be adequately mitigated.

Establishing a new responsible authority

55. This is the simplest option and is preferred by the Chinese medicine profession and

the Ministry. Costs of regulation would be met by the profession.

56. Stakeholders have raised concerns regarding cost duplication across the responsible authorities. For example, each authority incurs costs in relation to leases, information technology, and other operational expenses.

57. The Director-General of Health has previously recommended that the responsible authorities explore ways to share processes and reduce costs. Most responsible authorities have made significant progress in greater collaboration since that review, including co-locations and sharing administrative services.

58. Concerns were also raised about the number of professions applying for regulation and the threshold for regulation being too low. Cabinet expressed concern at the "proliferation of registration authorities" [CAB Min (07) 7/3 refers].

59. In response to this, the Ministry worked with stakeholders to develop a revised set of criteria for regulation (refer Appendix 1), and those criteria were applied in respect of the practice of Chinese medicine.

60. Establishing a new responsible authority can be cheaper than joining the profession to an existing responsible authority, provided the new authority can share some services with an established authority.

61. Establishing a new responsible authority may raise the expectations of other professions that have applied for regulation. Governance arrangements for each group of applicants for regulation is, however, considered on a case-by-case basis.

62. A standalone authority would enable the Chinese medicine profession to maintain its professional identity.

63. The Ministry is of the view that, provided costs can be minimised through sharing administrative services, the size and distinctiveness of the Chinese medicine profession provide sufficient justification for establishing a new responsible authority.

Amalgamate the profession with an existing responsible authority

64. The Minister of Health has the authority under s 115(1)(b)(ii) of the Act to amalgamate a new profession with an existing responsible authority. This may involve restructuring and renaming the authority.

65. This approach may be appropriate where the profession has similarities in practice or client groups and/or has strong working relationships with a profession already regulated under the Act.

66. Discussions with the applicants to determine an appropriate governance arrangement for regulating the Chinese medicine profession initially focused on amalgamating the profession with an existing responsible authority. Repeated efforts to identify an existing authority willing to regulate the profession of Chinese medicine were unsuccessful, and so this option could only now be progressed by forced amalgamation under s 115(1)(b)(ii) of the Act.

67. There are fundamental differences in the ideologies and therapeutic approaches upon which Chinese medicine and other professions are based. These differences could make it challenging to develop an effective working relationship.

68. If the Chinese medicine profession were to join an existing responsible authority, new Council members would be required, and this would increase governance costs. The combined authority would also need to establish new mechanisms and/or structures to garner advice on matters such as qualifications, scopes of practice, and competencies. The restructuring costs may mean this option is more costly than establishing a new authority.

Establishing a complementary medicine/ allied health responsible authority

69. As noted above, amalgamation of responsible authorities is currently possible under

the Health Practitioners Competence Assurance Amendment Act. [Refer s 116A of the Act.]

70. Theoretically, a multi-profession responsible authority could be established either by establishing a new responsible authority and subsequently adding other professions to it, or by renaming an existing authority, such as the Chiropractic Board, and amalgamating other professions with it.

71. Any future amalgamation of existing responsible authorities into a multi-profession authority would depend on the outcome of consultation with the affected responsible authorities, and a business case and regulatory impact analysis would need to be developed outlining the costs and benefits of such a proposal. This would further delay regulation of Chinese medicine and fail to address the risk of harm to the public in the meantime. Section 116A could be used in the future however, for example to establish a complementary medicine authority.

Conclusion

72. The Ministry's preferred option is to designate Chinese medicine as a health profession under Section 115 of the Act and establish a stand-alone responsible authority, the Chinese Medicine Council of New Zealand, to regulate the profession.

73. Regulation would not prohibit non-registered persons practising Chinese medicine. However, it would require a person who wishes to use the titles associated with the profession to register with the Council and to meet the required qualification and competence standards. Registration would provide some assurance to the public that anyone describing themselves as a Chinese medical practitioner is suitably qualified and competent.

3.2 What criteria, in addition to monetary costs and benefits, have been used to assess the likely impacts of the options under consideration?

74. The additional criteria used (refer section 4) include:

    a. Protection of the public. Will the risks of harm that have been identified be mitigated by the proposed option?

    b. Enforcement of standards. Does the option provide effective enforcement mechanisms?

    c. Unnecessary proliferation of authorities. Does the option propose establishment of a new authority and, if so, is that justifiable based on an analysis of the relative costs and benefits of all options?

    d. Professional identity. Is the proposed option likely to support practitioners' identification with the regulator (thereby facilitating effective and sustainable regulation)?

75. The Ministry's criteria for regulation of a health profession, which underpin and complement the impact analysis criteria, can be found in Appendix 1.

3.3 What other options have been ruled out of scope, or not considered, and why?

76. No other options have been identified.

Section 4: Impact analysis

Marginal impact: How does each of the options identified at section 3.1 compare with the counterfactual, under each of the criteria set out in section 3.2?

Criterion	Status quo	Enhanced status quo	Establish a new, dedicated responsible authority	Amalgamate with an existing responsible authority	Establish a new "Complementary Medicine" responsible authority
Protection of the public	**0** Inadequate to protect the public from the risk of harm No standardisation of codes of ethics, clinical standards, or qualifications No ability for registration bodies to investigate or discipline unsafe practitioners Does not prevent unqualified people from holding themselves out to be qualified members of the profession Difficult for public to check multiple Registers	+ The public may perceive the organisation as profession-centric The monitoring and accountability mechanisms in the HPCA Act would not apply	++ Risk of harm reduced via HPCA Act mechanisms	+ Risk of harm reduced via HPCA Act mechanisms, possibly complicated by multi-profession approach	+ Risk of harm reduced via HPCA Act mechanisms, possibly complicated by multi-profession approach
Enforcement of standards	**0** No authority to effectively enforce standards	+ Enforcement mechanisms bolstered, but weak	++ Authorised under HPCA Act	++ Authorised under HPCA Act	++ Authorised under HPCA Act
Unnecessary proliferation of	**0** No additional responsible authority created	+ No additional responsible authority created	**0** Analysis justifies establishment of a new, standalone responsible	**0** No additional responsible authority created	**0** A multiple profession authority would be justifiable

authorities			authority		
Professional identity	**0** No change to current status	**0** May be some (minor) boost to connection with regulator	**+** Supports professional identity and connection with responsible authority	**-** Practitioners' identification with responsible authority may be weakened	**-** Practitioners' identification with responsible authority may be weakened
Cost	**0** No change to costs paid by practitioners for self-regulation	**+** Minimal additional establishment and ongoing costs There is currently no mechanism for accrediting a registration organisation or register exists, so one would have to be developed	**0** Practitioners wishing to register will need to pay a registration fee and annual practising certificate fee (although this should be similar or lower for those already registered with NZASA or Acupuncture NZ). Costs minimised by collaboration with Nursing Council The new responsible authority would also benefit in other ways from the support, experience, and systems of the Nursing Council	**-** Additional costs involved to reconfigure responsible authority and governing board	**-** complex start-up process, larger governing board
Overall assessment	**0**	**+**	**++**	**+**	**+**

Key:

++ much better than doing nothing/the status quo

+ better than doing nothing/the status quo

0 about the same as doing nothing/the status quo

- worse than doing nothing/the status quo

- - much worse than doing nothing/the status quo

Section 5: Conclusions

5.1 What option, or combination of options, is likely best to address the problem, meet the policy objectives and deliver the highest net benefits?

77. The regulation of Chinese medicine will have benefits to consumers in terms of increased safety of practice and recourse to formal complaints and disciplinary procedures. The qualifications, standards, and scopes of practice set by the Chinese Medicine Council will reduce the risk of harm to the public by ensuring practitioners are competent and fit to practise Chinese medicine.
78. The Ministry, supported by the impact analysis above, prefers the option of establishing a new responsible authority, with operational support provided under contract by the Nursing Council. This option addresses the risk of harm to the public while minimising the costs to the profession. There are benefits to the Chinese medicine profession in being able to draw on the expertise and services of the Nursing Council and the other nine responsible authorities currently colocated with them.

5.2 Summary table of costs and benefits of the preferred approach

Affected parties	Comment:	Impact	Evidence certainty
Additional costs of proposed approach, compared to taking no action			
Regulated practitioners	Costs: One-off establishment fee, initial registration fee, ongoing Annual Practising Certificate fee (including Disciplinary Levy), and ongoing costs of maintaining competence year-to-year. Risks: Subject to HPCA Act competence, fitness, and conduct mechanisms.	Costs: Establishment cost estimated at $452 pp. APC fee estimated at $710 pp. (Comparable to current fees for most practitioners, although not all practitioners are currently registered, so some will face an increase.) Risks: Medium impact	High certainty
Regulators	New regulatory body established with costs met by profession.	Refer to Appendix 2 for estimate of establishment costs.	High certainty
Wider government	Costs: None.	Costs: No impact.	Medium certainty
Other parties	Costs: Possible increase in fees paid by members of the public if practitioners' costs increase (eg because of a high number of complaints). Risks: Reduced, with clear pathway for raising concerns.	Costs: Minimal increase, if any. Risks: High impact (significant reduction in risk).	Medium certainty

Total monetised cost	NA	NA	NA
Non-monetised costs	Costs met by profession, minimal impact on consumers.	Low	Medium certainty

Expected benefits of proposed approach, compared to taking no action			
Regulated practitioners	Enhanced public image as regulated professional.	Medium impact	Low certainty
Regulators	Positive engagement with profession.	Medium impact	Medium certainty
Wider government	Enhanced public safety.	Medium impact	Medium certainty
Other parties	Safety and quality of services provided can be expected to improve overall.	Medium impact	Medium certainty
Total monetised benefit	NA	NA	NA
Non-monetised benefits	Enhanced public safety.	Medium impact	Medium certainty

5.3 What other impacts is this approach likely to have?

Nil.

5.4 Is the preferred option compatible with the Government's 'Expectations for the design of regulatory systems'?

No areas of incompatibility have been identified.

Section 6: Implementation and operation

6.1 How will the new arrangements work in practice?

79. An Order in Council is required to designate Chinese medicine as a profession under the HPCA Act and establish a Chinese Medicine Council. The Council will be responsible for ongoing operation and enforcement. The Minister of Health has a number of statutory functions, such as tabling annual reports, which apply in respect of all responsible authorities.

80. Implementing regulation for the Chinese medicine profession would involve the following steps:

- Development of an Order in Council (subject to Cabinet agreement).
- Minister of Health appoints a Chinese Medicine Council.
- Nursing Council provides support for the establishment of the Council.
- Chinese Medicine Council (following consultation) prescribes fees and qualifications and sets standards of clinical and cultural competence and ethical conduct.
- Chinese medicine practitioners begin registering with the Chinese Medicine Council.

81. Compliance costs will be minimised as follows:

- The Nursing Council will provide operational functions (on a contracted, cost-recovery basis so that practitioners registered with the Nursing Council are not subsidising Chinese medicine practitioners and so that Chinese medicine practitioners are paying fair and reasonable fees). The Nursing Council has provided such services to several other responsible authorities for some years now.

6.2 What are the implementation risks?

82. Risks mentioned in consultation submissions include:

- An unknown number of current Chinese medicine practitioners may not meet the English language standard prescribed in the HPCA Act (refer s 16(b)) for registration, and
- Current practitioners hold a wide range of qualifications of varying quality and depth.
- The Chinese Medicine Council will need to consider what mechanisms it might use to protect the health and safety of the public while also meeting any obligations to 'grandparent' practitioners onto the Register. (For example, by considering where to set the English-language standard, the use of conditions on scope of practice, and/or the use of a provisional or transitional scope of practice.)

83. Other risks identified include:

- The Nursing Council could decide not to provide operational services. This is very unlikely as they have signed an MoU stating that they intend to provide services and have been working closely with the applicants for some time already. They also provide similar services to a number of other authorities.

- Some current Chinese medicine practitioners may refuse to register with the new responsible authority. If they continued to practise and claimed to be practising the Chinese medicine profession, they could be subject to conviction and fines under section 7 of the HPCA Act.

Section 7: Monitoring, evaluation, and review

7.1 How will the impact of the new arrangements be monitored?

84. Under the HPCA Act (refer s 122A), responsible authorities are now subject to five-yearly performance reviews. This provides a mechanism for monitoring the impacts of any new arrangements on key functions of a responsible authority.
85. Responsible authorities are also required to submit Annual Reports to the Minister of Health. This provides a mechanism for monitoring financial issues, registration growth, fitness, competence and conduct matters, and the development of the authority's systems.
86. Responsible authorities are also required to gazette any new fees, levies, and scopes of practice.

7.2 When and how will the new arrangements be reviewed?

87. There will be five-yearly performance reviews as noted above.

Appendix 1: Criteria for regulation

To determine whether a health profession should be regulated under the Act, primary and secondary criteria were developed and consulted on in 2009. The criteria for applying are based on the consultation and the Minister's agreement. The primary criteria are specific requirements set out in the Act and must therefore be met in order to be regulated under the Act. Applications that meet the primary criteria will then be assessed on the extent to which they meet the secondary criteria. The secondary criteria focus more on the practicalities of a profession being regulated under the Act and whether this is, in fact, the most appropriate means to protect the health and safety of the public.

The primary and secondary criteria are set out below, followed, in Section 5, by guidelines to interpreting and demonstrating each of the criteria.

Primary criteria

The following primary criteria apply to applications from new professions seeking regulation under the Act.

The primary criteria for regulation under the Act are that:

A. the profession delivers a health service as defined by the Act.

B. the health services concerned pose a risk of harm to the health and safety of the public.

C. it is otherwise in the public interest that the health services be regulated as a health profession under the Act.

Secondary criteria

If the primary criteria are met, the Ministry will apply the following second-level criteria to measure the appropriateness of regulation under the Act.

Criterion 1: Existing regulatory or other mechanisms fail to address health and safety issues.

Criterion 2: Regulation is possible to implement for the profession in question.

Criterion 3: Regulation is practical to implement for the profession in question.

Criterion 4: The benefits to the public of regulation clearly outweigh the potential negative impact of such regulation.

The Ministry has developed guidelines on how to interpret the criteria.

Appendix 2: Summary of indicative costs of regulation

The applicants have relied upon a robust analysis and estimation of costs conducted by the New Zealand Nursing Council's finance team to produce the figures reported below. The Nursing Council has a great deal of expertise and experience in this area, with a long history as an independent responsible authority and in providing financial services to other (smaller) authorities.

If a new Chinese medicine authority is established, they will need to conduct a full, cost-recovery based analysis and must consult stakeholders before setting any fees or a levy (as authorised under ss 130 - 132 of the HPCA Act). Once gazetted, fees are subject to review by Parliament's Regulations Review Committee and must also be reviewed by the responsible authority on a regular basis. (Refer also to The Treasury's *Guidelines for Setting Charges in the Public Sector* [2017] and the Controller and Auditor-General's *Good Practice Guide: Charging fees for public sector goods and services* [2008]).

The key assumptions made in generating the following indicative costs of regulation are summarised below.

Assumption	Risks	Risk management
That the Nursing Council will provide administrative services under a Service Level Agreement	Service Level Agreement is not achieved	The applicants have signed an MoU with the Nursing Council formalising the intent to enter into a Service Level Agreement
All costs are estimates	Estimates could prove to be inaccurate	Nursing Council has, with the assistance of the applicants, conducted a robust analysis using conservative estimates of income and have included a 10% contingency
1100 initial registrants	Fewer practitioners might choose to register	Numbers have been conservatively estimated, with reliance on ACC's current number of payees. (In the future ACC will only pay registered CM practitioners, which is a strong incentive for registration)
Adequate "disciplinary" reserve established	Costs exceed reserve in first few years.	A responsible authority can, in such a situation, levy practitioners to make up the shortfall

Section 122A performance reviews not costed	Financial deficit following first review	First reviews won't happen until at least 2022, allowing time for the authority to build the cost into future budgets/fees

Establishment costs* (GST excl.)

SERVICES (9-month start-up period)	**ESTIMATED COST**
Project management (3 months)	$7,800
Orientation	$19,780
Governance support	$2,000
Recruitment	$11,340
Staffing	$94,877
Legal services	$1,800
Finance and payroll	$5,202
IT (including database, website)	$118,726
Communications	$6,700
Capital items	$23,240
Lease and utilities	$5,502
Facilities management	$3,750
Office expenses	$6,798
Council fees (6 months)	$55,000
Council costs (6 months)	$21,250
Consultant(s)	$5,000
Other	$4,571
Estimated establishment costs	**$393,337**
+10% contingency	**$39,334**
TOTAL ESTIMATED ESTABLISHMENT COSTS	**$432,671**
ESTABLISHMENT FEE (Divide by 1100 practitioners) (GST incl.) (Offset for some in part through their professional association's reserves)	**$452 per practitioner**

Ongoing costs (GST excl.)

SERVICES (Annual)	ESTIMATED COST
Meeting costs	$141,450
Secretariat support and office expenses	$58,580
Conference and convention costs	$10,000
Advisory committees	$15,050
Registrar & Deputy Registrar & Professional Advisor	$190,210
IT	$39,960
Fitness to practise	$104,400
Registration	$39,275
Projects	$15,000
Budgeting and audit	$6,910
Other (insurance, communications, depreciation, legal, recertification, etc)	$56,710
TOTAL ESTIMATED ONGOING COSTS	**$677,545**
Estimated Annual Practising Certificate fee (including annual Disciplinary Levy of $99) (GST incl.)	**$708**

*NB. Not all costs are able to be calculated (eg bank fees).