

How Do We Determine if Statutory Regulation is the Most Appropriate Way to Regulate Health Professions?

Discussion document

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1 Introduction

The Health Practitioners Competence Assurance Act 2003 (the Act) came into force in September 2004. The Act provides a framework for regulating health professions to ensure the public is protected from harm when receiving health services. The Act currently regulates 21 health professions.

Section 115 of the Act allows the Minister of Health (the Minister) to recommend additional health services for inclusion under the Act. Before such a recommendation is made, the Minister must be satisfied under section 116 that the services pose a risk of harm to the public or it is otherwise in the public interest to regulate them.

The Director-General of Health (the Director-General) recently completed a review of the operation of the Act. Concerns were raised during the review that New Zealand has 'a proliferation of registration authorities'. The Director-General therefore recommended that the Ministry of Health (the Ministry) review the criteria it uses to advise the Minister whether regulation is justified.

The purpose of this discussion document is to:

- outline the policy principles that are relevant to regulating health professions
- discuss the Ministry's current criteria for regulation and those used in similar jurisdictions
- propose revised criteria to assist the Ministry in advising the Minister whether a profession 'poses a risk of harm' or 'it is otherwise in the public interest' to regulate that profession.

2 Invitation to Comment

Having reviewed the general policy principles that are relevant to regulating health professions, the Government's broader approach to occupational regulation and the approach taken in similar jurisdictions, the Ministry considers that the criteria it uses to apply section 116 require amendment.

You are invited to submit comments on the proposed criteria detailed in this document. In particular, it would be helpful to receive your response to all or any of the specific questions listed in section 13. Your submissions should be addressed to:

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Please note that all correspondence and submissions on this matter may be subject to a request under the Official Information Act 1982. If there is any part of your correspondence you think should be withheld under the Act, please include comment to that effect and give reasons why you want it to be withheld.

The closing date for submissions is 5 March 2010.

3 Health Practitioners Competence Assurance Act 2003

The Health Practitioners Competence Assurance Act 2003 (the Act) came into force in September 2004. It brought all registered health professions in New Zealand, which had previously been regulated under their own separate statutes, under one consistent regulatory framework.

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

Authorities are established to be responsible for each registered health profession. Authorities are responsible for:

- describing their professions in terms of one or more scopes of practice with associated qualifications
- registering and issuing annual practising certificates to practitioners who have shown continuing competence
- reviewing and promoting ongoing competence
- considering practitioners who may be unfit to practise
- setting standards of clinical competence, cultural competence and ethical conduct
- establishing professional conduct committees to investigate practitioners in certain circumstances.

4 Current Criteria and Process for Regulating a New Profession under the Act

At the time of its enactment, the Act applied to 15 registration authorities. Sections 115 and 116 establish a process for the Act to be extended to other health professions where regulation is considered necessary. Section 115 allows the Minister to make a recommendation to the Governor-General that the Act be extended to include a new health profession if the Minister is satisfied that the new profession meets the criteria in section 116. Section 116 states that the Minister must be satisfied, after consulting any interested organisation, that the new profession either poses a risk of harm to the public or it is otherwise in the public interest to regulate the profession. 'Risk of harm' and 'public interest' are not defined in the Act.

The Ministry provides advice to assist the Minister in making these decisions. The Ministry's current criteria for applying section 116 are set out in Appendix 1. New professions seeking regulation under the Act are encouraged to use the criteria as the basis for an application to become regulated. The Ministry then consults interested parties on whether the profession meets the criteria for regulation. This informs the Ministry's advice to the Minister.

If the Minister agrees that a profession meets the threshold for regulation, the Ministry then consults with the public on possible structures for a registration authority for the new profession. Again, this informs the Ministry's advice to the Minister.

It is only once the Minister has approved both the regulation of a profession and the appropriate structure for a registration authority that the Minister makes a recommendation to the Governor-General that the profession be included under the Act.

5 Recommendations from the Review of the Act

Section 171 of the Act required the Director-General to review the operation of the Act three years after it commenced, consider whether any amendments to the Act are necessary or desirable, and report the findings to the Minister.

The review was completed in June 2009 and found that overall, the Act has been received positively by the sector and is operating largely as Parliament intended. The Director-General did, however, recommend a number of legislative and operational changes which could be made to improve the timeliness and efficiency of processes set up under the Act.

The Director-General noted that the process for considering when and whether new professions come under the Act could be improved and, in some cases, there may be a case for amalgamating authorities to make more efficient use of resources. Four recommendations proposed changes in this area:

- **Recommendation 15:** That, after [the review] has been tabled in the House of Representatives, the Ministry of Health move promptly to make recommendations to the Minister of Health in respect of those groups who have applied for statutory regulation under the Health Practitioners Competence Assurance Act 2003.
- **Recommendation 16:** That the Ministry of Health examine and consult on criteria for the statutory regulation of unregulated health occupations with reference to criteria such as those proposed for Australia.
- **Recommendation 17:** That the Ministry of Health review the process for groups or existing authorities seeking to have a new health service regulated as a profession in order to gather full information with which to advise the Minister of Health on whether statutory occupational regulation is recommended and, if so, what arrangements are best for appointing a responsible authority in respect for that profession.
- **Recommendation 18:** That section 114 of the Health Practitioners Competence Assurance Act 2003 be amended to give the Minister the power by Order in Council to join and restructure two or more existing authorities and/or add other practitioner groups to an existing authority in situations where, after consultation, the Minister is satisfied that it is in the public interest to do so and the authorities and their professions are generally in agreement.

This discussion document has been developed in response to recommendations 16 and 17. The Ministry intends to review existing applications under recommendation 15 and, where necessary, ask the applicants to resubmit their applications based on the revised criteria. This is discussed in more detail in section 12 of this document.

Recommendation 18 proposes a legislative change which is being developed in a Health Practitioners Competence Assurance Amendment Bill.

6 When is Statutory Regulation Necessary?

Occupational regulation can occur through a range of mechanisms. Statutory regulation is one option, but other industry-led mechanisms are also effective. For example, the Advertising Standards Authority maintains a code of acceptable standards of advertising and a complaints and disciplinary process which advertising companies agree to abide by. The Master Builders Association uses a voluntary accreditation system. Self-regulation allows these groups to assure the public of quality and promote the good standing of their professions.

It is well recognised that statutory regulation is the mechanism which carries the most cost for both professionals and consumers. In New Zealand, the *Cabinet Office Circular* No (99)6 outlines the policy framework which Cabinet has agreed for regulating occupations. It notes that:

- intervention by the government in occupations should generally be used only when there is a problem or potential problem that is either unlikely to be solved in any other way or inefficient or ineffective to solve any other way
- the amount of intervention should be the minimum to solve the problem
- the benefits of intervening must exceed the costs.

Historically, health professions opted for self-regulation, but over time most international jurisdictions have introduced legislation covering first the medical profession and later other professions.

In New Zealand, registered health practitioners are regulated by the Act and unregistered practitioners may be regulated by an employer's standards for service delivery or through self-regulation. The Code of Health and Disability Services Consumers' Rights also applies across the board to all health professions, regardless of their registration status.

As with other occupational groups, statutory regulation carries the greatest cost for the health sector. Under the Act, each registration authority charges fees to cover the operating costs of the authority. These include fees for registration, annual practising certificates and disciplinary levies.

It was noted during the Director-General's review that 'a large number of occupational groups are seeking to become regulated, but concern over risk of harm to the public is often not the main driving force'. For example, regulation is perceived as giving 'mana' to a profession or it may enable the profession to gain funding (eg, Accident Compensation Corporation subsidies or other contracts).

To date, only one profession has been added since the Act commenced: the Psychotherapy Board of New Zealand was established in October 2007. At that time Cabinet noted the high costs associated with setting up a separate authority for this small group of professionals and expressed concern about the proliferation of responsible authorities. There was also concern that too many registration authorities with overlapping scopes of practice may lessen flexibility in the sector as practitioners must then comply with the qualification requirements and competencies set by multiple authorities.

It should be noted that regulation under the Act does not prevent people who may be untrained from working in the area, ie, regulation will not prevent others from operating in the sector as long as they do not 'hold themselves out to be a registered health professional'.

7 Criteria Used in Similar Jurisdictions

The growth of new groups requesting coverage by health regulation is not unique to New Zealand.

In Ontario, the Regulated Health Professions Act 1991 covers 23 health professions and a further four professions are seeking regulation. In the United Kingdom, 25 professions are regulated. There, a further 11 groups of health professionals have been recommended for regulation and 16 other professions have made representations in relation to regulation.

Due to the closeness of the regulatory environment between Australia and New Zealand, the Director-General's review specifically recommended that the review of the criteria used under section 116 consider the criteria used in Australia. In Australia, applications from new professions seeking regulation will be considered once the current reorganisation of health regulation is completed. The Australian Health Ministers have, however, confirmed the criteria that will be applied to new health occupations seeking statutory regulation. These are outlined in Appendix 2.

Although the specific criteria used in the United Kingdom, Ontario and Australia differ, each jurisdiction applies similar overriding principles when considering whether health professions should be statutorily regulated. A comparison of the criteria used in each jurisdiction is set out in Appendix 2.

The common principles include:

- the benefits of statutory regulation should outweigh the costs
- statutory regulation should only be considered if it is necessary to protect the public
- statutory regulation should be the most appropriate way to regulate that occupation
- the risk posed by those health services cannot be addressed by other mechanisms
- statutory regulation should be both practical and possible.

All three jurisdictions identify the most important principle as being the potential of risk of harm to the public. However, this can be interpreted as a 'low test' since any health service carries some risk of harm if performed inadequately. In New Zealand, the *Cabinet Office Circular 99(6)* notes that there is a possible case for intervention if harm is irreversible and involuntary **even** if there is a low probability of harm occurring.

While the overriding principles give an overall policy direction, assessing applications from new professions against these broad principles can be difficult. It is also difficult to set objective tests relating to both the costs and benefits of regulation. 'Second-level criteria' can assist in determining whether an application meets the overriding principles. For example, in the United Kingdom, the following 'second-level criteria' are used to assess the potential risk to the public:

- the type of intervention undertaken
- where the intervention takes place
- the level of supervision for the intervention
- how experienced the worker is at the intervention.

8 Proposal for Change

Concerns were raised during the Director-General's review that New Zealand already has a proliferation of registration authorities and that statutory regulation should only be used when the benefits outweigh the costs.

The Ministry advises the Minister on whether applications for regulation from new professions should be approved. The Director-General's report noted that the Ministry needs to be 'explicit about the criteria that will be used to advise the Minister as to whether regulation is justified'.

The Ministry proposes that New Zealand adopts the same overriding principles as the United Kingdom, Ontario and Australia when it considers applications from new professions seeking regulation. In determining whether those overriding principles have been met, the Ministry considers that more explicit second-level criteria, based on the criteria used in Australia, will provide applicants with a clearer understanding of where the threshold for statutory regulation lies. These proposals are outlined in more detail in the following paragraphs.

Amending the criteria that are used to apply section 116 will not require any legislative change to sections 115 or 116 of the Act.

9 Proposed Overriding Principles

It is proposed that the following overriding principles will apply to applications from new professions seeking regulation under the Act.

The overriding principles for regulation under the Act are that:

- the health services concerned pose a risk of harm to the public, or it is otherwise in the public interest that the health services be regulated as a health profession under the Act
- the profession delivers a health service as defined by the Act (where a health service means a service provided for the purpose of assessing, improving, protecting or managing the physical or mental health of individuals or groups of individuals)
- regulation under the Act is the most appropriate means to regulate the profession.

10 Proposed Criteria

To achieve these overriding principles, it is proposed that the Ministry will apply the following second-level criteria (based on the criteria used in Australia).

Criterion 1: The activities of the profession must pose a significant risk of harm to the health and safety of the public.

Criterion 2: Existing regulatory or other mechanisms fail to address health and safety issues.

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

Criterion 4: Regulation is practical to implement for the profession in question.

Criterion 5: The benefits to the public of regulation clearly outweigh the potential negative impact of such regulation.

Criterion 6: It is otherwise in the public interest that the provision of health services be regulated as a profession.

11 Information Required in Applications

In determining whether the second-level criteria have been met, the Ministry will require detailed information from applicant professions. The Ministry therefore proposes to provide the following guidelines to applicant professions.

Criterion 1: Do the activities of the profession pose a significant risk of harm to the health and safety of the public?

To be considered under this criterion the members of the profession must be involved in at least two of the following activities:

- invasive procedures (such as cutting under the skin)
- clinical intervention with the potential for harm
- making decisions or exercising judgement which can substantially impact on patient health or welfare, including situations where individuals work autonomously, ie, unsupervised by other health professionals.

To establish a 'significant risk of harm', the applicant must provide information that demonstrates:

- the nature and severity of the risk to consumers
- the nature and severity of the risk to the wider public
- the nature and severity of the risk to the professional.

Areas which should be explored when identifying a risk to public health and safety are:

- to what extent does the practice of the profession involve the use of equipment, materials or processes which could cause a significant risk of harm to the health and safety of the public?
- to what extent may the failure of a professional to practise in particular ways (that is, follow certain procedures, observe certain standards, or attend to certain matters), result in a significant risk of harm to the health and safety of the public?
- are intrusive techniques used in the practice of the profession which can cause a significant risk of harm to the health and safety of the public?
- to what extent are dangerous substances used in the practice of the profession, with particular emphasis on pharmacological compounds, chemicals or radioactive substances?
- is there significant potential for the professional to cause damage to the environment or some wider risk of harm to the health and safety of the public?
- is there epidemiological or other data, (for example, coroners' cases, trend analysis, complaints) which demonstrates the risks that have been identified?

Evidence should be provided on:

- the nature, frequency and severity of the harm to, or the consequences for, the patient
- the likelihood of the risk occurring
- the nature, frequency and severity of the potential risk to the public which arises from the practice of the profession (for example, the number of cases reported to the Health and Disability Commissioner on this profession)
- whether other sector stakeholders have public safety concerns about the practice of this health service
- whether members of the profession are regulated in similar overseas jurisdictions.

In addressing the risk of harm in this context, the applicant should identify the risks associated with the practice of the profession, as distinct from risks inherent in the area of health care within which the profession operates.

Criterion 2: Do existing regulatory or other mechanisms fail to address health and safety issues arising from the practice of the profession?

Can the potential health and safety issues that may cause harm to patients be addressed in any other way?

For example, can the identified risks of harm to the health and safety of the public be addressed through:

- any other New Zealand statute that restricts the activities of the profession, such as the Medicines Act 1981 or the Radiation Protection Act 1965
- other regulatory options which are available to limit the potential for harm, such as product regulation
- other groups of registered practitioners supervising the activities of the profession
- self-regulation by the profession?

Criterion 3: Is regulation possible to implement for the profession in question?

Matters that should be addressed are:

- does the profession have a defined body of knowledge that can form the basis for standards of practice?
- is the profession well defined?
- does the profession cover a discrete area of activity displaying some homogeneity?
- is this body of knowledge, with the skills and abilities necessary to apply the knowledge, teachable and testable?
- where applicable, have functional competencies been defined?
- do the members of the profession require accredited qualifications? (please give details)
- is the practice based on evidence of efficacy?
- are there defined routes of entry to the profession?
- are there independently assessed entry qualifications? (please give details)
- are there standards in relation to conduct, performance and ethics?
- are there procedures to enforce those standards?
- are the professionals committed to continuous professional development?
- what professional titles are used?

To establish this criterion, please provide evidence of how the qualifications, standards and competencies that will be expected of practitioners will reduce the risk of harm to the public or help achieve the public interest.

Criterion 4: Is regulation practical to implement for the profession in question?

Matters that should be addressed are:

- is there an alternative to regulation under the Act that is practical to implement to limit any risk of harm posed by the profession, such as self-regulation or accreditation?
- is there at least one established professional body or association which can represent a significant proportion of the profession?
- is there currently a voluntary register of members of the profession?
- does the professional leadership favour the public interest over occupational self-interest? (give details of policies or communications which demonstrate this)
- is it likely that individual professionals will welcome regulation and professional associations will encourage compliance amongst their members?
- are there sufficient numbers in the profession to make regulation cost-efficient and are members of the profession willing to contribute to the costs of statutory regulation? (please give numbers in the profession).

Criterion 5: Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?

Below are matters that should be addressed.

Benefits of regulation

The benefits of statutory regulation come from:

- setting the entry to the regulated professions
- setting standards
- promoting competence
- ensuring high-quality education to assure those standards
- removing from practice those who fall significantly short of those standards
- promoting and enforcing clinical and cultural competencies and standards of ethical conduct
- helping to foster, develop and sustain an ethos of professionalism amongst their registrants.

Costs of regulation

The costs of regulation include:

- the cost of the professional's time taken to comply with the requirements of the regulators, such as meeting re-certification requirements which may take professionals away from their primary purpose of providing quality care to patients
- the costs to employers of ensuring they have additional systems in place necessary for the employment of regulated professionals
- the costs of professional fees from registrants to their regulators as ultimately these costs are indirectly paid by the taxpayer (in publicly funded services) or the individual patient (in privately funded services)
- the transitional costs of establishing new regulatory regimes for newly regulated bodies
- statutory regulation of professionals in the health sector which implies a relatively high component of legal costs, with decisions being open to challenge in the courts, funded from legal indemnity insurance and the regulators' fees
- the significant anxiety for those professionals who fear that they may be deprived of their livelihood by vexatious complaints or unfair treatment
- the enshrining of professional roles in statute which can create 'closed shops'
- the costs of any duplication of effort between local systems of management and clinical governance on one hand, and regulatory oversight on the other, which also may result in the risk of confusion over roles and responsibilities
- the potential for gaps between different systems of oversight due to assuming wrongly that other parts of the system are taking responsibility for detecting and managing risks
- the putting in place of national systems which may result in a weakened local focus and the remaining need for employers to 'credential' professionals to ensure the person is able to perform a particular role in a particular setting
- the costs to trainees, employers and taxpayers of the higher standards of education and of the training infrastructure which statutory regulation may require in order to assure the quality of new entrants to the register
- the involvement of the regulator in some matters which are now dealt with internally by the employer, such as assessment of complaints.

Criterion 6: Is it in the public interest that the provision of health services be regulated as a profession?

In some scenarios, criteria 1–5 will not apply, but statutory regulation may still be in the public interest. Criterion 6 could include professional groups that:

- practise without the supervision or support of peers, managers and other regulated staff
- are highly mobile, locum or work on short tenure
- are not guided by a strong professional (or employer) code of conduct
- provide services to vulnerable or isolated individuals
- are subject to such large numbers of complaints about the quality of services that oversight of competence from an independent body is required
- carry out roles where the training and educational requirements are short and there is no extended period through which the ethos and values which underpin safe practice can be absorbed.

In rare situations, statutory regulation may be in the public interest if the public and other health professionals need assistance to identify appropriately qualified professionals.

Every application under this criterion will need to identify the costs associated with regulating the applicant profession and how the benefits that will flow from regulation will outweigh those costs.

12 Professions with Current Applications

The Ministry is currently processing applications from seven new professions seeking regulation:

- acupuncturists
- anaesthetic technicians
- clinical physiologists
- counsellors
- music therapists
- speech language therapists
- Western medical herbalists.

These applications are at varying stages in the application process. However, none of the applicants have progressed to the point where a recommendation to the Governor-General can be made.

If the criteria for applying sections 115 and section 116 of the Act are amended as proposed in this discussion document, the Ministry will need to consider when the policy change should be introduced. The timing of any policy changes may impact on professions that are currently awaiting the outcome of their applications and one implication may be that the professions are asked to re-submit their applications under the new criteria.

The Ministry is conscious that the interests of the current applicants will need to be balanced against the principle that all new professions seeking regulation, both now and in the future, should be treated equitably. The concerns raised during the Director-General's review about a proliferation of registration authorities and the Government's key priorities around reducing bureaucracy and costs in the health sector are also relevant.

13 Seeking Your Views

The Ministry of Health invites your views on the proposals outlined in this discussion document.

In particular, the Ministry is interested in your views on the following questions:

1. Are the principles for regulation set out in section 9 of this document appropriate? If not, why not?
2. Are the criteria set out in section 10 appropriate? If not, why not?
3. Are there any other criteria you think should be added to section 10?
4. Do you agree that to establish a 'risk of harm' the profession must be involved in at least two of the following activities:
 - invasive procedures
 - clinical intervention with the potential for harm
 - making decisions or exercising judgement which can substantially impact on patient health or welfare, including situations where individuals work autonomously, ie, unsupervised by other health professionals?
5. Should a profession be required to meet all of criteria 1–5 to establish that the health services pose a risk of harm to the public? If not, what are the minimum criteria a profession should meet?
6. Do the proposed criteria provide sufficient guidance on what factors will be taken into account in establishing whether it is 'otherwise in the public interest' to regulate a profession?
7. Should applicants be given the detailed guidelines outlined in section 11?
8. Should any other matters be included in the guidelines outlined in section 11?
9. Should any other information be added to the application form to guide applicants?
10. If the revised criteria are confirmed, do you have any comments about the timing for introducing the new criteria? In particular, do you have any comments about how introducing the proposed changes might impact on the new professions that currently have applications with the Ministry?
11. Do you have any other comments?

Appendix 1: Current Criteria for Assessing Applications by New Professions to Come under the Health Practitioners Competence Assurance Act 2003

1 Introduction

At the time of its enactment, the Health Practitioners Competence Assurance Act 2003 (the Act) applied to 15 registration authorities. At the same time, the Act contained provisions enabling the scope of the Act to be extended to cover other practitioners and professions that provide health services. This document discusses these provisions and provides guidance to groups who might seek to apply for inclusion in the Act.

Section 115 of the Act enables the Governor-General, on the advice of the Minister of Health, to designate health services of a particular kind as a health profession under the Act and to either:

- establish a registration authority to administer the registration of the profession or
- provide that the designated profession be added to the profession or professions in respect of which an existing authority is appointed – thus creating a ‘blended authority’.

The Act does not provide for new or blended authorities to receive Crown funding. The set up and operational costs of the new authority will need to be borne by registrants. The financial viability of any proposed authority may have a bearing on the decision as to which of the section 115 options is the better mechanism. Applicants may be asked to provide comment on this issue.

2 Process for satisfying these requirements

Purpose of Act paramount

Essentially, any application to come within the Act must show consistency with the purpose of the Act, the principal purpose of which is: ‘to protect the health and safety of members of the public by providing for mechanisms to ensure that health practitioners are competent and fit to practise their professions’ (sec 3(1)).

Implicit in the Act is the protection of the public interest through ensuring that the public can readily find out what services a health practitioner is competent and entitled to provide. This will enable the public to know what health services can be expected from their chosen practitioner, and to know that that practitioner is competent and safe. The concept of providing the public with clear information on the nature of a profession, and the scope of practice and competencies of its practitioners, is reflected in the requirements set out below.

The development of these steps is also guided by the policy framework for regulating occupations. The framework (*Cabinet Office Circular No (99)6*) includes that:

- 1) intervention by the government in occupations should generally be used only when there is a problem or potential problem that is either unlikely to be solved in any other way or inefficient or ineffective to solve any other way
- 2) the amount of intervention should be the minimum to solve the problem
- 3) the benefits of intervening must exceed the costs.

The following process and evidence requirements under the Act help ensure compliance with this framework.

Section 116 of the Act

Section 116 of the Act requires that, before recommending a health service be regulated as a health profession, the Minister must be satisfied that the health services pose a risk of harm to the public or that it is in the public interest that the health service be regulated.

The Minister must also be satisfied that the providers of health services are generally agreed on the:

- qualifications for any class of providers of those health services
- standards that any class of service providers are expected to meet
- competencies for scopes of practice for those health services.

Section 116 of the Act also requires that the Minister of Health consult with any organisation that, in the Minister's opinion, has an interest in the recommendations.

Evidence of need to regulate

Applications must establish that:

1. the application relates to the provision of a health service as defined by the Act, that is: 'a service provided for the purpose of assessing, improving, protecting, or managing the physical or mental health of individuals or groups of individuals'
2. the profession is identifiable:
 - what is the nature of the activities undertaken by members of that profession?
 - how many practitioners are participating in the profession?
 - are there any current professional organisations to which members of the profession belong or are eligible to join?
 - does the public see the members of the profession as an identifiable group?
 - has the profession provided evidence which states how the profession considers itself different from other professions that practice in similar areas (ie, identifying what the profession does that is not within the training or competence of another profession)?

3. there is evidence of a need for regulation – specifically, applications should identify:
 - the nature, frequency and severity of the potential risk to the public
 - the likelihood of the risk occurring
 - the nature, frequency and severity of the harm to, or the consequences for, the public
 - whether there are existing public safety concerns resulting from the activities of unregulated practitioners.

In addressing the risk of harm in this context you should endeavour to identify the risk associated with the practice of the proposed profession, as distinct from risks inherent in the area of health care within which the profession operates.

Where the focus of a proposal is more on the public interest than on the risk of harm, then to accord with the principal purpose of the Act there must also be some significant health-related aspect of the profession's work that makes it appropriate to seek to protect the health and safety of members of the public.

Supporting evidence should identify if the profession is regulated overseas, and what risks (especially those to the public) have been identified in overseas experience or studies.

Provide a list of the organisations and individuals consulted on the regulation of this health service together with a summary of issues and concerns raised, agreements reached and any other matters.

Evidence of general agreement on qualifications, standards and competencies

1. Identify how the profession has been consulted on the application and what views were expressed. [Note: the Ministry will then be able to use this information during the decision-making process as well as background for further discussions.]
2. Identify which qualifications are generally held by members of the profession and the degree of uniformity in qualifications amongst members.
3. Identify what sort of courses or training is currently offered for members of the profession.
4. List the agreed qualifications, standards and competencies expected of practitioners once regulated. [Note: in assessing the list of qualifications expected of providers, the Minister will be guided by the requirements in sec 11 and 12 of the Act. These sections are contained in the appendix.]
5. Provide evidence of how the qualifications, standards and competencies expected of practitioners reduce the public's risk of harm or help achieve the public interest.
6. Provide evidence of general agreement among the profession or representatives of the profession on the qualifications, standards and competencies expected of health practitioners of that profession.

7. Identify the relationship between the generally agreed qualifications, standards and competencies of the profession proposed to be regulated, and the current scopes of practice of existing responsible registration authorities. Where possible, this analysis should specify the similarities and differences in the qualifications, standards and competencies; at what educational level; whether at an accredited institution; and whether continuing competency is a requirement of the profession (with details of the programmes and auditing processes).
8. Identify if service providers (such as District Health Boards) and the New Zealand Quality Assurance/universities accord any standing or status to the profession and the qualifications.

3 New authority or addition of profession to existing authority?

Once the Minister of Health has decided if it is appropriate to regulate the profession, a further consultation process will be entered into to determine the most effective way to undertake this regulation.

4 Assessment and decision by Minister of Health

The Ministry of Health will advise the Minister of Health on decisions to be taken on any applications received. This will require the Ministry to independently assess whether the public is at risk of harm or whether it would be in the interest of the public to regulate the health service.

This will involve:

- reviewing the evidence provided in the application (including undertaking a separate investigation into overseas experience and evidence)
- consulting internally, drawing on available Ministry clinical expertise and if necessary, engaging independent clinical advisors to advise the Ministry
- consulting with any organisation that, in the Minister's opinion has an interest in the recommendations (this may include consulting with district health boards, registration authorities and individuals or organisations within the practitioner group).

If a decision is made to recommend that the health services in the application be designated as a health profession, a separate decision will be required on whether to create a new authority or to add that profession to the ambit of an existing authority.

To do this the Ministry will:

- consider the information provided by the applicant on the establishment of a new authority or the joining with an existing authority
- if a blended authority is going to be considered, arrange a discussion between the Ministry, the new profession and the existing authority to talk through issues (including whether the proposed new profession should be represented on the authority)

- if agreement is reached, go ahead with the rest of the process
- if agreement is not reached, look at why not and see if any of those issues can be dealt with.

5 Appointment of authority and requirement to register

The Minister will then give effect to any decisions by recommending to the Governor-General an Order in Council. Any such Order in Council will prescribe the date that the decisions will come into effect. It is likely that the date will take into account the time required to appoint authority members. The appointment process (which includes calling for nominations) can take some months.

The new authority (or any existing authority to which a profession has been added) will be required by the Act to gazette the necessary scopes of practice for that profession. Practitioners undertaking the services described in the scopes of practice will then be required to be registered with that authority.

Appendix 2: Comparison of Criteria Used by Similar Jurisdictions Overseas

Reference documents that state criteria used			
<p>New Zealand</p> <p>Criteria for assessing new professions under the Health Practitioners Competence Assurance Act 2003 (the Act) using Sections 2, 115 and 116 and the Framework (Cabinet Office Circular No (99)6).</p>	<p>Australia</p> <p>Criteria for assessing the need for statutory regulation of unregulated health occupations.</p> <p><i>(Intergovernmental Agreement for a National Registration and Accreditation Scheme for the Health Professions, 2008)</i></p>	<p>Canada Ontario</p> <p>Criteria for regulation under the Regulated Health Professions Act 1991 (and amendments)</p> <p>(Health Professional Regulatory Advisory Council, 2005)</p>	<p>United Kingdom</p> <p>There are two levels of information available:</p> <ol style="list-style-type: none"> 1 The Department of Health working group on extending professional regulation has set out criteria (Extending Professional Regulation Working Group, 2009) (set out in (1) below). 2 The Health Professions Council (HPC) has criteria for new professions or aspirant groups (set out in (2) below).
Several of these jurisdictions have sub-criteria that sit below the broad principles to enable the decision-makers to judge the applications for coverage			
Overarching principles			
<p>The purpose of the Act is paramount, ie, 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 practise their professions (section 3(1)).</p>	<p>Sole purpose of regulation is to protect the public interest and not to protect the interests of health occupations.</p>		<ol style="list-style-type: none"> 1 The primary purpose of regulation is to secure safe, effective, high quality, and respectful care for the individuals who depend on health care staff for their health and wellbeing. 2 Principles of the HPC are that an occupation is only eligible if its members are involved at least one of the following: <ul style="list-style-type: none"> • invasive procedures • clinical intervention with the potential for harm • exercise of judgement by unsupervised professionals which can substantially impact on patient health or welfare.

Criteria			
<p>Application relates to the provision of a health service as defined by the Act. That is: 'a service provided for the purpose of assessing, improving, protecting, or managing the physical or mental health of individuals or groups of individuals'.</p>	<p>Criterion 1: It is appropriate for Health Ministers to exercise responsibility for regulating the occupation in question, or does the occupation more appropriately fall within the domain of another Ministry?</p>	<p>Regulation under the Regulated Health Professions Act 1991 must be a more appropriate means to regulate the profession than other means.</p>	
<p>That the provision of the health services concerned poses a risk of harm to the public (section 116), ie, what are</p> <ul style="list-style-type: none"> • the nature, frequency and severity of the harm to, or the consequences for, the public • the likelihood of the risk occurring. <p>That it is otherwise in the public interest that the provision of health services be regulated as a profession under this Act.</p>	<p>Criterion 2: Do the activities of the occupation pose a significant risk of harm to the health and safety of the public?</p>	<p>Risk of harm</p> <p>A substantial risk of physical, emotional or mental harm to individual patients/clients arises in the practice of the profession.</p> <p>Public need for regulation</p> <p>The profession must demonstrate that a significant public need would be met through regulation.</p>	<p>Regulation should be proportionate to the risk to patients and the public:</p> <ul style="list-style-type: none"> • proportionate regulatory systems need to apply equally well across sectors and employment contexts, and • consistency and coherence of the principles of regulation is desirable.
<p>That providers of the health services concerned are generally agreed on:</p> <ul style="list-style-type: none"> • qualifications • standards • competencies. <p>The profession needs to be identifiable:</p> <ul style="list-style-type: none"> • what is the nature of the activities undertaken by members of that profession? • how many practitioners are participating in the profession? • are there any current professional organisations to which members of the profession belong or are eligible to join? • does the public see the members of the profession as an identifiable group? 	<p>Criterion 5: Is regulation practical to implement for the occupation in question?</p>	<p>Body of knowledge</p> <p>The members of the profession must call upon a distinctive, systematic body of knowledge in assessing, treating or serving their patients/clients. The core activities performed by members of this profession must be discernible as a clear and integrated whole and must be broadly accepted as such within the profession.</p>	<p>The profession:</p> <ul style="list-style-type: none"> • covers a discrete area of activity displaying some homogeneity • applies a defined body of knowledge • bases its practise on evidence of efficacy • has at least one established professional body which accounts for a significant proportion of that occupational group • operates a voluntary register • has defined routes of entry to the profession • has independently assessed entry qualifications • has standards in relation to conduct, performance and ethics

Criteria			
<ul style="list-style-type: none"> evidence provided by profession should state how the profession considers itself different from other professions which practice in similar areas (ie, identifying what the profession does that is not within the training and/or competence of another profession). 		<p>Educational requirements for entry to practice</p> <p>To enter the practice of the profession, the practitioner must successfully complete a post-secondary programme offered by a recognised educational institution. The educational programme must be available in Canada.</p>	<ul style="list-style-type: none"> has Fitness to Practise procedures to enforce those standards is committed to continuous professional development.
<p>Intervention by the government in occupations should generally be used only when there is a problem or potential problem that is either unlikely to be solved in any other way or inefficient or ineffective to solve any other way.</p> <p>(The framework, <i>Cabinet Office Circular No (99)6</i>).</p>	<p>Criterion 3: Do existing regulatory or other mechanisms fail to address health and safety issues?</p>	<p>Sufficiency of supervision</p> <p>A significant number of members of the profession do not have the quality of their performance monitored effectively, either by supervisors in regulated institutions, by supervisors who are themselves regulated professionals, or by other regulated professions who delegate services.</p>	<p>Regulatory systems need the confidence of the public and registrants:</p> <ul style="list-style-type: none"> patients, the public, employers and those responsible for service design should be involved in designing and the effective running of appropriate regulatory systems regulation should lead to improvements in the quality of care for health care users new regulatory systems need to take account of the wider matrix of regulation and governance systems to minimise duplication and maximise benefit.
	<p>Criterion 4: Is regulation possible to implement for the occupation in question?</p>	<p>Leadership's ability to favour the public interest</p> <p>The profession's leadership has shown that it will distinguish between the public interest and the profession's self-interest and in self-regulating will favour the former over the latter.</p> <p>There is membership support and willingness to be regulated and likelihood of complying with regulation.</p> <p>The members of the profession support self-regulation for themselves.</p>	

Criteria			
		<p>There are sufficient numbers and commitment to make widespread compliance likely.</p> <p>The practitioners of the profession are sufficiently numerous to staff all committees of a governing body with committed members and are willing to accept the full costs of regulation. At the same time, the profession must be able to maintain a separate professional association.</p>	
<p>The benefits of intervening must exceed the costs.</p> <p>The amount of intervention should be the minimum to solve the problem.</p> <p>The framework (<i>Cabinet Office Circular No (99)6</i>).</p>	<p>Criterion 6: Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation? (Council of Australian Governments, 2006)</p> <p>Note: must meet ALL six criteria.</p>	<p>Economic impact of regulation</p> <p>The profession must demonstrate an understanding and appreciation of the economic impact of regulation on the profession, the public and the health care system.</p>	