General Enquiries and Client Service
P 1800 777 156
F 1800 839 284

Claims and Legal Services
P 1800 839 280
F 1800 839 281

www.miga.com.au
miga@miga.com.au

Postal Address
GPO Box 2048, Adelaide South Australia 5001

28 June 2019

Dr Joanne Katsoris
Executive Officer, Medical
AHPRA

Via email – medboardconsultation@ahpra.gov.au

Dear Dr Katsoris

MIGA Submission – Complementary, unconventional and emerging medicine guidelines

Thank you for the opportunity to contribute to the Medical Board of Australia's consultation on draft complementary and unconventional medicine and emerging treatment guidelines (**the draft guidelines**).

As a medical defence organisation and professional indemnity insurer, MIGA's members and clients have a range of views and practices around complementary, unconventional and emerging medicine. It takes no position on clinical basis and indications for these practices. These are matters for clinical professional interests. MIGA's submission reflects its expertise and experience advising, assisting and educating doctors and other health practitioners who have a range of views and practices around these issues. Its focus is on ensuring clarity and practicality of regulation and expectations for all doctors.

MIGA's position

MIGA supports the intent behind Option 2 identified in the Board's consultation paper, namely to clarify guidance for doctors who provide complementary and unconventional medicine and emerging treatments. It does not support doing this through one single set of guidelines applying to all these modes of medical care. Such an approach offers significant potential for confusion and uncertainty, particularly around divisions between conventional and unconventional medicine.

MIGA considers

- There should be separate guidelines for each of
    - Complementary and unconventional medicine
    - Emerging treatments within a conventional medicine context, including practices such as off-label prescription, use of medical devices for unapproved uses and other practices where there is a conventional medicine evidence base for each
- Initial focus should be on finalising complementary and unconventional medicine guidelines, which the draft guidelines can be developed into
- Guidelines for emerging treatments within a conventional medical context require further development and consultation.

MIGA has considerable concerns about the expectations on doctors treating patients who are exploring or undergoing complementary, unconventional and emerging treatments, but who are not involved in providing those treatments. It would prefer to see these expectations omitted from the final guidelines where they

- May be too onerous and confusing
- Might not be appreciated by the broader profession as applying to all doctors as they are in guidelines focused on those providing complementary, unconventional or emerging treatments
- Could create dilemmas for a doctor who is focused on providing care and treatment for the patient
- May alter significantly both regulatory and professional disciplinary obligations on doctors and their common law duties of care, creating considerable medico-legal uncertainty
- Risk creating general duties to inquire of and advise patients around their use of complementary and unconventional treatments
- May create a 'duty to dissuade' a patient from undergoing a particular course of care or treatment in certain circumstances.

MIGA proposals and feedback

The basis for MIGA's position is detailed below, and various proposals are made.

Feedback on individual aspects of the draft guidelines are contained in the enclosed annotated version, in mark-up / embedded comments. This includes proposals both to clarify a range of uncertainties and to narrow the guidelines to complementary and unconventional medicine only.

Guidelines for complementary and unconventional medicine only

MIGA acknowledges the need to provide clearer guidance around expectations on the medical profession around complementary, unconventional and emerging medicine.

It does not believe an omnibus guideline covering a wide range of healthcare modalities, whether they be conventional, unconventional or complementary, is the best approach.

The range of modalities involved and how they relate to current practices requires a more modality specific, bespoke approach.

MIGA has particular concerns around the use of the terms 'emerging treatments' or 'emerging medicine'.

The concept of 'emerging' treatments or medicine can span both conventional and unconventional medicine.

Unlike complementary and unconventional medicine, 'emerging' treatment or medicine is a concept lacking broad consensus around its contents and limits. It can cover healthcare in both evidence-based and non-evidence based approaches in a conventional sense. It is open to interpretation by doctors, governments, regulators, disciplinary bodies, courts and professional bodies. This creates significant practical and medico-legal uncertainty.

There is a need for separate guidelines for each of

- Complementary medicine and unconventional medicine
- 'Emerging' medicine within a conventional medicine context, such as off-label prescribing, use of approved medical devices for unapproved indications and emerging practices where each of these have a conventional medicine evidence base and fit in with existing conventional practices.

In essence, this would draw a distinction between complementary and unconventional medicine on the one hand, including that with a non-conventional evidence base, and conventional, emerging medicine with a conventional medicine evidence base on the other.

MIGA sees this as the best way to ensure clarity of expectation for doctors, and minimise medico-legal uncertainty. However it acknowledges a better term or concept than emerging medicine within a conventional medicine context is likely to be needed.

Such an approach reflects existing regulator and professional guidance, which focuses on complementary and / or unconventional medicine, and does not attempt to cover conventional emerging medicine. It would also reflect distinctions drawn by those practising any or each conventional, unconventional and complementary medicine, including as set out in the Board's consultation paper.

Although the Board's consultation paper refers to off-label prescribing, use of approved medical devices for unapproved indications, innovative and emerging therapies and progressive practice, these practices can occur in a range of scenarios across each of conventional, unconventional and complementary medicine.

The draft guidelines would then be regulating each of conventional medicine on the one hand, and unconventional and complementary medicine on the other, covering their different philosophies, approaches and evidence bases.

For example, they would arguably apply to the "*unavoidable and very common*" off-label prescribing in paediatrics, obstetrics and palliative care identified in the consultation paper. This does not seem desirable where there are already a range of professional expectations and practices around such prescribing in a conventional medicine context.[1]

[1] See for example Council of Australian Therapeutic Advisory Groups, *Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines* (November 2013), available at www.catag.org.au/wp-content/uploads/2012/08/OKA9963-CATAG-Rethinking-Medicines-Decision-Making-final1.pdf

The content of both the draft guidelines and the Board's consultation paper indicate they are focused on complementary and unconventional medicine.

These are the healthcare modalities represented by the various definitions of complementary medicine and healthcare set out in the consultation paper (pages 3 to 4). They would also cover the examples of concerning practices identified on pages 4 to 5 and 8 to 9 of the consultation paper. The range of issues raised on pages 7 to 8 of the consultation paper focus on unconventional medicine.

Residual issues raised can be covered appropriately by separate conventional emerging medicine guidelines. All of this suggests the initial focus can be on refining the draft guidelines to focus on complementary and unconventional medicine.

Separate guidelines consultation and issues arising

In developing guidelines for emerging treatments within a conventional medical context, MIGA sees a need for further work on a suitable guidelines framework and subsequent consultation.

This would need to consider and reflect existing professional standards, guidance and practices around off-label prescription, use of approved medical devices for unapproved indications and other practices with an incomplete or evolving evidence base.

MIGA is also conscious that there is uncertainty and complexity, including from a medico-legal perspective, about the relationship between integrative medicine and the draft guidelines. In its view, part of this uncertainty and complexity arises because of the breadth of the draft guidelines as currently framed, including distinctions between conventional and unconventional medicine.

Noting the definition of integrative medicine in the Board's consultation paper, from a medico-legal perspective it sees issues around integrative medicine outside a complementary medicine context as ones to consider in the context of proposed guidelines around emerging medicine within a conventional medicine context.

It may be that clarity is ultimately best provided through bespoke integrative medicine guidelines. Further consultation is required.

Expectations on doctors not involved in complementary, unconventional or emerging treatments

MIGA is concerned that the expectations in the draft guidelines on doctors not involved in complementary, unconventional and emerging treatment / medicine are unduly onerous, may not be well-understood by them following implementation and may create significant professional and medico-legal uncertainty.

In particular, MIGA is concerned that these expectations may be interpreted in regulatory, disciplinary or civil claims contexts as generalised, positive duties to inquire, advise, warn and / or dissuade on all doctors where their patients are considering or receiving certain complementary, unconventional or emerging treatments or other care.

In terms of the provisions of the draft guidelines

- **Clause 1.1 – expectation to inquire of patients about use of complementary, unconventional and emerging treatments**
    - This could be interpreted as an open-ended obligation to remain up-to-date about a patient's use of complementary and unconventional medicine, irrespective of relevance to current treatment provided by the doctor
    - The proposal in the enclosed annotated version to restrict this expectation to inquire of a patient to "*where relevant to the medical care and treatment you are providing*" would provide some assistance in ensuring a reasonable expectation
    - Even with such a limitation, concerns remain about the scope of when such an inquiry would be required as there would be inevitable uncertainties about the relevance and impact of complementary and unconventional treatments on the other care and treatment a doctor is considering or providing
    - In its view there is no need to set out an additional expectation beyond current professional obligations and expectations

- **Clause 1.2 – expectation to take use of complementary, unconventional and emerging treatments into consideration when determining appropriate management**
    - This expectation is problematic for doctors who lack understanding of the patient's complementary and / or unconventional care and treatment by others
    - The proposal in the enclosed annotated version to consider use of such medication "*within the limits of your own knowledge and expertise*" would provide some assistance in ensuring a reasonable obligation
    - Even with such a limitation, significant uncertainties would remain, particularly how this expectation would interact with existing professional obligations and duties around determining appropriate care and treatment to recommend, and advising patients.
- **Clause 1.4 – expectation to inform patients where relevant there is limited evidence for use of some complementary, unconventional and emerging treatments**
    - This could be interpreted as a proactive, generalised 'duty to warn' a patient around the use of complementary and unconventional medicine in a context where a doctor may have little, if any, understanding of the treatment involved, making it difficult to discharge the duty
    - It could also be perceived as a proactive 'duty to dissuade' a patient in certain circumstances from undergoing or continuing such treatments, which goes well beyond current professional obligations and standards
    - Limiting the expectation by acknowledging that doctors who do not practice in such areas would not be expected to have knowledge of them may be of some, but insufficient, assistance in avoiding unintended or undesirable medico-legal implications
    - Even as a narrowed expectation, practical difficulties and concerns remain for doctors around
        - What they should say beyond a general warning about certain treatments
        - What may happen if a patient, in response to such a warning or other discussion, decides to cease a treatment and suffers an adverse outcome
        - If what conveyed to the patient is subsequently perceived, however wrongly, as being defamatory of another practitioner and actionable at law.
- **Clause 1.5 – advising patients there may be financial implications of choosing complementary, unconventional and emerging treatments**
    - This goes well beyond the existing obligation under clause 3.5 of the Board's *Good Medical Practice* Code to advise a patient there may be additional costs with a referral for investigation or treatment which a patient may wish to clarify
    - Why should a doctor not involved in providing such treatments bear a responsibility or other expectation to inform a patient about possible financial implications?
    - The content of what such advice should be is open to debate.

MIGA recommends the aspects of the draft guidelines relating to expectations on doctors not involved in providing complementary, unconventional and emerging medicine be omitted, with any further consideration being deferred pending assessment of the operation and impact of the draft guidelines. Such additional expectations on a broader group of doctors may ultimately be unnecessary.

Better approaches may involve community education from governments and professional boards around the use of complementary and unconventional medicine and / or standard material from the Board around complementary and unconventional medicine which patients can access.

If these expectations are to remain in some form, they should be refined and narrowed as proposed in the enclosed annotated version of the draft guidelines.

Integration with the Good Medical Practice Code

MIGA believes that more work needs to be done in the draft guidelines to

- Emphasise that the draft guidelines are to be used in conjunction with the Board's *Good Medical Practice* Code, particularly where they involve additional expectations
- Clarify, perhaps through separate guidance and case studies, what a "*financial and commercial conflict of interest*' under clause 3 includes and does not include, particularly where the draft guidelines hint at a potentially broader interpretation of this concept than in the *Good Medical Practice* Code
- Clearer explanation of what is considered acceptable evidence and information levels, given there is a range of views across the profession as to what is considered appropriate evidence, both in nature and level – MIGA sees that the best way to do this, at least for now, may be through drawing the distinction between conventional evidence and other non-conventional evidence or information.

The enclosed annotated version of the draft guidelines provides a range of proposals to address these issues.

Further issues – additional consultation and review

Supporting documents to provide information on scope of the guidelines and examples of complementary and unconventional medicine, as contemplated by the Board's consultation paper, should be developed in consultation with key professional stakeholders, including MIGA.

Given the complexities and challenges associated with the draft guidelines, there is merit in a shorter timeframe than five years for initial review. An appropriate time for initial review may be in three years' time.

If you have any questions or would like to discuss, please contact Timothy Bowen, [redacted] /
[redacted]

Yours sincerely

[redacted]

Timothy Bowen
Senior Solicitor – Advocacy, Claims & Education

[redacted]

Mandy Anderson
CEO & Managing Director

DRAFT Guidelines – MIGA feedback and comments

To be read in conjunction with MIGA's submission to the Board's consultation on the draft guidelines

<date>

Guidelines for registered medical practitioners - Complementary and unconventional medicine ~~and emerging treatments~~

Introduction

These guidelines have been developed by the Medical Board of Australia (the Board) under section 39 of the Health Practitioner Regulation National Law as in force in each state and territory (the National Law). They complement *Good medical practice: A code of conduct for doctors in Australia (Good medical practice)* and provide additional guidance for medical practitioners specific to complementary and unconventional medicine ~~and emerging treatments~~. They should be read in conjunction with *Good medical practice*.

The guidelines aim to inform registered medical practitioners and the community about the Board's expectations of medical practitioners in relation to complementary and unconventional medicine ~~and emerging treatments~~.

The guidelines apply to all medical practitioners including:

- medical practitioners whose patients may use complementary and unconventional medicine ~~and/or emerging treatments~~ but who don't themselves provide these treatments, and
- medical practitioners who provide complementary and unconventional medicine ~~and/or emerging treatments~~.

Definition

Complementary and unconventional medicine ~~and emerging treatments~~ include any assessment, diagnostic technique or procedure, diagnosis, practice,[1] medicine, therapy, ~~or~~ treatment or other care modality that is not usually considered to be part of conventional medicine, whether used in addition to, or instead of, conventional medicine. ~~This includes unconventional use of approved medical devices and therapies~~. It does not include practices within conventional medicine and with a conventional medicine evidence base, including off-label prescription and use of approved medical devices for unapproved uses.

[1] **Practice** means any role, whether remunerated or not, in which he individual uses their skills and knowledge as a health practitioner in their profession. For the purposes of these guidelines, practice is not restricted to the provision of direct clinical care. It also includes using professional knowledge in a direct non-clinical relationship with clients, working in management, administration, education, research, advisory, regulatory or policy development roles, and any other roles that impact on safe, effec ive delivery of services in the profession.

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Commented [TB1]: To reflect the proposal that the use of the term 'emerging treatments' to cover both conventional and non-conventional emerging treatments be abandoned, and separate guidelines created for conventional, emerging treatments - consistent changes have been made at various points below

Commented [TB2]: To cover situations involving healthcare where no treatment is recommended, such as non-intervention, wait and see approaches or other care not involving the things already identified – consistent changes have been made below

Commented [TB3]: Inserted to clarify application of the guidelines to complementary and unconventional medicine, not healthcare modalities within conventional medicine

Background

The use of complementary and unconventional medicine ~~and emerging treatments~~ is increasing and includes a wide range of practices from minimally invasive to major complex interventions.

The medicines and treatments may be used as an alternative to conventional medicine or used in conjunction with conventional medicine. They may be used with or without the knowledge of the patient's other treating practitioners.

Concerns have been expressed in relation to some aspects of these areas of practice. These include patients being offered and/or having treatments or other care:

- for which the safety and efficacy are not known, not proven or lack a conventional evidence base
- which may be unnecessary
- that expose them to serious side-effects, and
- that may result in delayed access to more effective treatment options.

Commented [TB4]: To recognise different approaches in the medical profession as to the nature of evidence or other information to support a treatment - consistent changes have been made at various points below

These treatments are provided by a variety of medical practitioners with a range of qualifications and expertise in the therapy and/or the patient's underlying condition.

Harm may occur directly from the treatment resulting in an adverse outcome or it may be indirect, associated with delays in accessing other treatment. While some treatments may be beneficial, others may have no effect, the benefit may be uncertain, or the effect may be harmful. The harm can be physical, psychological and/or financial.

The lines between research and commercial innovation can be blurred and conflicts of interest can arise if the provider has a financial interest in the product or service being offered. Some treatments are being offered on a commercial basis before full clinical trials have been completed. The requirements for clinical trials don't apply and patients are left without the usual protections.

Tests and treatments are generally funded privately by patients (not covered by Medicare or private health insurance) and can be expensive with uncertain results. Patients may seek complementary and unconventional medicine ~~and emerging treatments~~ because they have serious, chronic conditions and may be vulnerable to exploitation.

It is reasonable for patients consulting registered medical practitioners to expect that the medical practitioner will comply with the professional and ethical standards of conduct and competence expected of medical practitioners and defined by the Board. It is also reasonable for patients to expect that the medical practitioner will take into consideration the existing conventional evidence-based options when providing health care. Medical practitioners must ensure their patients' safety is their priority.

The Board does not wish to stifle innovation or research nor limit patients' right to choose their healthcare. Rather it considers there is a need for additional safeguards to protect patients who seek complementary and unconventional medicine ~~or emerging treatments~~. The Board aims to help registered medical practitioners meet their professional obligations by defining good medical practice.

Who (would) these guidelines apply to?

These guidelines (would) apply to all medical practitioners registered under the National Law. There is guidance for all medical practitioners in relation to complementary and unconventional medicine ~~and emerging treatments~~ as well as specific guidance for medical practitioners who provide complementary and unconventional medicine ~~and/or emerging treatments~~.

How (would) the Board use these guidelines?

Section 41 of the National Law states that an approved registration standard or a code or guideline approved by the Board is admissible in proceedings under this Law or a law of a co-regulatory jurisdiction against a practitioner registered by the Board as evidence of what constitutes appropriate professional conduct or practice for the profession.

These guidelines can be used to assist the Board in its role of protecting the public, by setting and maintaining standards of medical practice. If a medical practitioner's professional conduct varies significantly from this guideline, they should be prepared to explain and justify their decisions and actions. Serious or repeated failure to meet these guidelines may have consequences for a medical practitioner's registration.

Guidance for all registered medical practitioners

This section of the guidelines includes guidance for *all* registered medical practitioners including those doctors whose patients use complementary and unconventional medicine ~~and emerging treatments~~, but who don't themselves provide these treatments.

1. Discussion with patients

The use of complementary and unconventional medicine ~~and emerging treatments~~ is increasing. It is therefore important that all medical practitioners are aware of these areas of practice and how they may affect their patients and impact other treatments, regardless of whether they themselves provide or recommend these treatments. There are resources available for medical practitioners when discussing complementary and unconventional medicine ~~and emerging treatments~~ with their patients.[2]

In fulfilling the expectations on medical practitioners set out in the Board's *Good Medical Practice: A Code of Conduct for Doctors in Australia*,[3] ~~G~~good medical practice for all medical practitioners relating to complementary and unconventional medicine involves:

1.1. Asking your patients, where relevant to the medical care and treatment you are providing, about their use of complementary and unconventional medicine ~~and emerging treatments~~ regardless of whether you provide or recommend these treatments.

1.2. Within the limits of your own knowledge and expertise, ~~T~~taking into consideration your patient's use of complementary and unconventional medicine ~~and emerging treatments~~ when determining appropriate management for your patient.

1.3. ~~Advising~~ Informing your patients of the limits of your knowledge when discussing the benefits and risks of complementary and unconventional medicine ~~and emerging treatments~~ with them. It is not expected that medical practitioners who do not practise in these areas would have knowledge of ~~all~~ these areas of practice.

1.4. Informing your patients, where relevant to the medical care and treatment you are providing, that there is limited reputable scientific evidence for the use, safety, side effects and possible drug interactions of some complementary and unconventional medicine ~~and emerging treatments. There may also be limited information about the safety, side effects and possible drug interactions~~. It is not expected that medical practitioners who do not practise in these areas would have knowledge of these areas of practice.

1.5. ~~Advising~~ Informing patients that they should be aware of the possible financial implications of choosing complementary and unconventional medicine ~~and emerging treatments~~, and they would need to make their own inquiries about these implications.

1.6. Respecting your patient's right to make informed decisions about their health and their right to choose complementary and unconventional medicine ~~and emerging treatments~~.

[2] For example, Na ional Health and Medical Research Council (NHMRC), *Talking with your patients about Complementary Medicine – a Resource for Clinicians*, 2014 and NHMRC, *Stem Cell Treatments – A Quick Guide for Medical Practitioners*, 2013

[3] Available at www.medicalboard.gov.au

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Commented [TB5]: If this aspect of the guidelines is retailed, to clarify their relationship with the Board's Good Medical Practice Code, and confirm that no new expectations are being created, rather these represent how existing obligations are fulfilled

Commented [TB6]: To reduce the chance of creating a proactive general 'duty to inquire' about complementary and unconventional medicine use or consideration in any situation

Commented [TB7]: Ensuring the expectation to consider a patient's use of complementary and unconventional medicine does not create a standard level of expected knowledge or expertise about these healthcare modalities

Commented [TB8]: Using the term 'informing' instead of 'advising' avoids this being seen as an expectation to detail the limits of a doctor's own knowledge about complementary and unconventional medicine, and to ensure consistency with other expectations - a consistent change has been made further below

Commented [TB9]: Similarly to the need to avoid creating a proactive 'duty to inquire', to avoid creating a proactive general 'duty to warn' or 'duty to dissuade' a patient from pursuing or continuing a complementary or unconventional medicine

Commented [TB10]: A drafting amendment to clarify the expectation

Commented [TB11]: Added for clarification and consistency with other expectations

Commented [TB12]: To ensure any expectation is limited to bringing this issue to the patient's attention, and that it is for them to explore this issue further if they wish

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Guidance for registered medical practitioners who provide complementary and unconventional medicine ~~and emerging treatments~~

This section of the guidelines includes guidance for registered medical practitioners who *provide* complementary and unconventional medicine ~~and emerging treatments~~.

In addition to the expectations on medical practitioners set out in the Board's *Good Medical Practice: A Code of Conduct for Doctors in Australia*,[4] good medical practice for medical practi ioners who provide complementary and unconventional medicine involves the following:

2. Knowledge and skills

Safe patient care relies on the medical practitioner having the knowledge and skills in the area of medicine in which they practise. This is both for the treatments being provided and the conditions for which patients seek treatment. This is particularly important where treatments may not be part of conventional ~~standard~~ medical training~~, for alternative uses of conventional treatments and for new and emerging treatments that are continuously evolving~~.

Good medical practice for medical practitioners providing complementary and unconventional medicine ~~and emerging treatments~~ involves:

2.1. Ensuring you have current knowledge and skills for your scope of practice to ensure safe patient care.

2.2. Only offering treatments if you have the appropriate training, expertise and experience in both the treatment or other care and the condition being treated or managed.

2.3. Arranging appropriate and timely specialist advice and referral, when indicated.

2.4. Undertaking ~~necessary~~ appropriate training if you intend to change your scope of practice to include complementary and unconventional medicine~~ and emerging treatments~~.

3. Conflicts of interest

Conflicts of interest can arise when providing complementary and unconventional medicine~~ and emerging treatments~~. This is the case when there are ~~high~~ significant costs involved as well as because of the unproven, experimental and / or commercial aspects of some treatments or other care.

Good medical practice for medical practitioners providing complementary and unconventional medicine ~~and emerging treatments~~ involves:

3.1. Always acting honestly and only in your patient's best interests when providing complementary and unconventional medicine~~ and emerging treatments~~.

3.2. Ensuring that you do not have a financial or commercial conflict of interest that may influence the advice and/or treatment that you give your patients.

4. Informed consent

Patients have a right to know if the care or treatment they are being offered is not considered to be 'conventional medicine'. They have the right to know the evidence and information for its efficacy and safe use.

Medical practitioners proposing complementary and unconventional medicine ~~and emerging treatments~~ must obtain informed consent from their patient. Good medical practice involves:

4.1. Providing your patient with enough information, preferably in written form, for them to make informed decisions about proposed assessments, investigations, ~~and~~ treatments and other care.

4.2. Providing your patient with clear information about:

[4] Available at www.medicalboard.gov.au

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Commented [TB13]: Clarifying that these guidelines are not standalone for complementary and unconventional medicine, but represent additional expectations on doctors providing care and treatment within these fields, given the issues identified in the Board's consultation paper

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Commented [TB14]: To ensure consistency with terminology in the Board's consultation paper, general understandings about what medical training involves and potential misunderstanding around the term 'standard'

Commented [TB15]: What is 'necessary' may be interpreted as a legal obligation, rather than what is necessary in the context, as contemplated by the guidelines and the Board's consultation paper – 'appropriate' better expresses this expectation

Commented [TB16]: The term 'high' may be interpreted unintentionally narrowly

Commented [TB17]: To recognise that material relied on to support a complementary or unconventional medicine modality may not be 'evidence' in a conventional sense

4.2.1. the extent to which the assessment, investigation, ~~and~~ treatment and other care is consistent with conventional medicine and accepted by the medical profession or if it is considered complementary, alternative, ~~and/or~~ experimental and / or otherwise unconventional

4.2.2. the degree to which, and how, diagnostic investigations and tests have ~~been formally evaluated~~conventional evidence for them and what is known about their reliability, safety and risks

4.2.3. the degree to which, and how, the proposed treatments have ~~been formally evaluated or proven~~conventional evidence for them and what is known about their safety, side effects, risks, likely effectiveness and a realistic likelihood of benefit for the proposed use.

4.2.4. the range of possible outcomes, taking into consideration the patient's expectations

4.2.5. the likely number and nature of investigations and treatments required and the costs involved

4.2.6. other treatment and care options (including conventional treatments), their risks, likely benefits and efficacy based on the best current available conventional evidence and other information.

4.3. Ensuring that patients who may be vulnerable because of the serious and/or chronic nature of their condition and/or because conventional medicine has not been effective, are not exploited or unduly influenced.

4.4. Ensuring that information provided about complementary and unconventional medicine ~~and emerging treatments~~ does not create unrealistic patient expectations.

4.5. Informing your patient of their right to seek a second opinion regarding their treatment and options from another independent medical practitioner when proposing treatments that are complementary, ~~,~~ or unconventional ~~or emerging~~.

5. Assessment and diagnosis

Some medical practitioners providing complementary and unconventional medicine ~~and emerging treatments~~ use diagnostic methods and tests that are not considered to be part of conventional medicine.

Good medical practice in the assessment and diagnosis of patients involves:

5.1. Ensuring the assessment and examination of your patient is comprehensive and considers all relevant information.

5.2. Ensuring that any recommendation for investigations or tests is based on the best current available evidence and information, including conventional evidence.

5.3. Performing and/or ordering any generally recognised diagnostic investigations and tests that would be reasonably expected, including in conventional medicine, for appropriate patient care.

5.4. Ensuring you consider appropriate differential diagnoses for each individual patient.

5.5. Ensuring that your diagnosis is supported by sound clinical judgement and informed by the best current available information, including conventional evidence.

6. Treatment

Providing a treatment in the absence of an identified therapeutic need can unnecessarily expose a patient to risk of harm. Patient harm can also result if the provision of complementary and unconventional medicine ~~and emerging treatments~~ results in delays in accessing more appropriate treatments or care for the patient.

Good medical practice when providing complementary and unconventional medicine and emerging medicine involves:

Commented [TB18]: To clarify the scope of the guidelines as applying to complementary and unconventional medicine, not emerging, developing or evolving conventional medicine with an evidence base

Commented [TB19]: To use consistent language with other parts of the guidelines, and to recognise different approaches within the medical profession as to what constitutes appropriate evaluation, and draw a distinction from conventional medicine and its evidence base

Commented [TB20]: To ensure what a certain investigation or treatment involves is outlined

Commented [TB21]: To ensure clarity around what evidence a recommendation should be based on, which would include conventional evidence – consistent changes have been made below

6.1. Ensuring that you do not discourage the use of conventional treatment or care options when this is clinically appropriate.

6.2. Only recommending treatments or other care where there is an identified therapeutic need, quality and safety can be reasonably assured and that have a reasonable expectation of clinical efficacy and benefit.

6.3. Ensuring that the provision of any complementary and unconventional medicine ~~and emerging treatments~~ comply with any relevant Therapeutic Goods Administration requirements.[5]

7. Patient management

Good patient care is supported when there is good communication with, and coordination of care between, all treating practitioners. When the provider of complementary and unconventional medicine ~~or emerging treatments~~ does not have a role in the patient's regular or ongoing medical care it is important to ensure that there are measures in place for the coordination of care. Follow-up of patients is particularly important where treatment or care is provided that is experimental and/or part of a formal research clinical trial - both for the patient's wellbeing and for the contribution to medical knowledge.

Good medical practice for the care of your patients to whom you are providing complementary and unconventional medicine ~~and emerging treatments~~ involves:

7.1. Documenting information including the diagnosis, treatment, efficacy, side-effects and known risks of interactions in the patient's medical record.

7.2. Ensuring that you take responsibility for appropriate monitoring and follow-up of patients to whom you are providing complementary and unconventional ~~and emerging~~ treatments and other care. This is even more important when you are providing unproven or experimental treatments.

7.3. Encouraging your patients to tell their other health practitioners about their use of complementary and unconventional medicine ~~and emerging treatments~~.

7.4. With permission from your patient, communicating with their other treating doctors (if applicable). You should inform other treating medical practitioners of your care and treatment, including ~~the~~ investigations, the diagnoses, treatments, known risks of interactions and patient progress.

7.5. Reporting adverse events to the relevant authority to assist safety monitoring.

8. Advertising

Some patients who seek complementary and unconventional medicine ~~or emerging treatments~~ may be vulnerable to advertising that may lead to unreasonable expectations. The advertising provisions in Section 133 of the National Law include that a regulated health service must not be advertised in a way that is false, misleading or deceptive or creates an unreasonable expectation of beneficial treatment. Further provisions in Sections 115, 117, 118 and 119 of the National Law limit what claims can be made around qualifications and expertise.

Good medical practice when advertising complementary and unconventional medicine ~~and emerging treatments~~ involves:

8.1. Ensuring that all advertising material, including practice and practitioner websites and your contributions to other material, complies with the Board's *Guidelines for advertising of regulated health services*, including the advertising requirements of section 133 of the National

Commented [TB22]: Inserted to avoid an uncertainties around what 'experimental' medicine includes, as different doctors would have different thresholds for what is experimental and what is not

Commented [TB23]: To clarify the obligation is limited to the doctor's role in the patient's care and treatment

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Commented [TB24]: The National Law title protection provisions can also be relevant in this context, particularly around use of specialist titles or claims of specialty expertise

Commented [TB25]: To avoid uncertainties and unintentionally narrow readings around what advertising material includes

[5] For example, Therapeu ic Goods Administration (TGA), *Australian regulatory guidelines for complementary medicines*, 2018 and TGA, *Australian regulatory guidelines for biologicals*, 2017.

Law, of the Therapeutic Goods Administration and the Therapeutic Goods Advertising Code and of the Australian Competition and Consumer Commission.[6]

8.2. Ensuring that you do not create the impression that you are a specialist in an area of practice that is not a recognised specialty under the National Law.[7]

8.3. Ensuring advertising material does not create unreasonable patient expectations of the benefits of the complementary and unconventional medicine ~~and emerging treatments~~.

9. Research and advancing knowledge

Innovation and research in new treatments and modes of care is necessary to improve health outcomes. However, there must be protections in place for patients. Efforts to make advancements in treatments and care should not jeopardise patient safety.

Good medical practice in the research and advancement of complementary and unconventional medicine ~~and emerging treatments~~ involves:

9.1. Ensuring that research involving complementary and unconventional medicine ~~and emerging treatments~~ complies with the National Health and Medical Research Council's (NHMRC) current '*Australian Code for the Responsible Conduct of Research*' and *'National Statement on Ethical Conduct in Human Research'*.

9.2. Where tests, ~~and~~ treatments and other care are experimental or otherwise involve further research being undertaken, being prepared to contribute to and share new knowledge with the profession in appropriate ways.

Acknowledgements

The Board acknowledges the following organisations' codes and guidelines, which helped inform the development of the Board's draft guidelines:

- Medical Council of New South Wales (2015) *Complementary health care policy*
- Medical Council of New Zealand (2011) *Statement on complementary and alternative medicine*

Implementation date and review

These guidelines will take effect on <date>.

The Board will review these guidelines at least every five years.

Commented [TB26]: Needs more guidance – refer to title provisions and recent clarifications

Commented [TB27]: There is merit in a shorter timeframe for the initial review, perhaps 3 years, given the complexities and challenges involved

[6] For more information on these requirements, see the advertising resources available at www.ahpra.gov.au.

[7] For a list of medical specialties and specialty fields, see www.medicalboard.gov.au.

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