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Draft guidelines for registered medical practitioners – complementary and unconventional medicine and emerging treatments

AMA submission to the Medical Board of Australia

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Introduction

The AMA is pleased to respond to the Medical Board of Australia's discussion paper on proposed guidelines for medical practitioners on the use of complementary and unconventional medicine and emerging treatments.

The AMA agrees with the Board's concerns and supports its proposal to issue additional guidance to clarify 'good medical practice', which reflects clinically appropriate, ethical and professional practice.

Overall, the draft guidelines are clear and comprehensive. However, the AMA has some concerns regarding guideline implications for medical practitioners.

Communication with medical practitioners

The target audience of this document must be clearly articulated in the Medical Board's communication with medical practitioners. By looking at the title alone, the AMA is concerned that some medical practitioners may not think the guideline applies to them if they do not practise complementary medicine.

Off-label prescribing

Off-label prescribing is different from complementary and unconventional medicine in that it can be evidence-based and clinically appropriate in many circumstances, such as in palliative care. In some circumstances a medicine may not have Therapeutic Goods Administration (TGA) approval because it is not economically viable for the sponsor to apply, not because it is ineffective or has

no evidence-base. Off-label prescribing is common in particular settings if it is the best and only treatment for a patient[1].

Off-label prescribing should not exist within the same guidelines as complementary and unconventional medicine. The AMA is concerned that doctors may unnecessarily come under the scrutiny of the Medical Board for recommending medicine that is evidence-based. Confusion may also arise throughout the profession regarding the use of off-label prescribing, which may have unintended consequences on patient health.

The AMA recognises that there are clinical, safety, ethical, medico-legal and financial issues related to off-label use that warrant separate guidance from complementary and unconventional medicine. The AMA's policy is that: it should only be considered when other options are unavailable, exhausted, not tolerated or unsuitable; the patient/carer must be involved in the decision-making; and outcomes, effectiveness and adverse events should be monitored and reported to facilitate evidence-based decisions. The treating doctor should obtain informed consent from the patient or their Substitute Decision Maker, where the potential risks and benefits are discussed before deciding to use the off-label therapeutic.

The AMA supports the Council of Australian Therapeutic Advisory Group's *Rethinking Medicines Decision-making in Australian Hospitals: guiding principles for the quality use of off-label medicines* as an example of a separate guideline. This separate guideline should also be open to consultation with stakeholders.

A medical practitioner's duty of care

The AMA highlights the importance of clearly stating the Medical Board's expectations around a medical practitioner's involvement with complementary and unconventional medicine. The Board should include a statement that medical practitioners do not have to provide treatments that they consider are clinically inappropriate or of no medical benefit. Also, that it is unethical and unprofessional to provide a treatment in the absence of an identified therapeutic need. Medical practitioners have a duty of care to their patient and it should not be expected that they can advise on every unconventional and emerging medicine.

Comments – specific sections of the guideline

Some comments on aspects of the draft guidelines are provided below.

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The AMA supports the definition of complementary and unconventional medicine and emerging treatments. However, it may be worthwhile to also explain what is meant by 'conventional medicine'. Is it evidence-based medicine or is it medicine accepted by the majority of peers?

[1] Council of Australian Therapeutic Advisory Group (2013) *Rethinking Medicines Decision-making in Australian Hospitals: guiding principles for the quality use of off-label medicines*.

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Guidance for registered medical practitioners providing complementary and unconventional medicine and emerging treatments – It would be helpful to introduce this part of the guidelines with some key principles to which doctors should adhere when recommending or providing any diagnostic procedure or therapeutic treatment to patients. For example, only recommending treatments and therapies that are in the patient's best interests, facilitating informed decision-making, respecting patients' right to make their own health care decisions, informing patients of any interest in the treatment or therapy recommended, etc.

Paragraph 1.1 – It is important that discussions with patients are undertaken in a way that is respectful and not dismissive, otherwise there is a risk the patient may not disclose their use of complementary and unconventional medicine and emerging treatments. A patient's cultural background may also affect their beliefs about non-conventional medicine.

Paragraph 1.4 – It may be more accurate to say 'that there is limited reputable scientific evidence for the use of most (rather than some) complementary and unconventional medicine.

Paragraph 1.6 – It is important for doctors to explore why a patient chooses to use complementary treatments, particularly if it is in place of conventional medicine. It may be that the patient has negative experiences with conventional medicine and the doctor could discuss this with them. It could also be that the patient has been misinformed about the benefits of complementary therapies.

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Section 3 – In accordance with *Good Medical Practice* (8.11.3), a line should be added that 'good medical practice involves informing patients when you have an interest that could affect, or could be perceived to affect, patient care'. That is, there may be other conflicts of interest – not just commercial or financial – which should be disclosed to the patient.

Section 4 – This section should also address consent on behalf of a person with limited or impaired decision-making capacity, for example, a child or adult who lacks decision-making capacity.

It should be made clear under what circumstances it may be appropriate for a doctor to recommend complementary/unconventional/emerging treatments, for example, they should only be recommended where conventional treatment has been exhausted, not tolerated, unsuitable, etc.

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Section 5 – Do medical practitioners have a have a duty of care to use conventional medicine for diagnosis? Unless for some reason it doesn't exist? The requirements in 5.1-5.5 seem to be consistent with using conventional assessment and diagnostic procedures.

There are additional risks inherent in using diagnostic methods and tests that are not considered part of conventional medicine because they are also unlikely to be nationally accredited diagnostic services that are required to meet minimum standards of quality and safety.

Section 6 – As well as risk of harm to patients, it is also unethical and unprofessional to provide a treatment in the absence of an identified therapeutic need.

Paragraph 6. 1 – Should a doctor have a duty of care to recommend conventional treatments first? Or not offer experimental treatments unless conventional treatment has not worked? Unless it is part of an approved research trial which is already well-regulated.

Paragraph 6.2 – This description – 'has a reasonable expectation of clinical efficacy and benefit' – suggests that the treatment fits within the definition of a 'conventional' treatment.

The AMA would be happy to expand on any of these issues or comments.

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