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Public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.

1. *Do you agree with the proposed term 'complementary and unconventional medicine and emerging treatments'? If not, what term should be used and how should it be defined?*

   The term 'unconventional medicine' conveys a sense that practices are uncommon or irregular. This has no place alongside complementary medicine and emerging treatments, which are commonly available to and sought by consumers in Australia.

   'Complementary medicine' is a term defined by the AMA in a way that is understood by most health practitioners and consumers. It is an appropriate term for inclusion in this discussion, in that it covers approaches that are a complement to conventional medicine.

   'Emerging treatments' are those that are in the process of being trialled for or assessed as conventional practice. As such, it is a term that can perhaps be appropriately used in this discussion, although it falls within conventional practice, given that all conventional practices begin from a position of emerging.

2. *Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments – 'any assessment, diagnostic technique or procedure, diagnosis, practice,[4] medicine, therapy or treatment 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.' If not, how should it be defined?*

   In principle it makes sense for the definitions to be guided by those who practice in these areas. Notwithstanding that, there are two important issues.

   Emerging treatments include those which are *supported by the literature* but have yet to become standard practice; off-label use of approved drugs for purposes which are *supported by the literature*; treatments for which anecdotal evidence is at a level which *warrants open-label trial*. To define these as falling outside conventional medicine is to suggest that it is unconventional for doctors to make decisions based on available evidence. Just how problematic this definition is becomes evident when the consultation paper includes research, policy making and other non-clinical work as being part of medical practice. How is the practice of medicine to develop if emerging therapies are not considered part of normal practice?

The notion of conventional medicine implies a single accepted concept of what is and is not conventional. What has not been considered in the consultation paper is the cultural bias inherent in assuming a singular understanding of conventional within a multicultural society.

3. *Do you agree with the nature and extent of the issues identified in relation to medical practitioners who provide 'complementary and unconventional medicine and emerging treatments'?*

    - The words *generally accepted* appear to refer to acceptance by the MBA and not to acceptance by consumers, as evidenced by the consultation paper reference to two thirds of consumers using complementary medicines. Two thirds could reasonably be taken to indicate general acceptance by Australians.

    - The issue of *commercial innovation* applies also to research and prescribing practices in conventional medicine. It should be discussed in relation to all medical practice, not only complementary medicine and emerging therapies.

    - Where *regulated health professions* exist, these modalities should be considered to fall within conventional practice, as evidenced by the acceptance from regulatory bodies.

    - The *tribunal decisions* are evidence that the current system is operating well. They are not evidence that further regulation is required.

    - The information supplied about *current regulation and guidance* suggests that the current system is adequate. It does not imply a need for change, except in those situations where change is needed to better manage all medical practice, including conventional.

    - The issue of oversight appears to pay no attention to the question of who will assess the practice of clinicians who have education, training and clinical experience in complementary or emerging therapies. Current regulation presumably takes competence into account when appointing *review committees* and this same approach should apply to complementary and emerging practices.

    - Referring to *specialists for care of people with complex conditions* is impractical for those conditions where no specialty accepts responsibility for care. In fact, the more complex a condition, the less likely it is to fall neatly into a specialty. This difficulty becomes more pronounced when a condition is rare or poorly understood. General practitioners who develop expertise in these conditions provide a desperately needed service. For one condition alone, ME/CFS (Myalgic Encephalomyelitis), there are up to 250,000 Australians who do not fall under the responsibility of a specialty. They are best served by those doctors who educate themselves to expert status, regardless of whether they are a specialist or general practitioner.

    - The issue of limiting access for consumers to *treatments based on early research data* creates a problem for consumers whose condition does not attract adequate research funding. The only evidence may be early or limited evidence. When there is no

prospect of that changing due to a lack of research funding, many patients will have either no treatment at all or be restricted to emerging treatments.

- Where safety and efficacy are unknown, that does not mean that the therapy is necessarily unsafe or unhelpful. Research funding is necessary if *confirmation of safety and efficacy* is required. The consultation paper uses Lyme-like illness as a repeated example of emerging or unconfirmed tests and therapies. Until adequate research funding is made available, the status of the tests and therapies will not change. Patients will have either no help at all or help from emerging therapies and complementary medicine. The fault is not with the patients or their clinicians, but with the lack of research funding.

4. *Are there other concerns with the practice of 'complementary and unconventional medicine and emerging treatments' by medical practitioners that the Board has not identified?*

    - The years it takes for emerging therapies to translate from best practice to usual practice.

    - The years that pass between reviews of clinical guidelines or Cochrane reviews of specific practices that bring emerging therapies into mainstream guidance.

    - Complex presentations where usual practice presents a high risk of harm, necessitating individualised medicine based on evidence other than available clinical guidelines.

    - Undergraduate, postgraduate and professional development training in the assessment of evidence within the literature and its application to individual patients.

    - The lack of NHMRC-endorsed clinical guidelines for conditions where there has been inadequate research funding to acquire level 1 or 2 evidence. For patients with these conditions, their only medical care comes from doctors who have chosen to study the available literature and thus have relevant expertise.

    - The preference of research funders to place further funds in areas that have already been heavily researched, thus relegating many consumers to medical care that is rightly described as emerging rather than evidence-based.

    - The lack of adequate research funding for therapies, whether complementary or otherwise, that consumers report as helpful. The consumer voice has yet to be respected in the translational research that can shift anecdotal evidence into endorsed practice.

    - There is political impetus in Australia for innovation in medicine, including more rapid translation from new or emerging practice to usual practice. The MBA guidelines need to recognise and respond to this trend.

5. *Are safeguards needed for patients who seek 'complementary and unconventional medicine and emerging treatments'?*

   The literature contains many examples of failed safeguards in *conventional medicine*. There is no reason for complementary or emerging therapies to be treated any differently in terms of safeguards, which are currently in need of attention for *all* medical practice.

6. *Is there other evidence and data available that could help inform the Board's proposals?*

   The Board could be well served by commissioning research into the likely impact on consumers of separating complementary and emerging therapies from other styles of medical practice. Of particular concern is the risk of harm for consumers who may *avoid medical supervision* when they use therapies that might be construed as falling under the proposed Option 2.

7. *Is the current regulation (i.e. the Board's Good medical practice) of medical practitioners who provide complementary and unconventional medicine and emerging treatments (option one) adequate to address the issues identified and protect patients?*

   The current regulation does not adequately address prevention of harm from *conventional* medical practice. This is a serious concern. Addressing conventional medical practice should occur in the context of addressing all medical practice equally within the *current* guidelines.

8. *Would guidelines for medical practitioners, issued by the Medical Board (option two) address the issues identified in this area of medicine?*

   All medical practice must address effectiveness and risk of harm, whether a practice is considered to be conventional, complementary or an emerging therapy. The issues identified must therefore be addressed in the *current* guidelines.

9. *The Board seeks feedback on the draft guidelines (option two) – are there elements of the draft guidelines that should be amended? Is there additional guidance that should be included?*

   Amendments and additional guidance should be included in the *current* approved code of conduct if the current code is not adequate. All medical practice should be covered by the same guidelines.

10. *Are there other options for addressing the concerns that the Board has not identified?*

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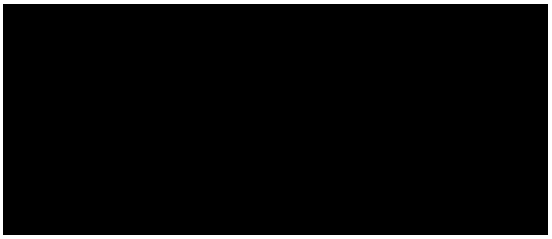
11. *Which option do you think best addresses the issues identified in relation to medical practitioners who provide complementary and unconventional medicine and emerging treatments?*

- *Option one – Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.*
- *Option 2 - Strengthen current guidance for medical practitioners who provide complementary and unconventional medicine and emerging treatments through practice-specific guidelines that clearly articulate the Board's expectations of all medical practitioners and supplement the Board's Good medical practice: A code of conduct for doctors in Australia.*
- *Other – please specify.*

Option 1 best addresses the issues.
The consultation paper says, "...the Board is not proposing significant changes to the current standards of ethical or professional conduct expected of all registered medical professionals." Given that all guidance should apply equally to *all* medical practice, Option 1 makes sense.



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