THE UNIVERSITY OF SYDNEY

29 June 2019

Executive Officer, Medical, AHPRA
GPO Box 9958
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To whom it may concern,

Re: "Public Consultation on clearer regulation of medical practitioners on complementary and unconventional medicine and emerging treatments"

We would like to thank the Medical Board of Australia for the opportunity to provide feedback on the proposed guidelines for the regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.

The Board has identified two options for the regulation going forward—to maintain the current general guidance, or alternatively to strengthen guidance through the introduction of practice-specific guidelines. We support the second option, as outlined in the proposed guidelines, which we believe are necessary to encourage safe practice, and to ensure that appropriate safeguards are put in place to protect patients.

Responses to questions raised by the Board:

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 proposed term has certain strengths, but also several weaknesses that should be addressed in any ongoing refinement.

A strength of the term is that it covers an extensive range of unconventional medical treatments. This will hopefully ensure that, when finalised, the practice-specific guidelines do not exclude any major areas of clinical practice that involve the use of treatments that fall outside the scope of acceptable standard practice.

However, we would make two suggestions:

First, the term "intervention" should be used instead of "treatment" as many things that are offered as so-called "treatments" have not yet been proven to be effective and may not actually "treat" anything.

Second, the terms "complementary" and "emerging" should be removed from the title. We have two reasons for suggesting this:

Obscuring important differences

First, including the two terms together in the same phrase could make it too easy to conflate "complementary" medicines (such as herbal medicines or homeopathy) with "unconventional" and "emerging" treatments that are part of conventional medical practice (such as the use of autologous stem cell therapies for multiple sclerosis). This may, in turn, call into question the legitimacy of "emerging" treatments, for which there is *currently* limited evidence of benefit, but which might, in time and through clinical trials—be shown to be safe and effective. This differentiates them from many "complementary" medicines, for which there has been no evidence of benefit over a prolonged period of time, such as for example, homeopathy for anxiety disorders, acupuncture for tinnitus or aromatherapy treatment for hypotension—sometimes despite repeated efforts to demonstrate efficacy.

Placing the two terms together also potentially obscures differences in the level of training and professional expertise of medical practitioners offering complementary treatments versus those offering emerging treatments. Take for example, an osteopath offering craniosacral therapy for the treatment of back pain versus a haematologist prescribing a medicine "off-label" as part of a cancer treatment regime.

Obscuring important similarities

Second (and somewhat paradoxically) using two labels ("complementary" and "emerging") side-by-side could lead people to believe that there are no important *similarities* between them. For example, from a patient safety point of view, there is little difference between a complementary medicine practitioner recommending an intensive regime of intravenous vitamins for cancer and a medically trained sports medicine doctor recommending stem cell "therapy" for dementia. In both cases, the practices are unproven and potentially dangerous, and it is problematic—from a regulatory point of view—for them to be treated as separate.

We would, therefore, suggest that the title of the new regulation be simply **"unconventional interventions"** and be organised according to a matrix along the following lines:

	Interventions that have been shown to be ineffective and/or unsafe, or for which there is no scientific rationale	Interventions that might prove to be effective (and safe) but have not yet been shown to be so
High risk unconventional interventions	Interventions offered by medical practitioners **e.g. Unproven "add ons" for patients undergoing in vitro fertilisation**	Interventions offered by medical practitioners **e.g, autologous stem cell interventions for multiple sclerosis or osteoarthritis**

	Interventions offered by CAM practitioners **e.g. high dose intravenous vitamins for cancer**	Interventions offered by CAM practitioners **e.g. high dose intravenous vitamins for fibromyalgia**
Low risk unconventional interventions	Interventions offered by medical practitioners **e.g. robotic surgery vs. more traditional modes of surgery** Interventions offered by CAM practitioners **e.g. homeopathy for the treatment of hypotension**	Interventions offered by medical practitioners **e.g. off-label prescribing of medicines that have been tested in adults but not in teenagers** Interventions offered by CAM practitioners **e.g. acupuncture as part of an integrative medicine regime for tinnitus**

Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments — any assessment, diagnostic technique or procedure, diagnosis, practice, 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.

As per our response to Question 1, we recommend referring to the above simply as "unconventional interventions". Then the definition works well, although there would then be a need to define "unconventional" in order to avoid circularity.

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

The Board has comprehensively addressed the nature and extent of the issues related to medical practitioners use of complementary, unconventional medicines and emerging treatments. That said, we would like to draw attention to several key issues that were not covered in the consultation paper or proposed guidelines.

Other areas of practice:

Other notable areas of practice in which unconventional interventions treatments are frequently used include:

- *Assisted Reproductive Technology (ART):* Adjuncts to traditional IVF therapy that are *not* currently supported by a robust evidence base include endometrial scratching, intracytoplasmic sperm injection for non-male factor infertility, and preimplantation genetic screening. Despite the lack of evidence

for these procedures, Australian IVF specialists are offering these procedures at a considerable cost for patients, with for example, IVF with ICSI costing over $1000 AU dollars more than traditional IVF.

- *Surgical techniques and devices:* Many novel surgical techniques and medical devices are introduced into clinical practice without being subjected to comprehensive clinical oversight. The introduction and rapid diffusion of transvaginal mesh for the treatment of pelvic organ prolapse reveals how dangerous this practice can be. Furthermore, novel surgical procedures are often significantly more expensive than existing techniques. For example, robotic assisted surgery is rapidly diffusing despite its high cost and lack of evidence for its benefit over laparoscopic surgery.

Response to the Draft Guidelines

The draft guidelines are clear and comprehensive. That said, they would benefit from additional clarification in certain sections:

- *Definition and background:* add a brief explanation of the terminology used (as per our suggested explanation above)

- *Section 1. Discussion with patients*: While the NHMRC guides on *Talking with your patients about Complementary Medicine – A Resource for Clinician* and *Stem Cell Treatments— A quick guide for Medical Practitioners* are helpful, they are tailed towards complementary or alternative treatments. Therefore, these guidelines fail to address many of the issues that arise in medical practitioners' use of unconventional interventions. While this may be outside the scope of this consultation, it would be important to develop a new guide that clearly defines the full range of practices (complementary and otherwise) that fall under the broad heading of "unconventional interventions"

- *Section 2. Knowledge and skills:* Define and provide examples of "appropriate training, expertise and experience". What counts as "appropriate" training? Is it limited to courses that count as CME training, or courses run by reputable medical institutes? For example, does a Professional Certificate in Clinical Aromatherapy from Nature Care College suffice as evidence of appropriate training? Do practitioners have to have reached a certain amount of practice hours prior to using novel technique with patients? Further clarification is needed in this section.

- *Section 3. Conflicts of interest:* Consider making specific reference to non-financial conflicts of interest and requiring the declaration of non-financial COI. Research has shown that medical practitioners frequently make the decision to use innovative treatments (which come under the Board's definition of "emerging treatments") in the absence of evidence, and in response to both financial and social pressures.

- *Section 4. Informed Consent*: This an important section, and it is worth ensuring that practitioners are given clear guidance regarding how to obtain informed consent from their patients when it comes to the use of unconventional interventions. Therefore, we suggest a brief guide may be useful to inform these discussions with patients.

- *Section 5. Assessment and diagnosis:* Provide illustrative examples in the full practice guidelines.

- *Section 7. Patient management:* Further clarity is required regarding the reporting of adverse events and of the consequences of failing to report adverse events for medical practitioners. Timely (and arguably, *mandatory*) reporting of adverse events could ensure that problems with unconventional interventions are detected early, so as to prevent additional patients from being harmed.

- *Section 8. Advertising:* The consequences of continuing to advertise unconventional interventions in a deliberately false and misleading way should be further described in the guidelines. If there is no enforcement of penalties for false, deceptive or misleading advertising, then this practice will not be successfully deterred.

We commend the Board for their work thus far on these important and much needed guidelines and thank you for the opportunity to provide input. We are currently conducting research in this area (see publications below) and would be happy to speak further about any of the above suggestions should that be of value.

Sincerely,

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