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RACP Submission: Medical Board of Australia (the Board) on options for clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments

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About The Royal Australasian College of Physicians (RACP)

The RACP trains, educates and advocates on behalf of over 17,000 physicians and 8,000 trainee physicians, across Australia and New Zealand. The College represents a broad range of medical specialties including general medicine, paediatrics and child health, cardiology, respiratory medicine, neurology, oncology, public health medicine, occupational and environmental medicine, palliative medicine, sexual health medicine, rehabilitation medicine, geriatric medicine, and addiction medicine. Beyond the drive for medical excellence, the RACP is committed to developing health and social policies which bring vital improvements to the wellbeing of patients.

Introduction

The Royal Australasian College of Physicians (RACP) welcomes the opportunity to provide feedback to the Medical Board of Australia (the Board) on options for clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.

The practice of medicine has become increasingly complex with the advent of new forms of treatments. The RACP supports good practice for complementary and unconventional medicine and emerging treatments to protect patients from unnecessary treatments and harm. We believe this is the professional and ethical duty of every practicing medical doctor.

This submission provides RACP's responses to the Board's consultation questions.

Preferred option to address the issues

Of the two options proposed by the Board, the RACP supports Option 2 - strengthening 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.

The RACP holds the view that all medical practitioners should perform their duties within the scope of their practice and use treatments and diagnostic tests which are supported by evidence. Patients' needs must be at the centre of medical practitioners' care.

With respect to the draft guidelines for registered medical practitioners on complementary and unconventional medicine and emerging treatments, the RACP supports it and considers it well crafted. We note that on point 2.4, the draft guideline makes mention of 'undertaking necessary training'. We would ask the Board to specify what is considered 'appropriate necessary training' in this case.

As far as these types of treatment are concerned, the proof or validity of such therapies is one of the current challenges. A such, the RACP recommends that further guidance regarding the communication of issues surrounding the proof or validity of a therapy be provided in the guidelines. We recommend the following information be provided in the guidelines:

- Proof may be contested by different medical systems such as conventional, unconventional and traditional medicine, which have different concepts of disease, treatment, evidence and proof.
- Proof within conventional medical practice generally follows from proof of concept to different phases of clinical trials – Phase 0 to Phase 4/5.
- The point at which it is believed that there is 'sufficient' evidence/proof to justify a medicine/therapy being prescribed, sold and reimbursed may also differ depending upon the body or person making the judgement.

Based on this discussion, the Board can mandate that where insufficient proof exists, treatments should not be advertised and offered outside of clinical trials and that when patients are enrolled in clinical trials or registries of such unproven therapies, they should not be required to pay for them, i.e. the Board should prohibit 'pay-to-participate' trials.

We would like to provide the following feedback specifically on the section for 'Guidance for all registered medical practitioners':

1. Discussion with patients	We recommend splitting point 1.4 into two parts: 1.4 Informing your patient when there is limited reputable scientific evidence for diagnoses, investigations or treatments which would be considered controversial or departs from the generally accepted standard of medical care. 1.5 Informing your patient when there is limited reputable scientific evidence for a complementary or unconventional treatment's safety, side effects and possible drug interactions.
6. Treatment	We recommend the word 'disparage' be added in point 6.1. 6.1. Ensuring that you do not discourage *or* *disparage* the use of conventional treatment options when this is clinically appropriate.
8. Advertising	This section can be further improved by including an additional point. 8.3 Ensuring that you do not represent yourself as a specialist in an area of practice without holding a recognised qualification ratified by AHPRA.
9. Research and Advancing knowledge	This section can be further strengthened by including additional points: 9.1. The use of Complementary and Alternative Medicines and Therapies (CAM) outside of approved clinical trials should not be represented as 'research'. 9.2 The use of unproven/unvalidated therapies and practices outside of approved clinical trials should not be represented as research. 9.3. Human research should only be conducted after review by and full approval of , a Human Research Ethics Committee ratified by the NHMRC. Furthermore, use of complementary or unconventional therapies should not be represented as 'research' unless this formal process has been undertaken. 9.4. All practitioners have a moral obligation to generate and share data and knowledge regarding the safety, efficacy, effectiveness and cost-effectiveness of new therapies and practices. 9.6. All research should be conducted by in accordance 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'.* 9.7. Where patients are enrolled in clinical trials or registries of unproven therapies, they should not pay to participate in these trials or pay for the therapy or practice under study

Proposed term and definition

The RACP is cognisant of the fact that to date there is no universal definition of treatments and therapies outside of conventional medicine. To regulate medical practitioners who provide complementary and unconventional medicine and emerging treatments, we are of the view that the Board needs to be able to clearly articulate what comprises conventional, unconventional and complementary medicine.

In this regard we note that there is already a suite of existing definitions of complementary and alternative medicines adopted by other bodies internationally and that the addition of a new definition can potentially confuse and conflate current issues in these areas of practice.

With regard to the definition proposed by the Board, the RACP is also concerned about the use of the word 'emerging' treatments in the Board's consultation paper and guidelines. We feel that this word has a connotation of a new practice or therapy that eventually becomes part of standard practice and that medical practitioners will adopt in future. In our view, 'unproven' and 'unvalidated' are better words of choice and are easier to distinguish from therapy that is proven and validated.

Safeguards needed for patients

Given the nature and extent of the issues in these areas of practice, the RACP is supportive of safeguards being put in place to protect patients and minimise charging for unproven and unsafe practices.

Patients who are seeking complementary and unconventional medicine and emerging treatments are often more vulnerable due to the failure of conventional medicine to treat their health conditions. In the case of children and adolescents, there should be special conditions imposed, in particular for those with complex needs. The Board should consider imposing direct supervision of unconventional medical treatments for children and adolescents or complete banning of some of unconventional treatments for children and adolescents.

The rapid development of these areas of practice underlines the need for more research so an evidence base for the safety and effectiveness of these practices can be established.

Other comments

We also note that traditional medicine is largely excluded from the proposed definition. The sole reference included in the discussion paper is the reference 7 – *the World Health Organisation's guidelines on developing consumer information on proper use of traditional, complementary and alternative medicine*. It is recommended that the Board make a clarifying statement as to what it understands by traditional medicine, and how this relates to complementary and alternative medicine.

Article 24 of the United Nations (UN) Declaration on the Rights of Indigenous peoples, which Australia has endorsed, sets out:

1. Indigenous peoples have the right to their traditional medicines and to maintain their health practices, including the conservation of their vital medicinal plants, animals and minerals. Indigenous individuals also have the right to access, without any discrimination, to all social and health services[1].

The New Zealand Ministry of Health has a voluntary standard in relation to traditional Māori medicine (Rongoā) named Tikanga ā-Rongoā [2]. According to their website, this standard is to articulate clear requirements for both registered and unregistered providers and encourage quality Rongoā care and the ongoing development of the Rongoā workforce. There is also guidance provided in separate toolkits on how these requirements can be realised.

[1] Australian Human Rights Commission: United Nations Declaration on the Rights of Indigenous Peoples. https://www.humanrights.gov.au/our-work/un-declaration-rights-indigenous-peoples-1
[2] New Zealand Ministry of Health. Tikanga a Rongoa. 2014. https://www.health.govt.nz/publication/tikanga-rongoa