

**Australasian College of Nutritional and Environmental Medicine**

**SUBMISSION TO MEDICAL BOARD OF AUSTRALIA**

**PUBLIC CONSULTATION ON CLEARER REGULATION OF MEDICAL PRACTITIONERS WHO PROVIDE COMPLEMENTARY AND UNCONVENTIONAL MEDICINE AND EMERGING TREATMENTS.**

**Executive summary**

The Australasian College of Nutritional and Environmental Medicine (ACNEM) represents a large body of doctors and health care professionals of whom, those who are aware of the review, are alarmed at the lack of clarity and clear distinction of definitions and terminology used in regulatory review processes in medical practice.

ACNEM is making this submission on behalf of all its members and stakeholders, respectfully acknowledging the trusted relationship between evidence-based nutritional and environmental medicine (NEM) practitioners and their patients, who exercise their right to prescribe and access effective, evidence-based NEM practices and protocols to prevent and treat health deficits.

ACNEM strongly opposes the definitions put forward by Medical Board of Australia (MBA) “*complementary and unconventional medicine and emerging treatments*” as these are clearly very different and highly variable areas of practice.

ACNEM is a major stakeholder in medical health and a peak industry body that educates a majority of the doctors whom this document may be targeting.

Of concern, ACNEM was not involved or consulted on the issues raised by the MBA and many of the issues noted e.g. stem cell treatments, platelet rich plasma and anti-aging cosmetic medicine are not relevant to NEM nor Integrative Medicine (IM).

**ACNEM chooses option 1, given that all doctors should follow one code of conduct and one set of guidelines for all Good Medical Practice.**

Nutritional and Environmental Medicine (NEM) and Lifestyle Medicine (LM) are becoming conventional medicine and ACNEM welcomes further discussions to support the MBA in improving on guidelines for patient safety and definitions of practice.

## **Section 1 – Case of Support: ACNEM chooses option 1.**

### **About ACNEM**

ACNEM was formed in 1982 by medical practitioners who wanted to educate fellow practitioners on the science of nutrition and the environment, in relation to disease and health outcomes.

Nutritional and Environmental Medicine is concerned with the interaction of nutritional and environmental factors with human biochemistry and physiology, the resulting physiological and psychological symptoms and pathology.

NEM is evidence-based, drawing on the latest biomedical and genetic science and research to develop new treatment approaches to illness and disease, for primary prevention and to promote optimal health and well-being.

Members of ACNEM are registered medical practitioners, dentists and associate members who are registered allied healthcare professionals. Our members and over 10,000 subscribers of the ACNEM journal and newsletter represent a growing body of health care professionals who increasingly recognise the role of nutrition, lifestyle and the environment in the prevention and treatment of disease.

As an evidence-driven organisation, ACNEM adheres to strict standards. Each Training and Education module undergoes a review process, to protect the practitioner and their patient. ACNEM's rigorous processes provide assurances that safety and efficacy standards are met and patients can build a trusted and collaborative relationship with their doctor for optimal health outcomes.

### **ACNEM's position**

ACNEM understands that the MBA review has come about because not all complementary medicine practices are equal and not all patients are discerning on what constitutes evidence.

ACNEM acknowledges that the digital economy is driving a 'direct to the consumer' market. A real risk of harm can occur when access, knowledge or position is abused, placing the layperson at greater risk of harm or injury. ACNEM defines this scenario as unintended consequences of complementary or experimental treatments accessed direct to the consumer.

This scenario highlights the imperative need for reinforcement of evidence-based NEM education and training to medical practitioners as they work their way through our learning pathways to become a Fellow, starting with a primary NEM course, through to many specialised modules, progressing to an ACNEM Certificate and eventually gaining an ACNEM Fellowship.

**Evidence-based NEM practices are vastly different to experimental or complementary therapy practices, and cannot logically be bundled or confused with the other.**

ACNEM understands the MBA review process is directed mostly at experimental treatments and new and emerging practices such as stem cell therapies and chelation therapies, but more work needs to be done on defining what constitutes 'new and emerging therapies'.

ACNEM supports the monitoring of any scattergun approach of new and experimental treatments such as non-evidence-based hormone therapy and stem cell therapy. Conversely if an emerging treatment enters the mainstream and shows

efficacy, ACNEM will undergo a robust review process of the literature and clinical data, which is peer reviewed by a medical faculty prior to being accepted as a NEM education and training module.

ACNEM's purpose is to transform healthcare and optimise patient health by making evidence-based nutritional and environmental health central to medical education, practice and protocols, reducing the burden of disease in society.

To remain true to purpose, ACNEM advocates the need for better regulation and monitoring to ensure the NEM practitioner remains distinct and separate to the experimental non-evidence-based practitioner. ACNEM takes Good Medical Practice and the Code of Conduct, as developed by the Medical Board of Australia seriously and continues to advocate this to our membership, as noted in ['A Review of the Medical Board of Australia Code of Conduct for Good Medical Practice'](#), published in the ACNEM Journal, June 2015. <sup>[1]</sup>

## Section 2 – Definitions.

In this public consultation, the medical board seeks feedback on *“options to more clearly regulate medical practitioners who provide complementary and unconventional medicine and emerging treatments.”*

The MBA is proposing the following definition: *Complementary and unconventional medicine and emerging treatments include 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.*

The MBA are asking stakeholders to define all these terms “unconventional” and “emerging treatments” and notes that there is no widely accepted definition of complementary and/or alternative medicine. It has listed some examples as integrative medicine and note that examples to fall within the definitions above include vitamins, minerals and nutritional supplements (in the absence of a deficiency).

**ACNEM would like the MBA to first define through a consultative process with ACNEM and other stakeholders, what does and does not constitute ‘conventional therapy’ in medical practice.**

The field of nutritional, lifestyle and environmental medicine today stems from strong and voluminous scientific evidence. Nutrition and lifestyle medicine are accepted as mainstream. Around 60–70% of all primary health care visits in developed countries are for lifestyle-based (and therefore preventable) diseases. As such, many more doctors and patients are, by necessity, turning to this field of largely non-pharmaceutical practice, addressing nutrition and the environmental factors contributing to chronic disease. NEM practices also play a large role in prevention.

For example, recently reported studies in the Mayo Clinic proceedings demonstrate that exercise is more effective than medication for reducing blood pressure and visceral fat. <sup>[2]</sup>

However, systematic exercise and nutrient prescriptions does not usually occur in short consultations, which make up the majority of ‘conventional’ practice. Many other evidence-based natural interventions have also been shown to be effective for lowering blood pressure, considered either nutritional medicine practice or complementary medicine practice include:

- A nutrient-dense, whole-foods diet
- Stress management
- Adequate sleep
- Sun exposure
- Supplements like magnesium, CoQ10, garlic extract

This is in line with the integrative treatment of a patient with chronic disease, and there is no clear demarcation between NEM and conventional medicine.

Therefore it is unclear and confusing to suggest that nutritional and integrative medicine fall into a poorly defined group of *'complementary and unconventional medicine and emerging treatments'* as per the MBA discussion paper.

ACNEM educates medical practitioners on the practice of bringing nutrition education and lifestyle modifications to patients. These are tools that are currently not taught at the undergraduate level, yet they are critical to the future of healthcare and widespread practice of medicine.

The practice of NEM trained doctors is described in detail in ['NEM - A New Paradigm for Understanding the Common Origins of the Chronic Disease Epidemic'](#), published in the ACNEM Journal 2018.<sup>[3]</sup>

Additional examples of where nutrition education and environmental medicine are science-based and have become mainstream, and have been the core of ACNEM supported education, include:

- The Australian Prevention Partnership is a government initiative which is acknowledging the gap that the healthcare system has and is working to get lifestyle medicine at the forefront of general practice.<sup>[4]</sup>
- The perinatal society of ANZ focuses on the effects of NEM on DOHaD (Developmental Origins of Health and Disease). Integrative and ACNEM trained doctors educate patients on the practice of improving outcomes with changing diets, adding nutrients and understanding nutrigenomics and epigenetics.<sup>[5]</sup>
- The Microbiome Research Centre is a government funded initiative for the translation of research in this emerging area of science and healthcare. It has been established that there is an inextricable link between the diversity and balance of our microbiome and our susceptibility to disease. Dysbiosis is associated with several diseases including cancer, inflammatory bowel disease, obesity and asthma. Our lifestyle choices, our diet, our use of antibiotics and medications and the environment we live in can influence the composition of the microbiome - all critically important concepts that are taught at ACNEM training and conferences for many years.<sup>[6]</sup>
- In Obstetrics and Gynaecology, the vitamin pyridoxine (B6) has been first line treatment for morning sickness for 30 years. The number of supplements recommended in pregnancy is continuing to grow every year for preconception and perinatal care, such as iodine, iron, vitamin D, folic acid and now fish oil is being recommended for prevention of preterm labour.

The 2019 ACNEM Conference in May 2019 demonstrated that the dividing line between Nutritional and Environmental Medicine and Conventional Medicine is no longer clearly visible. More than half of the conference speakers were Professors or Medical Specialists with a research and clinical interest in the role of NEM in their respective discipline. The conference speakers included Professors of Public Health, Nutrition and Dietetics, Biochemistry and Metabolism, Paediatric Gastroenterology, Pathology and Urology. Other specialist speakers included an Obstetrician and Gynaecologist, Gynaecologist/Fertility Specialist, Sports Medicine Physician, Renal Physician and an Anaesthetist. The rest of the speaker faculty were high-profile researchers, clinicians and academics. The high quality, expertise and passion of the speakers were reflected in the quality of the presentations and delegate feedback responses.

It is clear that integrative medicine and 'conventional medicine' have a large area of overlap and cannot be regulated separately.

### Section 3 - addressing MBA concerns.

ACNEM understands the MBA review process is directed mostly at experimental treatments and emerging practices for the safe guarding of the Australian public. However Complementary Medicines (CM), the use of nutritional supplements and Integrative Medicine (IM) have been inappropriately bundled together with emerging and unconventional, in one unclear definition.

ACNEM agrees that there are certain areas of practice that need better regulation and monitoring, such as unconventional off-label prescribing, prescribing compounded products, inappropriate prescribing and practitioner sales of supplements, but these are all addressed within the existing guidelines.

ACNEM educates and reminds practitioners on Good Medical Practice and the Code of conduct and has discussions on this at the [Primary Modules training in NEM](#), which is delivered three times per year.<sup>[7]</sup>

Doctors practicing IM, NEM and lifestyle medicine are usually members of ACNEM or Australasian Integrative Medicine Association (AIMA) or Australasian Society of Lifestyle Medicine (ASLM) or a combination. The RACGP also have a large Special Interest Group in Integrative Medicine.

It is not clear what the stakeholder concerns are, as mentioned in the Discussion Paper, as these have not been made transparent. It is also evident that ACNEM, National Institute of Complementary Medicine Health Research Institute or AIMA, as major stakeholders in the Australian IM and CM communities have not been consulted regarding these concerns and the public consultation.

Australia is one country in which CM use is particularly significant with some of the highest CM utilisation in the developed world. Coupled with high utilisation is a high CM practitioner population which outnumbers conventional medical providers in some areas.<sup>[8]</sup>

The increasing use of CM services by the general population has gradually resulted in CM becoming an important subject amongst Australian primary health care professionals and policy makers.

**As the leading NEM training and education industry body in Australia, ACNEM extends a call to consult and collaborate with the MBA to answer two key questions:**

- a) **What constitutes ‘conventional therapy’ in medical practice?**
- b) **What are the relative risks of all approaches (conventional, unconventional, complementary and emerging therapies) in medical practice to enable us, as a society, to accurately assess, educate and then to best protect patients and minimise harm, and give the patient the best possible evidence-based treatment?**

ACNEM supports the Medical Board in this endeavour, as it aligns with the College's vision of 'Better Health Outcomes' through evidence-based treatments.

A robust discussion should be had on the relative risk of conventional therapies, such as pharmaceutical drugs compared with complementary therapies, such as nutritional supplements. We cite, below, 4 TGA Adverse Drug Reports on common examples, comparing the use of fish oil, multivitamins, paracetamol and aspirin <sup>[9 - 12]</sup>:

- [TGA ADR Paracetamol](#)
- [TGA ADR Aspirin](#)

- [TGA ADR Multivitamins](#)
- [TGA ADR Fish oils](#)

It is clear that even what is considered benign medications, have significantly more risk than nutritional supplements (for example as used in the absence of nutritional deficiency).

[The Pharmaceutical Society of Australia 2019 Report, Medicine Safety: Take Care](#) further defines the extent of the problem of the risks of prescription medicines in conventional therapies. <sup>[13]</sup> Statistics from this document include:

- 250,000 hospital admissions annually are a result of medication-related problems with annual cost \$1.4 billion
- 400,000 additional presentations to emergency departments are likely to be due to medication-related problems
- 50% of this harm is preventable

The MBA would better support the health of Australians and offer safety by working with major stakeholders who have expertise in these areas, rather than impose regulation in an extensive health care sphere, with poorly- defined areas of practice.

The difference between IM and conventional medicine is that IM is focused on lifestyle interventions for chronic disease prevention and treatment and conventional medicine is focused on pharmacological and surgical management.

ACNEM would argue that the optimal health care system is where they work together to provide the best standard of care.

#### **ACNEM calls for one set of guidelines as the best way forward to regulate practice and protect patients.**

The future model of health needs to prevent disease and optimise health by encouraging people with the proper nutrition and lifestyle tools. This supports the maximum level of health, physical and mental, for each individual. It creates an optimal environment for the expression of that individual's genetic potential. The keys to achieving optimal health include the judicious use of nutrition and nutritional supplements, regular physical exercise, the avoidance of environmental pollutants, and the practice of positive outlook through simple techniques such as mindfulness. This concept of optimising health for everyone is foreign to the acute disease-based healthcare system and is glaringly absent from medical school curricula and training. <sup>[14]</sup>

Integrative and nutritional medicine doctors in Australia have undergone further training, over and above the usual post graduate pathways of general and specialty training.

The MBA should not revoke, control or suppress evidence-based NEM clinical practice or protocols that are highly effective in optimising patient health. This would be an illogical outcome for the MBA, practitioners and patients, placing the spotlight on the MBA for all the wrong reasons.

#### **Section 4 - Responses to the MBA questions for consideration:**

1. We do not agree with the proposed term ‘‘complementary and unconventional medicine and emerging treatments’.  
Combining the three terms is scientifically flawed. They have different, often contradictory meanings; are used in different clinical contexts and circumstances; and there are wide variations in safety, risks and costs.
2. No, the definition is poorly informed. The WHO, AMA and RACGP definitions for complementary medicine (that might also include terms such as traditional medicine and integrative medicine) need defining. More attention is needed when describing unconventional and emerging treatments that are not complementary medicine e.g.

off-label use of medicines that is increasingly a concern for paediatric and older adult populations, and other emerging technologies that are common in surgery, sports medicine, dermatology and cosmetic medicine. The defining features that determine an intervention or investigation are not conventional and who the adjudicating organisation or individual is, must all be clearly articulated, which is lacking here.

3. An ad-hoc set of statements and example are presented here, all of which are well managed under the current set of medical guidelines and code of conduct. Insufficient data and facts have been provided to make the case for extra regulation. This is an essential flaw in the Discussion Paper.
4. Our main concern is that the MBA needs to find common ground amongst stakeholders by addressing diverse perspectives to reduce controversy, for the good of the patient, the profession and the community as a whole. This involves embracing holistic, preventive, nutritional and integrative approaches for managing chronic disease, which is in epidemic proportion in medical practice today, and is better served by non-pharmaceutical and non-surgical approaches - or termed together as 'conventional medicine'.
5. Yes, safeguards are required for all aspects of medicine. However, the MBA has failed to demonstrate why current safeguards and regulations are inadequate.
6. After having properly identified and quantified the risks of various medical practices, the MBA should consult the relevant stakeholders, colleges and peak professional bodies.
7. Based on the information presented by the MBA, there is insufficient evidence that current guidelines are inadequate. Option one would therefore appear adequate.
8. The current proposed guidelines confuse rather than clarify the issues. Such poor definitions are highly problematic in a regulatory environment and serve to cause more distress to doctors who are already severely subject to Physician Burnout.
9. The MBA should abandon these guidelines as the MBA has failed to adequately make a case for Option 2.
10. Stronger engagement with the relevant colleges and peak professional bodies is needed before being able to address the important issues around patient care and safety.
11. Given all of the above, Option 1 is clearly the answer.

## References

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5. [Perinatal Society of Australia and New Zealand, https://www.psanz.com.au/](#)
6. [Microbiome Research Centre, https://microbiome.org.au/](#)
7. <https://www.acnem.org/sites/default/files/pdf/2019/2019-07%20Perth%20-%20Primary%20Modules.pdf>
8. Reid R, Steel A, Wardle J, Trubody A, Adams J. Complementary medicine use by the Australian population: a critical mixed studies systematic review of utilisation, perceptions and factors associated with use. *BMC Complement Altern Med*. 2016;16:176. Published 2016 Jun 11. doi:10.1186/s12906-016-1143-8 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4902999/>
9. [TGA ADR Paracetamol](#), <https://www.tga.gov.au>
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12. [TGA ADR Fish oils](https://www.tga.gov.au), <https://www.tga.gov.au>
13. [The Pharmaceutical Society of Australia 2019 Report, Medicine Safety: Take Care](#)
14. [Brighthope, I, The forces against health in Australia, \*ACNEM Journal Vol 31 No 3\*, December 2012](#)