THE AUSTRALASIAN ACADEMY OF ANTI-AGEING MEDICINE
Providing education in preventative integrative and personalised medicine
to promote healthy ageing and better patient outcomes.

MEDICAL BOARD OF AUSTRALIA SUBMISSION

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

EXECUTIVE SUMMARY

- The Australasian Academy of Anti-Ageing Medicine (A5M) is making a non-complaint submission on behalf of all its members and stakeholders who are potentially targeted by this document.

- As a major stakeholder and body that educates many of the doctors who this document may be targeting, A5M will provide feedback to the issues raised by the Medical Board of Australia (MBA). As with all of the other associated Integrative Medical (IM) organisations, A5M was not involved or consulted on the issues.

- The proposed guidelines may create a system which is likely to cause isolation for integrative doctors.
  Integrative medicine is a philosophy of health care with a focus on individual patient care. Integrative medicine reaffirms the importance of the relationship between practitioner and patient, collaboration with allied health care practitioners with focuses on the whole person. IM makes use of all appropriate therapeutic approaches, health care professionals and disciplines to achieve optimal health and healing.
  IM considers the physical, psychological, social and spiritual wellbeing of the person with aim of using the most appropriate, safe and evidence-based treatments available.

- A5M strongly opposes the definitions put forward by Medical Board of Australia *"complementary and unconventional medicine and emerging treatments"* as these are clearly very different and highly variable areas of practice.

- A5M chooses **Option 1**, given that all doctors should follow one code of conduct and one set of guidelines for all Good Medical Practice. All medical practitioners should be subject to the same guidelines.

- Our members and advisory panel believe that integrative, preventative, nutritional, environmental and lifestyle medicine are becoming conventional medicine and we would welcome further discussions to support the Medical Board to improve on guidelines for patient safety and definitions of practice.

- Our members with their extensive post graduate education and constant improving of their skills, are encouraged to practice within the Good Medical Practice Code of Conduct, and the Code of Conduct as developed by the Medical Board of Australia and the A5M Code of Conduct, including regular updates on safe medico-legal practice and evidence based models from globally recognised professors and educators.

INTRODUCTION

The Australasian Academy of Anti-Ageing Medicine (A5M) was founded in 2006 by medical and allied health practitioners to educate fellow practitioners in evidence-based practices for early detection, prevention and treatment of dysfunction, disorders and chronic disease management and achieve improved patient health outcomes.

A5M is a recognised key education provider in Australia, representing a large body of registered medical practitioners, dentists and allied health professionals, with an interest in the fields of preventative, integrative and personalised medicine. A5M represents over 500 members and over 8,000 practitioners who regularly access our programs, communications and events.

With a shift toward integrative personalised and lifestyle medicine occurring within healthcare, and health consumers seeking a more proactive, predictive, and preventive paradigm: A5M recognised a need to educate practitioners on the root causes of disease and chronic illness in a more comprehensive and clinically relevant approach. A5M aims to prepare practitioners to adapt to this essential method of health care by providing professional development that bridges the gap between conventional, complementary and internal medicine. A5M connects integrative and preventative medicine, providing members with contemporary evidence-based insights into healthy ageing, wellbeing, chronic disease management, nutrition, preventative and integrative medicine to drive better patient outcomes and enhance patient safety. In particular, the A5M Education Program is a comprehensive evidence-based training in the fundamental key pillars of Integrative Medicine, to equip the graduates to be broadly informed and competent in the extensive IM field.

The A5M educational program teaches the practice of medicine that reaffirms the importance of the therapeutic practitioner-patient relationship. A5M promotes the whole person, evidence-based medicine that integrates all appropriate therapeutic approaches (including exercise, diet & nutrition, lifestyle & relaxation, nutritional supplementation, and metabolic balance), health care professionals, to achieve optimal personalised health and wellbeing for each individual patient.

This educational model draws on established trends and innovative training from recognised and respected international integrative and preventative medicine programs presented by University of Michigan University Integrative Family Medicine Program, George Washington University Integrative Medicine Fellowship, Harvard Medical School Integrative Medicine Fellowship, University of Arizona Centre for Integrative Medicine, and the Academic Consortium of Integrative Medicine and Health, to name a few.

The latest evidence based biomedical and genetic science and research are presented by academically qualified practitioners on the treatment approaches to promote optimal health and wellness in patients in all our educational programs.

A5M MISSION

To provide healthcare practitioners with the highest standard of education, training and support in preventative medicine and disease management to promote healthy ageing and provide better patient outcomes.

MEMBER CODE OF CONDUCT AND TRANSPARENCY

A5M members receive a copy of the A5M Code of Conduct and are also encouraged to practice within the AMA's Good Medical Practice Code of Conduct, and the Code of Conduct as developed by the Medical Board of Australia. A5M provides regular updates on medico-legal issues including safe medico-legal practice and evidence-based models from globally recognised lawyers, professors and educators at A5M conferences and workshops. https://bit.ly/2LrxNS8

Our members are encouraged to provide transparency on all costs associated with consultations upfront. If members wish to stock practitioner pharmaceutical-grade supplements in their practice for patient convenience, then disclosure of profits is stipulated, as well as offering patients the opportunity to purchase these tailored, prescribed treatment modalities elsewhere commercially.

Private pathology testing is individualised for patients and typically prioritised for patients to spread a burden of costs over time. These integrative pathology tests are offered as a service to patients; patients have the choice of accessing these services at their own discretion. Test price lists are included in the pathology kits so that patients are aware of the costs before initiating the tests. A5M members are encouraged to provide patients with welcome letters ahead of the initial consultation with all of these details outlined for full transparency.

As an evidence driven organisation, A5M adheres to strict standards with each training and education module undergoing a peer review process to protect the practitioner and the patient. A5M works to provide assurances that safety and efficacy standards are met, and patients can build a trusted and collaborative relationship with their doctor for their optimal health outcomes.

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", "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).

A5M would like the MBA to first define what constitutes 'conventional therapy' in medical practice.

The field of integrative, preventative, nutritional, lifestyle and environmental medicine today stems from strong 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. The RACGP published article "The case for establishing an Australasian integrative medicine practice-based research network" stated that in a nationwide survey of Australian GPs, around one-third self-identified as practising integrative medicine.
Many doctors and patients are turning to this field of largely non pharmaceutical practice; addressing nutrition, lifestyle and the environmental factors contributing to chronic disease, and playing a large role in prevention.
The Royal Australian College of General Practitioners (RACGP) defines integrative medicine as: "the blending of conventional and evidence-based natural and complementary medicines and/or therapies with lifestyle interventions to deliver holistic, patient-centred care. The overarching aim of integrative medicine is to use the most appropriate, safe, ethical and evidence-based modality(ies) available, with a particular focus on prevention and lifestyle interventions".
https://www.racgp.org.au/afp/2016/december/the-case-for-establishing-an-australasian-integrative-medicine-practice-based-research-network/

A5M educates medical practitioners on the practice of teaching nutritional education and lifestyle modifications to patients. These are fundamental and foundational health interventions and are key tools that are unfortunately not taught at the undergraduate level yet are critical to the future of healthcare and widespread practice of medicine, as well as reducing the enormous growing burden of health costs to our Medicare system.

Integrative and preventative medicine and A5M trained doctors educate patients to improve their personalised health outcomes through such measures as modifying diets, screening for and correcting nutritional deficiencies, and implementing interventions tailored to their personalised nutrigenomic and epigenetic screens.

Government funded research and initiatives such as The Microbiome Research Centre https://microbiome.org.au/ have 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 have been taught at A5M training and conferences for many years.

In obstetrics and gynaecology, the vitamin therapy of pyridoxine has been first line treatment for morning sickness for 30 years and magnesium for pre-eclampsia. The number of supplements recommended in pregnancy is continuing to grow every year for preconception and perinatal care, such as iodine, iron, vitamin D, folinic acid and now fish oil is being recommended for prevention of preterm labour integrative medicine. Clearly, 'conventional medicine' has a large area of overlap and cannot be regulated separately.

ADDRESSING MBA CONCERNS

A5M understands the MBA review process is directed for the safeguarding 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 sweeping definition.

Doctors practicing integrative nutritional preventative and lifestyle medicine in Australia are usually members of A5M, Australasian Integrative Medicine Association (AIMA), ACNEM 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; nor the "stakeholders" disclosed. It is also evident that A5M, AIMA, ACNEM (Australian College of Nutritional and environmental Medicine), National Institute of Complementary Medicine or Australasian Society of Lifestyle Medicine (ASLM) – as the major stakeholders in the Australian Integrative Medicine and Complementary Medicine (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.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4902999/

Associate Professor Vicki Kotsirilos, who served on both the Australian Drug Reactions Advisory Committee (ADRAC) and the Therapeutic Goods Administration's (TGA) Complementary Medicines Regulatory Committee, recently stated that the "incidence of reported adverse reactions or interactions to ADRAC for a CM compared with pharmaceuticals is less than 2% of the total reported incidents."(M. Woodley, News GP 3/6/2019, www1.racgp.org.au).
This illustrates a significant disparity in the incidence of iatrogenic disease of CM compared with pharmaceutical medications.

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.

Therefore, A5M extends a call to collaborate with the MBA to answer two key questions:

1. **What constitutes conventional therapy in medical practice and**
2. **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 access, educate and then to best protect patients and minimise harm?

A5M supports the Medical Board in this endeavour, as it aligns with the A5M Mission to "promote healthy ageing and provide better patient outcomes" and we support discussion on the relative risk of conventional therapies, such as pharmaceutical drugs compared with complementary therapies, and nutritional supplements.

The MBA would better support the health of Australians and offer patient safety by working with the major stakeholders who have expertise in these areas, rather than to impose additional onerous regulation in an extensive health care sphere, which has been fundamentally ill-defined in its working document.

The difference between integrative medicine and conventional medicine is that integrative medicine is focussed on lifestyle and nutritional interventions for acute and chronic illness prevention and

treatment; whereas conventional medicine is focussed on pharmacological and surgical management for disease.

We would argue that the best system is where they work together to provide the best standard of care. **One set of guidelines is therefore 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 meditation and mindfulness. This concept of optimising health for everyone is foreign to the reactive acute disease-based healthcare system and is alarmingly absent from medical school curricula and training.

Integrative and nutritional medicine doctors in Australia have undergone extensive 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 integrative 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. It also denies patients' right to make their own informed health choices and is anti-competitive.

WORLD HEALTH ORGANISATION (WHO)

The inclusion of the umbrella term 'complementary medicine' in the proposed guidelines without an accepted definition presents a further problem. The World Health Organisation states that "…the highest attainable standard of health as a fundamental right of every human being." and in Australia is included in the umbrella term 'complementary medicine'. These guidelines could be perceived as violating the human rights of all Australians including indigenous and Torres Strait Islander people.

Another feature of rights-based approaches is meaningful participation. Participation means ensuring that national stakeholders – including non-state actors such as non-governmental organizations – are meaningfully involved in all phases of programming: assessment, analysis, planning, implementation, monitoring and evaluation.

Therefore, the proposed guidelines could be perceived as being contradictory to the aims and objectives of the WHO strategy, violating the human rights of all Australians and particularly indigenous peoples.
https://www.who.int/news-room/fact-sheets/detail/human-rights-and-health

RESPONSES TO THE QUESTIONS FOR CONSIDERATION

1. The introduction of a separate set of differential guidelines (as proposed in Option 2) sets a dangerous precedent. Currently one set of guidelines applies equally to ALL doctors. Introducing a second, separate set of guidelines will create a two-tiered

"apartheid" system. We believe there would be severe deleterious consequences for the medical community and medical culture in Australia if the new guidelines are introduced.

Adopting the proposed guidelines will promote unequal treatment of medical practitioners. The proposed guidelines specifically target practitioners of complementary, non-mainstream and emergent therapies, by inference categorising them as less qualified, unethical, unscientific, unsafe, financially exploitative of their patients and in need of greater monitoring. This is unproven, extremely prejudicial, a "direct discrimination" based solely on type of medical practice and a breach of human rights.

The medical profession is by nature hierarchical and competitive and it is this dynamic which underpins its endemic levels of bullying and harassment. Legislated differential guidelines for doctors will solidify an already hierarchical structure within the medical culture and is likely to increase bullying and harassment within the profession.

We believe that the proposed guidelines could act as a "Carte Blanche" sanction for an increase in bullying, harassment and isolation of integrative doctors through vexatious complaints and unnecessary medical board investigations, overregulation and sham peer reviews.

We do not agree with the proposed term ''complementary and unconventional medicine and emerging treatments". Combining the three terms is flawed, and not possible to merge into a single term. Each of these three separate terms, 'complementary', 'unconventional' and 'emerging', describes a different concept scientific approach/set of conditions and while there may be some overlap, combining them as a single term is highly problematic for regulatory purposes, let alone being highly flawed as a scientific definition.
As a stakeholder, A5M supports AIMA's proposal that the three terms be debated along the following lines:

- Complementary – eg Traditional Chinese Medicine, western herbal medicine, mindfulness, probiotics, vitamins, osteopathy, massage, yoga
- Unconventional – this term implies a cultural approach to acceptable practice rather than an evidence-based scientific approach. Who decides what is conventional? This term should not be used to describe a practice of medicine. Its use could be seen as cultural discrimination or bigotry.
- Emerging – Medicine is a rapidly changing field, new concepts arise all the time, giving rise to new discoveries and advances which may or may not stand the test of time. Eg Marshall & Warren, The Cause of Gastric Ulcers, H. pylori and the Nobel Prize.

The term which should be used is Medical Practice which is 'outside the Code of Good Medical Practice '. It should be defined by the lack of adherence to the Code of Good Medical Practice not by the vague, polarising, and ineffectual term, "conventional".

2. No, the definition is poorly informed. The WHO, AMA and RACGP have definitions for complementary medicine (that might also include terms such as traditional medicine and integrative medicine). 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. What are the defining features that determine an intervention or investigation is not conventional and who should adjudicate it must all be clearly articulated, which is lacking here?

3. An ad-hoc set of statements and examples presented in the discussion paper, all of which would have been fully 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, which is an essential flaw in the Discussion Paper.
   There is no evidence that patients of integrative general practitioners are more likely to suffer harm as a result of their medical treatment.

4. As a result of their training in both conventional and integrative therapies, integrative GPs are better placed to ensure that harm does not occur.
   a. Integrative Medicine should be supported, encouraged and fostered as a newer speciality which brings a high level of expertise to improve patient safety, management and outcomes.
   b. We feel strongly that the Medical Board could do more to address the different ways of thinking that serve to accentuate controversy, and vexatious complaints, which severely impact the mental health and well-being of doctors and are a major contributor to physician burn-out. Direct liaison with the IM stakeholders, will greatly benefit the patient, the profession and the community as a whole.
   c. 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 'conventional medicine'
   d. Integrative GPs are better placed to manage patients with multi-system illnesses as they have a broad skill base and expertise in seeing patients suffering complex health issues and tackling them in a systematic fashion for personalised care.

5. Yes, safeguards are required for all aspects of medicine. However, the Board has failed to provide any evidence to substantiate why the current safeguards and regulations are inadequate. We believe this fails to uphold the COAG principle 1, "establishing a case for action before addressing a problem". Council of Australian Governments Best Practice Regulation: A Guide of ministerial councils and national standard setting bodies, October 2007, p 4).

   a. A5M believes that the current guidelines are sufficient to ensure patient safety. The proposal of additional guidelines is potentially discriminatory against IM doctors, effectively creating an apartheid system. Such a system could discourage IM doctors from continuing to practise, as well as discourage new doctors from training in this vital area of medicine. It could potentially promote ostracism of IM doctors, and further fuel vexatious complaints.
   b. No additional safeguards are necessary for patients who seek Integrative GP consultations.

6. After having properly identified and quantified the risks of various medical practices, the Medical Board of Australia (MBA) should consult the relevant stakeholders, colleges and peak professional bodies. Indeed, COAG principle 7 stipulates that key stakeholders are to

be consulted "effectively' at all stages of the regulatory cycle (Council of Australian Governments Best Practice Regulation: A Guide of ministerial councils and national standard setting bodies, October 2007, p 4).

7. Based on the information presented by the MBA, there is insufficient evidence that current guidelines are inadequate. **Option 1** is therefore adequate. COAG principle 3 refers to "adopting the option that generates the greatest net benefit for the community". (Council of Australian Governments Best Practice Regulation: A Guide of ministerial councils and national standard setting bodies, October 2007, p 4).

8. We believe the benefits of Integrative Medicine for optimising health far outweigh risks to the Australian community. Furthermore, the World Health Organisation (WHO) Constitution (1946) states that "the highest attainable standard of health as a fundamental right of every human being". (www.who.int- Human rights and health)
   The current proposed guidelines confuse rather than clarify the issues. Such ill-defined classification terminology is highly problematic in a regulatory environment and serves to cause more distress to doctors who are already severely subject to Physician Burnout.

9. The MBA should abandon these guidelines as the Board has failed to adequately make a case for Option 2. In addition, it has fundamentally breached the **COAG guidelines** for impartiality by suggesting that option 2 is its preferred option. An underlying COAG principle of developing best practice regulations is that there should be no attempt to pre-justify a preferred solution. (Council of Australian Governments Best Practice Regulation: A Guide for Ministerial councils and national standard setting bodies, October, 2007 P 10).

   We are also highly concerned that multiple members of the Board are published members of the Friends of Science in Medicine (FSM), implying a significant potential conflict of interest. FSM openly opposes healthcare modalities outside of the 'conventional' model. We are concerned that this potential conflict of interest may have introduced a significant bias into the Board's position.

10. Strong engagement with the relevant colleges and peak professional bodies is essential before being able to address the important issues around patient care and safety.

11. Given the all of the above, **Option 1 is our preferred option, continuing the single set of standards for all Australian medical practitioners.**

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