Integrating Complementary and Mainstream Medicine

Australasian Integrative Medicine Association (AIMA)

Response to

The Medical Board of Australia

Public Consultation

Clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments

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Summary

AIMA is the peak body representing and advocating for doctors and other practitioners who practice integrative medicine.

Integrative medicine has a focus on individualised patient care. It combines the best of current western medical practice with evidence-based complementary medicine and therapies.

Integrative medicine and integrative doctors will be adversely affected by the imposition of a separate set of guidelines beyond the current *Good medical practice a code of conduct for doctors in Australia* guidelines.

AIMA chooses Option 1 – to retain the status quo

AIMA strongly objects to 'Option 2', as the proposed guidelines:

1. create an unequal system which is likely to foster a culture of bullying, harassment and isolation of integrative doctors
2. are unnecessary
3. do not conform to COAG Principles for best practice regulation
4. are poorly defined creating ambiguity and uncertainty
5. are discriminatory
6. potentially compromise patient safety

These points are addressed in the document below.

This is a non-compliant submission

Terms

In this document we will be referring to the 'public consultation paper on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments' as the 'proposed guidelines'.

We refer to *Good medical practice a code of conduct for doctors in Australia* as the 'existing guidelines' and as '*Good medical practice'*.

We refer to the preamble of the public consultation as the 'discussion paper'.

The Medical Board of Australia is referred to as both the MBA and the Board (when quoting from the discussion paper).

About AIMA

Founded in 1992 the Australasian Integrative Medicine Association (AIMA) is the peak medical body representing the doctors and other health care professionals who practice integrative medicine. We work to build a vibrant integrative medicine community which is united, recognised, supported, informed and connected.

AIMA is an independent not-for-profit organisation supported by its membership and governed by a volunteer board.

Our current work includes developing a mentored education pathway for doctors to become AIMA endorsed integrative medicine doctors. We are developing this with NICM Health Research Institute at Western Sydney University, Southern Cross University, the Australasian College of Nutritional and Environmental Medicine (ACNEM) along with international stakeholders. This pathway will be launched at the end of 2019.

We have also developed a communications package including a series of letter templates to facilitate better communication between doctors and practitioners of other modalities. We are developing this resource into an education course for allied health and complementary therapists.

What is integrative medicine

Integrative medicine is a philosophy of healthcare with a focus on individual patient care. It combines the best of current western medical practices with evidence-based traditional and complementary medicines and practices.

Integrative Medicine reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic approaches, health care professionals and disciplines to achieve optimal health and healing.

Integrative medicine takes into account the physical, psychological, social and spiritual wellbeing of the person with the aim of using the most appropriate and safe evidence-based treatments available.

What is an integrative medical practitioner

All integrative medical practitioners are/have:

- educated within accredited universities to meet Australian standards of medical care and knowledge including the ability to self-regulate practice and apply scientific principles to understanding medicine and the practice of medicine
- equally trained within Australian hospitals and under appropriate medical colleges (general practice and specialist)
- agreed to meet ongoing criteria for continuing medical education to maintain quality of practice and registration
- agreed to follow the MBA's approved code of conduct outlined in *Good medical practice* as part of registration

- educate themselves and train in modalities that enhance health outcomes for their patients in addition to their base medical knowledge
- no different than their colleagues other than their integrated wholistic approach to medicine and associated increased range of treatment modalities.

Why AIMA chooses Option 1 – to keep the status quo

1. The proposed guidelines create an unequal system which is likely to foster a culture of bullying, harassment and isolation of integrative doctors

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 serious deleterious consequences for the medical community and medical culture in Australia if the proposed 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 emerging 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[1] and a breach of human rights[2].

The medical profession is by nature hierarchical and competitive. This dynamic[3] which underpins the endemic levels of bullying and harassment in medicine.[4] Legislated differential guidelines for doctors will solidify an already hierarchical structure within the medical culture and are likely to increase bullying, harassment and discrimination within the profession.

We believe that the proposed guidelines could act as a "Carte Blanche" sanction for an increase in bullying, harassment, discrimination and isolation of integrative doctors through vexatious complaints and unnecessary medical board investigations[5], overregulation[6] and sham peer reviews.[7]

We are deeply concerned about the potential impact on the mental health of practitioners who are targeted,[8] specifically in the context of already high rates of psychiatric morbidity and suicide in doctors[9]. Doctors are under huge stress, introducing further (unnecessary) guidelines will increase this burden of stress and could have significant impact on doctors' mental health.

AIMA believes that the proposed guidelines will inadvertently support the ongoing campaign to prevent doctors practising Integrative Medicine from political lobby groups, like the Friends of Science in Medicine,[10] whose approach to integrative and complementary medicine is pseudoscientific, informed by ideology, professional rivalries and health economic stakeholding rather than scientific principle. And that the proposed guidelines will prove a vehicle for ideological campaigns which will result in an increase of vexatious complaints.

The public consultation around the proposed guidelines has already resulted in an atmosphere of fear and distrust with potential deleterious outcomes amongst doctors. AIMA has heard from our members that many are not willing to place their names on submissions to this public consultation for fear of calling attention to their practice and being "targeted" by the MBA, or by colleagues with

ideological differences. This atmosphere of distrust is borne of the long history of vexatious complaints and persecution against integrative doctors and adds to the already high levels of stress and pressure doctors are working under.

Assurances from the MBA that the proposed guidelines are not aimed at integrative doctors or integrative medicine do not reassure our community. These proposed guidelines are for doctors who use "complementary medicine", by definition integrative doctors use complementary practises (see 'What is integrative medicine' above) therefore they absolutely will be subject to these proposed guidelines.

There are far reaching consequences in this toxic atmosphere of fear and anxiety for doctors with impact on intellectual freedom, advances in medicine and the development of integrative medicine as a best practice model. Ultimately this will impact on both patients' ability to access the best practice medicine of their choice and on the overall health of the general population.

The role of the Medical Board of Australia is to protect the public as well as the medical community. Decisions of the Medical Board should be objective and fair. We suggest that the proposed guidelines are contrary to the stated aims of the Board[11]. The proposed guidelines will not protect the public or doctors, rather they will be deleterious to the medical culture and place the future practice of medicine in Australia on a worse path. Adopting the proposed guidelines will change how medicine is practiced in Australia, it will increase intra-professional bullying and lead to a decline in doctor health and wellbeing. For these reasons we support Option 1 – retaining the status quo.

2. The proposed guidelines are unnecessary

The proposed guidelines provide no additional protection for either patients or doctors.

AIMA conducted a thorough point by point analysis of the proposed guidelines against the current *Good medical practice a code of conduct for doctors in Australia*. Our analysis found that each protection of the proposed guidelines is adequately covered in the current guidelines.

To perform this analysis, we listed each of the proposed guidelines then referred to *Good medical practice* to see if the concern raised was covered in the existing guidelines. We undertook this analysis to see if the proposed guidelines provided any new or further protection for patients.

Our analysis (see Attachment 1) shows that the existing guidelines adequately cover ALL aspects of the proposed guidelines. From this assessment it is clear that the proposed guidelines are unnecessary, they do not add anything in terms of patient safety or clarity of practice for doctors, rather they add another layer of bureaucracy and provide a further vehicle for vexatious complaints.

For this reason, we support 'Option 1'. As each protection of the proposed guidelines is in the current guidelines there is no need to introduce new differential guidelines.

3. The guidelines don't conform to COAG Principles for best practice regulation

COAG Principles for best practice regulation[12] have not been applied in the development of the proposed guidelines.

COAG Principle 1: Establishing that action is needed

COAG Principle 1 is to 'establish a case for action before addressing a problem'[13].

The proposed guidelines fail to establish that there is a case for action. As a rationale of the need for additional guidelines the discussion paper offers the following:

> "concerns have been raised by stakeholders about this area of practice"[14]

Nowhere are these 'stakeholders' named, nor are their concerns listed. There is neither qualitative nor quantitative evidence of need presented. No evidence-based 'case for action' has been offered.

The only evidence of need presented in the discussion paper is a list of cases which have appeared before the Tribunal. As these cases have been effectively dealt with under the current guidelines, they cannot be used to establish a case for action, rather they demonstrate that the current system works effectively to protect patient safety.

No evidence on the 'magnitude (scale and scope) of the problem'[15] is presented in the proposed guidelines. Rather than providing data on why separate regulations are needed the proposed guidelines state:

> "It is difficult to source data relating to the numbers of adverse events occurring with complementary and unconventional medicine and emerging treatments."[16]

If there is no data, what is the case for action based on?

AIMA had little difficulty sourcing data on relative risk between 'conventional' and 'complementary' medicines. An email to the Therapeutic Goods Administration Adverse Event and Medicine Defect Pharmacovigilance and Special Access Branch provided the following statistics of Adverse Drug Reaction (ADR) reports of 'conventional' vs complementary medicines (CM):

Year	ADR Reports	CM ADR Reports[17]
2014	16,251	171
2015	17,034	209
2016	16,949	280

This data clearly indicates that the relative risk of complementary medicines as reported to the TGA is exponentially less than the risk posed by 'conventional' pharmacological treatments. This data supports the case for Option 1 – maintaining the status quo.

This public consultation has failed to meet COAG Principle 1. No case on the need for further guidelines has been established. No evidence of a problem has been provided. There is no demonstration that the current regulations are inadequate[18] nor any cogent argument given as to the need for additional regulation[19].

<u>Not pre-justifying a preferred solution</u>

An underlying COAG principle of developing good regulations is that there should be no attempt to pre-justify a preferred solution[20].

The proposed guidelines on several occasions state that 'the Board prefers Option 2'[21].

Clearly the proposed guidelines pre-justify a preferred solution and therefore do not conform to COAG principles. At the very least the statement of preference for Option 2 creates a case for bias and is a breach of due process and procedural fairness.

COAG Principle 4 - Restriction of competition and consumer choice

Principle 4 of the COAG principles concerns restriction of competition and consumer choice [22].

The structure of the proposed guidelines which specifically divides the scope of intent into "Guidance for all registered medical practitioners" and then "Guidance for registered medical practitioners who provide complementary and unconventional medicine and emerging treatments" is anti-competitive.

Imposing special guidelines (proposed guidelines 2 through to 9) on one cohort of doctors, while exempting another cohort creates a two-tiered system which is open to being challenged as onerous, restrictive and anti-competitive. This may well impact on service availability, create additional costs to the patient and restrict of consumer choice.

COAG principles allow for a restriction of competition and consumer choice only when:

a. the benefits of the restrictions to the community as a whole outweigh the costs, and
b. the objectives of the regulation can only be achieved by restricting competition; [23]

The proposed guidelines provide no evidence of need, they fail to establish a case for further regulation, so they cannot be seen to meet the test that restricting competition and consumer choice in this instance is justified. Therefore, the proposed guidelines may be perceived as non-adherent to the COAG principles.

COAG Principle 7 – Consulting with key stakeholders

COAG Principle 7 instructs that key stakeholders are to be consulted 'effectively' at all stages of the regulatory cycle. [24]

We acknowledge that the MBA regards the current public consultation as fulfilling this obligation to consult with stakeholders. However, the key word in this principle is 'effectively'. At no stage (to our knowledge) has the MBA consulted with any of the various groups who represent integrative and complementary medicine, this includes industry groups, peak bodies and educational institutions.

Further, COAG principle 7 specifies that stakeholder who will be affected must be consulted, this by definition includes consumer and patient groups. To our knowledge the MBA has not consulted with any of the key consumer health groups. This is despite consumer/patient co-design in health being an identified priority of the Australian Commission on Safety and Quality in Healthcare (NSQH Standard 2). [25] AIMA's Board consumer representative (Ms Tricia Greenway) will be addressing this concerning lack of consumer consultation in a separate submission, particularly concerning how the development of the proposed guidelines are not in accord with the ACSQHC Charter of Patient Rights [26].

The proposed guidelines have been developed without seeking input from the people who will be affected by their implementation – doctors, patients, peak bodies, universities and educational institutions. They have been developed without expert input. Nor do they demonstrate any understanding of the history or practice of integrative medicine in Australia. In contravention of COAG principle 7 there has been no stakeholder consultation. This lack of consultation has resulted in the development of a flawed and unworkable set of guidelines.

We contend that Principles 1, 4 and 7 of the COAG principles have not been met in developing the proposed guidelines for this reason we support Option 1 – retaining the status quo.

4. The terminology in the proposed guidelines is poorly defined creating ambiguity and uncertainty

The lack of any clear definitions in the proposed guidelines of key terms such as ‘complementary’, ‘conventional’, ‘unconventional’, ‘unnecessary’, ‘unproven’ and ‘emerging’ is unsatisfactory. The absence of this common framework makes meaningful analysis of responses to the public consultation impossible. Further, if adopted the proposed guidelines will be ambiguous and open to abuse.

Conflating three distinct groups into one definition is not scientific

The proposed working definition of ‘complementary and unconventional medicine and emerging treatment’ states:

> ***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.*

There is no basis for complementary medicine, unconventional medicine and emerging therapies being grouped into a single definition. The underlying assumption in any definition when grouping entities is that the groups defined share commonalities. This is not the case with the three groups identified in the proposed guidelines. Doctors who practice complementary medicine within integrative medical practice do not share unique commonalities with doctors practicing unconventional medicine or emerging therapies. As such the definition lacks scientific cohesion and is not evidence-based.

The stated commonality which rationalises grouping of these three disparate modalities together into one definition is that the MBA perceives them as medical practices outside of the conventional practice of medicine. They are defined by what they <u>are not</u> rather than by what they <u>are</u>. Thus, the proposed definition is a negative one, defining a cluster of practices, by what they are not, as opposed to a positive definition of defining something by what it is. Negative definitions are always problematic as they depend on a clear definition of the excluded object, in this case, ‘conventional medicine’. The MBA provides no definition of ‘conventional medicine’, and therefore, the proposed definition cannot be objectively interpreted.

For a comprehensive analysis of this please see ATTACHMENT 2

AIMA asserts that complementary medicine, unconventional medicine and emerging therapies have no commonality and should not be combined into a single definition. AIMA repudiates the proposed definition as a political artifice which is scientifically unsound and recommends that it be scrapped. Further the lack of commonly agreed definitions will make analysis of feedback to the public consultation ambiguous and open to biased interpretations. For these reasons AIMA supports Option 1 – retaining the status quo.

5. The inclusion of complementary medicine in these guidelines is discriminatory

The inclusion of the umbrella term ‘complementary medicine’ in the proposed guidelines without an accepted definition presents a further problem. The World Health Organisation’s Traditional Medicine Strategy 2014-2023 devotes attention to prioritising health services and systems including traditional and complementary medicine products, practices and practitioners.

> "As the uptake of T&CM (traditional and complementary medicine) increases, there is a need for its closer integration into health systems. Policy makers and consumers should consider how T&CM may improve patient experience and population health. Important questions of access as well as population and public health issues must be addressed." [27]

> "Health systems around the world are experiencing increased levels of chronic illness and escalating health care costs. Patients and health care providers alike are demanding that health care services be revitalized, with a stronger emphasis on individualized, person-centred care. This includes expanding access to T&CM products, practices and practitioners." [28]

The proposed guidelines could be perceived as being contradictory to the aims and objectives of the WHO strategy (which Australia is a signatory to) violating the human rights of all Australians particularly minorities including migrant communities and Australia's indigenous peoples.

6. The introduction of further guidelines could compromise patient safety

Currently an estimated 70% of the population use one or more complementary medicines or therapies in managing their health. It is imperative that doctor education in Australia, particularly for GPs, include more advanced learning on the range of modalities and supplements which patients are using to self-integrate their care.

In 2018 AIMA commissioned the Health Issues Centre (HIC) to research 'patterns of disclosure for people choosing complementary treatments/medicines'. Our research found that only 57% of respondents had fully informed their GP that they were using non-pharmaceutical medicines, 24% admitted to partial disclosure and 19% to no disclosure at all. Stated reasons for why patients are not disclosing their full health management practices to their primary care doctor include:

> *"They generally are totally uneducated about CM/TM. They are not interested. They are hostile."*

> *"I have had negative experience with very mainstream specialists who unfortunately I needed opinion from. I am selective because I don't appreciate the disrespect."*

> *"They are narrow minded…"*

Patients feel belittled and judged by many doctors. These proposed guidelines, by marginalising complementary medicine (something that an estimated 70% of the population use!), endanger patient safety. The added bureaucracy of adhering to a second set of guidelines beyond *Good medical practice* will discourage doctors from enquiring into how patients self-manage their care. By conflating complementary medicines with dangerous practice, the proposed guidelines will actively discourage sceptical doctors from broadening their education to better care for their patients safely.

The integrative medicine community is also concerned that the imposition of a second set of guidelines, with attendant procedures and bureaucracy, will compromise their ability to practice effectively. Many are concerned that they will no longer be able to provide their patients with the care they need and choose. Thus, even patients whose health choices are currently respected and safely managed by their doctor may have to revert to self-care, compromising their safety.

The proposed guidelines are an active disincentive for doctors to manage their patients self-integrated care. This could lead to adverse effects on patient safety. For this reason, we choose Option 1 – retaining the status quo.

Conclusion

The development of the proposed guidelines and their subsequent presentation of Option 2 as the 'preferred choice' of the MBA, has occurred in the absence of procedural fairness. Stakeholder groups and individuals who will be directly impacted by adoption of the proposed guidelines have not been effectively consulted. Basing the need for additional guidelines on 'concerns' raised by the unidentified stakeholders does not constitute evidence of need. A choice of the status quo in Option 1 OR the already developed guidelines in Option 2 is not a process of wide consultation in the assessment of the <u>need to develop</u> the proposed guidelines, only on the <u>adoption</u> of the proposed guidelines.

AIMA has presented evidence that the proposed guidelines are fundamentally flawed, COAG principles have not been upheld and the guidelines have been developed without any evidence of need. In addition, the scope of the guidelines is poorly defined which has created confusion and considerable distress and there is a lack of rigour in the terminology and definitions used in the proposed guidelines which may lead to these guidelines being abused if adopted. The proposed guidelines as they stand can be seen to potentially breach patients' human rights, particularly by the inclusion of complementary medicine (which encompasses traditional medicines) which the WHO includes as a human right.

This public consultation process has created an atmosphere of distress and uncertainty among integrative doctors and their patients. Much of this distress could have been avoided had the MBA adhered to COAG principle 7 and consulted widely and effectively with key stakeholders. AIMA calls on the MBA to adopt Option 1 – maintaining the status quo. AIMA is keen to work with the MBA to explore how integrative doctors (and by inference patients who choose to integrate their care) can be best represented and protected by the MBA.

Answering the questions posed in the public consultation

Question 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?

No. We do not agree with the term ‘complementary and unconventional medicine and emerging treatments’.

Each of these three separate terms, ‘complementary’, ‘unconventional’ and ’emerging’, describes a different concept/scientific approach/set of conditions combining them as a single term is highly problematic for regulatory purposes, let alone being highly flawed as a scientific definition.

In the context of medicine, ‘complementary’, ‘unconventional’ and ’emerging’ are not fixed, definite terms but can be considered, qualitative and subjective terms whose individual definitions can be debated ad infinitum. It is not possible to merge the three terms into a single entity.

Defining these terms is a larger, more complex and nuanced piece of work than is reasonable to canvass in a written response to this public consultation. AIMA proposes that the MBA, AIMA and other key stakeholder groups collaborate in a series of facilitated meetings to develop agreed definitions of these terms.

Question 2

Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments – 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?

No, we do not agree with the proposed definition.

It is impossible to answer this question without first attempting to define the term ‘conventional medicine’.

It would appear that the MBA is confusing ‘good medical practice’ with ‘conventional medicine’ as if they are one and the same. ‘Good medical practice’ includes, but is not limited to, ‘conventional medicine’.

‘Good medical practice’ in Australia is currently determined through the professional, ethical and legal framework set out in *Good medical practice*.

‘Conventional medicine’ is not adequately defined. If the therapeutic guidelines are used as the basis of what determining what constitutes ‘conventional medicine’ the scope of ‘conventional practice’ would be narrowly defined as the use of drugs, radiation or surgery. Clearly, there is much that falls outside of this definition which still falls well within good medical practice.

The issue remains that the definition of ‘conventional medicine’ has not itself been scientifically determined and that all medical practice in Australia is already subject to the code of *Good medical conduct*.

The proposed definition appears to assume that patients always fall into clear cut, singular diagnoses that should be treated using a linear pathway (which is ‘conventional’). In contrast, most medical practice occurs in the grey zones of differential diagnoses, multifactorial aetiologies and psychosocial contexts.

Question 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’?

No.

The discussion paper provides ***examples*** of the ***nature*** of the issues identified by un-named stakeholders but there is no quantitative publication of the ***extent*** of the issues identified. Many of the issues raised are conjecture which have not been subject to rigorous investigation. To conflate conjecture with real risk runs counter to the principles of evidence-based medicine.

The ***nature*** of the issues identified in the discussion paper is applicable across the whole of medicine. In no way could this be seen as limited to those doctors who might find themselves included in ‘complementary and unconventional medicine and emerging practice’.

The nature of the issues provided is absolutely relevant to how medicine is practiced across all realms, hence the code of *Good medical practice*.

For example:

A single case of an iatrogenic death from an emerging treatment is reported; a case of liposuction where a consent process, pre-operative preparation and post-operative management were all inadequate. Liposuction has been in common use since at least the 1980s. There is an existing regulatory framework to deal with such situations and it hardly applies to what most people would consider ‘integrative’, ‘nutritional’, ‘complementary’ or ‘alternative’ medicine. Compared to the staggering rates of iatrogenic complications within mainstream medicine, a single case (apart from not being relevant to the issues in question) actually speaks positively about the relative safety of the sorts of approaches under consideration.

The discussion paper also lists a number of Tribunal decisions in situations which have been dealt with under existing regulations. Five of the seven cases cited were for the inappropriate use of hormone prescriptions. Hormones are commonly prescribed now; the issue in these cases was simply whether the medical justification was appropriate in these individual cases, not whether anything complementary, unconventional or emerging was being offered. There is an existing regulatory framework to deal with this type of problem.

Question 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?

Yes, there are other concerns.

The concerns raised by the MBA are not actually issues relevant to ‘complementary and unconventional medicine and emerging treatments’ but rather are related to *Good medical practice*.

Our concern in fact is that ***not enough*** doctors consider the possibility of evidence-based "complementary" or "unconventional" or "emerging" approaches, which indeed many patients are actively seeking, especially when their needs are not being met through a 'conventional' medical approach. We wonder to what extent many doctors who practice conventionally' access and implement up-to-date, evidence-based medicine in their practices.

There is *"unease with the medical model may be contributing to doctors' low morale and to problems with the recruitment and retention of the medical workforce. But the unease is also being expressed in how doctors are thinking about and practising medicine. Some doctors are expressing concern about overdiagnosis and overtreatment and the attendant potential for harm and waste, particularly among people with multiple conditions and those who are frail or at the end of their lives. Others are concerned about the limited effectiveness of what they have to offer in the face of the wider social determinants of health*." [29]

The Board could do more to address the unnecessary and unhelpful polarising reactions to different ways of thinking that serve to accentuate controversy rather than find common ground between all stakeholders, for the good of the patient, the profession and the community as a whole.

We would encourage the broader consideration of evidence for holistic or non-pharmaceutical approaches, especially in chronic conditions. The quick and easy method of prescribing medication is no longer a tenable default management option. It also breaches the central Quality Use of Medicines (QUM) tenet of the Australian National Medicines Policy, where the practice of QUM sets out clearly to articulate to patients all non-pharmacological approaches as part of using medicine wisely.

Drawing directly from The HEALTH PRACTITIONER REGULATION NATIONAL LAW (NSW), as at 25 February 2019, Act 86a of 2009, known to the MBA as The National Law, Part 1, Section 3 [30] includes the following:

"Objectives and guiding principles
(e) to facilitate access to services provided by health practitioners in accordance with the ***public interest*** [31]*; and*
(f) to enable the continuous development of a flexible, responsive and sustainable Australian health workforce and to enable ***innovation*** *in the education of, and service delivery by, health practitioners.*
(3) The guiding principles of the national registration and accreditation scheme are as follows--
(a) the scheme is to operate in a ***transparent, accountable, efficient, effective and fair way****;"*

Given the lack of relevant stakeholder engagement in the process of developing and delivering this discussion paper, proposed guidelines and call for public submissions and the nebulous definitions therein, questions arise as to the actual intended targets of these proposed guidelines and to the interpretation by the MBA of the terms *"public interest", "innovation", " transparent, accountable, efficient, effective and fair"*.

Question 5

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

Yes, as they are for ALL of medicine.

No evidence has been provided for an assertion that ***additional*** safeguards are needed.

In fact, safeguards for patients may best be provided, or at least advised upon, by an integrative GP who is well-trained in individualised risk/benefit analysis and shared decision-making with individual patients and their treating team.

Further, a specialty-specific code of *Good medical practice* is not required beyond the code of conduct.

The current code of conduct appears to cover these areas fully.

Question 6

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

There may be, however as "*concerns from stakeholders"* is the only evidence of need presented it is impossible to interrogate this in a meaningful way.

There is NO need for a different standard or guidelines for integrative medicine. The same burden of evidence needs to be applied by the MBA to all forms of medical practice. There is no shortage of evidence of the risks and costs across to the community from conventional medicine. For example:

- Missing or ineffectual discharge summaries from hospitals to GPs[32]
- Iatrogenic mortality due to 'conventional' medical practices[33]
- Hyper polypharmacy[34]
- Unnecessary procedures[35]
- Hidden or exorbitant costs[36]

The *Good medical practice* can be considered "the constitution of medicine in Australia" and needs to be adequate to protect the community. If it is deemed adequate to protect those who practise 'conventional medicine' then it should be adequate to protect the community who see IM doctors. IM doctors need to continue to work under the *Good medical practice*, to work according to evidence-based medicine (best available evidence, clinical experience, patient preference).

Question 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?

As we have stated earlier, the definition, "**complementary and unconventional medicine and emerging treatments"** is not a workable one but YES *Good medical practice* addresses all the issues raised.

There appears to be no justification provided in the MBA's discussion paper or proposed guidelines, for the use of an ill-defined notion of "usual practice" as the gold standard, against which all other interventions should be measured.

Question 8

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

No. However, ***appropriate early stakeholder participation*** in discussions around issues of concern would contribute to a more constructive and consensus-building process. This may lead to

enhancement of the current 'conventional' model by different ways of practicing medicine, with the distinct possibility of better outcomes for all. We would welcome such engagement at this time and at any time in the future.

Question 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?

Again, we fundamentally disagree with the need for a separate set of guidelines. We believe that this has the potential to create an official (let alone an unofficial, as is already the case) two-tiered system in which one group of doctors practices very conservative, defensive, medicine, ensuring that their practice falls squarely within that practiced by their peers and condoned by their governing organisations, while any doctor who dares to practice in a way which may not be seen to conform to such convention risks losing their livelihood even though their practice is both safe and effective, and delivered in accordance with *Good medical practice*.

We will not be offering guidance or specific comments on amending the proposed guidelines. We will however, offer some guidance on how this process can and should be better managed and we are, as previously stated, open to appropriate engagement at this and any future time.

As a major stakeholder with an obvious place in the history of integrative medicine in Australia we, AIMA, were surprised that the MBA did not consult with us before drafting these guidelines. We call on the MBA to abide by the COAG principles[37] (especially *7: Consulting effectively with affected key stakeholders at* ***all*** *stages of the regulatory cycle*;) which demand that appropriate expert, stakeholder and community consultation take place BEFORE further guidelines are developed. We call on you, the MBA, to withdraw the proposed guidelines. If in the future there is an adequate and proven case for the need for any additional guidelines to be developed for the practice of integrative medicine, we would advise a collaborative process from the beginning. The MBA would be advised to seek guidance on the development of guidelines for use within a specific area of medicine from clinicians and experts in the relevant field.

In order to progress, the Medical Board needs to:

1. Present evidence that separate guidelines are necessary
2. Define what they mean by 'conventional practice' and be explicit about who determines what constitutes 'conventional'
3. Clearly articulate and describe ALL terms and definitions that they use. It is not acceptable to define something by its opposite. Precision is needed to define what is meant by 'conventional practice', 'complementary medicine', 'emerging practises' and 'unconventional medicine'. The terms and definitions used need to be clarified in a satisfactory manner
4. Input and guidance from relevant stakeholders including, but not limited to, AIMA, should be sought as a matter of course in any issue relating to integrative medicine, just as any specialty college or expert group would be asked for advice in the case of alleged malpractice or suspicious activity within its realm
5. The MBA has a role to protect the public but not to assert or control the style of medical practice patients choose.

Question 10

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

Yes. The Board could put a lot more energy into finding out why more than 70% of consumers elect to use approaches to their health that are outside of the 'conventional' mainstream practice of simply relying on drugs and surgery, before assuming that their decisions to do so are based on the fact that they must be gullible and easily led. (Most studies actually seem to indicate the opposite[i][38].)

The discussion paper points to the extent to which consumers are voting with their feet and their wallets, in terms of unconventional approaches. Very few patients would completely abandon 'conventional medicine' in favour of alternatives; but a large proportion elect to gain the benefits of both, as shown by the positive correlation between the use of 'conventional' care and complementary and alternative medicine use[ii].

[i] Note, though, that these studies may tend to conflate health literacy with multi-morbidities and higher education with socio-economic confounders. Sharp D, Lorenc A, Morris R, et al. Complementary medicine use, views, and experiences: a national survey in England. BJGP Open. 2018;2(4): bjgpopen18X101614. Published 2018 Nov 14. doi:10.3399/bjgpopen18X101614
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Question 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. The MBA's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments are adequately and fully covered under the current approved *Good medical practice* code of conduct.

Attachment 1

Comparison of proposed guidelines and existing guidelines (*Good medical practice a code of conduct for doctors in Australia*)

Following is a comparison of the proposed guidelines for 'complementary and unconventional medicine and emerging treatments' with the extant *Good medical practice a code of conduct for doctors in Australia*. The detailed analysis below demonstrates that all aspects of the proposed guidelines are adequately covered through the existing guidelines, obviating the need for further guidelines.

Each proposed new guideline is discussed below as numbered in the document, and with the corresponding current guideline identified:

1. Discussions with patients – the referenced NHMRC document is too brief and non-specific to be used as a reference point for patients seeking advice about complementary therapies. Medical practitioners would be best advised to refer their patient to a colleague trained in Integrative Medicine, or to a qualified naturopath in order for them to be provided with adequate information to make an informed choice. Only qualified practitioners with specific training in the area of use complementary, unconventional and emerging therapies should be providing in-depth discussion with people.
   - 1.1 is covered by the current 2.1.1 and 3.2.2
   - 1.2 is covered by the current 2.1.2 and 3.2.2
   - 1.3 is covered by the current 2.2.1
   - 1.4 is a statement which SHOULD NOT BE USED by medical practitioners who do not have the relevant training or information to be able to have an informed discussion. This statement is fundamentally flawed, non-specific and potentially mis-leading. The most ethical response would be to state that they do not know the level of evidence, or the potential benefits or risks and that they advise their patient to seek an opinion from someone with specific knowledge of this area.
   - 1.5 is covered by 2.2.4
   - 1.6 is covered by 2.1.5
2. The opening paragraph simply reiterates what is already covered adequately in the current 2.2.1 and 2.2.2
   - 2.1 is covered by the current 2.2.1 and 2.2.2
   - 2.2 is covered by the current 2.2.1 and 2.2.2
   - 2.3 is covered by 2.1.4 and 2.2.9
   - 2.4 is covered by the current 1.4
3. The opening statement is true for many medical interventions, surgeries, devices and does not need to be specifically isolated to this paper is adequately covered by the current 3.3.6
   - 3.1 is covered by the current 1.4
   - 3.2 is covered by the current 3.2.5 and 3.5.3
4. The whole issue of informed consent is already adequately covered in the current guidelines under section 3.5 and the term 'conventional medicine' is not adequately defined – what percentage of practitioners need to be adopting a certain approach for it to be considered a part of 'conventional medicine"? The wording of this whole section creates a 2-tiered expectation for the depth, breadth and length of consultation compared with any other area of medicine. This statement is also adequately covered by the current 3.3.3
   - 4.1 is covered by the current 3.2.5, 3.3.3 and 3.3.4
   - 4.2 is standard medical practice however the degree of expectation outlined in these points is well above and beyond that expected of other medical practitioners

4.2.1 is covered by the current 3.2.5, 3.3.3 and 3.3.4 and
4.2.2 is covered by the current 3.3.3, 3.3.4 and 3.5.2 and this statement again creates a 2-tiered expectation compared with consenting for other medical investigations and tests
4.2.3 is covered by 3.3.3, 3.3.4 and 3.5.2 and this statement again creates a 2-tiered expectation compared with consenting for other medical investigations and tests
4.2.4 is covered by the current 2.1.5, 2.2.11
4.2.5 is covered by the current 2.2.10, 2.4.4,3.3.3 and 3.5.4
4.2.6 is covered by the current 2.1.2 and 3.3.3

4.3 is already adequately covered by the current 1.4, 2.2.7,2.2.11, 3.2.1 and 3.2.5
4.4 is already adequately covered by the current 2.1.1, 2.1.2, 2.2.4, 2.2.5,2.2.6, 2.2.12
4.5 is already adequately covered by the current 2.1.4 and 2.2.9

5. Again, the terms 'complementary' and 'alternative' and 'emerging' and 'conventional' are not clearly defined, and this ambiguity creates uncertainty. The area of diagnostic methods and tests is already adequately covered by the discussions of 4.2 above and this is a repetition
   5.1 is already adequately covered by the current 2.1.1
   5.2 is already adequately covered by the current 2.1.2 and 2.2.4
   5.3 is already adequately covered by the current 2.1.1 and 2.2.2
   5.4 is already adequately covered by the current 2.1.1 and 2.2.2
   5.5 is already adequately covered by the current 2.1.1, 2.1.2, 2.2.6 and 2.2.10
6. The statement 'in the absence of an identified therapeutic need' is completely unworkable as it excludes ALL preventative medicine AND it requires proper definition of 'therapeutic need' – according to whom? – according to what standard? - does this breach the respect of the patients views and involvement in shared decision making? Any delay in accessing 'more appropriate' treatment is also poorly defined – more appropriate according to whom? And any delays would have to be shown to have caused harm to be in contravention of the current guidelines and this is adequately dealt with by the current 1.4, 2.1.2, 2.2.4, 2.2.62.2.10, 2.4.1 and 2.4.4
   6.1 is already adequately covered by the current 2.2.6, 3.2.5, 3.3.3 and 3.3.4
   6.2 is already adequately covered by the current2.2.6, 3.3.4 and 3.3.6
7. Is just sound medical practice and AIMA has developed templates to assist on good communication between practitioners involved in shared care
   7.1 is already adequately covered by the current 2.2.3
   7.2 is already adequately covered by the current 2.1.3
   7.3 is already adequately covered by the current 2.1.3, 2.2.9 and 2.2.11
   7.4 is already adequately covered by the current 3.4.2 and 3.4.3
   7.5 is already adequately covered by the current 3.10 and 3.10.7
8. the whole if section 8 is already adequately covered by the "guidelines for advertising of regulated health services" and there is no need for this section
9. the whole of this section is adequately covered by "Australian Code for the Responsible Conduct of Research" and the "National Statement on Ethical Conduct in Human Research" and there is no need for this section

As a result of our assessment, we do not believe that clearer regulation or the development of further guidelines is necessary. If there is more information and evidence provided going forward which meets the requirements of the COAG Principles and an adequate case can be made for such a process, then we propose to start this consultation process from the beginning while working collaboratively with AIMA.

Attachment 2

Response to the Proposed Definition

The proposed working definition of 'complementary and unconventional medicine and emerging treatment' states:

> ***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 proposed definition needs to be considered within the context of the consultation paper. In the background, the MBA notes that "*feedback has been received from stakeholders that additional guidance for medical practitioners is needed in relation to the practice of 'complementary and alternative medicine' by medical practitioners*". The definition is proposed without outlining what this feedback is and from whom it has been received; without providing any meaningful data demonstrating that the feedback warrants concern; and without any consultation with experts within the field of complementary or integrative medicine. On face value, any reasonable person would consider this definition to lack context, and any reasonable scientist would be concerned about the evidence that justified such a proposed definition.

Characteristically, definitions by their nature, combine different objects together to create commonality. For instance, "pigeons, pelicans and kookaburras are a group of endothermic vertebrates known as birds which share biological characteristics." The first difficulty with the proposed MBA definition is that complementary medicine, unconventional medicine and emerging treatments are three distinct and very different medical approaches. The MBA Consultation Paper provides no data that links these three medical approaches and no data that demonstrates they have any commonality. This raises a critical question, 'what do these three disparate elements have in common that warrants them to be grouped by the MBA into one definition?' The only rational reason for this grouping is that these are perceived by the MBA as medical practices outside of the conventional practice of medicine. The definition states "*not usually considered to be part of conventional medicine, whether used in addition to, or used instead of, conventional medicine*". As such, the proposed definition is a negative one, defining a cluster of practices, by what they are not, as opposed to a positive definition of defining something as what it is. Negative definitions are always problematic as they depend on a clear definition of the excluded object, in this case, 'conventional medicine'. The MBA provides no definition of 'conventional medicine', and therefore, the proposed definition cannot be objectively interpreted.

The concept of 'conventional medicine' is a social construct and not necessarily democratically derived or evidence-based. AIMA would propose that 'conventional medicine' should be defined as an '*evolving practice that is based on the best available scientific evidence, coupled with clinical expertise and patient-centred care*'. This is based on the definition of evidence-based medicine proposed by David Sackett and colleagues[1]. Based on such a definition, evidence-based complementary medicine can be considered to fall within the realm of 'conventional medicine' and therefore, the proposed definition fails in its negative premise and is untrue. Until the MBA provides a working definition of 'conventional medicine' with clear evidence that complementary medicine

falls outside of it, the definition as it stands appears at best meaningless. At worst, the definition may have political purpose other than a scientific one.

It would be worthwhile to understand why the MBA would attempt to take three distinct and very different medical approaches and cram them into a single unifying definition. Unpacking, the concept of definitions may provide some understanding. Ian and Jan Hacking propose that definitions can be usefully thought of as human-made "ideas" that we have about the "objects" of our world that we share for various social purposes[2]. Serle provides an important distinction, which is that definitions are institutional, not brute, facts[3]. Both of these perspectives consider that definitions per se are social constructs and not necessarily scientific or objective truths. Schiappa considers that definitional disputes should be treated less as philosophical or scientific questions of what "is" and more as sociopolitical and pragmatic questions of what "ought"[4]. In making this argument, he advocated for a greater emphasis on the ethical and normative ramifications of the act of defining. Considering these ethical and normative ramifications, Abbott argues that the way things are defined is not so simple and so obvious as might at first appear, but is in fact, an essentially ideological matter. He notes that definitions not only have consequences within an individual discipline but also for the applications of that discipline within a wider context[5]. If Abbott is indeed correct, and this is an ideological matter, then the MBA proposed definition is substantially less scientific and purposefully more political. As such, in the era of evidence-based policy making, such a definition for veracity and transparency needs to include why these groups are linked and the purpose of their linkage. The attempt to define these practices together as scientific without clarifying the ideological intent makes the definition pseudoscience, where pseudoscience is defined as non-science posing as science. In this instance, making a political definition disguised as a scientific one.

AIMA asserts that complementary medicine, unconventional medicine and emerging therapies have no commonality and should not be combined into a single definition. AIMA repudiates the proposed definition as a political artifice which is scientifically unsound and recommends that it be scrapped.

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Deputy NSW Ombudsman Chris Wheeler lists seven elements that better round out the full process that should take place:

- *complying with applicable law (both its letter and spirit);*
- *carrying out functions fairly and impartially;*
- *complying with the principles of procedural fairness/natural justice;*
- *acting reasonably;*
- *ensuring accountability and transparency;*
- *exposing corrupt conduct or serious maladministration;*
- *avoiding or properly managing private interests conflicting with official duties; and*
- *acting apolitically in the performance of official functions.*

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