SUBMISSION

MEDICAL BOARD OF AUSTRALIA CONSULTATION ON COMPLEMENTARY AND UNCONVENTIONAL MEDICINE AND EMERGING TREATMENT

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NICM
Health Research Institute

SUMMARY

This submission outlines the response of NICM Health Research Institute (NICM), Western Sydney University to the Medical Board of Australia (MBA) public consultation paper entitled 'Public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments'.

The consultation paper was released by the Medical Board of Australia on February 15, 2019. It seeks feedback on options for clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments. Submissions to the consultation close June 30, 2019.

NICM's position can be summarised as follows:

- **No additional regulation of doctors who use complementary medicine as part of integrative medicine practice is required.**
- **The MBA definition attempted to unify three disparate approaches to medical practice into a single definition that NICM rejects as both unsound and unnecessary.**
- **The MBA did not build a solid evidence-based case for the need for additional guidelines having failed to articulate the nature and importantly the extent of issues raised by unspecified stakeholders or the data proving the need for additional guidelines.**
- **The MBA did not consult with key stakeholders knowledgeable in the area of complementary and integrative medicine in the development of the proposed guidelines.**
- **No evidence is provided that patients of integrative medicine GPs are more likely to suffer harm as a result of their medical treatment than the patients of other GPs.**
- **All GPs should be subject to the same good practice guidelines.**
- **The proposed new guidelines may constitute a discrimination against GPs who practise integrative medicine and are out of step with Australia being a signatory to the World Health Organization (WHO) Traditional Medicine Strategy 2014-2023.**

QUESTION 1-5

Use of the term 'complementary and unconventional medicine and emerging treatments'

NICM does not agree with the use of the term 'complementary and unconventional medicine and emerging treatments' for the following key reasons:

1. this term conflates three distinct concepts which should be treated separately, and

2. the risk profile attached to each concept differs significantly.

Where a number of items are grouped, as is the case with the term proposed by the MBA, then there is an assumed commonality of concept to the terms that have been combined. Aside from not being 'usually considered to be part of conventional medicine', each of these terms - 'complementary', 'unconventional' and 'emerging' - describes a different concept. As such, combining the three concepts into a single term is highly problematic for regulatory purposes.

To further clarify, the three terms may be described along these lines:

- Complementary medicine by the Cochrane Collaboration[i] and the Australian Therapeutic Goods Administration.[ii]

- Unconventional medicine is by default defined as anything that is not 'conventional' medicine, which changes over time. This term connotes a cultural approach to acceptable practice rather than an evidence-based scientific approach which begs the question: Who gets to decide what is conventional? It is questionable whether this term should be used to describe a practice of medicine.

- Emerging treatments or emerging medicine is a rapidly changing field and new concepts develop all the time, giving rise to new discoveries and advances which may or may not stand the test of time. The Nobel Prize in Physiology or Medicine 2005 was awarded jointly to Barry Marshall and Robin Warren for their discovery of the role the bacterium Helicobacter pylori plays in gastritis and peptic ulcer disease, when prior to this the causes of peptic ulcer were considered to be stress and lifestyle.[iii] This discovery was first opposed by 'conventional' medical colleagues, but in the end the hard science lead to a change in the treatment of peptic ulcers and was an emerging practice at the time.

Furthermore, the risk profile attached to each of these terms is remarkably different. The risks of low-risk complementary medicine therapies with or without scientific evidence, particularly those that are neither emerging nor innovative due to their long-standing traditional use or ubiquitous presence in nature, are insignificant when compared to expensive, high risk unconventional and emerging and innovative treatments. A case in point is off-label use of medicines - a practice not uncommon in many medical specialities - which are often expensive, risky and non-evidence-based.[iv,v,vi] Including complementary medicines in this overarching term thus places an onerous burden on integrative medicine GPs compared to conventional medicine doctors when the risk profile of complementary medicines does not warrant such treatment.

For these reasons it is not possible, nor is it appropriate, to merge these three medical approaches into a single definition.

A key point requiring clarification is what the MBA see as emerging treatment

At any given point in time, a particular approach to a condition, symptom, or disease may be solidly placed in the core of conventional practice, being taught at medical schools, in postgraduate training programs and being written about in CME journals. However, such conventional practice will likely in time become regarded as outdated, irrelevant or dangerous. Similarly, practices which were not regarded as conventional previously, which may have been seen as complementary, unconventional or emerging, can and do become part of conventional medical practice as evidence strengthens.

The 'decision' as to whether a particular practice (be it diagnostic, therapeutic or otherwise) is 'conventional' is therefore a somewhat arbitrary one, based on opinion from a range of experts and subject to change as the evidence base changes.

Need for consultation

The primary jurisdiction of the Board is to protect the public, and an important aspect of this responsibility is to consult with experts in specific areas of medical practice to determine the nature of evidence that support particular approaches to practice. The MBA did not appear to have made contact with key stakeholders in the area of complementary or integrative medicine in an effort to determine the nature and extent of evidence in support of particular practices raised as issues by other unspecified stakeholders. The MBA did not reach out to NICM Health Research Institute (NICM) as one of the premier research institutes in complementary medicine in Australia, or the Australasian Institute of Integrative Medicine (AIMA) as the peak medical body representing the doctors and other healthcare practitioners who practise integrative medicine to determine if the concerns were warranted.

The need for factual evidence-based data

The MBA Consultation paper provided no factual evidence-based data to make a case that the concerns raised by the unspecified stakeholders had validity. Outside the death of one individual due to stem cell therapy (an emerging treatment), the MBA failed to make a case that there was any significant risk related to the practice of evidence-based complementary medicine by medical practitioners.

The failure to make an evidence-based case as to why these three groups should be defined together or why it is necessary to implement new guidelines for medical practitioners that integrate complementary medicine into their medical practice raises significant concerns.

Term to be used rather than that proposed by the MBA

As noted above, NICM recommends strongly against using the combined term proposed by the MBA. With regard to what term should be used rather than that proposed by the MBA and how it should be defined, NICM believes there is need for clarification of how and for what this term will be used.

Further to this, the examples of issues raised in the discussion paper require further elucidation on the part of the MBA as it is not clear additional regulations are required. NICM notes that the examples listed are examples of certain practices - mostly not pertaining to the integration of complementary medicine with conventional medicine - which fall outside of the *Code of Good Medical Conduct*, and that the examples cited have been dealt with appropriately through the existing medical practice guidelines, with which all doctors must comply. It is, therefore, necessary that the MBA elucidate specific examples of the issues requiring further regulation as this is not clear from the consultation paper. It is insufficient to state that "feedback has been received from stakeholders." What evidence prompted the MBA to call for a wider consultation? This evidence, if any, is not included in the consultation paper.

If a new term is to be used, it is imperative the Board builds a rock-solid evidence-based case for its use and need and that this is outlined and articulated logically in a new consultation.

Proposed definition of complementary and unconventional medicine and emerging treatments

The MBA proposed 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.*

NICM does not agree with the proposed definition of complementary and unconventional medicine and emerging treatments due to the problems associated with linking the three terms outlined above.

As noted above, these medical approaches are disparate and should not be grouped together and that further the risk profile associated with each term is substantively different. Further to this, an important aspect of the definition proposed by the MBA is that the Board is

referring broadly to medicine that is not 'usually considered to be part of conventional medicine'. NICM would like to draw to the Board's attention that the medicine described as 'conventional medicine' is not in itself based on any particular levels of scientific evidence in many instances.[vii] As such, this begs the questions: Who is doing the 'considering' and what are the usual circumstances under which this 'consideration' is taking place? Are there any biases and is this an independent and scientifically rigorous assessment?

Moreover, the National Health and Medical Research Council (NHMRC) is now examining whether a Grades of Recommendation Assessment, Development and Evaluation (GRADE) Working Group approach to clinical guideline development is appropriate.[viii] If the GRADE approach to clinical guideline development is adopted in Australia, the strength of a recommendation will no longer be based solely on the evidence hierarchy and a simplistic approach to the determination of evidence. Such a substantive change to assessment of evidence if operationalised will likely result in a significant change to the evidence-base of clinical practice in many areas of medicine. It is highly probably that large areas of medical practice such a psychiatry and surgery will be found to not be based on high levels of evidence. While practised widely, will the MBA classify these areas of medical practice as 'unconventional'?

AIMA has put the case to the MBA 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'.* A definition which is based on David Sackett's proposal for evidence-based medicine.[ix] Based on such a definition, evidence-based complementary medicine may be considered to fall within the realm of 'conventional medicine'.

Nature and extent of issues identified in relation to medical practitioners who provide 'complementary and unconventional medicine and emerging treatments'

The consultation paper does not provide adequate detail of both the nature and extent of the issues identified by stakeholders about the area of practice covered broadly by the term 'complementary and unconventional medicine and emerging treatments'; there is no description of the process used to determine the nature and extent of these issues aside from noting in the consultation paper that '*feedback has been received from stakeholders'*.
This is problematic as readers are expected to comment on issues raised by an undisclosed group of stakeholders - with the extent of these issues not quantified - that lead to the production of draft guidelines for a set of practices arbitrarily grouped as 'complementary, unconventional and emerging'. This is not an evidence-based process. Not only does the process lack evidence, it lacks logical consistency and plausibility. Given the large effort being undertaken in other areas of medicine to ensure that medical guidelines represent the highest level of evidence available, and that the evidence on which the guidelines are based is transparently available to replicate the findings, it would appear that the MBA is out of step with current scientific process.

With regard to specific issues raised, no evidence is provided in this discussion paper that patients of integrative GPs are more likely to suffer harm as a result of their medical treatment than patients of others GPs. For example, the Board's concern that the use of 'complementary and unconventional medicine and emerging treatments' may result in harm due to missed opportunities for other forms of potentially more effective treatments is no less valid a concern for Integrative GPs than for conventional medicine doctors. This argument has been consistently raised by opponents of complementary medicine without ever providing any evidence to base this claim upon. Without evidence, it remains a theoretical conjecture, and it is disappointing that the MBA promulgate this conjecture in the total absence of evidence in the consultation document. Integrative GPs, who are trained in both conventional and complementary medicine, are arguably in a better position to ensure that such harm does not occur.

Furthermore, the Board raises the issue of "non-evidence-based treatments", a term which is arguably of no relevance to the practice of integrative medicine where therapeutic modalities used by integrative GPs have an evidence base and are graded in a fashion similar to other forms of medicine. It is inappropriate to assert that doctors should only use level 1 evidence as it is well known that many treatments used in conventional medicine do not hold level 1 evidence.[vii]

NICM argues that issues raised by the MBA in this consultation paper need to be more robustly investigated and reported in an evidence-based fashion and, importantly, compared with the published rates of iatrogenic complications within mainstream medicine, such as adverse drug events and medical errors.[x,xi]

Finally, many of the cases cited in the discussion paper are either irrelevant to integrative medicine practice and/ or an existing regulatory framework is already in place to deal with the issue raised. The fact that the existing regulatory framework is being used to deal with the issues raised indicates that no additional guidelines are needed.

Other concerns with the practice of 'complementary and unconventional medicine and emerging treatments' by medical practitioners not identified by the Board

NICM notes that the additional issues highlighted in the consultation document could apply to all doctors:

- Failure to consider differential diagnoses
- Unproven therapies
- Entrepreneurial medicine
- Progressive practice[1]

Safeguards needed for all forms of medicine and treatments

Safeguards are needed for all forms of medicine and treatments, but no strong evidence has been provided for the assertion that additional safeguards are needed, compared to those that are already in place, for patients who seek help from Integrative GPs.

A specialty-specific *Code of Good Medical Conduct* is not required beyond the current code of conduct.

[1] The Board needs to define what this term means.

QUESTION 6

The same burden of evidence needs to be applied by the Board to all medical practices. Conventional medicine can and does cause harm to patients, with well documented examples being adverse drug reactions and events and medication errors,[xii] some of which lead to hospitalisations.[x] The *Code of Good Medical Practice* is considered adequate to protect the community. If the code is adequate to protect the community who use standard medical practice, which has well documented risks and harms, then it should be adequate to protect the community who see integrative medicine GPs, who use evidence-based complementary medicine which has low risk and causes substantively less harm. Integrative medicine GPs need to continue to work under the *Code of Good Medical Practice.*

QUESTION 7-10

NICM considers that the current regulations are adequate and that additional guidelines for doctors who practise integrative medicine are unnecessary.

As NICM fundamentally disagrees with the need for a separate set of guidelines, NICM will not be offering guidance or specific comments on amending the proposed guidelines.

It appears that the MBA did not consult with key stakeholders prior to drafting these guidelines and there is no evidence that the MBA did any significant research on the nature and extent of the issues raised in this area by unspecified stakeholders. The lack of further research undertaken by the MBA on the issues raised is cause for serious concern, as it shows a disregard for due process and leaves stakeholders uneasy as to the validity of the process that resulted in these draft guidelines. The Board is claiming that particular types of medicine are not evidence-based but has failed to meet their own standard with regard to the development of the proposed guideline.

Furthermore, the MBA has indicated their preferred option (being Option 2). Accordingly, the development of the proposed additional regulations (Option 2) do not conform to Principle 1 of the best practice principles outlined in the Council of Australian Government (COAG) document *Best Practice Regulation - A guide for councils and national standard setting bodies*[xiii] as follows:

a. COAG Principle 1 is to *'establish a case for action before addressing a problem'* and NICM asserts it is not apparent from this consultation paper that the MBA undertook necessary action to examine closely if there is indeed a problem requiring additional regulation. Firstly, there is no description of the scope and magnitude of the problem the MBA identifies. Secondly, the MBA does not address whether the identified problem is NOT adequately regulated via the current regulations. Indeed, we argue the existing guidelines adequately cover all aspects of the proposed guidelines.

b. COAG Principle 1 also states there should be no attempt to pre-justify a preferred option, and the MBA in the consultation paper states its preference for Option 2 rather than Option 1.

Furthermore, it appears the development of the proposed additional regulations (Option 2) does not satisfy COAG Principle 4 as an unnecessary regulatory burden placed on some medical practitioners may well restrict competition in the space:

c. COAG Principle 4 is that *'legislation should not restrict competition unless it can be demonstrated that the benefits of the restrictions to the community as a whole outweigh the costs, and the objectives of the regulation can only be achieved by restricting competition'*. Whilst not specifically legislation, this additional guidance proposed under Option 2 is separate to the regulatory guidance provided to all registered medical practitioners and may well impact on service availability and impose additional costs. These would need to be examined as part of compliance with COAG principles.

In addition, Australia is a signatory to both the international and regional policies on traditional and complementary medicine, and regulatory changes that impact this area must consider these policies.

The World Health Organization (WHO) Traditional Medicine Strategy 2014-2023, to which Australia is a signatory, notes the following with regard to traditional and complementary medicine:

> *"Traditional medicine (TM) is an important and often underestimated part of health services. In some countries, traditional medicine or non-conventional medicine may be termed complementary medicine (CM). TM has a long history of use in health maintenance and in disease prevention and treatment, particularly for chronic disease.*
>
> *The WHO Traditional Medicine (TM) Strategy 2014–2023 was developed in response to the World Health Assembly resolution on traditional medicine (WHA62.13) (1). The goals of the strategy are to support Member States in:*
>
> - *harnessing the potential contribution of TM to health, wellness and people-centred health care;*

- *promoting the safe and effective use of TM by regulating, researching and integrating TM products, practitioners and practice into health systems, where appropriate*.

The strategy aims to support Member States in developing proactive policies and implementing action plans that will strengthen the role TM plays in keeping populations healthy." (page 11)

It would appear that the MBA is segregating practitioners who use complementary medicines by proposing significant additional unjustified regulatory burden, in lieu of proactive support and greater integration as per the WHO Strategy. The delineation and segregation of integrative medicine practitioners proposed by the Board is not in the spirit of the WHO policy.

Complementary medicines are regulated in Australia by the Therapeutic Goods Administration (TGA) and all medical practitioners, including Integrative Medicine doctors using complementary medicines, are regulated by the current *Code of Good Medical Conduct.*

Options for addressing the concerns raised that the Board has not identified

The process that led to the development of the consultation paper and proposed guidelines appears to lack any serious academic rigour which unfortunately undermines trust in both the Board and its process.

The Australian population continues to use complementary medicines and integrative medicine in large numbers. It is imperative that the Board works with knowledgeable and well-informed stakeholders to progress this area of medical practice.

Rejecting complementary medicine (and integrative medicine) outright seems inconsistent with patient choice and breaches the Australian National Medicines Policy which consider the Quality Use of Medicines (QUM) as a core tenant. QUM unequivocally states that every time a medicine is considered, that all options are considered, pharmacological, complementary and non-pharmacological approaches. This appears to be the desire of the Australian public and should be considered the standard for medical practice.

QUESTION 11

NICM can only countenance Option 1 - Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.

REFERENCES

i Zollman C, Vickers A. What is complementary medicine? BMJ. 1999; 319(7211): 693-6.

ii Therapeutic Goods Administration. Complementary medicines [Internet]. Canberra: Therapeutics Goods Administration; [cited 2019 Jun 25]. Available from: https://bit.ly/2jtvWKP

iii Nobel Media AB. Nobel Prizes and Laureates [Internet]. Stockholm: Nobel Media AB; 2019 [cited 2019 Jun 25]. Available from: https://bit.ly/2X786NH

iv Gazarian M, Kelly M, McPhee JR, Graudins LV, Ward RL, Campbell TJ. Off-label use of medicines: consensus recommendations for evaluating appropriateness. Med J Aust. 2006; 185(10): 544-8.

v Gupta SK, Nayak RP. Off-label use of medicine: Perspective of physicians, patients, pharmaceutical companies and regulatory authorities. J Pharmacol Pharmacother. 2014; 5(2): 88-92.

vi Council of Australian Therapeutic Advisory Groups. Guiding principles for the quality use of off-label medicines [Internet]. Darlinghurst: Council of Australian Therapeutic Advisory Groups; 2013 [cited 2019 Jun 25]. Available from: https://bit.ly/2J5V49s

vii Garrow JS. How much of orthodox medicine is evidence based? BMJ. 2007; 335(7627): 951.

viii National Health and Medical Research Council. Guidelines for guidelines: Assessing certainty of evidence [Internet]. Canberra: National Health and Medical Research Council; 2018 [cited 2019 Jun 25]. Available from: https://bit.ly/2KFvw64

ix Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. BMJ. 1996; 312:71

x Zhang H, Du W, Gnjidic D, Chong S, Glasgow N. Trends in adverse drug reaction-related hospitalisations over 13 years in New South Wales, Australia. Intern Med J. 2019; 49(1): 84-93.

xi Roughead EE, Semple SJ, Rosenfeld E. Literature review: medication safety in Australia [Internet]. Sydney: Australian Commission on Safety and Quality in Health Care; 2013 [cited 2019 Jun 25]. Available from: https://bit.ly/2X6htNy

xii Runciman WB, Roughead EE, Semple SJ, Adams RJ. Adverse drug events and medication errors in Australia. Int J Qual Health Care. 2003; 15 Suppl 1: i49-59.

xiii Council of Australian Governments. Best practice regulation: A guide for councils and national standard setting bodies [nternet]. Canberra: Department of the Prime Minister and Cabinet; 2007 [cited 2019 May 20]. Available from: https://bit.ly/2IMMhu8

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