AIMA

Integrating Complementary and Mainstream Medicine

Dr Anne Tonkin
Chair, Medical Board of Australia
GPO Box 9958
Melbourne VIC 3001

20 March 2019

Dear Dr Tonkin

Request for an immediate and full retraction of the '*public consultation paper on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.'*

Thank you for meeting with AIMA in Canberra on 6 March 2019. Thank you also for your assurances about the extent and scope of the proposed guidelines. Despite these assurances, AIMA and the Integrative Medicine community continue to have serious concerns about the development, intent and scope of the consultation paper and guidelines. These concerns now lead us to formally request that the Medical Board of Australia retract the proposed guidelines and cease the current consultation process.

Our request is based on five primary concerns:

1. That the proposed guidelines are unnecessary
2. That the guidelines don't conform to COAG Principles for best practice regulation
3. That the scope of the proposed guidelines is poorly defined creating ambiguity and uncertainty
4. That the amalgamation of three disparate groups into one definition is not scientific
5. That there has been a lack of procedural fairness in the development of the proposed guidelines

We have addressed all five of these concerns below.

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'.

1. That the proposed guidelines are unnecessary

We have 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 (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 these reasons we call upon the Medical Board to withdraw the proposed guidelines and cease the current consultation process.

2. That the guidelines don't conform to COAG Principles for best practice regulation

On review of the COAG Principles[1] we have concerns that there has not been adequate rigor in applying these principles to the development of the proposed guidelines.

COAG Principle 1 is to 'establish a case for action before addressing a problem'[2]. The proposed guidelines provide no evidence of need, indeed by citing cases which have had Tribunal hearings they prove that the current *Good medical practice* guidelines work effectively to protect patient safety. There is no evidence presented in the proposed guidelines on the 'magnitude (scale and scope) of the problem'[3], there is no demonstration that the current regulations are inadequate[4] nor any cogent argument given as to the need for additional regulation[5]. Indeed from AIMA's analysis of the current guidelines and the proposed guidelines (see point 1 above) and from TGA reporting of adverse drug responses (ADR) which shows that only 1% of ADRs are from complementary medicines (see Attachment 2) there is no clear case for action.

Element 2 of Principle 1 clearly states that there should be no attempt to pre-justify a preferred solution. The proposed guidelines on several occasions state that 'the Board prefers Option 2'. Element 3 states that a range of options should be presented and if only the status quo and one other option are presented, there needs to be sound justification for considering only 2 options. The proposed guidelines only present Option 1, the status quo, and option 2, the 'preferred option' without having presented any other options or providing sound justification for Option 2 being the only option. The statement of preference for Option 2 at the very least creates a case for bias and is a breach of due process and procedural fairness.

Principle 4 of the COAG principles concerns restriction of competition and consumer choice[6]. 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 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 overly onerous, restrictive and anti-competitive. This may well impact on service availability, additional costs to the patient and restriction of consumer choice. Thus the proposed guidelines may be perceived as non-adherent to the COAG principles.

We contend that Principles 1 and 4 of the COAG principles have not been met and on this basis ask the MBA to withdraw the proposed guidelines and cease the current public consultation.

3. That the scope of the proposed guidelines is poorly defined and creates ambiguity and uncertainty

The lack of any clear definitions in the proposed guidelines creates significant uncertainty and makes responding meaningfully to the public consultation impossible. Further, without clear definitions for terms such as 'complementary', 'conventional', 'unconventional', 'unnecessary', 'unproven' and

[1] Council of Australian Governments Best Practice Regulation: A Guide for ministerial councils and national standard setting bodies, October 2007.
[2] Ibid p4
[3] Ibid p9
[4] Ibid P9
[5] Ibid p10
[6] Ibid p5

'emerging' there is no common framework for the MBA to be able to analyse or assess responses received.

There is also the very real concern that grouping three distinctly separate areas together in this proposal – complementary, unconventional and emerging – artificially and inappropriately aligns each area with the same degree of potential harm or risk which is clearly inappropriate and there is no evidence base for such an incongruous nomenclature.

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. 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.

We ask the MBA to withdraw the proposed guidelines and attendant public consultation due to lack of clarity about who and what they are intended to cover which compromises and confuses the consultation process.

4. That the amalgamation of three disparate groups into one definition is not scientific

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 something in common. 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 only apparent component of the definition that possibly provides cohesion is that the MBA sees all these practices as non-conventional. This makes this definition political and not scientific as it revolves around what the concept of conventional medicine is in this age of evidence-based practice. It is estimated that one third of general practitioners incorporate some aspects of complementary medicine within their medical practice so it could be argued that this constitutes current conventional medicine. The MBA would need to define conventional medicine to ascertain if this political definition has validity.

We ask the MBA to withdraw the proposed guidelines and attendant public consultation due to lack of science in the amalgamated definition.

5. That there has been a lack of procedural fairness in the development of the proposed guidelines

The development of the proposed guidelines and their subsequent presentation as Option 2 being the 'preferred choice' of the Board, has occurred in the absence of procedural fairness. The stakeholder groups and individuals who stand to be directly impacted by adoption of the proposed guidelines have not been given fair opportunity to contribute to the development of the guidelines. 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 development of the proposed guidelines, only on the adoption of the proposed guidelines.

AIMA believes 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 is has created confusion and considerable distress. For these reasons we are calling on the MBA to withdraw the proposed guidelines and cease the current public consultation.

The Way forward

Like the MBA/AHPRA, the board of AIMA hold patient safety, doctor wellbeing, and appropriately integrated evidence-based practices as central to the current and future practice of all medicine. We do not believe in any way that rogue doctors doing dangerous, unregulated and unrestrained treatments have any part to play in our profession and support the Board in action against them.

As discussed at our meeting, considering consumers' wide usage of complementary therapies, the broad integration of complementary therapies into the practice of 30% of Australian GPs and the substantial adoption of undergraduate teaching of Integrative Medicine with clinical integration into University based clinics (particularly amongst leading universities in the US), we need to engage in a discerning, transparent, well defined and collaborative discussion with the MBA, professional bodies and other medical authorities. AIMA is ready for this engagement and to assist in facilitating collaboration and understanding.

AIMA has been working to better define what integrative medicine is and what skills and training a doctor needs to call themselves an integrative doctor: we are developing a formal training pathway through collaboration with the professional bodies, education providers and academics within Integrative Medicine and Complementary Medicine; we are developing structures and processes to create safety and efficacy standards for practice (see attached Guidelines for Integrative Medicine published in our journal) and we are promoting and facilitating ongoing professional development. All of these initiatives aim to promote patient safety and minimise dangerous and unprofessional practice amongst doctors who identify themselves as integrative.

AIMA is keen to work collaboratively with the Medical Board in any way we can, however on the basis of our current assessment of the proposed guidelines, we do not believe that clearer regulation or the development of new guidelines is necessary. If, in the future, evidence is provided that supports the need for new guidelines we would welcome the opportunity to work collaboratively with the MBA from the beginning of the scoping process to maximise community ownership.

As you are aware the proposed guidelines and consultation process have caused considerable distress in the integrative medicine community. For the wellbeing of our doctors and patients we kindly ask that you expedite this request and let us know your decision as soon as possible.

Yours sincerely

Dr Penelope Caldicott
President, AIMA

ATTACHMENT 1

COMPARISON OF PROPOSED GUIDELINES AND EXISITING 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 new 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 and 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 a 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 new 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

-------- Original message --------
From: ADR Reports <ADR.Reports@health.gov.au>
Date: 23/08/2017 15:57 (GMT+10:00)
To: Subject: ADRs for CMs latest statistics CRM:0014116 [SEC=UNCLASSIFIED]

Thank you for your email to the TGA requesting statistics about ADR Reports for CM and pharmaceuticals. I am unclear exactly what information you are requesting as this is very general and broad question. I have provided an overview table comparing the total number of ADR reports to ADR Reports of CM for the last three years. We are currently overhauling the TGA ADR database which will improve the capture of CM in ADR Reports.

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

Adverse Event and Medicine Defect
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