Public Health Association
AUSTRALIA

# Public Health Association of Australia submission on regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments

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# Preamble

## The Public Health Association of Australia

The Public Health Association of Australia (PHAA) is recognised as the principal non-government organisation for public health in Australia working to promote the health and well-being of all Australians. It is the pre-eminent voice for the public's health in Australia.

The PHAA works to ensure that the public's health is improved through sustained and determined efforts of the Board, the National Office, the State and Territory Branches, the Special Interest Groups and members.

The efforts of the PHAA are enhanced by our vision for a healthy Australia and by engaging with like-minded stakeholders in order to build coalitions of interest that influence public opinion, the media, political parties and governments.

Health is a human right, a vital resource for everyday life, and key factor in sustainability. Health equity and inequity do not exist in isolation from the conditions that underpin people's health. The health status of all people is impacted by the social, cultural, political, environmental and economic determinants of health. Specific focus on these determinants is necessary to reduce the unfair and unjust effects of conditions of living that cause poor health and disease. These determinants underpin the strategic direction of the Association.

All members of the Association are committed to better health outcomes based on these principles.

## Vision for a healthy population

A healthy region, a healthy nation, healthy people: living in an equitable society underpinned by a well-functioning ecosystem and a healthy environment, improving and promoting health for all.

The reduction of social and health inequities should be an over-arching goal of national policy and recognised as a key measure of our progress as a society. All public health activities and related government policy should be directed towards reducing social and health inequity nationally and, where possible, internationally.

## Mission for the Public Health Association of Australia

As the leading national peak body for public health representation and advocacy, to drive better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health.

# Introduction

PHAA welcomes the opportunity to provide input to the consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments. The draft complementary medicine policy statement of the PHAA (attached) notes that evidence-based traditional, complementary and integrative health care (TCIHC) use and practice can form part of a holistic health system. A broader evidence base is required in the fields of traditional, complementary and integrative health care. Best world practice and policy in this topic should be continually informed by research.

Key policy positions of the PHAA in relation to complementary medicine include:

- National and international leadership are required for critical public health research to contribute to understanding and evaluating traditional, complementary and integrative health care use and practice.
- Traditional, complementary and integrative health care should be appropriately regulated to ensure adequate protection for those who choose to use TCIM practitioners and products.
- Public health perspectives on TCIHC should be appropriately integrated where applicable into health policy and health care delivery initiatives.
- TCIHC is a sector of considerable significance in the health sector, with numerous commercial, professional and political interests. Appropriate public protections and regulations must be enacted to ensure such interests do not adversely impact public health.

# PHAA Response to the consultation paper

### 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?

PHAA believes that the term "unconventional and emerging treatments" better fits the proposed terms for the draft guidelines. The term "complementary medicine" is highly nuanced, and as a definition of exclusion is highly problematic in its use. Although used as a moniker of convenience the term is heterogeneous and – whilst some forms remain fringe and warrant further regulatory attention – it is no longer true to suggest that all complementary medicine is "non-evidence-based" or "not considered part of conventional care" (from definitions on p.3).

The risks and benefits of "complementary medicine" can vary widely depending on whether it is used as an "alternative" to conventional care, or whether it is "integrated" to complement conventional care. This risk profile of complementary medicine contrasts with the "consistently high risk" treatments presented in the document as examples of unconventional or emerging treatments. Although the areas of concern as noted in the draft relate primarily to the latter, the current introduction problematises both the former and the latter.

The term "complementary medicine" can also incorporate both treatments that have an established evidence-base and significant levels of use by medical practitioners along with fringe, unorthodox treatments that have no place in modern medical practice. For example, nearly two-thirds of general practitioners formally refer to a chiropractor or osteopath via the Chronic Disease Management Medicare Items.[1] Since 1984 medical practitioners have been able to be reimbursed for acupuncture services under the Medicare Benefits Schedule, with over 500,000 services currently reimbursed annually.[2]

Whilst we understand this document has been developed from previous policies on "complementary medicine" alone, we note that the proposed increased scope of this policy extends – quite appropriately – well beyond the concept of complementary medicine. The current draft guidelines read as an attempt to merge an existing policy framework on complementary medicine with emerging regulatory concerns on new medical technologies and untested treatment approaches, and some of the messaging is confusing and convoluted.

Rather than trying to fit a 'round peg into a square hole', we would recommend listing traditional and complementary medicine as a subcategory of broader "unconventional medicine and emerging medicine" in the draft guidelines. We believe that this could be achieved as an additional bullet point under the definition or introduction (i.e. noting that some forms of traditional and complementary medicine can be considered unconventional or emerging). The new proposed definition seeks to link three disparate groups that have no shared traits or qualities, and this will become potentially problematic in the practical application of the guidelines.

As indicated on p8-9 of the proposed draft, complementary medicine is only one of six proposed areas of practice identified by the Board, and most concerns arising from their use come not from their status as complementary medicines, but from their unconventional (i.e. non-evidence-based or unsafe) use. Ultimately, the issue at hand is whether there is evidence to support the clinical use of individual treatments and whether a risk-benefit assessment supports their use. For traditional medicine, this may also include inappropriate misrepresentation of 'traditional knowledge' or practice traditions (e.g. homeopathic vaccination). Limiting the definition to "unconventional medicine and emerging treatments" (with *some* traditional and complementary medicine as a subset under this definition) better fits this definition and allows focus on inappropriate use of complementary medicine, rather than potentially problematizing appropriate integration of complementary medicine.

## 2. Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments? If not, how should it be defined?

**'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'**

We agree with this definition, with the caveat that complementary medicine should be listed as a potential subset of unconventional and emerging treatments. We would also note that current WHO terminology is "Traditional, Complementary and Integrative Medicine". We would suggest that the addition of the sentence "this may include some forms of traditional complementary medicine" – or an additional contextual statement in the guidelines – may help to address this issue.

### 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'?

We agree with the broad direction of the nature and extent of the issues identified. One area of concern not captured in detail in the current draft is where alternative or unorthodox standards supplant medical standards during their integration of complementary, unconventional or emerging treatments.[3] Few of the issues raised are unique to complementary and unconventional and emerging treatments. Existing guidelines for medical practice already cover all aspects of the proposed guidelines, and an explicit statement that these standards are expected for medical practitioners practising *any* form of treatment may be warranted.

We also believe that the Board needs to expand several sections, particularly as they specifically relate to complementary, unconventional or emerging treatments. For example, advice relating to financial conflicts-of-interest as currently presented in the guidelines is likely to result in non-compliance (3.2). Most medical practitioners will have a financial interest in the treatments that they recommend and provide, regardless of whether they are practising complementary, unconventional or emerging treatments (e.g. a surgeon providing three surgical options – as well as no surgery – will benefit differently from each of these recommendations). As such, rather than requiring that medical practitioners do not have any financial interest (an impossible task), full guidelines on how to manage the inherent conflict in medical practice – particularly as they relate to complementary, unconventional and emerging treatments should be made clear. These may include:

- Providing full information to the patient about:
    - The evidence that the prescribed treatment is appropriate for the condition being treated.
    - The evidence for the risks and benefits of the treatment.
    - The ongoing cost to the patient of using the treatment
    - Any financial interest the medical practitioner has in relation to the treatment, and
    - Any mark-up on costs related to the treatment, which ideally should be no more than to render the transaction cost-neutral to the medical practitioner
- Offer the patient purchasing options by providing information on alternative methods of sourcing the treatment in question.
- Maintain accurate clinical records for products purchased by each patient, including the type and amount, its delivery method and the period of treatment.[4]

### 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?

There are some specific practice areas that may warrant further attention from the Board – for example, we would urge the Board to consider the increasing use of invasive, ineffective and potentially dangerous treatments for autism.[5] The NPS *Choosing Wisely* framework may offer a guide for identifying further areas of practice that warrant attention. Additionally, we believe that the Board has missed the opportunity to examine the issue of the use of "pay-to-participate" clinical trials in unconventional and emerging treatments to promote experimental treatments of unknown safety and effectiveness. This has been identified as an area of potential ethical concern in stem cell treatment in Australia and internationally,[6] and is equally applicable to other experimental treatments. Although often presented as a means to address funding gaps in research – which may be the case in some circumstances – such trials may also be

used to make treatments available as consumer products even at the consumer stage.[7] Guidelines around responsible research conduct – or around misrepresentation of experimental treatments as research projects – may be warranted.

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

The PHAA believes that safeguards are needed for patients who seek complementary and unconventional and emerging treatments. Complementary medicine is extraordinarily popular in Australia: 70% of Australians use complementary medicines at some time, and approximately 1/3 use complementary medicine and integrative medicine regularly.[8] The risks of complementary medicine are highest when these therapies are not integrated with, or are used as an alternative to, conventional medical therapies or practices.[9] Considering this, it is vital that to ensure patient safety, medical practitioners are equipped to understand and guide the appropriate use of these treatments. The development of these guidelines need to ensure that the new regulatory norms do not discourage medical practitioners from advising patients on complementary medicine or integrating complementary treatments *where appropriate*, and instead focus medical practitioner attention on ensuring that such integration is performed in a safe, effective and ethical manner.

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

The PHAA would note that current regulations and policies are largely adequate to address the concerns raised in the consultation document. The regulatory and legislative safeguards are already there – most are already included in the *Good Medical Practice* guidelines – but many regulations are not largely enforced. For example, comparative analysis of complementary health practitioner boards versus conventional health practitioner boards demonstrates that, while similar disciplinary issues arise across all boards in relation to practice standards, complementary health practice boards are significantly more active in disciplinary action against practitioners who do not meet professional standards. This is particularly true for those area identified as concerning such as financial exploitation, monopolisation of care or unsafe practice.[10]

Additionally, some areas related to areas of practice that are of concern already fall under the jurisdiction of other legislation, or other initiatives. We would urge the Board to make better use of existing strategies. Prescription of non-approved therapeutic goods or use of non-approved therapeutic devices, for example, is already a criminal offence under *Therapeutic Goods Act 1989*. Any new policies should be more explicit in highlighting legislative and regulatory restrictions around practice that go beyond the Board's own policies or guidelines.

## 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 stated previously, the PHAA notes that current regulations and policies are largely adequate to address the concerns raised in the consultation document. The regulatory and legislative safeguards are already there – most are already included in the *Good Medical Practice* guidelines – but many regulations are not largely enforced. Most of the issues raised in the draft guidelines are not unique to complementary and unconventional and emerging treatments, and as such we would recommend that the document is

reviewed to make it overt that these standards are not applicable only to these forms of treatment, but to medical treatment in general.

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

Guidelines would be helpful. However, they should lay out a pathway to safe, effective and ethical practice for practitioners who do choose to integrate complementary, unconventional or emerging treatments. The PHAA would also urge the Board to consider other mechanisms available to it to achieve the aims of identifying issues in medical practice. For example, the Chiropractic Board has issued specific statements (e.g. on anti-vaccination advice and care of pregnant patients) when it has identified practice issues within that profession.[11] This has enabled flexibility and specificity to target specific areas of concern in a way in that development of broader guidelines cannot and which may be useful to highlight some of the examples listed on p8-9 of the draft guidelines.

### 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?

One area of concern is that the current guidelines pose complementary, unconventional and emerging treatments as an area of concern only. There appears to be no overt pathway or guidance for medical practitioners to integrate complementary or emerging treatments in a safe, effective and ethical manner. This approach may be counter-productive if it causes medical practitioners to ignore complementary medicine use among their patient base or to cease to report or publicise their integration of complementary treatments.

Guidelines should lay out a pathway to safe, effective and ethical practice for practitioners who do choose to integrate complementary, unconventional or emerging treatments, rather than just point out potential problems. We believe that this could be achieved via incorporation of a statement similar to the introduction of the draft PHAA policy on complementary medicine, which notes that integration can be positive, but that such integration must be evidence-based and ethical:

- Evidence-based traditional, complementary and integrative health care (TCIHC) use and practice can form part of a holistic health system.

We believe that the inclusion of such a statement in the introduction would reduce concerns that the development of these guidelines may impinge on safe, effective and ethical practice of complementary and unconventional and emerging treatments, or stifle innovation in medical practice.

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

Other options to supplement the Medical Board's proposed approach to address issues associated with medical practitioners providing unconventional and emerging treatments have been outlined in this submission. These include the Board developing specific guidance statements on identified areas of interest as well as stronger disciplinary action against medical practitioners that breach regulations detailed in the Good Medical Practice guidelines. There is also an option for the Board to develop an overt guidance pathway or guidance for medical practitioners to integrate complementary or emerging treatments in a safe, effective and ethical manner.

**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 Two – Strengthen current guidance for medical practitioners who provide complementary and unconventional medicine and emerging treatments through practice-specific guidelines that clearly articulate the Board's expectations of all medical practitioners and supplement the Board's *Good medical practice: A code of conduct for doctors in Australia*.**

Note: this recommendation is based on the caveat that the issues raised above are appropriately considered.

# Conclusion

PHAA supports the broad directions of the proposed draft guidelines. However, we are keen to ensure that these guidelines highlight the potential of integration of complementary and emerging treatments, as well as their challenges. We are particularly keen that the following points are highlighted:

- That the qualitatively significant differences between complementary, unconventional and emerging treatments are appropriately acknowledged in the guidelines
- That the guidelines incorporate a pathway to guide *appropriate practice* for medical practitioners using complementary or unconventional or emerging treatments, not just a warning on *inappropriate practice*

The PHAA appreciates the opportunity to make this submission and the opportunity to work with the Medical Board of Australia on developing standards for appropriate integration of complementary and unconventional and emerging treatments.

Please do not hesitate to contact us should you require additional information or have any queries in relation to this submission.

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