



## Public consultation paper

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February 2019

### Public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments

#### Summary

This public consultation paper seeks feedback on options for clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.

The National Law<sup>1</sup> empowers the National Boards to develop and approve codes and guidelines to provide guidance to registered health practitioners. The National Law requires National Boards to ensure there is wide-ranging consultation on the content of any proposed registration standard, code or guideline.

The Medical Board of Australia (the Board) is inviting feedback on the issues and options outlined in the discussion paper. There are also specific questions which you may wish to address in your response.

#### Making a submission

Please provide written submissions by email, marked: 'Consultation on complementary and unconventional medicine and emerging treatments' to [medboardconsultation@ahpra.gov.au](mailto:medboardconsultation@ahpra.gov.au) by close of business on **12 April 2019**.

Submissions for publication on the Board's website should be sent in Word format or equivalent.<sup>2</sup>

Submissions by post should be addressed to the Executive Officer, Medical, AHPRA, GPO Box 9958, Melbourne 3001.

#### Publication of submissions

The Board publishes submissions at its discretion. The Board generally publishes submissions on its website to encourage discussion and inform the community and stakeholders. Please let us know if you do not want us to publish your submission, or want us to treat all or part of it as confidential.

We will not place on our website, or make available to the public, submissions that contain offensive or defamatory comments or which are outside the scope of the subject of the consultation. Before publication, we may remove personally-identifying information from submissions, including contact details.

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<sup>1</sup> Health Practitioner Regulation National Law, as in force in each state and territory

<sup>2</sup>You are welcome to supply a PDF file of your feedback in addition to the word (or equivalent) file, however we request that you supply a text or word file. As part of an effort to meet international website accessibility guidelines, AHPRA and National Boards are striving to publish documents in accessible formats (such as word), in addition to PDFs. More information about this is available at [www.ahpra.gov.au/About-AHPRA/Accessibility.aspx](http://www.ahpra.gov.au/About-AHPRA/Accessibility.aspx)

The views expressed in the submissions are those of the individuals or organisations who submit them and their publication does not imply any acceptance of, or agreement with, these views by the Board.

The Board accepts submissions made in confidence. These submissions will not be published on the website or elsewhere. Submissions may be confidential because they include personal experiences or other sensitive information. Any request for access to a confidential submission will be determined in accordance with the *Freedom of Information Act 1982* (Cth), which has provisions designed to protect personal information and information given in confidence.

**Published submissions will include the names of the individuals and/or the organisations that made them, unless confidentiality is requested.**

## Background

Under section 39 of the National Law, the National Boards may develop and approve codes and guidelines to provide guidance to registered health practitioners about matters relevant to the exercise of the National Board's functions.

An approved registration standard, code or guideline is admissible in proceedings under the National Law or the law of a co-regulatory jurisdiction regarding a medical practitioner as evidence of what constitutes appropriate professional conduct or practice of the profession.

The Board is considering options for clearer regulation of medical practitioners who provide complementary or unconventional medicine or emerging treatments. Concerns have been raised by stakeholders about this area of practice suggesting that additional guidance for medical practitioners is needed to support safe practice and ensure safeguards for patients.

The Board is proposing the following definition:

**Complementary and unconventional medicine and emerging treatments** include any assessment, diagnostic technique or procedure, diagnosis, practice,<sup>3</sup> 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.

## Options

The Board has identified two options in developing this proposal.

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.

Option 2 - 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*.

## Preferred option

The Board prefers Option 2.

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<sup>3</sup> **Practice** means any role, whether remunerated or not, in which the individual uses their skills and knowledge as a health practitioner in their profession. For the purposes of these guidelines, practice is not restricted to the provision of direct clinical care. It also includes using professional knowledge in a direct non-clinical relationship with clients, working in management, administration, education, research, advisory, regulatory or policy development roles, and any other roles that impact on safe, effective delivery of services in the profession.

## Issues for consultation

A discussion paper outlining the issues is attached to aid the consultation.

The discussion paper includes examples of treatments and therapies being offered as well as identifying the concerns about the practice to aid stakeholders understanding of the issues.

The draft guidelines provide guidance on good medical practice in relation to areas of practice that are within the Board's definition of complementary and unconventional medicine and emerging treatments.

However, if approved, the guidelines will be a standalone document and will not include the examples currently in the discussion paper. The Board will develop supporting documents (based on the discussion paper) that will be available with the guidelines to provide information on the scope of the guidelines and include examples of complementary and unconventional medicine and emerging treatments. Providing this additional information separately from approved guidelines will enable the Board to update it as needed as the scope of this area of practice can be subject to rapid changes.

## Relevant sections of the National Law

The relevant sections of the National Law are sections 39, 40 and 41.

## Questions for consideration

The Board is inviting feedback on the issues and options outlined in the discussion 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?
2. Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments – 'any assessment, diagnostic technique or procedure, diagnosis, practice,<sup>4</sup> 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.'  
If not, how should it be defined?
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'?
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?
5. Are safeguards needed for patients who seek 'complementary and unconventional medicine and emerging treatments'?
6. Is there other evidence and data available that could help inform the Board's proposals?

## Options

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

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<sup>4</sup> **Practice** means any role, whether remunerated or not, in which the individual uses their skills and knowledge as a health practitioner in their profession. For the purposes of these guidelines, practice is not restricted to the provision of direct clinical care. It also includes using professional knowledge in a direct non-clinical relationship with clients, working in management, administration, education, research, advisory, regulatory or policy development roles, and any other roles that impact on safe, effective delivery of services in the profession.

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?
10. Are there other options for addressing the concerns that the Board has not identified?
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 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.
  - Option 2 - 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*.
  - Other – please specify.

### Attachments

1. Discussion paper – *Clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments*
2. Draft *Guidelines for registered medical practitioners – Complementary and unconventional medicine and emerging treatments*
3. The Board's statement of assessment against AHPRA's Procedures for the development of registration standards, codes and guidelines and Council of Australian Governments (COAG) principles for best practice regulation



## Discussion paper

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February 2019

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

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## Background

The Medical Board of Australia (the Board) is considering options for clearer regulation of medical practitioners who provide complementary or alternative medicine and other related areas of practice.

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. In particular, concerns have been raised about insufficient information being provided to patients, inappropriate tests being ordered, inappropriate prescribing and inappropriate treatments being provided to vulnerable consumers. 

The Board agreed to look at this area of practice, to determine the concerns and issues, define the size and nature of the issues, and scope potential options for addressing these concerns.

This discussion paper provides an overview to facilitate consideration and discussion of the issues and options.

## Definition

The term 'complementary and alternative medicine' is in common use. However, this term, as it is generally used, does not clearly include all the areas of medical practice about which concerns have been raised. 

There is no widely accepted definition of complementary and/or alternative medicine. Current definitions of similar terms include:

- Complementary health care
  - non-evidence based care (Medical Council of New South Wales, 2015)<sup>1</sup>
- Complementary medicine
  - therapeutic good consisting of designated active ingredients (as per Therapeutic Goods Administration (TGA) list) (TGA, 2013)<sup>2</sup>
  - a wide range of products and treatments with therapeutic claims that are not presently considered to be part of conventional medicine (Australian Medical Association, 2018)<sup>3</sup>
  - not within the domain of conventional medicine (National Health and Medical Research Council, 2014)<sup>4</sup>
  - a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system...it includes all such practices and ideas self-defined by their users as preventing or treating illness or promoting health and well-being (National Institute of Complementary Medicine)<sup>5</sup>

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<sup>1</sup> Medical Council of New South Wales, *Complementary Health Care Policy*, 2015 available at: [https://www.mcnsw.org.au/sites/default/files/dd15\\_43664\\_policy\\_-\\_complementary\\_health\\_care\\_-\\_version\\_3\\_finalised.pdf](https://www.mcnsw.org.au/sites/default/files/dd15_43664_policy_-_complementary_health_care_-_version_3_finalised.pdf)

<sup>2</sup> Therapeutic Goods Administration, *An overview of the regulation of complementary medicines in Australia*, 2013 accessed at: <https://www.tga.gov.au/overview-regulation-complementary-medicines-australia>

<sup>3</sup> Australian Medical Association, *Position statement: Complementary medicine*, 2018 available at: <https://ama.com.au/position-statement/ama-position-statement-complementary-medicine-2018>

<sup>4</sup> National Health and Medical Research Council, *Talking with your patients about complementary medicine*, 2014, available at: <https://www.nhmrc.gov.au/guidelines-publications/cam01>

<sup>5</sup> National Institute of Complementary Medicine, *Understanding complementary and integrative medicine*, accessed at: [https://www.westernsydney.edu.au/nicm/health\\_information/information\\_for\\_consumers/understanding\\_cm](https://www.westernsydney.edu.au/nicm/health_information/information_for_consumers/understanding_cm)

- Complementary and alternative medicine
  - not generally considered part of conventional medicine (College of Physicians and Surgeons of Ontario, 2011)<sup>6</sup>
  - not integrated into the dominant health care system (WHO, 2004)<sup>7</sup>
- ‘Complementary medicine’ and ‘alternative medicine’
  - *complementary medicine* is that which is used **together with** conventional medical practice whereas *alternative medicine* is used **in place of** conventional medical practice (Clinical Oncology Society Australia, 2013)<sup>8</sup>
- Integrative medicine
  - a philosophy of healthcare...combining the best of conventional western medicine and evidence-based complementary medicine and therapies within current mainstream medical practice (Australasian Integrative Medicine Association).<sup>9</sup>



Examples of complementary and alternative **medicines** that are commonly considered to fall within the definitions above include; vitamins, minerals and nutritional supplements (in the absence of a deficiency), herbal medicines, homeopathic preparations and aromatherapy products.



Examples of complementary and alternative **therapies** that are commonly considered to fall within the definitions above include; homeopathy, naturopathy, energy therapies and Reiki.

Some definitions of complementary and/or alternative therapies include the regulated health professions of chiropractic, osteopathy, Chinese medicine and acupuncture.

Other areas of clinical practice where concerns have been raised but which do not fit within the definitions of complementary and/or alternative medicine as defined above, include:

- diagnosis of conditions which are not generally accepted, for example:
  - Lyme disease (in patients who have not been outside Australia)
- unconventional diagnostic techniques and methods, for example:
  - applied kinesiology
  - pathology testing in non-accredited laboratories
- conventional medicines and accepted therapies provided outside accepted therapeutic guidelines or protocols and/or without usual clinical indications including off-label use, for example:
  - long term antibiotics in the absence of identified infection
  - hormone therapy and supplements in the absence of a hormone deficiency/identified therapeutic need



<sup>6</sup> The College of Physicians and Surgeons of Ontario, *Policy statement Complementary/Alternative Medicine*, 2011 available at: <http://www.cpso.on.ca/Policies-Publications/Policy/Complementary-Alternative-Medicine>

<sup>7</sup> World Health Organisation, *Guidelines on developing consumer information on proper use of traditional, complementary and alternative medicine*, 2004 available at: <http://apps.who.int/medicinedocs/en/d/Js5525e/4.html>

<sup>8</sup> Clinical Oncology Society of Australia, *Position statement on the use of complementary and alternative medicine by cancer patients*, 2013 available at: [https://www.cosa.org.au/media/1133/cosa\\_cam-position-statement\\_final\\_new-logo.pdf](https://www.cosa.org.au/media/1133/cosa_cam-position-statement_final_new-logo.pdf)

<sup>9</sup> Australian Integrative Medicine Association, *What is integrative medicine*, accessed at: <https://www.aima.net.au/what-is-integrative-medicine/>

- stem cell therapy for conditions without supporting evidence for their use
- chelation therapy for conditions such as cancer or cardiovascular disease
- new and emerging therapies.

In addition to 'complementary' and/or 'alternative' medicine, the Board has considered a number of other definition issues so as to ensure that all the relevant areas of practice are captured:

- unconventional medicine
- off-label prescribing<sup>10</sup>
- experimental practice
- unproven therapies
- emerging therapies
- innovative therapies
- entrepreneurial medicine
- progressive practice.



The Board is using the comprehensive description 'complementary and unconventional medicine and emerging treatments' in its consultation. The reasons for using these terms are:

- 'complementary' to include practice such as herbal medicines and homeopathy – those commonly thought of as 'complementary and alternative medicine'
- 'unconventional' to include conventional treatments provided outside conventional protocols (such as long-term antibiotics for Lyme-like illness)
- 'emerging' to include new and experimental treatments such as the expanding use of stem cell therapy.



The following working definition is proposed:

**Complementary and unconventional medicine and emerging treatments** include any assessment, diagnostic technique or procedure, diagnosis, practice,<sup>11</sup> 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.



<sup>10</sup> "Off-label" prescribing occurs when a drug is prescribed for an indication, a route of administration, or a patient group that is not included in the approved product information document for that drug. Prescribing off label is unavoidable and very common, especially (in a) practice which includes children, pregnant women or palliative care. Off-label prescribing means that the TGA has not approved the indication, route of administration or patient group. It does not mean that the TGA has rejected the indication. Commonly the TGA has not been asked to evaluate the indication... The onus is on the prescriber to defend their prescription for an indication that is not listed in the product information... if, in the opinion of the prescriber, the off-label prescription can be supported by reasonable quality evidence.' Day, R (2013) 'Off-label prescribing', *Australian Prescriber* 36:182-3.

<sup>11</sup> **Practice** means any role, whether remunerated or not, in which the individual uses their skills and knowledge as a health practitioner in their profession. For the purposes of these guidelines, practice is not restricted to the provision of direct clinical care. It also includes using professional knowledge in a direct non-clinical relationship with clients, working in management, administration, education, research, advisory, regulatory or policy development roles, and any other roles that impact on safe, effective delivery of services in the profession.

## Provision and use of complementary and unconventional medicine and emerging treatments

### Practitioners

A range of medical practitioners are practising in the areas of complementary and unconventional medicine and emerging treatments, including medical practitioners with different levels of experience and training and varying specialties.

It is not known how many registered medical practitioners practise in this area. The Australian Integrative Medicine Association (AIMA) represents doctors and other health care professionals who practise 'integrative medicine'. Their membership numbers are not available. However, many of those who practise complementary or unconventional medicine, or who use emerging treatments, would not consider themselves as practising 'integrative medicine' and are not members of the AIMA.

Submissions to the TGA's 2016 consultation on 'Regulation of autologous cell and tissue products and proposed consequential changes to the classification of biologicals' conservatively estimated that there are over 40 private clinics in Australia offering stem cell therapies and this area is growing.<sup>12</sup>

### Consumer expenditure

There are various data on the prevalence and use of complementary medicines. Recent figures report that the sector in Australia generates revenue of up to \$3.5 billion annually – this would include over the counter products.<sup>13</sup> A large proportion of consumers (more than two-thirds), report using complementary medicines.<sup>14</sup>

### Issues and concerns about this area of practice

The information available to the Board indicates that the use of complementary and unconventional medicine and emerging treatments is increasing and includes a wide range of practices from minimally invasive to major complex interventions. The medicines and therapies may be used as alternatives to conventional medicine or used in conjunction with conventional medicine. They may be used with or without the knowledge of a patient's other treating practitioners.

The available information indicates that patients are being offered treatments for which the safety and efficacy are not known. They may be having treatments which may be unnecessary or may result in delayed access to more effective treatment options. Unnecessary treatments may expose patients to adverse side effects. Harm may occur directly from the treatment resulting in an adverse outcome or it may be indirect, associated with delays in accessing other treatment or from the promises of 'false hope'. While there may be benefits - treatment and therapies may also have no effect, the benefit may be uncertain, or the effect may potentially be harmful. The harm can be physical, psychological and/or financial.

These treatments are provided by a variety of medical practitioners with varying qualifications and expertise in the therapy and/or the patient's underlying condition. There are reports of medical practitioners who are not specialists, providing treatments for complex conditions without necessarily having the specialist level knowledge of the disease and its progression. The lines between research and commercial advancement can be blurred and conflicts of interest can arise if the provider has a financial interest in the product or service being offered. Some treatments are being offered on a commercial basis before the usual clinical trials have been completed. Patients don't have the usual protections where clinical trials have not been undertaken. Patients may also be offered treatments, tests or products which are available only through the practitioners offering them, or through other entities with which the practitioners have commercial associations, which may not be disclosed to the patients.

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<sup>12</sup> The TGA consultation paper and the submissions are available at <https://www.tga.gov.au/consultation/consultation-regulation-autologous-cell-and-tissue-products-and-proposed-consequential-changes-classification-biologicals>.

<sup>13</sup> Review of Medicines and Medical Devices Regulation – Stage Two, *Report on the regulatory frameworks for complementary medicines and advertising of therapeutic goods*, 2015 available at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation>

<sup>14</sup> NPS Medicinewise, *NPS Annual Consumer Surveys: Findings about complementary medicines use*, 2008, available at: <http://www.nps.org.au/about-us/what-we-do/our-research/complementary-medicines/nps-consumer-survey-cms-use-findings>

Many of these treatments are funded privately, can be expensive, and may have uncertain results. Patients may seek complementary and unconventional medicine or emerging treatments because of serious and/or chronic conditions and may be vulnerable to exploitation, including financial exploitation. Consumers who see direct-to-consumer marketing of 'therapies for health and wellness' may not realise that these are medical interventions with associated risks.

The risk to patients depends on a range of factors such as:

- the extent to which the practitioner is practising outside accepted practice
- the level of risk of the procedures and interventions, and
- the health and risk profile of the patient.



An added element of complexity in this area of practice is that many of the treatments offered are variations of existing accepted treatments. For example, stem cell treatments are being offered for a range of conditions, extending beyond those for which they are accepted treatments or for which there is a sound and established evidence base.

**Concerns about therapies and treatments being offered include:**

- safety and efficacy of treatments not known (experimental treatments outside clinical trials)
- unnecessary treatments, or treatments for which there is no clearly demonstrable need
- risk of harm associated with some treatments (unnecessary exposure to serious side effects)
- inappropriate prescribing - not in accordance with therapeutic guidelines (in particular, hormone therapy and antibiotic therapy)
- unconventional off-label prescribing
- recommending hormone, vitamin and mineral supplements without accepted indications
- prescribing substances not approved by the TGA without scientifically defensible reasons
- prescribing substances not approved for human therapeutic use
- prescribing compounded products:
  - where a commercial product is available and suitable
  - where there is a lack of evidence to support the compounded product's use
  - that have been manufactured in circumstances that don't meet expected quality assurance processes<sup>15</sup>
  - that have been manufactured in bulk rather than to meet an individual's needs
- accepted treatments provided without indications/medical justifications
- accepted treatments provided beyond the accepted indications
- risks associated with route of administration of treatments
- methods used to harvest and administer stem cells
- varied techniques and lack of standardisation and quality control, e.g. variable numbers of stem cells in the injections
- variable levels of training, skill and expertise in the administration of treatments and procedures
- the providers offering treatments do not have experience or expertise in treating the underlying condition/disease

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<sup>15</sup> Unlike medicines on the Australian Register of Therapeutic Goods, compounded medicines are not subject to the same rigorous assessment for product efficacy, quality and safety by the Therapeutic Goods Administration.

- practitioners using an identical treatment approach, including unconventional investigation and prescribing for most or all patients, and failing to make a proper diagnosis of each patient's specific condition
- practitioners encouraging indiscriminate or unnecessary use of regulated health services with limited evidence of benefits
- vulnerable patients (including patients with mental health conditions) who have tried conventional medicine and are willing to try anything are at risk of exploitation and unnecessarily exposed to risk of harm.

**Concerns as to practices include:**

Conflicts of interest, including:

- blurred lines between research and commercial innovation
- treatments marketed direct to consumers based on early research data which would normally lead to further research – insufficient to justify marketing direct to consumers outside formal clinical trials
- conflict of interest because of the commercialised nature of some procedures – where the provider has a pecuniary interest in a related company.

Concerns about inadequate consent including:

- known risks not fully disclosed
- potential lack of benefit not communicated clearly
- unsupported claims of efficacy and safety
- false claims of benefit
- failure to inform patient of full costs (treatments are expensive and patients pay privately).

Poor patient management, including:

- inadequate or inappropriate testing or investigation
- missed, incorrect, or delayed diagnosis
- delayed or inadequate referral to appropriate specialists
- inadequate or inappropriate follow-up/monitoring or review (including lack of long term follow-up after experimental procedures)
- inadequate co-ordination of care - failed to obtain medical history from the patient's existing treating practitioners/failure to notify other treating practitioners of concurrent treatments
- inadequate, inaccurate or misleading health records: examinations are not recorded and/or not routinely performed.

**Areas of practice**

The following are some of the areas of medical practice with more specific examples of the procedures and treatments being offered and some of the concerns. For some areas of practice, the concerns relate to the practice itself, for others the concerns are about individuals practising outside accepted practice. Clearer regulation would need to address these areas:

- *Complementary and alternative medicine* – medical practitioners who use complementary and alternative medicine in conjunction with 'conventional' medicine may refer to themselves as practising 'integrative medicine'. Risks to patients are increased when practitioners offer 'alternative' treatments for conditions such as cancer, in place of conventional therapies.

- *Lyme-like illness and Lyme disease* – practitioners who diagnose and treat Lyme disease in patients who have never left Australia sometimes describe themselves as ‘Lyme-literate’. Some use diagnostic tests that are not well accepted and/or testing in non-accredited laboratories. Treatment options include conventional treatments such as antibiotics provided outside accepted treatment protocols.
- *Stem cell therapies* – haematopoietic stem cell transplants (autologous (self) or donor) are a standard, proven treatment for certain diseases including blood cancers. There are however, private Australian clinics offering autologous stem cell therapy for an increasing range of conditions including osteoarthritis, rheumatoid arthritis, tendinitis, migraines, diabetes, chronic obstructive pulmonary disease (COPD), multiple sclerosis, motor neurone disease, Alzheimer’s disease, Parkinson’s disease, hearing loss and hair loss. The stem cells are sourced from the patient’s blood or from their adipose (fat) tissue (by liposuction). While there is some evidence from early clinical trials of possible benefit for select patients with certain conditions, this does not align with the broad benefits suggested by some direct to consumer marketing.
- *Platelet rich plasma (PRP)* – blood is taken from the patient and put through a centrifuge. The plasma with a higher concentration of platelets (small fragments of cells that are important for normal blood clotting) than regular blood is injected back into the patient. This is most commonly promoted for arthritis and muscle and tendon injuries but is increasingly being promoted for aesthetic purposes with limited evidence. Variations of these treatments include autologous conditioned serum (‘Orthokine’) therapy where blood is extracted and incubated before centrifugation, to increase anti-inflammatory cytokines.
- *Anti-ageing cosmetic regenerative medicine* – includes procedures offered by cosmetic practitioners, such as PRP injections for ‘facial rejuvenation’, stem cells for hair loss and ultrasound therapy for skin tightening. Where the aim of the procedure is to improve appearance, these procedures would be included in the definition of ‘cosmetic procedures’ in the Board’s *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures*. Concerns particularly relate to the claims of benefit being made.
- *Anti-ageing treatments, performance enhancing treatments and health and wellness therapies* – includes steroid and hormone injections such as peptides, growth hormone, testosterone and thyroid hormones. Some practitioners use bio-identical hormones and compounded products (in association with compounding pharmacists). While often associated with body-building and sports performance, these treatments are increasingly being marketed to a wider patient base for other uses such as weight loss (Growth hormone-releasing hormone<sup>16</sup>) and tanning (Melanotan II<sup>17</sup>). Some marketing messages are generalised, for example offering ‘hormone restoration’, ‘optimise hormone levels’ and ‘minimise premature ageing’. While they are sometimes promoted as ‘anti-ageing’, some of these therapies are marketed as ‘health and wellness therapies’ and don’t aim for and/or result in traditional cosmetic aesthetic changes (‘feel younger’ as opposed to ‘look younger’). Therefore, these would not be covered by the Board’s existing *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures*. The predominant concerns are around whether the treatments are necessary, effective or safe.

Some concerns have been raised about the provision of medicinal cannabis. However, changes to Commonwealth and state and territory legislation allows for lawful access to medicinal cannabis through the TGA Authorised Prescriber Scheme and Special Access Scheme. Medical cannabis is classified as a schedule 4 or schedule 8 medicine and prescribing is highly regulated. The TGA has published [clinical guidance](#) for prescribers of medical cannabis.

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<sup>16</sup> Growth hormone acts on enzymes to increase breakdown of fat.

<sup>17</sup> Melanotan II is a synthetic melanocortin peptide hormone (melanocyte-stimulating hormone) which causes pigmentation of skin.

## Adverse events data

It is difficult to source data relating to the numbers of adverse events occurring with complementary and unconventional medicine and emerging treatments. There is a range of therapies and treatments provided by medical practitioners with different registration types and specialties. Patients may not tell their general practitioner or other specialist that they are having other treatments or that they have had an adverse reaction. Notifications and complaints data may provide an indication of the range of adverse events but under-reporting is thought to be common.

In 2016, there was a coroner's case following the death of a patient in NSW who had stem cell therapy for dementia. The patient died from blood loss associated with the liposuction procedure used to source the stem cells (as opposed to a problem with the stem cells themselves). The Coroner found that the consent process, the pre-operative preparation and post-operative management were all inadequate. In his report, the Coroner also raised concerns about the 'unproven nature and efficacy' of the procedure and the conflict of interest in this area of commercialised medicine. He recommended that NHMRC develop guidelines for clinical practice in relation to 'experimental or innovative' practice.<sup>18</sup>

Submissions to the TGA consultation on regulation of autologous cell and tissue products included reports of some adverse events from stem cell therapies administered in a clinical trial setting.<sup>19</sup>

## Complaints as a source of information

Complaints to the Board provide some insight into the types of concerns that patients report. Concerns related to complementary and unconventional medicine and emerging treatments include:

- unconventional and unproven diagnostic techniques and equipment, e.g. thermography to detect breast cancer
- diagnosis and subsequent treatments based on results from non-accredited laboratories
- failure to consider differential diagnoses
- treating most or all patients for the same condition and/or providing the same treatments regardless of their presentation
- failure to refer patients with complex diagnoses to specialists
- failure to manage co-existing medical conditions
- providing alternative therapies for cancer treatment in place of conventional treatments with inadequate consent process
- treatment outside accepted treatment protocol/therapeutic guidelines, e.g. long-term antibiotics in the absence of an identified infection
- promoting indiscriminate use of health services without proven benefits, e.g. intravenous vitamins for wellbeing, hormones for performance enhancement
- prescribing when not clinically indicated, e.g. hormones for a person without a hormone deficiency
- complications from inappropriate or unnecessary treatments e.g. infection from peripherally inserted central catheter (PICC) lines inserted into the venous system and remaining for a prolonged period of time to administer long term antibiotics.
- high fees and complaints about financial exploitation.

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<sup>18</sup> Coroners Court of New South Wales, *Inquest into the death of Sheila Drysdale*, 15 July 2016, available at: <http://www.coroners.justice.nsw.gov.au/Documents/Findings%20Drysdale.pdf>

<sup>19</sup> The TGA consultation paper is available at <https://www.tga.gov.au/consultation/consultation-regulation-autologous-cell-and-tissue-products-and-proposed-consequential-changes-classification-biologicals>. The TGA has published the submissions at <https://www.tga.gov.au/submissions-received-regulation-autologous-cell-and-tissue-products-and-proposed-consequential-changes-classification-biologicals>.

Concerns about the cost and exploitation of patients are more commonly raised by other parties; patients don't tend to complain about the cost.

In some cases, the pharmacists who filled the prescriptions for the medical practitioners have also been subject to notifications and regulatory action.<sup>20</sup>

### **Relevant tribunal decisions**

There have been a number of tribunal decisions in relation to the provision of complementary and unconventional medicine and emerging treatments provided by medical practitioners. Examples include:

#### Alternative cancer treatments

- State Administrative Tribunal of Western Australia (2015)<sup>21</sup> - a medical practitioner with general registration was suspended for recommending treatment for a cancer patient which included intravenous administration of Vitamin C, Carnivora, and mistletoe extract. The tribunal had particular concerns in relation to:
  - financial conflict of interest – the doctor providing the treatment was a director and shareholder in the company that sold the treatment to the patient
  - providing treatment to the patient in circumstances when there was no evidence that the treatment would be effective.
- Health Practitioners Tribunal of South Australia (2016)<sup>22</sup> – a specialist general practitioner was found to have engaged in professional misconduct for providing a nutritional and detoxification program for a terminally ill patient when there was no reasonable expectation of benefit.

#### Hormones – steroids

- Victorian Civil and Administrative Tribunal (2017)<sup>23</sup> – a junior doctor was found guilty of unprofessional conduct for prescribing testosterone and human growth hormone without clinical justification.
- State Administrative Tribunal of Western Australia (2017)<sup>24</sup> – a specialist physician was found to have engaged in professional misconduct for prescribing anabolic androgenic steroids, Clenbuterol and Ephedrine, Caffeine and Aspirin (ECA) where there was no therapeutic basis, unnecessarily exposing patients to the adverse effects of those substances or drugs.
- State Administrative Tribunal of Western Australia (2014)<sup>25</sup> – a specialist general practitioner had his registration cancelled for prescribing anabolic androgenic steroids, human growth hormone and stimulants when there was no proper therapeutic indication, and when such prescribing unnecessarily put the patients for whom he was prescribing at risk of the potential adverse effects of those drugs.
- State Administrative Tribunal of Western Australia (2014 and 2011)<sup>26</sup> – a specialist general practitioner was suspended and had conditions imposed for prescribing testosterone and pituitary hormones without medical indication. He was suspended for a second time for breaching the conditions.
- State Administrative Tribunal of Western Australia (2013)<sup>27</sup> – a specialist general practitioner was suspended and had conditions imposed for prescribing anabolic steroids without medical indication.

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<sup>20</sup> [Pharmacy Board of Australia v Balestra](#)

<sup>21</sup> [Medical Board of Australia v Barnes](#)

<sup>22</sup> [Medical Board of Australia v Siow](#)

<sup>23</sup> [Medical Board of Australia v Abi Haila](#)

<sup>24</sup> [Medical Board of Australia v Singh](#)

<sup>25</sup> [Medical Board of Australia v Ismail](#)

<sup>26</sup> [Medical Board of Australia v Bradshaw](#), [Medical Board of Australia v Bradshaw](#)

### Lyme-like illness

- State Administrative Tribunal of Western Australia (2016)<sup>28</sup> – a specialist general practitioner had conditions imposed following concerns about the administration of vitamins for Lyme-like illness using a peripherally inserted central catheter (PICC).
- Victorian Civil and Administrative Tribunal (appeal) (2016)<sup>29</sup> – a specialist general practitioner had conditions imposed following concerns about his use of homeopathic medicine and his prescribing practices, especially in relation to antibiotics for Lyme-like disease.
- Queensland Civil and Administrative Tribunal (appeal) (2014)<sup>30</sup> - a specialist general practitioner had conditions imposed following concerns about his diagnosis and treatment of Lyme-like illness.

### Stem cell therapies

- Queensland Civil and Administrative Tribunal (2010 – prior to the National Registration and Accreditation Scheme)<sup>31</sup> – a medical practitioner had his registration cancelled in relation to his provision of a ‘stem cell treatment’ (an unspecified injection to stimulate stem cells) for a patient with Adhesive Arachnoiditis (chronic inflammation of the arachnoid matter of the spinal meninges) in contravention of the then Queensland Medical Board’s policy *Unconventional medical practice* (2009).

## Current regulation and guidance in Australia

There is some existing regulation relating to this area of practice as well as guidance for medical practitioners (both those who practise in this area and for those practitioners whose patients use these medicines and therapies). A number of organisations have published information for consumers on ‘complementary medicine’ and ‘stem cell treatments’.

### **National Law**

The Health Practitioner Regulation National Law, as in force in each state and territory (the National Law) defines unprofessional conduct and professional misconduct. In Section 5 of the National Law, the definition of unprofessional conduct includes:

- (d) providing a person with health services of a kind that are excessive, unnecessary or otherwise not reasonably required for the person’s wellbeing
- (h) referring a person to, or recommending that a person use or consult, another health service provider, health service or health product if the practitioner has a pecuniary interest in giving that referral or recommendation, unless the practitioner discloses the nature of that interest to the person before or at the time of giving the referral or recommendation.

Registered medical practitioners must comply with the National Law and approved registration standards and are expected to follow any approved codes and guidelines issued by the Board to provide guidance about the Board’s expectations of the medical profession with regards to appropriate professional conduct and/or practice.

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<sup>27</sup> [Medical Board of Australia v Durston](#)

<sup>28</sup> [Medical Board of Australia v Du Preez](#)

<sup>29</sup> [Kemp v Medical Board of Australia](#)

<sup>30</sup> [Ladhams v Medical Board of Australia](#)

<sup>31</sup> [Medical Board of Australia v Tarvydas](#)

### **Medical Board of Australia *Good medical practice: a code of conduct for doctors in Australia***

The Board's code of conduct, *Good medical practice: a code of conduct for doctors in Australia*, includes guidance on providing good care, and obtaining consent.<sup>32</sup> It states that doctors should provide 'treatment options based on the best available information'.

Section 8 of the code states obligations in relation to advertising including that good practice involves ensuring information 'is factual and verifiable' 'making only justifiable claims' and 'not exploiting patients' vulnerability'. Section 11 of the code provides guidance for practitioners when 'Undertaking research'.

### **National Health Practitioner Boards' *Guidelines for advertising regulated health services***

The *Guidelines for advertising regulated health services* explain and provide guidance on the obligations of advertisers in relation to Section 133 of the National Law which relates to advertising of regulated health services.<sup>33</sup> Section 133 states:

1. A person must not advertise a regulated health service, or a business that provides a regulated health service, in a way that—
  - a. is false, misleading or deceptive or is likely to be misleading or deceptive; or
  - b. offers a gift, discount or other inducement to attract a person to use the service or the business, unless the advertisement also states the terms and conditions of the offer; or
  - c. uses testimonials or purported testimonials about the service or business; or
  - d. creates an unreasonable expectation of beneficial treatment; or
  - e. directly or indirectly encourages the indiscriminate or unnecessary use of regulated health services.

### **Australian Competition and Consumer Commission (ACCC)**

All businesses, including regulated health services, must comply with the Australian Consumer Law (ACL) which makes it illegal to make false or misleading claims about the quality, value, price, age or benefits of goods or services.

Compliance and enforcement of the ACL is the responsibility of the Australian Competition and Consumer Commission (ACCC), however, it's not ACCC's role to resolve individual complaints – individuals can take their complaint to their local office of consumer affairs and fair trading or other relevant industry body.

### **Therapeutic Goods Administration (TGA)**

The Therapeutic Goods Administration (TGA) regulates 'complementary medicines' such as products containing herbs, vitamins, minerals, nutritional supplements, homeopathy and aromatherapy preparations as 'therapeutic goods'. Most complementary medicines are listed or registered on the Australian Register of Therapeutic Goods. Higher risk medicines are registered after assessment by the TGA for quality, safety and efficacy whereas lower risk medicines (the majority of complementary medicines) are listed based only on manufacturer's declarations. The TGA's 'Australian regulatory guidelines for complementary medicines' details regulatory requirements for complementary medicines in relation to safety, labelling, manufacturing, advertising and quality criteria.<sup>34</sup>

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<sup>32</sup> Medical Board of Australia, *Good Medical Practice: A code of conduct for doctors in Australia*, 2014 <http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx>

<sup>33</sup> Medical Board of Australia, *Guidelines for advertising regulated health services*, 2014 <http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Guidelines-for-advertising-regulated-health-services.aspx>

<sup>34</sup> TGA, *Australian regulatory guidelines for complementary medicines*, 2018, available at: <https://www.tga.gov.au/publication/australian-regulatory-guidelines-complementary-medicines-argcm>

An independent panel undertook a Review of Medicines and Medical Devices Regulation including the 'Regulatory frameworks for complementary medicines' and made recommendations for the TGA to improve regulation of these therapeutic goods.<sup>35</sup> In February 2017, the TGA released a consultation paper 'Reforms to the regulatory framework for complementary medicines: Assessment pathways' which proposes a risk-based framework for the regulation of complementary medicines, to address recommendations from that review.<sup>36</sup> The consultation has closed and the TGA is implementing reforms.<sup>37</sup>

The TGA regulates human cell and tissue-based products (as 'therapeutic goods' known as 'biologicals'). However, to date autologous cells and tissues have been excluded from the regulation when used in certain circumstances by a medical practitioner (Excluded Goods Order). Therefore, 'stem cells' which are collected from a patient by a medical practitioner for 'manufacture and manipulation' and therapeutic application for the same patient by the same medical practitioner have not been regulated under therapeutic goods legislation.

In 2015 and 2016, the TGA consulted on options for regulation of autologous cell and tissue products.<sup>38</sup> The TGA identified a number of concerns including increasing 'manipulation' of the cells, higher risk routes of administration and treatments being offered directly to consumers with little or no supporting evidence. As these treatments have been excluded from TGA regulation, the TGA restrictions on direct to consumer advertising did not apply, the TGA requirements relating to clinical trials did not apply and there was no obligation to report adverse events to the TGA. In October 2017, the TGA announced changes to increase the regulation of autologous cell and tissue products.<sup>39</sup> Changes commenced on 1 July 2018 with a one-year transition period and include restrictions on direct advertising to consumers and regulation of more products as biologicals with the level of regulation determined by the risk to patient safety.<sup>40</sup>

The TGA has published a guide to stem cell treatments for consumers.<sup>41</sup>

### **National Health and Medical Research Council (NHMRC)**

The National Health and Medical Research Council (NHMRC) has undertaken a number of activities in response to 'reports of non-evidence based treatments, including complementary and alternative medicine, being used to treat conditions that are chronic, serious, or could become serious, in place of evidence-based treatments'. They have published a resource for clinicians, *Talking with your patients about Complementary Medicine* and have undertaken a review of homeopathy and a series of systematic reviews of natural therapies.<sup>42</sup> The NHMRC concluded that 'there are no health conditions for which there is reliable evidence that homeopathy is effective'.<sup>43</sup>

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<sup>35</sup> Review of Medicines and Medical Devices Regulation – Stage Two, *Report on the regulatory frameworks for complementary medicines and advertising of therapeutic goods*, 2015, available at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation>

<sup>36</sup> TGA, *Consultation: Reforms to the regulatory framework for complementary, unconventional and emerging medicine medicines: Assessment pathways*, 2017, available at: <https://www.tga.gov.au/consultation/consultation-reforms-regulatory-framework-complementary-medicines-assessment-pathways>

<sup>37</sup> TGA response: Reforms to the regulatory framework for complementary medicines: Assessment pathways, 2017, available at: <https://www.tga.gov.au/submissions-received-and-tga-response-reforms-regulatory-framework-complementary-medicines>

<sup>38</sup> In 2015 the TGA released a discussion paper, *Regulation of autologous stem cell therapies*, available at: <https://www.tga.gov.au/consultation/consultation-regulation-autologous-stem-cell-therapies#invite>  
In 2016 the TGA undertook further consultation on *Regulation of autologous cell and tissue products and proposed consequential changes to the classification of biologicals*, available at <https://www.tga.gov.au/consultation/consultation-regulation-autologous-cell-and-tissue-products-and-proposed-consequential-changes-classification-biologicals#invitation-to-comment>

<sup>39</sup> TGA, Media release – *Regulation of autologous cell and tissue products*, 2017, available at: <https://www.tga.gov.au/media-release/regulation-autologous-cell-and-tissue-products>

<sup>40</sup> TGA, Communication to stakeholders: Autologous human cells and tissue products, 2018, available at: <https://www.tga.gov.au/communication-stakeholders-autologous-human-cells-and-tissues-hct-products>

<sup>41</sup> TGA, *Stem cell treatments and regulation - a quick guide for consumers*, 2016, available at: <https://www.tga.gov.au/community-qa/stem-cell-treatments-and-regulation-quick-guide-consumers>

<sup>42</sup> NHMRC, *Talking with your patients about Complementary Medicine*, 2014, available at: <https://www.nhmrc.gov.au/guidelines-publications/cam01>

<sup>43</sup> NHMRC *Statement on Homeopathy*, 2015, available at: <https://www.nhmrc.gov.au/guidelines-publications/cam02>

Another NHMRC resource is the publication *Stem Cell Treatments – A Quick Guide for Medical Practitioners* to assist medical practitioners in discussing stem cell treatments with their patients, and the risks involved in undergoing unproven treatments.<sup>44</sup> They have also published FAQs for consumers on stem cell treatments.<sup>45</sup>

### Professional associations

There are a number of membership based associations for practitioners who practise in this area such as the Australian Integrative Medicine Association (AIMA) for doctors who practise integrative medicine and the Australian Cell Therapy Society (ACTS) for doctors and others interested in cellular therapies. The role of these associations is in part to promote the area of practice and advocate for their members. While some have codes of practice, membership is optional, self-regulation is limited and adherence to those codes is not enforceable.

A number of colleges and associations have issued position statements on these areas of medical practice:

- The Royal Australia College of General Practitioners (RACGP) issued a *Position statement (on) homeopathy* which states that the position of RACGP is that 'Medical practitioners should not practise homeopathy, refer patients to homeopathic practitioners, or recommend homeopathic products to their patients'.<sup>46</sup>
- The Australasian College of Sports and Exercise Physicians (ACSEP) issued a *Position statement on the use of Autologous mesenchymal stem cells (MSC) in sport and exercise medicine (2017)*. It states that there is insufficient evidence to support the use of MSC therapy in routine management of musculoskeletal conditions or degenerative conditions typically managed by sport and exercise physicians.<sup>47</sup>
- The Australian Orthopaedic Association and the Australian Rheumatology Association (ARA) issued a *Position statement on stem cell therapies* in 2014. It states that there is currently not enough evidence to recommend stem cell therapy as treatment for osteoarthritis outside a clinical trial setting.<sup>48</sup>
- The Australian Medical Association (AMA) have a *Position statement on complementary medicine*.<sup>49</sup> The statement notes that there is limited evidence for the use of complementary medicine.
- The Clinical Oncology Society of Australia issued a *Position statement on the use of complementary and alternative medicine by cancer patients*.<sup>50</sup> The Society encourages health professionals to have discussions with their patients regarding complementary and alternative medicine. It states that health professionals should support its use if evidence demonstrates its safety and benefits and should actively discourage patients from delaying potentially curative (conventional) treatment.

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<sup>44</sup> NHMRC, *Stem Cell Treatments – A Quick Guide for Medical Practitioners*, 2013, available at: <https://www.nhmrc.gov.au/guidelines-publications/rm001>

<sup>45</sup> NHMRC, *Stem Cell Treatments – Frequently asked questions*, 2013, available at: <https://www.nhmrc.gov.au/guidelines-publications/rm001a>

<sup>46</sup> RACGP, *Position statement: homeopathy*, 2015, available at: <http://www.racgp.org.au/download/Documents/Policies/Health%20systems/PPI-PositionStatement-Homeopathy-v1.pdf>

<sup>47</sup> ACSEP, *Position statement - The use of Autologous mesenchymal stem cells in sport and exercise medicine, 2017*, available at: <https://www.acsep.org.au/page/news/position-statements>.

<sup>48</sup> AOA and ARA, *ARA Position statement on stem cell therapies*, available at: <https://rheumatology.org.au/gps/documents/ARASemCellPA042014July2017.pdf>

<sup>49</sup> AMA, *Position statement: Complementary medicine*, 2018, available at: <https://ama.com.au/position-statement/ama-position-statement-complementary-medicine-2018>

<sup>50</sup> Clinical Oncology Society of Australia, *Position statement on the use of complementary and alternative medicine by cancer patients*, 2013, available at: [https://www.cosa.org.au/media/1133/cosa\\_cam-position-statement\\_final\\_new-logo.pdf](https://www.cosa.org.au/media/1133/cosa_cam-position-statement_final_new-logo.pdf)

## Senate inquiry

A Senate inquiry into ‘The growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients’ concluded last year. Much of the debate focused on the treatment protocols offered by the treating doctors, including prolonged antibiotic therapy. The Senate Committee heard evidence and submissions that some of these doctors have been subject to notifications to the Board. The Committee made recommendations for further research and treatment guidelines.<sup>51</sup>

## Other jurisdictions’ approach to regulating complementary and alternative medicine

The Medical Council of NSW’s *Complementary Health Care Policy* (2015) outlines the requirements for registered medical practitioners providing complementary health care, particularly in relation to consent.<sup>52</sup>

A number of international jurisdictions have policy statements on complementary and alternative medicine.

For example, the Medical Council of New Zealand (MCNZ) *Statement on complementary and alternative medicine* (2011) informs doctors of the standards of practice expected of them by MCNZ for those who practise complementary or alternative medicine and those whose patients use complementary or alternative medicine.<sup>53</sup> It is currently under review.<sup>54</sup>

Similarly, the College of Physicians and Surgeons of Ontario’s *Policy statement – Complementary/alternative medicine* (2011) outlines how the principles and obligations for professional, competent and ethical medical practice apply to complementary and alternative medicine and provides guidance for both doctors who use complementary or alternative medicine and those whose patients use complementary or alternative medicine.<sup>55</sup>

The College of Physicians and Surgeons of British Columbia’s *Practice Standard – Complementary and Alternative Therapies* (2017) provides guidance for physicians who choose to use complementary or alternative therapies in their practice.<sup>56</sup>

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<sup>51</sup> Community Affairs References Committee, *The growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients - Final Report*, 2016, available at:

[http://www.apf.gov.au/Parliamentary\\_Business/Committees/Senate/Community\\_Affairs/LymelikeIllness45/Final\\_Report](http://www.apf.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/LymelikeIllness45/Final_Report)

<sup>52</sup> MCNSW, *Complementary Health Care Policy*, 2015 available at: <http://www.mcnsw.org.au/page/317/resources/policies/>

<sup>53</sup> Medical Council of New Zealand, *Statement on complementary and alternative medicine*, 2011, available at: <https://www.mcnz.org.nz/assets/News-and-Publications/Statements/Complementary-and-alternative-medicine.pdf>

<sup>54</sup> Medical Council of New Zealand consultation on Complementary and alternative medicine, available at: <https://www.mcnz.org.nz/news-and-publications/consultations/medical-council-consultation-on-complementary-and-alternative-medicine-cam/>

<sup>55</sup> The College of Physicians and Surgeons of Ontario, *Policy statement Complementary/Alternative Medicine*, 2011 available at: <http://www.cpso.on.ca/Policies-Publications/Policy/Complementary-Alternative-Medicine>

<sup>56</sup> The College of Physicians and Surgeons of British Columbia, *Practice standard – Complementary and Alternative Therapies* (2017) available at: <https://www.cpsbc.ca/files/pdf/PSG-Complementary-and-Alternative-Therapies.pdf>

## Options for clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments

The Board derives its powers and responsibilities from the National Law. The Board must balance its responsibilities to protect the public while facilitating access to services in accordance with the public interest. The Board can only act within the scope of its powers under the National Law.

Under section 39 of the National Law, the Board may develop and approve codes and guidelines to provide guidance to the health practitioners it registers. Codes and guidelines apply to all medical practitioners in all states and territories.

The Board has identified two options which are available for this area of practice.

### 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**

Under this option no action is proposed and effectively the status quo is retained.

All medical practitioners (including those who provide complementary or unconventional medicine or emerging treatments) must comply with approved registration standards, and are expected to comply with codes and guidelines published by the Board.

Guidance for medical practitioners who provide complementary or unconventional medicine or emerging treatments is provided in existing codes and guidelines. The Board could issue a statement drawing attention to the code, to inform consumers and medical practitioners.

The Board's code of conduct, *Good medical practice*, outlines the standards expected of all medical practitioners. It includes guidance on providing good care, working within the health care system and with other health care professionals, professional behaviour and maintaining professional performance.

The Board's *Guidelines for advertising regulated health services* provide guidance on the advertising provisions in the National Law. They include guidance on a medical practitioner's professional obligations when advertising services and describe advertising that is not permitted such as testimonials and content that misleads consumers.

If medical practitioners are fellows of a college, additional codes of practice and protocols issued by the colleges provide guidance on acceptable practice. Some professional associations also provide their medical practitioner members with guidance.

However, not all medical practitioners are members of a professional association (or may be members of more than one association) and the primary role of a professional association is to promote and protect the interests of the members. Medical practitioners who are not affiliated with a college or association are not subject to those codes.

Professional self-regulation of medical practitioners who provide complementary or unconventional medicine or emerging treatments may not be a viable option into the future to improve standards as there is not a college or professional association that represents all medical practitioners who provide these treatments. Colleges and associations only represent their members and membership is not required to practise in this area of medicine.

### Option 2

#### **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*.**

The purpose of providing clearer regulation for this area of medical practice is to protect the public and support practitioners. The aim is to ensure that there is clearer guidance for medical practitioners and the necessary safeguards for patients when they are considering complementary and unconventional medicine or emerging treatments.

The second option is for the Board to develop and approve guidelines for medical practitioners who provide complementary or unconventional medicine or emerging treatments which explicitly outline the Board's expectations of medical practitioners practising in this area of practice.

Guidance would apply to all registered medical practitioners – both doctors whose patients use complementary and unconventional medicine and emerging treatments and for doctors who practise in these areas.

Unlike the current guidance provided through the Board's code of conduct, which is generic and covers all types of medical practice, these guidelines would include specific guidance for medical practitioners who provide complementary or unconventional medicine or emerging treatments on the key risk areas identified by the Board.

The areas that guidelines would provide guidance on include conflicts of interest, practitioner knowledge and skills, patient assessment, informed consent, treatment and advertising.

### **Benefits and impacts of the proposed options**

Option one (status quo) would provide no additional benefits or safeguards for consumers who seek complementary or unconventional medicine or emerging treatments. There would be no change for medical practitioners.

Option two (strengthened guidance) provides an opportunity for the Board to make expectations of medical practitioners clearer to help provide safeguards for consumers. Guidelines may help ensure that consumers have the information to make informed choices about complementary and unconventional medicine and emerging treatments.

Guidelines that define good practice for complementary and unconventional medicine and emerging treatment:

- would not reduce consumer choice
- would not restrict medical practitioners' practice
- would not result in significant cost increases for consumers or medical practitioners
- would not restrict existing, accepted practice that may fall within the definition of complementary and unconventional medicine and emerging treatments
- would not stifle innovation or clinical research and trials.

### **Preferred option**

Based on the information available and subject to the outcome of consultation with stakeholders, **option two** is the preferred option at this time.

The Board considers that option two would have only a minor impact on practitioners and consumers and would provide the greatest benefits to the community.

For consumers this should include improved safeguards and access to better information while still enabling choice.

For medical practitioners, there would be clear, nationally consistent guidance about the Board's expectations of medical practitioners in relation to the provision of complementary and unconventional medicine and emerging treatments. While some medical practitioners would need to review their processes and practices, the guidelines are expected to have a minimal regulatory impost.

Any administrative costs associated with implementing the guidelines would be met by the Board with no additional cost for registrants.



## DRAFT Guidelines

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<date>

### Guidelines for registered medical practitioners - Complementary and unconventional medicine and emerging treatments

#### Introduction

These guidelines have been developed by the Medical Board of Australia (the Board) under section 39 of the Health Practitioner Regulation National Law as in force in each state and territory (the National Law). They complement *Good medical practice: A code of conduct for doctors in Australia (Good medical practice)* and provide additional guidance for medical practitioners specific to complementary and unconventional medicine and emerging treatments. They should be read in conjunction with *Good medical practice*.

The guidelines aim to inform registered medical practitioners and the community about the Board's expectations of medical practitioners in relation to complementary and unconventional medicine and emerging treatments.

The guidelines apply to all medical practitioners including:

- medical practitioners whose patients may use complementary and unconventional medicine and/or emerging treatments but who don't themselves provide these treatments, and
- medical practitioners who provide complementary and unconventional medicine and/or emerging treatments.

#### Definition

**Complementary and unconventional medicine and emerging treatments** include any assessment, diagnostic technique or procedure, diagnosis, practice,<sup>1</sup> 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.

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<sup>1</sup> **Practice** means any role, whether remunerated or not, in which the individual uses their skills and knowledge as a health practitioner in their profession. For the purposes of these guidelines, practice is not restricted to the provision of direct clinical care. It also includes using professional knowledge in a direct non-clinical relationship with clients, working in management, administration, education, research, advisory, regulatory or policy development roles, and any other roles that impact on safe, effective delivery of services in the profession.

## Background

The use of complementary and unconventional medicine and emerging treatments is increasing and includes a wide range of practices from minimally invasive to major complex interventions.

The medicines and treatments may be used as an alternative to conventional medicine or used in conjunction with conventional medicine. They may be used with or without the knowledge of the patient's other treating practitioners.

Concerns have been expressed in relation to some aspects of these areas of practice. These include patients being offered and/or having treatments:

- for which the safety and efficacy are not known
- which may be unnecessary
- that expose them to serious side-effects, and
- that may result in delayed access to more effective treatment options.

These treatments are provided by a variety of medical practitioners with a range of qualifications and expertise in the therapy and/or the patient's underlying condition.

Harm may occur directly from the treatment resulting in an adverse outcome or it may be indirect, associated with delays in accessing other treatment. While some treatments may be beneficial, others may have no effect, the benefit may be uncertain, or the effect may be harmful. The harm can be physical, psychological and/or financial.

The lines between research and commercial innovation can be blurred and conflicts of interest can arise if the provider has a financial interest in the product or service being offered. Some treatments are being offered on a commercial basis before full clinical trials have been completed. The requirements for clinical trials don't apply and patients are left without the usual protections.

Tests and treatments are generally funded privately by patients (not covered by Medicare or private health insurance) and can be expensive with uncertain results. Patients may seek complementary and unconventional medicine and emerging treatments because they have serious, chronic conditions and may be vulnerable to exploitation.

It is reasonable for patients consulting registered medical practitioners to expect that the medical practitioner will comply with the professional and ethical standards of conduct and competence expected of medical practitioners and defined by the Board. It is also reasonable for patients to expect that the medical practitioner will take into consideration the existing evidence-based options when providing health care. Medical practitioners must ensure their patients' safety is their priority.

The Board does not wish to stifle innovation or research nor limit patients' right to choose their healthcare. Rather it considers there is a need for additional safeguards to protect patients who seek complementary and unconventional medicine or emerging treatments. The Board aims to help registered medical practitioners meet their professional obligations by defining good medical practice.

### Who (would) these guidelines apply to?

These guidelines (would) apply to all medical practitioners registered under the National Law. There is guidance for all medical practitioners in relation to complementary and unconventional medicine and emerging treatments as well as specific guidance for medical practitioners who provide complementary and unconventional medicine and/or emerging treatments.

### How (would) the Board use these guidelines?

Section 41 of the National Law states that an approved registration standard or a code or guideline approved by the Board is admissible in proceedings under this Law or a law of a co-regulatory jurisdiction against a practitioner registered by the Board as evidence of what constitutes appropriate professional conduct or practice for the profession.

These guidelines can be used to assist the Board in its role of protecting the public, by setting and maintaining standards of medical practice. If a medical practitioner's professional conduct varies significantly from this guideline, they should be prepared to explain and justify their decisions and actions. Serious or repeated failure to meet these guidelines may have consequences for a medical practitioner's registration.

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## Guidance for all registered medical practitioners

This section of the guidelines includes guidance for *all* registered medical practitioners including those doctors whose patients use complementary and unconventional medicine and emerging treatments, but who don't themselves provide these treatments.

### 1. Discussion with patients

The use of complementary and unconventional medicine and emerging treatments is increasing. It is therefore important that all medical practitioners are aware of these areas of practice and how they may affect their patients and impact other treatments, regardless of whether they themselves provide or recommend these treatments. There are resources available for medical practitioners when discussing complementary and unconventional medicine and emerging treatments with their patients.<sup>2</sup>

Good medical practice for all medical practitioners involves:

- 1.1. Asking your patients about their use of complementary and unconventional medicine and emerging treatments regardless of whether you provide or recommend these treatments.
- 1.2. Taking into consideration your patient's use of complementary and unconventional medicine and emerging treatments when determining appropriate management for your patient.
- 1.3. Advising your patients of the limits of your knowledge when discussing the benefits and risks of complementary and unconventional medicine and emerging treatments with them. It is not expected that medical practitioners who do not practise in these areas would have knowledge of all these areas of practice.
- 1.4. Informing your patients, where relevant, that there is limited reputable scientific evidence for the use of some complementary and unconventional medicine and emerging treatments. There may also be limited information about the safety, side effects and possible drug interactions.
- 1.5. Advising patients that they should be aware of the possible financial implications of choosing complementary and unconventional medicine and emerging treatments.
- 1.6. Respecting your patient's right to make informed decisions about their health and their right to choose complementary and unconventional medicine and emerging treatments.

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<sup>2</sup> For example, National Health and Medical Research Council (NHMRC), [Talking with your patients about Complementary Medicine – a Resource for Clinicians](#), 2014 and NHMRC, [Stem Cell Treatments – A Quick Guide for Medical Practitioners](#), 2013

## Guidance for registered medical practitioners who provide complementary and unconventional medicine and emerging treatments

This section of the guidelines includes guidance for registered medical practitioners who *provide* complementary and unconventional medicine and emerging treatments.

### 2. Knowledge and skills

Safe patient care relies on the medical practitioner having the knowledge and skills in the area of medicine in which they practise. This is both for the treatments being provided and the conditions for which patients seek treatment. This is particularly important where treatments may not be part of standard medical training, for alternative uses of conventional treatments and for new and emerging treatments that are continuously evolving.

Good medical practice for medical practitioners providing complementary and unconventional medicine and emerging treatments involves:

- 2.1. Ensuring you have current knowledge and skills for your scope of practice to ensure safe patient care.
- 2.2. Only offering treatments if you have the appropriate training, expertise and experience in both the treatment and the condition being treated.
- 2.3. Arranging appropriate and timely specialist referral, when indicated.
- 2.4. Undertaking necessary training if you intend to change your scope of practice to include complementary and unconventional medicine and emerging treatments.

### 3. Conflicts of interest

Conflicts of interest can arise when providing complementary and unconventional medicine and emerging treatments. This is the case when there are high costs involved as well as because of the experimental and commercial aspects of some treatments.

Good medical practice for medical practitioners providing complementary and unconventional medicine and emerging treatments involves:

- 3.1. Always acting honestly and only in your patient's best interests when providing complementary and unconventional medicine and emerging treatments.
- 3.2. Ensuring that you do not have a financial or commercial conflict of interest that may influence the advice and/or treatment that you give your patients.

### 4. Informed consent

Patients have a right to know if the treatment they are being offered is not considered to be 'conventional medicine'. They have the right to know the evidence for its efficacy and safe use.

Medical practitioners proposing complementary and unconventional medicine and emerging treatments must obtain informed consent from their patient. Good medical practice involves:

- 4.1. Providing your patient with enough information, preferably in written form, for them to make informed decisions about proposed assessments, investigations and treatments.
- 4.2. Providing your patient with clear information about:
  - 4.2.1. the extent to which the assessment, investigation and treatment is consistent with conventional medicine and accepted by the medical profession or if it is considered alternative and/or experimental
  - 4.2.2. the degree to which, and how, diagnostic investigations and tests have been formally evaluated and what is known about their reliability, safety and risks

- 4.2.3. the degree to which, and how, the proposed treatments have been formally evaluated or proven and what is known about their safety, side effects, risks, likely effectiveness and a realistic likelihood of benefit for the proposed use.
- 4.2.4. the range of possible outcomes, taking into consideration the patient's expectations
- 4.2.5. the likely number of investigations and treatments required and the costs involved
- 4.2.6. other treatment options (including conventional treatments), their risks, likely benefits and efficacy based on the best current available information.
- 4.3. Ensuring that patients who may be vulnerable because of the serious and/or chronic nature of their condition and/or because conventional medicine has not been effective, are not exploited or unduly influenced.
- 4.4. Ensuring that information provided about complementary and unconventional medicine and emerging treatments does not create unrealistic patient expectations.
- 4.5. Informing your patient of their right to seek a second opinion regarding their treatment and options from another independent medical practitioner when proposing treatments that are complementary, unconventional or emerging.

## 5. Assessment and diagnosis

Some medical practitioners providing complementary and unconventional medicine and emerging treatments use diagnostic methods and tests that are not considered to be part of conventional medicine.

Good medical practice in the assessment and diagnosis of patients involves:

- 5.1. Ensuring the assessment and examination of your patient is comprehensive and considers all relevant information.
- 5.2. Ensuring that any recommendation for investigations or tests is based on the best current available information.
- 5.3. Performing and/or ordering any generally recognised diagnostic investigations and tests that would be reasonably expected for appropriate patient care.
- 5.4. Ensuring you consider appropriate differential diagnoses for each individual patient.
- 5.5. Ensuring that your diagnosis is supported by sound clinical judgement and informed by the best current available information.

## 6. Treatment

Providing a treatment in the absence of an identified therapeutic need can unnecessarily expose a patient to risk of harm. Patient harm can also result if the provision of complementary and unconventional medicine and emerging treatments results in delays in accessing more appropriate treatments for the patient.

Good medical practice when providing complementary and unconventional medicine and emerging medicine involves:

- 6.1. Ensuring that you do not discourage the use of conventional treatment options when this is clinically appropriate.
- 6.2. Only recommending treatments where there is an identified therapeutic need, quality and safety can be reasonably assured and that have a reasonable expectation of clinical efficacy and benefit.
- 6.3. Ensuring that the provision of any complementary and unconventional medicine and emerging treatments comply with any relevant Therapeutic Goods Administration requirements.<sup>3</sup>

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<sup>3</sup> For example, Therapeutic Goods Administration (TGA), [Australian regulatory guidelines for complementary medicines](#), 2018 and TGA, [Australian regulatory guidelines for biologicals](#), 2017.

## 7. Patient management

Good patient care is supported when there is good communication with, and coordination of care between, all treating practitioners. When the provider of complementary and unconventional medicine or emerging treatments does not have a role in the patient's regular medical care it is important to ensure that there are measures in place for the coordination of care. Follow-up of patients is particularly important where treatment is provided that is experimental and/or part of a formal research clinical trial - both for the patient's wellbeing and for the contribution to medical knowledge.

Good medical practice for the care of your patients to whom you are providing complementary and unconventional medicine and emerging treatments involves:

- 7.1. Documenting information including the diagnosis, treatment, efficacy, side-effects and known risks of interactions in the patient's medical record.
- 7.2. Ensuring that you take responsibility for appropriate monitoring and follow-up of patients to whom you are providing complementary and unconventional and emerging treatments. This is even more important when you are providing experimental treatments.
- 7.3. Encouraging your patients to tell their other health practitioners about their use of complementary and unconventional medicine and emerging treatments.
- 7.4. With permission from your patient, communicating with their other treating doctors (if applicable). You should inform other treating medical practitioners of the investigations, the diagnoses, treatments, known risks of interactions and patient progress.
- 7.5. Reporting adverse events to the relevant authority to assist safety monitoring.

## 8. Advertising

Some patients who seek complementary and unconventional medicine or emerging treatments may be vulnerable to advertising that may lead to unreasonable expectations. The advertising provisions in Section 133 of the National Law include that a regulated health service must not be advertised in a way that is false, misleading or deceptive or creates an unreasonable expectation of beneficial treatment.

Good medical practice when advertising complementary and unconventional medicine and emerging treatments involves:

- 8.1. Ensuring that all advertising material, including practice and practitioner websites, complies with the Board's *Guidelines for advertising of regulated health services*, including the advertising requirements of section 133 of the National Law, of the Therapeutic Goods Administration and the Therapeutic Goods Advertising Code and of the Australian Competition and Consumer Commission.
- 8.2. Ensuring that you do not create the impression that you are a specialist in an area of practice that is not a recognised specialty.
- 8.3. Ensuring advertising material does not create unreasonable patient expectations of the benefits of the complementary and unconventional medicine and emerging treatments.

## 9. Research and advancing knowledge

Innovation and research in new treatments is necessary to improve health outcomes. However, there must be protections in place for patients. Efforts to make advancements in treatments should not jeopardise patient safety.

Good medical practice in the research and advancement of complementary and unconventional medicine and emerging treatments involves:

- 9.1. Ensuring that research involving complementary and unconventional medicine and emerging treatments complies with the National Health and Medical Research Council's (NHMRC) current '*Australian Code for the Responsible Conduct of Research*' and '*National Statement on Ethical Conduct in Human Research*'.

- 9.2. Where tests and treatments are experimental, being prepared to contribute to and share new knowledge with the profession.

### Acknowledgements

The Board acknowledges the following organisations' codes and guidelines, which helped inform the development of the Board's draft guidelines:

- Medical Council of New South Wales (2015) *Complementary health care policy*
- Medical Council of New Zealand (2011) *Statement on complementary and alternative medicine*

### Implementation date and review

These guidelines will take effect on <date>.

The Board will review these guidelines at least every five years.

DRAFT

## Statement of assessment

Board's statement of assessment against AHPRA's *Procedures for the development of registration standards, codes and guidelines* and COAG principles for best practice regulation

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

The Australian Health Practitioner Regulation Agency (AHPRA) has *Procedures for the development of registration standards, codes and guidelines* which are available at: [www.ahpra.gov.au](http://www.ahpra.gov.au)

These procedures have been developed by AHPRA in accordance with section 25 of the Health Practitioner Regulation National Law as in force in each state and territory (the National Law) which requires AHPRA to establish procedures for the purpose of ensuring that the National Registration and Accreditation Scheme (the National Scheme) operates in accordance with good regulatory practice.

Below is the Medical Board of Australia's (the Board) assessment of their proposal for clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments against the three elements outlined in the AHPRA procedures.

### 1. The proposal takes into account the National Scheme's objectives and guiding principles set out in section 3 of the National Law

#### Board assessment

The Board considers that the proposed draft guidelines meet the objectives and guiding principles of the National Law.

The proposal takes into account the National Scheme's key objective of protecting the public by setting out the ethical and professional standards of conduct expected of medical practitioners against which they will be measured to ensure that only those who practise in a competent and ethical manner are registered.

The proposed draft guidelines also support the National Scheme to operate in a transparent, accountable, efficient, effective and fair way. The proposal gives clear guidance on the Board's expectations of medical practitioners and there are protective actions that can be taken under the National Law if a practitioner does not fulfill these expectations.

### 2. The consultation requirements of the National Law are met

#### Board assessment

The National Law requires wide-ranging consultation on proposed guidelines. The National Law also requires the Board to consult the other National Boards on matters of shared interest.

The Board is ensuring that there is public exposure of its proposal and the opportunity for public comment by undertaking an eight week public consultation process. The process includes the publication of the consultation paper on its website and informing medical practitioners via the Board's electronic newsletter sent to more than 95% of registered medical practitioners.

The Board will also draw this paper to the attention of key stakeholders including the other National Boards.

The Board will take into account the feedback it receives when finalising its guideline.

Medical Board of Australia

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### 3. The proposal takes into account the COAG Principles for Best Practice Regulation

#### Board assessment

In developing the draft revised guideline, the Board has taken into account the Council of Australian Governments (COAG) *Principles for Best Practice Regulation*.

As an overall statement, the Board has taken care not to propose unnecessary regulatory burdens that would create unjustified costs for the profession or the community.

The Board makes the following assessment specific to each of the COAG principles expressed in the AHPRA procedures.

#### COAG Principles

##### A. Whether the proposal is the best option for achieving the proposal's stated purpose and protection of the public

#### Board assessment

The Board considers that its proposal is the best option for achieving the stated purposes. The proposed draft guidelines do not propose significant changes to the current ethical and professional standards of conduct expected of medical practitioners and they complement the principles contained in the Board's current code of conduct *'Good medical practice: A code of conduct for doctors in Australia'*.

The proposal would protect the public by making clear the standards of ethical and professional conduct expected of medical practitioners by the Board, their professional peers and the community. The proposal would provide more specific guidance for medical practitioners about their obligations when providing complementary and unconventional medicine and emerging treatments.

##### B. Whether the proposal results in an unnecessary restriction of competition among health practitioners

#### Board assessment

The proposal will not restrict competition as it would apply to all registered medical practitioners.

##### C. Whether the proposal results in an unnecessary restriction of consumer choice

#### Board assessment

The proposal will not result in any unnecessary restrictions of consumer choice as the proposed draft guidelines would apply to all registered medical practitioners. Guidelines don't prohibit these treatments, they allow for informed consumer choice.

The proposal has the potential to improve a consumer's confidence that all registered medical practitioners are held to the same ethical and professional standards of conduct.

##### D. Whether the overall costs of the proposal to members of the public and/or registrants and/or governments are reasonable in relation to the benefits to be achieved

#### Board assessment

The Board has considered the overall costs of the proposed draft guidelines to members of the public, medical practitioners and governments and concluded that the likely costs are minimal as the Board is not proposing significant changes to the current standards of ethical and professional conduct expected of all registered medical practitioners.

Subject to stakeholder feedback on the proposed draft guidelines, the benefits of having clear guidelines for medical practitioners on the principles that underpin good medical practice outweigh any minimal costs related to medical practitioners and other stakeholders being required to become familiar with the guidelines, if approved.

*Statement of assessment – Clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments*

**E. Whether the proposal's requirements are clearly stated using 'plain language' to reduce uncertainty, enable the public to understand the requirements, and enable understanding and compliance by registrants**

**Board assessment**

The Board considers the proposed draft guidelines have been written in plain English that will help practitioners to understand the standards of good medical practice expected by the Board, their professional peers and the community.

**F. Whether the Board has procedures in place to ensure that the proposed registration standard, code or guideline remains relevant and effective over time**

**Board assessment**

If approved, the Board will review the guidelines at least every five years, including an assessment against the objectives and guiding principles in the National Law and the COAG principles for best practice regulation.

However, the Board may choose to review the guidelines earlier, in response to any issues which arise or new evidence which emerges to ensure the guidelines continued relevance and workability.