



# COMPLEMENTARY AND UNCONVENTIONAL MEDICINE AND EMERGING TREATMENTS

A SUBMISSION IN RESPONSE TO  
THE MEDICAL BOARD OF  
AUSTRALIA'S CONSULTATION ON  
CLEARER REGULATION

June 2019

## ABOUT RESEARCH AUSTRALIA

Research Australia is the national alliance representing the entire health and medical research pipeline, from the laboratory to patient and the marketplace.

**Our vision:** Research Australia envisions a world where Australia unlocks the full potential of its world-leading health and medical research sector to deliver the best possible healthcare and global leadership in health innovation.

**Our mission:** To use our unique convening power to position health and medical research as a significant driver of a healthy population and contributor to a healthy economy.

### Our role:

Engage  
Australia in a conversation  
about the health benefits  
and economic value of its  
investment in health and  
medical research.

Connect  
researchers, funders  
and consumers to  
increase investment  
in health and medical  
research from all sources.

Influence  
government policies that  
support effective health  
and medical research  
and its routine translation  
into evidence-based  
practices and better  
health outcomes.

Nadia Levin  
CEO & Managing Director  
02 9295 8547  
[nadia.levin@researchaustralia.org](mailto:nadia.levin@researchaustralia.org)

[www.researchaustralia.org](http://www.researchaustralia.org)  
384 Victoria Street Darlinghurst NSW 2010

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## Summary of recommendations

<b>Option 2</b>	<p>Research Australia supports the adoption of the Medical Board of Australia's Option 2</p> <ul style="list-style-type: none"> <li>• <b>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.</b></li> </ul>
<b>Consumer Warnings</b>	<p>Research Australia recommends that specific consumer warnings be given to prospective patients considering the purchase of complementary and unconventional medicine and emerging treatments.</p> <p>The guidelines should require practitioners to provide standard written consumer warnings to prospective patients. These would have some similarities with the new notices required under the TGA Advertising Code, and notices required to be given to prospective customers under the <i>National Consumer Credit Protection Act 2009</i>.</p> <p>The Guidelines should require patients be provided with such a statement in writing before the treatment is undertaken, eg. when the appointment is made, or following an initial consultation if this precedes the treatment. The statement should be provided as a separate document.</p>

# COMPLEMENTARY AND UNCONVENTIONAL MEDICINE AND EMERGING TREATMENTS

## Introduction

Research Australia welcomes the opportunity to make a submission to the Medical Board of Australia's consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.

Research Australia is the peak body for Australia's health and medical research and innovation sectors. Our members strive to create new knowledge and develop new medicines, therapies, technologies and interventions that can deliver better health outcomes and improve human health and wellbeing. Ultimately this depends not just on the availability of products to people, but the decisions they make as consumers in respect of these products.

This is the interest and perspective we bring to this consultation- enabling consumers to make decisions about medicines and treatments that will enhance their health and wellbeing.

There is an expectation in the community that the medicines and treatments provided by medical practitioners are evidence based and supported by science. Medical practitioners are required to undertake lengthy periods of formal training, and as a community we invest significantly in the provision of healthcare, and in health and medical research to discover new treatments and therapies.

These investments have the support of the community. Research Australia has been undertaking annual opinion polling since 2003, and the results consistently show that funding for hospitals and the health care system is Australia's number one priority for Government funding. Just as significantly Australians have always nominated more funding for health and medical research as one of the top 10 priorities for Government funding.<sup>1</sup>

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<sup>1</sup> Research Australia, Australia Speaks! 2018 Opinion Polling for health and medical research, p.4

Australians associate the medical treatment they receive with science and research. This is why they donate to research to find cures and treatments. Better health for Australians is the top reason nominated by Australians for supporting health and medical research.<sup>2</sup> 89% of Australians believe health professionals who see patients and also undertake research provide the best care to patients, because they are more aware of new developments and the latest practices.<sup>3</sup>

Australians are increasingly familiar with clinical trials, and there is significant support across all levels of government for more clinical trials in Australia. All participants in a clinical trial are aware that the therapy they are undergoing is experimental and that while there is an expectation that it will be effective, there is not yet strong enough evidence for this therapy to be included as normal care. The purpose of the clinical trial is to evaluate whether the new treatment is safe and effective.

And just as Australians believe that health and medical research is important because it leads to new and better health care, the corollary is true: Australians believe that the health care they receive is based on scientific evidence. They trust the health system to deliver high quality, safe and effective care. This expectation is reasonable in most cases.

However, when it comes to complementary and unconventional medicine and emerging treatments, this trust in the system is misplaced. Instead of focusing on the basic questions such as 'Is this treatment safe?' and 'Is this treatment effective?' they are more likely to be focused on questions of whether they can afford it. There is an assumption that the treatment is safe and that it will work.

The questions of safety and efficacy won't arise because when consulting a registered medical practitioner, Australians assume the treatments they are being offered are safe, effective and supported by evidence. There is an expectation that if this wasn't the case it wouldn't be offered, or that it would be part of a clinical trial.

Research Australia believes that consumers need to be alerted to the circumstances where they cannot rely on the health system to provide them with safe, effective evidence-based care, and where they need to question their normal assumptions. Research Australia recommends that the provision of complementary and unconventional medicine and emerging treatments is accompanied by a clear and concise consumer warning.

Such a warning would have parallels with the information required to be provided in respect of therapeutic goods by the Therapeutics Goods Advertising Code 2018; and further afield, the warnings provided with credit products. The same underlying rationale applies: consumers need to be alerted to some of the relevant factors they should consider if they are to make informed decisions, and to provide informed consent.

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<sup>2</sup> Research Australia, Australia Speaks! Research Australia Opinion Polling 2017 p.9

<sup>3</sup> Ibid, p.11

## Questions for consideration

Research Australia provides the following responses to the questions posed in the consultation paper.

### **1. Do you agree with the proposed term ‘complementary and unconventional medicine and emerging treatments’?**

**If not, what term should be used and how should it be defined?**

Research Australia is satisfied that the proposed term appropriately covers the subject matter and is relatively clear.

### **2. Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments – ‘any assessment, diagnostic technique or procedure, diagnosis, practice, medicine, therapy or treatment that is not usually considered to be part of conventional medicine, whether used in addition to, or instead of, conventional medicine. This includes unconventional use of approved medical devices and therapies.’**

**If not, how should it be defined?**

Research Australia agrees with the proposed definition.

### **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’?**

Research Australia is generally in agreement with the nature and extent of the issue the Medical Board has identified.

We have a particular concern with the way in which many complementary and unconventional medicines and emerging treatments seek to use scientific research to give themselves undeserved credibility and legitimacy.

The range of different practices claiming to use stem cells as a treatment is a clear example. The scientific understanding of the role of stem cells is well advanced and there are genuine expectations that stem cells will provide an effective new therapy to treat a range of conditions. However, the technical challenges to isolating, manipulating and using stem cells as a therapy are, and remain, very significant, despite decades of research.

This has not prevented some practitioners from using the general public’s awareness of stem cell science to promise they can extract and use stem cells despite a lack of evidence that what they are doing is safe or efficacious, or even, in many cases, that they are actually providing stem cells.

This behavior can have the consequence, over time, of bringing the field of stem cell science and legitimate stem cell therapies into public disrepute, eroding the community's trust in science and the health system.

**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?**

Generally the issues are correctly identified.

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

Yes. Research Australia recommends that specific consumer warnings be given to prospective patients considering the purchase of complementary and unconventional medicine and emerging treatments. Further detail is provided in our response to Question 9.

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

Research Australia is not aware of other relevant evidence and data.

**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?**

No.

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

Yes.

**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?**



Yes. Research Australia recommends that specific consumer warnings be given to prospective patients considering the purchase of complementary and unconventional medicine and emerging treatments.

The guidelines should require practitioners to provide standard written consumer warnings to prospective patients. These would have some similarities with the 'required statements' under the TGA Advertising Code (referenced on page 7 of the *Draft Guidelines*), and notices required to be given to prospective customers under the *National Consumer Credit Protection Act 2009*. Further information about the National Consumer Credit Act and an example of a Notice is provided in the Appendix.

The Guidelines should require patients be provided with such a statement in writing before the treatment is undertaken, i.e. when the appointment is made or following an initial consultation if this precedes the treatment. The statement should be provided as a separate document.

The following is provided as an example of the type of notice that could be provided.

### **NOTICE: THIS IS A COMPLEMENTARY OR UNCONVENTIONAL MEDICINE OR AN EMERGING TREATMENT**

The treatment being offered to you is classified as a **complementary or unconventional medicine or an emerging treatment** by the Medical Board of Australia.

This means:

- There is **not** good evidence that this medicine/treatment is safe (it might harm you)
- There is **not** good evidence that this medicine/treatment works

#### **You will not be part of a clinical trial**

While clinical trials are often undertaken by researchers and clinicians to establish if an emerging treatment is safe and effective, you are not undertaking this treatment as part of a registered clinical trial.

This medicine/treatment is not funded by Medicare or the Pharmaceutical Benefits Scheme (PBS). Medicare and the PBS will only fund new treatments that are proven to be safe and effective.

#### **QUESTIONS YOU SHOULD ASK THE PERSON PROVIDING THE TREATMENT:**

- What evidence do you have that it works?
- Why do you think it will work for me?
- What are the risks (what could go wrong)?
- What are your qualifications?
- How many times have you provided this treatment?
- What have the results been?

#### **WHAT TO DO IF YOU ARE NOT SURE...**

- If the person offering this treatment is not your regular doctor, consult your regular doctor first.
- If the person offering this treatment is your regular doctor, or you don't have a regular doctor, seek the opinion of another doctor from a different practice before proceeding.

Specific notices could be developed for any complementary or unconventional medicine or emerging treatment that is considered by the Medical Board to be particularly high risk and/or particularly prevalent.

Consideration should also be given to requiring the provision of a similar notice to patients after the treatment with information about what they should do if they are not satisfied with the treatment.

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

Research Australia proposes that Option 2 be augmented with specific consumer warnings to be given to prospective patients considering the purchase of complementary and unconventional medicine and emerging treatments. Further detail is provided in our response to Question 9.

**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 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.**
- **Other – please specify.**

Research Australia broadly supports Option 2 but proposes that it be augmented with specific consumer warnings to be given to prospective patients considering the purchase of complementary and unconventional medicine and emerging treatments. Further detail is provided in our response to Question 9.

## Conclusion

Research Australia envisions a world where Australia unlocks the potential of its world-leading health and medical research sector to deliver the best possible healthcare and global leadership in health innovation.

Health and medical research enjoys strong public support because people recognise that health and medical research leads to safer, higher quality and more effective health care. The prominence of health and medical research organisations and their close links to the health care sector create an expectation in the public that all the healthcare they receive from registered medical practitioners is safe, effective and evidence based. While this is a reasonable assumption in most cases, consumers deserve to be alerted to those circumstances where this is not the case. We applaud the recognition of Medical Board of Australia of the need for clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.

Research Australia's members work hard to contribute to an evidence-based healthcare system that is continually improving the healthcare delivered to patients. This is achieved through the development of new treatments based on scientific evidence which have been rigorously tested and evaluated to ensure they are safe and effective.

In doing so, our members have helped create the impression that all existing healthcare is evidence-based, safe and effective. When this is not the case, we have an obligation to ensure that people are aware that what they are receiving is not routine care, and to alert them to the associated risk and other matters they should consider. Research Australia believes that the proposed Option 2, augmented by clear, specific and mandatory consumer warnings, will help achieve this objective.

## Appendix- Consumer Credit Code

As its name implies, the aim of the *National Consumer Credit Protection Act 2009* (and the accompanying Consumer Credit Code and regulations) is to protect consumers who are entering credit contracts from unscrupulous conduct and ensure they understand the contract and their obligations. In addition to regulating and licensing credit providers, it requires specific information to be provided to consumers by credit providers. The content and form of the information to be provided to consumers is specified, as is the circumstances in which the information must be provided.

In seeking to protect consumers and promote informed decision making, the Act has similarities with the Medical Board of Australia's proposal for clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.

An example of one Notice required under the Act is provided below.

### Form 5 Information statement

**paragraph 16 (1) (b) of the Code  
regulation 70 of the Regulations**

### Things you should know about your proposed credit contract

This statement tells you about some of the rights and obligations of yourself and your credit provider. It does not state the terms and conditions of your contract.

If you have any concerns about your contract, contact the credit provider and, if you still have concerns, your credit provider's external dispute resolution scheme, or get legal advice.

### The contract

#### 1 How can I get details of my proposed credit contract?

Your credit provider must give you a precontractual statement containing certain information about your contract. The precontractual statement, and this document, must be given to you before—

- \_your contract is entered into; or
- \_you make an offer to enter into the contract;

whichever happens first.

#### 2 How can I get a copy of the final contract?

If the contract document is to be signed by you and returned to your credit provider, you must be given a copy to keep. Also, the credit provider must give you a copy of the final contract within 14 days after it is made. This rule does not, however, apply if the credit provider has previously given you a copy of the contract document to keep.

If you want another copy of your contract, write to your credit provider and ask for one. Your credit provider may charge you a fee. Your credit provider has to give you a copy—

- \_within 14 days of your written request if the original contract came into existence 1 year or less before your request; or
- \_otherwise within 30 days of your written request.

### **3 Can I terminate the contract?**

Yes. You can terminate the contract by writing to the credit provider so long as —

- \_you have not obtained any credit under the contract; or
- \_a card or other means of obtaining credit given to you by your credit provider has not been used to acquire goods or services for which credit is to be provided under the contract.

However, you will still have to pay any fees or charges incurred before you terminated the contract.

### **4 Can I pay my credit contract out early?**

Yes. Pay your credit provider the amount required to pay out your credit contract on the day you wish to end your contract.

### **5 How can I find out the pay out figure?**

You can write to your credit provider at any time and ask for a statement of the pay out figure as at any date you specify. You can also ask for details of how the amount is made up.

Your credit provider must give you the statement within 7 days after you give your request to the credit provider. You may be charged a fee for the statement.

### **6 Will I pay less interest if I pay out my contract early?**

Yes. The interest you can be charged depends on the actual time money is owing. However, you may have to pay an early termination charge (if your contract permits your credit provider to charge one) and other fees.

### **7 Can my contract be changed by my credit provider?**

Yes, but only if your contract says so.

### **8 Will I be told in advance if my credit provider is going to make a change in the contract?**

That depends on the type of change. For example—

- \_you get at least same day notice for a change to an annual percentage rate. That notice may be a written notice to you or a notice published in a newspaper.
- \_you get 20 days advance written notice for—
  - \_a change in the way in which interest is calculated; or
  - \_a change in credit fees and charges; or
  - \_any other changes by your credit provider;

except where the change reduces what you have to pay or the change happens automatically under the contract.

RESEARCH AUSTRALIA LIMITED  
384 Victoria Street, Darlinghurst NSW 2010  
**P** +61 2 9295 8546 **ABN** 28 095 324 379  
[www.researchaustralia.org](http://www.researchaustralia.org)