Australian Government
Department of Health

Deputy Secretary

Dr Anne Tonkin, Chair
Medical Board of Australia
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Dear Anne

Re: **Consultation on complementary and unconventional medicine and emerging treatments**

At the Board's request, I provide a submission from the Therapeutic Goods Administration (TGA) on your current public consultation on regulation of medical practitioners who provide complementary medicines and unconventional and emerging treatments. We do not require our submission to be confidential. Our response to your consultation questions are as follows:

1. *Do you agree with the proposed term 'complementary and unconventional medicine and emerging treatments'*?
   In general yes, although the conflation of complementary, unconventional and emerging would do well from some granularity. For example if the three are lumped together it could have linked therapies such as immune checkpoint inhibitors, CAR-T cell therapies and homoeopathy in one group, while the evidence base for such treatments varies wildly.

2. *Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments –*
   'Complementary and unconventional medicine and emerging treatments include any assessment, diagnostic technique or procedure, diagnosis, practice, medicine, therapy or treatment that is not usually considered to be part of conventional medicine, whether used in addition to, or instead of, conventional medicine. This includes unconventional use of approved medical devices and therapies.'
   Yes, with one small adjustment for completeness – after *medical devices* add *', therapies and treatments.'*

[redacted]

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'?*

   Yes.

4. *Are there other concerns with the practice of 'complementary and unconventional medicine and emerging treatments' by medical practitioners that the Board has not identified?*

   There are a range of risk categories with (established) low-risk complementary medicines and unconventional treatments. The biggest risks are either emerging treatments that are unproven, or unconventional treatments which may be used in preference to established proven treatments. More stringent guidance may be required for higher risk treatments and medicines – at the moment it is a little generic.

   There could be more specific discussion of the challenging situation that medicinal cannabis has exposed for prescribers - unapproved medicines (obtained through Special Access Schemes), variable evidence for efficacy, strong pressure by some patient groups and individual patients for access to the products (with some seeing that it is a "right" to access a prescription substance). While the focus is on medicinal cannabis now, there will be other emerging treatments that will pose a very similar set of challenges for individual clinicians and for the Medical Board in the future.

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

   Yes. It is important that consumers are well informed on the use of such medicines and treatments in order to make the most appropriate choice for their health care. This of course requires prescribers to be well informed and the medicinal cannabis example has revealed a number of cases where clinicians were not aware of where there is an isn't efficacy evidence, what the safety issues were and also the process by which these medicines can be accessed through Special Access Schemes.

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

   Not to our knowledge, but this an area where the Medical Board could take more steps to review experiences internationally by similar practitioner regulators as to how they have managed delivery of complementary and unconventional medicine and emerging treatments.

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. We support strengthening of the current guidelines with practice –specific guidelines.

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

   Yes. We agree that specific practice guidelines that supplement the baseline requirements for Medical Practitioners would help address the issues identified in relation to use of complementary and unconventional treatments. Without this, there may be no change in behaviours or compliance.

In further strengthening the guidelines we suggest the following for your consideration:

- It would be beneficial for practitioners and their patients to have a better understanding of how complementary medicines are regulated in Australia. Primarily, practitioners should be aware that:
  - to be legally supplied in Australia, unless exempt, complementary medicines are required to be included in the Australian Register of Therapeutic Goods (ARTG). Lower risk medicines are listed in the ARTG, while higher risk medicines are registered.
  - registered medicines have an AUST R number on the medicine label and are fully evaluated by the TGA for safety, quality and efficacy prior to market access, while there are 2 types of lower risk listed medicines:
    - listed medicines with an AUST L number are not assessed by the TGA pre market and assessed listed medicines with an AUSTL(A) number are assessed for efficacy by the TGA pre market

- The AHPRA's draft guidelines provide general expectations for medical practitioners in relation to use of complementary and unconventional treatment. We recommend that as more knowledge is gained in these areas, more practice specific guidelines are developed, particularly for higher risk medicines and treatments.

- In discussing the supporting evidence for medicines, devices, therapies and procedures, practitioners should inform consumers as to the nature of any trial that has been undertaken i.e. was it an informal trial or a formal ethics committee endorsed and documented clinical trial?

We thank you for the opportunity to provide comment.

Yours sincerely

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Adj. Professor John Skerritt
Health Products Regulation Group

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