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Medical Board of Australia

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

15 May 2019

To the Executive Officer, Medical, AHPRA

Thank you for seeking feedback on options for clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.

In the interest of ensuring that clear, nationally consistent guidance be provided about the Medical Board of Australia's expectations of medical practitioners in relation to complementary and unconventional medicine and emerging treatments, we support Option 2, noting that we have a number of recommendations in relation to this option which we provide for your consideration in this submission.

We reiterate that the Board should make every effort to ensure that the Guidelines:

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

Additionally; we urge the Board to ensure that the Guidelines do not unfairly tarnish the reputation of the Australian complementary medicines industry nor undermine the real benefit that some products may provide to patients.

If you require any further information, please do not hesitate to contact us.

Kind regards

Amne Alrifai

Director | Avicenna Consulting Pty Ltd

15 May 2019

About Avicenna Consulting

Avicenna Consulting was born from the belief that sponsors of complementary and listed medicines needed frank, clear, and timely advice about the regulation of listed and complementary medicines. Our number one priority is to provide professional and courteous services to help sponsors maintain compliance with legal obligations and bring only the highest quality medicines to domestic and international markets.

Our team is made up of former TGA staff with expert knowledge of the regulatory and technical requirements which apply to complementary and listed medicines. Avicenna Consulting provides a responsive service unlike any other.

We offer our regulatory consulting services to new and existing sponsors, industry associations and regulators who seek risk-based, strategic advice.

Industry confidence

The Australian complementary medicines industry has often been described as the “gold standard” internationally because the requirements for our products often exceed those put in place by other regulators.

Patients in Australia and internationally can be assured that complementary medicines that are listed on the Australian Register of Therapeutic Goods (ARTG) are not laced with contaminants or illegal ingredients and are ultimately safe for use.

In this context, it is important that any guidance provided by the Board to medical practitioners does not imply that Australia complementary medicines are unsafe or unsuitable for use.

Definition of complementary and unconventional medicine and emerging treatment

We do not agree with the definition of complementary and unconventional medicine and emerging treatment as we believe that there is a broad spectrum of medicines, procedures, and practices that may fall within

this definition which may not be substantiated by the same types of evidence. Thus, we suggest that these products should not be grouped under the one definition.

Complementary medicines are regulated in Australia by the Therapeutic Goods Administration based on risk. Higher risk medicines; that is, prescription and over-the-counter medicines are ‘registered’ medicines, and lower risk medicines are ‘listed’ medicines.

Some ‘complementary medicines’ are a subset of listed medicines which contain one or more ‘designated active ingredient’ per Schedule 14 of the Therapeutic Goods Regulations 1990. These ingredients include plant or herbal material, homoeopathic ingredients, minerals, sugars, and vitamins. Although listed medicines are not subject to a pre-market evaluation of the final formulation, the indications made by many listed medicines are supported by rigorous scientific evidence.

Other complementary medicines may be registered on the ARTG and are subject to a thorough evaluation of their safety, quality, and efficacy before they can be supplied on the market. These products are



commensurate with over-the-counter medicines.

In our view, it would be problematic to group scientifically supported treatments with those which are not, or unregulated treatments with those that are, particularly given the widespread use of alternative therapies in Australia.

Instead, we suggest that the Medical Board of Australia consider separating these terms and defining “complementary medicine,” “alternative therapies,” “unconventional medicine,” and “emerging treatments.”

Safeguards for patients who seek complementary and unconventional medicine and emerging treatments

Informed choice

It is our view that complementary medicines can play an important role in the prevention and treatment of conditions when properly recommended by medical practitioners. Both patients and medical practitioners require further education about the regulation of complementary medicines in Australia so that there is a better appreciation of the range of evidence which may be available to support particular claims, and the difference between products that are supported by scientific evidence and traditional knowledge.

We believe that patients and medical practitioners should be making informed choices based on a proper understanding of the evidence supporting an indication.

It is important that medical practitioners do not dismiss a patient’s desire to use complementary medicines (or other alternative therapies). Anecdotally, we know that patients who are unsatisfied with the information provided to them by a medical

practitioner will seek information from disreputable sources online or may even purchase unregulated complementary medicines online. This poses a significant risk to patients.

It would be beneficial to patients if medical practitioners were able to help them navigate the large range of complementary medicines that are available on the market. Simply knowing the difference between a listed and registered medicine would go a long way towards increasing consumer awareness of their options.

Misuse of complementary medicines

We are concerned by the suggestion that some practitioners are using complementary and alternative medicines in place of conventional therapies in relation to serious conditions such as cancer.

We reiterate the need for medical practitioners to be aware of how complementary medicines should be used. In Australia, listed complementary medicines should not be used for the treatment of a serious disease, condition, ailment or defect. In fact, a listed complementary medicine which makes such claims would be illegal.

Most complementary medicines should only be used for self-diagnosable or self-manageable conditions. Patients should be safeguarded against the misuse of complementary medicines through the provision of advice by their medical practitioner.

Medicine interactions and adverse events

We recommend that the section of the Draft Guidelines on Informed Consent (page 5) include reference to medicine interactions.

Practitioners should be aware that some complementary medicines can negatively interact with conventional medicines. We recommend that practitioners regularly ask their patients about whether they are using a complementary medicine, particularly since such a large number of Australians use these products.

In addition, medical practitioners should be aware of the potential for these products to cause adverse effects and should be aware of way in which these events can be reported to the TGA. This advice should be provided to patients as appropriate.

Regulatory guidelines

We note that point 6.3 of the Draft Guidelines (page 6) state that medical practitioners should ensure *“that the provision of any complementary and unconventional medicine and emerging treatments comply with any relevant Therapeutic Goods Administration requirements.”*

We do not agree that this the appropriate measure for determining appropriate treatment with complementary medicines. This is because the Australian Regulatory Guidelines for Complementary Medicines (ARGCM) are guidelines for the evaluation of complementary medicine ingredients and products, not treatment guidelines. In our view, the ARGCM would not be useful to medical practitioners.

Instead, we recommend that medical practitioners ensure that complementary medicines are either listed or registered on the ARTG. The Board may wish to consider including a section on ensuring that patients understand the difference between products that include an “AUST L” or “AUST R” number, and those which do not (i.e those that have been evaluated by the TGA and those that have not).

