Australian **Skeptics** Inc.

May 12, 2017

Regulatory Reforms Team
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

To Whom It May Concern,

Re: Consultation: Options for the future regulation of "low risk" products

Submission from Australian Skeptics Inc

We write in response to the invitation for submissions on options for the future regulation of "low risk" products.

Australian Skeptics is a loose confederation of groups across Australia that investigate paranormal and pseudo-scientific claims from a responsible scientific viewpoint. These groups are made up of many thousands of formal and informal supporters of a scientific approach to the study and assessment of claims of pseudoscience and the paranormal. It was founded in 1980, and is the oldest independent skeptical body in the world. Over the years, various Skeptics groups and individuals have put much effort into the study of complementary and alternative medicine. The body of knowledge gathered in this period is relevant to the current review.

Our focus with this particular submission is on four complementary medicine products:

- Ear candles;
- Aromatherapy products (essential oils);
- Vitamins and minerals; and
- Homeopathic products.

We have several issues with the classification of these products and services as "low risk" or "very low risk", particularly considering the rationale for the low risk classification system and the application of two of its criteria, that they be "Scientifically well-founded" and "Performs well in practice". We deal with these issues in the relevant sections below.

We have made our preferred options clear, with the overriding view that these products lack definitive scientific support for their claims in many instances, and in the case of some products lack any scientific evidence at all. In all cases, they should be subjected to consumer protection laws and not given the imprimatur of listing with the TGA and the implied endorsement that these products are efficacious and safe.

Thus in all cases we would recommend that these products should not be regarded as therapeutic, and should be removed from the ART list.

Our more detailed assessment follows.

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Ear Candles

Ear candles have been shown to have potentially very dangerous impacts on users, even if used as directed. These dangers include damage to the inner and outer ear through the application or misapplication of hot wax.

The US Food & Drug Administration warns that "ear candles can cause serious injuries, even when used in accordance to manufacturers' directions. 'Also,' says Mann [Eric Mann, MD, PhD, clinical deputy director of FDA's Division of Ophthalmic, Neurological, and Ear, Nose, and Throat Devices], 'FDA believes that there is no valid scientific evidence for any medical benefit from their use.'"

- https://www.fda.gov/forconsumers/consumerupdates/ucm200277.htm

Classifying ear candles as "very low risk" is a misrepresentation of the serious dangers these products represent.

The fact that these products are listed in the ARTG "with therapeutic claims to the effect of 'for relaxation', 'general wellbeing' and 'ear wax cleaning'" indicates that the TGA listing for these products is ineffective and misleading.

Thus we would recommend Option 3 – "Exclude ear candles from the regulatory framework".

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Aromatherapy products (essential oils)

While essential oil products are sometimes promoted as cosmetic and for relaxation purposes, the use of these products as more than cosmetic, ie beneficial to a user's health, is unproven at best. As the US Mayo Clinic says: "Research on the effectiveness of aromatherapy - the therapeutic use of essential oils extracted from plants - is limited."

- http://www.mayoclinic.org/healthy-lifestyle/consumer-health/expert-answers/aromatherapy/faq-20058566

This means that these products should not be considered to be "scientifically well-founded", and should be removed from the ARTG list.

Thus we would recommend Option 3 – "Declare essential oils not to be therapeutic goods".

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Vitamins and minerals

We would agree with the Consultation paper's statement that: "When considering the risk of vitamin and minerals, not all of these supplements represent equal risk."

But we do have concerns that consumers are not always aware of this range in efficacy, which can be as low as ineffective and, in some cases, dangerous if used improperly or even according to the supplier's instructions.

The statement that "Claims of vitamin and mineral supplementation must also be accompanied by a statement that 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate' or 'Vitamin supplements should not replace a balanced diet'" may well be true in theory, but in practice this is not always the impression given in manufacturers' promotion of their products, which can often be extremely misleading.

This means that the TGA should be the proper body to monitor such promotion, but as these claims are still readily made, and that adverse findings by the TGA are often subverted by the manufacturers simply changing the name and marketing of a product, means that the TGA's role is largely ineffective.

Therefore we cannot support Option 1 – "Maintain the status quo regulation of vitamins and minerals".

We would thus recommend that Option 3 – "Declare vitamins and mineral not to be therapeutic goods" – is more appropriate for these products.

While this blanket action is a forceful move – and an equally forceful statement – which impacts on all vitamins and minerals, it does mean that suppliers of some products, if they feel that their products do have therapeutic value, would be beholden to undertake and present proper scientific assessment to prove any efficacy. But until that becomes standard – and at the moment it is far from standard – the blanket application of Option 3 should be applied.

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Homeopathic products

The commanding view of homeopathic products could not be clearer: they have no scientific validity; they have no medical validity; their claimed manufacturing methods and apparent modality are ludicrous; and they do not work.

The National Health & Medical Research Council's 2015 review of homeopathy found that: "Based on the assessment of the evidence of effectiveness of homeopathy, NHMRC concludes that there are no health conditions for which there is reliable evidence that homeopathy is effective. Homeopathy should not be used to treat health conditions that are chronic, serious, or could become serious. People who choose homeopathy may put their health at risk if they reject or delay treatments for which there is good evidence for safety and effectiveness."

In other words, homeopathy is not "scientifically well-founded" nor "performs well in practice' and, in fact, in the situation of users' substituting reliable proven treatments with unproven homeopathic treatments, can be anything but "very low risk" and are truly dangerous.

It would be tempting to say that two options might apply:

- Option 2 – Serious therapeutic claims must be supported by scientific evidence (which would effectively eliminate homeopathic products); and
- Option 4 – Declare homeopathic products not to be therapeutic goods.

In the circumstances, we would recommend Option 4.

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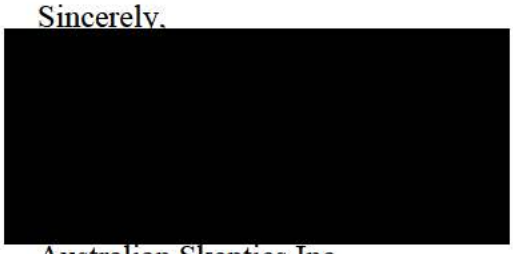
We thank you for this opportunity to respond to the discussion on these issues.

Sincerely,



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