



Australian Skeptics Inc.

January 11, 2018

Committee Secretary
Senate Community Affairs Legislation Committee
Department of the Senate
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Secretary

Re: Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017

Submission from Australian Skeptics Inc

We write in response to the invitation for submissions to the Australian Senate review of the Therapeutic Goods Amendment Bill and specifically about **Schedule 2, Part 1, section 26BF of the Bill - Permissible indications**. ‘The Minister may, by legislative instrument, make a determination in relation to either or both of the following: (a) indications; (b) requirements in relation to indications.’

Summary:

The following are sources of great concern to us:

- The TGA’s final proposed list of permitted indications (D17-3503756, 14 Dec 2017) accepts a number of industry proposed indications for complementary medicines that rely on concepts that are either scientifically unproven or disproven.
- There is a serious lack of meaningful consumer warnings on indications which do not have scientific evidence.
- The TGA’s ‘Permitted indications consultation outcomes’ document (D17-3525712) accepts a mandatory requirement for Ayurvedic and Traditional Chinese medicine only such as “Seek advice from a registered Chinese medicine practitioner or Ayurvedic medicine practitioner to ensure this medicine is right for you’. This creates the ludicrous position of practitioners whose methodology lacks scientific evidence being used as an arbiter of the effectiveness of a product that lacks scientific evidence. And yet even this weak advice does not apply to other equally-unsupported traditional indications such as products purveyed by homeopaths, naturopaths and herbalists.
- The fact that the Commonwealth Dept of Health’s own review of private health insurance has declared that some of the modalities under discussion - including homeopathy, herbalism, naturopathy, and aromatherapy – show “no clear evidence demonstrating efficacy”.

Scientific investigations of pseudoscientific and paranormal claims

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In other words, the TGA's final permitted indication list contains many indications that are demonstrably unscientific and inefficacious – even under the Government's own advice – will allow products to be sold with the imprimatur of the TGA, without prior vetting for advertising accuracy or honesty, without consumer warnings, and reflecting inconsistencies and contradictions in Government policy.

It would seem that the numerous industry submitted and TGA endorsed traditional indications give increased benefit to the purveyors of non-scientific products while decreasing the protection of consumers.

We thus ask for a delay in the finalisation of the legislative instrument to implement this system (by regulation) until these inconsistencies are clearly explored and a satisfactory solution found.

Background:

Australian Skeptics is a loose confederation of groups across Australia that investigate pseudoscientific and paranormal claims from a responsible scientific viewpoint. These groups are made up of many thousands of formal and informal supporters of this scientific approach. 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.

Discussion:

The National Health & Medical Research Council's 2015 report on homeopathy found that "there are no health conditions for which there is reliable evidence that homeopathy is effective".

https://www.nhmrc.gov.au/files/nhmrc/publications/attachments/cam02_nhmrc_statement_homeopathy.pdf

Likewise the private health insurance reforms announced by the Federal Minister for Health, Greg Hunt, on 13 October 2017, state that, as of April 1, 2019, "Cover for the following natural therapies will be removed from all private health insurance products: Alexander technique, aromatherapy, Bowen therapy, Buteyko, Feldenkrais, herbalism, homeopathy, iridology, kinesiology, naturopathy, Pilates, reflexology, Rolfing, shiatsu, tai chi, and yoga." [http://www.health.gov.au/internet/main/publishing.nsf/Content/57047B73A322A745CA2581B700753086/\\$File/Private%20health%20insurance%20reforms%20facts%20sheets.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/57047B73A322A745CA2581B700753086/$File/Private%20health%20insurance%20reforms%20facts%20sheets.pdf)

The statement goes on to say that "A review undertaken by the former Commonwealth Chief Medical Officer found there is no clear evidence demonstrating the efficacy of the listed natural therapies."

While such products are not banned – although distributing products of no value and efficacy should be an area for action by the Australian Competition & Consumer Commission – we do feel that consumers should be made aware that Government authorities, on several occasions, have unequivocally stated that certain complementary medicine products are, effectively, useless.

And yet, in a classic case of the left-hand not knowing what the right-hand is doing, another Government authority is not only effectively endorsing such products, but allowing – even encouraging – them to make claims (based on TGA endorsed indications) that are pseudoscientific nonsense, but is at the same time depriving consumers of important information to make informed choices.

For instance, the revised draft list of permitted indications for so-called ‘traditional’ products include such unsupported claims as “Harmonise middle burner (Spleen and Stomach)” - #1; “Unblock/open/relax meridians” - #6; “Soothe/descend the flow of Stomach Qi” - #79 (and other indications for “Qi” treatments that follow); “Replenish essence” - #80; “Tonify/nourish/strengthen/replenish gate of vitality” - #105; “Balance Yin and Yang” - #115; and the wonderfully vague “Release exterior [fluid]” - #153 and “Disinhibit water” - #171. There are many other examples of similarly unsupported and in some cases nonsensical claims.

To compound this iniquitous situation, the TGA mandates that, in the case of traditional Chinese medicine and Ayurvedic indications (only), the consumer should consult their TCM or Ayurvedic practitioner to be reassured that the product is effective. This is like asking a real estate salesman if this is a good time to buy or sell property. The difference is that property, at least, has some real benefit; many of these traditional and complementary products have none.

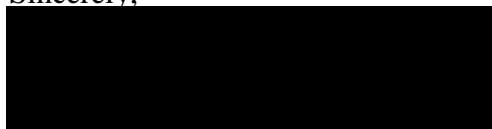
While indications such as these are being proposed, at the same time meaningful consumer warnings that are fully justified are being removed. This is in direct contradiction of best practice of consumer protection.

We would prefer that non-scientific indications be not allowed at all in the new permitted indications system. At the very least, there should be a consumer warning that all ‘traditional’ indications are not supported by scientific evidence

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We thank you for this opportunity to respond to the review of these issues.

Sincerely,



Australian Skeptics Inc