Australian **Skeptics** Inc.

March 26, 2017

Complementary Medicines Reform Section
Complementary and OTC Medicines Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

To Whom It May Concern

Re: Consultation: Reforms to the regulatory framework for complementary medicines: Assessment pathways

Submission from Australian Skeptics Inc

We write in response to the invitation for submissions on reforms to the regulatory framework for complementary medicines, specifically the concept of "assessment pathways".

Australian Skeptics Inc is the umbrella body of a confederation of skeptical groups within Australia, 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.

The scope of this consultation includes four elements:

- The development of a three-tiered risk-based framework for the regulation of complementary medicines. This will introduce a new assessment pathway sitting between the existing Listed medicine (low risk) and registered medicine (high risk) pathways.
- The development of a list of permitted indications which must be used by the lowest risk complementary medicines.
- Allowing sponsors to claim that their medicine has been assessed by the TGA for efficacy where that medicine has undergone pre-market assessment by the TGA.
- Mechanisms to incentivise innovation for the complementary medicines sector.

For the purposes of this submission, we will concentrate on the third element, and specifically Evidence Requirements (proposal 4) and Claiming Evidence of Efficacy (Section 5 – criteria for use of 'claimers').

We submit that the most important issues with regard to any medical product, and particularly

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so for complementary medicines, are their efficacy and the need for transparency in the information provided to consumers.

We feel that the current 'pathways' discussion has implications beyond the three-tier approach as described. By this we mean that the requirements for second-tier listing can be easily matched with those on the first-tier self-certified Listing, albeit without the issue of permitted indications. The reform involving a second-tier Listing presents a great opportunity to create an effective and efficient evidence-based system, without any increased burden on the TGA or suppliers, but with great benefit to consumers.

With this in mind, we make the following recommendations:

- All suppliers of complementary medicines must supply scientific evidence of the efficacy of their products with the TGA at the time of submission.
- All suppliers of complementary medicines must have an indication on their product label to the effect that the product has either been assessed or has not been assessed by the TGA (or some other recognised body).

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A detailed response follows.

Key issues

The consultation paper stresses are number of guiding principles for reform, including:

- Health professionals and consumer confidence in TGA regulation of complementary medicines must be maintained.
- There will be transparency for consumers and healthcare professionals as to the level of assessment by the TGA for complementary medicines entered on the ARTG.
- The reforms should provide incentives to the industry to improve the evidence base for complementary medicines.

The paper also lists a number of objectives of the reforms, including:

- Encourage industry to improve the standard of evidence regarding the efficacy of complementary medicines.
- Avoid consumers being misled by the indications on the medicine label and reduce the rate of non-compliant indications being included on the ARTG.
- Increase transparency for health professionals and consumers about the evidence bases for health claims, and thereby improve he evidence base for complementary medicines.

Note that, while these principles and objectives are included in a paper concerning the creation of a middle tier level of assessment, they equally apply to the current "Listed" level and what would be a lower tier. In fact, they would apply more to that lower tier, which is not subject to assessment, does not require evidence to be submitted and include products whose claims and labelling can easily mislead consumers and health professionals.

Evidence Requirements

Australian Skeptics Inc supports the notion of a level of risk-based assessment of complementary products, particularly, as recommended in the discussion paper, and that this should apply to finished products rather than ingredients. We have felt for some time that this sort of formal assessment of self-certified Listed products has been sadly lacking in the regulation of complementary medicine.

The existing regime of *ad hoc* testing of Listed products has allowed many suppliers to claim efficacy for their products which is not justified. Their claims to have supporting scientific evidence for their products and claims – a mandatory requirement in the self-certification process – is often found not to be true.

Except in certain rare circumstances, the producer of a Listed product is not required to prove that it actually has any evidence to support a claim, or that the evidence is of sufficient quality to support these same claims.

The problem is that the facilities required to establish, in all cases, whether any scientific evidence exists and, if it does, whether it is of sufficient quality to support claims of efficacy, are beyond the current resources of the TGA.

The system is therefore open to abuse, and we suggest that this occurs regularly. The Department of Health has reported that, based on 2009-10 data, as many as 90 per cent of Listed products reviewed were found to be non-compliant with regulatory requirements, and a "significant number" were subsequently removed from the ARTG.

This is indicative that lack of compliance (and, by implication, evidentiary support) is a considerable concern.

The mere promise of being able to present such evidence in the unlikely event that it is called upon is not enough.

Registration or Listing on the ARTG gives a product a strong imprimatur of an independent and trusted authority, particularly as the Therapeutic Goods Act of 1989 requires that the efficacy of complementary medicines must be demonstrated before they can be supplied in Australia.

However, despite this implicit and explicit requirement on the authority to ensure efficacy of products, there is no effective and reliable method to ensure that this is the case.

The requirements, therefore, to substantiate the efficacy of some products are not implemented or complied with or scientifically valid in many cases.

The currently discussed process for the three-tiered "pathway" requires that those companies wishing to be included on the second tier of Listing must submit their scientific evidence. The assumption is that they actually have what they claim – and are required – to have, and that they are willing to have that evidence assessed.

Recommendation #1:

Suppliers of all Listed products must submit the scientific evidence they claim to have at the time of submission.

This should not be difficult or onerous to suppliers – if they say they have the scientific evidence to support their claims, then submitting that evidence is simply a matter of attaching a file. The evidence need not be assessed at this stage and it need not be made public; it is purely a matter of submitting the evidence. Such evidence may be assessed at a later stage, but in the meantime, if they do not submit this evidence, they should not be allowed to list: "no evidence, no listing".

To be frank, we would suggest that this provision would mean that many suppliers will not list products, knowing full well that they do not have scientific evidence either of sufficient quality, or even at all. Listing on the ARTG is a requirement for medicines to be made available to the public. The requirement to supply evidence will therefore be an incentive for suppliers to ensure they have evidence of efficacy so they can gain the benefit of the TGA's imprimatur.

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Criteria for use of 'claimers'

Currently, the only formal 'claimer' used on the labels of Listed products is the "Aust L" number. This may be different on advertising and promotional material, where statements along the lines of "Listed by the TGA" or "Listed on the TGA register" are often used to add further *bona fides* to a product.

The discussion paper says that, in regard to second-tier products, "The Panel recommended that sponsors should be able to include a claimer on promotional materials, including the product label, to recognise the considerable effort for sponsors to obtain an approval for a medicine via the new pathway. In doing so, this will also improve the transparency of the efficacy claims for consumers."

It goes on to ask: "What other considerations should be taken into account in implementing this recommendation?"

We would suggest that "the transparency of the efficacy claims for consumers" is more than just a beneficial aspect of registration - it should be the prime concern for all authorities and paramount in any consideration for Listing, at whatever level.

The paper says: "Under the current legislative requirements, medicine sponsors cannot imply that the TGA or any other foreign government authority has endorsed or approved the efficacy of any product."

The question is whether *not* including such a statement is a clear indication (or implication) that the product has not been tested, or whether it is an assumption by the public that "Listed" automatically means "assessed". The paper's need to make a clear statement regarding endorsement and approval means this is a problem that is a very real consideration.

If it is acceptable to suggest, as the paper does, that second-tier products can have statements such "The evidence held by the sponsor to support the indications for this medicine has been reviewed by the TGA" or, more succinctly, "Evidence has been reviewed by the TGA" on their labels, then we believe that it is equally important that products that have not been reviewed also make this clear.

A simple statement – a minor variation to the above 'claimers' – to this effect would lead to greater transparency and therefore greater benefit for consumers.

Recommendation #2:

That Listed products indicate on their labels whether or not they have been reviewed by the TGA and/or a similar recognised organisation.

Suggested statements could be: "The evidence held by the sponsor to support the indications for this medicine has not been reviewed by the TGA" or, more succinctly, "Evidence has not been reviewed by the TGA".

Such statements would take up no more label 'footprint' than the statements suggested for those second-tier products that they have been reviewed.

Note that such a statement is not an indication of efficacy or lack of efficacy. Rather it is a simple and clear statement of fact, and should be accepted as a requirement of suppliers as much as is the current situation regarding listing of ingredients.

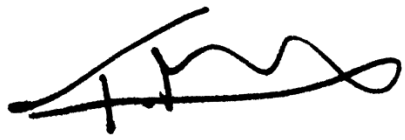
Such labelling would encourage suppliers of Listed products that have not been reviewed to do so, adding to greater confidence for consumers, something which we feel should be the principal concern of all health product regulators.

We suggests that these recommendations should take advantage of the current reforms, and be incorporated in the three-tier approach, for the following reasons:

- Consistency of approach to evidence-based medicine.
- Greater transparency for consumers across the whole range of Listed complementary products rather than a small selection of it.
- Greater clarity and confidence for consumers in knowing which products have been properly assessed and which have not.
- Minimal impact on the activities and resources of the TGA.

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

Sincerely,



Tim Mendham

Executive Officer

Australian Skeptics Inc