Submission to the TGA regarding Homeoepathic products

I strongly support option 1 – Maintain the status quo regulation of homeopathic products. I also strongly reject option 4 – to remove status as a therapeutic good.

Option 1 recognises homeopathic products as being therapeutic (which they are). It also recognises that beyond a level of dilution (as outlined by the TGA) they are completely safe. It also maintains a level of safety protection in the manufacture and distribution of homeopathic medicines as well as providing a benchmark for therapeutic claims which protect the Australian consumer against unfounded low level therapeutic claims.

Some points I would like the TGA to consider in support of option 1 of the submission:

**Regarding the therapeutic aspect of homeopathic medicines**

It is widely accepted that homeopathic medicines are taken only for therapeutic purposes. The World Health Organisation recognises homeopathy as a traditional/ complimentary medicine, in fact the largest worldwide.

It is incorporated as therapeutic medicine into numerous public health systems worldwide including the UK. I only quote the UK as the TGA in option 1 refers to the 2009 UK review of homeopathic evidence as a reason to potentially exclude homeopathy from this option.

As the TGA is probably aware, the findings of this 8 year old review were never adopted, and in fact, this review and its findings were soundly disendorsed by the UK Govt. The UK Govt continues to incorporate homeopathy as a therapeutic medicine in their public health system.

Based on worldwide usage, including WHO recognition as such, and including the UK Govt current recommendations, homeopathy is a form of medicine – therefore a therapeutic good. Why would Australia want to differ from this worldwide view?

**Regarding its standing among other evidence based medicine therapeutic goods**

In its concerns about adopting option 1 the TGA states concerns of counting it as therapeutic along with other evidence based products. It bases this concern on the NHMRC review of Homeopathic evidence which "found no reliable evidence for homeopathy for a range of conditions."

This NHMRC review is currently before the Australian Ombudsman for numerous reasons that raise significant concerns as to the legitimacy of its findings, including irregularities in conducting of the review, changing of its established guidelines in evidence inclusion, and numerous other concerns. Because of this, the outcome of this review should not be used as a measure of

homeopathic therapeutic evidence base, until the Ombudsman investigation has been completed.

One example of such irregularity is that efficacy trials were only considered in the review if they met the following two criteria:

1. A quality rating of 5 (range being 1-5 in quality rating of the trial). So only those trials that qualified at the very highest level of quality.

2. Only trials that included 150 or more subjects.

There are many, many goods currently approved by the TGA as therapeutic that do not have an evidence base that meet these criteria. To exclude homeopathy goods alone based on this criteria, but continue to approve other products as therapeutic that do not meet this evidence base criteria could only be considered discriminatory.

Were the TGA to use this criteria to establish inclusion as a therapeutic product, then it should be applied across the board to all products approved as therapeutic by the TGA. Again, not to do so would be highly discriminatory against one particular health intervention only.

No doubt though, were this rule applied, then **many** products currently used therapeutically by millions of Australians would be removed as therapeutic goods, which would severely narrow the amount of options available to Australians for their healthcare.

I also note that the TGA has not considered the Swiss Govt review of Homeopathic evidence, only those two reviews mentioned. Is there a reason why this review was also not considered or mentioned?

I do realise that review of evidence is not the primary role of the TGA, so this may be an oversite, and I draw your attention to it. It finds homeopathy to be very effective for a number of conditions.

The TGA's primary role is to establish the safety of therapeutic goods and protect the Australian consumer from dangerous goods.

It is firmly established that homeopathic medicines are very safe, and without any dangerous side effects. It also comes at zero cost to the Australian taxpayer. Removing it as a therapeutic good would limit access to this very safe, and very cheap form of medicine. Why would the TGA wish to do this?

Thank you for considering my submission.

Kylie Turner