Submission 4: Submitted by multiple organisations/individuals separately

Consultation - Options for the future regulation of low risk products

RE: TGA Consultation on Homoeopathics

The proposal to reform the therapeutic goods status of Homoeopathic goods is unacceptable.

I agree with:

- ***Option 1** – Maintain the status quo regulation of homoeopathic products, and*
- ***Option 2** – Serious therapeutic claims must be supported by scientific evidence*

I strongly disagree with Option 3 and Option 4.

I believe Options 3 and 4 could impact manufacturers, practitioners and the public in a negative way:

- *No claims could ever be made on Homoeopathic products, not even traditional claims, which are currently allowed.*
- *The future of Homoeopathic Practitioners could be highly problematic due to restricted access to homoeopathic medicines. Legal implications to practitioners would also be uncertain with regard to prescribing non-therapeutic goods.*
- *The public will in turn will not have choice in accessing their preferred health care options.*

As a long time consumer of natural medicines and homeopathic products, both OTC and directly from a private practitioner during a consultation, I believe that all consumers have the absolute right to freedom of choice for their healthcare needs.

Points to consider:

- *Homeopathic Medicine is a Traditional medicine used worldwide by millions of people and is recognized by the World Health Organisation. On that basis alone it should be recognized as a therapeutic option. Under no circumstances should Homeopathy be removed as a therapeutic option.*
- *The TGA has the ability and discretion to recognize Traditional forms of medicine and not just evidence based therefore it should continue to do so in the case of Homeopathy.*
- *The TGA's role is to protect public safety, not make value judgments about products Australians freely choose to use as therapeutic goods.*
- *The NHMRC report set a higher standard to Homeopathy than the TGA currently use to assess efficacy and will use in the future to assess efficacy and therefore should not have been mentioned in this consultation paper as it is misleading and not relevant.*
- *The NHMRC report is subject to a complaint to the Ombudsman and therefore should not have been cited in this consultation paper.*
- *The Consultation paper refers to the NHMRC Homeopathy Review, which applied much higher levels of evidence than the TGA does for its scientific evidence.*
- *For instance, the TGA may accept a study with 10 participants for studies on natural medicines however the NHMRC would not accept a study below 150 participants for homeopathy for a trial to be 'reliable'. The NHMRC report also specified an unusually high 100% quality rating for a trial to be considered 'reliable'. Both criteria are arbitrary and not justified.*

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- *To use the NHMRC threshold as evidence criteria may not be relevant for TGA's purposes of listing products on the Australian Register of Therapeutic Goods (ARTG). It subjects homeopathic evidence to a much higher standard of assessment than any other evidence assessed by the TGA, lacking fairness.*
- *Homeopathic medicines should be afforded the same opportunity to meet the criteria as other complementary medicines for traditional or scientific evidence. The NHMRC's findings are irrelevant, since TGA does not use or accept the same criteria as NHMRC applied to its Review.*
- *The UK government review cited in consultation paper was rejected by the UK Government and therefore should not have been mentioned to imply validity to its unaccepted conclusion.*
- *There is a Swiss Report on Homeopathy which stated "There is sufficient evidence for the preclinical effectiveness and the clinical efficacy of homeopathy and for its safety and economy compared with conventional treatment." – Why was this not included in the recommendations to give perspective and balance?*

Changing the regulations will change lives, health, businesses, income and families NEGATIVELY.

The Therapeutic Goods Administration must move forward with "Option 1 – Maintain the status quo regulation of homoeopathic products".

- **26 submissions were received using the template above or variations of this template.**
- **26 organisations/individuals selected a publishing restriction:**
  - 20 selected "Publish my submission only on the TGA website, do not publish my name or work title"
  - 5 selected "Do not publish my name or work title or my submission on the TGA website"
  - 1 selected "Only publish my name and work title on the TGA website, do not publish my submission"
- **No organisations/individuals indicated that their submissions could be published on the TGA website**, including their name and work title as it appears on their submission.