Submission to the Therapeutic Goods Administration (TGA)

Consultation: Options for the future regulation of "low risk" products.
12 May 2017

We the undersigned are Clinicians at National Institute of Integrative Medicine, 21 Burwood Road, Hawthorn VIC 3122.

We support Option 1 and Option 2 when adopted in conjunction with Option 1.

•Homeopathic Medicine is a Traditional medicine used worldwide recognized by 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 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.

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 homoeopathy 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.

• The NHMRC report is subject to a complaint to the Ombudsman and therefore should not have been cited in this consultation paper.

Homoeopathic 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 the consultation paper, was rejected by the UK Government[1] and therefore should not have been mentioned to imply validity to its unaccepted conclusion.

• A Swiss Report on Homeopathy [2] 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?

• Option 2: requiring scientific evidence for higher therapeutic claims will be captured in the new guidelines and would be acceptable if adopted in conjunction with Option 1..

• Option 3: This option is unacceptable as it would remove homeopathic products from Good Manufacturing Practice (GMP) in production.

Regulatory monitoring is required to ensure public safety (e.g. adverse reaction monitoring). This includes ensuring that products sold in Australia are manufactured according to Good Manufacturing Practice.

• Option 4: Does not recognize the use and continued endorsement of Homeopathy by governments and the general public worldwide. It is out of step with regulatory frameworks worldwide.

TGA's role is to protect public safety, not make value judgments about products Australians freely choose to use as therapeutic goods.

Australia's close ACSS Consortium regulatory partner, Switzerland, is giving homoeopathy the same status as conventional medicine by May 2017 when it comes to health insurance.

The TGA consultation paper selectively excludes any mention of the Swiss situation, or the widespread inclusion of homoeopathy in multiple other international jurisdictions - indicating an unbalanced approach.

The TGA paper selectively excludes mention of multiple positive research published on homoeopathy, including a positive Swiss Health Technology Assessment.

The TGA consultation paper also makes the incorrect, biased value judgment that homoeopathy is 'not evidence based' (as stated in Option 1). The website Homeopathy Research Institute (HRI) website includes accurate information about positive homoeopathy research.

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1. https://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/45/4507.htm
2. *Homeopathy in Healthcare: Effectiveness, Appropriateness, Safety, Costs* by Gudrun Bornhöft and Peter F. Matthiessen (Editors). 2011. ISBN 978-3-642-20637-5.