Submission 12: Submitted by multiple organisations/individuals separately

Australian Government Department of Health Therapeutic Goods Administration Consultation: Options for the future regulation of "low risk" products

Submission for consideration on homeopathic products

I write to you in response to your request for feedback on the potential regulatory options for low risk products, and specifically how they may be applied to Homeopathic products.

This submission is made solely with respect to homeopathic medicine and medicines, and with the understanding that the role of the Therapeutic Goods Administration [TGA] is limited to a consideration of goods intended for therapeutic use, more especially to ensure safety of therapeutic substances and devices, and that TGA has neither expertise nor statutory authority to make determinations on homeopathic therapy or its practitioners.

TGA have put forward for discussion four options (CP pp.46-49):

Option 1 – Keep Homeopathy regulated the way it is.

1. The Consultation paper refers to the NHMRC Homeopathy Review, which applied much higher levels of evidence than the TGA does for its scientific evidence.
2. 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.
3. So 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.
4. Therefore mention of the NHMRC report may not be relevant to this decision process, which needs to be outlined to the TGA.
5. 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.
6. 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.
7. TGA's role is to protect public safety, not make value judgments about products Australians freely choose to use as therapeutic goods.

Option 2 – Keep it the way it is but require scientific evidence for high level claims. This option is acceptable as most appropriate given homeopathic medicines are not to be prescribed merely upon a 'named' condition, rather, for the individual response of the patient in that condition.

Option 3 – Exempt Homeopathy from listing.

. Relatively few homeopathic products listed on the Australian Register of Therapeutic Goods (ARTG) cannot be considered an undue regulatory burden on the resources of TGA, and exempting such homeopathic preparations (below the 4x dilution) introduces the real risk that products, unchecked, may be introduced with significant quantities of restricted substance undetected until after adverse reactions have been reported.

. The Traditional use of Homeopathy of course should be acknowledged and preserved.

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Option 4 – Declare Homeopathic products NOT to be therapeutic goods

- This will be contrary to the rest of the world.
- Australia's close ACSS Consortium regulatory partner, Switzerland, is giving homeopathy 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 homeopathy in multiple other international jurisdictions - indicating an unbalanced approach
- The TGA paper selectively excludes mention of multiple positive research published on homeopathy, including a positive Swiss Health Technology Assessment, which the TGA would have in its library
- The TGA consultation paper also makes the incorrect, biased value judgment that homeopathy is 'not evidence based' (see under Option 1). Go to the Homeopathy Research Institute (HRI) website for accurate information about positive homeopathic research.

I summary Homeopathy is recognized by the World Health Organisation (WHO) as a traditional medicine, used worldwide and included in the National Health systems of a number of countries. Over 200 million people worldwide use homeopathy on a regular basis.

The Australian people come from a broad range of cultural backgrounds, many of which consider Homeopathy as the norm. Indeed, the complementary health care industry in Australia is becoming increasingly popular as a first choice health option and the popularity of Homeopathy is increasing.

Homeopathy, therefore, should continue to be recognized as a therapeutic option under TGA administered regulations. I propose that Option 1 be adopted, which provides a balance between regulatory requirements and consumer confidence in quality and safety.

- **13 submissions were received using the template above or minor variations of this template.**
- **11 organisations/individuals selected a publishing restriction:**
  - 8 selected "Publish my submission only on the TGA website, do not publish my name or work title"
  - 1 selected "Do not publish my name or work title or my submission on the TGA website"
  - 2 selected "Only publish my name and work title on the TGA website, do not publish my submission"
- **2 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.