
TGA Consultation: Options for the future regulation of 'low risk' products

I would like to respond to this submission

I DO **NOT** SUPPORT

- ❖ The adoption of OPTION 4 in any form

I DO SUPPORT

- ❖ OPTION 1
- ❖ OR OPTION 2 so long as Traditional use of Homeopathics is acknowledged and preserved and only high level claims are required to have scientific evidence and so long as the rules for the scientific evidence are the same for all forms of therapeutics and not made more rigorous for Complementary medicines
- ❖ IF OPTION 3 IS CONSIDERED it must be with the Traditional use of Homeopathics acknowledged and preserved and my ability to work as a Homeopath and to prescribe and sell my homeopathic remedies is not hampered by any unreported agenda that will affect the ability to do this.

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- I am a practicing Homeopath so the outcome if this submission basically brings my ability to follow my career to an end if the wrong choices are made here by the government. It is not only I but some nearly 800 other practitioners would be consigned to losing their livelihoods as well – is the government really wanting to have to financially support these people – who are presently actively working and contributing to their local and national economies via spending and taxes.
 - I came to using Homeopathy in 1989 after the failure of the medical system to treat my child's chronic tonsillitis effectively. I am educated, believe in science (but not the censored form of science the NH&MRC seems use when it suits them). Homeopathy was far more effective (both in time frame and lack of side effects and efficacy in my child's overall health not just the tonsillitis) than the 2 or so years of medical treatment with round after round of antibiotics and cycling infections - then the only solution given was to give antibiotics for a year straight! Having already been personally subjected to lengthy antibiotic use and the detriment to my own health – I sought other modalities to treat my child. I was so impressed with the results I have used it personally as my major form of health care for myself, my children and now my grandchildren. I then had the opportunity in 1997 to study it as a profession – in a state education facility ie Nambour TAFE QLD in the first 4 year course ever undertaken by TAFE (also run at South Bank TAFE QLD). It was OK for you to accept it as a form of career then – but now want to effectively outlaw my career choice by covert changes?

The right to choose

- The TGA's role is to ensure that the products and treatments available to Australians are safe for use. It is not to arbitrarily decide what the Australian public can and can't use especially when safety, as with homeopathy, is not an issue.
- Australians have the basic right to choose treatments which best suit them. Government agencies should not regulate to restrict their access to information about that treatment.
- We have already been through a 'witch hunt' by the NH&MRC (and all the fear and the angst that this has caused multiple people in this profession) in their quest to outlaw Homeopathy – to which ends they had to somehow produce a paper on Homeopathy which supported the leaked document where they called Homeopathy unethical and ineffective – BEFORE they did any research. The research they finally published is now before the Ombudsman regarding complaints of serious irregularities, some of which include:
 - conflicts of interest,
 - bias and absence of fairness,
 - the withholding of important information and commentary from the Australian public, and
 - the expectation that homeopathy should meet a much higher standard of evidence than that set for other therapies or medicines – conventional or complementary?

Their methods which fly in the face of all established research protocols and are certainly not the same protocols which are applied to medical standards of research. They came to a conclusion that should not have been drawn from the information they gathered – the response should have been that there is a 'need for further investigation', and had it been any medical modality this is exactly what would have been published. It is well known that there is a concerted campaign to get rid of Homeopathy in Australia. So much so that it should be before the Fair Trading Commission on the grounds of unfair dealings with a 'competitor' in the market. It is already known that Homeopathy is of low risk to consumers and considering that iatrogenesis is the 3rd biggest killer in the USA (and if figures were available – likely the same here) one would consider that the actual focus should be on the main stream medical shortcomings and known widespread fraud and fudging in pharmaceutical research eg Vioxx – where the companies knew it was deadly but chose to hide it – this is being seen more and more – and where the focus actually should be. Double blinded randomised controlled trials are NOT the gold standard they are touted to be they are just the gold standard the pharmaceutical companies WANT us to believe are the best while they remove raw data and make sure their results fit the ones they want.

Unlike prescription drugs which “contributed to 330 of the state's 420 overdose deaths in 2015” in Victoria alone, there is **no evidence** to suggest that homeopathics have harmed or contributed to the death of anyone. (<http://www.abc.net.au/news/2016-04-05/pharmaceutical-drugs-in-nearly-80pc-of-victorian-overdose-deaths/7300036>).

Homeopathy should not be restricted by regulations used by “high-risk” drugs.

- The NH&MRC report also failed a very simple common sense test. In 2005 the World Health Organisation (WHO) published an Atlas of Traditional, Complementary and Alternative Medicine (TCAM) which showed that homeopathic medicine was the most used form of TCAM in countries with a GDP > \$15,000, and the second most used form of TCAM in the remainder. Thus it can be estimated that over the last 200 years homeopathy has been used successfully by billions of people, and has been administered by millions of practitioners with MB BS (or equivalent) qualifications as well as others with specialised health science and homeopathic training, and is part of government public health systems in countries around the world. Yet by inference all these patients, practitioners and governments are wrong, and the NH&MRC is right – an incongruity for which no explanation was offered! It simply doesn't make common sense.

Evidence is easily found

- In referring to the flawed NHMRC report, the TGA says regulating homeopathic products as part of evidence-based medicine will be an “issue”. The inference is that the NHMRC report is correct and there is no evidence for homeopathy. A significant and growing body of evidence is available for those prepared to look. [See the Homeopathic Research Institute as one source:] Why does the TGA ignore this in favour of flawed reports?
- Millions of people worldwide acknowledge the benefits of homeopathy. It would not be growing at the rate it is if it didn't work.

Homeopathy Worldwide

- Homeopathy is recognised by the World Health Organization (WHO) as the most popular and widely used complementary medicine worldwide. Entire communities depend on it for healthcare and the prevention of epidemic disease. That being so, why would the TGA consider restricting the access of Australians to it?
- The Swiss Report on Homeopathy says, “There is sufficient evidence for the preclinical effectiveness in the clinical efficacy of homeopathy and for its safety and economy compared with conventional treatment.” That being the case, why did the TGA exclude this favourable report from its consultation paper yet refer to two negative reports, one of which is currently before an Australian ombudsman for bias and irregularities, and the other, already rejected by the UK Parliament?
- Why would the TGA consider removing the access of Australians to homeopathic information and products when, based on the evidence, the TGA's Swiss counterpart has given homeopathy the same status as conventional medicine in regard to health insurance?
- By not recognizing homeopathic remedies as therapeutic goods in Option 4 of the consultation, the TGA will be out of step with other governments, worldwide, who do.

It must be noted that if Option 4 is adopted and homeopathic products are 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 homeopathy research (that can be quoted).
- The TGA and every drug regulating authority around the world considers homeopathic remedies to be “low-risk” medicines – there's no reason for that position to change now.
- Consumers and users of homeopathy (including myself) **do not want:**
 - Self-help information about homeopathy and the symptoms and ailments it treats, restricted.
 - Homeopathic prescribers to be stopped from providing that information, or prescribing homeopathic remedies.
 - Regulations designed for high-risk medicines applied to homeopathy which, by the TGA's own description, is a “low-risk” medicine.

- Consumer and user access to homeopathic remedies restricted.
- Changes to the regulations that would inhibit, restrict, or deny the importation, exportation, or manufacture of homeopathic remedies by homeopathic manufacturers and pharmacies.
- Changes in the current regulations that would either encourage or make it easier for those antagonistic to homeopathy to lodge vexatious complaints.

If Option 1 is adopted – ie keep Homeopathy regulated the same way as it is. The following points need to be considered

- 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.
- 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
- Therefore the mentioning of the NHMRC report should not be seen as relevant to this decision process 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.
- 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.
- TGA's role is to protect public safety, not make value judgments about products Australians freely choose to use as therapeutic goods.