

I wish to submit to the inquiry the strong view that homeopathic products **are** therapeutic goods, and therefore I support Option 1 – keep homeopathy regulated the way it is.

The opposite view, that homeopathic products are not therapeutic goods, flies in the face not only of (a) common sense but also of (b) demonstrated evidence.

(a) The WHO Atlas of Traditional, Complementary and Alternative Medicines indicated that homeopathy is used by around 500 million people in most countries in the world. Apart from India, there are tens of thousands of orthodox medical practitioners who practice homeopathy as well as tens of thousands of trained homeopaths. There is a wealth of evidence (either ignored or defined away by the NHMRC and sceptics) showing the therapeutic effects of homeopathic products.

I have not long returned from India where I was invited by the *Department of AYUSH* to present at a conference which focussed on the prevention and treatment of epidemic diseases which are prevalent in India, and ways to improve research in homeopathic disease treatment and prevention. The Department is in part responsible for the over 200,000 homeopathic doctors in India. Such a huge and successful therapeutic use of homeopathy in hundreds of millions of people provides overwhelming real-world evidence that homeopathic products are therapeutic goods.

Following that I worked for 3 days at the *Central Council for Research in Homeopathy* which has a staff of around 1,000 doctors and scientists. It produces high quality research including (i) Human pathogenetic trials (provings); (ii) Case studies; (iii) Clinical/epidemiological research (involving humans); and (iv) Basic research (involving plants, animals etc), showing the therapeutic effectiveness of homeopathic products. To contend that all these highly-trained professionals are delusional denies reality.

(b) There have been numerous presentations and summaries of the evidence base of homeopathy in both treatment and prevention. One of the best summaries is contained on the resource pages of the website of the Homeopathy Research Institute <https://www.hri-research.org/resources/>.

Against this depth of evidence the TGA has cited the recent NHMRC report on homeopathy; “This is particularly relevant given the Australian National Health and Medical Research Council (NHMRC) recently concluded that there is no reliable scientific evidence that homeopathy is effective.”

I contend that this report should be given nil standing in the TGA inquiry for the following reasons:

1. The then CEO and Chairman of the NHMRC both declared a bias against homeopathy before the NHMRC inquiry began and declared that it was ineffective.
2. The NHMRC committee contained no experts in homeopathy, but did contain a member who had supported claims that natural medicines, including homeopathy, were ineffective.
3. The NHMRC was tasked to, and they declared that their approach was similar to a *Health Technology Assessment* (HTA), when in fact they defined out of their inquiry any consideration of health, any consideration of disease prevention, any consideration of the quality of homeopathic medicines, any consideration of the safety of homeopathic medicines, or analysis of the cost-benefit of homeopathy. They also excluded studies not in English. It was clearly not an HTA.
4. The NHMRC employed a consultant firm to collect and assess evidence. Because they found the results did not to suit their purpose they dismissed this consultant and hired a second consultant. Apparently the second consultants were also finding evidence positive to

homeopathy because part way through the second analysis the NHMRC changed the rules of the research project (something which is generally unacceptable in reputable research) and imposed an arbitrary limit of 150 participants (the TGA may accept a study with 10 participants for studies on natural medicines) and a Jadad score of 5 (Professor Jadad declared that studies with a ranking of 3 or more should be considered in analyses), thus reducing the number of studies from an original 1,800 to 5 (one of which was positive). These few “cherry-picked” for the basis of their conclusions.

5. The NHMRC requested 3 reviewers to assess their report. Two of the three advised the NHMRC to deliver a different finding. The NHMRC ignored the majority advice that they themselves sought.

Clearly the findings of the NHMRC report are compromised by both bias and significant methodological weaknesses. The NHMRC report should be disregarded by the TGA.

In fact the most thorough HTA of homeopathy, prepared as part of a review by the Swiss government, produced a finding clearly supportive of homeopathy. As a result 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 also referred to “A 2009 U.K. government review”, the major recommendations of which were subsequently rejected by the UK Parliament due to its bias and reliance on a discredited 2005 analysis by Shang and others in the Lancet.

Summary: The massive use of homeopathy internationally for over 200 years, including its current use by half a billion people and hundreds of thousands of orthodox medical practitioners, demonstrates that the suggestion that homeopathic products are placebo would require the assumption that a huge number of people and practitioners are deluded. The suggestion also requires ignoring the substantial evidence base of effectiveness which was “defined away” by the NHMRC report but yet stands on the public record, including research with animals and in-vitro research where placebo responses do not occur. Further, the claims against the effectiveness of homeopathy are based on reports which have been proven to be biased and methodologically unsound.

The only possible evidence-based conclusion is that homeopathic products are therapeutic goods. Thus maintaining the way homeopathic products are regulated by the TGA (option 1), is the preferable evidence-based action to be taken by the TGA.

(Full references available on request)