Submission to the Therapeutic Goods Administration (TGA)

*Consultation: Options for the future regulation of "low risk" products.*

To:
Regulatory Reforms Team
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## Background:

My submission specifically relates to proposed changes to the regulation of homeopathic products in the consultation paper.

I have been a naturopath and yoga teacher for the past 25 years in Sydney and Canberra and a parent of several children. I have used and prescribed homeopathic medicines for my clients and my children's health issues have been consistently and predominantly been dealt with homeopathy. We have used other systems, including going to the GP, as appropriate. Homeopathy is part of the mix of therapies available to the community and supporting diversity and equity in choice is important.

I am aware of the deeply held skepticism in agencies such as TGA, which are disconnected with the multitude of complementary therapies ordinary Australian use and value. I understand that TGA does not employ staff with specialist expertise in homeopathic medicine, who clearly were not involved in drafting what is a very imbalanced consultation paper with regard to the proposed regulatory changes to homeopathic medicines.

## Submission:

I **strongly support Option 1** - maintenance of regulatory status quo.

I **also support Option 2**, which closes what appears to be a loophole in the legislation relating to the (inappropriate) ability of homeopathic products to make high level claims. It appears this is compatible to and could be conjoined with adoption of Option 1.

I **strongly reject Options 3 and 4**, which appear to make little sense.

**TGA's primary responsibility is to protect public health and safety and this is its primary statutory role**. Options 3 and 4 go against the guiding principles of the MMDR

reform agenda, including requiring a complete redefinition of 'homeopathic product'. The current definition is perfectly adequate **and should be retained**.

Pushing the responsibility to the ACCC under consumer law does nothing for protecting public health and safety, since this is **not a specialist regulator**. It does not have the regulatory framework in place to provide adequate cover for homeopathic medicines, which are therapeutic goods (not consumer goods). TGA is the **only specialist regulator** available as the viable option.

**Option 3** would result in a deregulated environment, encouraging poor quality products entering the market that do not meet TGA GMP standards will enter the market.

It would **disincentivise** those manufacturers that are licenced TGA GMP facilities that attempt to 'do the right thing'. In a deregulated market, adverse reaction events would increase and problems associated with poor quality products would affect the reputation and viability of those attempting to do the right thing.

This option seems to be geared towards preventing homeopathic products from being eligible from entry on the Australian Register of Therapeutic Goods (ARTG) - placing an entire sector at an unfair competitive disadvantage.

The basis of this seems to be TGA's **preformed conclusion** that homeopathic medicines are not "evidence based" in stating (p.46):

> *"An issue of maintaining the current regulation of homoeopathic products under the same framework as evidence based medicines is that it may imply government endorsement of these products."*

This statement is explicitly biased, even stating that regulating them equates to "endorsing" them. **Such a position is not taken on any of the other product types in the consultation paper**.

The paper then **openly cites the NHMRC homeopathy review as 'evidence' - which I have seen is subject to an Ombudsman complaint over research fraud**. TGA has therefore aligned itself with this controversy. TGA may be aware of press releases that have been released internationally, for example https://www.hri-research.org/wp-content/uploads/2017/04/20170405_HRI-NHMRC-PRESS-RELEASE-Full-Analysis.pdf

TGA may also be interested in the following summary of the Ombudsman complaint: https://www.hri-research.org/wp-content/uploads/2017/04/Executive-Summary-to-Ombudsman-Complaint-re-NHMRC-Homeopathy-Review-FINAL.pdf

It is wholly unacceptable that TGA align itself to such fraudulent conduct, while at the same time not providing the community with any reference to the many positive reports on homeopathy and its evidence base.

The TGA paper then refers to a political UK report that the UK government and department of Health rejected years ago. TGA may have forgotten that the NHMRC itself got into trouble for perceived bias, when it decided to form a position statement on homeopathy in 2011 solely based on this report (leaked to the media through the Consumers Health Forum, in April 2011).

**In other words, TGA seems to have taken a biased, preformed position on this consultation - as evidenced in the way it has presented the information in the consultation paper**.

It seems clear that TGA is conducting the consultation with Options 3 and/or 4 in mind, which should be rejected.