FEEDBACK ON THE POTENTIAL REGULATORY OPTIONS FOR LOW RISK PRODUCTS THAT ARE DISCUSSED IN THE TGA CONSULTATION DOCUMENT: WHICH (IF ANY) MIGHT BE MOST APPROPRIATE AND WHY.

I practice natural medicine since 1996, with Homoeopathy as a main modality since 2002. Based on my professional experience I am strongly supporting OPTION 1 - to maintain the regulation of homoeopathic products under the current framework.

In regards to this option, TGA expresses its apprehension that this may imply government endorsement of Homoeopathy, which in their opinion would be contrary to

- the conclusion of the Australian National Health and Medical Research Council (NHMRC) that there is no reliable scientific evidence that homeopathy is effective
- a 2009 U.K. government review stating that: 'By providing homeopathy on the NHS and allowing MHRA licensing of products which subsequently appear on pharmacy shelves, the Government runs the risk of endorsing homeopathy as an efficacious system of medicine. To maintain patient trust, choice and safety, the Government should not endorse … homeopathy.'
- a 2016 the US Federal Trade Commission similar findings.

In responding to the above apprehensions, I would like to bring everyone's attention to the following considerations:

1. **The UK government review quoted above was rejected by the UK Government,** therefore it should not have been used by TGA to imply any validity that could mislead the Australian public. Instead it would be helpful to bring into the spotlight a Swiss Report on Homeopathy stating that "There is sufficient evidence for the preclinical effectiveness and the clinical efficacy of homeopathy and for its safety and economy compared with conventional treatment."

1. **Currently the NHMRC report is subject to a complaint to the Ombudsman**, therefore TGA reference to it in this consultation paper would better be avoided.

1. **TGA has its own standards to assess efficacy which should be applied equally to all modalities** (including Homoeopathy) **and not allowed to be altered by any organisation** (including NHMRC) which set a much higher standard for Homeopathy than TGA does for any scientific evidence. Therefore in this consultation paper on TGA's options of listing products on the Australian Register of Therapeutic Goods (ARTG) it may not be appropriate for TGA to refer to the deeply flawed and misleading NHMRC report.
2. To this date the **TGA had the power and was capable to exercise it in acknowledging Homoeopathy as a traditional form of medicine** and not just evidence based. Shouldn't TGA continue to do so without being sidetracked by any biased reports similar to the one done by NHMRC?
3. According to World Health Organisation: "Traditional medicines are…based on an extensive history of use… Traditional use may infer community knowledge of the existence and application of a substance but does not necessarily carry with it any scientific assessment or scrutiny. **Evidence of traditional use may be used to support claims for therapeutic goods**. … **Traditional therapies are considered to include** Traditional Chinese Medicine (TCM), traditional Ayurvedic medicine, traditional western herbal medicine, **traditional homeopathic medicine**, aromatherapy and other indigenous medicines. With

respect to multigenerational use of homeopathic medicines, it is recognised that homeopathic medicine represents a special case where the manufacturing process of serial dilution is a major component of the tradition of use of the therapy. Providing that a new substance is prepared according to principles described in homeopathic pharmacopoeia, and satisfies safety requirements, claims may be assessed on an "evidence of traditional use" basis. **Evidence of traditional use includes independent written histories of use in traditional or contemporary homeopathic literature, multigenerational use, homeopathic proving, records of clinical use and records of the set of symptoms provoked by a "crude" substance. Claims made in relation to homeopathic products must be consistent with the homeopathic picture of the remedy or remedies on which the claim is based**… Should scientific evidence be contrary to the evidence based on traditional use, the claim used must reflect the truth, on balance of the evidence available." (Essential Medicines and Health Products Information Portal / A World Health Organisation resources / apps.who.int)

4. **The NHMRC claims in relation to Homeopathic medicines are not consistent with the homeopathic picture of the remedies on which their claim is based.** The NHMRC depends heavily on research guidelines that drug companies adhere to. None of the specialists involved on their panel had a proper training or expertise in Homoeopathy, hence their so called "scientific evidence" is contrary to the evidence based on traditional use, and their claim does not reflect the truth.
5. **Being endorsed by World Health Organisation as a traditional medicine, Homoeopathy is successfully used in many countries by over 500 million people.** Are they all imagining its effectiveness? In Australia people also use it increasingly and they are paying for it largely from their own pocket. Would it happen if it was ineffective? These facts alone could point to the necessity of giving Australian people the choice to use Homoeopathy as a therapeutic option in their health care. **Homoeopathy as a therapeutic option should remain paramount to all citizens in our free society.**

ADVANTAGES OF THE OPTION 1:

I strongly support OPTION 1 and agree with the TGA's statement that "sponsors and manufacturers who are already familiar with the regulatory framework would not need to understand or implement any regulatory changes"; and I would like to add that using Homoeopathy as a therapeutic option also benefits the health of Australians, and it gives government and taxpayer significant financial relief by reducing the burden on already struggling public health system.
It is also important to mention that regulatory monitoring is required to ensure public safety (e.g. adverse reaction monitoring) not only in relation to homeopathic products but especially allopathic medicines which are notoriously known for incurring side effects, sometimes adverse. TGA's role is to protect public safety, not to make value judgments about products Australians freely choose to use as therapeutic goods.

I do not support all other proposed Options, and I especially request that the TGA does not adopt Options 3 and 4, as I agree with my colleagues whose comments are as follows:

- "**Option 3 will remove** the requirement of Good Manufacturing Practice standards and does not allow homoeopathic products to be Listed or Registered on the Australian Register of Therapeutic Goods (ARTG). It appears to not be well thought out, neither fulfilling TGA's responsibility to safeguard public safety, nor fulfilling industry's needs."
- "**Option 4 – to Declare homoeopathic products NOT to be therapeutic goods -** will be contrary to the rest of the world.
- 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, which the TGA would have in its library
- The TGA consultation paper also makes the incorrect, biased value judgment that homoeopathy is 'not evidence based' (see under Option 1). This assumption is incorrect. According to the Homeopathic Research Institute in the UK: https://www.hri-research.org/resources/homeopathy-faqs/there-is-no-scientific-evidence-homeopathy-works/ - by the end of 2014, 189 randomised controlled trials of homeopathy on 100 different medical conditions had been published in peer-reviewed journals. (http://www.facultyofhomeopathy.org/research/)Of these, 104 papers were placebo-controlled and were eligible for detailed review:
- **41% were positive (43 trials)** – finding that homeopathy was effective
- **5% were negative (5 trials)** – finding that homeopathy was ineffective
- **54% were inconclusive (56 trials)**

If these statistics are compared to conventional medicine it will be seen that there are similar findings.
An analysis of 1016 systematic reviews of RCTs of conventional medicine had strikingly similar findings:

- **44% were positive** – the treatments were likely to be beneficial
- **7% were negative** – the treatments were likely to be harmful
- **49% were inconclusive** – the evidence did not support either benefit or harm.

Although the percentages of positive, negative and inconclusive results are similar in homeopathy and conventional medicine, it is important to recognise a **vast difference in the quantity** of research carried out: 188 individual trials on homeopathy, in contrast to 1016 reviews on conventional medicine, each analysing multiple trials.
Despite the NHMRC review having resulted in a negative perception of homeopathy as a modality in Australia these findings do not reflect the status of homeopathy worldwide. I refer to **The Swiss report, 2011** compiled on behalf of the Swiss Federal Office for Public Health which presented the findings of a seven-year review of the evidence on homeopathy. It concluded that homeopathy, as practiced in Switzerland, is clinically effective, cost-effective and safe. Homeopathy has since become available to the Swiss public as part of their national healthcare scheme."

As a Homoeopath, I am appealing to the TGA to prevent the negative effect on the practice of all health practitioners prescribing homeopathic medicines should there be changes made to the current regulations, especially if options 3 or 4 are implemented. If Homoeopathy in Australia is denied a therapeutic status this

would detrimentally impact not only the future of this modality in Australia, but also the wellbeing of those who already rely on it and wish to continue benefiting from it. In fact, right now those people are removing a great burden from our overburdened public and private health systems. Australian consumers should have the right to choose to see a qualified homeopathic practitioner and if Option 4 is adopted that consumer choice could be taken away.