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

Homeopathic Medicine is a Traditional medicine used worldwide and recognized by The World Health Organisation. Homeopathy is used therapeutically Worldwide, over 200 million people use homeopathy on a regular basis.i

India leads in terms of number of people using homeopathy, with 100 million people depending solely on homeopathy for their medical care.ii

There are over 200,000 registered homeopathic doctors currently, with approximately 12,000 more being added every year. iii

In regards to your evidence including the recent NHMRC report and as well as reviews by other international jurisdictions - The NHMRC report should not be considered by the TGA as this report is under investigation by the Commonwealth Ombudsman, due to a complaint about their conduct with alleged breaches of research standards and ethics.

The UK government review cited in consultation paper was rejected by the UK Govt. and therefore should not have been mentioned to imply validity to its unaccepted conclusion.

Where is the positive government findings of the Swiss Report on Homeopathy where they stated "There is sufficient evidence for the preclinical effectiveness and the clinical efficacy of homeopathy and for its safety and economy compared with conventional treatment." – Why was this not included?

Option 2: requiring scientific evidence for higher therapeutic claims will be captured in the new guidelines and should be considered.

Option 3 is only viable if it allows product manufactures to continue to make low level claims with regards to its worldwide traditional use as a medicine.

Option 4 is contrary to international norms and the continued traditional use of Homeopathic products. As already stated, over 200 million people worldwide use homeopathy on a regular basis as a therapeutic agent. Option 1 is best placed to regulate Homeopathic medicines as a therapeutic good.

i Use of Homeopathy across the world, HRI, https://www.hri-research.org/resources/homeopathy-thedebate/essentialevidence/use-of-homeopathy-across-the-world/

ii Homeopathy boomin in India <a href="https://www.ncbi.nlm.nih.gov/pubmed/18035598">https://www.ncbi.nlm.nih.gov/pubmed/18035598</a>

iii A short history about the development of homeopathy in India. <a href="https://www.ncbi.nlm.nih.gov/pubmed/20471616">https://www.ncbi.nlm.nih.gov/pubmed/20471616</a>