Low risk products consultation

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

Context

You're no-doubt aware that Homeopathic medicine is a Traditional medicine, used worldwide, and recognised by the World Health Organisation. Homeopathy is also included in the national health systems of a number of countries, playing an important role in the healthcare of citizens, such as in India, where 100 million people depend on homeopathy for their medical care[i].

According to the Homeopathy Research Institute (HRI), over 200 million people worldwide use homeopathy on a regular basis[ii]. Homeopathy's use in western countries with similar healthcare systems is also high:

- 29% of the European Union's population use homeopathic medicines in their day-to-day healthcare
- 10% of people in the United Kingdom use homeopathy, with the market for homeopathy growing at around 20% per year.

Although Australia may be a microcosm of this, in this interconnected world and society consisting of people from a broad range of cultural backgrounds where the use of Homeopathy is considered the norm, we're not isolated from Homeopathy's global impact and the desire for citizens to seek out Homeopathic products.

On this basis, Homeopathy should be continued to be recognised as a therapeutic option under TGA administered regulations. On balance, Option 1 appears to be best placed to meet this, while retaining consumer and sector confidence in regulating quality and safety.

Discussion of options

Option 1 – Maintain the status quo

Benefits

Option 1 provides a mechanism by which Homeopathic products continue to be recognised as a therapeutic good, consistent with international norms and traditional use. With continued TGA oversight, along with the GMP standards, community and sector expectations with regards to product quality and safety are also maintained.

There is a risk that excluding Homeopathic products, as per option 3 and 4, will likely erode this, along with the gains the TGA have made over the years to improve the quality and safety of the complementary medicines sector.

Perceived issues

Your paper raises a number of perceived issues with Option 1:

A) Issue of implied endorsement

Implied endorsement is not a unique issue for a Homeopathic product but applies universally to any listed therapeutic product, be it a complementary medicine or otherwise. This is a non-issue as the report does not cite any research which concludes that the listing of therapeutic good on ARTG confers any marketing advantage.

B) Evidence

A separate TGA-lead consultation is underway, looking at the pathways for entry of complementary medicines, based on a hierarchy of evidence and permitted indications for listed medicines. Evidence considerations in relation to listed Homeopathic products should await the conclusion of that consultation, to ensure consistency in approach, as well as fairness of the application of evidence criteria.

It must be noted that as a traditional medicine, a body of knowledge for the use of specific Homeopathic medicines has been developed over many generations. Traditional indications need to be recognised in any evidence framework for complementary and traditional medicines, including those used for Homeopathic products.

With regards to evidence, your paper cites the recent NHMRC report, as well as reviews by other international jurisdictions:

- **NHMRC review** – this report should not be considered in the TGA's deliberations due to multiple factors:
  - The NHMRC report sets a higher standard to Homeopathy than the TGA currently and continues to use to assess efficacy of *any* therapeutic good.
  - The NHMRC report, along with the process the NHMRC followed to produce the report, is currently the subject of an investigation by the Commonwealth Ombudsman, due to a complaint about their conduct with alleged breaches of research standards and ethics.

- **UK House of Commons review –** your report cites the 2009 UK 'government' review. This was not a government-initiated scientific review, but a House of Commons (parliamentary) committee and politically-driven review, which is not subject to good research design and oversight. In response, the findings of this paper were rejected by the UK government, and Homeopathy continues to be delivered as part of the UK national healthcare system. As the conclusions of this report were not-accepted, they are irrelevant to this consultation.

Although you've cited potentially problematic examples for government, it appears you've ignored reviews where governments have made a positive finding. For example, the Swiss Report of Homeopathy 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."

Through this consultation, the TGA needs to ensure there is balance in the examples it cites, otherwise it may be accused of bias.

Option 2 – Serious therapeutic claims must be supported by scientific evidence

Pathways of entry consultation

As mentioned above, a separate TGA-lead consultation is underway, looking at the pathways for entry of complementary medicines, based on a hierarchy of evidence and permitted indications for listed medicines.

The consideration of Option 2 in relation to listed Homeopathic products needs to await the conclusion of that consultation, to ensure consistency in approach, as well as fairness of the application of evidence criteria.

Traditional medicines

As previously stated, the indications for the use of traditional medicines, such as Homeopathic medicines, has been developed over many generations. The TGA have the ability and discretion to recognise Traditional forms of medicine and not just evidence-based, and it should continue to do so with Homeopathy.

Option 3 – Exemption from listing in the ARTG and/or GMP

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 – Declare homeopathic products not to be therapeutic goods

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-the-debate/essentialevidence/use-of-homeopathy-across-the-world/

ii Ibid.