Low risk products consultation

I am responding to the request for comment on the proposed options for future regulation of “low risk products”. My response provides feedback on the potential regulatory options for “low risk products”, specifically as may applied to homeopathic products.

Background

Homeopathy is a medical science developed by the German physician Dr Samuel Hahnemann some 200 years ago. It is used and practiced worldwide and still employs the principles established by Hahnemann. It is recognised by the WHO as a form of medicine. The Homeopathy Research Institute estimates that homeopathy is used by more than 200 million people.

Homeopathy has been integrated into the national health care systems of many countries, including India, Mexico, Pakistan, Sri Lanka, and the United Kingdom[1]. More recently the Swiss Government integrated homeopathy and other complementary modalities into their National Health system following a five year trial period.[2]

Homeopathy also plays an important role in the healthcare of citizens in India, where more than 100 million people depend on homeopathy for their primary health care. The populations of Bangladesh and Pakistan are also significant consumers of homeopathy.

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.

Australia is one of the world’s most successful multicultural societies. Our population is made up of people from a broad range of cultural backgrounds and within many of these cultures it is commonplace for homeopathy to be used for personal and family medicine.

The last twenty five to thirty years there has seen significant growth in the numbers of practicing homeopaths in Australia to service the growth in the numbers of people electing to use homeopathy in their mix of health care modalities. The rights of families and individuals to continue to have access to their chosen forms of health care are fundamental.

When these facts are taken into account it is clear that homeopathic products should continue to be available and recognised as a therapeutic option under TGA administered regulations. 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

This option continues to regulate homeopathic medicines under the offices of the TGA. With continued TGA oversight, along with the GMP standards, community and sector expectations with regards to product quality and safety are also maintained. The existing makers of homeopathic medicines will have to confidence to continue and grow their businesses and create employment while maintaining their technical and manufacturing excellence in Australia.

Risks

The consultation paper raises a several issues in relation to Option 1.

The issue of implied government endorsement raised in this consultation is not unique to homeopathic products. It could be implied that regulation of medicines or any therapeutic product, for that matter, infers endorsement by the government. Rather, the role of the regulator is to ensure that the manufacture of any therapeutic product meets the standards for quality and safety.

This is a non-issue as the NHMRC report does not cite any research which concludes that the listing of therapeutic good on ARTG confers any marketing advantage.

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 the homeopathic canon has been developed over more than 200 years. The historical literature must to be recognised along with more recent studies and clinical data 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. Thiswas 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 the consultation paper has cited potentially problematic examples for government, it appears to have 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."

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.

References.

1. http://apps.who.int/medicinedocs/pdf/h2943e/h2943e.pdf (p3)
2. https://www.admin.ch/gov/de/start/dokumentation/medienmitteilungen.msg-id-61140.html
3. https://www.hri-research.org/resources/homeopathy-thedebate/essentialevidence/use-of-homeopathy-across-the-world/