Australian Government Department of Health – Therapeutic Goods Administration

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

Homoeopathic products

Introduction

The focus of this submission is on homoeopathic products, as 'low risk' products.

The primary principle of Homoeopathy is 'Primum non nocere' ('First, do no harm'). Homoeopathy has its origins in the desire to minimise the harmful effects of the medicines which doctors were using at the time that the founder of Homoeopathy, Dr Samuel Hahnemann, was practicing medicine over two-hundred years ago. His scientific and clinical observations laid the principles for how homeopathic medicines are to be prepared using dilution and succussion, or potentisation.

This principle of 'First, do no harm' continues to be the guiding principle of homoeopathy today and reiterates the principle that medications and treatments should not place any patient at risk. Homeopathic medicines, by their very nature, are therefore 'low risk products' and should continue to be regarded as such. Any proposal to reform the current therapeutic goods status of Homoeopathic goods is therefore rejected.

Given homoeopathy's efficacy and the lack of risk it poses to people's health, it is currently the second most-used system of medicine in the world, used globally by many millions of people and officially recognized by the World Health Organisation. The Swiss Report on Homeopathy[1] stated that, 'There is sufficient evidence for the pre-clinical effectiveness and the clinical efficacy of homeopathy and for its safety and economy compared with conventional treatment'. Given this level of international recognition and acceptance, it is astonishing that the TGA and the Australian National Health and Medical Research Council's (NHMRC) persist in questioning the efficacy of homoeopathy and continue their drive to undermine its practise.

This submission sets outs the preferred option as provided by the TGA's consultation process, namely *qualified* support for Option 1, and provides additional commentary on the TGA's Consultation Paper.

Commentary

Characterisation of 'homoeopathic products'

While the TGA's characterisation of 'homoeopathic products' (Australian Government 2017, 'Consultation: Options for the future regulation of "low risk" products' of March 2017, p. 46) requires a more detailed critique, as it does not adequately reflect the nature of homoeopathic products nor their efficacy, it is not within the scope of this submission to provide further detailed analysis.

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[1] *Homeopathy in Healthcare: Effectiveness, Appropriateness, Safety, Costs* by Gudrun Bornhöft and Peter F. Matthiessen (Editors). 2011. ISBN 978-3-642-20637-5. https://www.hri-research.org/resources/homeopathy-the-debate/the-swiss-hta-report-on-homeopathy/

Questionable methodology

The Consultation paper states that, in order to 'objectively define what is meant by "low risk" it became apparent that a mechanism was needed' - the Low Risk Classification System (LRCS) was therefore determined.

This mechanism and its criteria are described as a 'simple linear model that provides an overall risk score'. It must be said that many of the criteria/dimensions in this model are subjective and cannot be said to be particularly rigorous or provide a reliable evidence base. However, this is not as worrying as the stated fact that 'The LRCS also implements a modest form of the "wisdom of crowds" approach, where 'the aggregated *opinion* of a group is superior to most or even all members of the group'. The Consultation paper validates this approach as being 'scientifically well-founded' by pointing to an approach used to publically rate hotels and restaurants (e.g. on "Trip Advisor"), car smash repairers etc. It is indeed worrying that the TGA promotes such subjectivity and opinion-based mechanisms, and likens the determination of the risk of therapeutic goods to hotel rooms, restaurants and car repairers! This at the same time that the TGA and the NHMRC continue to attack Homoeopathy for its lack of scientific rigour!

A Consideration of Options

It is noted that the available options provided in the TGA Consultation Paper are somewhat limited in their scope and do not encourage a more broad-ranging response. Be that as it may, this submission provides the following comments with regard to the options as provided.

Option one:

This submission indicates qualified support for Option One, namely to "Maintain the status quo regulation of homoeopathic products".

The support for Option One extends only to the continued regulation of homoeopathic products as listed complementary medicines or exempt goods.

This submission does not support the implication that a preference for Option One, 'may imply government endorsement of these products', more especially in light of the Australian National Health and Medical Research Council's (NHMRC) erroneous conclusion that 'there is no reliable scientific evidence that homeopathy is effective'[2]. It is also noted that reference in the TGA Consultation Paper to the NHMRC Homeopathy Review is inappropriate as the NHMRC's report is currently the subject of an objection, currently with the Federal Ombudsman, and therefore constitutes a failure to follow due process, which could potentially be a matter for the Administrative Appeals Tribunal to consider.

It is noted that the TGA's Consultation Paper includes a veiled threat that an approach such as that adopted by the United Kingdom's National Health Service[3] and/or the so-called 'findings' of the US Federal Trade Commission (2016)[4], could be under consideration by the TGA and/or NHMRC. The Consultation Paper fails to indicate that the UK Government subsequently rejected the UK NHS review findings – thereby deviously implying validity and adoption, where none exists.

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[2] https://www.nhmrc.gov.au/guidelines-publications/cam02

[3] https://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/45/4507.htm

[4] https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-staff-report-homeopathic-medicine-advertising-workshop/p114505_otc_homeopathic_medicine_and_advertising_workshop_report.pdf

Other options:

Options two, three and four are roundly rejected.

With regard to Option Two – the TGA is calling for 'Serious therapeutic claims being supported by scientific evidence' – this submission holds that the NHMRC, as supported by the TGA, has itself failed to apply the principle of 'scientific evidence'. The NHMRC's assessment of Homeopathy 2010-2015 (*NHMRC Homeopathy Review*), demonstrates a complete lack of scientific method and rigour.

The practise of Homoeopathy and rigorous research about its efficacy has yielded a multitude of contemporary studies throughout the world that demonstrate scientific evidence and homoeopathy's efficacy and application. These examples of scientific evidence and research were provided to the NHMRC, which saw fit to reject them and to redefine the selection criteria and sample group stipulations as well as its definitions of what constitutes scientific replicability.

With regard to Options Three and Four, the application of these options could negatively impact on manufacturers, practitioners and the public, and would result in a restriction of choice. These options are therefore rejected.

Conclusion

If homoeopathic medicines are deemed by its detractors, such as the NHMRC and others, to be 'placebo' and to not contain any active agent due to their high dilutions, they should logically then be viewed as 'low risk' and of causing no harm. Why then do homoeopathic medicines continue to receive such attention and why is so much Government time and effort spent on regulating and restricting their use and on limiting the freedom of the public to choose homoeopathy as a health modality?