Please accept my submission on the Consultation Options Future Regulation Low Risk Products in relation to Homoeopthic Products.

I **strongly agree** with **Option 1**.

I **strongly disagree** with **Options 3 and 4**.

Thank you.

Homoeopathic products

Background: A 'homoeopathic product/preparation/medicine' is based upon the principles of homoeopathic pharmacy 'potentisation,' which is the serial dilution and succussion of a stock. Homoeopathic products are derived from a wide variety of natural source materials, mostly plants and minerals. Some of these source materials are poisonous, for example: *Atropa belladonna*. The highly diluted nature of homoeopathic products is considered to render the starting materials non-toxic and therefore safe for therapeutic use.

A mother tincture in homoeopathy is the first extract of herb or plant upon which further dilutions are made.

As of October 2014, there were 220 products listed on the ARTG as 'homoeopathic' or 'homoeopathic/other products'. Of these 220 products:

- 91 met the criteria for exemption (Item 8 of Schedule 5 to the Regulations) and even though they are listed, they are not required to be included on the ARTG. It is assumed that the sponsors either listed these products because they were unaware of the regulatory requirements or believe that by doing so there was a marketing advantage in representing the product as a TGA-listed medicine.
- 29 were required to be listed on the ARTG as they contained ingredients at 1:1000 or lesser dilutions (1X, 2X or 3X).
- 16 were required to be listed on the ARTG because they had indications for the treatment of a disease, condition, ailment or defect.
- 84 were required to be listed on the ARTG as their formulations included non-homoeopathic ingredients in combination with homoeopathic ingredients.

As at February 2017, there were 142 homoeopathic preparations entered in the ARTG. The number of exempt homeopathic preparations on the market in Australia is unknown.

Current regulatory oversight: Homoeopathic preparations are exempt from being entered in the ARTG if it is more dilute than a one thousand fold dilution of a mother tincture[1] (4X and above), is not required to be sterile, does not include ingredients of human or animal origin and does not make

[1] The first dilution of a Mother tincture is considered 2X so a one thousand fold dilution of a mother tincture is 4X

reference to serious diseases or conditions. Preparations that meet these conditions are also exempt from requiring the manufacturer to hold a GMP licence.

Preparations less dilute than 4X, which only contain permitted ingredients, are not sterile and/or make reference to serious diseases or conditions, are required to be listed in the ARTG. Products that are required to be supplied sterile would require registration in the ARTG, as they can only be supplied as registered medicines.

An overview of the international approach to the regulation of homoeopathic products can be found in Appendix 2.

Options for reform

Option 1 - Maintain the status quo regulation of homoeopathic products

Under this option TGA continues to regulate homoeopathic products as listed complementary medicines or exempt goods depending on their composition and dilution and would continue to be required to meet the regulatory requirements detailed above.

> **Please note:** The Government has agreed to further MMDR recommendations to reform the regulation of complementary medicines. Recommendations 38 and 39 cover the establishment of three pathways for entry of complementary medicines in the ARTG based on a hierarchy of evidence and permitted indications for listed medicines.
>
> Those proposals are further detailed in a separate complementary medicines consultation paper which is currently open for consultation[2].

- An issue of maintaining the current regulation of homoeopathic products under the same framework as evidence based medicines is that it may imply government endorsement of these products. This is particularly relevant given the Australian National Health and Medical Research Council (NHMRC) recently concluded that there is no reliable scientific evidence that homeopathy is effective[3].

This issue is also being considered by other regulators. A 2009 U.K. government review[4] concluded 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 the use of placebo treatments, including homeopathy.'

In November 2016, the US Federal Trade Commission in the USA concluded similar findings.[5]

An advantage with this option is that sponsors and manufacturers who are already familiar with the regulatory framework would not need to understand or implement any regulatory changes.

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[2] https://www.tga.gov.au/consultation/consultation-reforms-regulatory-framework-complementary-medicines-assessment-pathways (consultation closes on 28 march 2017)
[3] https://www.nhmrc.gov.au/guidelines-publications/cam02
[4] https://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/45/4507.htm
[5] 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

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

Currently, Item 5 of Part 1 to Schedule 4 of the Regulations states that homoeopathic preparations that refer to the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Advertising Code are eligible for listing. This is inconsistent with the regulation of other listed medicines.

Under this option it is recommended that the Regulations be amended to require homoeopathic products that make high level claims to be registered in the ARTG and require supporting scientific evidence, as per non homoeopathic medicines that make high level claims.

Homoeopathic products relying on traditional evidence would only be able to make therapeutic claims acceptable for minor claims in relation to self-limiting conditions that do not require healthcare practitioner supervision.

This option allows for greater consistency with international regulatory frameworks (see Appendix 2) by ensuring that those goods which refer to the treatment of a serious condition are not listable but rather must be registered and evaluated for their quality, safety and efficacy.

Premarket assessment of evidence could potentially cause delays to market for registrable homoeopathic medicines.

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

Under this option, it is proposed that all homoeopathic products would be exempted from Parts 3-2 and 3-3 of the Act.

Exempt products remain therapeutic goods under the auspices of the Act and therefore still subject to the regulatory requirements detailed above.

This option represents a lower barrier to market for those homeopathic products that were not previously exempt and could result in a greater range of products for consumers.

A potential risk under this proposal is that products are supplied into the market that contain therapeutically significant quantities of restricted ingredients. However, any product containing levels of substances captured in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) that breach the scheduled limits would be subject to appropriate regulatory action, as is currently the case.

Any homoeopathic product containing ingredients of human or animal origin as currently specified in Schedule 5 would be required to comply with the TGA policy on TSE and would not be subject to any further regulatory requirements.[6]

Option 4 – Declare homeopathic products not to be therapeutic goods

This option is to exclude all homoeopathic products from the regulatory framework, using an instrument under s7AA of the Act.

This would remove the regulatory burden under the Act for the sponsors of the existing 142 homoeopathic preparations listed in the ARTG, however homoeopathic preparations would continue to be consumer goods and be subject to the Australian Consumer Law enforced by the ACCC.

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[6] https://www.tga.gov.au/transmissible-spongiform-encephalopathies-tse-tga-approach-minimising-risk-exposure

Under this option, it is proposed to also prevent homoeopathic products making therapeutic claims and requiring them to be clearly labelled as homoeopathic products with a direction for use statement such as “as directed by your healthcare practitioner”.

As per the previous option, if certain products supplied into the market contained therapeutically significant quantities of restricted ingredients, these products would still be subject to appropriate regulatory action, as is currently the case.

This option would allow the TGA to focus more resources on the regulation of higher risk therapeutic goods.

In the event that Option 4 (or a version thereof) is the supported way forward and the TGA were to no longer regulate homoeopathic products, then a new definition for what a ‘homoeopathic’ product represents must be developed. Further consideration should be given to defining the term with reference to concentrations, so that concentrated preparations remain within the purview of the therapeutic goods regime.