Submission on "Consultation: Options for the future regulation of "low risk" products"

Below is my submission on the Options for the future regulation of "low risk" products with comments on ear candles, aromatherapy products and homoeopathic products.

The general principle is that all these products lack rigorous evidence of demonstrated therapeutic value should not be in the TGA regulatory framework as this implies there is some therapeutic value that may mislead consumers. There is a risk that consumers may be harmed by using ineffective treatments in-lieu of proven treatments with supporting scientific evidence.

Low risk products currently regulated as medicines and other therapeutic goods (other than herbal complementary medicines)

Item: Ear candles

- Preferred Option: **Option 3 – Exclude ear candles from the regulatory framework**
- Comments:
  Ear candles have not demonstrated therapeutic value and may cause harm through hot wax dripping into the ear canals. Including them in the TGA regulatory framework implies there is some therapeutic value that may mislead consumers.

Review of certain complementary medicine products

Item: Aromatherapy Products

- Preferred Option: **Option 3 – Declare essential oils not to be therapeutic goods**
- Comments:
  Unless specific aromatherapy products have demonstrated therapeutic value (as shown by clinical trials comparable in quality and scope to that applied to regulated therapeutic) then they should not be classed as therapeutic goods.

Item: Homoeopathic Products

- Preferred Option: **Option 4 – Declare homeopathic products not to be therapeutic goods**
- Comments:
  Current requirements for exemption (high dilutions) may indicate that the likelihood of direct harm is low from use of the product. However, there are risks of indirect harm caused by these products being used to treat illnesses when a more effective registered product is available. The risk to consumers is on forgoing effective treatment. Including them in the TGA regulatory framework implies there is some therapeutic value that may mislead

consumers.

Option 2 – "*Serious therapeutic claims must be supported by scientific evidence*" may be an acceptable alternative if, (and only if), individual homeopathic products require supporting scientific evidence, as per non-homoeopathic medicines that make high level claims. However, the criteria of *"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*" as proposed as part of Option 2 should **NOT** be allowed. Acceptance of this weak criteria to allow products in the TGA regulatory framework implies there is some therapeutic value that may mislead consumers. Option 2 should only be applied to products making high level claims.