CONSULTATION: OPTIONS FOR THE FUTURE REGULATION OF 'LOW RISK' PRODUCTS

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INTRODUCTION

I support Option 1 in the consultation paper, namely to maintain the status quo for regulation of homeopathic products.

Homeopathy has an unusually long recorded history of therapeutic effects The track-record of a core group of medicines goes back more than 200 years. The effects of these medicines have been systematically recorded and collated in various ways over that period, most recently through scientific investigation.

The sections that follow outline the reasons why homeopathic medicines should be regarded as having therapeutic effects, essentially due to the wide variety of different forms of evidence of those effects.

EVIDENCE OF EFFECTS

Overview

It is common in quality assurance in other contexts to place reliance on the concept of 'triangulation'. The concept of triangulation is a powerful one and yields more reliable findings than reliance on one form of evidence alone. Essentially the objective is to find different forms of evidence that are aligned, all pointing to the effectiveness of a process or intervention but from different perspectives.

In the case of homeopathy, we can cite the combination of:

- 'provings', in which generations of homeopaths have laid the foundations of the materia medica through trials of the 'primary effects' (i.e. the initial adverse effects) of homeopathic medicines, corresponding to the symptoms being treated
- the work of master practitioners/scholars, who aggregated the evidence from provings and clinical experience into the materia medica and repertories used as the basis for prescribing
- high quality case studies such as those on the site: Homeopathy 4 Everyone. Homeopathic Medicine & Homeopathy Remedies
- observational studies of large numbers of homeopathic patients with one or many different conditions and the outcomes of their treatments, not contrasted with a control group

- randomized controlled trials (RCTs) of which many hundreds have been published in the peer-reviewed scientific literature, many of them positive.
- studies of the effects of homeopathic medicines on other biological systems, such as the growth rates of plants and animals
- other animal studies
- studies on the physical structure of homeopathic medicines.

Clinical Evidence

The recorded clinical effects have been collated in works such as Frans Vermeulen's *The Concordant Materia Medica* (Vermeulen 2003).

A well-regarded example of a series of positive RCTs includes the series of RCTs on homeopathic treatment for childhood diarrhea (Jacobs et al 2003).

Some examples follow of the concordance between recorded clinical experience and contemporary research.

Homeopathy has been show to produce major improvements in injuries. For example, the homeopathic literature has shown *Natrum sulphuricum* to be effective in brain injuries for at least the last 100 years (see entry in Vermeulen 2003). In 1999 the effectiveness of homeopathic treatment for brain injuries was also demonstrated in a trial by Chapman et al. There were small numbers of patients in the trial (common in unfunded trials), but the combined forms of evidence are persuasive.

There is a similar mix of evidence showing that homeopathic *Symphytum* can accelerate the healing of fractures. Clinical experience has been recorded and aggregated again for over 100 years (Vermeulen 2003). In addition, there is a positive randomised controlled trial (Sharma, Sharma and Sharma 2012). Further work is now being undertaken by the Homeopathy Research Institute: Can homeopathic medicines accelerate fracture healing?

The most rigorous and comprehensive systematic review of all the RCTs to date by Mathie et al (2014) found reliable studies that were positive for homeopathy, although the effect sizes reported were small. The overall conclusions were cautiously positive and consistent with the position that homeopathic medicines have therapeutic effects.

To this, we can add observational studies of large numbers of homeopathic patients and the outcomes of their treatments. For example, the study on all patients treated with homeopathy at the Lucca hospital over seven years Rossi et al (2009) found that 74% reported at least moderate improvement.

These are only examples of the material body of evidence available for the effectiveness of homeopathic medicines. Further substantive evidence is outlined at the following sites:

- National Center for Homeopathy Research Library

- Research - The Faculty of Homeopathy
- Research - European Committee for Homeopathy
- Homeopathy Research Institute (HRI): Current projects

In 2015, the National Health and Medical Research Council reached unfavourable conclusions on the basis of a selective sample of RCTs, but these conclusions have been rebutted by the Homeopathy Research Institute. The full version of HRI's analysis is not yet public, but a short summary is available from: https://www.hri-research.org/wp-content/uploads/2016/02/HRI-Response-to-NHMRC-Information-Paper.pdf

Mechanism of Action

The Faculty of Homeopathy has summarised the current status of research on the properties of homeopathic medicines (with 16 scientific references) (http://facultyofhomeopathy.org/research/basic-science-research/) as follows:

> [One possible} mechanism is suggested by the results of research on molecular clustering in water solutions, which has shown that as a solution is made more and more dilute, very stable and larger 'clumps' of material develop in dilute solutions rather than in more concentrated solutions. This means that residual molecular clusters of the original substance might be present in homeopathic dilutions. Succussion might also be responsible for creating very tiny bubbles (nanobubbles) that could contain gaseous inclusions of oxygen, nitrogen, carbon dioxide and possibly the homeopathic source material.
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> A recent meta-analysis evaluated 67 in-vitro biological experiments in 75 research publications and found that high-potency effects were reported in nearly 75% of all replicated studies; however, no positive result was stable enough to be reproduced by all investigators. One example of a series of in-vitro experiments in homeopathy is the model of the allergic response to antibody using the human basophil degranulation test. The earliest study reported inhibition of degranulation with ultra-molecular dilutions of anti-IgE. These initial experiments did not prove to be reproducible. Subsequent studies using a modified method, and using ultra-molecular dilutions of histamine, have shown positive results however. These findings have been reproduced in several independent laboratories, as well as in a multi-centre series of experiments.

Bell et al (2012) developed a comprehensive model of the actions of homeopathic medicines on biological systems, based on integrating the findings of 247 scientific papers.

While the research into possible mechanisms of action is incomplete, it is material and indicative. The development of sophisticated models for the actions of homeopathic medicines makes it increasingly difficult to dismiss homeopathy on a priori grounds.

CONCLUSION

The other options given in the consultation paper are not appropriate.

Exemption from listing would lower quality controls on the manufacture of homeopathic medicines, as the consultation paper acknowledges.

Declaring homeopathic medicines not to be therapeutic goods would be a polemical position, which flies in the face of the evidence accumulated over 200 years. The only justification for such an extreme position would be that homeopathic medicines are not distinguishable from water and therefore must be inactive on first principles. This position is inconsistent with the status of the current research on this issue referred to above.

The final paragraph of this section of the consultation paper concludes:

> 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.

This represents a logical contradiction. It makes no sense to declare that homeopathic medicines are not therapeutic goods and then seek to keep some of them within the therapeutic goods regime. There is no distinction in homeopathy between the effects of products manufactured with low dilutions and those manufactured with high dilutions. Therapeutic effects have been observed at all levels both in the clinical and in the scientific literature. This distinction would have no basis in the scientific literature on the effects of homeopathic medicines, and no other therapeutic regime in the world has made such a distinction.

The profile of evidence on homeopathic medicines is not consistent with the profile of evidence for other substances that lack any clinical effects. It is only consistent with substances that do have therapeutic effects.

References

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