Submission to the Consultation on Options for the future regulation of low risk products, in particular in relation to Homoeopathic Medications.

It is noted that the intention is not to fundamentally change the definition of a medicine although changes to the approach to regulation under the Therapeutics Goods Act will be considered.

In relation to the conduct of clinical trials and Evidence Based Medicine (EBM) it should be pointed out that Samuel Hahnemann in the preface to the second edition of his book the Organon called for accurate clinical trials as early as 1818, modern EBM is a relatively new phenomena and can be traced to the early 1990's (Claridge and Fabian 2005). The two systems of conducting and evaluating clinical trials differ considerably and both deliver evidence of effectiveness of particular medications in specific conditions. Unfortunately the vast majority of Homoeopathic clinical trials do not follow either system and as a result only rarely satisfy the criteria of either system. The trials that are used in the protocols of the International Institute of Advanced Homoeopathy (IIAH) ensure that they produce a result that corresponds to a Number Need to Treat of 3 or less, which indicates effectiveness. An addendum to this submission indicates the requirements that Hahnemann placed on assessing the effectiveness of a medication and briefly describes a trial conducted by the IIAH in which the writer was involved.

It should also be clarified that while the 'homoeopathic' medications listed by the TGA use the principles of homoeopathic pharmacy, that homoeopathic practice prescribes on the basis of the diagnosis plus the characteristic symptoms displayed by the patient. For example a right sided headache with photophobia would call for a totally different medication to a left sided headache with vertigo and without photophobia. The compound medications usually contained in the listed 'homoeopathic' medications do not account for proper individualisation.

In relation to the six broad criteria for risk assessment we assume that there is no problem with the safety of the ingredients, the allowed route of administration, or the quality of manufacture in facilities regulated by the TGA. Homoeopathic practitioners would have the same concerns that the general medical profession would have with patients self treating with over the counter medications without diagnosis or proper management, these concerns would be increased if non self-limiting conditions are being treated in this way.

In relation to the Proposed Option for Reforms

From the position of professional homoeopathic practitioners Option 2, that serious therapeutic claims must be supported by scientific evidence would obviously be the option adopted. However we do recognise that Homoeopathic Pharmacies do supply medications that have a following in the public and this should be continued. Manufacturers would more than likely opt for Option 4 that homoeopathic products are declared not to be therapeutic goods, this may also reduce the regulatory burden of the TGA.

After some consideration we feel that a modified version of Option 4 be adopted, our suggested modifications would be that:
As already adopted by some Indian Homoeopathic Pharmacies the medications be labelled as "Micro Dosage Medications" rather than Homoeopathic Medications, this could be supplemented with "made with homoeopathic dispensing protocols" and also include the with direction for use statement "as directed by your health care practitioner". We feel that subject to manufacturers being restricted to using 4x or higher dilutions and the overview of the ACCC would provide sufficient control over the manufacture and distribution of these products.

Addendum:
Hahnemann's instruction on what is to be known about a medication and how the International Institute of Advanced Homoeopathy (IIAH) conducts trials using Hahnemann's criteria.

Initially it should be pointed out that modern Evidence Based Medicine (EBM) is relatively recent. According to Claridge and Fabian (2005) " *The term "evidence-based medicine" is relatively new. In fact, as far as we can tell, investigators from McMaster's University began using the term during the 1990s. EBM was defined as "a systemic approach to analyse published research as the basis of clinical decision making." Then in 1996, the term was more formally defined by Sacket et al., who stated that EBM was "the conscientious and judicious use of current best evidence from clinical care research in the management of individual patients*."

There were various systems of gathering evidence in use for many years before the current form of EBM was developed. In 1818 Samuel Hahnemann in the preface to his second edition of the "Organon of Medicine" stated that "*The true healing art is in its nature a pure science of experience, and can and must rest on clear facts and on the sensible phenomena pertaining to their sphere of action, for all the subjects it has to deal with are clearly and satisfactorily cognizable by the senses through experience. Knowledge of the disease to be treated, knowledge of the effects of the medicines, and how the ascertained effects of the medicines are to be employed for the removal of diseases, all this experience alone teaches adequately. Its subjects can only be derived from pure experiences and observations, and it dares not take a single step out of the sphere of pure well-observed experience and experiment, if it would avoid becoming a nullity, a farce. ..... Sober, unprejudiced reflection, on the other hand, can easily convince us that to hold correct views about every case of disease we have to cure, to obtain an accurate knowledge of the true powers of medicines, to employ them on a plan adapted to each morbid condition and to administer them in proper dose, - in a word, the complete true healing art, can never be the work of self-satisfied ratiocination and illusory opinions, but that the requisites for this, the materials as well as the rules for its exercise, are only to be discovered by due attention to nature by means of our senses, by careful honest observations and by experiments conducted with all possible purity, and in no other way; and, rejecting every falsifying admixture of arbitrary dicta, must be faithfully sought in this the only way commensurate to the high value of precious human life.*"

Hahnemann was in fact a proponent of EBM, the problem that arises is that the system of conducting trials according to Hahnemann and those of modern EBM differ. And unfortunately those evaluating the effect of homoeopathic medications, and all to often those conducting homoeopathic clinical trials, do not appear to understand Hahnemann's system of experimentation. Hahnemann's system did not make use of double blinding but based on his teaching the International Institute of Advanced Homoeopathy (IIAH) has conducted extensive case based trials over a period of some 70 years with a database of more than 14,000,000 case records. In order that the methodology of the IIAH is understood it is essential to examine Hahnemann's instructions on the subject. Aphorism 3 of the Organon requires that:

1. An accurate diagnosis of the disease is made
2. That the pharmacodynamics of the medication is known
3. That "*he knows how to adapt, according to clearly defined principles, what is curative in medicines to what he has discovered to be undoubtedly morbid in the patient, so that recovery must ensue, to adapt it as well in respect to*":
    - The suitability of the medication to its mode of action in the case (disease) before him
    - The exact mode of preparation and quantity required (dose)
    - The proper period for repeating the dose
    - That he knows the obstacles to recovery and how to remove them.

Unfortunately the number of patients required to conduct a clinical trial like this are just not available in most homoeopathic clinical studies. The writer was involved in a portion of one of the trials conducted by the IIAH it was conducted in a number of stages.

1. A study of the case files held by the IIAH was conducted looking for cases suffering from a particular complaint that had been prescribed a specific medication and had shown positive results from the treatment. The study was designed to find clusters of symptoms that appeared in the cases and that were not necessarily diagnostic of the disorder.
2. Once these clusters of symptoms were identified groups of patients that suffered from the diagnosed condition and that displayed the particular cluster of symptoms previously identified were recruited into the study. There were 10 groups each of 100 patients. Each group was prescribed a different dilution of the same medication or a placebo. The dilutions used were Mother Tincture, 3x, 3c, 6c, 12c, 30c, 200c and 1000c and two groups had placebo. The clinicians recruited were not aware of what medication was being used or which group had which dilution or placebo. This potion of the study obviously required 1,000 patients and were recruited in a number of clinical centres.
3. Once the required number of cases were completed it could be shown that only two of the groups had a response considerably better than the placebo. The case notes of these patients in these two groups were studied to find if there was any indication that could be used to differentiate them. When comparing these two groups to the placebo groups in terms of modern day EBM it could be shown that the Numbers Needed to Treat (NNT) was lower than 3. When the sum of the responses of the other dilutions are compared to the placebo groups the NNT is 34. (Confidence interval 95%)
4. Once it had been determined that there was a NNT equal to or below 3 a study is conducted comparing different intervals in the repetition of the medication. It shows that there is a noticeable difference in outcome depending on the spacing of the doses.

The final outcome is a medication for a specific condition based on a number of specific symptoms in addition to those required to make the diagnosis, with a specific dilution and repetition of dose.

Obviously the system used by the IIAH provides a series of medications that if prescribed correctly produce a NNT of 3 or less and should be considered as evidence of effectiveness.

However the NHMRC review would not accept the validity of the IIAH studies because they were not randomised. The studies that they reviewed would equally not meet IIAH standards because they did not independently study the effectiveness of different dilutions or different intervals of repetition.

References

Claridge and Fabian (2005), History and development of evidence-based medicine.“, World J Surg. 2005 May;29(5):547-53.