8 May 2017

Consultation: Options for the future regulation of low risk products

Homeopathy has been much used and much loved by Australian families for over 200 years. In the early days of the settlements, they would bring their homeopathic kits from the old country with them and it was often the only form of medicine they would have on hand. It has continued to play this part, despite the many ups and downs and persecutions it has suffered over the decades.

Homeopathy offers a low risk and, according to its millions of users around the globe, effective solution to a variety of minor ailments which don't require a trip to the GP or ED, or as a support alongside medical treatments and medications. There are many other therapeutic products that can be accessed over the counter in a pharmacy or health food shop, in the same way as homeopathics, some of which are much less safe.

The problem for homeopathy has always been the lack of understanding and evidence for how it has worked, but empirical and clinical evidence has always been the mainstay of its proof. In the 21st century, with the demand for evidence-based research, we struggled at first to make this happen, but there is now a large and ever growing body of good quality evidence which shows the effectiveness of homeopathy.

Mums and Dads know how well it can work for a child with a fever or an upset tummy. This is important, because while there is fear put on parents about the danger of not seeking medical help when necessary, there is also scientific evidence to show the dangers of using drugs such as Panadol and Neurofen too early and too often and the chronic conditions which may be triggered. Many parents know this. Increasingly parents are becoming well informed, they do their own research and they know good research when they see it. Many of the families who use homeopathy are highly educated, but equally many are just ordinary mums and dads wanting the best for their kids. They are all trying to do the best for their children in terms of food, medicine, education, etc.

In terms of acute ailments and injuries, parents need something! For their own peace of mind and for the comfort of their child. With an overburdened medical system sometimes they can't get into see a GP, which is what they are told to do at the drop of a hat. Emergency departments are often overworked and understaffed and frequently send a parent home with nothing other than Panadol for a sick child, and the words "see how they go and go to your GP if you need to". As a practitioner, I frequently hear of parents seeing the GP and being offered only antibiotics or Panadol, or actually being offered nothing at all. Again "just go home and see how they go". So what are they supposed to do?!

Homeopathy has always been safe, even though we can now only refer to it as low risk, and it has always been effective. Nothing has changed with how homeopathy works or its safety. However, the NHMRC Review, which was frankly malicious, with its application of new and excessively stringent criteria for homeopathy has resulted in a false perception of this safe system of medicine and the resurrection of the term "snake oil" which has so often been applied to homeopathy. However, the public do not believe this and continue to support and want homeopathy in their first aid kits, because they are the ones who know how well it works in practice.

I have read the options being proposed for homeopathy and would like to comment as follows.

As a general first comment, I would like to note that the NHMRC Homeopathy Review is referred to several times in the consultation paper. Since this review is currently with the Ombudsmen based on the lack of integrity of the process and the unusual and overly rigid criteria, against which the

homeopathic research was measured, this seems unreasonable. The review also showed extreme bias and there was an undercurrent of hidden agendas in relation to homeopathy. While we don't know what the outcome will be, it seems unfair to refer to this review at this stage, while there are so many questions around its legitimacy.

The criteria under which the NHMRC review considered homeopathy was set at a much higher level, unrealistically so according to Cochrane, than the TGA currently requires for scientific evidence for any other modality or product category. For instance, the TGA may accept a study with 10 participants for studies on natural medicines however the NHMRC would not accept a study below 150 participants for homeopathy for a trial to be 'reliable'. The NHMRC report also specified an unusually high 100% quality rating for a trial to be considered 'reliable'. Both criteria are arbitrary and not justified.

Therefore, using the NHMRC threshold as evidence criteria may not be relevant for TGA's purposes of listing products on the Australian Register of Therapeutic Goods (ARTG). It would also subject homeopathic evidence to a much higher standard of assessment than any other evidence assessed by the TGA, again lacking fairness. Surely the level of evidence required should be the same across all therapies and products.

Evidence is not the only measure of a therapeutic good, as regulatory monitoring is also required to ensure public safety (e.g. adverse reaction monitoring) and this includes ensuring that products sold in Australia are manufactured according to Good Manufacturing Practice.

TGA's role is to protect public safety, not make value judgments about products Australians freely choose to use as therapeutic goods.

Option 3 suggests exempting homeopathy from listing, removing the requirement of Good Manufacturing Practice standards. It would not allow homoeopathic products to be Listed or Registered on the Australian Register of Therapeutic Goods (ARTG), reducing the level of claims which could be made. It appears to not be well thought out, neither fulfilling TGA's responsibility to safeguard public safety, nor fulfilling industry's needs.

Option 4 recommends declaring homoeopathic products NOT to be therapeutic goods

This is essentially a ban on the sale of homeopathic products to the public! There is no explanation in the consultation paper as to why this would be considered and what homeopathic products would actually be if this were to be the final decision. Flower Essences? Cosmetics? Foods?

This option would be contrary to the rest of the world, where homeopathy is a popular and accepted form of complementary medicine. Australia's close ACSS Consortium regulatory partner, Switzerland, is giving homeopathy the same status as conventional medicine when it comes to health insurance. In the UK, the government has announced it is continuing to support the inclusion of homeopathy on the NHS, after a long public battle to keep it. Even in the USA, where the FDA has been going down the same route as TGA appears to be taking, they have not gone to these extreme lengths.

The TGA consultation paper selectively excludes any mention of the Swiss decision, or the widespread inclusion of homeopathy in multiple other countries around the world - indicating an unbalanced approach.

The TGA paper selectively excludes mention of multiple positive research published on homeopathy, including a positive Swiss Health Technology Assessment, which the TGA would have in its library.

Measured at the level TGA usually applies to evidence, there is a wealth of positive research. The Homeopathic Research Institute in the UK is just one database of quality evidence based research available to all. https://www.hri-research.org/resources/homeopathy-faqs/.

The TGA consultation paper also makes the incorrect, biased value judgment that homeopathy is 'not evidence based'. Again, there is a wealth of evidence on the benefits of homeopathy worldwide, which was not reviewed by the NHMRC report because of the extremely stringent criteria used for this particular review.

Homeopathy is a much used, low risk system of traditional medicine. The danger in declaring homeopathy to not be a therapeutic good is that people will then buy their products overseas, putting consumers at risk from lower manufacturing standards and regulation, as we have recently seen with the Hyland's Teething tablets.

Personally, I question why the TGA/government/health department would wish to effectively ban this very low risk, very effective system of traditional medicine, which supports so many families through minor acute illnesses, bumps and bruises in the home. As already stated, our health system is overburdened and often unable to provide safe and effective solutions, and antibiotic resistance is becoming a real potential.

There appears to be no good or valid reason to change the way that homeopathy is regulated, except bias.

Option 1 or **Option 2** seem the most sensible route forward, with Option 2 providing an additional level of claim be allowable based on scientific evidence, at the same level as TGA currently requires.

Option 1, leave the regulation as it is, seems the best option and covers all requirements for safety, GMP, levels of claim.

All that industry and consumers request is a fair and transparent consideration of this matter, without using the NHMRC report as the only benchmark. Rather the decision should be made based on public need, public safety and equity amongst all modalities and products, and within the remit of the TGA.

Thank you

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