## TGA Submission – Options for the future regulation of 'low risk' products

This submission is made in support of homeopathic medicines as safe and effective complimentary medicines for therapeutic use.

Of the four regulatory options under consideration, I would like to request that the TGA consider adopting Option 1 or Option 2 and strongly oppose Option 3 and Option 4.

Homeopathics, around the world, are considered safe and effective low-risk medicines. As concluded by Bornhoft *et al.* (2006) in a review of the effectiveness, safety and cost-effectiveness of homeopathy in general practice, the effectiveness of homeopathy can be supported by scientific and clinical evidence and professional and adequate application be regarded as safe.

Here are a few statements from scientific studies on homeopathics that I would like to draw your attention to:

- Homeopathics can be an effective and non-inferior alternative to conventional and other complementary medicines (Derasse, Klein & Weiser, 2005; Haidvogle et al. 2007; Riley et al. 2001), may be significantly better tolerated (Adler et al. 2009) and in some cases, found to be superior (Wustrow 2004).
- Homeopathic treatment results in clinical, measurable improvement of illnesses and health concerns (Jacobs *et al.* 2008; Steinsbekk *et al.* 2005; Weatherley-Jones *et al.* 2004)

I would also like to point out that if the TGA is struggling to collate appropriate, peer-reviewed, scientific articles on the safety and efficacy of homeopathics, that can be used to support the inclusion of homeopathics as a safe, complementary medicinal treatment option, <a href="https://www.greenmedinfo.com">www.greenmedinfo.com</a> has collated over 100 abstracts on homeopathic research.

I am concerned that the TGA is basing the review of homeopathics on a report that is currently being investigated for complaints of serious irregularities and so is **basing policy decisions on science omission**.

## **Personal Story**

I am a mum to a young toddler. I started using professionally and self-prescribed homeopathics as part of our home first-aid kit after I had a very positive experience with a homeopathic product, Rescue Remedy, when my son had a cold. He was irritable, crying, restless and becoming inconsolable at night time because of his blocked nose interfering with normal breathing and breastfeeding. Aromatherapy chest rubs, vaporizers and herbal nasal decongestants were providing only minimal relief. After trying these remedies and not having much improvement, my friend offered Rescue Remedy (we were traveling and staying at her place). On three consecutive occasions that night, after receiving a few drops of Rescue Remedy on his forehead, he stopped crying, rolled over and went back to sleep. I found it to be such an

incredible and immediate response! It was so astounding for me because he stopped crying so immediately, during the application of rescue remedy, even when a breastfeed couldn't calm him! Sleep and recovery from the cold was then easy and I have included homeopathics as a goto remedy for health concerns for our family ever since. I am continuing to learn about the incredible amount of scientific and clinical evidence in support of the efficacy and safety of homeopathics and believe that homeopathics offer a substantially safer, primary-care option for treating illnesses and health concerns than pharmaceuticals. There is MUCH scientific and clinical evidence to be found on the harmful and negative impacts of pharmaceutical medicines and treatments. For this reason, I believe that homeopathics offer a safer alternative for the primary treatment of illnesses and health concerns and ask that the TGA ensure that homeopathic products and treatments remain available to Australians as therapeutic medicines.

## References

Adler, U.C., Paiva, N.M.P., Cesar, A.T., Adler, M.S., Molina, A., Padula, A.E. & Calil, H.M. 2009. Homeopathic Individualized Q-potencies versus Fluoxetine for Moderate to Severe Depression: Double-blind, Randomized Non-inferiority Trial. *Evid Based Complement Alternat Med*. PMID: 19687192

Bornhöft, G., Wolf, U., von Ammon, K., Righetti, M., Maxion-Bergemann, S., Baumgartner, S., Thurneysen, A.E. & Matthiessen, P.F. 2006. Effectiveness, safety and cost-effectiveness of homeopathy in general practice - summarized health technology assessment. *Forsch Komplementmed*. 13 Suppl 2:19-29. PMID: <u>16883077</u>

Derasse, M., Klein, P. & Weiser, M. 2005.0The effects of a complex homeopathic medicine compared with acetaminophen in the symptomatic treatment of acute febrile infections in children: an observational study. *Explore*. 1(1):33-9. PMID: <u>16781498</u>

Haidvogl, M., Riley, D.S., Heger, M., Brien, S., Jong, M., Fischer, M., Lewith, G.T., Jansen, G. & Thurneysen. A.E. 2007. Homeopathic and conventional treatment for acute respiratory and ear complaints: a comparative study on outcome in the primary care setting. *BMC Complement Altern Med*. PMID: 17335565

Jacobs, J., Jiménez, L.M., Malthouse, S., Chapman, E., Crothers, D., Masuk, M. & Jonas, W.B. 2008. Homeopathic treatment of acute childhood diarrhea: results from a clinical trial in Nepal. *J Invest Dermatol*. 128(10):2429-41. PMID: 10784270

Riley, D., Fischer, M., Singh, B., Haidvogl, M. & Heger, M. 2001. Homeopathy and conventional medicine: an outcomes study comparing effectiveness in a primary care setting. *J Altern Complement Med*. 7(2):149-59. PMID: 11327521

Steinsbekk, A., Fønnebø, V., Lewith, G. & Bentzen, N. 2005. Homeopathic care for the prevention of upper respiratory tract infections in children: a pragmatic, randomised,

controlled trial comparing individualised homeopathic care and waiting-list controls. *Complement Ther Med.* 13(4):231-8. PMID: <u>16338192</u>

Weatherley-Jones, E., Nicholl, J.P., Thomas, K.J., Parry, G.J., McKendrick, M.W., Green, S.T., Stanley, P.J. & Lynch, S.P.J. 2004. A randomised, controlled, triple-blind trial of the efficacy of homeopathic treatment for chronic fatigue syndrome. *J Psychosom Res.* 56(2):189-97. PMID: 15016577

Wustrow, T.P.U. 2004. Alternative versus conventional treatment strategy in uncomplicated acute otitis media in children: a prospective, open, controlled parallel-group comparison. *Int J Clin Pharmacol Ther*. 42(2):110-9. PMID: <u>15180172</u>