To,
The Regulatory Reforms Team,
Therapeutic Goods Administration,
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Reply to: TGA Consultation Paper on Homeopathic products

Sir/Madam

LMHI is a world organisation for homeopathic doctors and homeopathic associations with members from 76 countries. It was founded in Rotterdam on 10 September 1925 by fourteen homeopathic physicians from nine countries. The American Dr. Roy Upham was its first President. The LMHI was established under the terms of Swiss civil law with Geneva designated as its registered office. The new seat of the LMHI is since 2013 in Köthen-Germany, Walstrasse 45, House of S. Hahnemann. It is now registered as Non Profit Organization. The purpose of LMHI is education in and development of homeopathy worldwide and the creation of a link between homeopaths with medical diplomas and also between societies and persons who are interested in homeopathy. For details, our website can be accessed at http://www.lmhi.org/

We thank TGA for offering an opportunity to offer an opinion on the regulatory reforms pertaining to Homoeopathic Medicinal Products (HMPs), and accordingly submit, after reveiwing the options carefully, that *OPTION 2 – 'Keep it the way it is but require homeopathic scientific evidence for high level claims'* is the most valid, scientific and pragmatic options of all.

To support this suggestion, we submit the following arguments:

1. Homeopathy is widely used in over 80 countries, and its uniquely prepared compounds are considered as drugs, or medicines, with specific therapeutic effects, in most areas where it is available.

2. The regulatory status of Homeopathy may vary from country to country, but, broadly, some regulations do exist for HMPs, be it as a part of Complementary Medicine Therapies, or Conventional Medicine as a whole, with some countries having an official document regulating its production and marketing, such as the Homeopathic Pharmacopoeia of the United States (HPUS), Homoeopathic Pharmacopoeia of India (HPI), Brazilian Homoeopathic Pharmacopeia, apart from European Homoeopathic Pharmacopeia.

3. Recently, LMHI participated actively in a unique international forum on 'Regulation of Homeopathic Medicinal Products: National and Global strategies' held in New Delhi on

23-24 February 2017. The forum had representations from regulators, manufacturers and pharmacopeia experts from 24 countries, as well as from World Health Organization (WHO). The panellists at the forum, recommended that given the worldwide usage of Homeopathy, harmonisation, or at least, collaboration, convergence and reliance on regulations of HMPs is required, in the best interest of public, the ultimate beneficiaries of this system of medicine. It was unanimously palpated that better regulatory standards for HMPs would also assure implementation of Good Pharmacacopeial Practices. It was suggested that exchange of information should be encouraged for harmonisation and collaboration for research on mapping the diversity in pharmacopeial standards for HMPs, and finding out ways to evaluate and compare points of convergence and divergence across various countries, in terms of: HMPs regulations, pharmacopoeia and industry standards.

The forum also hoped that better HMP regulation would mean more organised and scientific growth of homeopathic industry.

4. Emphasising on scientific evidence for high level claims by HMPs, as required in Option 2, would be a kind of presage to homeopathy manufacturers/researchers to exercise caution as to what they should claim their medicines can do, as well as encourage them to undertake scientific research for better credibility. Currently, there is scientific evidence for the clinical effect of homeopathy and the studies touted to discredit homeopathy's efficacy have been proven false and misleading by reputable experts in the field. We look forward for unbiased and irrefutable reassessment of the evidence by all stakeholders.

LMHI hopes the above submission will find due consideration at the end of TGA authorities, before taking a final call about regulation of HMPs.

Yours sincerely

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