



Liga Medicorum Homoeopathica Internationalis (LMHI)
LMHI Secretariat

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LMHI Response to European Academies Science Advisory Council (EASAC) statement on Homeopathic Products and Practices

The statement on Homeopathic Products and Practices by the European Academies Science Advisory Council (EASAC) was written to “build on” ...and...”reinforce criticism of the health and scientific claims made for homeopathic products.” The analysis and conclusions are, purportedly, “based on the excellent science-based assessments already published by authoritative and impartial bodies.” It is disappointing to see the statement, aimed to guide policy makers, so misguided, disingenuous, inadequate and largely depending on previously published negative studies and reports that have been fully discredited by well recognized researchers and experts in the homeopathic field, the legitimate authorities in homeopathic science and medicine. Examples of these discredited reports, foundational to the EASAC statement follow.

The biased NHMRC and EC2 report

The highly biased NHMRC report on Homeopathy is based on heterogeneous clinical studies selected arbitrarily. Several organizations have discredited the report as being biased, inaccurate and flawed^{1,2,3} As a public funded body, the NHMRC currently finds itself under investigation by the Commonwealth Ombudsman for a number of irregularities in the way it conducted its review. In violation of NHMRC’s own guidelines there was not a homeopathy expert on the committee. they also used an analysis method that has never been used in any other review, before or since. NHMRC was extremely selective in their review of homeopathic research data. Only a few select systematic reviews were considered and the small committee ignored hundreds of case series studies, cohort studies, case control trials, and randomized controlled trials.⁴

The EC2 report is not a scientific document, as no systematic scientific method was applied. Additionally, it was not carried out by expert academics in the field and it was not peer reviewed. Thus, the report has received widespread criticism from fellow representatives and lawmakers. Most importantly, the Government’s response rejected the recommendations of the report and endorsed a patient’s right to continue to access homeopathy on the NHS. Thus, any statement for policymakers should not rely on reports having serious procedural and scientific misconduct.

¹ https://aurumproject.org.au/the-king-and-nhmrc-reports/?mc_cid=4a18cf97ad&mc_eid=e0ce7c17bf

² <https://www.hri-research.org/resources/homeopathy-the-debate/the-australian-report-on-homeopathy/>

³ [http://www.homeopathyjournal.net/article/S1475-4916\(15\)00069-7/fulltext](http://www.homeopathyjournal.net/article/S1475-4916(15)00069-7/fulltext)

⁴ <http://www.lmhi.org/Article/Detail/231>



The Scientific plausibility

There is an increasing body of evidence for the scientific and plausible understanding of the mechanisms of homeopathic medicines. Studies have revealed that homeopathic remedies contain nanoparticles (NPs) of source materials, act by modulating biological function of the allostatic stress response network, evoke biphasic actions on living systems via organism-dependent adaptive and endogenously amplified effects and improve systemic resilience. Homeopathic remedies act by stimulating hormetic adaptive systems rather than by linear pharmacological effects.^{5,6,7,8,9} Further studies on animal models have found that homeopathic medicines are able to kill cancer cells by modulating gene expression.^{10,11,12} Such research is ignored, and therefore, implausibility is not a valid argument, particularly when there is a massive amount of clinical evidence, which, even though not from the highest tiers of the evidentiary pyramid, is extant in thousands of peer reviewed journals from around the world published along two hundreds years of homeopathy's existence, including a century during which homeopathy was used to treat deadly infectious diseases and epidemics prior to the antibiotic era and proving significant less mortality than the conventional approach. Such positive results and lower mortality are maintained to a significant degree in the antibiotic era.¹³ In spite of the available bulk of meta-analyses evaluating effects of homeopathy over placebo, only two meta-analyses¹⁴⁻¹⁵ have focused on individualized homeopathy, and both are positive and warranted further quality researches. The negative meta-analyses or those with insignificant effect sizes have ignored the basic tenants of homeopathy (i.e. individualization and model validity). It is to emphasize that P value derived from RCT is useless if flawed methodology is employed, i.e. homeopathic remedies act identical to placebo if not properly individualized; e.g. the recently

5 Metal nanoparticle induced hormetic activation: a novel mechanism of homeopathic medicines Chikramane, Prashant S. Et al. Homeopathy, Volume 106, Issue 3, 135 - 144

6 Fisher, P. Homeopathy, hormesis, nanoparticles and nanostructures. Homeopathy. 2015; 104: 67–68

7 Dei, A. and Bernardini, S. Hormetic effects of extremely diluted solutions on gene expression. Homeopathy. 2015; 104: 116–122

8 Calabrese, E.J. Hormesis: principles and applications. Homeopathy. 2015; 104: 69–82

9 Bell, Iris & Koithan, Mary. (2012). A model for homeopathic remedy effects: Low dose nanoparticles, allostatic cross-adaptation, and time-dependent sensitization in a complex adaptive system. BMC complementary and alternative medicine. 12. 191. 10.1186/1472-6882-12-191.

10 KHUDA-BUKHSH, Anisur Rahman; SAHA, Santu Kumar; ROY, Sourav. Evidence in support of gene regulatory hypothesis: Gene expression profiling manifests homeopathy effect as more than placebo. International Journal of High Dilution Research, [S.l.], v. 12, n. 45, p. 162-167, dec. 2013.

11 Khuda-Bukhsh AR. Potentized homeopathic drugs act through regulation of gene expression: A hypothesis to explain their mechanism and pathways of action in vivo. Complement Ther Med 1997;5:43-6

12 Khuda-Bukhsh AR. An overview of research at University of Kalyani in exploring some basic issues of Homoeopathy. Indian J Res Homoeopathy 2017;11:147-57

13 Saine, A. (2013, May 20). Homeopathy: Great Medicine or Dangerous Pseudoscience? Retrieved Aug 4, 2017, from The Canadian Academy of Homeopathy: http://homeopathy.ca/debates_2013-03-22_SummaryResponseFromAndreSaine.shtml

14 Mathie RT, Lloyd SM, Legg LA, Clausen J, Moss S, Davidson JRT, et al. Randomised placebo-controlled trials of individualised homeopathic treatment: systematic review and meta-analysis. Systematic Reviews 2014;3:142.

15 Linde K, Melchart D. Randomized controlled trials of individualized homeopathy: a state-of-the-art review. J Altern Complement Med. 1998;4:271-288.



published dysmenorrhea RCT¹⁶ where homeopathic medicines are no better than placebo simply by prescribing the wrong homeopathic remedy (very few prescribed in this trial are enlisted as 1st grade remedies in repertories).

Safety and Quality

Homoeopathy is being practiced by qualified and trained professional's around the world and homoeopathic medicines are prescribed based on a patient's condition and symptoms, at such dosages that cannot harm anyone directly or indirectly. There is consensus on the fact that homoeopathic treatment is safe and causes minimal to no adverse effects.¹⁷ On the contrary, the iatrogenic death rate in the US (death caused by doctors and/or medical treatments) is 783,936 a year, usually from pharmacological toxic effects.¹⁸ Long-term experience, confirmed by research, demonstrates that homeopathic medicines have a high safety profile.¹⁹ To assure safety and quality of homoeopathic medicines, the WHO developed a document on Safety Issues in the Preparation of Homoeopathic Medicines²⁰, detailing the technical aspects of production and manufacture of homoeopathic medicines, calling for international and national quality standards and specifications for homoeopathic medicines, as well as for quality control. There are regulations for Homoeopathic medicinal products, either as part of Complementary and Traditional Medicinal Therapies or Conventional Medicine, 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 Pharmacopoeia, and the European Homoeopathic Pharmacopoeia. The WHO guidelines along with official pharmacopoeias that include standardized guidelines about manufacturing homoeopathic medicines are used to maintain the quality and safety standards for the public. The authorisation of a homeopathic medicinal product to be marketed in the EU for human use is regulated by Directive 2001/83/EC, drafted with specific provisions for the evidence of quality, safety and efficacy referred to in Directive 2003/63/EC. Elsewhere, in Brazil, the drug homeopathic preparation is supervised by a governmental agency (ANVISA) which is responsible for the quality of medicines. The rule (RDC 26/07) of the Brazilian regulatory document refers to the registration of industrialised homoeopathic, anthroposophic and anti-homotoxic medicinal products. Such regulation affects compounding pharmacies who must also comply with GMP. In India, there is well-developed ethical and regulatory framework with Homoeopathic medicines covered under the provisions of the Drugs & Cosmetic Act, 1940 and defined under Rule 2(DD) of Drugs and Cosmetics Rules, 1945. Standards for homoeopathic medicines must be gathered for the manufacture, sale, distribution or importation. They are defined under Second Schedule of the Drugs and Cosmetics Act (item N.4a), import of new homoeopathic medicine under Rule 30AA;

16 Charandabi SMA, Biglu MH, Rad KY. Effect of homeopathy on pain intensity and quality of life of students with primary dysmenorrhea: a randomized controlled trial. *Iran Red Crescent Med J.* 2016;18:e30902.

17 Bornhoft G, Matthiessen PF. *Homeopathy in healthcare—effectiveness, appropriateness, safety, costs.* Berlin: Springer; 2011.

18 <https://draxe.com/conventional-medicine-is-the-leading-cause-of-death/>

19 <http://www.echamp.eu/our-sector/practice-and-evidence/clinical-data-and-research/fewer-side-effects>

20 World Health Organisation. *Safety issues in the preparation of homeopathic medicines.* 2009



and, Packing and Labelling of Homoeopathic medicine under rule 32 (A).²¹ Recently, at the World Integrated Medicine Forum, a unique international forum on 'Regulation of Homeopathic Medicinal Products: National and Global strategies' was organised on 23-24 February 2017 in New Delhi, India wherein rigorous discussions were held about vital points such as regulations of HMPs, harmonisation of pharmacopeias and linking industry and regulators' sectors towards unified efforts for global development of Homoeopathy.²²

The growing popularity

The growing market of homeopathic medicinal products signals its growing popularity. The main drivers for this trend are: increased focus on maintaining superior quality of life, increasing awareness of homeopathic medicines as empirically effective, a lower priced treatment, with significant lower side effect profile and toxicity . There is an evident shift in trend of public's preferences for therapy selection from standard biomedicine to other systems including Homoeopathy that offer holistic and individualised treatment. A recent report by Bundesverband der Pharmazeutische Industrie e.v (BPI) from Germany²³, has declared that "Homeopathy is a recognized and effective therapy for patients," and expressed its support to Homeopathy. According to this report, the survey shows that many people integrate, use and value homeopathy as a complementary treatment option. Approximately half of the respondents had taken homeopathy, of which 70% were satisfied or very satisfied with its efficacy and tolerability. Homoeopathy is second most popular CAM modality in EU. Intelligent and educated consumers don't require, or appreciate, misguided paternalistic mandates.

²¹ National Health Profile. Available from: https://www.nhp.gov.in/Status-of-Homeopathy-in-the-Drugs-and-Cosmetic-Act-and-rules_mtl. [Last accessed on 2016 Apr 05]

²² Kaur H, Chaudhary A, Khurana A, Hoover T, van Haselen R, Manchanda RK. World integrated medicine forum on the regulation of homoeopathic medicinal products: National and global strategies. *Indian J Res Homoeopathy* 2017;11:123-35.

²³ <http://www.bpi.de/home/nachrichten/nachrichten/patienten-vertrauen-homoeopathischen-arzneimitteln/>



Overall responses

The official response to the EASAC statement by BPI, a German national pharmaceutical industry trade association²⁴ provides a clear opinion on this matter. European Coalition for Homeopathic and Anthroposophic Medicinal Products (ECHAMP) whilst sharing EASAC's goal of allowing and supporting consumer choice and continuously ensuring an appropriate regulatory environment for these products have also opined that the statement should be based on accurate and up-to-date information, reflecting current European practice.²⁵ Furthermore, the British Homoeopathic Association (BHA) levelled criticism against the EASAC statement by citing the questionable studies and reports listed above, and its failure to adopt an objective approach to scientific analysis they espouse to champion.²⁶ LMHI shares these organization's viewpoint.

Therefore, we advise policy makers not to consider, and actually reject, the EASAC's statement and any other statements emitted by their member organizations, because it is biased, has no merit, and is actually defamatory, libellous, promotes an unfair and biased restriction of trade for homeopathy, and is immoral, by denying a potentially beneficial and cost effective medical care to millions of people.

Dr. Alok Pareek
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Dr. Bernardo A Merizalde
Secretary of Public Relation

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Secretary of Research

²⁴ https://www.hri-research.org/wp-content/uploads/2017/09/2017-09-28_BPI-Position_on_EASAC_Publication.pdf

²⁵ <http://www.echamp.eu/echamp-resources/echamp-positions/2017-09-22-easac-echamp-response.pdf/view>

²⁶ <https://www.britishhomeopathic.org/bha-blog/bha-response-easac-statement/>