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Australian Register of Homoeopaths response to the National Health and Medical Research Council Draft Information Paper: *Evidence on the effectiveness of homeopathy for treating health conditions* [April 2014]

Submitted 2nd June 2014

Contents

Acknowledgments:

The Australian Register of Homoeopaths Ltd would like to acknowledge the contributions of the following people:

Dr Nick Goodman, Snēhi Jarvis, David Levy, Jenny Heywood, Shashi Reddy and Julia Twohig.

Introduction

The National Health and Medical Research Council (NHMRC) released its Draft Information Paper on homoeopathy for community consultation on 9/4/14.This Draft Information Paper is an example of NHMRC's function to "advise the community" under section 7(1)(a) of the NHMRC Act 1992.

This response is by the Australian Register of Homoeopaths Ltd (AROH).

Question 1: **Is the Draft Information Paper presented and written in a manner that is easy to understand?**

The Draft Information Paper is misleading in its presentation, and is seemingly difficult for people to understand. It has failed to provide an unbiased view of the evidence reviewed, and the content, conclusion and the concept of a 'draft document' in this context have been misunderstood. In addition, there is a failure to adequately explain the external and internal contexts of this Review.[i]Consequently, it should not be used as a guide for the public, medical practitioners or anyone else looking at homoeopathy until it is amended.

Point 1: The presentation

AROH suggests the following changes be made:

- The NHMRC says it '*...is of the view that when offering treatments for illness, all health practitioners must give consideration to the evidence for the effectiveness of such treatments*.' yet it has failed to use all available data; excluding level lV studies (that include effectiveness of consultations), and animal and laboratory studies. These exclusions narrow the field, and do skew the outcome. **It is suggested that all available evidence be used so the NHMRC's recommendations are produced after giving 'full consideration' to the evidence, as is suggested in its own guidelines. Once the limited approach is corrected and the evidence reviewed the revised Paper can then be presented for public consultation.**

- The NHMRC have ignored the published fact that only 10% of research in conventional medicine meets Randomised Control Trial (RCT) level-1 standard. As an example, this finding is confirmed by the Cochrane Review of influenza immunisations. The Review report found the same percentage of research (10%) met the level-1 standard. and the findings of the recent Cochrane summary of the evidence supporting influenza immunisation[ii]. The recent

report on *Relenza* and *Tamiflu*[iii] could have been mentioned to assist with providing comparator context of quality evidence gathering and how the NHMRC applies it. It is difficult to understand why the Draft Information Paper fails to provide such contextual information. **It is suggested that this contextual information is added to the Draft Information Paper to help the public contextualise the recommendations and the revised Paper then be presented for public consultation.**

- The perplexing exclusion of the substantial evidence available in the Submission made by AROH to the Natural Therapy Review Advisory Committee (NTRAC) in April 2013 needs to be addressed. The NHMRC chose to persist with the two smaller submissions by the Australian Homoeopathic Association (AHA) and Australian Medical Fellowship of Homoeopathy (AMFoH). **The AROH submission should be used to extend the available trial data so a more complete Review is undertaken being more in line with the NHMRC's guidelines. Then the revised Paper then be presented for public consultation.**

- The NHMRC employed OPTUM in a contractual relationship that would, of its nature, generate a conflict of interest (COI) and yet that COI was not declared. Nor were COI's given for the Homeopathic Working Committee (HWC) who authored the widely misunderstood interpretation stated on page 19 of the Draft Information Paper. **It is suggested that the COI's are declared in the Draft Information Paper so the public will be able to appreciate the possible misinterpretation of the data. The revised Paper can then be presented for public consultation.**

Point 2: The manner of writing

- As for being *'...written in a manner that is easy to understand.*', the Draft Information Paper is written in a way which ensures a negative response because it lends itself to misinterpretation. The NHMRC is said to not be able to conclusively make a decision based on the Review, and that it is a '*... paucity of good-quality studies of sufficient size that examine the effectiveness of homoeopathy...*' which is the issue, not that homoeopathy is not effective in any human clinical condition. While this statement infers that the NHMRC cannot make a decision, the Draft Information Paper goes on to make an unequivocal statement, unrelated to the Review, by implying that the Review has somehow proved ineffectiveness. It does not make clear that a lack of high quality evidence does not imply lack of therapeutic effectiveness, but quite possibly lack of research. **The manner in which it has been written is misleading and this**

needs correcting and then the revised Paper can be presented for public consultation.

This Draft Information Paper would be much easier to understand if the NHMRC explained why it did not follow established scientific and ethical principles.

- If the NHMRC had developed criteria 'a priori', it would not have had to use an unpublished, untested criterion for inclusion and exclusion of evidence.
- If the NHMRC had followed systematic review criteria, it would have genuinely involved experts in homoeopathy, as per the advice of respected evidence-based medicine commentators [3, 4 & 8], and would also have considered the perspectives and evidence provided to them by AROH.
- If the NHMRC had followed the ethical requirements of AMSTAR, it would have published in full its brief to OPTUM, the commercial research organisation it employed to carry out the work; it would have named the reviewer and checker, and it would have published conflicts of interest for all involved in the investigation, and also published the author of the information paper.
- If the NHMRC had followed the principles of consistency and logic, the *'interpretation of the assessment'* on page 19 of the Draft Information Paper would have accurately reflected the results of the review. It does not do this.
- The bias and lack of understanding of the personnel who have undertaken this Review is indicated on p 14 of the Draft Report. It says that: *'Homeopathy is not more effective than placebo for the treatment of these health conditions '.* Homoeopathy can be practiced in a variety of ways, and the particular treatment does not represent all homeopathic practice in total. It would be more reasonable to say: The way of prescribing homoeopathy in a particular trial showed no statistical significance under the particular conditions constraining the practitioners and the trial inclusion criteria.

The NHMRC is misleading the Australian public in this Draft Information Paper in that it contends Australians spent around AUS$8.5 million (in 2008) on homoeopathic medicines, so the Australian public needs reliable information with which to understand the potential benefits and risks. Compare this gross amount with the $1.8 billion in annual revenues for complementary medicine companies' sales in Australia, (the majority of which is for nutritional and herbal products)[iv].As homoeopathy represents a mere 0.5% of the $1.8 million sales, why has the NHMRC had a particular focus on homoeopathy, particularly as the *'NHMRC did not assess evidence of the safety of ingredients of homeopathic medicines'.* The NHMRC also claims that in the last 13 years it has spent $86 million on complementary medicine research, yet

neglects to indicate that this is less than 1% of the NHMRC research funding, none of which was spent on research trials of homoeopathy. **This misrepresentation needs to be corrected and then the revised Paper can be presented for public consultation.**

The nature of the final sentence in the OPTUM *Overview Report* is suggestive of a misinterpretation of the data in that *'... there being no compelling evidence...'* is being interpreted by some as meaning no evidence. This is indicative of poor manner of writing that does not explain sufficiently well enough for the truth to be clearly read. **This needs to be corrected and then the revised Paper can be presented for public consultation**

The FoSiM, a group of well known homoeopathy antagonists, seem to have misunderstood the following: *'To be confident that the health benefits of homeopathy that were reported in some studies were not just due to chance or the placebo effect, they would need to be confirmed by other large, well-designed studies.'* Instead of calling for research to investigate homoeopathy once and for all, the FoSiM took the Draft Information Paper's finding as a final verdict on homoeopathy, and are using the OPTUM *Overview Report's* final sentence as a platform for a vilification attack on the homoeopathic profession.It is to be noted that AROH protested the presence of certain individuals on the HWC with links to the Friends of Science in Medicine (FoSiM). Yet this COI was discounted by the NHMRC. AROH's concerns were borne out by the immediate and very public media campaign by this organisation. There is an open letter dated 8/4/14 on the FoSiM's website[v] which indicates a failure to understand the meaning of the term 'draft', yet this organisation had links on the Homeopathy Working Committee (HWC). **This COI needs to be acknowledged and corrected, and then the Paper can be presented for public consultation.**

Conclusion

This Draft Information Paper is very misleading in the way the information is presented and the way it is written.

If the NHMRC had followed established scientific guidelines, designed to avoid prejudice and bias, the Paper would not have proved as problematic for people to grasp. This difficulty is evidenced by the apparent misinterpretation and manipulation of the information contained within it by both opponents of homoeopathy and the media.

The Draft Information Paper does not provide the general public with the information the NHMRC deems they require to make informed health care choices.

The Draft Information Paper needs careful reconsideration before being presented for a second round of public consultations.

Question 2. Does the Draft Information Paper clearly outline how the evidence was reviewed and interpreted by the Homeopathy Working Committee?

Point 1: Evidence reviewed

AROH suggests a failure to clearly outline how the evidence was reviewed and interpreted is due to the following:

The Draft Information Paper is not clear on how it has accommodated the problems associated with clinical trial evidence failing to comply with external validity. The NHMRC failed to assess this whilst concentrating on internal validity quality criteria.

The Draft Information Paper fails to explain why the HWC chose to subjectively interpret the findings of *'less than reliable evidence of efficacy'* as if the findings were of no evidence at all.

The Draft Information paper does not explain why homeopathy is treated as a single product and this is not adequately explained.

The NHMRC failed to include a single individual with detailed knowledge of homoeopathy practice in the HWC and review team. This is very poor scientific practice. It is not clear how evidence can be accurately reviewed and interpreted without genuinely involving experts in the field.

Possible reasons for this failure that need considering:

- Homoeopathy is reported as if a single product, when it is, in fact, a collection of a number of different ways of conceptualising and responding to perceived similarity, one or some of which were utilised in each trial. A large number of products are used as remedies, and these cannot all be regarded as a single product, any more than Vioxx and Avandia can be regarded as a single product. Although some trials do not demonstrate the difference between the homoeopathic remedies used and placebo, it is illogical to imply that homoeopathy, when applied in other ways, is ineffective in conditions that are not under investigation. This would be like claiming lack of evidence for safety of Vioxx and Avandia translates into safety concerns about conventional medicine as a whole.

- Controlled trials describe average outcomes obtained from a group of people, usually in regard to one or a few measured outcomes. In practice, homoeopathy is applied to individuals who may have chosen this health management system after dissatisfaction with other medical interventions. Whilst there is a need to consider using a proven treatment, many patients seeking homoeopathic treatment have found that conventional treatment has not fulfilled these

criteria. Homoeopathy is an individualised form of health care, and large observational studies suggest that around 75% of patients are satisfied with their homoeopathic treatment.

- No comparison is provided of the proportion of conventional medicine therapeutics in common use that would pass this NHMRC standard, as applied per health condition to homoeopathy trials. It would also be relevant for the public to be advised why issues of safety, cost effectiveness and improvement over time (as demonstrated in level lV studies) [vi] are treated as irrelevant by the NHMRC for the public's consideration.

Point 2: Evidence interpretation

2.1 The logic behind the interpretation is not clear. The interpretation of evidence is not justified nor appropriately expressed, in that:

- Whilst it is reasonable to consider trial quality in assessing the degree of reliance that can be placed on the results of trials, it is unreasonable to give the impression that homoeopathy is ineffective on the basis that few trials have been conducted that were designed in a way that could provide a sufficient quality assessment. Compounded by the fact that many of these types of trials utilised a homoeopathic prescribing process that differs from that used in conventional practice.

- Half of all primary Randomised Control Trials (RTC's) showed significant benefit from homoeopathy. If homoeopathic interventions were ineffective, it would be expected that a distribution of results from < 5% of the trials would be seen. Consequently, the evidence that does exist as a whole supports the effectiveness of homoeopathy, but the Draft Information Paper fails to communicate this.

- Criteria used in the Review have been designed according to the risks, and personal and financial characteristics of a competing industry, rather than the industry the NHMRC is evaluating. This differing industry context and the resultant limitation of the ability of the NHMRC to take this into account without involving the homeopathic community has not been communicated clearly.

- The global prescription drug industry has a current annual turnover of around $1000 billion, which compares to $2.8 billion for homoeopathic medicine sales.

The development of drugs is an expensive process, largely because of the cost of trials.[vii] Synthetic substances have a significant side effect or risk, which has led to the development of an increasingly rigorous evaluation regime over the last decades. The industry is not organised around generating the same quality of evidence. In addition, homoeopathic products are not generally patentable, making it uneconomic to employ commercial research organisations, and practitioners/researchers are mostly generalists, who cannot individually collect patients in sufficient numbers to satisfy the size criteria used by the NHMRC.

A more accurate expression of the results would be: On balance the totality of the evidence available suggests that homoeopathy may be an effective treatment. However, the quality of most trials and because trials are spread over many clinical conditions with few trial repetitions of the same homoeopathic intervention in any one condition, the NHMRC is not convinced that homoeopathy is effective in any one condition by the evidence so far evaluated. The potential for cost effective treatment utilising this modality warrants further targeted research.

2.2 The Draft Information Paper does not clearly outline how NHMRC planned to follow standard criteria as listed in the AMSTAR Toolkit for avoiding bias. Obvious examples of the presence of bias are demonstrated with:

- '*For each clinical condition, the null hypothesis was that homoeopathy has no effect as a treatment for that condition. The HWC decided that the null hypothesis would be assumed, unless there is sufficient reliable evidence to demonstrate otherwise.'* (p 278 ORA). This has the effect of dismissing a body of evidence, even if it were almost sufficient - 99% convincing evidence = zero. Only 100% conviction avoids the statement *'that homoeopathy has no effect as a treatment for that condition.'* The NHMRC appears to have a reluctance to develop a vocabulary to acknowledge the evidence that lies between 0% and 100%. This problem is echoed in the next two examples.
    - In regard to placebo comparator (p 279 ORA): 'A *significant difference in favour of homeopathy is reported by all (or a substantial proportion of) studies, but these studies are undersized and/or of poor methodological quality'* was reflected by the HWC as: *'3. Based on the body of evidence evaluated in this review there is* ***no reliable evidence*** *that homeopathy is more effective than placebo for the treatment of Y'.*
    - In regard to other comparators: *'No significant difference (or a significant difference in favour of homeopathy) reported by all studies (or a substantial proportion of studies), but these studies are undersized and/or of poor methodological quality….'* was reflected by the HWC as: *'3. Based on the body of evidence evaluated in this review there is* ***no***

reliable evidence *that homeopathy is as effective as [the other therapies] for the treatment of Y'*

2.3 Two NHMRC specifically related beliefs, taken from p 19 of the Draft Information Paper, deserve comment.

It is far from clear how these "interpretations of the assessment" were arrived at. They do not represent an interpretation of the Draft Information Paper as presented or of the review itself:

'People who choose homeopathy instead of proven conventional treatment may put their health at risk if safe and evidence based treatments are rejected or delayed in favour of homeopathic treatment. Homeopathy should not be used to treat health conditions that are serious, or could become serious.'

- The NHMRC fails to mention the context of the state of general medical research as reported on the BMJ website.[viii] Of the 3000 treatments evaluated by research, 11% are rated as beneficial, 24% likely to be beneficial, 7% as a 'trade off 'between benefits and harms, 5% unlikely to be beneficial, 3% likely to be ineffective or harmful, and 50% being of unknown (undemonstrated) effectiveness'. The NHMRC could have reasonably clarified that people who choose 65% of evaluated conventional treatments may put their health at risk if treatments with the other 35% (when indicated) are delayed.

- Why single out homoeopathy when in comparison homoeopathic trial evidence suggests a similar proportion, with unknown effectiveness. Why does the NHMRC feel the need to investigate on behalf of 5% of the population using homoeopathy without also investigating the wider context that probably affects the whole population? Even proven conventional treatment doesn't help all the people it is applied to. In fact it is generally proven not to help a proportion of patients, and usually there is a period of waiting to see if the treatment's benefits outweigh the side effects in any individual patient.

- There are many published cases of patients with serious health conditions recovering under or assisted by homoeopathic management, even when regular medical care has failed to assist them. Any health condition, including apparently good health can deteriorate suddenly, and become serious. A practical aspect is to clarify how serious a health problem is at any one time, and patients usually see a doctor for this purpose, and after trying what is offered they assess their options. Certainly it is the responsibility of all health practitioners to make ongoing assessments of the potential seriousness of the

condition of every patient, and whether what they have to offer is the most advisable choice at the time, considering the individual circumstances involved.

- Higher levels of education are the most likely way to avoid mistakes concerning this type of professional decision. Yet the FoSiM and others are lobbying to keep the training of complementary and alternative medicine (CAM) practitioners out of universities and the Vocational Education and Training sector. This action is not in the public's interest.

- Two out of three Australians use CAM therapies.[ix] This increasing use is associated with consumers making decisions based on information from a variety of sources. This usually involves their personal experiences and those of friends or relatives, andrelates to dissatisfaction with available conventional treatment, and/or the usefulness of the alternatives. These alternatives are sometimes recommended by their medical practitioner for their particular circumstances. However, patients may sometimes be better informed about these matters than medical practitioners. If patients are to be encouraged to consult their GPs about alternative treatments, the education of GPs would have to be greatly extended to incorporate the additional training required.

2.4 Finally, the fact that the 'NHMRC will only give consideration to submissions that address the public consultation questions, are within the scope of the review, and meet the criteria regarding evidence discussed below.'

By providing only 3 limited questions to respond to on an electronic portal and by forcing a 22,000 character limit per response, albeit it is acknowledged that the limit has been lifted, the ability to make a relevant response is stymied.

Apart from the three questions there is nowhere for the question asking if the NHMRC's 'beliefs' concerning homoeopathy are appropriate. Additionally, are they evidence based, or appropriately expressed in regard to the NHMRC's stated objective, which to provide accurate information to the Australian public?

In conclusion

This Draft Information Paper does not clearly outline how the evidence is reviewed and interpreted by the Homeopathy Working Committee for the reasons stated above.

The evidence and interpretation needs to be revisited in an unbiased way with homoeopathic experts on the HWC who are well versed in homoeopathic practice and research. Additionally, the homoeopathic profession needs to be genuinely engaged.

Being restricted to providing responses to only 3 limited questions for such an important Draft Information Paper does not provide a vehicle for constructive dialogue. This restrictive approach to feedback needs addressing in a second round of public consultation.

Question 3. Is there additional evidence on the effectiveness of homoeopathy for the treatment of clinical conditions in humans that needs to be considered?

Yes, the following trials need to be considered:

ADHD

Frei H, Thurneysen A. Treatment for hyperactive children: homeopathy and methylphenidate compared in a family setting. *British Homoeopathic Journal* (2001).; 90(4): 183-188.
http://www.sciencedirect.com/science/article/pii/S1475491699905064

Praveen Oberai, S. Gopinadhan1, Roja Varanasi, Alok Mishra, Vikram Singh, Chaturbhuja Nayak. Homoeopathic management of attention deficit hyperactivity disorder: A randomised placebo-controlled pilot trial. Indian J Res Hom (2013)7;4: 158-162
http://www.ijrh.org/temp/IndianJResHomoeopathy74158-1303459_033714.pdf

Allergic skin reactions

NaidooP ,Pellow J. A randomized placebo-controlled pilot study of Cat saliva 9cH and Histaminum 9cH in cat allergic adults. *Homeopathy* (2013)102: 123–129.
http://www.homeopathyjournal.net/article/S1475-4916(13)00012-X/abstract

Allergic rhinitis

Teixeira MZ. Effectiveness of individualized homeopathic treatment in perennial allergic rhinitis (PAR).*International Journal of High Dilution Research* (2009) 8(28): 141-143.
http://www.feg.unesp.br/~ojs/index.php/ijhdr/article/viewFile/351/403

Cough

Alessandro Zanasi, Massimiliano Mazzolini , Francesco Tursi, Antonio Maria Morselli-Labate, Alexandro Paccapelo, Marzia Lecchi. Homeopathic medicine for acute cough in upper respiratory tractinfections and acute bronchitis: A randomized, double-blind, placebo-controlled trial. *Pulmonary Pharmacology & Therapeutics* 27 (2014)

102e108
http://linkinghub.elsevier.com/retrieve/pii/S1094553913001259?via=sd

Fracture healing

Mazzocchi A, Montanaro F. Observational study of the use of Symphytum 5CH in the management of pain and swelling after dental implant surgery. *Homeopathy* (2012) 101(4): 211-216.
http://journals2.scholarsportal.info/journal.xqy?uri=/14754916

Sharma S, Sharma N, Sharma R. Accelerating the healing of bone fracture using homeopathy: a prospective, randomized double-blind controlled study. *BMC Complementary and Alternative Medicine* (2012) 12(Suppl 1): O61.
http://www.biomedcentral.com/1472-6882/12/S1/O61

Haemorrhoids

Chakraborty PS, Varanasi R, Majumdar AK, Banoth K, Prasad S, Ghosh MS, Sinha MN, Reddy GRC, Singh V, Nayak, C. *Effect of homoeopathic LM potencies in acute attacks of haemorrhoidal disease: A multicentric randomized single-blind placebo-controlled trial. Indian J Res Homoeopathy(2013)* **7**: 72-80.http://www.ijrh.org/article.asp?issn=0974-7168;year=2013;volume=7;issue=2;spage=72;epage=80;aulast=Chakraborty

Heavy metal toxicitiy

Belon P, Banerjee A, Karmakar SR, Biswas SJ, Choudhury SC, Banerjee P, Das JK, Pathak S, Guha B, Paul S, Bhattacharjee N, Khuda-Bukhsh AR. Homeopathic remedy for arsenic toxicity? Evidence-based findings from a randomized placebo-controlled double blind human trial.*Science of the Total Environment* (2007) 384(1-3): 141-150.
http://www.sciencedirect.com/science/article/pii/S0048969707006766

Khuda-Bukhsh AR, Banerjee A, Biswas SJ, Karmakar SR, Banerjee P, Pathak S, Guha B, Haque S, Das D, De A, Das D, Boujedaini N .An initial report on the efficacy of a millesimal potency Arsenicum Album LM 0/3 in ameliorating arsenic toxicity in humans living in a high-risk arsenic village. *Zhong Xi Yi Jie He XueBao; Journal of Chinese Integrative Medicine* (2011) Jun; 9(6): 596-604.
http://europepmc.org/abstract/MED/21669162

Khuda-Bukhsh AR, Roy-Karmakar S, Banerjee A, Banerjee P, Pathak S, Biswas SJ, Haque S, Das D, Boujedaini N, Belon P. A follow-up study on the efficacy of the homeopathic remedy Arsenicum Album in volunteers living in high risk arsenic contaminated areas. *Evidence-Based Complementary and Alternative Medicine*; Mar 9 [Epub]. (2011); 2011: 129214
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3094698/

Hypertension

Saha S, Koley M, Hossain SI, Mundle M, Ghosh S, Nag G, Datta AK, Rath P. Individualized homoeopathy versus placebo in essential hypertension: A double-blind randomized controlled trial. *Indian J Res Homoeopathy* (2013) **7**: 62-71. http://www.ijrh.org/article.asp?issn=0974-7168;year=2013;volume=7;issue=2;spage=62;epage=71;aulast=Saha

Immune function

Kuzeff RM. Homeopathy, sensation of well-being and CD4 levels: A placebo-controlled, randomized trial. *Complementary Therapies in Medicine* (1998) 6(1): 4-9. http://www.researchgate.net/publication/239444973_Homeopathy_sensation_of_well-being_and_CD4_levels_a_placebo-controlled_randomized_trial

Influenza

Derasse M, Klein P, Weiser M. The effects of a complex homeopathic medicine compared with acetaminophen in the symptomatic treatment of acute febrile infections in children: an observational study. *Explore (NY)* (2005) 1(1): 33-39. http://www.explorejournal.com/article/S1550-8307(04)00007-2/abstract

Vincent S et al. Management of Influenza-Like Illness by Homeopathic and AllopathicGeneral Practitioners in France During the 2009-2010 Influenza Season. *J Altern Complement Med.*2013 Feb;19(2):146-52. doi: 10.1089/acm.2011.0706. Epub 2012 Jul 17. http://www.ncbi.nlm.nih.gov/pubmed/22803696

Chakraborty PS, Lamba CD, Nayak D, John MD, Sarkar DB, Poddar A, Arya JS, Raju K, Vivekanand K, Singh HBK, Baig H, Prusty AK, Singh V, Nayak C. Effect of individualized homoeopathic treatment in influenza like illness: A multicenter, single blind, randomized, placebo controlled study. *Indian J Res Homoeopathy* (2013)**7**: 22-30. http://www.ijrh.org/article.asp?issn=0974-7168;year=2013;volume=7;issue=1;spage=22;epage=30;aulast=Chakraborty

Insomnia

Bell IR, Howerter A, Jackson N, Aickin M, Baldwin CM, Bootzin RR. Effects of homeopathic medicines on polysomnographic sleep of young adults with histories of coffee-related insomnia. *Sleep Medicine* (2011)12(5): 505-511. http://download.journals.elsevierhealth.com/pdfs/journals/1389-9457/PIIS1389945710001735.pdf

Hellhammer J, Schubert M. Effects of a homeopathic combination remedy on the acute stress response, well-being, and sleep: A double-blind, randomized clinical trial. *Journal of Alternative and Complementary Medicine* (2012) Sep 10 [Epub]. http://online.liebertpub.com/doi/abs/10.1089/acm.2010.0636

Bell IR, Howerter A, Jackson N, Aickin M, Bootzin RR, Brooks AJ. Nonlinear dynamical systems effects of homeopathic remedies on multiscale entropy and correlation dimension of slow wave sleep EEG in young adults with histories of coffee-induced insomnia. *Homeopathy* (2012) **101**: 182-192.
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3402916/

Harrison CC, Solomon EM, Pellow J (2013). The effect of a homeopathic complex on psychophysiological onset insomnia in males: a randomized pilot study. *AlternTher Health Med.* 2013;**19**:38-43.
http://www.ncbi.nlm.nih.gov/pubmed/23981403

Low back Pain

Pach D, Brinkhaus B, Roll S, Wegscheider K, Icke K, Willich SN, Witt CM (2011). Efficacy of injections with Disci/Rhustoxicodendron compositum for chronic low back pain – A randomized placebo-controlled trial. *PLoS One*; 6: e26166. Epub 2011 Nov 8.
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3210748/

Malnutrition

Villanueva DFD, Rodríguez AP, García LRG, Osés CAM. Use of homeopathic formula in malnourished children.*International Journal of High Dilution Research* (2012) 11(38): 25-32.
http://www.feg.unesp.br/~ojs/index.php/ijhdr/article/view/551/559

Menapausal symptoms

Colau JC, Vincent S, Marijnen P, Allaert FA. Efficacy of a non-hormonal treatment, BRN-01, on menopausal hot flashes: A multicenter, randomized, double-blind, placebo-controlled trial. *Drugs in R and D* (2012) 12(3): 107-119.
http://www.ncbi.nlm.nih.gov/pubmed/22852580

Relton C, O'Cathain A, Nicholl J. A pilot 'cohort multiple randomised controlled trial' of treatment by a homeopath for women with menopausal hot flushes. *ContempClin Trials* (2012) 33:853-859.
http://www.contemporaryclinicaltrials.com/article/PIIS1551714412000973/abstract

Mental Fatigue

Dean ME, Karsandas R, Bland JM, Gooch D, MacPherson H (2012). Homeopathy for mental fatigue: lessons from a randomized, triple blind, placebo-controlled cross-over clinical trial. *BMC Complement Altern Med*;12:167.
http://www.ncbi.nlm.nih.gov/pubmed/23025450

Mucositis

Sencer SF, Zhou T, Freedman LS, Ives JA, Chen Z, Wall D, Nieder ML, Grupp SA, Yu LC, Sahdev I, Jonas WB, Wallace JD, Oberbaum M (2012). Traumeel S in preventing and treating mucositis in young patients undergoing SCT: a report of the Children's Oncology Group. *Bone Marrow Transplant;*47:1409-1414
http://www.ncbi.nlm.nih.gov/pubmed/22504933

Musculoskeletal

Rossignol M, Begaud B, Engel P, Avouac B, Lert F, Rouillon F, Benichou J, Massol J, Duru G, Magnier AM, Guillemot D, Grimaldi-Bensouda L, Abenhaim L. Impact of physician preferences for homeopathic or conventional medicines on patients with musculoskeletal disorders: results from the EPI3-MSD cohort. *Pharmacoepidemiology and Drug Safety* (2012) 21(10): 1093-1101.
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Nappy rash

Pellow J, Swanepoel M. A randomised pilot study on the efficacy of milking cream and a homeopathic complex topical cream on diaper dermatitis. *Health SA Gesondheid*; 2013)18; #680.
http://www.hsag.co.za/index.php/HSAG/rt/printerFriendly/680/836

Neuropathy

Pomposelli R, Piasere V, Andreoni C, Costini G, Tonini E, Spalluzzi A, Rossi D, Quarenghi C, Zanolin ME, Bellavite P. Observational study of homeopathic and conventional therapies in patients with diabetic polyneuropathy. *Homeopathy* (2009) 98(1): 17-25.
http://www.ncbi.nlm.nih.gov/pubmed/19135955

Nocturnal enuresis

Ferrara P, Marrone G, Emmanuele V, Nicoletti A, Mastrangelo A, Tiberi E, Ruggiero A, Fasano A, PaoliniPaoletti F. Homotoxicological remedies versus desmopressin versus placebo in the treatment of enuresis: a randomised, double-blind, controlled trial. *Pediatric Nephrology* (2008) 23:269–274.Epub 2007 Feb 20.
http://www.deepdyve.com/lp/springer-journals/homotoxicological-remedies-versus-desmopressin-versus-placebo-in-the-uU6C4Kz2mc

Otitis media

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In conclusion

There is additional evidence on the effectiveness of homeopathy for the treatment of clinical conditions in humans that needs to be considered.

The above trials need to be considered and the impact of these trials on the previous conclusion in the Draft Information Paper needs to be communicated in a second round of public consultations.

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