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FREQUENTLY ASKED QUESTIONS ARISING FROM PUBLIC CONSULTATION

NHMRC advice on the effectiveness of
homeopathy for treating health conditions

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Context

These Frequently Asked Questions (FAQs) have been developed in response to questions raised in public consultation submissions and expert review of the draft *NHMRC Information Paper: Evidence on the effectiveness of homeopathy for treating a clinical condition*.

Further detail on some of the questions below can be found in the final NHMRC information paper, available at www.nhmrc.gov.au/guidelines-publications/cam02.

1 What was the context for undertaking the homeopathy review?

- In 2012, NHMRC decided to undertake a comprehensive evidence assessment on the effectiveness of homeopathy, to ensure all relevant peer reviewed research was considered.
- The outcomes of this evidence assessment have informed the development of an NHMRC Information Paper on homeopathy.
- This work addressed the major health issue *examining alternative therapy claims* identified in NHMRC's 2010–2012 Strategic Plan.
- Homeopathy was the first Complementary and Alternative Medicine (CAM) selected as it is commonly used, both in Australia and around the world, however its underlying premise is not consistent with our current understanding of the biological, physiological and pharmacological sciences.
- The NHMRC's 2013–2015 Strategic Plan identified *Claiming benefits for human health not based on evidence*, as a major health issue for consideration as there are concerns that products and procedures are often promoted as beneficial to health with little or no evidence of their benefit beyond the placebo effect. In some instances, patients may be misled into rejecting practices and treatments that are evidence-based.
- NHMRC aims to provide practitioners and patients with evidence based health advice on the effectiveness of a number of CAM.

2 How does NHMRC support homeopathy research?

- NHMRC provides funding for health and medical research through a peer review application process.
- Most applications for research are investigator initiated, which means the researchers (investigator) propose what research they wish to undertake in their areas of interest.
- NHMRC applications for research are assessed using an internationally recognised peer-review process, underpinned by the NHMRC Principles of Peer Review, to ensure that all applications are assessed in a fair, honest and transparent manner.
- Since 2000, NHMRC has committed over \$86 million towards research involving CAM (research grants that have been identified as having a connection with the research area of *Complementary and Alternative Medicine* through a search of the Chief Investigator provided keywords and titles contained in the NHMRC research database). Relevance to the research area in question may be either immediate or be a longer term perceived benefit. Current as at December 2013, available at www.nhmrc.gov.au/grants-funding/research-funding-statistics-and-data/burden-disease-and-health-issues.
- No grant applications specific to homeopathy have been received by NHMRC in this time.

Independence/Bias

3 Why was there no homeopathy expert on the Homeopathy Working Committee?

- The composition of committees for clinical guidelines is different from the composition of committees for Health Technology Assessments (HTA). Clinical guideline working committees typically include representatives from the target clinical disciplines that will use the final guideline. In contrast, HTA committees typically include experts in research methods and technical fields, who need not be experts in the particular branch of medicine in which the technology will be used.
- This approach is consistent with other HTA committees such as the Medical Services Advisory Committee, the Pharmaceutical Benefits Advisory Committee (PBAC) and the Therapeutic Goods Administration Statutory Advisory Committees. (NB: Whilst several PBAC members are clinicians, they are not selected to match the discipline in which a medicine will be used, rather, they are selected for their expertise in assessing risk/benefit etc).
- The purpose of NHMRCs assessment of homeopathy was to find and interpret evidence for whether or not homeopathic medicines are effective – not to develop a clinical guideline for practising homeopaths.
- The Homeopathy Working Committee comprised experts in evidence-based medicine, clinical trials, and complementary and alternative medicines research.
- In developing the Information Paper, the HWC made its evaluation based on the evidence assessment presented by an external consultant. The HWC did not perform the evidence assessment; however, it did develop the standardised approach to evidence statements.

4 Why are the Disclosures of Interest of the contractors involved in the homeopathy review, Cochrane and Optum, not made public?

- NHMRC engages independent experts to perform services relating to the development and presentation of evidence based health advice through its Health Evidence and Advice Panel (HEP).
- OptumInsight (Evidence Assessment) was engaged through the HEP. Under the Deed of Standing Offer for the HEP, agreed by OptumInsight, *“the Contractor warrants that to the best of it (sic) knowledge, at the time this Contract was entered into, no conflict of interest exists or is likely to arise in the performance of its obligations under this Contract, by it or its Personnel involved in performing the Services, other than as disclosed in writing to NHMRC before this Contract was entered into.*

The Contractor must not during the Term, engage in any activity, transaction or arrangement that may result in a conflict of interest arising or continuing (including any activity, transaction or arrangement which NHMRC may reasonably view as a conflict of interest), unless NHMRC has given its written approval for the Contractor to engage in that activity.

If, during the performance of its obligations under this Contract, a conflict arises, or appears likely to arise, the Contractor must:

- notify NHMRC immediately in writing;*
 - make full disclosure of all relevant information relating to the conflict; and*
 - take such steps as NHMRC reasonably requires to resolve or otherwise deal with the conflict”.*
- The Australasian Cochrane Centre (Methodological Review) was engaged via a purchase order. Under general Commonwealth Purchase Order conditions: *“The Supplier warrants that no conflicts of interest exists, or is anticipated, relevant to the performance of its obligations under the Contract. If a conflict of that kind arises, the Supplier must notify the Commonwealth immediately”.*
 - No conflicts of interest were disclosed by either contractor during their contracted period.
 - OptumInsight is not a pharmaceutical company (a review of the company website suggests that the company contracts its services to industries outside of government, which may include the pharmaceutical industry). Participation in the HEP does not preclude companies from undertaking other work, notwithstanding the contractual obligations above.

5 Why has NHMRC been influenced by lobby groups such as Friends of Science in Medicine in developing its position on homeopathy?

- Suggestions that NHMRC/the HWC have been influenced by groups such as Friends of Science in Medicine (FSM) are rejected. NHMRC has no relationship to FSM.
- As part of the formal appointment to an expert committee, prospective members are required to disclose any factors that may cause or be perceived to cause, a conflict of interest with their duties.
- NHMRC is aware that Professor Peter Brooks was a member of FSM from January to April 2012. NHMRC is also aware that Prof. Brooks has an interest in evidence-based CAM and was involved in establishing the Australian Centre for Complementary Medicine Education and Research at the University of Queensland, in association with Southern Cross University.
- Prof Brook’s disclosures of interest were considered by the chair of the HWC and by the NHMRC. Based on his expertise, he was appointed to the HWC. Prof Brooks declarations of interest are publicly available on the NHMRC website at www.nhmrc.gov.au/health-topics/complementary-medicines/membership-homeopathy-working-committee.
- The evidence review was overseen by the HWC as a whole; no one committee member influenced committee deliberations.

Scope

6 Why did the NHMRC review of evidence focus only on the treatment of clinical conditions and not prevention (including homeopathic vaccines)?

- NHMRC did not evaluate the use of homeopathy in the prevention of health conditions (including evidence about homeopathic vaccines) or general wellbeing.
- Research of this type is considerably more complex: a robust study design is required to account for potential confounders and sources of bias; along with challenges in outcome measurement due to the large sample size and significant period of follow-up necessary to demonstrate any effect. This would have considerably expanded both the breadth and the timeframe of NHMRC's already extensive homeopathy review.
- An examination of the cost effectiveness of homeopathy was also beyond the scope of NHMRC's homeopathy review.

7 Why did the NHMRC review of evidence exclude published systematic reviews in languages other than English?

- The NHMRC review searched for systematic reviews published in English, because that is generally an efficient method for identifying the broad range of research findings in an overview of evidence.
- The review included evidence from individual studies published in languages other than English, where these studies were identified by systematic reviews.
- Of the 176 primary studies identified by the systematic reviews; 62 (36%) were originally published in languages other than English (based on a review of study title/journal).

8 Why did the NHMRC review of evidence ignore evidence from animal studies?

- The approach adopted by NHMRC is consistent with other Health Technology Assessments.
- For new medicines, animal and laboratory studies are initial steps to identify whether a medicine is worth testing in patients.
- For all therapies (medicines, treatments, procedures and devices), laboratory studies and evidence from animal studies (or human studies other than clinical trials in patients) are unreliable as a predictor of clinical effects in patients with the clinical condition.

9 Why did the NHMRC review of evidence assess systematic reviews instead of individual studies?

- A full review of randomised controlled trials (RCT) of homeopathy for the treatment of a range of clinical conditions would have been resource intensive, rendering this approach unfeasible. Instead, the evidence assessment used an overview of available systematic reviews (SR) to identify the existing body of evidence: high-quality SRs serve as a window onto RCTs
- Had there been good quality studies with a large effect size favouring homeopathy, the approach adopted would have identified this.
- OptumInsight analysed the reported results of the studies on homeopathy. Consideration was also given to the quality and design of the studies as reported by the author of the SR.

10 Why did the NHMRC review of evidence focus on trials comparing homeopathy with placebo rather than trials comparing homeopathy with conventional medicines?

- The first priority in establishing the effectiveness of a treatment is to show that it is effective compared with placebo.
- Research studies that compare a medicine with another treatment are designed to test whether the medicine is as, or more, effective than the current gold standard treatment. This type of study is normally conducted when previous studies have already shown that the test medicine is more effective than placebo.
- Comparative studies can only provide useful information if the comparator treatment itself is already known to be effective.
- The overview did include comparative trials where these were identified by systematic review, however it should be noted that in an under-powered trial with a weak comparator (antibiotics often only have a modest effect in otitis media, for example); statistically equivalent outcomes do not establish efficacy of the test intervention – in this case homeopathy.
- When the HWC considered the results of clinical trials that compared homeopathic medicines with conventional medicines, the HWC did not assume that the conventional medicine was effective for the condition. This was one of the reasons that the NHMRC review focussed on clinical trials that compared treatments with placebo in the first instance.
- In some studies considered in the assessment of the evidence, homeopathy was compared with treatments that were not standard treatments for the condition. In those studies, it was not possible to judge the true effect of homeopathy on the health condition.

Methodology

11 When reviewing the evidence for homeopathy, why did NHMRC use methods that have been developed for mainstream medicine?

- In a number of submissions received through the public consultation process, comments identified that homeopathy focuses on treating the ‘whole person’ and emphasises the importance of the consultation – not just the medicine – in achieving health effects. Contemporary conventional medicine also aims to provide holistic care.
- The effect of any treatment, including conventional medicines, is partly due to the quality of the relationship between healthcare professional and patient, so it is necessary to test *any* medicine by making standardised comparisons, using clinical trials designed to distinguish the effect of the medicine itself from the effects of the consultation and any other factor that affects health (e.g. trials in which all patients receive similar care from the same practitioner or similar practitioners, which compare the medicine with placebo).
- Clinical trial designs have been developed to distinguish the effect of medicine from the effects of the consultation.
- The objective of the NHMRC assessment of homeopathy was to determine whether homeopathic medicines are effective, not to assess the efficacy of homeopathic care (i.e. a combination of consultation and prescribing).
- As many studies included consultation in both arms of the study, the only variable was the presence or absence of the homeopathic medicine. Interaction with the homeopath was constant in most studies considered.
- In a number of submissions received through the public consultation process, comments identified that some homeopaths tailor the treatment for each individual, so each person’s treatment may be unique. Tailoring of treatment is also common in mainstream healthcare.
- When treatments are intended for use in regimens that differ between patients (e.g. individualised doses or combinations of medicines), it is still necessary to test whether the medicine is effective or not.
- It is possible to design high-quality trials that are appropriate for assessing treatment approaches that involve individualisation, including homeopathic medicines.
- The HWC maintains that homeopathy can be judged by the same standards as conventional medicines.

12 Should long-standing (traditional) treatments be considered differently to new treatments?

- Longstanding use does not prove that a medicine is effective, whether it is a conventional medicine used in mainstream health care, a traditional medicine, or a complementary and alternative medicine.
- All medicines should be tested in well-designed clinical trials and the results should be analysed objectively.
- Claims of effectiveness should be based on supporting evidence, whether treatments are traditional, alternative or used in conventional medicine.

13 Did NHMRC apply a higher standard to homeopathy than it applies to conventional medicines?

- NHMRC acknowledges that the use of some common conventional medicines is not supported by evidence, however, the evidence base for treatments is increasingly being interrogated, for example by re-evaluating the results of clinical trials by systematic reviews and specialised statistical methods.
- When assessing the effectiveness of a medicine, the standard approach used in HTAs is to place the onus of proof on those who are proposing that the treatment be used (e.g. manufacturers, practitioners or researchers). This means that any claims about the effectiveness of a medicine are not accepted without evidence from clinical trials that compare the treatment with placebo in patients with the clinical condition.
- When the HWC considered the results of clinical trials that compared homeopathic medicines with conventional medicines, the HWC did not assume that the conventional medicine was effective for the condition. This was one of the reasons that the NHMRC review emphasised clinical trials that compared treatments with placebo in the first instance over trials that only compared homeopathy with another treatment.

14 Why did the NHMRC review group together evidence from different types of homeopathy (different homeopathic medicines and different homeopathic practices) for each clinical condition?

- There is no standardised method for this type of overview. The approach taken by the NHMRC review, to group together various homeopathic treatments for a particular clinical condition is uncommon but not unprecedented.
- The review considered various regimens under the title 'homeopathy' just as other studies have assessed the efficacy of an entire class of therapies: for example under the headings 'antibiotics' or 'physiotherapy' for some conditions. This is also a common approach for reviews where a group of similar agents are considered together, e.g. Beta-blockers for the treatment of hypertension.
- The overview method used, enabled the reviewers to identify the broad range of studies evaluating homeopathy. Of the studies identified by the included systematic reviews, there were no good quality studies with a large effect size favouring homeopathy. If such a study had been identified (provided the study was of sufficient quality i.e. well designed and large enough to be reliable), this may have warranted making a closer assessment of the evidence for that clinical condition.

- NHMRC commissioned the Australasian Cochrane Centre to review the methods used in the overview and ensure that processes for identifying and assessing the evidence were scientifically rigorous, consistently applied, and clearly documented. In its report, the Australasian Cochrane Centre noted *synthesising the findings of the included systematic reviews, and their component trials, was a complex undertaking. While there is guidance on the conduct of Overviews of systematic reviews, there are many unresolved methodological challenges and no single best approach. Overall, the conclusions arising from the review appear justified based on the evidence presented.*

15 How did NHMRC develop its approach to formulating evidence statements?

- Given the large number of clinical conditions (68) that were covered by the overview, the HWC agreed that it was necessary to develop a set of criteria to guide the content and formulation of the evidence statements.
- This guidance was considered important to ensure that the approach for developing the evidence statements was consistent and transparent across each of the 68 clinical conditions in the overview.
- The criteria were developed by the HWC with the assistance of the evidence reviewer, and in line with the principles outlined in (2009): www.nhmrc.gov.au/guidelines-publications/information-guideline-developers/resources-guideline-developers.
- The nature of these criteria, and indeed the need for them at all, reflects many of the features of this evidence review, particularly:
 - it was very broad in nature and it captured a large number of clinical conditions;
 - being an overview, the data on individual trials available to the evidence review was limited by the information reported in the included systematic reviews and the quality, reliability and currency of those systematic reviews; and
 - the overall shortcomings of the primary evidence base, which was largely comprised of small trials that were not of high quality.

Interpretation

16 Why did the NHMRC review of evidence assume that homeopathy is ineffective unless proven effective (instead of starting with the assumption that that homeopathy is effective)?

- There are two approaches for designing studies to evaluate medicines; null hypothesis and estimation of effect.
- The standard approach used in HTAs is null hypothesis, with the onus of proof on those who are proposing that the treatment be used (e.g. manufacturers, practitioners or researchers).
- Any claims about the effectiveness of a medicine are not accepted without evidence from clinical trials that compare the treatment with placebo in patients with the clinical condition.
- In this review, the null hypothesis for each clinical condition was that homeopathy has no effect as a treatment for that condition unless there was sufficient reliable evidence to demonstrate otherwise.
- The only exceptions to this principle were:
 - where there were no studies (or only one small and/or poor/unknown quality study) identified for a particular clinical condition; or
 - where the evidence was so poorly reported so as to be uninterpretable.
 - In these cases, the HWC determined that no conclusion could be drawn about effectiveness, rather than assuming the null hypothesis.

17 Why did the NHMRC review consider that homeopathy studies with fewer than 150 participants were too small to provide reliable evidence?

- Thresholds for descriptions of trial sizes were determined by the HWC as a general guide for intervention studies of this nature, based on the (generally) continuous outcomes measured in the trials. HWC considered the following study in the development of these thresholds *Influence of trial sample size on treatment effect estimates: meta-epidemiological study* (www.bmj.com/content/346/bmj.f2304).

18 The absence of evidence showing that a treatment is effective is not the same as evidence showing that a treatment is ineffective. If the review reported a lack of reliable evidence about homeopathy, why was NHMRC's overall conclusion negative?

- A study was considered reliable if it was well designed, conducted in such a way that the influence of bias or confounding influencing the result were limited, and had enough participants to give a meaningful result. A study was considered unreliable if it was not well designed, not well conducted, or if it had too few participants to give a meaningful result. Unreliable studies cannot show whether or not homeopathy is effective.

- The review of evidence found three types of evidence:
 - studies that reported that homeopathy was not more effective than placebo for the health conditions studied.
 - studies that reported that homeopathy was more effective than placebo, but these studies were unreliable.
 - studies that reported that homeopathy was as effective as or more effective than another treatment, but these studies were unreliable.
- Therefore, the HWCs overall conclusion was that there was no health conditions for which there was reliable evidence that homeopathy was effective—no good-quality, well-designed studies with enough participants for a meaningful result reported either that homeopathy caused greater health improvements than a substance with no effect on the health condition (placebo), or that homeopathy caused health improvements equal to those of another treatment.

19 But what about the 2006 and 2012 publications of a review by Bornhöft and others, often cited as a Swiss Government Report, which found evidence in favour of homeopathy?

- The Swiss Government undertook an evaluation program (Programm Evaluation Komplementärmedizin) of five complementary and alternative medicines, one of which was homeopathy, from 1998-2005.¹
- For homeopathy, the evaluation program included a number of components: a meta-analysis on homeopathy trials and of matched trials in conventional medicine, by Shang et al, 2005²; and a broad analysis of the literature, which incorporated publications and unpublished reports on studies of various methodologies, by Bornhöft et al 2006.³
- Whilst Bornhöft et al declared this analysis of the literature to be a Health Technology Assessment, the final report of the Swiss Governments evaluation program did not classify it as such.
- The Swiss government evaluation program resulted in a decision to end any existing coverage for homeopathy in 2005.
- This decision was reversed in 2011 due to popular opinion. Whilst an advisory committee concluded that the proof of efficacy, effectiveness, appropriateness and cost impact was not convincing enough, a 2009 vote in support of complementary and alternative medicines was taken into account.
- Bornhöft et al 2006 was considered in the assessment of the evidence.

1 Gurtner F. The report "Homeopathy in healthcare: effectiveness, appropriateness, safety, costs" is not a "Swiss report". *Swiss Med Wkly* 2012;142:w13595

2 Schang A, Huwiler-Müntener K, Nartey L, et al. Are the clinical effects of homeopathy placebo effects? Comparative study of placebo-controlled trials of homeopathy and allopathy. *Lancet*. 2005;366:726–32.]

3 Bornhöft G, Wolf U, Von Ammon K, Righetti M, Maxion-Bergemann S, Baumgartner S, Thurneysen A, Matthiessen PF (2006) Effectiveness, safety and cost-effectiveness of homeopathy in general practice - Summarized health technology assessment. *Forsch Komplementärmed* 13(SUPPL. 2):19-29