

## **NHMRC DRAFT INFORMATION PAPER: EVIDENCE ON THE EFFECTIVENESS OF HOMEOPATHY FOR TREATING HEALTH CONDITIONS [APRIL 2014]**

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## About NHMRC

NHMRC is Australia's peak body for supporting health and medical research by funding the best research selected through a competitive peer review process. NHMRC also develops health advice for the Australian community, health professionals and governments in the form of public health and clinical practice guidelines, Public Statements, Information Papers and evidence reviews. NHMRC also provides advice on ethical behaviour in health care and in the conduct of health and medical research.

The work of NHMRC is guided by its Strategic Plan, and defined by the *National Health and Medical Research Council Act* (1992). The Strategic Plan covers a three year period and is submitted to the Health Minister for approval, prior to being tabled in Parliament. The NHMRC Strategic Plan 2013-2015 has identified 'claiming benefit for human health not based on evidence' as a major health issue for consideration.

Within our health system, there are practices which are currently not based on sturdy evidence. Health and medical research is the means by which we test the value of procedures, processes, systems and products offered to patients, or proposed as preventive means by the health system and its policy and decision makers. NHMRC is a strong advocate for the development and use of evidence to inform policy and practice and in recent years, NHMRC and other health research funding bodies have increased funding for such research.

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. Published research on a topic of interest has been identified, analysed and synthesised into a summary of the evidence for the Australian community, health professionals and policy makers. This information can then be utilised to assist people in making healthcare choices, guide clinical practice or influence policy and perhaps new funding approaches, all of which lead to improvements in health and health care delivery.

NHMRC 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. This consideration should be reflected in their professional ethics and clinical practices.

## Introduction

### Purpose

This information paper provides an overview of evidence<sup>\*</sup> from research on the effectiveness of homeopathy in treating health conditions in humans.

It summarises the findings of an assessment of homeopathy undertaken by National Health and Medical Research Council (NHMRC), which included an overview of published systematic reviews,(1) evaluation of information provided by homeopathy interest groups and the public,(2) and consideration of clinical practice guidelines and government reports on homeopathy published in other countries.

### Scope

NHMRC assessed the evidence on homeopathy to answer this question: *Is homeopathy an effective treatment for health conditions, compared with no homeopathy, or compared to other treatments?*

NHMRC did not consider evidence for whether or not homeopathy is effective for preventing health conditions (including evidence about homeopathic ‘vaccines’), or whether homeopathy is good for general health.

NHMRC did not assess evidence on the safety of the ingredients of homeopathic medicines.

### What is homeopathy?

Homeopathy is a type of complementary and alternative medicine. It is based on the principle that ‘like cures like’ – the belief that substances that may cause illness or symptoms in a healthy person can, in very small doses, treat those symptoms in a person who is unwell.

Homeopathy is also based on the belief that molecules in highly diluted substances retain a ‘memory’ of the original substance. Specifically, homeopathic remedies are repeatedly diluted and agitated in a process known as ‘potentisation’ or ‘dynamisation’.

Homeopathic medicines are prepared by taking a substance (e.g. plants, animal material, or chemical), diluting it in water or alcohol, then forcefully hitting the container against a hand or a surface. This process is repeated several times. Homeopathic medicines can include pellets placed under the tongue, tablets, liquids, ointments, sprays and creams.

Homeopaths mostly provide ‘individualised homeopathy’. This means that the homeopath matches all the person’s symptoms to a single homeopathic medicine, rather than treating the person for a particular health condition using one or more homeopathic medicines. Some homeopaths provide ‘clinical homeopathy’. This means that the homeopath chooses one or more homeopathic medicines to treat a particular health condition.

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<sup>\*</sup> In this information paper, evidence is defined as health research in humans using internationally accepted methods (e.g. properly designed research studies). It does not include individual experiences, testimonials or case reports, or research that was not done using standard methods.

## Why did NHMRC conduct an assessment of homeopathy?

NHMRC is responsible for providing Australians with reliable advice and the best available evidence to help people make informed health decisions. This includes decisions about using complementary and alternative medicines.

NHMRC is concerned that unconventional products and procedures are often promoted to improve people's health when there is little or no evidence of their benefit, except for the benefits people experience when they believe that a treatment is effective (the placebo effect).(3, 4) Sometimes patients may be misled into rejecting practices and treatments that are proven to be effective.

NHMRC is supporting research on complementary and alternative medicines and therapies,<sup>†</sup> and is helping health professionals and patients to find reliable information about these treatments.(3, 4)

Homeopathy is commonly used around the world and in Australia. A 2009 World Health Organisation review on the safety of Homeopathy estimated that each year, Australians spend an estimated US \$7.3 million on homeopathic medicines.(5) Some homeopathic medicines are listed on the Australian Register of Therapeutic Goods.<sup>‡</sup> However, people disagree about whether or not homeopathy is effective.

People who use homeopathy need to understand the potential benefits and risks. Health professionals also need to know what homeopathy is, be aware of the current scientific evidence from research on homeopathy, and understand any possible benefits and risks to patients – particularly when people decide to use homeopathy instead of other treatments, especially in place of other, evidence based treatments.

There have already been several reviews and reports on the effectiveness of homeopathy. However, reports on homeopathy commissioned by foreign governments have reached different conclusions.(6, 7)

NHMRC undertook an assessment of the evidence, to provide Australians with reliable information on this topic.

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<sup>†</sup> Since 2000, NHMRC has provided more than \$86 million in funding for scientific research into complementary medicine and alternative therapies. [Source: <http://www.nhmrc.gov.au/your-health/complementary-and-alternative-medicines>]

<sup>‡</sup> Medicines listed on the Australian Register of Therapeutic Goods are labelled with an Australian listing (AUST L) number. An AUST L number issued by the Therapeutic Goods Administration indicates that the product's ingredients have been assessed for quality and safety and have a low risk of poisoning or major side effects. However, the TGA does not assess the effectiveness of these products. For more information, visit the Therapeutic Goods Administration's website (<http://www.tga.gov.au/consumers/information-medicines-label.htm>).

## About the NHMRC assessment of the evidence

### NHMRC's approach to assessing health evidence

When assessing the effectiveness of treatments for health conditions, not all evidence has equal value.

It is not possible to tell whether a health treatment is effective or not simply by considering individuals' experiences or healthcare practitioners' beliefs. One reason that personal testimonials are not reliable is that people experience health benefits when they believe that a treatment is effective (the placebo effect). Another is that healthcare practitioners cannot always tell whether changes in a person's health condition are due to the treatment or some other reason.

Research studies<sup>§</sup> provide more information, but some types of studies provide stronger evidence than others because of how they are designed. Reliable information about whether a particular medicine is effective for treating a health condition comes from studies in which:

- the medicine is compared with a substance that has no effect (placebo) in a group of people with the health condition (placebo-controlled trial), or the medicine is compared with an effective standard treatment (controlled trial)
- each participant is given either the medicine or the placebo/other treatment at random (randomised trial)
- participants and researchers do not know whether they are taking the medicine or the placebo/other treatment until the study is finished (double-blinded trial)
- there are enough participants to be reasonably confident that, if there is a bigger change in the health condition in one group, this is not just due to chance
- the correct statistical methods are used to analyse the results.

The results of individual studies need to be repeated in other independent studies, to make sure the effects seen were not just due to chance. The most reliable information comes from research that combines the results of all available similar studies and analyses the results together (systematic reviews).

When reviewing health evidence and drafting health advice, NHMRC uses a rigorous approach developed by Australian experts in research methods.<sup>(8)</sup> In the NHMRC system for evaluating health evidence there are different levels of evidence, ranging from level one (highest level, strongest evidence) to level four (lowest level, weakest evidence).<sup>(8)</sup> NHMRC considers the level of each study, to decide how much that study's results should be relied on when judging the overall evidence.

A treatment is considered effective for treating a health condition if it meets all of these key criteria:

- The treatment causes health improvements that cannot be explained by the placebo effect
- Health improvements that occur in people taking the treatment are unlikely to be due to chance

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<sup>§</sup> In this information paper, a research study means a planned, structured scientific research project designed to see whether a treatment is effective in humans (e.g. a trial).

- The health improvements caused by the treatment are meaningful for a person's overall health
- The health improvement occurs consistently in several studies.

## **How did NHMRC find evidence about homeopathy?**

NHMRC used a combination of three main sources of information about the effectiveness of homeopathy (Figure 1):

- published systematic reviews (summarised in the overview report)(1)
- information provided by homeopathy interest groups and the public (summarised in the review of submitted literature)(2)
- clinical practice guidelines and government reports on homeopathy published in other countries.

The NHMRC's assessment was guided by a committee of experts appointed in 2012 (see The Homeopathy Working Committee).

### ***Overview of systematic reviews***

Many systematic reviews of homeopathy studies have already been published. NHMRC commissioned a professional research group (Optum) to do a thorough search of published research to identify systematic reviews of studies that compared homeopathy with no homeopathy, or with other treatments, and measured effectiveness in patients with any health condition.

The search was designed to find systematic reviews that included prospective, controlled studies.\*\* The researchers searched databases of health publications to find reports of systematic reviews published in English between January 1997 and 3 January 2013.

For each health condition, the research group collated the findings of the systematic reviews and assessed the quality and reliability of the evidence. The findings are described in detail in the overview report.(1)

### ***Literature provided by homeopathy interest groups and individuals***

NHMRC considered published articles on the effectiveness of homeopathy provided by the Australian Homoeopathy Association and the Australian Medical Fellowship of Homeopathy. NHMRC also considered articles submitted by members of the public. Evidence was only considered if it had been provided to NHMRC before the NHMRC's assessment process began.

All articles received were assessed by a professional research group (Optum) to identify evidence within the scope of NHMRC's assessment. Only the types of evidence that were included in the overview (prospective, controlled studies) were assessed in detail. For each study included, the researchers assessed its quality and the reliability of its results, and summarised the findings in the review of submitted literature.(2)

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\*\* 'Prospective' design means the health outcomes to be measured were defined in advance, the way to measure the effects of treatment on these outcomes was planned in advance, and the results were then measured at specified times. 'Controlled' means homeopathy was compared with either placebo or another treatment in similar groups of people with the health condition.

NHMRC and the Homeopathy Working Committee considered this evidence when preparing this information paper.

***Evidence-based guidelines and government reports***

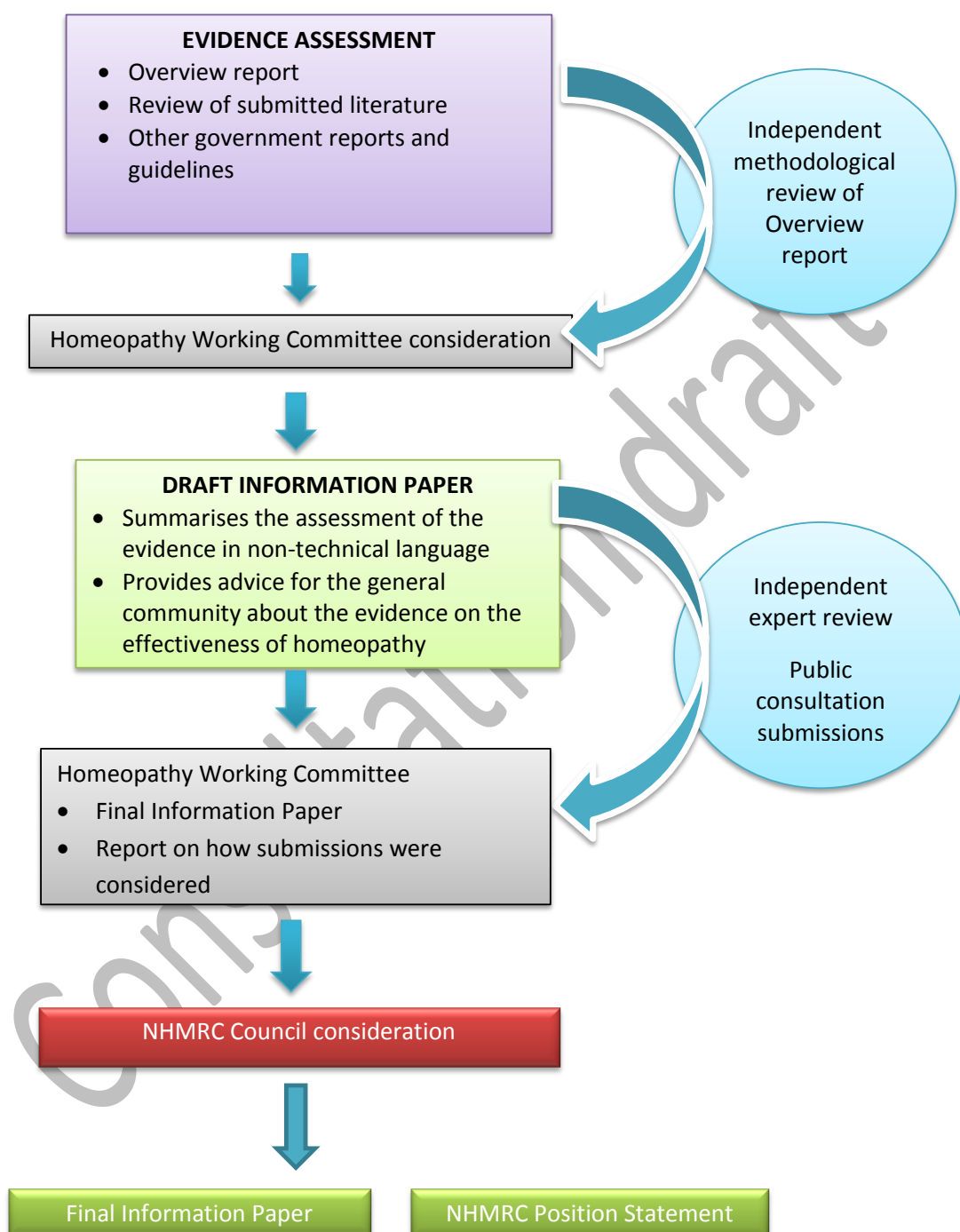
NHMRC looked for major reports by other government bodies. Two recent major government reports were identified:

- House of Commons Science and Technology Committee. *Evidence check 2: Homeopathy*. London: The Stationery Office; 2010.
- Bornhöft G, Matthiessen P, editors. *Homeopathy in healthcare – Effectiveness, appropriateness, safety, costs*. Berlin: Springer; 2012.

NHMRC also found several evidence-based clinical practice guidelines that included recommendations about the use of homeopathy in the treatment of various health conditions.(9-14). All were published or funded by the UK National Institute for Health and Clinical Excellence.

The Homeopathy Working Committee considered these reports and clinical practice guidelines when developing this information paper.

Figure 1. Components of NHMRC's assessment of homeopathy



NHMRC's assessment of the evidence on homeopathy produced two publicly available technical reports [an overview report(1) and a review of submitted literature(2)] and an information paper on the overview of the evidence. NHMRC also compiled a dossier of evidence-based clinical practice guidelines on homeopathy and reports on the effectiveness of homeopathy commissioned by other governments, for the Homeopathy Working Committee to consider.



## How did NHMRC assess the evidence about homeopathy?

NHMRC used standardised, accepted methods for assessing the quality and reliability of evidence for whether or not a therapy is effective for treating health conditions (see [NHMRC's approach to assessing health evidence](#)).

The overview considered only evidence from systematic reviews that included prospectively designed and controlled studies conducted in humans (including randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials and prospective cohort studies).

For each health condition, the overview of systematic reviews assessed:<sup>(1)</sup>

- the number of systematic reviews that reported evidence on that health condition
- the quality of the systematic reviews, using a standard, internationally accepted method<sup>††</sup>
- the number and type of research studies that were included in the systematic reviews
- the quality of each study and its number of participants, as reported in the systematic reviews
- the overall level of confidence in the body of evidence for the use of homeopathy for that health condition, ranging from 'very low' to 'high'.<sup>‡‡</sup>

The methods are described in the overview report.<sup>(1)</sup>

For each health condition, the Homeopathy Working Committee summarised the body of evidence in a statement, using standard wording and applying the same considerations consistently (see [Findings of the NHMRC overview](#)).

When assessing the extra information provided by homeopathy interest groups and the public (a total of 343 articles), a similar method of assessment was applied: only prospectively designed and controlled studies conducted in humans (including randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials and prospective cohort studies) were considered.

Articles that had already been identified in the overview of systematic reviews and included in the overview report were not considered again. For the remaining prospectively designed and controlled studies that had not already been included in a systematic review, the researchers evaluated the quality of each study using a standardised internationally accepted method.<sup>§§</sup>

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<sup>††</sup> Systematic reviews were assessed using the Assessing the Methodological Quality of Systematic Reviews (AMSTAR) method (Shea BJ, Grimshaw JM, Wells GA, et al. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. *BMC Med Res Methodol* 2007; 7: 10.).

<sup>‡‡</sup> The level of confidence in the body of evidence was recorded as 'very low' if any estimate of effect was uncertain (i.e. overall, the quality of the available information was not good enough to be able to estimate the true effect of homeopathy on that health condition). The level of confidence in the body of evidence was recorded as 'high' when further research was very unlikely to change confidence in the estimate of effect (i.e. the available evidence was high quality and the effect of homeopathy in that health condition was clear).

<sup>§§</sup> The quality of studies was assessed using the quality appraisal methodology checklists developed by the Scottish Intercollegiate Guidelines Network (Scottish Intercollegiate Guidelines Network. *SIGN 50: a guideline developer's handbook* (2011). Available at: <http://www.sign.ac.uk/guidelines/fulltext/50/index.html>)

The methods are described in the review of submitted literature.(2)

## What quality checks were applied to NHMRC's assessment of the evidence on homeopathy?

NHMRC commissioned an independent organisation with expertise in research methodology (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. Optum considered all the reviewer's comments and suggestions in consultation with the Homeopathy Working Committee, and amended the report accordingly.

*[NHMRC has invited experts in evidence based medicine, clinical trials, and complementary medicines research to review this information paper, at the same time as the current public consultation process. All comments received will be collated and considered by the Homeopathy Working Committee.]*

## Summary of evidence

### Overall finding

NHMRC concludes that the assessment of the evidence from research in humans **does not** show that homeopathy is effective for treating the range of health conditions considered.

There were 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.

- For some health conditions, homeopathy was found to be not more effective than placebo.
- For other health conditions, some studies reported that homeopathy was more effective than placebo, or as effective as another treatment, but those studies were not reliable.
- For the remaining health conditions it was not possible to make any conclusion about whether homeopathy was effective or not, because there was not enough evidence.

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.

### Evidence included in the overview

The overview considered 57 systematic reviews that assessed the effectiveness of homeopathy for treating health conditions.(1)

The systematic reviews searched for published research on homeopathy for 68 health conditions, and found published research on 61 of these conditions. No published research was found for the remaining 7 conditions.(1)

NHMRC took a range of factors into account when considering the evidence in the systematic reviews:

- whether it was relevant to the question of whether or not homeopathy is effective for treating health conditions
- the type of studies and whether they were well designed
- whether the reports included enough information to judge whether the studies were done well and whether the results were likely to be reliable or unreliable
- whether studies included enough participants to provide meaningful results
- whether studies compared homeopathy with placebo or with another treatment.

The overview considered only studies with these features:<sup>\*\*\*</sup>

- The health outcomes to be measured were defined in advance, the way to measure the effects of treatment on these outcomes was planned in advance, and the results were then measured at specified times (prospectively designed studies).
- The study compared a group of people who were given homeopathic treatment with a similar group of people who were not given homeopathic treatment (controlled studies).

NHMRC did not consider observational studies, individual experiences and testimonials, case series and reports, or research that was not done using standard methods.

For each health condition, all the available evidence was grouped together to form a body of evidence on that condition. A body of evidence was considered more reliable if it included studies that were high quality, well designed and with enough participants to make its results meaningful. A body of evidence was considered less reliable if there were very few studies, or if the studies were poor quality, badly designed, or included too few participants.

For more information on NHMRC's processes for reviewing evidence, see [About the NHMRC assessment of homeopathy](#).

## Findings of the NHMRC overview

The quality of the evidence was generally low, so it was not possible to be confident that the evidence was reliable.<sup>(1)</sup>

Based on all the evidence considered, there were 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 placebo, or caused health improvements equal to those of another treatment.<sup>(1)</sup>

Table 1 summarises the evidence.

### ***Homeopathy compared with placebo***

Research studies that compare a medicine with placebo are designed to test whether the medicine is effective as a treatment for the health condition. The systematic reviews

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<sup>\*\*\*</sup> The following types of studies were considered if included in systematic reviews: randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials and prospective cohort studies.

identified research studies that compared homeopathy with placebo for 55 health conditions.<sup>†††</sup>

For 13 health conditions, homeopathy was reported to be not more effective than placebo in either:

- all the studies found (regardless of size and quality), or
- a large majority of those studies that were reliable (good-quality, well designed and with enough participants for a meaningful result).(1)

For 14 health conditions, some studies reported that homeopathy was more effective than placebo, but these studies were not reliable. They were not good quality (well designed and well done), or they had too few participants, or both.(1) To be confident that the reported health benefits were not just due to chance or the placebo effect, they would need to be confirmed by other large, well-designed studies.(1)

For 29 health conditions, only one study that compared homeopathy with placebo was found, and each of these studies was unreliable. They were either poor quality (poorly designed or poorly done) or unknown quality, or they had too few participants, or both.(1) For these conditions, it was not possible to make any conclusion about whether homeopathy was effective or not.

### ***Homeopathy compared with other treatments***

Research studies that compare a medicine with another treatment are designed to test whether the medicine is as effective as (or more effective than) existing treatment options. This type of study is normally used when previous studies have already shown that the test medicine is more effective than placebo. The systematic reviews identified research studies that compared homeopathy with at least one other treatment for 15 conditions (these included 10 health conditions for which there were also studies that compared homeopathy with placebo).

Comparative studies can only provide useful information if the comparator treatment is already known to be effective. Some studies that compare two treatments also include a group of people who receive placebo, to make sure health effects in the groups taking the test medicine or the comparator treatment are not just due to the placebo effect.

In some studies considered in NHMRC's assessment, homeopathy was compared with treatments that were not standard treatments for the condition.(1) In those studies, it was not possible to judge the true effect of homeopathy on the health condition.

For 8 health conditions, some studies reported that homeopathy was as effective as another treatment, or more effective than another treatment, but these studies were not reliable. They were not good quality (well designed and well done), or they had too few participants, or both.(1) To be confident that the reported health benefits were not just due to chance or the placebo effect, they would need to be confirmed by other large, well-designed studies.

For 7 health conditions, only one study that compared homeopathy with another treatment was found, and each of these studies was unreliable. They were either poor quality (poorly designed or poorly done) or unknown quality, or they had too few participants, or both.(1)

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<sup>†††</sup> These included one condition (diarrhoea in children) for which studies of a combined homeopathy tablet (clinical homeopathy) and studies of individualised homeopathy were analysed separately by NHMRC.

For these conditions, it was not possible to make any conclusion about whether homeopathy was effective or not.

These findings are reported in detail in *Effectiveness of homeopathy for any clinical condition: evaluation of the evidence. Overview report.*(1)

Consultation draft

*Table 1. Summary of evidence from studies of homeopathy*

| Conclusions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Why NHMRC reached this conclusion                                                                                                                                                                                                                                                                                                                                      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Homeopathy is not more effective than placebo for the treatment of these health conditions:</p> <ul style="list-style-type: none"> <li>• adenoid vegetation in children (abnormal growth of adenoid tonsils behind the nose)</li> <li>• asthma</li> <li>• anxiety or stress-related conditions</li> <li>• diarrhoea in children – combined homeopathy tablet (clinical homeopathy)</li> <li>• headache and migraine</li> <li>• muscle soreness (delayed onset)</li> <li>• labour (inducing or shortening labour)</li> <li>• pain due to dental work</li> <li>• pain due to orthopaedic surgery</li> <li>• postoperative ileus (abnormally slow movement of bowel after surgery)</li> <li>• premenstrual syndrome</li> <li>• upper respiratory tract infections (e.g. colds)</li> <li>• warts.</li> </ul> | <p>For each condition, homeopathy was reported to be not more effective than placebo in either:</p> <ul style="list-style-type: none"> <li>• all the studies found (regardless of size and quality), or</li> <li>• a large majority of those studies that were reliable (good-quality, well designed and with enough participants for a meaningful result).</li> </ul> |
| <p>There is no reliable evidence that homeopathy is more effective than placebo for the treatment of these health conditions:</p> <ul style="list-style-type: none"> <li>• allergic rhinitis</li> <li>• attention deficit/hyperactivity disorder (ADHD) in children</li> <li>• bruising</li> <li>• chronic fatigue syndrome</li> <li>• diarrhoea in children – individualised homeopathy</li> <li>• fibromyalgia</li> <li>• hot flushes in women who have had breast cancer</li> <li>• human immunodeficiency virus (HIV) infection</li> <li>• influenza-like illness</li> <li>• rheumatoid arthritis</li> <li>• sinusitis</li> <li>• sleep disturbances or circadian rhythm disturbances</li> <li>• stomatitis (inflammation of the mouth) due to chemotherapy</li> <li>• ulcers.</li> </ul>               | <p>For each condition, although some studies reported that homeopathy was more effective than placebo, these studies were not reliable. They were not good quality (well designed and well done), or they had too few participants to give a meaningful result, or both.</p>                                                                                           |

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| <p>There is no reliable evidence that homeopathy is as effective as the other therapies for the treatment of these health conditions:</p> <ul style="list-style-type: none"> <li>• acute otitis media or otitis media with effusion (inflammation of the middle ear) in children (compared with antibiotics, mucolytic medicines, secretolytic medicines, antipyretic medicines, nasal sprays, or monitoring the condition but not providing treatment ['watchful waiting'])</li> <li>• allergic rhinitis (compared with antihistamines, cortisone or intranasal cromolyn sodium)</li> <li>• anxiety or stress-related conditions (compared with lorazepam, diazepam or cognitive behavioural therapy)</li> <li>• depression (compared with fluoxetine or diazepam)</li> <li>• eczema (compared with corticosteroids, antihistamines, or other unspecified therapies)</li> <li>• non-allergic rhinitis (compared with aspirin, xylometazoline or other therapies)</li> <li>• osteoarthritis (compared with paracetamol or various nonsteroidal anti-inflammatory drugs)</li> <li>• upper respiratory tract infection (compared with anti-inflammatory drugs, antibiotics or other therapies).</li> </ul> | <p>For each condition, although some studies reported that homeopathy was as effective as or more effective than another treatment, these studies were not reliable. They were not good quality (well designed and well done), or they had too few participants to give a meaningful result, or both.</p> |
| <p>There is no reliable evidence on which to draw a conclusion about the effectiveness of homeopathy, compared with placebo, for the treatment of these health conditions:</p> <ul style="list-style-type: none"> <li>• acne vulgaris</li> <li>• acute otitis media (inflammation of the middle ear) in children</li> <li>• acute ankle sprain</li> <li>• acute trauma</li> <li>• amoebiasis and giardiasis (gastrointestinal conditions caused by parasites)</li> <li>• ankylosing spondylitis</li> <li>• boils and pyoderma (types of skin infections)</li> <li>• Broca's aphasia in people who have had a stroke</li> <li>• bronchitis</li> <li>• cholera</li> <li>• cough</li> <li>• chronic polyarthritis</li> <li>• dystocia (difficult labour)</li> <li>• eczema</li> <li>• heroin addiction</li> <li>• knee joint haematoma (bruising)</li> <li>• lower back pain</li> <li>• nausea and vomiting associated with chemotherapy</li> <li>• oral lichen planus</li> <li>• osteoarthritis</li> <li>• proctocolitis</li> </ul>                                                                                                                                                                        | <p>For each condition, only one study that compared homeopathy with placebo was found, and this study was unreliable. It was either poor quality (poorly designed or poorly done) or unknown quality, or it had too few participants to give a meaningful result, or both.</p>                            |

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| <ul style="list-style-type: none"> <li>• postoperative pain-agitation syndrome</li> <li>• radiodermatitis (skin damage caused by radiotherapy) in women with breast cancer</li> <li>• seborrhoeic dermatitis</li> <li>• suppression of lactation after childbirth in women who elect not to breastfeed</li> <li>• stroke</li> <li>• traumatic brain injury (mild)</li> <li>• uraemic pruritis</li> <li>• vein problems due to cannulas in people receiving chemotherapy.</li> </ul>                                                                                        |                                                                                                                                                                                                                                                                                          |
| <p>There is no reliable evidence on which to draw a conclusion about the effectiveness of homeopathy compared with other therapies for the treatment of these health conditions:</p> <ul style="list-style-type: none"> <li>• burns (second- and third-degree)</li> <li>• fibromyalgia</li> <li>• irritable bowel syndrome</li> <li>• malaria</li> <li>• proctocolitis (inflammation of the rectum and colon)</li> <li>• recurrent vulvovaginal candidiasis (yeast infection of the vagina and/or vulva, also called 'thrush')</li> <li>• rheumatoid arthritis.</li> </ul> | <p>For each condition, only one study that compared homeopathy with another treatment was found, and this study was unreliable. It was either poor quality (poorly designed or poorly done) or unknown quality, or it had too few participants to give a meaningful result, or both.</p> |

Notes:

Systematic reviews included in the overview searched for, but did not find, studies assessing homeopathy in people with these conditions: borderline personality disorder, dementia, constipation in children, glaucoma, nocturnal enuresis (bedwetting), lower urinary tract symptoms in men, and chronic facial pain.

Systematic reviews included in the overview searched for, but did not find, studies that compared homeopathy with placebo in people with these conditions: burns (second and third degree), depression, irritable bowel syndrome, lower back pain, malaria, non-allergic rhinitis, and vulvovaginal candidiasis. For these conditions, systematic reviews found only studies that compared homeopathy with other treatments.



## Information provided by homeopathy interest groups and individuals

In addition to commissioning an overview of systematic reviews,(1) NHMRC assessed evidence provided by homeopathy interest groups and the public. The findings from these submissions are summarised in the report *Effectiveness of homeopathy for any clinical condition: evaluation of the evidence. Review of submitted literature*.(2)

The submissions included published research studies on three more health conditions that were not included in the systematic reviews:(2)

- pain after total abdominal hysterectomy
- tracheal secretions in critically ill patients with a history of tobacco use and chronic obstructive pulmonary disease
- wound healing after foot surgery.

These studies were of poor quality. Problems included poor design, poor reporting of the study design or method, or too few participants.(2)

The results of these studies did not alter NHMRC's overall conclusions about the effectiveness of homeopathy because of their poor quality, and because they were only selected examples of studies on those conditions. To reach a conclusion about whether homeopathy was effective for treating those conditions, it would be necessary to search for all available homeopathy studies on each condition and assess them as a single body of evidence in a systematic review.

## Evidence-based guidelines and government reports

A number of evidence-based clinical practice guidelines published or funded by the UK National Institute for Health and Clinical Excellence recommend against the use of homeopathy for treating various health conditions, due to lack of evidence for its effectiveness.(9-14)

A report by the UK House of Commons Science and Technology Committee stated that 'the systematic reviews and meta-analyses conclusively demonstrate that homeopathic products perform no better than placebos'.(6) This report concluded that any health benefits that people experience when they use homeopathy is solely due to the placebo effect.(6) In contrast, a Swiss Health Technology Assessment report on Homeopathy commissioned by the Swiss government concluded that homeopathy is a 'valuable addition to the conventional medical landscape'.(7) The difference between the findings of the UK and Swiss reports was mainly due to their different methods for assessing research evidence.

Both the UK and Swiss reports have been criticised by those who disagree with their methods and findings. The UK report was criticised by the British Homeopathic Association, which argued that the House of Commons Science and Technology Committee failed to take into account certain systematic reviews and meta-analyses, and omitted or misrepresented evidence in favour of homeopathy.(15) The Swiss report was criticised by a review that argued it was 'scientifically, logically and ethically flawed', 'misinterprets studies previously exposed as weak' and 'attempts to discredit randomised controlled trials as the gold standard of evidence'.(16)

In assessing the evidence, NHMRC considered these reports and their methodologies.

## **Limitations of the assessment and evidence base for homeopathy**

The studies of homeopathy were generally poor quality. For some health conditions, this meant that no conclusion could be made on whether or not homeopathy was effective. For other conditions, this meant that NHMRC could not be confident that the results reported by studies were reliable.

NHMRC's overview was based on finding systematic reviews of homeopathy, rather than searching for all individual published studies of homeopathy. The advantage of this strategy was to make use of the large amount of work that had already been done by researchers around the world in finding and assessing studies. However, there were also some disadvantages:

- As the overview only included systematic reviews, some individual studies of homeopathy may not have been considered (particularly recent studies published since the latest systematic reviews). NHMRC offset this risk by also considering evidence provided by homeopathy interest groups and the public, which included some extra studies,<sup>(2)</sup> and by inviting public consultation.
- To assess the quality of individual studies, the research group had to rely on the way that these were reported by systematic reviews. Details of study design (e.g. the outcomes measured and the length of follow up), the statistical significance of the results, and the clinical importance of any reported health benefits, were not always available. Also, the description of an individual study was sometimes inconsistent between systematic reviews.
- The systematic reviews varied in quality. Poor reporting and flawed methodology in individual studies was sometimes exacerbated by incomplete reporting in the systematic reviews.
- It was not possible to separate the evidence for clinical homeopathy and individualised homeopathy, because most of the systematic reviews did not analyse these separately.
- It was not possible to make conclusions about the effects of homeopathy on each of the specific health outcomes (e.g. pain, mobility) relevant to a particular health condition (e.g. arthritis), because of the large number of outcomes and the different reporting of outcomes between the different systematic reviews. Instead, outcomes were aggregated for each health condition and a single conclusion was made.
- It was often difficult to find the details of other treatments with which homeopathy was compared in research studies. To interpret the studies that compared homeopathy with another treatment, it is necessary to understand whether the other treatment was an effective standard treatment. This information was often not available from the systematic reviews.

## **NHMRC's interpretation of the assessment of the evidence on the effectiveness of homeopathy**

In line with NHMRC's function to "advising the community" under section 7(1)(a) of the *National Health and Medical Research Council Act 1992* (the Act) and based on the assessment of the evidence of effectiveness of homeopathy NHMRC believes:

- There is no reliable evidence that homeopathy is effective for treating health conditions.
- 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.
- People who are considering whether to use homeopathy should first get advice from a health professional (e.g. GP, specialist, nurse practitioner or pharmacist). Those who use homeopathy should tell their health professionals, and should keep taking any conventional medicines that they have been prescribed.

## Definition of special terms

|                                                       |                                                                                                                                                                                                                                                                                                                                                    |
|-------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Body of evidence                                      | The set of collected research evidence on a specified research question                                                                                                                                                                                                                                                                            |
| Complementary and alternative medicine                | The range of health care practices, therapies, procedures and devices that are not currently considered to be part of conventional medicine                                                                                                                                                                                                        |
| Controlled trial (controlled study)                   | A research study in which the treatment being evaluated was compared with either another treatment, or placebo (a treatment or substance known to have no health benefits), in similar groups of people with the health condition                                                                                                                  |
| Effectiveness (of a treatment for a health condition) | The extent to which a treatment works or not when used to treat health conditions in patients                                                                                                                                                                                                                                                      |
| Evidence (medical evidence or clinical evidence)      | Published findings of health research in humans using internationally accepted methods (e.g. studies that have been properly designed to assess whether or not a treatment is effective). It does not include individual experiences, testimonials or case reports, or research that was not done using standard methods.                          |
| Health condition (also clinical condition)            | Any medical condition or health problem that causes a person to have symptoms or causes physical changes that can be recognised by a health professional. Health conditions include side effects of treatments such as medicines or surgery.                                                                                                       |
| Homeopathy                                            | A type of complementary and alternative medicine (See <a href="#">What is homeopathy?</a> [page 5])                                                                                                                                                                                                                                                |
| Placebo (in research studies)                         | A sham treatment that is compared with the treatment being tested                                                                                                                                                                                                                                                                                  |
| Placebo effect                                        | An effect people experience when they believe that a treatment is effective, even if the treatment is a sham (e.g. an empty pill capsule or coloured water used in a research study)                                                                                                                                                               |
| Prospective trial (prospective study)                 | A research study that measures effects as they occur over time, beginning from an agreed time point (not by using records made in the past). The health outcomes to be measured are defined in advance, the way to measure the effects of treatment on these outcomes is planned in advance, and the results are then measured at specified times. |

|                             |                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Randomised controlled trial | A research study conducted in a standardised way to test whether a treatment is effective or not, by comparing it with another treatment or with placebo. This involves randomly allocating participants to receive the treatment or not, and measuring the effects on their health using pre-defined measurements.                                                                                                                    |
| Study (research study)      | A planned, structured scientific research project designed to see whether a treatment is effective in humans (e.g. a trial)                                                                                                                                                                                                                                                                                                            |
| Systematic review           | A type of research that involves searching for all the published evidence (e.g. research studies) to answer a particular question, such as whether a particular treatment is more effective than no treatment or as effective as another treatment for treating a specified health condition in a certain group of patients (e.g. children, adults). There are internationally accepted standards for good-quality systematic reviews. |

## The Homeopathy Working Committee

The Homeopathy Working Committee was made up of experts in evidence-based medicine, clinical trials, and complementary medicines research. The Committee's roles were:<sup>†††</sup>

- to guide an independent review of the evidence on the effectiveness of homeopathy. This included providing advice on methods of evaluating and interpreting relevant information.
- to guide NHMRC to produce a document that summarises current evidence on whether homeopathy is effective for health conditions, and give Australians information to help them make decisions about using homeopathy as part of their health care.

Homeopathy Working Committee members are listed in Table 2.<sup>§§§</sup>

*Table 2. The Homeopathy Working Committee*

| Name and qualifications                                                                          | Job title and other relevant roles                                                                                                                                                                                                                                                                                       |
|--------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Chair</b><br>Professor Paul Glasziou, MBBS, PhD, FRACGP                                       | General practitioner<br>Professor and Director of the Centre for Research into Evidence-Based Practice, Bond University, Queensland<br>Expert in evidence-based medicine                                                                                                                                                 |
| Professor Peter Brooks, AM, MBBS, MD (Lund), FRACP, FAFRM, FAFPHM, MDHonCausa, FRCP (Glas, Edin) | Rheumatologist<br>Director of the Australian Health Workforce Institute, University of Melbourne, Victoria (To September 2013)<br>Executive Director Research, Northern Hospital, Epping, Victoria<br>Former board member, Australian Centre for Complementary Medicine Education and Research, University of Queensland |
| Professor Frederick Mendelsohn, AO, MB BS, PhD, MD, FRACP                                        | Neuroscientist<br>Former Chair in Medicine and Director of the Howard Florey Institute, University of Melbourne, Victoria                                                                                                                                                                                                |
| Mr John Stubbs, BA, DipAcct                                                                      | Consumer<br>Executive Officer, canSpeak<br>Honorary Associate, School of Medicine, University of Sydney, New South Wales<br>Member, Australian Health Ethics Committee, NHMRC<br>Member, Consumer Consultative Group, NHMRC                                                                                              |
| Dr Evelin Tiralongo, BPharm(Hons), PhD, GradCertHigherEd                                         | Pharmacist<br>Senior lecturer and researcher, School of Pharmacy and Griffith                                                                                                                                                                                                                                            |

<sup>†††</sup> The Homeopathy Working Committee's full terms of reference are listed at NHMRC's *Complementary and alternative medicines* web page (<http://www.nhmrc.gov.au/your-health/complementary-and-alternative-medicines>).

<sup>§§§</sup> Information about individual committee members' credentials and conflicts of interest is available on the NHMRC website (<http://www.nhmrc.gov.au/your-health/complementary-and-alternative-medicines>).

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|--------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                  | <p>Health Institute, Griffith University, Gold Coast, Queensland</p> <p>Member, Clinical Trials Coordinating Centre, Griffith University</p> <p>Member, Society for Medicinal Plant and Natural Product Research</p>                                                                                                                                                             |
| <p>Dr Nikolajs Zeps, BSc(Hons), PhD</p>                                                                                                          | <p>Research scientist</p> <p>Director, St John of God Subiaco Hospital Research network</p> <p>Adjunct Associate Professor, School of Surgery and School of Pathology and Laboratory Medicine, University of Western Australia</p> <p>Adjunct Associate Professor, Faculty of Medicine, University of Notre Dame, Western Australia</p> <p>Member, Research Committee, NHMRC</p> |
| <p>Professor Chris Baggoley, AO, BVSc(Hons), MBBS, BSocAdmin, FACEM, FIFEM</p> <p>Member May 2012–March 2013</p> <p>Observer March–June 2013</p> | <p>Australian Government Chief Medical Officer</p>                                                                                                                                                                                                                                                                                                                               |

## References

1. Optum. Effectiveness of homeopathy for any clinical condition: evaluation of the evidence. Overview report. Canberra: NHMRC; 2013.
2. Optum. Effectiveness of homeopathy for any clinical condition: evaluation of the evidence. Review of submitted literature. Canberra: NHMRC; 2013.
3. National Health and Medical Research Council. NHMRC Strategic Plan 2010–2012. Canberra: NHMRC; 2010.
4. National Health and Medical Research Council. NHMRC Strategic Plan 2013–2015. Canberra: NHMRC; 2012.
5. World Health Organization. Safety issues in the preparation of homeopathic medicines. Geneva: WHO; 2009.
6. House of Commons Science and Technology Committee. Evidence check 2: Homeopathy. London: The Stationery Office; 2010.
7. Bornhöft G, Matthiessen P, editors. Homeopathy in healthcare – Effectiveness, appropriateness, safety, costs. Berlin: Springer; 2012.
8. NHMRC levels of evidence and grades for recommendations for developers of guidelines: NHMRC; 2009.
9. National Institute for Health and Clinical Excellence. Caesarean section. NICE clinical guideline 132 [Last modified August 2012]. London: NICE; 2011.
10. National Institute for Health and Clinical Excellence. Neonatal jaundice. NICE clinical guideline 98. London: NICE; 2010.
11. National Institute for Health and Clinical Excellence. Surgical management of otitis media with effusion in children. NICE clinical guideline 60. London: NICE; 2008.
12. National Collaborating Centre for Women's and Children's Health. Induction of labour. London: RCOG Press; 2008.
13. Royal College of Physicians. The management of lower urinary tract symptoms in men. NICE Clinical Guidelines No. 97. London: National Clinical Guideline Centre, The Royal College of Physicians; 2010.
14. National Collaborating Centre for Women's and Children's Health. Atopic eczema in children. Management of atopic eczema in children from birth up to the age of 12 years. London: RCOG Press; 2007.
15. British Homeopathic Association. The Science & Technology Select Committee Evidence Check on Homeopathy: British Homeopathic Association response to report: British Homeopathic Association; 2010 [cited 2013 September]. Available from: <http://www.britishhomeopathic.org/wp-content/uploads/2013/08/ST-parts-1-6.pdf>.
16. Shaw DM. The Swiss report on homeopathy: a case study of research misconduct. Swiss Med Wkly. 2012;142:w13594.