



Submission to the
Department of Health

*Consultation: Review of Pharmacy Remuneration and
Regulation Interim Report*

Prepared by the

Australian Homœopathic Association Inc.
PO Box 7108 Toowoomba South QLD 4350
admin@homeopathyoz.org

and

Australian Register of Homœopaths Ltd.
PO Box 1614 Wollongong DC NSW 2500
exec@aroh.com.au

To:
The Expert Panel
Review of Pharmacy Remuneration and Regulation
pharmacy.review@health.gov.au

23 July 2017

Table of Contents

Background:.....	2
Executive Summary.....	3
Introduction.....	4
Absence of expert consultation and perceived bias.....	4
Absence of consideration of relevant reports or consultation with relevant regulatory jurisdictions.....	5
‘Risk of harm’ argument - opinion, not evidence-based.....	6
TGA adverse reaction reporting confirms exemplary safety record of homeopathic products:.....	7
Positions of professional pharmacy bodies.....	7
Option 3-4 contrary to Pharmacy Review’s Strategic vision.....	7
Sale of homeopathic products in pharmacy overseas (EU).....	8
Breach of consumer/ civil rights.....	9
Strategic vision & WHO Traditional Medicines Strategy 2014-2023.....	10
Use of homeopathic medicines internationally:.....	10
Homeopathy’s ‘controversial’ mechanism of action & research NHMRC excluded from consideration.....	12
Real-world ‘effectiveness’ studies - excluded from NHMRC Review:.....	13
NHMRC Homeopathy Review.....	15
Expert peer reviewer feedback ignored and not publically disclosed:.....	17
The hidden ‘First Review’.....	18
Conflicts of interest:.....	19
Appendix A - Post-hoc, undisclosed Changes to the NHMRC (Optum) Homeopathy Review research protocol.....	20

Background:

The Australian Homoeopathic Association (AHA) and the Australian Register of Homoeopaths (AROH) welcome the opportunity to contribute a submission on the Department of Health’s consultation on the ‘Review of Pharmacy Remuneration and Regulation Interim Report’.

AROH is the chief registration body for professional homoeopaths in Australia; its role is to maintain accredited standards of practice that meet government and community standards.

The AHA is the main practitioner organisation representing professional homoeopaths in Australia.

Executive Summary

AHA/AROH strongly opposes Option 3-4 of the Interim Report to prevent the sale of homeopathic products in PBS-approved pharmacies.

Around a million Australians regularly use homeopathic products and services and pharmacies should cater to the needs of all Australians, not just those of a particular ideological viewpoint (who are free not to purchase homeopathic products). Option 3-4 does not reflect the views of the wider cross-section of the Australian community, 70% of which used natural medicine services and products (including homeopathic products).

The Panel did not conduct any face-to-face consultations with stakeholders or experts in homeopathic research in reaching the conclusion that “homeopathy and homeopathic products do not belong in community pharmacies”. The ‘Commissioned Research’ documents include no specific reference to any views on homeopathic products, instead acknowledging the overwhelming support for the inclusion of complementary medicines in pharmacy.

The independence and impartiality of Expert Panel member(s) is also questioned, on the basis of anti-complementary medicine/ homeopathy statements expressed in the public domain by Prof King, constituting a conflict of interest that mars the integrity of the Review process.

The Interim Report’s proposal solely references the National Health & Medical Research Council (NHMRC) review of homeopathy, which is not representative of the broader homeopathic research evidence base - 90% of which NHMRC excluded from scope of its review. For example, it excluded from scope any assessment of ‘effectiveness’, ‘safety’, ‘cost effectiveness’, ‘quality’, meta-analyses or *in vitro* laboratory studies that consistently demonstrate positive outcomes for homeopathy.

The Interim report selectively fails to present any consideration of this broader evidence base and other more comprehensive reports showing positive outcomes for homeopathy. For example, the findings of a comprehensive Swiss Health Technology Assessment, which assessed a far broader range of evidence categories than the NHMRC review, has (inappropriately) not been considered or presented to the public. The wealth of positive clinical and laboratory research data relating to homeopathy and homeopathic products (excluded from scope of the NHMRC Review) is not consistent with a therapy lacking in effect - *it is only consistent with a therapy and products with a therapeutic effect*.

Instead, the Interim Report references the position of groups such as the PSA - which are solely based on the flawed NHMRC report, thereby presenting a circular argument. The Interim Report does not take into account the widespread use of homeopathy internationally, nor its growth in popularity and demand.

Option 3-4 is incompatible with the principles of the Review’s ‘strategic vision’. It is also out of step with international best practice, for example the widespread use of homeopathic products in overseas Pharmacy (e.g. the European Union, India, South America), without any evidence of safety concerns. It is also not aligned with the goals of the World Health Organisation (WHO) ‘2014-2023 Traditional Medicines Strategy’, to which Australia is a party.

Homeopathic products have one of the best safety records of any class of medicine, as evidenced by the negligible number of adverse safety events registered with the Therapeutic Goods Administration (TGA). The Interim Report presents *no* research evidence to substantiate its ‘risk of harm’ argument, which constitutes opinion and is not evidence-based. The NHMRC Homeopathy Review excluded assessment of ‘safety’ from its scope and similarly, presented a position based on speculation and not evidence. By contrast, other reviews that have assessed the safety of homeopathic products and demonstrated their clinical and ‘real-world’ safety and effectiveness have been ignored.

Formal investigation of NHMRC's conduct of the Homeopathy has revealed bias, undisclosed conflicts of interest, maladministration, scientific misconduct and inaccurate reporting¹. This has been referred to the Commonwealth Ombudsman for review and is also subject to a call for a Senate inquiry into maladministration and scientific misconduct².

A report that excludes assessment of the vast majority of the available research evidence and that is under review for maladministration and scientific misconduct, cannot be used as a credible document to inform health policy - especially when it presents drastic options that impinge on consumers' basic right of choice and civil liberties. Thus, AHA/AROH dispute the use of this review as a source of evidence cited against the sale of homeopathic products in pharmacies.

Due to the absence of expert consultation, absence of consideration of international HTA reports, a perceived reliance on one review document (which excluded assessment of safety, effectiveness or cost effectiveness and is currently subject to an Complaint process with the Commonwealth Ombudsman), international best practice and a gross imposition of Government on the rights of consumers, that AHA/AROH strongly oppose Option 3-4 of the Interim Report.

Introduction

AHA/AROH welcomes the Review Panel's invitation to provide feedback on the proposed options and new information that may warrant consideration as the Panel develops its Final Report.

AHA/AROH did not provide a submission to the Review of Pharmacy Remuneration and Regulation Discussion Paper in July 2016, which did not identify homeopathic products as a special class of 'complementary medicines' under review.

The Interim Report's proposal to ban the sale of homeopathic products in pharmacies (Option 3-4) directly impacts the homeopathy sector, of which AROH and AHA are key stakeholders. The AHA/AROH submission pertains to Section 3-5 ('Homeopathic Products') and Option 3-4.

Absence of expert consultation and perceived bias

The Interim Report states (p.67):

"The general consensus as demonstrated by submissions to the Review and the Panel's face-to-face consultations is that homeopathy and homeopathic products do not belong in community pharmacies. The majority of pharmacists and other stakeholders argued that these products lack any evidence base and have sufficient evidence of non-efficacy to preclude their ethical sale in community pharmacies."

AHA/AROH note that the Expert Panel's consultation process was incomplete and imbalanced, evidenced by the fact that no face-to-face consultations were conducted with stakeholders or research experts in the homeopathy or complementary medicines sector. The "general consensus" referred to is indicative of a particular viewpoint, not necessarily representative of the broader community's and not that of stakeholders with expertise in homeopathy research evidence.

Indeed, the AHA/AROH express concern over anti-complementary medicine personal views expressed by Professor King during public briefings and media appearances (e.g. Four Corners, February 2017³), in particular towards homeopathic products.

¹ See www.nhmrchomeopathy.com

² 'Your Health Your Choice'. www.yourhealthychoice.com.au

³ 'King shares views on homeopathic drops and discounters', Pharmacy News, <http://www.pharmacynews.com.au/news/latest-news/king-share-views-on-homeopathic-drops-and-discount>

Such public comments constitute an explicit conflict of interest, bringing into question the “impartiality” and “independence” of the Review.

Further, AHA/AROH question the impartiality and independence of the Consumers Health Forum (CHF), which for many years has harboured anti-CM lobbyists such as Dr Ken Harvey and Ms Alison Marcus (Friends of Science in Medicine). In 2011, the negative NHMRC Draft Position Statement on homeopathy (developed in the absence of expert consultation or evidence assessment) was leaked to the media via the CHF, at the time when Dr Ken Harvey was the CHF’s ‘complementary medicines spokesperson’. The leak occurred the same day that AHA accidentally learned of the NHMRC Draft Statement process (20 April 2011).

The ‘Commissioned Research’ documents detailing research commissioned by the Review of Pharmacy Remuneration and Regulation contain no reference to any ‘consensus’, or to any other comments specifically relating to homeopathic products in pharmacy.

The absence of documentation substantiating such (alleged) feedback lacks transparency; the general public and other stakeholders are therefore being asked to accept what appears to be the subjective opinion of the Expert Panel, without recourse to any documented qualitative research data.

Absence of consideration of relevant reports or consultation with relevant regulatory jurisdictions

The Interim Report’s discussion is skewed around the claim that homeopathic products “*lack any evidence base and have sufficient evidence of non-efficacy*”, which is a polemic position, predicated solely upon the National Health & Medical Research Council (NHMRC) review of the evidence on homeopathy (as confirmed by the Interim Report), without reference to/ consideration of any other published evidence, or more comprehensive and balanced reports that have reached opposing conclusions.

For example, a comprehensive Swiss Health Technology Assessment (HTA) report published in English in 2012 officially concluded that evidence from laboratory studies and clinical research shows that homeopathy is clinically effective, cost effective and safe⁴. The Swiss HTA report found that 20 out of 22 systematic reviews of clinical trials into homeopathy showed a positive direction of evidence in favour of homeopathy and concluded:

“There is sufficient evidence for the preclinical effectiveness and the clinical efficacy of homeopathy and for its safety and economy compared with conventional treatment.”

The Swiss HTA report authors state that it, “*confirms homoeopathy as a valuable addition to the conventional medical landscape – a status it has been holding for a long time in practical health care.*”

It is unclear why the Expert Panel ignore such relevant research - particularly since the Swiss HTA assessed parameters of direct relevance to the Pharmacy Review (‘safety’, ‘quality’, ‘effectiveness’ and ‘cost-effectiveness’), *all* of which were excluded from the scope of the NHMRC Review.

Moreover, Switzerland:

- Is one of Australia’s close regulatory partners, part of the Australia-Canada-Singapore-Switzerland ([ACSS](#)) Consortium administered by the Therapeutic Goods Administration (TGA). The stated goal of the Consortium is “*to maximise international cooperation, reduce duplication, and increase each agency’s capacity to ensure consumers have timely access to high quality, safe and effective therapeutic products*”.

⁴ Homeopathy in Healthcare: Effectiveness, Appropriateness, Safety, Costs by Gudrun Bornhöft and Peter F. Matthiessen (Editors). 2011. ISBN 978-3-642-20637-5

- These goals are of direct relevance to the Expert Panel's deliberations.
- In June 2017, contemporary to the Pharmacy Review consultation period, the Swiss Federal Government announced that specific medical services using complementary medicine, including homeopathy, are to be covered by mandatory health insurance, acknowledging that complementary medicine (including homeopathy) meets statutory regulations when it comes to effectiveness, guaranteeing high quality and safety⁵ (noting, "By law, only those services that are effective, appropriate and cost-effective (art. 32 of the requirements of the Federal Act on Health Insurance) can be covered").

AHA/AROH express concern that the Expert Panel has not consulted on, considered or presented to the public the findings of such international best practice developments - in this case, by one of Australia's closest regulatory partners belonging to a Consortium administered under the umbrella of the Department of Health.

'Risk of harm' argument - opinion, not evidence-based

The Interim Report provides the following rationale (p.68), echoing the 'risk of harm due to absence of evidence of efficacy' position of the 2015 NHMRC Statement on Homeopathy:

"In particular, the Panel notes that the supply of homeopathic products through pharmacies is not benign but, rather, risks creating a perception of reliability and efficacy in the mind of the consumer based on the status of the pharmacy as a healthcare provider. This may encourage patients to choose a homeopathic product over a conventional medicine with robust evidence of efficacy, which creates a risk of harm to the patient's health."

The NHMRC Homeopathy Review did not include any assessment of the 'safety' of homeopathy, nor any studies comparing the relative benefits/risks of using homeopathy versus conventional medicine; in fact all safety studies submitted to NHMRC during the Review were excluded as 'out of scope'. Yet the NHMRC Statement on Homeopathy claims, "People who choose homeopathy may put their health at risk".

The presence of this statement within a section called "NHMRC's interpretation of the assessment of the evidence on the effectiveness of homeopathy" **misleads the public into believing that it is based on the findings of their Overview, when it is not. It is speculation, not evidence-based.**

This false impression is strengthened further by NHMRC repeatedly and inaccurately describing the Homeopathy Review to the public as a 'Health Technology Assessment' (HTA)⁶. HTAs by definition do assess safety, but NHMRC did not conduct a HTA, it conducted an 'Overview' and excluded all customary HTA parameters, with the exception of 'efficacy'.

In adopting the NHMRC's position, the Expert Panel is adopting (without critical evaluation) a position based on **opinion, not assessment of evidence**. By contrast, the Swiss HTA report (referenced above) *did* assess 'safety' evidence in reaching its conclusion, "There is sufficient evidence for the preclinical effectiveness and the clinical efficacy of homeopathy and for its safety and economy compared with conventional treatment."

- The critical flaws of the NHRMC Review, including its extensive exclusion criteria (preventing the results of 97% of the included efficacy studies from contributing to the Review's findings), are outlined below in the submission.

⁵ Dakomed press release, 'Complementary medicine in Switzerland now a mandatory health insurance service'. <https://www.dakomed.ch/>

⁶ NHMRC Information Paper, p.5 & 38; FAQ document, p.4, 9 & 11; Administrative Report, p.5-6.

Further, in overseas jurisdictions where homeopathic medicines are available through pharmacy and are popular and widely used (such as in European Union countries), no evidence exists that they are associated with any 'safety' risks.

TGA adverse reaction reporting confirms exemplary safety record of homeopathic products:

The TGA measures the risk profile of products on the Australian Register of Therapeutic Goods (ARTG) according to adverse reactions and international safety data.

The TGA Database of Adverse Event Notifications (DAEN)⁷ confirms that homeopathic products have an exemplary safety record - one of the best of any class of medicine. This is consistent with overseas data.

Positions of professional pharmacy bodies

The Interim Report's reference to the positions of 'professional pharmacy bodies' such as Pharmaceutical Society of Australia (PSA), included to give 'weight of consensus' to its position, presents a circular argument, since such bodies have based their positions on the same flawed NHMRC report.

As the PSA 'Position Statement on Homeopathy' confirms⁸:

"PSA endorses the NHMRC report, released in March 2015..."

Option 3-4 contrary to Pharmacy Review's Strategic vision

The Interim Report's recommendation that, "*homeopathy and homeopathic products should not be sold in PBS-approved pharmacies*" does not meet the criteria of the Pharmacy Review's 'strategic vision': that is, "*there will be a need for a greater focus on integrated, rather than episodic, care*" (p.3), which is:

- 'Consistent with a forward-looking, twenty-year time frame'
- 'Allows and encourages innovation in community pharmacy is adaptable to the changing needs of the Australian public and the broader healthcare system'
- 'Is adaptable to the changing needs of the Australian public and the broader healthcare system'.

The removal of homeopathic products is neither 'forward-looking', 'encourages innovation' nor consistent with 'adapting to the changing needs of the Australian public'.

Of particular concern to AHA/AROH is the Expert Panel's **sole reliance on/ reference to the NHMRC Homeopathy Review, which excluded from scope over 90% of the available research evidence on homeopathy.**

- The NHMRC (mis)informed the community that the findings of the Homeopathy Review was the result of a "*rigorous assessment of over 1,800 papers*"⁹. In fact only 176 studies were included in scope of the NHMRC Overview, with the rest ignored altogether (see p.11 of the Optum Overview Report, which also shows 367 of the "1800 papers" were duplicate citations).

⁷ <https://www.tga.gov.au/database-adverse-event-notifications-daen>

⁸ <http://www.psa.org.au/downloads/ent/uploads/filebase/policies/position-statement-complementary-medicines.pdf>

⁹ NHMRC Releases Statement and Advice on Homeopathy, NHMRC media release, 11 March 2015

The Pharmacy Review *exclusively* cites the NHRMC report, without critical evaluation of its significant limitations and flaws (outlined below). It also does not provide evidence that it has considered the broader evidence base, which was excluded from scope of the NHMRC Review (i.e. 'effectiveness', 'cost-effectiveness', 'safety' and 'quality' studies and other published reviews and reports).

AHA/AROH express concern that the Expert Panel's approach is indicative of a partial approach being taken to the subject.

AHA/AROH considers this approach to be inappropriate to the Pharmacy Review process, especially where such a drastic measure to remove citizens' right of choice to an entire healthcare option in pharmacy is being proposed. This is also particularly in light of this class of medicines having:

1. A demonstrated (and un-refuted) record of safe use in Australia and internationally
2. Both a research profile and history of traditional use that is indicative of therapeutic products demonstrating efficacy, effectiveness and safety.

In Australia, the largest manufacturers of homeopathic products comply with Good Manufacturing Practice (GMP) standards prescribed by the TGA, thereby also ensuring that their products sold in pharmacy comply with community expectations of quality.

Sale of homeopathic products in pharmacy overseas (EU)

The Interim Report does not provide any contextual information or analysis relating to the sale of homeopathic products in international jurisdictions. The European Union (EU) provides a pertinent context relating to the sale of homeopathic products in pharmacy, given widespread prevalence and support from both pharmacy and community. In the EU, there is strong support amongst pharmacies to sell homeopathic products, given such a large proportion of the population use and benefit from them.

The EU is a highly regulated jurisdiction, where 29% of EU citizens regularly use homeopathic products to support their healthcare needs (representing over 100 million Europeans who use over-the-counter or prescribed homeopathic medicines)^{10,11}.

Since 2003, the demand for homeopathic and anthroposophic medicinal products has increased by 20%, in response to growing demand by European citizens¹². There is significant/ high demand for homeopathic and anthroposophic medicinal products in at least two thirds of EU Member States and the EU market for homeopathic and anthroposophic medicinal products is valued at €1.24 billion a year (ex-factory sales)¹³.

In the EU, almost all sales to the public of homeopathic medicinal products occur through retail pharmacies. In most EU countries, homeopathic medicinal products are exclusively sold in pharmacies, since they are classed as medicinal products (only in some Scandinavian countries, such as Sweden, are they sold out of pharmacies, due to regional low population density).

¹⁰ di Sarsina PR, Iseppato I, 2011, Looking for a person-centred medicine: non-conventional medicine in the conventional European and Italian setting, *Evidence-based Complementary and Alternative Medicine*, vol 2011, article id 382961

¹¹ European Commission, 2007. http://www.echamp.eu/eu-legislation-and-regulation-documents/Commission_Report_Dir_9273_and_9274_Homeo_July_1997.pdf

¹² ECHAMP, *Homeopathic and Anthroposophic Medicine in Europe. Facts and Figures*, ECHAMP E.E.I.G, Brussels, Belgium, 2007

¹³ ECHAMP, *A thriving European tradition*. <http://www.echamp.eu/our-sector>

The pattern of usage of homeopathic products in EU community pharmacy illustrates the widespread integration and acceptance of homeopathic products by the medical and pharmacy sector¹⁴:

2.4 Need for information

Citizens express a wish for more support and information regarding complementary and alternative medicine (CAM) from the medical professionals. They need and want easily accessible and trustworthy information that can support an informed decision about treatment options.³¹

Word-of-mouth recommendation from friends and family is still the main reason users try homeopathy, although recommendations from doctors and pharmacists are also important.

Market surveys show:

- 67% of **Germans** try homeopathy on the recommendation of a friend or family member, 53% on the recommendation of a doctor or practitioner and about a third (37%) on the recommendation of the pharmacist;³²
- in **Italy**, 31% of users were first recommended a homeopathic medicine by a specialist, 23% by a friend or family member, 22% by their general practitioner and 16% by a pharmacist;³³
- 34% of **Belgians** use homeopathy on the recommendation of a close friend or relative, while 27% and 25% do so on the recommendation of their doctor or pharmacist respectively,³⁴ although 36% of Belgians also turn to the internet for information;³⁵
- a similar picture in **Spain**: 53% of Spanish people have heard about homeopathy from friends or family, and 21% from their pharmacist or doctor.³⁶

Breach of consumer/ civil rights

Such an extreme proposal to ban the sale of an entire class of medicines impinges on consumer right of access to medicines of their choice and is a civil liberties issue. *Singling out* a particular class of medicines for government prohibition that:

- Have been available in pharmacies for decades both in Australia and multiple overseas jurisdictions without any real-world evidence of ‘safety risk’ or harm (real or perceived)
- Are underpinned by a growing body of evidence showing efficacy, effectiveness, cost-effectiveness, safety and quality
- Are being increasingly used and demanded by consumers (including by around a million Australians)

represents an extraordinary and unprecedented imposition on behalf of government on consumer choice.

The Expert Panel would be aware that no precedent exists for an entire class of medicines to be targeted for selective prohibition of sale, particularly where they are underpinned by a long traditional history of use and growing research evidence base demonstrating efficacy and effectiveness.

Yet the Expert Panel is proposing such an extreme option on the *sole* basis of a deeply flawed (NHMRC) report that excluded for consideration the vast majority of this extant evidence base.

¹⁴ Homeopathic and Anthroposophic Medicinal Products in the EU - Profile of an industry 2015.
<http://www.echamp.eu/echamp-resources/echamp-brochures/november2015-profile-of-an-industry.pdf>

AHA/AROH notes the Expert Panel's recognition that, "*regulation presents costs to the public, the government and the participants in the medicine supply chain. Regulation must be sufficient but not excessive and must underpin sustainable consumer access.*"

Further, the PSA ethics guidelines (Care Principle 2) states that a pharmacist must "*respect patient choice*". The Interim Review Option 3-4 is not consistent with this guiding principle.

Option 3-4 involves an excessive level of regulation (i.e. prohibition) that is discriminatory, inconsistent with a growing profile of positive research evidence and prevents sustainable consumer access.

Strategic vision & WHO Traditional Medicines Strategy 2014-2023

The World Health Organisation (WHO) *Traditional Medicine Strategy 2014-2023*, to which Australia is a signatory, acknowledges that forms of complementary medicine (CM) such as anthroposophic medicine, chiropractic, homeopathy, naturopathy and osteopathy are in "extensive use".

The WHO Strategy acknowledges the important role of traditional medicines (including homeopathy) to global community health into the future and "*aims to support Member States in developing proactive policies and implementing action plans that will strengthen the role traditional medicine plays in keeping populations healthy*".

This aim, which encompasses ensuring community access to homeopathic medicine, directly aligns with the stated principles of the 'strategic vision' of the Pharmacy Review.

Any proposal to remove homeopathic medicines from pharmacy not only contravenes the principles of the Review's strategic vision, it is also out of step with international best practice and with Australia's obligations under the WHO's goal to improve global health by ensuring access to traditional forms of medicine, which includes homeopathy as an extensively used class of therapeutic goods.

Use of homeopathic medicines internationally:

The widespread and growing popularity and use of homeopathy/ homeopathic products worldwide **is not consistent with a therapeutic system lacking a therapeutic effect** - irrespective of whether its mechanism of action is currently well understood.

Homeopathy is a traditional system of medicine used and practiced in the majority of countries. Worldwide, over 200 million people use homeopathy on a regular basis^{15,16} (a conservative estimate). It is integrated into the national healthcare systems of a number of countries e.g. Brazil, Chile, France, Germany, India, Mexico, Pakistan, Switzerland, United Kingdom.

Further, homeopathy is formally taught in the curricula of pharmacy schools in many countries, for example in France and Brazil.

¹⁵ Prasad R. Homeopathy booming in India. *Lancet*, 2007; 370:1679-80

¹⁶ Homeopathic medicinal products. Commission report to the European Parliament and the Council on the application of Directives 92/73 and 92/74

Homeopathy, alongside other CM therapies, has been covered by public and private insurance in many countries since the 1990s, with an increasing number of medical professionals being interested in integrating such therapies¹⁷.

This coverage and increase in usage is based on its record of 'effectiveness' (real-world observational and cohort studies), 'safety', 'quality' and 'cost effectiveness', which remains refuted by evidence to the contrary.

- It is important to note that the NHMRC Homeopathy Review, which the Pharmacy Review cites to the exclusion of any other evidence (suggestive of a partial approach), excluded in its entirety all real-world clinical studies and other relevant evidence customarily assessed during Health Technology Assessment.

This excluded body of evidence consistently demonstrated the 'safety', 'effectiveness' and 'cost-effectiveness' of homeopathy/ homeopathic medicines in real-world clinical settings, .

Following are examples of the usage of homeopathy internationally (which is not comprehensive):

In India, there are two categories of CM practitioners, with 785,185 registered Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) practitioners¹⁸ and an estimated one million village-based, traditional AYUSH community health workers¹⁹. India leads in terms of number of people using homeopathy, with 100 million people depending solely on homeopathy for their primary medical care²⁰. There are over 200,000 registered homeopathic doctors currently in India, with approximately 12,000 more being added every year²¹.

In France, a significant proportion of French doctors specialise in homeopathy and acupuncture, which are reimbursed by the French Social Security scheme. In Belgium, the Socialist Mutual Insurance of Tournai-Ath in Belgium has partially reimbursed specific CM treatments such as homeopathic remedies since 1997.

In Finland, acupuncture and other complementary/alternative therapies are covered by the Social Insurance Institution (SII). In Germany, public and private insurance provides the same kind of coverage for some complementary/alternative treatments²².

In Switzerland, specific medical services using complementary medicine, including homeopathy, are now covered by mandatory health insurance, acknowledging that complementary medicine (including homeopathy) meets statutory regulations when it comes to effectiveness, guaranteeing high quality and safety²³ (as also outlined above).

¹⁷ WHO traditional medicine strategy: 2014-2023

¹⁸ AYUSH in India. New Delhi, Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH), 2010 (<http://www.indianmedicine.nic.in/index1.asp?lang=1&linkid=18&lid=42>).

¹⁹ Report of the Steering Committee on AYUSH for 12th Five Year Plan (2012–17). New Delhi, Ministry of Health and Family Welfare Planning Commission, 2011.

²⁰ Prasad R. Homoeopathy booming in India. *Lancet*, 2007; 370:1679-80

²¹ Ghosh AK. A short history of the development of homeopathy in India. *Homeopathy*, 2010;**99**(2):130-6

²² World Health Organization. Legal status of traditional medicine and complementary/ alternative medicine: a worldwide review: WHO/EDM/TRM/2001.2. Geneva, World Health Organization, 2001.

²³ Dakomed press release, 'Complementary medicine in Switzerland now a mandatory health insurance service'. <https://www.dakomed.ch/>

Homeopathy's 'controversial' mechanism of action & research NHMRC excluded from consideration

The basis of the controversy surrounding homeopathy is its poorly understood mechanism of action, which underpinned the NHMRC's prejudgment of homeopathy's 'implausibility'²⁴. This viewpoint appears to underpin similar anti-homeopathy prejudice evident in the Interim Report (through its sole reliance on the NHMRC report, absence of consideration of the broader evidence base and lack of expert stakeholder consultation).

It is important to note that the NHMRC Homeopathy Review excluded from scope the research evidence base pertaining to this topic (i.e. laboratory studies where the 'placebo effect' is not a relevant factor). This is an active area of cutting edge research²⁵ that shows, on balance, that homeopathic medicines are biologically active:

- Around 75% of *in vitro* experiments on ultra-high dilutions (where there is no 'placebo effect') show the substance having an effect, and nearly 75% of replications have been positive²⁶. Reproducibility is increasing as scientists gain more experience and gradually understand what factors are influencing the results²⁷.

Many laboratory studies have shown that ultra-high dilute homeopathic medicines have biological effects; inconsistent with the claim they are 'just water' or 'just sugar pills'. For example, basophil (white blood cell) degranulation experiments:

- 28 scientific papers have been published on this topic, 23 of which reported positive results. 11 publications have been judged to be of high quality, of which 8 report positive results²⁸.

A further example includes research in amphibians. Over almost 20 years, various teams have tested homeopathic dilutions of thyroxine on frogs by adding it to the bathing water tadpoles are kept in (in amphibians, the hormone thyroxine stimulates metamorphosis):

- An independent meta-analysis of these trials identified 22 experiments – 15 carried out by the original team in Austria and 7 by independent researchers²⁹. All 22 experiments found the same trend – that thyroxine 30X (diluted beyond Avogadro's limit using the homeopathic manufacturing process) inhibits metamorphosis, though the exact results varied.
- This effect has now been observed and confirmed by 7 researchers from Austria, Germany, Switzerland and the Netherlands.

²⁴ 2010/11 (leaked) Draft Position Statement on Homeopathy; NHMRC Complementary Medicines webpage 2012-2015.

²⁵ <https://www.hri-research.org/hri-research/how-do-homeopathic-medicines-work/>

²⁶ Witt CM, Bluth M, Albrecht H, Weissshuhn TE, Baumgartner S, Willich SN. The in vitro evidence for an effect of high homeopathic potencies—a systematic review of the literature. *Complement Ther Med.*, 2007; **15**(2): 128-38

²⁷ Endler P, Thieves K, Reich C, Matthiessen P, Bonamin L, Scherr C, Baumgartner S. Repetitions of fundamental research models for homeopathically prepared dilutions beyond 10(-23): a bibliometric study. *Homeopathy*, 2010; **99**(1):25-36

²⁸ Witt CM, Bluth M, Albrecht H, Weissshuhn TE, Baumgartner S, Willich SN. The in vitro evidence for an effect of high homeopathic potencies—a systematic review of the literature. *Complement Ther Med.*, 2007; **15**(2):128-38

²⁹ Harrer B. Replication of an experiment on extremely diluted thyroxine and highland amphibians. *Homeopathy*, 2013; **102**(1):25-303

Recent breakthrough research investigating the physico-chemical properties of high dilutions has confirmed their effect on specialist (solvatochromic) dyes³⁰. Spectral changes observed with these dyes in the presence of homeopathically prepared potencies have been found to be “both substantial and reproducible”³¹. This research has been published in the last two years, post-publication of the NHMRC Review.

Such a research profile is consistent with interventions that have therapeutic effects - and inconsistent with those lacking any evidence of clinical effects.

The Expert Panel should note that this evidence base was excluded from scope of the NHMRC Homeopathy Review in its entirety. Yet NHMRC pre-judged homeopathy to be ‘implausible’, without testing this presumption - by excluding from scope the assessment of published peer-reviewed research in this area. NHMRC’s position was therefore founded on *opinion*, not evidence; **as such it cannot be used or relied upon to inform health policy.**

Real-world ‘effectiveness’ studies - excluded from NHMRC Review:

Observational studies examining the ‘effectiveness’ of homeopathic interventions in real-world clinical settings consistently report positive outcomes for patients. This evidence, of direct relevance to the Pharmacy Review’s consideration of the real-world benefits of homeopathic products to community health, **was excluded from scope of the NHMRC Homeopathy Review in its entirety.**

Evidence from observational studies provides insight into changes in patients who have received homeopathic treatment. These studies consistently show that patients improve clinically following homeopathic treatment (often from chronic, difficult to treat conditions); some also highlight areas of potential economic benefit for the health system as a whole in terms of reduced prescribing of conventional drugs. Examples of good quality studies include (see <https://www.hri-research.org/resources/homeopathy-the-debate/essentialevidence/observational-studies/>):

In Germany, a study commissioned by a German health insurance company to determine whether to continue covering homeopathic treatment assessed the value of homeopathy in treating chronic conditions commonly seen in general practice³². In this study, 493 patients (315 adults, 178 children) treated by general practitioners received either conventional medicine or homeopathy. The study found that patients in the homeopathy group reported greater improvement than the conventional medicine group ($p=0.002$) with no significant difference in cost.

- The physicians’ assessments also showed that children who received homeopathy had a better clinical response than those who received conventional medicine ($p<0.001$). Conditions treated included headache, low back pain, depression, insomnia and sinusitis in adults, and atopic dermatitis, allergic rhinitis and asthma in children. Following publication of this study the insurance company (Innungskrankenkasse Hamburg) decided to continue to cover homeopathic treatment.

³⁰ Cartwright SJ. Solvatochromic dyes detect the presence of homeopathic potencies. *Homeopathy* 2016; 105: 55e65 ([http://www.homeopathyjournal.net/article/S1475-4916\(15\)00062-4/fulltext](http://www.homeopathyjournal.net/article/S1475-4916(15)00062-4/fulltext))

³¹ Interaction of homeopathic potencies with the water soluble solvatochromic dye bis-dimethylaminofuchson. Part 1: pH studies Cartwright, SJ. *Homeopathy*, 2017; **106**(1):37-46 (<https://www.hri-research.org/wp-content/uploads/2017/03/Cartwright-pH-studies-2017.pdf>)

³² Witt C, Keil T, Selim D, et al. Outcome and costs of homeopathic and conventional treatment strategies: a comparative cohort study in patients with chronic disorders. *Complement Ther Med*, 2005; **13**: 79-86

A multi-centre, 8-year longitudinal cohort study that followed over 3,500 adults and children receiving routine homeopathic care from GPs, found that “patients who seek homeopathic treatment are likely to improve considerably” - experiencing steady, long-term health benefits³³.

- At the start, 97% of participants were diagnosed with a chronic complaint, with 95% declaring prior conventional treatment for their condition. Disease severity decreased significantly ($p < 0.001$) between the start of the study, after 2 years and after 8 years of homeopathic treatment. Notably, after 8 years, figures were almost identical to 2-year follow-up, indicating steady long-term health benefits.

Four published observational studies carried out from 1999 to the present day have tracked the outcome of patients being treated at UK National Health Service (NHS) homeopathic hospitals. These studies consistently show that patients improve clinically following homeopathic treatment (often from chronic, difficult to treat conditions); some also highlight areas of potential economic benefit in terms of reduced prescribing of conventional drugs.

- The largest study at Bristol Homeopathic Hospital followed over 6,500 consecutive patients with over 23,000 attendances in a six-year period³⁴. 70% of follow-up patients reported improved health; 50% reported major improvement.

The most common diagnostic groups were Dermatology, Neurology, Rheumatology, Gastroenterology, Psychiatry and Ear, Nose & Throat. The largest improvements were reported in childhood eczema or asthma, and in inflammatory bowel disease, irritable bowel syndrome, menopausal problems and migraine.

- An outcome survey carried out at the Liverpool department of homeopathic medicine over a 12 month period in 1999-2000 surveyed 1,100 patients³⁵; 76.6% reported an improvement in their condition since starting homeopathic treatment and 60.3% regarded their improvement as major. 814 patients were taking conventional treatment for their condition and 424 (52%) of these were able to reduce or stop conventional medication.

The main conditions treated were osteoarthritis, eczema, chronic fatigue syndrome, asthma, anxiety, headaches, inflammatory arthritis and irritable bowel syndrome

- A 500-patient survey at the Royal London Homeopathic Hospital showed that many patients were able to reduce or stop conventional medication following homeopathic treatment³⁶. The extent of improvement varied between diagnoses e.g. 72% of patients with skin complaints reported being able to stop or reduce their conventional medication; for cancer patients there was no reduction. The study also showed that many patients seek homeopathy because of their concerns about the safety of conventional treatment.

A recent randomised controlled trial carried out in a public research hospital in Mexico City assessed two treatments for moderate to severe depression in 133 menopausal women³⁷. This study, published in 2015, found that both individualised homeopathic treatment and Fluoxetine (a.k.a. Prozac) were safe and more efficacious than placebo. However, homeopathy resulted in

³³ Witt, C. M., Lüdtkke, R., Mengler, N. & Willich, S. N. How healthy are chronically ill patients after eight years of homeopathic treatment?--Results from a long term observational study. *BMC Public Health* 8, 413 (2008).

³⁴ Spence D, Thompson E A, Barron S J. Homeopathic treatment for chronic disease: a 6-year university-hospital outpatient observational study. *J Altern Complement Med*, 2005; **5**: 793-798

³⁵ Richardson W R. Patient benefit survey: Liverpool Regional Department of Homoeopathic Medicine. *Br Homeopath J*, 2001; **90**: 158-162

³⁶ Sharples F, van Haselen R, Fisher P. NHS patients' perspective on complementary medicine. *Complement Ther Med*, 2003; **11**: 243-248

³⁷ Macías-Cortés, E. d. C., Aguilar-Faisal, L. & Asbun-Bojalil, J. (2013) Efficacy of individualized homeopathic treatment and fluoxetine for moderate to severe depression in peri- and postmenopausal women (HOMDEP-MENOP): study protocol for a randomized, double-dummy, double-blind, placebo-controlled trial, *Trials*, **14**:105

greater clinical improvement in symptoms of depression than fluoxetine, and also improved the patients' menopausal symptoms, whereas fluoxetine did not.

Homeopathy is widely used in France and a major study following 8,559 patients attending GP practices (2008-2012) was used to assess the effectiveness of homeopathic treatment. This 'EPI3 study'³⁸ was managed by LA-SER a UK-based company specialised in scientific evidence for medicine and health technologies (<http://www.la-ser.com/>). The project team included individuals from high-profile institutions such as the Institut Pasteur in Paris, University of Bordeaux and McGill University, Montreal; Lucien Abenheim is the French General Director of Health (Surgeon General).

Key findings of the EPI3 project were:

- **Upper respiratory tract infections (URTIs)**
Patients treated by GPs trained in homeopathy did as well clinically as those treated with conventional medicine, but used fewer conventional drugs³⁹.
- **Musculoskeletal disorders (MSDs)**
Patients treated with homeopathy did as well clinically as those treated with conventional medicine, but used only half the amount of non-steroidal anti-inflammatory drugs (NSAIDs) and had fewer NSAID-related side effects⁴⁰.
- **Sleep, anxiety and depressive disorders (SADD)**
Patients treated by certified homeopathic physicians were less likely to be prescribed psychotropic drugs⁴¹.

NHMRC Homeopathy Review

AHA/AROH express concern at the Expert Panel's sole reliance on the 2015 NHMRC Homeopathy Review (that concluded there was 'no reliable evidence' for homeopathy in treating health conditions) as "evidence" to support Option 3-4.

The Expert Panel should note the following. NHRMC informed the public that it "rigorously assessed over 1800 papers" in reaching its conclusions, whereas only 176 Randomised Controlled Trials (RCTs) were included in scope (as outlined above).

Of these 176 RCTs, around 50% reported statistically significant (positive) outcomes for the homeopathic interventions they tested, with only 5% being negative and the rest 'inconclusive'⁴². This is a strikingly similar proportion to that seen in conventional research⁴³

³⁸ Grimaldi-Bensouda, L. et al. Benchmarking the burden of 100 diseases: results of a nationwide representative survey within general practices. *BMJ Open*, 2011; **1**: e000215

³⁹ Grimaldi-Bensouda, L. et al. Management of upper respiratory tract infections by different medical practices, including homeopathy, and consumption of antibiotics in primary care: the EPI3 cohort study in France 2007-2008. *PLoS One*, 2014; **9**: e89990

⁴⁰ Rossignol, M. et al. Impact of physician preferences for homeopathic or conventional medicines on patients with musculoskeletal disorders: results from the EPI3-MSD cohort. *Drug Saf.*, 2012; **21**: 1093-1101

⁴¹ Grimaldi-Bensouda, L. et al. Who seeks primary care for sleep, anxiety and depressive disorders from physicians prescribing homeopathic and other complementary medicine? Results from the EPI3 population survey. *BMJ Open*, 2012; **2**

⁴² Australian Register of Homeopaths submission to NHMRC, 2013.

⁴³ El Dib RP, Atallah AN, Andriolo RB. Mapping the Cochrane evidence for decision making in health care. *J Eval Clin Pract*, 2007; **13**(4):689-92

Of 104 *placebo-controlled* RCTs published in peer-reviewed journals by the end of 2014 (before NHMRC published its report), 41% were positive, 54% inconclusive and only 5% negative⁴⁴ - again a strikingly similar proportion to that observed in published conventional medical research.

The question is, how did NHMRC develop definitively negative findings of “no reliable evidence” based on the basis of a relatively small but predominantly positive RCT evidence base?

The answer to this question has been revealed through a formal two-year investigation, uncovering bias, undisclosed conflicts of interest, procedural irregularities, methodological flaws and inaccurate reporting.

As a result of the investigation, a formal Submission of Complaint has been lodged with the Commonwealth Ombudsman to investigate issues of maladministration (see below).

Stakeholders are also calling for a Senate Inquiry into maladministration and scientific misconduct associated with the NHMRC’s conduct of the Homeopathy Review.

Resources and links:

- NHMRC Review investigation information website: www.nhmrchomeopathy.com
- Executive Summary to Ombudsman Complaint: <https://www.hri-research.org/wp-content/uploads/2017/04/Executive-Summary-to-Ombudsman-Complaint-re-NHMRC-Homeopathy-Review-FINAL.pdf>
- Link to YouTube video, expert scientific analysis of NHMRC Review: <https://www.youtube.com/watch?v=QvF8KxbCXzA>
- Senate petition to investigate NHMRC conduct (via): www.yourhealthychoice.com.au (<https://www.yourhealthychoice.com.au/wp-content/uploads/2017/07/Senate-Petition-2.pdf>)

In uncritically accepting the NHMRC’s position, the Expert Panel is, by default, endorsing the NHMRC’s conduct and unique thresholds for assessing the “reliability” of evidence.

That is, NHMRC determined that for the results of a randomised controlled trial (RCT) to be considered “reliable”, it would need to satisfy the following *minimum thresholds*:

1. **Have at least 150 trial participants** - irrespective of the trials’ statistical significance or the presence of power calculations; AND
2. **Be given an unusually high (100%) quality rating** - i.e. 5/5 on the Jadad scale (or the equivalent using another rating scale).

Any trial that did not meet either of these thresholds was dismissed from “any further consideration”⁴⁵; this meant its results did not contribute (at all) to the Review’s findings.

What the NHMRC did not inform the public was:

- **These arbitrary thresholds dismissed the results of 171 out of the 176 Overview studies (97%) from any consideration in the findings, effectively reducing the entire Review to only 5 “reliable trials”^{46,47}**

⁴⁴ Faculty of Homeopathy (UK), <http://facultyofhomeopathy.org/research/>

⁴⁵ NHMRC Information Paper, p.35

⁴⁶ Independent expert analysis of NHMRC’s methods and data, Homeopathy Research Institute (HRI), included in Ombudsman Submission of Complaint

- **The thresholds were created and applied to the data many months *after* the research protocol had been agreed and finalised⁴⁸ and after the contractor (Optum) had already completed the evidence assessment⁴⁹.**

These *post-hoc* changes to the research protocol were **not disclosed in NHMRC's reporting of the Review**, despite the fact they underpinned the Review's published findings. Thus, customary (and required) safeguards protecting scientific inquiry processes from bias were removed, meaning that the Review's findings could be manipulated in whatever way NHMRC wanted.

- **Appendix A details the *post-hoc* changes made to the Optum Review research protocol and their impact on the Review's findings.**
- **See also:** <http://www.nhmrchomeopathy.com/incaccuratereporting.html>

Furthermore, the concept of “reliable” evidence is entirely unique to the NHMRC Review. This is why the framework and its component criteria are:

- Not recognised by any scientific standards;
- Have never been applied by any other research group (including NHMRC) before or since;
- Not recognised by TGA evidence guidelines; thus not applied by TGA to the assessment of any class of medicine (including registered prescription drugs).

For example, NHMRC regularly funds and collaborates on trials with fewer than 150 participants, which are not regarded as “unreliable” (while noting that the highly respected *BMJ* Clinical Evidence Reviews accepting trials with as few as 20 participants, with smaller trials being acceptable for review in areas where little research evidence exists⁵⁰).

By accepting the findings of the NHMRC report, the Expert Panel is endorsing these scientifically unjustifiable criteria and holding homeopathic evidence to a much higher evaluation standard than any other class of product, as a measure of whether they are ‘evidence based’.

If the Expert Panel is to accept these thresholds being applied to homeopathic products, it would also need to accept their application to all other classes of medicines sold in community pharmacy, thereby demonstrating observance of equity principles in its process.

The Expert Panel has an ethical duty to take account of the above information, now that it is in full knowledge of the serious flaws associated with the NHMRC Homeopathy Review process (particularly in light of the NHMRC Review being the sole evidence cited).

Expert peer reviewer feedback ignored and not publically disclosed:

The NHMRC ignored and did not publicly disclose expert peer reviewer feedback that disagreed with its findings and methods, despite publishing a dedicated ‘Expert reviewer comments’ document.

For details, see: <http://www.nhmrchomeopathy.com/unreported.html>

Examples of significant obfuscated peer review feedback include:

“If the intent is to provide general statements about the effectiveness of homeopathy, then ‘no reliable evidence’ may not adequately reflect the research. For example, when a substantial

⁴⁷ Expert scientific analysis of NHMRC Review (HRI): <https://www.youtube.com/watch?v=QvF8KxbCXzA>

⁴⁸ NHMRC Freedom of Information document 2014/15 004 Section 58

⁴⁹ HWC face-to-face meeting minutes, 18 March 2013. NHMRC FOI 2015/16 007-03

⁵⁰ Evidence, B. C. (2016) *Nuts, bolts, and tiny little screws: how Clinical Evidence works*

proportion of small (but good quality) studies show significant differences, [...] 'no reliable evidence' does not seem an accurate reflection of the body of evidence."

- Undisclosed expert methodological peer reviewer feedback, 30 Aug 2013

"The dismissal of positive systematic reviews compounded with the lack of an independent systematic review of high quality randomised controlled trials leaves me uncertain of the definitive nature of the Report's conclusions."

- Undisclosed expert reviewer advice, May 2014

"High quality RCTs with narrow confidence intervals (Level 1 evidence) should have been searched for and included in this review. Systematic reviews (SRs) have considerable weaknesses as reliable sources of evidence. Personally, I would prefer a much more reserved approach to their use as Level 1 evidence. For example, we know that SRs can come to quite contrasting conclusions pending the grading RCT scale they adopt. (See Juni et al, JAMA, 1999 http://rds.epi-ucsf.org/ticr/syllabus/courses/18/2009/04/16/Lecture/notes/Hazards_of_quality_scoring.pdf)."

- Undisclosed expert reviewer advice, May 2014

"I am concerned that no homeopathic expert was appointed to the NHMRC Review Panel. I cannot imagine this being agreed in oncology, orthopaedics or other disciplines."

- Undisclosed expert reviewer advice, May 2014

The hidden 'First Review'

The NHMRC has also concealed from public knowledge that between April and August 2012 it commissioned an original contractor to review the evidence on homeopathy. This tax-payer funded process was prematurely terminated in early August 2012, within days of NHMRC receiving the reviewer's final Draft Report titled 'A Systematic Review of the Evidence on the Effectiveness of Homeopathy'.

More information can be accessed at: <http://www.nhmrchomeopathy.com/firstreview.html>

Freedom of Information documents reveal:

- The reviewer was a principal author of NHMRC's own seminal guidelines on how to review health evidence (that NHMRC referenced against the Homeopathy Review).
- The review was of high methodological quality, as evidenced by feedback such as⁵¹:

"The summary of the methods is good, given that a fixed format has been used for all of the analyses, which is a positive feature of the overall report."

"The template reporting structure makes for dense reading but conversely it is very concise and contains a lot of information."

"Overall, the consistent use and reporting of the same criteria for each of the evaluations is a strength and reveals the careful systematic approach that has been brought to these evaluations."

"I believe that the assessment of secondary literature has been performed very well with careful systematic analysis and the results are supported factually with strong supporting material."

⁵¹ Homeopathy Working Committee (HWC) member feedback to NHMRC on the July 2012 version of the first reviewer's Draft Report, 12 July 2012. NHMRC FOI 2014/15 021-08 & NHMRC FOI 2016/17 016-13

"Overall, a lot of excellent work has gone into this review and the results are presented in a systematic, unbiased and convincing manner."

Such feedback is not consistent with a review so deeply flawed it warranted terminating so shortly thereafter. The stakeholder investigation into NHMRC's procedures and methods presents evidence that this 'first review' was terminated under suspicion of improper purpose, because it reported positive findings for homeopathic research in several medical conditions, which was contrary to NHMRC's expectations of the outcome.

Conflicts of interest:

NHMRC involved multiple undisclosed, unmanaged conflicts of interest in the Review process, while excluding the involvement of any homeopathy subject or research experts (in breach of mandatory quality assurance standards).

For details, see: <http://www.nhmrchomeopathy.com/conflictsofinterest.html>

Undisclosed/ unmanaged conflicts included:

- First Chair of the Homeopathy Working Committee (HWC), who was a member of Friends of Science in Medicine (FSM), a conflict that was not formally managed.
- In 2014, appointment of a contractor to assess additional evidence who was a FSM Supporter
- Multiple FSM Supporters on NHMRC Council and the Health Care Committee that the HWC reported to
- The NHMRC CEO, who personally instigated the process and selected members to the HWC to the exclusion of subject/ research experts, while publicly declaring his ideological opposition to homeopathy throughout the Review
- The second HWC Chair, who publicly voiced his anti-homeopathy position on matters exceeding the Reviews Terms of Reference
- The NHMRC Chairman, who in 2011 revealed: *"Let me assure you I am no supporter of homeopathy. As Chairman of NHMRC I can also assure you that NHMRC does not support homeopathy"* during the planning stages of the Review.

Appendix A - Post-hoc, undisclosed Changes to the NHMRC (Optum) Homeopathy Review research protocol

Post-hoc changes to the Optum review research protocol and their impact on the evidence assessment:

Date	Post-hoc changes to the research protocol for the Optum review:	Impact on the Review:	Disclosed/ reported?
22 Dec 2012	Research protocol for Optum review agreed and finalised.	Pre-agreed criteria to be applied to the evidence review.	No, FOI
Jan-Mar 2013	Optum completes evidence assessment.	Evidence assessment completed according to agreed research protocol; evidence of attempt to modify the protocol.	No, FOI
Apr-Jun 2013	HWC Sub-Group process established to further refine the research protocol.	All Elements and criteria of the Review's published evidence statement framework created during this process.	No, FOI
29 Apr 2013	ONHMRC/ HWC Chair (Prof Paul Glasziou) proposes that the 'null hypothesis' approach be adopted. Approved by HWC early May 2013.	From this point, homeopathy is <i>'assumed to be ineffective unless reliable evidence proves otherwise'</i> . The criteria underpinning the concept of 'reliable evidence' do not yet exist.	No, FOI
29 Apr - May 2013	ONHMRC develops an 'adapted GRADE' tool for providing a 'level of confidence (LOC)' rating of the evidence (Element 2 of the evidence statement framework). Applied by ONHMRC, since Optum is <i>'unfamiliar with the tool'</i> .	The 'adapted' tool does not pass either round of independent methodological peer review (see below). GRADE calculations are not published, despite use of a novel tool.	No, FOI
6 May 2013	'Conclusive statements' added as a component of Element 3 of the evidence statement framework.	Original protocol stipulated that the purpose of the Overview was to <i>'inform the community of the evidence'</i> and <i>'not draw conclusions'</i> .	No, FOI
24 May 2013	ONHMRC proposes an N=200 trial sample size threshold for	Does not pass ACC peer review (see below).	No, FOI

	whether a trial is 'adequately powered' (Element 1 of the evidence statement framework).		
9 Jul 2013	First round of independent methodological peer review by the Australasian Cochrane Centre (ACC).	ACC advises NHMRC/ HWC that linking sample size to 'trial power' is not scientifically valid ACC notes critical flaws of the 'adapted GRADE' tool. ACC also questions the overly definitive nature of the draft evidence statements.	No, FOI
11-12 Jul 2013	HWC approves an N=150 trial sample size exclusion threshold for whether a trial is 'reliable'. Modification to Element 1 of the evidence statement framework.	Dismisses the results of 146 out of the 176 trials (83%) from their results being considered 'any further' in the Review's findings.	No, FOI Expert analysis, HRI (38)
Late Jul/ Aug 2013	New criterion added to Element 1 of the evidence statement framework: a trial now ALSO had to be rated 5/5 using the Jadad (or equivalent) rating scale to be 'good quality' and hence 'reliable'.	Dismissed 25 out of the 30 remaining trials from their results being considered 'any further' in the Review's findings.	No, FOI Expert analysis, HRI
30 Aug 2013	Second round of ACC methodological peer review feedback to ONHMRC/ HWC.	ACC advises that the definitive nature of the Review's findings ' <i>does not accurately reflect the research</i> '. ACC advises that key flaws of the 'adapted GRADE' tool have not been addressed (ignored).	No, FOI
October 2013	Optum Overview Report finalised. ONHMRC prepares Draft Information Paper for public comment.	Original research protocol not published; protocol changes and their impact on the analysis not reported.	N/A