Submission to the Department of Health and Ageing

Review of the Australian Government Rebate on Private Health Insurance for Natural Therapies

Prepared by the

Australian Register of Homœopaths Ltd.

and its corporate member associations:

Australian Homœopathic Association Inc.

Homeopathic Education and Research Association

Australian Association of Professional Homeopaths Inc.

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AUSTRALIAN REGISTER OF HOMŒOPATHS LTD

122 Church St Wollongong NSW 2500

Phone: 0488 060 145

Email: admin@aroh.com.au Website: www.aroh.com.au

ABN: 69 088 314 818

Executive Summary

We thank you for giving the Australian Register of Homoeopaths Ltd. (AROH) the opportunity to present this body of work. This Submission by AROH, the peak body for the homoeopathic profession in Australia, presents an overview of homoeopathic research over the last 10 years and beyond, within the constraints of the Review guidelines.

This Submission documents the interactions between the homoeopathic profession and the National Health and Medical Research Council (NHMRC) since the announcement of the NHMRC's intention to develop a position statement on homoeopathy.

This Submission provides evidence of a body of research in support of the efficaciousness, safety, quality and cost effectiveness of homoeopathy, not just in Australia but around the globe.

This Submission identifies well documented positive findings for homoeopathic treatment in a number of pathological conditions, and positive outcomes of randomised controlled trials and systematic reviews of homoeopathic research.

This Submission provides the compellingly positive data derived from observational studies of homoeopathic treatment, and of preclinical trials and the veterinary application of homoeopathy.

This Submission, whilst adhering to the NHMRC guidelines, is also constrained by these limitations, as they do not allow us to accurately or adequately represent our profession. Homoeopathy is a holistic medical practice, and provides a substantial evidence base covering evidence gathered from a much broader base than that required by this Review. AROH feels it has supplied more than adequate evidence to support the continued tax rebate, despite the disadvantage placed upon it by the limited scope of this Submission. It is of some concern that the requested evidence does not take this into consideration. The requested evidence is almost completely restricted to research of a quantitative nature. Qualitative research is a well-accepted method of building a picture of evidence, and it is our understanding that, had it been taken into account, this Submission would give a more complete account of homoeopathic practice.

There is a discussion on the benefits of continuing access to private health tax rebates for patients who choose to use homoeopathy in the management of their health. AROH supports the retention of private health insurance rebates for homoeopathic consultations, and offers considerable evidence as the foundation for this support.

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List of Abbreviations

AROH	Australian Register of Homœopaths Ltd.
CAM	complementary and alternative medicine
GP	general practitioner
NHMRC	National Health and Medical Research Council
RCT	randomised controlled trial
UK	United Kingdom
USA	United States of America
WHO	World Health Organization

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Notes to the Reader

The Australian Register of Homœopaths Ltd.

The Australian Register of Homœopaths Ltd. (AROH) is a company limited by guarantee, providing a framework for professional standards and the accreditation of educational courses for homoeopaths since 1999. It also facilitates communication between the profession and Government agencies, private health insurance companies and the general public. On behalf of the public and its registrants AROH liaises with the private health insurance industry to facilitate eligibility requirements for health insurance rebates on homoeopathic consultations. One of AROH's main functions is to receive, investigate and resolve complaints concerning its registrants.

AROH has 683 registrants for whom homoeopathy is their primary professional health care modality. All AROH registered homoeopaths meet the national competency standards established by the profession (Homoeopathic Industry Reference Group, 1999) and training endorsed by the federal government. Registrants also meet the criteria as "recognised professional" recommended in the 2003 Government report: *Complementary Medicines in the Australian Health System* (Expert Committee on Complementary Medicines in the Health System, 2003). This requirement was subsequently endorsed by the Federal Government in their 2005 response to the Expert Committee's report (Australian Government, 2005).

AROH registrants are bound by a Code of Professional Conduct and are required to have current indemnity insurance, engage in continuing professional development and possess a current Senior First Aid certification. Homoeopathy is the only non-Government registered complementary and alternative medicine (CAM) modality that has a register of practitioners.

The spelling of homoeopathy

Many organisations have chosen to simplify the spelling of *homœopathy* by replacing the diphthong "œ" with an "e". AROH favours the spelling homoeopathy in all its documents, only using the diphthong "œ" in the company name. In this Submission, variations in spelling will occur where source texts are directly quoted and for the names of organisations and publications.

Background reading on homoeopathy

Background reading on the history, theory and clinical practice of homoeopathy is attached as Appendix 1: *The Submission of the Australian Homoeopathic Association Inc. to the National Health & Medical Research Council: review of the evidence towards the development of a position statement on Homoeopathy*. This report was submitted in 2011 by the Australian Homœopathic Association Inc. for consideration by the National Health and Medical Research Council (NHMRC) in the development of their position statement on homoeopathy.

The report also includes a discussion of the controversy around the ultra-molecular dilutions used in homoeopathic medicine, and cites a substantial body of research evidence supporting the biological activity of ultra-molecular dilutions. These studies used various biological models such as isolated cells, plants and animals, and demonstrate responses to ultra-molecular substances, with several studies yielding repeatable results.

1. Introduction

AROH, Australia's peak homoeopathic body, has prepared this report as a Submission to the *Review of the Australian Government Rebate on Private Health Insurance for Natural Therapies*. This review is being conducted by Australia's Chief Medical Officer through the agency of the Natural Therapies Review Advisory Committee, and is advised by the Homoeopathy Working Committee of the NHMRC.

This report presents a detailed analysis of the evidence for the clinical efficacy, cost-effectiveness, safety and quality of homoeopathic medicine to be used in the review of the evidence base for a range of natural therapies currently eligible for rebates under the Australian Government Private Health Insurance Rebate scheme.

This report addresses the following areas related to homoeopathic health care:

- positive findings for homoeopathic treatment in 98 human randomised controlled trials and 38 pre-clinical and veterinary trials
- broadly positive findings in 11 out of 29 systematic reviews of homoeopathic research
- compellingly positive data derived from observational studies of homoeopathic treatment at a population level
- relative safety of homoeopathic medicine and few side-effects from professionally executed homoeopathic care
- cost-effectiveness of homoeopathic treatment due to the lower costs of homoeopathic medicines compared to conventional drugs, through reduced expenditure by homoeopathically treated patients on Pharmaceutical Benefit Scheme listed products and through reductions in consultations with General Practitioners
- further savings potential through improved patient health as a result of homoeopathic care, and related reductions in patient's time away from productive activity and associated costs
- that the very limited benefit of savings which may be derived from the removal of rebates for homoeopathic consultations would be defrayed through subsequent loss of taxation payments by the homoeopathic profession
- the quality of production of homoeopathic medicines world-wide.

The extension of private health insurance rebates for CAM therapies was established primarily in response to community demand. The removal of private health insurance rebates will significantly affect both privately insured patients and the profession of homoeopathy in Australia. Patient freedom of choice in health care would be curtailed by

such a measure, and arrangements through which privately insured consumers currently receive coverage of their health costs would be undermined by any substantial removal of the current rebates scheme. The viability of hundreds of small homoeopathic practices across Australia would also be adversely affected by the removal of rebates for homoeopathic health care.

AROH and its corporate member organisations support the retention of private health insurance rebates for homoeopathic consultations, and offers the evidence provided in this report as the foundation for that support.

2. Context of the Review

It is important to consider the world-wide and Australian context of the use of CAM and homoeopathic medicine. In this section, we present the World Health Organization (WHO) Statement on Traditional Medicine and a discussion of the world-wide and Australian use of CAM and homoeopathic medicine followed by a discussion of health care rebates and the current political and media environment as it affects the profession of homoeopathy in Australia.

2.1. World Health Organization Statement on Traditional Medicine

The Beijing Declaration adopted by the WHO Congress on Traditional Medicine, Beijing, November 2008.

Participants at the World Health Organization Congress on Traditional Medicine, meeting in Beijing this eighth day of November in the year two thousand and eight:

- Recalling the International Conference on Primary Health Care at Alma Ata thirty years ago and noting that people have the right and duty to participate individually and collectively in the planning and implementation of their health care, which may include access to traditional medicine;
- Recalling World Health Assembly resolutions promoting traditional medicine, including WHA56.31 on Traditional Medicine of May 2003;
- Noting that the term 'traditional medicine' covers a wide variety of therapies and practices which may vary greatly from country to country and from region to region, and that traditional medicine may also be referred to as alternative or complementary medicine;
- Recognizing traditional medicine as one of the resources of primary health care services to increase availability and affordability and to contribute to improved health outcomes including those mentioned in the Millennium Development Goals;
- Recognizing that Member States have different domestic legislation, approaches, regulatory responsibilities and delivery models;
- Noting that progress in the field of traditional medicine has been obtained in a number of Member States through implementation of the WHO Traditional Medicine Strategy 2002-2005;
- Expressing the need for action and cooperation by the international community, governments, and health professionals and workers, to ensure proper use of traditional

medicine as an important component contributing to the health of all people, in accordance with national capacity, priorities and relevant legislation;

In accordance with national capacities, priorities, relevant legislation and circumstances hereby make the following Declaration:

I. The knowledge of traditional medicine, treatments and practices should be respected, preserved, promoted and communicated widely and appropriately based on the circumstances in each country.
II. Governments have a responsibility for the health of their people and should formulate national policies, regulations and standards, as part of comprehensive national health systems to ensure appropriate, safe and effective use of traditional medicine.
III. Recognizing the progress of many governments to date in integrating traditional medicine into their national health systems, we call on those who have not yet done so to take action.
IV. Traditional medicine should be further developed based on research and innovation in line with the 'Global strategy and plan of action on public health, innovation and intellectual property' adopted at the Sixty-first World Health Assembly in resolution WHA61.21 in 2008. Governments, international organizations and other stakeholders should collaborate in implementing the global strategy and plan of action.
V. Governments should establish systems for the qualification, accreditation or licensing of traditional medicine practitioners. Traditional medicine practitioners should upgrade their knowledge and skills based on national requirements.
VI. The communication between conventional and traditional medicine providers should be strengthened and appropriate training programs be established for health professionals, medical students and relevant researchers.

2.2. The use of CAM therapies and homoeopathy world-wide

Research carried out by Professor Edzard Ernst on behalf of the WHO (Ernst, 2000) found that the prevalence of the use of CAM therapies ranged from 9% to 65% when studies from Australia, Austria, Canada, China, Germany, Scotland and the USA were reviewed. According to the report, the practice of homoeopathy is widespread across the globe, and is the first or second most popular form of CAM in many countries, several of which include reimbursement for homoeopathic treatment in mandatory or private health insurance. Homoeopathy is practiced in the following countries: Argentina, Australia, Austria, Belgium, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Cyprus, Czech Republic,

Denmark, Ecuador, Finland, France, Hungary, Germany, Greece, India, Italy, Japan, Kenya, Latvia, Luxembourg, Malaysia, Netherlands, Nepal, New Zealand, Nicaragua, Norway, Philippines, Portugal, Romania, Russian Federation, Saudi Arabia, Spain, Sweden, Switzerland, South Africa, United Kingdom (UK), United States of America (USA) and Venezuela, amongst others.

Swiss researchers, Bornhoft and Matthiesen (2012) analysed the use of CAM in 52 studies from nine countries. They found that, one-third of respondents used CAM therapies for one year, while for two-thirds of respondents, use of CAM therapies was life-long. More than half of the CAM therapy users were satisfied with their treatment, and 80% gave a positive answer when asked if their condition had improved due to CAM therapy usage. The take-up of CAM therapy options in health care was found to be increasing in the countries studied.

The Complementary Medicine Evaluation Programme, undertaken by Bornhoft and Matthiesen (2012) on behalf of the Swiss government, found that about half of the Swiss population uses and values CAM therapies, and that half of physicians, the majority of CAM therapy users and 40% of cancer patients consider CAM to be effective treatments. Different surveys in Switzerland have suggested that between 11% and 27% of GPs and internists prescribe homoeopathic medicines. In the Netherlands, 45% of physicians consider homoeopathic medicines effective and 47% of medical doctors use one or more CAM therapies, with homoeopathy being the most popular (Fisher & Ward, 1994).

Other European studies found that three out of four Europeans know about homoeopathy and that 29% use it for their own health care, representing 100 million Europeans (di Sarsina & Isapatto, 2009). Studies with more detail about the use of homoeopathic medicine in just a few countries gives insight into the prevalence of CAM therapies and homoeopathic health care and provides evidence of the considerable growth in the use of homoeopathy over the past two to three decades.

Homoeopathy is the leading complementary therapy in France, where the percentage of homoeopathy users grew from 16% in 1982, to 29% in 1987 and to 36% in 1992 (Fisher & Ward, 1994). A survey by French pharmacists in 2004 found that 94.5% of pharmacists reported advising pregnant women to use homoeopathic medicine (Damase-Michel et al., 2004). The French medical profession is well-disposed towards homoeopathy: 70% of physicians consider homoeopathy effective and 25,000 French doctors prescribe homoeopathic medicines for their patients (Ullman, 2010). Homoeopathy is taught in at least seven medical schools and there are numerous postgraduate training programs. Courses in

homoeopathy are taught in 21 of France's 24 pharmacy schools, in two dental schools, in two veterinary medical schools and in three midwifery schools.

CAM has considerable support in Germany at both community and institutional levels. The German Government has mandated that all medical school curricula include information about natural medicine. In 2002, a study in the *British Medical Journal* reported that 75% of Germans have used complementary medicine (Tuffs, 2002). The number of medical practitioners training in homoeopathy has grown considerably in recent years. In 1993 there were 1,993 medical doctors who had formal qualifications in homoeopathy, and this figure had increased to 6,073 by 2006 (Joos et al., 2008). In a national health care survey in 2005, it was found that 38% of German doctors prescribed homoeopathic medicine (Stange et al., 2008). Sales of homoeopathic medicines in Germany were worth approximately $US 428 million in 1991, growing at a rate of about 10% per year. The support for homoeopathy in the German medical community is evident in the fact that 85% of sales of homoeopathic medicines were from physician prescriptions. A study of obstetric hospitals in North-Rhine Wesphalia found that almost 96% of obstetric departments offered homoeopathic medicines for obstetric care, principally provided by midwives on the basis of observed effectiveness and patient demand (Munstedt et al., 2009).

A study undertaken in Italy in 2009 provided data on the uptake of CAM therapies within conventional medical settings (di Sarsina & Iseppato, 2011). The authors found that the use of CAM therapies was increasing among the Italian population, as in the rest of Europe. Sales of alternative remedies are growing, and likewise the number of medical doctors who practice non-conventional medicine. There are 20,000 medical doctors with homoeopathic training in Italy (ECHAMP, 2009). A survey conducted in 2004 showed that a total of 7.5 million Italians use homeopathic medicines, 2.5 million more than a similar survey showed in 2000 (Ullman, 2010). Thirty homoeopathic laboratories produce homoeopathic medicines, and almost half of the pharmacies in Italy sell these medicines.

In 2005, David Reilly, the consultant physician at the Glasgow Homeopathic Hospital and honorary senior lecturer in medicine at Glasgow University, reported that public demand for homoeopathy had soared, and with it interest from medical professionals (Reilly, 2005). In 2000, approximately 20% of Scotland's GPs had completed basic training in homoeopathy: by 2003–2004, 49% of 323 general practices in Scotland were prescribing homoeopathic remedies. Reilly also suggested that the views of hospital consultants were reflecting reduced medical scepticism in that country.

The sales of homoeopathic and anthroposophical medicines in Europe grew by 60% between 1995 and 2005, from 590 million Euros in 1995, to 775 million Euros in 2001 and to $930 million Euros in 2005, according to figures provided by the European Coalition on Homoeopathic and Anthroposophic Medicinal Products (ECHAMP, 2007). The percentage of pharmacies in Europe selling homoeopathic medicine rose from 14% in 1980 to 43% in 2000. France and Germany lead sales of homoeopathic and anthroposophical medicines, followed by Italy. Approximately 49% of French people, 46% of German people and 35% of British people use CAM therapies. There are an estimated 54,000 specialist homoeopathic medical doctors and practitioners in Europe (ECHAMP, 2009). Some of the five homoeopathic hospitals working within the UK National Health Service have a two-year waiting list for non-emergency visits to a homoeopath. This population of patient consumers of homoeopathic medicine would have been negatively affected had the Sense About Science push to have homoeopathy removed from the National Health Service not have failed so resoundingly in 2010 (Ullman, 2010).

In India, over 100 million people depend solely on homoeopathic medicine. There are hundreds of State and Central government-owned homoeopathic hospitals in India that provide both inpatient and outpatient facilities (Prasad, 2007). According to an AC Neilsen survey in India, 62% of current homoeopathy users have never tried conventional medicines, and 82% of homoeopathy users would not switch to conventional treatments (Business Standard, 2007).

2.3. The use of CAM therapies and homoeopathy in Australia

In Australia, two out of three Australians used complementary medicines in 2010-2011 (National Institute of Complementary Medicine, 2009). Consumers appear sensitive to anecdotal evidence (the health care experiences of family members, friends and acquaintances) in making their health care choices, with formal research being a less important guide to their uptake of CAM therapies.

The Department of Health and Ageing's Expert Committee on Complementary Medicines in the Health System (2003) advised that Government has a social responsibility to fund complementary medicine research given the high community use of these therapies and medicines. Australia, otherwise renowned internationally for the strength of its medical research, provides one of the lowest levels of investment for research of CAM therapies (National Institute of Complementary Medicine, 2009). Such research would play a vital role

in responding to consumer trends, facilitate better-informed consumer choice and provide a guide to public policy development reflecting the Australian context.

An absence of funding for genuine research inquiry into CAM therapies in general and homoeopathy in particular promotes a public policy environment wherein hasty, ill-informed decisions may be made. While the NHMRC website informs us that almost $69 million (National Health and Medical Research Council, 2013) has been set aside for complementary medicine research during the 2010–2012 triennium, AROH is unaware of any publically funded research in homoeopathy that is currently being undertaken in Australia.

The enquiry into the public provision of health rebates for natural therapies takes place at a time of continuing growth in the use of CAM therapies in Australia. Numerous local studies have been conducted into this community-led phenomenon (Xue et al., 2006; Xue et al., 2007; Xue et al., 2008; Zhang et al., 2007). As described above, international studies have shown that the demand for CAM therapies has risen at similar rates across different countries in Europe and North America over the past thirty years (Andrews et al., 2003; Dixon et al., 2003; Eisenberg et al., 1993; Eisenberg et al., 1998). Australian studies show that the uptake of CAM therapies has increased: over half of all medicine users use complementary medicines (Morgan et al., 2012) and the amount of money spent on CAM medicines and treatments grew by 62% between 1996 and 2002 (MacLennan et al., 2002).

2.4. Health care rebates

Currently in Australia, the majority of private health insurers offer rebates for a range of natural therapies consultations, including homoeopathic consultations. The current review concerns the question about whether the Government will withdraw its contribution to insurance premiums via the tax rebate. In a study investigating the coverage of health care costs by private health insurance providers and other funding agencies, Pelletier and Astin (2002) found the following motivators for this provision, in order of importance: market research, retention of members, demand by members or consumers, incentives for new members, possible savings, a possibly less invasive care model and demand by providers and companies.

It is apparent that the wishes of the consumers of health insurance play a key role in informing the decision-making of insurers. Australian research has shown that consumers of CAM therapies are predominantly female, better educated, have higher incomes and are more likely to be employed than non-users (MacLennan et al., 2002; Morgan et al., 2012).

This is similar to findings from European research (Bornhoft & Matthiesen, 2012), and it is to this demographic that private health insurers have responded in extending rebates to CAM therapies. While it is a regrettable matter of gross inequity that lower income, less well-educated health consumers have restricted access to health care choice, the mostly female, better educated, higher income users of CAM therapies may be particularly negatively impacted by any restriction of rebates in this field.

In Switzerland, a Health Technology Assessment (Bornhoft & Matthiesen, 2012) was initiated following the Swiss government's decision to provisionally include various complementary medicine disciplines in the services covered by the Swiss national statutory health insurance scheme. The Health Technology Assessment was part of that government's Complementary Medicine Evaluation Programme and found that the majority of the Swiss population would prefer to have access to a CAM hospital, and 85% of respondents supported a continuation of national health insurance for CAM treatments. As a result of these investigations, the Swiss Government resumed health insurance compensation for homoeopathy and other CAM therapies. The authors noted that the use of CAM therapies in the countries investigated (USA, Germany, UK and France) was not marginal, but has been steadily increasing over the years.

The evolution of consumer choice towards increasing use of holistic forms of health care is mirrored in statements on health care by the European Commission. Its White Paper titled *Together for Health: A Strategic Approach for the EU 2008-2013* emphasises citizens' empowerment as a core value (European Parliament, 2008). It states that, "healthcare is becoming increasingly patient-centred and individualised, with the patient becoming an active subject rather than a mere object of healthcare", and that, "community health policy must take citizens' and patients' rights as a key starting point". Choice of health care among the privately insured, as indeed among all health care consumers, is such a right.

2.5. The political context of the review

2.5.1. The information and media environment

The media environment in which the current inquiry into natural therapies is being conducted has generated considerable concern amongst the homoeopathic profession. In relation to homoeopathy, media comment has been highly vituperative, relying primarily on name-calling as a means of de-legitimising homoeopathy, rather than contributing to informed discussion of relevant issues. Our otherwise highly valued (and publically funded)

national radio has been a regular source of misinformation and insult directed at CAM in general, and at homoeopathy in particular.

In a manner which clearly pre-empted findings of the then merely proposed NHMRC inquiry into homoeopathy, front pages of our national newspapers quoted the NHMRC and reported that, "… [it is] unethical for health practitioners to treat patients using homoeopathy , for the reason that homoeopathy (as a medicine or procedure) has been shown not to be efficacious" (Medew, 2012; O'Brien, 2012). Government agencies, having publically initiated the inquiry into homoeopathy in these negative terms, have failed to act to halt the degrading level of public debate being advanced through the media. Coverage of the 2012–2013 Federal Budget reported the removal of rebates for CAM therapies as a fait accompli, and not as an eighteen-month-long genuine cost-benefit analysis of CAM therapies on behalf of the community and the public purse. That important matters of public policy are able to be carried out in such a manner is suggestive of prejudice rather than rational inquiry, and of decisions being reached prior to the work of government agencies being duly and fairly undertaken.

2.5.2. The influence of international events

It has been of concern to the Australian homoeopathic profession that the report on homoeopathy by the UK House of Commons Science and Technology Committee, *Evidence Check 2: Homoeopathy, 2010* (House of Commons Science and Technology Committee, 2010) was identified by the NHMRC as the principal source of information for the inquiries of the NHMRC and its related agencies.

The work and conclusions of the UK House of Commons Science and Technology Committee were widely criticised, and its recommendations were not endorsed by the parliament of the UK. The NHMRC, however, appeared to repeat both the language and opinion of this source, and named the discredited UK House of Commons Science and Technology Committee report as the basis of the NHMRC inquiry (Medew, 2012).

In Submissions to the NHMRC in 2011, both the Australian Homoeopathic Association Inc. and the Australian Medical Fellowship of Homoeopathy outlined serious reasons for caution in regard to the findings of the UK House of Commons Science and Technology Committee. The proceedings and protocols were widely criticised on the following grounds: the selection of its members, the protocols engaged for its meetings and hearings, a perceived bias in its appraisal of the evidence before it and the restricted number of committee members who voted to pass its recommendations.

It is important to emphasise that a recommendation of the House of Commons Science and Technology Committee – to restrict the availability of homoeopathy through the National Health Service – did not receive the support of the UK Parliament, and that homoeopathy remains a funded arm of the UK National Health Service.

In its idiosyncratic and highly unscientific approach to research, the House of Commons Science and Technology Committee relied on a single research study of homoeopathic medicine (Shang et al., 2005) in reaching its negative conclusions on homoeopathy, with only three members out of thirteen presiding over this decision. The study by Shang et al. (2005) has received comprehensive criticism due to the inferior methodology applied to its research (Rutten & Stolper, 2008). The reporting of research trials has a profound effect on the reception of such results (Goldacre, 2012). In an effort to avoid reporting of biased results, a checklist of standards to improve the quality of reporting of meta-analyses and randomised controlled trials was devised by a group of clinical epidemiologists, clinicians, statisticians, editors and researchers (Moher et al., 1999). This checklist is referred to as the QUOROM (Quality of Reporting of Meta-analyses) guidelines. In accepting Shang's paper, *The Lancet* overlooked the failure of that study to conform to the QUOROM guidelines which *The Lancet* otherwise espouses. Such an action damages the prestige of that journal and leaves it open to questions about the integrity of both scientific inquiry and the championing of such publication protocols by the research community.

The importance for science of avoiding the cherry picking of data, as occurred at the House of Commons Science and Technology Committee, was emphasised by Sir Paul Nurse, Nobel Laureate and head of the UK Royal Society, in a recent address to scientists in Melbourne (Nurse, 2013). Sir Paul Nurse also pointed out that science should seek the consensus view of scientists expert in the field investigated, and that it is important to keep science as far as possible from political and ideological influence. The House of Commons Science and Technology committee may well have been compromised in this regard by the participation on its review panel of Ms Tracey Brown, the director of Sense About Science. The Sense About Science website revealed that over one-third of money raised for the organisation between 2004 and 2009 came from the pharmaceutical industry (Ullman, 2011). Several leading homoeopathic researchers and clinicians were frustrated in their attempts to address the Science and Technology Committee by the apparent absence of neutrality in the committee's key investigators (Baldwyn, 2010; Sumner, 2010).The controversies surrounding the study by the Shang group were discussed in considerable detail in the 2011 Australian Homeopathic Association Inc. Submission to the NHMRC (see Appendix 1, p.30).

AROH and its corporate member organisations rely upon the Natural Therapies Review Advisory Committee, the Homoeopathy Working Committee and the NHMRC to conduct a detailed review of the full body of available research evidence for homoeopathy and to reach their conclusions in a fair and unprejudiced manner. This Submission from AROH draws widely on homoeopathic research sources to provide an accurate overview of the research evidence in homoeopathy, and recommends this research to the inquiry's careful attention. Much of cited homoeopathic research evidence has been analysed and categorised according to the Levels of Evidence hierarchy adopted by the NHMRC in assessing the scientific adequacy of medical research.

3. Research Challenges for Homoeopathic Medicine

Homoeopathic best practice uses an integrated approach to health and disease, and takes into account the complex relationships between the biological, psychological and environmental factors characterising the individual patient. It is through this focus on the whole patient (rather than solely on the disease), and through the scrupulous attention given to the selection of the similimum (or most similar medicine), that homoeopathy embodies the complexity paradigm in medicine (Bellavite & Signorini, 1995).

While the concept of evidence is multi-faceted, the RCT is accepted as the highest level of evidence in contemporary medical research, and seeks to prove the efficacy of a single agent in a specific disease. There is an inherent paradigm clash when the whole-person/whole-medicine approach of homoeopathy is measured within the parameters of the single disease focus of a typical drug trial (Ivanovas, 2012a). While it is clearly necessary for homoeopathy to exhibit efficacy within this model, and there is evidence that this has been achieved in some studies in spite of these challenges, it is imperative that the methodological complexities peculiar to homoeopathy are understood by those reviewing the homoeopathic research literature, and future RCTs need to take this complexity into account. In the conventional research model, high methodological quality is defined by high internal validity. Requirements for external validity are ignored in what has been called the "quiet, dismal scandal" (Goldacre, 2012, p.179) of the irrelevance of many trials to real-world populations. In placebo-controlled RCTs, high internal validity is achieved at the expense of external validity.

These important issues relate to the distinction between the efficacy and effectiveness of medical interventions (Fisher, 2008). Efficacy can be established under the restricted ideal conditions that may apply in a research trial, while effectiveness describes real-world conditions. The clinical effectiveness of a treatment pertains to the multiplicity of factors met in population usage, where length of use, side effects, co-morbidities and drug interactions are ultimately displayed. A drug deemed highly efficacious from RCT evidence may later be withdrawn once real-world conditions of its use exhibit effects beyond those seen in the original trial, and there have been many high-profile examples of such drug withdrawals. Assessments of clinical effectiveness and responsiveness to findings at this level of evidence (real world effectiveness) are clearly so vital as to warrant a change of status for population-level or outcomes studies which may more accurately report treatment effects.

These considerations place RCTs in context as a valuable research tool, but inadvisable as the principal deciding factor in health care delivery. In homoeopathic research, more comprehensive measures encompassing clinical effectiveness may be established through comparisons of usual care with the new intervention, and through observational studies, where real-world conditions are more readily reflected. A holistic, real-world application of evidence-based medicine would have the capacity to integrate individual clinical expertise with the best available evidence from systematic research (Sackett et al., 1996). Widely regarded as the father of evidence-based medicine, David Sackett (1997) is explicit in his description of what constitutes evidence-based medicine:

> … [it] requires a bottom-up approach that integrates the best external evidence with individual clinical expertise and patient choice, it cannot result in slavish, "cook-book" approaches to individual patient care. External clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that decides whether the external evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision. Similarly, any external guideline must be integrated with individual clinical expertise in deciding whether and how it matches the patient's clinical state, predicament, and preferences, and thus whether it should be applied. Finally, in terms of study designs, evidence-based medicine is not restricted to randomized trials and meta-analyses. It involves tracking down the best external evidence with which to answer our clinical questions.

An evidence-based medicine that is based on RCTs and meta-analyses to the exclusion of other study designs might provide a method of standardising care, aiming to address standard patterns of pathology. By contrast, Sackett focuses his attention on the uniqueness of every patient and each clinical encounter, and emphasises clinical expertise and the judicious use of a wide range of external evidence in addressing an individual's clinical needs. Sackett's prescription for a greater equality across the range of research evidences holds particular relevance to homoeopathic research. The design of many randomised controlled trials have been found to limit a full evaluation of the effect of a homoeopathic prescription (Ward, 2012): these research findings are often in stark contrast to surveys of patient satisfaction with homoeopathic treatment which find satisfaction levels to be typically very high (Marian et al., 2008; Rodrigues-Neto et al., 2009; van Wassenhoven & Ives, 2004) and in contrast to observational studies of patients at large homoeopathic hospitals which also identify very positive outcomes (International Data Collection Centres for Integrative Medicine, 1998; Richardson, 2001; Spence et al., 2005; Witt et al., 2005).

Many attempts at adequate research of homoeopathy have been stymied by the absence of the individualised approach typical of whole-person/whole-remedy homoeopathic practice. In many studies, prescribing may be based on pathology rather than the patient's characteristics, for example, or isopathic preparations or combinations (complexes) of homoeopathic medicines may be employed, contradicting the principles of traditional (simplex or single simillimum) homoeopathy. The inclusion of trials with different homoeopathic prescribing methods (individualised, complex or isopathic) compromises the validity of systematic reviews or meta-analyses, which rely on both the quality of the RCTs included in the reviews and on the homogeneity of the studies included.

A review of 192 human RCTs in homoeopathy by the Faculty of Homeopathy (2011b) (see Appendix 2) shows the heterogeneous nature of homoeopathic research, where different prescribing models were employed: 61 individualised, 61 complexes, 15 isopathy and 55 single remedy. Most of the RCTs in this table are single trials, but where more than one trial investigates a particular pathology, different modes of treatment may have been used, or homoeopathic complexes prescribed. In the absence of multiple trials, studies cannot be combined into a meta-analysis with any reliable degree of research rigor. To more easily satisfy internal trial validity requirements, many systematic reviews also incorporate trials testing homoeopathic methodologies not typically used in clinical practice.

As well as variability in the type of homoeopathic prescribing practice investigated, other unmatched variables may include: disease definition; trial inclusion and exclusion criteria; end-point definition; placebo versus treatment equivalence methodology and trial randomisation or blinding criteria. Trial size, a critical factor in assessing validity, may be influenced by economic factors in a way that is disadvantageous to homoeopathy. For example, the largest trials are likely to be those testing isopathic preparations or homoeopathic complexes. The preference for researching these forms of homoeopathic medicine is commercially driven – these products may be marketable as over-the-counter medicines, and are therefore attractive to investors.

Systematic reviews incorporating highly heterogeneous trials or trials which fail to represent homoeopathic usual-practice are inadequate for measuring the efficacy of homoeopathy. These commonly encountered obstacles in homoeopathic research potentiate the Yule–Simpson effect. Known as Simpson's paradox, this phenomenon is common in medical research: it describes the effect where an effect appearing in different groups of data, disappears when these groups are combined, and the reverse effect appears for the aggregate data.

Current developments in research in homoeopathy seek to address the issues particular to homoeopathic research to improve model validity (Mathie et al., 2012). Mathie et al. identified relevant judgmental domains to use in assessing the model validity of homoeopathic treatment. The authors defined model validity of homoeopathic treatment as the extent to which a homoeopathic intervention and the main measure of its outcome, as implemented in a RCT, reflect state-of-the-art homoeopathic practice.

Elsewhere, consensus guidelines for reporting homoeopathic methods and treatments were established. Dean et al. (2007) identified 28 items to supplement the *Consolidated Standards for Reporting Trials* statement items 2, 3, 4 and 19. The requirement that published reports describe the details of prescribing strategies and treatments would improve the capacity of reviewers to more accurately assess homoeopathic research (Dean et al., 2007). The observation that research disturbs and alters the subject of that research is a phenomena long recognised in the social sciences and in applied scientific and medical research. Research developments by Mathie and Dean seek to minimise this potential in the context of homoeopathic research.

The requirement that reviewers have a good understanding of the field they interpret is an issue stressed by Charlton (1996) for medical research in general. He states:

> … the prestige of meta-analysis is based upon a false model of scientific practice. Interpreting empirical research is an extremely complex activity requiring clinical and scientific knowledge of the field in question; and teams of professional 'meta-analysts' with a primary skill base in information technology and biostatistics cannot take over this role … the summary estimate from a meta-analysis can only be directly applied to a target population when the "meta-protocol" and "meta-population" match the target situation in all relevant particulars. These constraints can rarely be satisfied in practice, so the results of meta-analysis typically require adjustment—which is a complex, assumption-laden process that negates many of the statistical power advantages of a meta-analysis. Lacking any understanding or acknowledgement of the need for adjustment, most meta-analyses must be regarded as an abuse of the technique.

These matters relate particularly to homoeopathic research. Statistical methods may be especially limited when applied to regulatory therapies such as homoeopathy (Ivanovas, 2012a), and adequate trial design for homoeopathic research needs to be based on a sufficient understanding of the healing processes that homoeopathic therapy stimulates (Ivanovas, 2012b).

4. Homoeopathy Research

4.1. RCTs of homoeopathy

The tables in Appendix 2 summarise RCTs of homoeopathy treatment and prevention that have been published in peer-reviewed journals from 1950 to 2012. We included RCTs that used any form of homoeopathy (individualised or non-individualised) and studies in any language. The majority of studies were identified from the Faculty of Homoeopathy website page (Faculty of Homeopathy, 2011a) where they are identified as a RCT if they used prospective random assignment to treatment groups. For placebo-controlled trials, explicit mention of double-blinding was required, and for trials that were not placebo-controlled, observer-blinding was sufficient for inclusion. They also required that inter-group statistical analyses had been reported, with a minimum of five subjects per group. Studies were considered statistically significant if they reported a 95% confidence interval that excluded zero, or a p-value <0.05. RCTs reporting statistically significant findings were considered positive or negative if the homoeopathic treatment group was superior or inferior to the control group, respectively. Statistically non-significant trials were considered inconclusive.

A total of 81 different medical conditions were represented in the RCTs noted in this Submission, 39 (48%) of these had been studied by two or more RCTs and 42 (52%) had been studied by a single trial. A clearly positive direction of evidence was seen for 9 (11%) of the 81 medical conditions: ADHD, fibromyalgia, heavy metal toxicity, influenza, insomnia, seasonal allergic rhinitis, osteoarthritis, otitis media and sinusitis. A tentatively positive direction of evidence was seen for 29 (36%): childhood diarrhoea, low back pain, otitis media, psoriasis, brain injury, bronchitis, chronic fatigue syndrome, common cold, depression, extended sports recovery time, immune function, non-allergic rhinitis, perennial allergic rhinitis, plantar fasciitis, post-operative oedema, post-operative wound healing, postpartum bleeding, postpartum lactation, premenstrual syndrome, radiodermatitis, renal failure, seborrhoeic dermatitis, sepsis, snoring, stomatitis, tracheal secretions, upper respiratory infections, uraemic pruritus, vertigo and varicose veins.

Of the 192 RCTs noted in this Submission, classical or individualised homoeopathy was investigated in 61 (35 positive, 24 inconclusive and 2 negative), a mixture of remedies (complexes) was investigated in 61 (31 positive, 29 inconclusive and 1 negative), isopathy was investigated in 15 (10 positive, 4 inconclusive and 1 negative) and pathological prescribing was investigated in 55 (20 positive, 31 inconclusive and 4 negative).

4.2. Efficacy of homoeopathy

When reviewing the research in homoeopathy, it is possible, depending on the criteria used, to conclude that homoeopathy is more effective than placebo. The reverse claim, that homoeopathy is nothing but placebo, cannot be substantiated as long as every positive trial is not over-ridden by a larger negative trial: it takes just one positive trial to reject the nothing-but-placebo claim. There are at least 98 human RCTs and a minimum of 38 preclinical and veterinary RCTs that are positive for homoeopathy. As discussed above, undertaking systematic reviews in homoeopathy encounters several problems. The UK Faculty of Homeopathy (2011b) summarised these difficulties:

> The small number of original research papers, the differing criteria reviewers have used for data extraction, the disparate styles of homoeopathy used, and the fact that a diverse range of medical conditions has been examined collectively, all restrict the value of formal comprehensive systematic review, such as those attempted by Linde's and Shang's groups.

The problem of heterogeneity of medical conditions has been avoided in 29 systematic reviews focused on RCTs of homoeopathy in specific clinical areas (Faculty of Homeopathy, 2011b). Eleven of the 29 systematic reviews yielded conclusions broadly positive for homoeopathy. These reviews included studies of: allergies and upper respiratory tract infections (Bell et al., 2011; Brooks et al., 2010); childhood diarrhoea (Carlini et al., 1987); influenza treatment (Naude et al., 2010); post-operative ileus (Aabel et al., 2000); rheumatic diseases (Aabel, 2000); seasonal allergic rhinitis (hay fever) (Aabel, 2001; Kim et al., 2005; Reilly et al., 1986; Weiser et al., 1999); and vertigo (Wiesenauer & Gaus, 1985).

Bornhöft and Ammon (2012) provide a detailed discussion of the complexities encountered in systematic reviews of homoeopathy, and despite these limitations they concluded that, "… the effectiveness of homoeopathy has to be rated as 'likely'". The relevance of a systematic review prevails only until another trial is discovered or published which fulfils the relevant inclusion criteria. Approximately 100 RCTs, many in languages other than English, have just been acknowledged (Mathie et al., 2013). The findings of these trials are likely to affect the state of knowledge in homoeopathic research once they are translated and reviewed. Ward (2012) discussed the frequently misleading conclusions of systematic reviews in relation to the homoeopathic treatment of asthma. In her non-exhaustive review of 32 research papers in asthma there were: four systematic reviews; seven RCTs; nine observational and qualitative studies; five pilot and open studies; and 147 case studies. Ward found that:

> Research outcomes considered to be highest in the hierarchy of evidence are mostly negative or inconclusive, whereas all others are positive. This clearly identified trend is analysed against trial designs and treatment strategy. It was found that usually the designs of RCTs limit the full evaluation of the effect of a homeopathic prescription and recommendations for future trials and research designs are made. (p.281)

Trials investigating individualised homoeopathy present particular challenges to double-blinded RCT design, where internal validity is favoured over external validity. These challenges occur when treating patients with chronic disease: patient assessments are made on multiple occasions, and treatment decisions are made under trial conditions, where it is not known if the patient had received the active remedy or placebo. These conditions add an extra variable to an already complex clinical decision, a variable not present in normal practice. If trial design does not avoid these confounding issues, then ambiguous conclusions may result. The following 28 RCTs, which suffered from this design problem, reached the following conclusions:

- 10 were positive (Adler et al., 2011; Bell et al., 2004; Campistrous Lavaut, 1999; Cavalcanti et al., 2003; Gibson et al., 1980; Naude et al., 2010; Rastogi et al., 1999; Riveron-Garrote, 1998; Sharma & Sharma, 2012; Weatherley-Jones et al., 2004)
- 17 were inconclusive (Andrade et al., 1991; Bonne et al., 2003; Brien et al., 2011; Jacobs et al., 2005b; de Lange de Klerk et al., 1994; Fisher et al., 2006; Gaucher et al., 1994; Jacobs et al., 2005a; Kainz et al., 1996; Katz et al., 2005; Lokken et al., 1995; Rastogi et al., 1999; Siebenwirth et al., 2009; Straumsheim et al., 2000; White et al., 2003; Whitmarsh et al., 1997; Thompson et al., 2005)
- 1 was negative (Fisher & Scott, 2001).

It is remarkable that 36% of these trials reached significantly positive results, despite this obstacle, and most were non-conclusive. However, it is even more enlightening to compare these findings with the group of trials of individualised homoeopathy that were designed to avoid this problem, either because all the critical treatment decisions were made prior to placebo randomisation, or they were comparison trials to regular care, which didn't involve placebo.

Of the 33 individualised RCTs that compared one prescribing episode with usual care, 76% produced results that are significantly in favour of homoeopathy:

- 25 were positive (Bell et al., 2011; Brigo & Serpelloni, 1991; Chapman et al., 1999; Colau et al., 2012; Fisher, 1986; Fisher et al., 1989; Frass et al., 2005a; Frass et al., 2005b; Frei et al., 2005; Gmunder & Kissling, 2002; Haila et al., 2005; Harrison et al., 1999; Jacobs et al.,

1994; Jacobs et al., 2000; Jacobs et al., 2001; Kundu et al., 2012; Kuzeff, 1998; Lamont, 1997; Manchanda et al., 1997; Mousavi et al., 2009a; Mousavi et al., 2009b; Relton et al., 2009; Sinha et al., 2012; Sharma & Sharma, 2012; Steinsbekk & Ludtke, 2005; Yakir et al., 2001)

- 7 were inconclusive (Brooks et al., 2010; Fisher et al., 2006; Jacobs et al., 1993; Thompson et al., 2011; van Erp & Brands, 1996; Friese et al., 1997; Walach et al., 1997)
- 1 was negative (Witt et al., 2009a).

If of these 33 RCTs, only the placebo-controlled trials are considered, then 20 of 25 RCTs (80%) are positive; Gmunder and Kissling (2002); Harrison et al. (1999); Relton et al. (2009); Sinha et al. (2012); Thompson et al. (2011); Steinsbekk et al. (2005b); van Erp and Brands (1996); Witt et al. (2009a) were not placebo-controlled. Investigations of usual homoeopathic practice gives clearer and more accurate evidence of efficacy, as these studies demonstrate. Conversely, when research questions are restricted to trials that are easier to perform, and which may be classified as of higher quality given internal validity measures (Nicolai, 2005), outcomes may obscure, rather than exemplify usual homoeopathic practice. An example appears in the clinical trials in this Submission: In 8 RCTs Arnica was given to groups of runners in races, with seven inconclusive and one positive result. Similarly, in 14 trials investigating the peri-operative usefulness of Arnica, 6 were positive, 6 inconclusive and 2 negative. These researches did not focus on the main sphere of action of this remedy, which is principally used to treat bruising rather than lacerations or muscle fatigue. It may be better to trial Arnica in boxers. It is noteworthy that these 22 trials of marginal are 11% of the human RCTs in this Submission.

4.3. Trial evidence by pathology

Research conducted in homoeopathy on specific medical conditions is summarised below. Each trial has been categorised according to the Levels of Evidence (I–IV). Each trial has also been scored for the direction of evidence as: +1 for a positive trial, 0 for an inconclusive trial and −1 for a negative trial. For each condition with two or more trials, the scores have been added to calculate an overall direction of evidence summary score: +3 suggests a clearly positive, +2 suggests tentatively positive, −3 suggests clearly negative, −2 suggests tentatively negative and scores from −1 to +1 are inconclusive. For conditions with only a single study, +1 is considered tentatively positive, 0 is considered inconclusive and −1 is considered tentatively negative.

This does not replace formal assessment procedures, such as systematic review and meta-analysis, which also determine a trial's intrinsic quality and the size of treatment effect for a specified outcome measure. This summary method is intended to give an overall impression of the nature of the evidence for each medical condition, in the absence of more formal systematic reviews.

The following shows the direction of evidence in a linear format. This information is not included in tables 1 and 2.

- A clearly positive direction of evidence was seen for 5 (6%) of the 77 medical conditions: fibromyalgia, influenza, insomnia, seasonal allergic rhinitis and sinusitis.
- A tentatively positive direction of evidence was seen for 29 (37%) conditions:
  Replicated research: childhood diarrhoea, low back pain, otitis media, psoriasis and vertigo.
  Non-replicated research singleton RCTs: brain injury, bronchitis, chronic fatigue syndrome, common cold, depression, extended sports recovery time, immune function, non-allergic rhinitis, perennial allergic rhinitis, plantar fasciitis, post-operative oedema, post-operative wound healing, postpartum bleeding, postpartum lactation, premenstrual syndrome, radiodermatitis, renal failure, seborrhoeic dermatitis, sepsis, snoring, stomatitis, tracheal secretions, uraemic pruritus and varicose veins.
- An unclear direction of RCT were evidence in 39 (51%) conditions:
  Replicated research: attention-deficit hyperactivity disorder, allergic, asthma, anxiety blood coagulation, childhood asthma, eczema, female infertility, hypertension, insect bites, irritable bowel syndrome, menopausal symptoms after breast cancer, migraine, muscle soreness, osteoarthritis, post-operative bruising, post-operative pain, post-operative pain/swelling, rheumatoid arthritis, upper respiratory tract infection, warts
  Non-replicated research, singleton RCTs: adenoid vegetations, arsenic toxicity, body weight loss, cholera, conjunctivitis, dengue fever symptoms, headache, HIV, induction of labour, lead poisoning, malaria, minor burns, orthostatic hypotension, post-operative bleeding, post-operative haematoma, postpartum pain, shift lag, tinnitus and withdrawal of benzodiazepines.
- tentatively negative direction of RCTs showed in 4 (5%) conditions:
  Non-replicated research, singleton RCTs: leg ulcers, post-operative analgesic intake, post-operative ileus and vulvo-vaginal candidiasis.

Table 1 summarises the direction of evidence for research of homoeopathic medicine for specific medical conditions. Type of study, with direction of evidence, type of therapeutic

intervention and level of evidence is categorised. It is to be noted that Level IV studies are not clearly positive as the conditions are often of an acute nature that would get better over time. This is followed by Table 2, which summarises lower levels evidence.

Table 1. Strongly positive evidence in twelve conditions

Study by condition	Direction of evidence	Therapeutic intervention	LOE
ADHD			
Bolognani (2011)	Positive	Zincum Met 12C	IV
Frei and Thurneysen (2001a)	Positive		III-3
Frei et al. (2005)	Inconclusive		II
Jacobs et al. (2005b)	Inconclusive	Individualised	II
Lamont (1997)	Positive	Individualised	III-1
Ramchandani (2010)	Positive	Zincum Met 30	III-1
Strauss (2000)	Positive	Complex	II
Allergic rhinitis			
Aabel (2000)	Negative	Isopathy homeopathic aggravation in low pollen season	
Aabel (2001)	Inconclusive	isopathy	
Aabel et al. (2000)	Positive	Isopathy	
Ammerschlager et al. (2005)	Positive	Euphorbium complex	III-2
Colin (2006)	Positive	Individualised	IV
Kim et al. (2005)	Positive	isopathy	
Reilly et al. (1986)	Positive	isopathy	
Teixeira (2009)	Positive	Individualised	III-3
Weiser et al. (1999)	Positive	Luffa comp-Heel	
Wiesenauer and Ludtke (1995)	Inconclusive	Galphimia	
Wiesenauer and Ludtke (1995)	Inconclusive	Galphimia	
Wiesenauer et al. (1983)	Positive	Galphimia	
Wiesenauer et al. (1990)	Positive	Galphimia	
Childhood diarrhoea			
Berchieri et al. (2006)	Positive	Veterinarian Isopathy	
Camerlink et al. (2010)	Positive	Veterinarian Isopathy	
Jacobs et al. (1993)	Inconclusive	Individualised	
Jacobs et al. (1994)	Positive	Individualised	
Jacobs et al. (2000)	Positive	Individualised	
Jacobs et al. (2006)	Inconclusive	Complex	

Study by condition	Direction of evidence	Therapeutic intervention	LOE
Fibromyalgia			
Bell et al. (2004)	Positive		
Fisher (1986)	Positive		III-1
Fisher et al. (1989)	Positive		
Relton et al. (2009)	Positive		III-2
Heavy metal toxicity			
Belon et al. (2006)	Inconclusive		
Belon et al. (2007)	Positive		
Beringhs-Bueno et al. (2006)	Positive		
Datta et al. (1999)	Positive	Laboratory Isopathy	
Datta et al. (2001)	Positive	Laboratory Isopathy	
Khuda-Bukhsh et al. (2005)	Positive		IV
Khuda-Bukhsh et al. (2011a)	Positive		III-2
Khuda-Bukhsh et al. (2011c)	Positive		III-2
Padilha et al. (2011)	Inconclusive		
Influenza Treatment			
Attena et al. (1995)	Inconclusive		
Brydak and Denys (1999)	Positive	Gripp-Heel	
Ferley et al. (1989)	Positive	Oscillococcinum	
Nahler et al. (1998)	Positive	Gripp-Heel	III-2
Papp et al. (1998)	Positive	Oscillococcinum	
Vincent et al. (2012)	Positive		III-2
Insomnia			
Bell et al. (2011)	Positive	Individualised	
Brooks et al. (2010)	Positive	Individualised	
Carlini et al. (1987)	Inconclusive		
Hellhammer and Schubert (2012)	Positive	Dysto-loges S	
Naude et al. (2010)	Positive	Individualised	
Ruiz-Vega et al. (2003)	Positive	Laboratory	
Waldschütz and Klein (2008)	Positive	Neurexan	
Osteoarthritis			
Hielm-Bjorkman et al. (2009)	Positive	Zeel complex Veterinarian	
Maronna (2000)	Positive	Zeel complex	
Nahler et al. (1998)	Positive	Zeel complex	III-2
Neumann et al. (2011)	Positive	Veterinarian	
Shealy et al. (1998)	Positive	Individualised	

Study by condition	Direction of evidence	Therapeutic intervention	LOE
Shipley et al. (1983)	neg/ In-c	Different remedies	
Strosser and Weiser (2000)	Positive	Zeel complex	
van Haselen and Fisher (2000)	Positive	Complex gel	
Otitis media			
Frei and Thurneysen (2001a)	Positive	Individualised	III-3
Friese et al. (1997)	Positive	Individualised	III-2
Haidvogl et al. (2007)	Positive	Individualised	III-2
Harrison et al. (1999)	Positive	Individualised	III-2
Jacobs et al. (2001)	Positive	Individualised	
Riley et al. (2001)	Positive	Individualised	III-2
Sinha et al. (2012)	Positive	Individualised	
Taylor and Jacobs (2011)	Positive	Ear drops	
Sinusitis			
Adler (1999)	Positive	Another complex	IV
Bawden (2012)	Positive	Individualised	IV
Friese and Zabalotnyi (2007)	Positive	Sinfrontal	
Kneis and Gandjour (2009)	Positive	Sinfrontal	
Weiser and Clasen (1994)	Positive	Euphorbium complex nasal spray	
Wiesenauer et al. (1989)	Inconclusive	Other remedies	
Witt et al. (2009d)	Positive	Individualised	IV
Zabolotnyi et al. (2007)	Positive	Sinfrontal	
URTIs, common cold			
Ammerschlager et al. (2005)	Positive	Euphorbium complex	III-2
de Lange de Klerk et al. (1994)	Inconclusive	Individualised	
Gassinger et al. (1981)	Positive	Eup-per D2	III-2
Haidvogl et al. (2007)	Positive	Individualised	III-2
Maiwald et al. (1988)	Positive	Gripp-Heel	
Nayak et al. (2010)	Positive	Individualised	IV
Rabe et al. (2004)	Positive	Gripp-Heel	III-2
Ramchandani (2010)	Positive	Individualised	IV
Riley et al. (2001)	Positive	Individualised	III-2
Schmiedel and Klein (2006)	Positive	Engystol	III-2
Steinsbekk et al. (2005a)	Inconclusive	pathological prescribing by parents	
Steinsbekk et al. (2005b)	Positive	Individualised	
Trichard et al. (2004)	Positive		III-2

Study by condition	Direction of evidence	Therapeutic intervention	LOE
Trichard et al. (2005)	Positive	Individualised	III-2
Vertigo			
Issing et al. (2005)	Positive	Vertigoheel	
Klopp et al. (2005)	Positive	Vertigoheel	III-2
Weiser et al. (1998)	Positive	Vertigoheel	
Wolschner et al. (2001)	Positive	Vertigoheel	III-2

Note. LOE = level of evidence

Table 2. RCTs and lower grades of positive evidence for homoeopathy, including data from animal and laboratory trials (with studies older than 10 years highlighted) (Faculty of Homeopathy, 2011a)

Study by condition	Direction of evidence	Therapeutic intervention	LOE
Allergies	Positive		
Colin (2006)	Positive		IV
Frenkel and Hermoni (2002)	Positive		IV
Grundling et al. (2012)	Positive		IV
Anxiety			
Baker et al. (2003)	Inconclusive		
Bellavite et al. (2011)	Positive	Laboratory	
Bellavite et al. (2012)	Positive	Laboratory	
Bonne et al. (2003)	Inconclusive		
Davidson et al. (1997)	Positive	Laboratory	IV
Lakshmipathy Prabhu et al. (2012)	Positive	Laboratory	
McCutcheon (1996)	Inconclusive		
Paris et al. (2012)	Inconclusive		
Tavares Carvalho et al. (2009)	Positive	Laboratory	
van den Meerschaut and Sunder (2009)	Positive	Laboratory	III-2
Anal fissure			
Bignamini et al. (1991)	Positive		
Asthma			
Castellsagu (1992)	Positive		IV
Castellsague and Sturza (1998)	Positive	Individualised	IV
Colin (2006)	Positive	Individualised	IV
Gariboldi et al. (2009)	Positive	Laboratory Isopathy	
Jack (1993)	Positive	Individualised	

Study by condition	Direction of evidence	Therapeutic intervention	LOE
Lewith et al. (2002)	Inconclusive	Isopathy	
Matusiewicz (1997)	Positive	Complex	
Mohan (2007)	Positive	Individualised	IV
Reilly et al. (1994)	Positive	Isopathy	
Riveron-Garrote (1998)	Positive	Individualised	III-2
Shafei et al. (2012)	Positive	Individualised	IV
Autistic spectrum disorder			
Barvalia (2011)	Positive		IV
Blood coagulation			
Baillargeon et al. (1993)	Inconclusive	Different remedies	
Eizayaga et al. (2005)	Positive	Laboratory	
Heusser et al. (2009)	Positive		
Kundu et al. (2012)	Positive		
Brain injury			
Chapman et al. (1999)	Positive		
Bronchitis			
Diefenbach et al. (1997)	Positive		
Burn scars regression			
Harrison et al. (1993)	Positive		IV
Cancer			
Banerjee et al. (2010b)	Positive	Laboratory	
Bhattacharjee et al. (2009)	Positive	Laboratory	
Biswas and Khuda-Bukhsh (2004)	Positive	Laboratory	
Biswas et al. (2005)	Positive	Laboratory	
Chatterjee et al. (2011)	Positive		IV
Datta et al. (1999)	Positive	Laboratory	
Datta et al. (2001)	Positive	Laboratory	
Frenkel et al. (2010)	Positive	Laboratory	
Guimarães et al. (2009)	Positive	Laboratory	
Khuda-Bukhsh et al. (2011b)	Positive	Laboratory	
Kumar et al. (2007)	Positive	Laboratory	
Pathak et al. (2003)	Positive		IV
Pathak et al. (2006)	Positive	Laboratory	
Chronic fatigue Syndrome			
Weatherley-Jones et al. (2004)	Positive		

Study by condition	Direction of evidence	Therapeutic intervention	LOE
Crohn's Disease			
Jack (1993)	Positive		IV
Maas (1993)	Positive		IV
Depression			
Adler et al. (2011)	Positive		
Davidson et al. (1997)	Positive		IV
Katz et al. (2005)	Inconclusive		
Eczema			
Eizayaga and Eizayaga (2012)	Positive		IV
Fisher et al. (2006)	Inconclusive		
Itamura (2007)	Positive		IV
Itamura and Hosoya (2003)	Positive		IV
Rossi et al. (2012)	Positive		IV
Siebenwirth et al. (2009)	Inconclusive		IV
Spence (1991)	Positive		IV
Fever in children			
Derasse et al. (2005)	Positive		III-2
Foot and mouth disease			
Lotfollahzadeh et al. (2012)	Positive	Veterinarian	
Fracture healing			
Mazzocchi and Montanaro (2012)	Positive		III-2
Sharma et al. (2012)	Positive		
Spin-Neto et al. (2010)	Positive	Laboratory	
Headache (including migraine)			
Brigo and Serpelloni (1991)	Positive		
Danno et al. (2012)	Positive		IV
Muscari-Tomaioli et al. (2001)	Positive		IV
Straumsheim et al. (2000)	Inconclusive		
Walach et al. (1997)	Inconclusive		
Whitmarsh et al. (1997)	Inconclusive		
HPV infection			
Gimeno (1996)	Positive		IV
Jaeger et al. (2008)	Positive		IV

Study by condition	Direction of evidence	Therapeutic intervention	LOE
Hypertension			
Bignamini et al. (1987)	Inconclusive		
Campistrous Lavaut (1999)	Positive		
Hitzenberger and Rehak (2005)	Inconclusive		
Immune function			
Kuzeff (1998)	Positive		
de Oliveira et al. (2011)	Positive	Laboratory	
Bonamin et al. (2012)	Positive	Laboratory	
Guimarães et al. (2009)	Positive	Laboratory	
dos Santos et al. (2007)	Positive	Laboratory	
Chandrakant Nimgulkar et al. (2011)	Positive	Laboratory	
Infectious disease prevention remedy			
Attena et al. (1995)	Inconclusive		
Bandyopadhyay et al. (2010)	Positive	Laboratory	
Berchieri et al. (2006)	Positive	Veterinarian	
Bracho et al. (2010)	Positive		III
Camerlink et al. (2010)	Positive	Veterinarian	
de Souza et al. (2012)	Positive		III
Glatthaar-Saalmuller (2007)	Positive	Laboratory	
Jacobs et al. (2007)	Inconclusive		
Lyrio et al. (2011)	Positive		
Marino (2008)	Positive		III
Mroninski et al. (2001)	Positive		III
Varshney and Naresh (2005)	Positive	Veterinarian	
Labour time and complications			
Beer and Heiliger (1999)	Inconclusive		
Dorfman et al. (1987)	Positive		
Eid et al. (1993)	Positive		III-3
Low back pain			
Gmunder and Kissling (2002)	Positive		
Stam et al. (2001)	Positive		
Witt et al. (2009b)	Positive		IV
Malaria			
Bagai et al. (2012)	Positive	Laboratory	
van Erp and Brands (1996)	Positive		IV

Study by condition	Direction of evidence	Therapeutic intervention	LOE
Male infertility			
de Souza et al. (2012)	Positive	Veterinarian	IV
Gerhard and Wallis (2002)	Positive		IV
Malnutrition			
Villanueva et al. (2012)	Positive		III-2
Menopausal hot flushes			
Clover and Ratsey (2002)	Positive		IV
Colau et al. (2012)	Positive		
Musculoskeletal diseases / injury			
Oryan (2012)	Positive	Laboratory	
Rossignol et al. (2012)	Positive		III-2
van Wassenhoven (1996)	Positive		IV
Neuropathy			
Cairo et al. (2001)	Positive		IV
Mohammadi et al. (2012)	Positive	Laboratory	
Pomposelli et al. (2009)	Positive		III-2
Neuralgia post tooth extraction			
Albertini et al. (1985)	Positive		III-2
Oral Lichen planus			
Mousavi et al. (2009b)	Positive		III-2
Ovarian cysts			
Gimeno (1991)	Positive		IV
Parasites			
Chaudhuri and Varshney (2007)	Positive	Veterinarian	
Silva et al. (2008)	Positive	Veterinarian	
Sukul et al. (2005)	Positive	Laboratory	
Plantar fasciitis			
Clark and Percivall (2000)	Positive		
Post-op pain			
Alibeu and Jobert (1990)	Positive		
Banerjee et al. (2010a)			III-2
Hart et al. (1997)	Inconclusive		
Lokken et al. (1995)	Inconclusive		
Paris et al. (2008)	Inconclusive		
Robertson et al. (2007)	Positive		

Study by condition	Direction of evidence	Therapeutic intervention	LOE
Singer et al. (2010)	Inconclusive		
Stevinson et al. (2003)	Inconclusive		
Wolf et al. (2003)	Inconclusive		
Post-op bruising, wound healing, oedema, infection			
Bononi (2000)	Positive		
Cornu et al. (2010)	Inconclusive		
Karow et al. (2008)	Positive		
Kaziro (1984)	Negative		
Kotlus et al. (2010)	Inconclusive		
Seeley et al. (2006)	Positive		
Totonchi and Guyuron (2007)	Positive		
Postpartum bleeding			
Oberbaum et al. (2005)	Positive		
Postpartum lactation			
Berrebi et al. (2001)	Positive		
Premenstrual syndrome			
Danno et al. (2013)	Positive		IV
Martinez (1990)	Positive		IV
Yakir et al. (2001)	Positive		
Prostatism			
Hati et al. (2012)	Positive		IV
Vozianov and Simeonova (1990)	Positive		IV
Psoriasis			IV
Witt et al. (2009c)	Positive		
Pulmonary tuberculosis recovery			
Sharma and Sharma (2012)	Positive		
Radio-dermatitis			
Balzarini et al. (2000)	Positive		
Kulkarni et al. (1988)	Positive		
Schlappack (2004)	Positive		IV
Renal failure			
Saruggia and Corghi (1992)	Positive		

Study by condition	Direction of evidence	Therapeutic intervention	LOE
Rheumatoid arthritis			
Andrade et al. (1991)	Inconclusive		
Brien et al. (2011)	Inconclusive		
Fisher and Scott (2001)	Negative		
Gibson et al. (1980)	Positive		
Gibson et al. (1978)	Positive		III-2
Patil et al. (2011)	Positive	Laboratory	
Patel et al. (2012)	Positive	Laboratory	
Seborrhoeic dermatitis			
Smith et al. (2002)	Positive		
Sepsis			
Frass et al. (2005b)	Positive		
Snoring			
Lipman et al. (1999)	Positive		
Stomatitis			
Mousavi et al. (2009a)	Positive		
Oberbaum et al. (2001)	Positive		
Supra-ventricular tachycardia			
van Wassenhoven (1998)	Positive		IV
Thalassaemia			
Banerjee et al. (2010a)	Positive		III-2
Toxic neuropathy			
Cairo et al. (2001)	Positive		IV
Tracheal secretions			
Frass et al. (2005a)	Positive		
Uraemic pruritis			
Cavalcanti et al. (2003)	Positive		
Uterine fibroids			
Popov (1992)	Positive		IV
Varicose veins			
Ernst et al. (1990)	Positive		
Warts			
Reilly et al. (1986)	Inconclusive		
Labrecque et al. (1992)	Inconclusive		
Manchanda et al. (1997)	Positive		

Study by condition	Direction of evidence	Therapeutic intervention	LOE
Xerostomia			
Haila et al. (2005)	Positive		III-2
Zinc deficiency			
Badulici et al. (1994)			IV

Note. LOE = level of evidence

There is clear evidence of efficacy in nine conditions: ADHD with individualised homoeopathy; allergic rhinitis with isopathy (plus two related RCTs with Galphimia glaucaD4); fibromyalgia with individualised homoeopathy; heavy metal toxicity with isopathy; influenza with Oscillococcinum; insomnia with individualised homoeopathy; osteoarthritis with Zeel comp (two human and two veterinary RCTs) and one RCT with each of individualised treatment and a gel (complex homoeopathic); otitis media with individualised homoeopathy ; and sinusitis with the complex remedy Sinfrontal. There is very close to clear evidence in three conditions: URTIs with one RCT with each of two remedies, both having independent cohort study confirmation; vertigo with two RCTs (Vertigoheel) from similar authors and independent confirmation from cohort studies; and childhood diarrhoea in two RCTs with individualised prescribing from a similar team (and with some veterinary studies using isopathy).

4.4. Clear evidence of an action greater than placebo

In considering the 192 RCTs identified in this Submission, if homoeopathy were identical to placebo, one would expect a maximum of nine trials to favour homoeopathy with $p<0.05$. (Or fewer considering that several had values down to 0.01 and smaller.) Ninety-six trial results with positive findings for homoeopathy, more than ten times the possible chance occurrence, counters the argument that it is a placebo effect. Of the 149 RCTs that used placebo as a comparison, 74 were statistically significant with $p<0.05$, where one would expect only seven to be positive if the homoeopathic medicines were placebos. If the 67 RCTs with homoeopathic potencies as or more dilute than C12 vs. placebo are examined, 36 were statistically significant with $p<0.05$, whereas chance would dictate that only three would be positive if those remedies were placebos. A recently published paper by Mathie et al. (2013) identified a total of 263 journal papers describing approximately 285 RCTs investigating homoeopathy in humans, of which 41 placebo controlled studies were eligible

for, but were missed by Shang et al. (2005), 30 of which Linde et al. (1997) also did not include in that meta-analysis.

There are also approximately another 100 clinical RCTs (mostly in German, French, Italian, Russian and Portuguese) investigating homoeopathy that are not included in this Submission, but will be subject to further systematic review during 2013. In the unlikely event that none of all the extra 100 RCTs turn out to be positive for homoeopathy , one would then expect only 14 of the total to be positive, if the homoeopathic interventions were indeed placebos. With 96 already known to be positive, there is evidence against the proposition that appropriately prescribed homoeopathic medicines are placebos. The addition of veterinary and laboratory RCTs (see Appendix 2) strengthens the conclusion that homoeopathic medicines exhibit an action greater than placebo.

4.5. Homoeopathy as good as or better than conventional medical care?

The following studies report benefits from homoeopathic treatment that are as good as, or better than, conventional care, either by direct comparison or as an additional treatment: Adler et al. (2011); Ammerschlager et al. (2005); Banerjee et al. (2010a); Bignamini et al. (1991); Bononi (2000); Cairo et al. (2001); Chapman et al. (1999); Chaufferin (2000); Derasse et al. (2005); Dorfman et al. (1987); Eid et al. (1993); Frass et al. (2005a); Frass et al. (2005b); Frenkel and Hermoni (2002); Frei and Thurneysen (2001b); Friese et al. (1997); Gerhard and Wallis (2002); Gimeno (1996); Goldstein and Glik (1998); Haidvogl et al. (2007); Harrison et al. (1999); Iannotti and Melo (2012); Jacobs et al. (2003); Karow et al. (2008); Kundu et al. (2012); Marian et al. (2008); Pomposelli et al. (2009); Rabe et al. (2004); Relton et al. (2009); Riley et al. (2001); Rodrigues-Neto et al. (2009); Rossignol et al. (2012); Sinha et al. (2012); Sharma and Sharma (2012); Sharma et al. (2012); Schmiedel and Klein (2006); Studer and Busato (2011); Totonchi and Guyuron (2007); Trichard et al. (2004); Trichard et al. (2005); van den Meerschaut and Sunder (2009); van Wassenhoven (1998); van Wassenhoven and Ives (2004); Villanueva et al. (2012); Vincent et al. (2012); Witt et al. (2008); (Witt et al., 2009a).

The post-treatment impairment of pulmonary tuberculosis patients was improved by homoeopathic treatment in a study conducted in 2012 (Sharma & Sharma, 2012). Individualised homoeopathic treatment was given to 61 patients, while 57 patients received identical placebo treatment in this double-blind randomised controlled trial. After six months treatment, significant improvement was observed in the homoeopathy group: FEV1 ($p<0.001$), forced vital capacity ($p<0.001$) and FEV/FVC ratio ($p=0.002$). Increased body weight ($p<0.0001$) and improved quality of life ($p<0.05$) scores were better in the

homoeopathy group compared with the control group (p=0.003). The placebo group deteriorated after one year, while the homoeopathy group maintained their improvements. Physician visits were reduced by 58.0% (p=0.002) in the homoeopathically treated patients compared with the control (p<0.0001) (Kundu et al., 2012).

The usefulness of individualised homoeopathy was investigated in the management of haemophiliac patients. Twenty-eight patients with moderate to severe disease received standard management for one year, then standard management plus homoeopathy for a subsequent year. Transfusion requirements, bleeding scores and pain scores were evaluated by independent experts. Homoeopathic medicines reduced the frequency and extent of bleeding and the quantity of blood products consumed. Pain scores also improved (p<0.0001), along with improved well-being in these patients.

Banerjee et al. (2010a) examined the potential benefits of homoeopathic treatment of thalassemic patients on Hydroxyurea therapy. Blood examinations were conducted before treatment and three months post-treatment to determine differences in 38 patients treated with homoeopathy plus Hydroxyurea therapy and those treated only with Hydroxyurea therapy (38 patients). Homoeopathic remedies were prescribed on the basis of similarity. There was a significant decrease in serum ferritin and an increase in fetal haemoglobin in the group receiving combined treatment. In most patients with splenomegaly, there was a significant decrease in the size of the spleen and improvements in general health. Gaps between transfusions were greater for those on the combined treatment. Banerjee concluded that homoeopathy may be a useful adjunctive therapy for thalassemic patients, particularly in developing countries where the safety conditions of blood transfusions may be compromised

Homoeopathy may be useful in optimising metabolic functioning in cases of malnutrition. A mixture of potencies of calcium (Calcium carbonate, Calcium fluoride and Calcium phosphate) was shown to be beneficial in establishing normal weight in a group of malnourished children in Cuba (Villanueva et al., 2012). The children in the study were below the third percentile for height-weight ratio and they were randomly assigned either the standard protocol for malnourishment (dietary in nature) or that protocol plus the standardised homoeopathic treatment. After one year, 84% of the children given homoeopathic treatment reached normal weight compared with 30% of those receiving the standard diet.

Symptoms of diabetic neuropathy improved in both conventionally treated and homoeopathically treated groups in an observational study (Pomposelli et al., 2009). The

homoeopathy group however made improvements which were significantly better than their baseline scores (p=0.016), and only the homoeopathically treated patients had scores for quality of life improve.

A homoeopathic complex, Grip-Heel was compared with acetaminophen in the treatment of acute febrile conditions in 198 children treated at 38 clinics in Belgium (Derasse et al., 2005). The homoeopathic complex was found to be as effective as acetaminophen, and it was better tolerated.

Jacobs et al. (2003) conducted three double-blind RCTs of 242 children experiencing acute diarrhoea. Individualised homoeopathy was compared with placebo, with doses taken after each episode of unformed stool. Both parents and visiting health workers monitored the children's progress. Duration of diarrhoea was defined as the time until there were less than three unformed stools per day for two consecutive days, and a meta-analysis of the effect size of the three studies was conducted. The combined analysis showed duration of diarrhoea of 3.3 days in the treated group compared with 4.1 days in the placebo group (p=0.008).

A homoeopathic complex Euphorbium compositum nasal drops was compared with xylometazoline in patients suffering from inflammatory diseases of the upper respiratory tract (Ammerschlager et al., 2005). The homoeopathic complex was found to be comparably effective as xylometazoline for these conditions.

The treatment of mild viral infections was investigated in a cohort of 485 patients in an observational, prospective study using the complex homoeopathic medicine Grip-Heel (Rabe et al., 2004). Fever, headache, muscle pain, and sore throat were found to be responsive to Grip-Heel, with 67.9% of this group considered asymptomatic at the end of Grip-Heel therapy compared with 47.9% of patients in the control group. The homoeopathy group were considered successfully treated in 78.1% of cases compared with 52.2% of the placebo group. In terms of compliance and tolerability, 88.9% of the verum group judged this as "very good" compared with 38.8% in the control group.

Patients who had failed to respond to vitamin therapy for neuropathy were treated with various potencies of Carbon Sulphate and Tabacum (Cairo et al., 2001). Fifteen patients with optic neuropathy improved by 73% and sixteen patients with peripheral neuropathy improved 12.5% within three months of treatment.

Patients who had previous unsuccessful microsurgical treatment of human papilloma virus were treated with individualised homoeopathy (Gimeno, 1996). Cytology assessments were made before treatment, during treatment and after one year of use of homoeopathy. At

the final assessment, 11 of the 14 patients were assessed as cured of the human papilloma virus. Gimeno (1991) also studied the effects of homoeopathic treatment of patients with menstrual symptoms related to diagnoses of ovarian cysts. Forty cases were followed over a nine-month period with the following results: 24/25 had improvements in menstrual regularity; 18/18 had disappearance of pelvic pain; 6/6 had improvement in the incidence of spotting between menstrual periods; 10/10 had improvement in prolonged or heavy bleeding; 21/21 experienced improved moods; 6/6 had relief of pre-menstrual migraines, while 31/33 had improvements in other symptom presentations.

Homoeopathic care of women in labour was found to shorten the time of labour (5.1 hours vs. 8.5 hours) and the rate of post-delivery complications (11.3% vs. 40%) (Dorfman et al., 1987).

4.6. Onset of improvement faster in homoeopathically treated patients

In several of these studies, where the outcomes are similar for conventional and homoeopathic interventions, the rate of onset of improvement was found to be faster for the homoeopathically treated groups. In a study of homoeopathic treatment compared with conventional treatment in acute respiratory and ear complaints (Haidvogl et al., 2007), patients using homoeopathy improved faster than those treated conventionally, and the homoeopathically treated adults experienced fewer adverse events that those treated conventionally. The onset of improvement within the first seven days after treatment was significantly faster in children ($p=0.0488$) and in adults ($p=0.0001$) than in the conventional group. Schmiedel and Klein (2006) compared homoeopathy with allopathic treatment in upper respiratory infections, and while outcomes were similar, the homoeopathy group improved faster (77.1% better within 3 days compared with 61.7%). Fewer adverse events were recorded in research comparing conventional and homoeopathic treatments for upper respiratory and ear complaints (Riley et al., 2001). While outcomes were again similar, the homoeopathically treated patients not only reached resolution of the illness more quickly but experienced fewer adverse events from treatment than those conventionally treated.

Frei and Thurneysen (2001a) compared the rate of resolution of a homoeopathically treated group of children with otitis media with a similar group receiving placebo. After 72 hours, the group receiving homoeopathy experienced significant relief of symptoms, which was 2.4 times faster than the response to placebo.

Homoeopathic treatment achieves improvements across a range of measures as shown in the study by Trichard et al. (2005). This study of treatment for acute rhinopharyngitis

found that homoeopathic treatment was superior to antibiotics in terms of medical effectiveness. The number of episodes of acute rhinopharyngitis was 2.71 vs. 3.97 for the group treated with antibiotics (p=0.001), while there were fewer complications in the homoeopathy group than the antibiotic group (1.25 vs. 1.95, p=0.0001). The global quality of life score was better in the homoeopathy group (21.38 vs. 30.43, p=0.001), and medical costs were lower for the homoeopathically treated patients (88 Euros vs. 99 Euros, p= 0.05). Fewer parents required sick leave on behalf of the homoeopathically treated children (9.5%) compared with the antibiotic group (31.6%).

4.7. Satisfaction rated high by homoeopathic patients

There is a range of positive evidence of efficacy and of effectiveness in 60 conditions as outlined in the above discussion. Across the broad spectrum of patients consulting homoeopaths, 67–89% are satisfied with their choice of health care (Adler, 1999; Bawden, 2012; Cairo et al., 2001; Clover, 2000; di Sarsina & Iseppato, 2011; Goldstein & Glik, 1998; Marian et al., 2008; Reilly et al., 2007; Richardson, 2001; Robinson, 2006; Rodrigues-Neto et al., 2009; Rossi et al., 2009b; Sevar, 2005; Spence et al., 2005; Steinsbekk & Ludtke, 2005; Witt et al., 2008; van Wassenhoven & Ives, 2004).

A Brazilian study (Rodrigues-Neto et al., 2009) analysed 3,080 responses to a questionnaire, and found that 73% of homoeopathy patients were satisfied or very satisfied with the treatment received. The primary reason for seeking homoeopathy for this group was that "conventional treatment did not have any effect".

Long-term follow-up of data was achieved in a Swiss-German multi-centre study of 103 primary care practices where a total of 3,709 patients were studied and 73% contributed to an eight-year follow-up (Witt et al., 2008). The most common complaints were allergic rhinitis and headache in adults and atopic dermatitis and multiple recurrent infections in children. Disease severity decreased significantly (p=0.0001) between the baseline and at two years and at eight years and quality of life scores also increased significantly. Researchers found that younger age, female gender and more severe disease at baseline were predictive of better therapeutic success.

Similar high levels of satisfaction were recorded for patients treated homoeopathically when compared to those treated conventionally in a primary care setting (Marian et al., 2008). A survey of 6,778 patients achieved a 46.1% response rate. Statistically significant differences were found in health status (homoeopathy patients had a higher incidence of chronic and severe complaints), in the perception of side effects (2–3 times higher reporting

of side effects in the conventionally treated group) and in patient satisfaction, where the percentage of patients satisfied with treatment was higher in the homoeopathy patients.

van Wassenhoven and Ives (2004) found patient satisfaction with homoeopathy was very high in 782 patients from 80 medical practices in Belgium. Ninety-five per cent of patients were fairly or very satisfied with their treatment, and rates of improvement were high by both patient and physician assessments (89%).

Seventy-eight per cent of 489 homoeopathy patients achieved a positive clinical response in a study of data collected over a 12 month period in a UK National Health Service general practice clinic (Robinson, 2006). Various homoeopathic treatment strategies were used in this setting (problem-based, patient-based, context-based and combined strategies) and the beneficial effects of homoeopathy were delivered within ten-minute consultation time-frames. In a much larger study of 6,544 patients being treated for chronic complaints in a university out-patient observational study, 70.7% of patients reported positive health changes, with 50% of these changes graded as +2 or +3 for the degree of change(Spence et al., 2005). In an earlier study by Spence (1991), 130 cases of eczema were followed for up to 11 years: 91% of these patients were either better or much better, while 7.4% were unchanged and 1.6% had deteriorated.

In the Norwegian study by Steinsbekk and Ludtke (2005), 70% of patients recorded a meaningful improvement in their main complaint after six months of homoeopathic treatment. This degree of improvement was matched in a similar study of homoeopathic patients in nine clinics in Los Angeles where 71% reported improvement in their health status after four months of treatment (Goldstein & Glik, 1998). These outcomes contrasted with the patient's previous experience of orthodox treatment for the same complaints, which was unsuccessful.

Patient self-rating of improvement shows significant degrees of improvement in other large scale, hospital-based surveys. Clover (2000) conducted a patient benefit survey of 1,372 patients at Tunbridge Wells Homoeopathic Hospital. Positive changes predominate, with greater percentage change measures increasing with the degree of positive change: −3 (2%), −2 (3%), −1 (4%), 0 (17%), +1 (19%), +2 (24%) and +3 (31%). Similar results were found by Richardson (2001)who surveyed 1,100 patients at Liverpool Regional Department of Homoeopathic Medicine. Patient rankings of their improvement were: −3 (0.09%), −2 (1.3%), −1 (0.9%), 0 (21%), +1 (16.3%), +2 (27.7%), +3 (31.5%) and +4 (1.1%).

An interesting study by Iannotti and Melo (2012) inquired into the capacity of doctors to solve the presenting problems of their patients. This research found that homoeopathic

doctors were better at solving patient's problems than conventional practitioners and homoeopathic doctors also ordered fewer diagnostic tests. This study examined the influence of the doctors' speciality on primary health care problem solving in Belo Horizonte Brazil, comparing homoeopathic with family health doctors, from both the point of view of management and of patients. In Belo Horizonte, both family health and homoeopathic doctors work in primary health care. The index of resolvability is used to compare resolution of problems by doctors. Official data from the Secretariat of Health and test requests made by the doctors, plus 482 structured interviews with patients were used in this project. A total of 217,963 consultations by 14 homoeopaths and 67 family health doctors between 1 July 2006 and 30 June 2007 were analysed. It was found that the medical speciality of homoeopathy has an impact on problem solving: homoeopaths requested fewer tests and have better index of resolvability compared with family health doctors, and that specialisation in homoeopathy is an independent positive factor in problem solving at primary health care level in Belo Horizonte, Brazil.

4.8. Prior dissatisfaction with conventional medical treatment

Many patients in the following studies had been dissatisfied with the treatment which they had received prior to seeking homoeopathic treatment: Goldstein and Glik (1998); Marian et al. (2008); Rodrigues-Neto et al. (2009); Sevar (2005); van Wassenhoven and Ives (2004).

Eighty per cent of the patients enrolled in the survey by Goldstein and Glik (1998) had had previous orthodox medical treatment for their conditions, which they had found unsuccessful. The complaints of patients in this study were most commonly respiratory, gastrointestinal and female reproductive disorders. The survey was conducted at nine clinics in the Los Angeles area and 77 patients participated; while the majority of the patients in the survey were highly educated, they had little knowledge of homoeopathy prior to their treatment. At four months of treatment, 71% of those surveyed reported improvements in their health.

In the study by van Wassenhoven and Ives (2004), all the surveyed patients had diseases of major organ systems, and for 78% of these patients, their complaints were of sufficient severity to interfere with daily living. Patient satisfaction with homoeopathic treatment was very high (95%), compared with their ratings of previous treatment (20% satisfaction rating). As noted, significant improvements in the health status of patients were recorded after homoeopathic treatment by both patients and physicians. Previous conventional treatment, on the other hand, had brought about improvements in only 13% of cases, had made no

difference for 32% of patients and had worsened the condition over half of the patients (55%).

Four hundred and fifty-five patients who were unsuitable for conventional treatment or whose previous treatment was unsuccessful provided information in the study by Sevar (2005). Of these, 67% derived benefit from homoeopathy and 33% were able to stop or to maintain a substantial reduction in their use of pharmaceutical drugs. Rodrigues-Neto et al. (2009) found that the main reason that patients in their survey sought homoeopathic treatment was because conventional treatment had failed. Approximately 73% of the homoeopathic patients in this study were satisfied or very satisfied with their treatment, and for 70.2% of users, it was considered reasonable or cheap.

4.9. Homoeopathy ameliorates the effects of environmental toxins

Environmental toxins have been an increasing problem, particularly affecting developing countries where regulatory mechanisms may be lacking. Populations affected by contact with environmental toxins may benefit from treatment with homoeopathic preparations of the toxic substance (isopathy), as shown by the results of several studies. In a double-blind placebo-controlled study, a potentised remedy of homoeopathic Arsenicum album 30c and a placebo (Succussed Alcohol 30c) were given randomly to volunteers (Belon et al., 2007). Arsenic contents in urine and blood were analysed, as were several widely accepted toxicity biomarkers and pathological parameters in blood, with samples taken before and after two months of administration of either verum or placebo. The administration of Arsenicum album 30c appeared to make positive modulations of these parameters, suggesting that the homoeopathic has ameliorative potential. Most of the subjects reported better appetite and improvement in general health, thereby indicating the possibility of its use in remote arsenic-contaminated areas as an interim health support measure to a large population at risk.

In a study that tested whether a high dilution of homoeopathically prepared Mercury could act as a chelating agent for Mercury, 52 people exposed to mercury poisoning were treated homoeopathically (Beringhs-Bueno et al., 2006). Random assignment of either Merc sol 30 or placebo was given to this group. Mercury levels in blood, urine and hair samples were taken before the trial, at 30 days and 60 days after Merc sol or placebo delivery. Quality of life measures as well as blood, urine and hair analyses were made. Mercury content of hair samples decreased and evidence of urinary elimination was established, along with improvements in symptomatology of the mercury-affected patients.

Arsenic in groundwater affects populations in more than twenty countries world-wide. Potentised Arsenicum album was given to a group of arsenic-affected people and arsenic contents of blood and urine were subsequently tested (Khuda-Bukhsh et al., 2005). Levels of toxicity markers and enzymes in blood samples were monitored over a period of three months and the positive results suggest that a homoeopathic preparation of arsenic may alleviate the effects of arsenic poisoning.

Kunda-Bukhsh conducted further studies examining the potential of homoeopathic treatment of environmentally-induced toxicity. In 2011, 14 people living with an arsenic contaminated water supply were treated with either Arsenicum album LM 0/3 or placebo for two months (Khuda-Bukhsh et al., 2011a). The verum group had modulations of a number of markers for arsenic poisoning. In another study of homoeopathic arsenic, 96 people were treated with Arsenicum album 200c for six months, and 65 people continued the treatment for one year and 15 for two years. A period of initial improvement in the first three months was maintained in relation to general health, spirit, appetite and sleep. Biomarkers for toxicity levels remained within normal range. Those patients who had concurrent skin complaints experienced further improvements from treatment with Arsenicum album in homoeopathic potency.

4.10. Homoeopathy in Epidemics

The history of homoeopathy describes many instances of its use at a population level during epidemic outbreaks, such as the 1918 influenza epidemic (Winston, 1999). Recent population level uses of homoeopathy in epidemics provide contemporary evidence of its usefulness, effectiveness and very low cost relative to standard treatment protocols.

Cuban use of a homoeopathic prophylactic for the annually occurring Leptospirosis outbreak is the largest-ever research study assessing a homoeopathic medicine (Bracho et al., 2010). Leptospirosis is a potentially fatal infectious disease caused by exposure to contaminated water. During the 2007 epidemic in Cuba, when extreme flooding worsened the potential for disease incidence and very little conventional vaccine was available, a novel approach was used. A homoeopathic medicine, nosoLep, was prepared from four inactivated strains of Leptospirosis-causing bacteria and given to 2.3 million people at high risk of infection, while the remaining 8.8 million of the population were untreated. The homoeopathic treatment was “strongly associated with a drastic reduction of disease incidence resulting in complete control of the epidemic” (Bracho et al., 2010), while in the untreated population, the rates of infection were as anticipated.

Within weeks of the intervention being given, a dramatic decrease was seen in the number of confirmed cases, from 38 per 100,000 to 4–6 cases per 100,000 per week. The projected incidence for this period had been 111–461 cases per 100,000 per week; the homoeopathic intervention represented a decrease of between 91.8% and 65.8%. This drop in disease incidence occurred at the point when homoeopathic treatment had been received by 70% of the population.

The treatment regime involved two oral doses of nosoLEP 200c given 7–9 days apart. Treatment was continued 10–12 months later with two oral doses of nosoLEP 10MC given 7–9 days apart. The protective effect extended into the 2008 rainy season, when incidence of Leptospirosis in the untreated population increased by 22% from 2007, while in the homoeopathically treated population, infection rates dropped by 84%. This population-scale use of a homoeopathic medicine was also associated with a substantial reduction in the cost of treatment compared with conventional and less effective vaccine programs.

In Brazil in 2007, a homoeopathic complex preparation (Phosphorus 30c, Crotalus 30 c and Eupatorium 30c) was used in a Government campaign against dengue fever. In one county in Rio de Janeiro, 156,000 doses were distributed to asymptomatic patients and 129 to symptomatic patients treated in outpatient clinics. The incidence of the disease fell by 93% in the first three months of 2008 compared with the corresponding period in 2007, while in the rest of Rio de Janeiro, there was a 128% increase in the incidence of dengue fever.

In another Brazilian study (Mroninski et al., 2001), the homoeopathic nosode Meningococcinum was used during an outbreak of B serotype meningococcal disease. A protection rate of 95% was found from one dose of Meningococcinum 30c, and this protective effect extended for a period of six months from the dosing.

5. Cost-effectiveness of homoeopathic medicine

Government rebates for CAM therapies in Australia represent 0.08% of the total Federal Government expenditure on private health insurance rebates (Baggoley, 2012). Rebates for all natural therapies totalled $87 million in 2010–2011, with $27 million coming from the Federal Government. The greatest increase in the use of ancillary services of private health insurance were for natural therapies, which represented an 18% increase in 2011–2012 compared with the previous year (Harvey, 2012b). While CAM therapies account for a small proportion of ancillary services (5.6%), they include the widely-used modalities of acupuncture, traditional Chinese medicine, herbalism and naturopathy as well as several other smaller health care modalities. Specific figures homoeopathy are unavailable, but rebates for homoeopathic consultations are likely to represent a very small proportion of the total Federal Government private health insurance rebates for CAM therapies.

In the wider context of public health care funding, Medicare Australia provides financial support for medical consultation fees to a vastly greater extent than the Government rebate support for homoeopathic consultations. This broader perspective is informative, as the following discussion of the cost-effectiveness of homoeopathy will identify several areas of potential cost-savings from this form of treatment. These savings could represent a substantial benefit to the public purse if homoeopathic care was made more accessible to Australian health consumers. Proposals to remove the Federal Government rebates for homoeopathic health care would directly restrict accessibility and impinge upon the rights of current privately insured patients to access the range of therapies presently covered in the health care plan to which they have subscribed. Anecdotal evidence from clients informs us that the available coverage of CAM therapies has provided the impetus for many users of homoeopathy and other CAM practices to commence their subscription to private health insurance.

Adequate provision of public health care represents an ever-increasing burden on Government resources. The introduction of Federal Government rebates was designed to encourage the uptake of private health insurance, and generate a greater portion of health funding from the private sector. Support for consumer choice through rebates for homoeopathic consultations may raise more money in taxation revenue from practitioners than is spent on the rebate: a fair cost–benefit analysis would include these taxation considerations. While the proportion of the homoeopathic consultation fee covered by the health fund varies considerably, and the total offered annually is usually limited, the rebate

may be estimated at an average of 40% of the fee. Based on this figure, every dollar of Government funding directed at homoeopathic consultation fees is associated with $2.33 of the patient's contribution to the fund, plus another $5 of patient gap payment to the practitioner. The practitioner may therefore notionally receive $8.33 and, depending on the applicable tax bracket, is likely to pay $2 in taxation. On the basis of these estimates, the Federal Government doubles the value of its investment in homoeopathic consultations over approximately two years: an apparently highly judicious investment.

This likely positive cost–benefit equation of Federal Government outlays and related taxation revenue from homoeopathy can be added to the potential cost-savings to the community (public and private) which homoeopathic health care may offer. Some patients will not be deterred from attending a homoeopathic practitioner by the loss of insurance cover, but for others it is likely to result in increased GP consultations. Medicare supports approximately 85% of the doctor's fee; to this amount can be added investigation costs and medication costs (if Pharmaceutical Benefits Scheme listed) and costs for any ancillary health professionals (accessed via Health Care Plans). Less than one third of these outlays will come back to the Government as in the form of taxation payments.

The following discussion of the research reports savings that arise from the provision of homoeopathic health care.

5.1. The cost-effectiveness of homoeopathy

The issue of cost-effectiveness is critical in evaluating decisions about health care delivery. In 2011, the National Institute of Complementary Medicine released the results of a study demonstrating the relative value of complementary medicine interventions to the Australian community (National Institute of Complementary Medicine, 2009). This study conducted by Access Economics found that millions of health care dollars could be saved without compromising patient outcomes if complementary medicine was more widely used. These results are pertinent at a time when health care costs are rising faster than the general cost of living, and the percentage of gross national product expended on health care continues to escalate (Australian Institute of Health and Welfare, 2011).

Mirroring the findings of the Access Economics survey, a UK study by a leading economist found that significant savings to national health budgets would result from a greater use of complementary therapies (Smallwood, 2005). This study estimated that if only 4% of British GPs were to offer homoeopathy as a frontline approach to treatment, an annual saving to the National Health Service of 190 million pounds sterling would result.

Potential cost-savings attributable to community-based homoeopathic care are described in the following review of the research literature. In the absence of local studies, Australian inquiry must rely on European and other research. A wide range of studies indicate potential savings from the provision of homoeopathic health care, with equal or improved clinical effectiveness. Multiple factors contribute to lowered costs and these include: reduced duration of illness, reduced need for drug treatments, lower cost of homoeopathic medicines compared with pharmaceutical drugs, reduced demand for GP consultations; reduced health-related costs, such as loss of productivity due to time off work; reduced compensation payments as a result of illness; savings from absence of side effects of drug therapy and subsequent treatments; and improved overall health and quality of life of homoeopathic patients.

Studies (see Table 3 below) examining the cost-effectiveness of homoeopathy show:

- reduced costs of homoeopathy with similar or improved clinical effectiveness (Bracho et al., 2010; Chaufferin, 2000; Jain, 2003; Kneis & Gandjour, 2009; Pomposelli et al., 2009; Torres et al., 2001; Trichard et al., 2005; Rodrigues-Neto et al., 2009; Swayne, 1992; van Wassenhoven & Ives, 2004)
- homoeopathic treatment is cheaper than conventional prescriptions (Bononi, 2000; Bracho et al., 2010; Chaufferin, 2000; Jain, 2003; Kneis & Gandjour, 2009; Pomposelli et al., 2009; Rodrigues-Neto et al., 2009; Rossi et al., 2009a; Studer & Busato, 2011; Torres et al., 2001; Trichard et al., 2005; van Wassenhoven & Ives, 2004)
- reduced need for other prescriptions contributes to lowered costs (Bracho et al., 2010; Chaufferin, 2000; Frei & Thurneysen, 2001b; Frenkel & Hermoni, 2002; Jain, 2003; Marino, 2008; Pomposelli et al., 2009; Rossi et al., 2009a; Rossi et al., 2009b; Sevar, 2005; Taylor et al., 2000; Trichard et al., 2005; van Haselen, 2000; van Wassenhoven & Ives, 2004; Witt et al., 2009b)
- reductions in GP consultations (International Data Collection Centres for Integrative Medicine, 1998; Sharples et al., 2003)
- reduced work-absenteeism and reduced parental absence due to child illness (Frei & Thurneysen, 2001b; Frenkel & Hermoni, 2002; Sevar, 2005; Swayne, 1992; Trichard et al., 2005; van Haselen, 2000; van Haselen et al., 1999)
- an absence of side effects due to not taking conventional medicines (Marian et al., 2008; Studer & Busato, 2011; van Wassenhoven & Ives, 2004; Zuzak et al., 2010)

- high levels of patient satisfaction (Kliems & Witt, 2011; Marian et al., 2008; Pomposelli et al., 2009; Rodrigues-Neto et al., 2009; Studer & Busato, 2011; Trichard et al., 2004; van Wassenhoven & Ives, 2004; Vincent et al., 2012; Witt et al., 2009b)

Table 3. Summary of studies of the cost-effectiveness of homoeopathy (studies older than 10 years have been highlighted).

Author	Study description	Findings
Bononi (2000)	Forte S homoeopathic formula was used for prophylaxis of post-operative infections. Forte S was compared with ceftazidime and cetriaxone.	This homeopathic medicament proved to be equally effective and much less expensive.
Bracho et al. (2010)	In 2007, the population of a region of Cuba (2,500,000 people) were administered the homoeopathic prophylactic against Leptospirosis, due to insufficient supply of the conventional vaccination material. Leptospirosis is an annually occurring epidemic with a typically high morbidity rate, even when the usual vaccination is employed.	Only ten people developed the disease, in marked contrast to the tens of thousands normally infected each year. No lives were lost and the program was highly cost-effective in comparison to the conventional and less effective vaccine programs. The protective effect continued (without re-dosing) into 2008 with an 84% reduction in leptospirosis cases for the treated area. Leptospirosis infections in non-homoeopathically treated areas increased by 22% in 2008.
Chaufferin (2000)	The financial crisis of health insurance systems sometimes drives public policy-makers to take precipitate action dominated by economic imperatives. The question addressed here consists in defining homoeopathy's scope of intervention, its place in health care strategies, recourse to treatment, and especially economic data appraising homoeopathy's impact on expenditures and outlay covered by health insurance in France. We used the General Evaluation Model to define the study (to whom is the evaluation made, situations, criteria, measurement of these criteria, quality and precision).	The main results are in terms of costs, as follows: For reimbursable medicines the public sales price of homeopathic products is a quarter of the average. The total reimbursement for a prescription of allopathic products is three times more than for a prescription of homeopathic products. Homeopathic physicians incur annual reimbursement outlays which are half those of general practitioners. The differences observed cannot be explained by the patient profile or the diseases treated. Furthermore, a study carried out in France showed that 87% of patients whose physicians had prescribed homeopathic treatment did not see another physician for the same problem.
Frenkel and Hermoni (2002)	The effects of homoeopathic intervention on the consumption of medication in atopic and allergic disorders.	Fifty-six percent of patients in this study reduced their use of conventional medication following the homeopathic intervention. Patients who used conventional medications for their allergic disorders reduced their medication expense by an average of 60% in the 3-month period following the homeopathic intervention.
Jain (2003)	Data were collected for 4 years on all patients who were treated homoeopathically by one GP. Costs of homoeopathic remedies and costs of conventional drugs which otherwise would be prescribed for these patients was calculated for the total duration of treatment.	Savings were calculated. One hundred patients were included in the study. Average cost savings per patient was £60.40. The majority of patients had improved and most did not report any side-effects. Calculated costs in this study are based on drugs only, it does not take into account doctor's time, special investigations and time off sick.

Author	Study description	Findings
Kliems and Witt (2011)	The objective of this study was to identify the factors that make a good doctor, both from a patient and a physician perspective. Is there a connection between practising homoeopathy and being a good doctor? This was a qualitative study of homeopathically trained physicians and their patients, using observation of patient-physician interactions (n=29) and interviews with patients (n=20) and with physicians (n=4).	Patients identified the availability of time, both in itself and as a prerequisite for other physician characteristics, as the single most important factor. Other factors include scope of diagnosis/holistic approach, patient-centeredness/empathy, and perceived competence/therapeutic success. Patients did not link these factors to the homeopathic orientation of their physician, while physicians clearly made this connection.
Kneis and Gandjour (2009)	Sinfrontal is a complex homeopathic medication, the efficacy and safety of which has been demonstrated in a number of clinical studies of patients with sinusitis. Sinfrontal was compared with placebo in a cost-utility analysis based on data from a randomized controlled clinical trial over 3 weeks (Sinfrontal group: n = 57; placebo group: n = 56). Trial data were analysed from a societal perspective; resource use was valued with German unit costs for 2005. In a secondary analysis, the longer-term cost utility of Sinfrontal versus placebo was estimated over a total of 11 weeks based on an 8-week post-treatment observational phase. In addition, the cost effectiveness of Sinfrontal versus antibacterials was determined based on an indirect comparison of placebo-controlled trials.	Sinfrontal led to incremental savings of euro 275 (95% CI 433, 103) per patient compared with placebo over 22 days, essentially due to the markedly reduced absenteeism from work (7.83 vs 12.9 workdays). Incremental utility amounted to 0.0087 QALYs (95% CI 0.0052, 0.0123), or 3.2 quality-adjusted life-days (QALDs). Bootstrapping showed that these findings were significant, with Sinfrontal being dominant in 99.9% of simulations. The results were robust to a number of sensitivity analyses. In the secondary analysis, Sinfrontal led to incremental cost savings of euro 511 and utility gains of 0.015 QALYs or 5.4 QALDs compared with placebo. Compared with antibacterials, Sinfrontal had a significantly higher cure rate (11% vs 59%; $p < 0.001$) at similar or lower costs. The results of this economic evaluation indicate that Sinfrontal may be a cost-effective treatment for AMS in adults.
Marian et al. (2008)	The main objective of this study is to investigate patient satisfaction and perception of side effects in homoeopathy compared with conventional care in a primary care setting. A total of 6778 adult patients received the questionnaire and 3126 responded (46.1%).	Statistically significant differences were found with respect to health status (higher percentage of chronic and severe conditions in the homeopathic group), perception of side effects (higher percentage of reported side effects in the conventional group) and patient satisfaction (higher percentage of satisfied patients in the homeopathic group).
Marino (2008)	This paper describes experiences of the use of homoeopathy in the prevention and treatment Dengue fever in São José do Rio Preto, São Paulo, Brazil. May 2001, a single dose of the homeopathic remedy Eupatorium perfoliatum 30cH was given to 40% of residents of the most highly affected neighbourhood.	Dengue incidence decreased by 81.5%, a highly significant decrease as compared with neighbourhoods that did not receive homeopathic prophylaxis ($p<0.0001$). Between April and September 2007, a homeopathic complex composed of Eupatorium perfoliatum,Phosphorus and Crotalus horridus 30cH, were given to 20,000 city residents. This trial was aborted prematurely due to national political intervention, Dengue incidence decreased by 81.5%, a highly significant decrease as compared with neighbourhoods that did not receive homeopathic prophylaxis ($p<0.0001$). Between April and therefore, only partial and isolated data could be recorded. However, the results suggest that homoeopathy may be effective in the prevention and treatment of Dengue epidemics.

Author	Study description	Findings
Pomposelli et al. (2009)		Diabetic neuropathy symptoms improved in both groups, but was significantly better than baseline only on the homoeopathy group (p=0.016).QOL scores improved only in the homoeopathy group. The cost of conventional drugs decreased in the homoeopathy group by 20%.
Rodrigues-Neto et al. (2009)	This study analysed 3080 replies to a semi-structured questionnaire.	The prevalence of the use of homoeopathy was 2.4%. The main reason that led to seeking homoeopathy was "Conventional treatment did not have any effect". For 70.2% of the users, the cost of the treatment was considered reasonable or cheap. About 73% were satisfied or very satisfied with the treatment received through homoeopathy.
Rossi et al. (2009a)	A retrospective observational study was conducted on 105 out of 233 patients suffering from chronic respiratory disease attending the Homeopathic Clinic of the Campo di Marte Hospital in Lucca (Tuscany, Italy) between October 1998 and May 2003. We assessed the cost of conventional medicinal products using Anatomic Therapeutic Chemical (ATC) classification, specific for the pathology in question, and the general costs in the year preceding the first appointment at the Homeopathic Clinic vs. the first and second year subsequent to homeopathic treatment. The costs of conventional drugs for a group of patients affected by asthma (8 patients) and recurrent respiratory infections (16 patients) with long term use of conventional medicine treated by homoeopathy were compared with the expenses of conventional drugs of a matched group of 16 and 32 patients, respectively.	Costs of pharmacological therapy specific for respiratory diseases were reduced by 46.3% (n = 105) in the first year (P < 0.01); and by 47.5% (n = 72) in the second year (P < 0.01) of homeopathic treatment. Reduction in general drug costs during homeopathic therapy was 42.4% in the first year (P < 0.01); and 49.8 in the second year (N.S.). Costs for patients affected by chronic asthma showed a reduction in expenses of 71.1% for specific medicines relative to the group in homeopathic treatment vs. an increase of 12.3% in the group treated only with conventional drugs after the first year of follow-up and, respectively, a reduction of 54.4% for homeopathic treatment vs. +45.2% after the second year. For patients with recurrent respiratory infections we found a reduction of 35.8% in the homeopathic group in the first year, compared to an increase 8.6% of costs for specific drugs in the control group; in the second year the respective figures were 43.6% versus +7.8% in the control group. Homeopathic treatment for respiratory diseases (asthma, allergic complaints, Acute Recurrent Respiratory Infections) was associated with a significant reduction in the use and costs of conventional drugs. Costs for homeopathic therapy are significantly lower than those for conventional pharmacological therapy.

Author	Study description	Findings
Sevar (2005)	This paper reports an audit of clinical outcome in 455 consecutive patients (1100 consultations) presenting for private homeopathic treatment of a chronic illness in which conventional treatment had either: failed, reached a plateau in effect, or was contra-indicated by side effects, age or condition of the patient.	Three hundred and four patients (66.8%) derived benefit from homeopathic treatment. One hundred and forty-eight patients (32.5%) were able to stop or maintain a substantial reduction in their conventional drugs. The 10 most frequent clinical conditions treated were eczema, anxiety, depression, osteoarthritis, asthma, back pain, chronic cough, chronic fatigue, headaches and essential hypertension. These 195 patients constitute 43% of the total, 151 of them (77%) were improved. The success rate of treatment is similar between age ranges. There was a difference in outcome between the sexes in adults: 296 females treated, success rate 71.3%; 159 males treated, success rate 58.5%. Two patients (0.4%) had prolonged aggravation of their presenting complaints apparently attributable to homeopathic treatment.
Sharples et al. (2003)	To examine patients' reasons for seeking complementary and alternative medicine (CAM) in the National Health Service, including the nature and duration of the patient's main health problem, the impact of CAM on this, satisfaction with clinical care, and usage of conventional prescription medication. Survey (n=499). Out-patient Department, The Royal London Homeopathic Hospital, a National Health Service facility dedicated to CAM.	Five hundred and six questionnaires were returned, 499 were analysed. Patients' most frequent reasons for seeking CAM were that other treatment had not helped, and concerns about or experience of adverse treatment reactions. Two hundred and ninety-seven patients (63%) had had their main problem for more than 5 years. Musculoskeletal system problems were the most frequent diagnostic group (n=151, 32%). Satisfaction with clinical care was high (443/490: 90%). Three hundred and eighty patients (81%) indicated their main problem had improved very much, moderately or slightly. Of the 262 patients who had been taking prescription medicines when they first attended, 76 (29%) had stopped, and 84 (32%) had reduced their intake. The results suggest that orthodox medicine is not meeting the needs of some patients and that CAM may wholly or partly substitute for conventional medicines. Most patients indicated their problem had improved with CAM. Implications for future research are discussed.
Studer and Busato (2011)	This study sought to compare practice costs of physicians applying CAM with those of physicians applying solely conventional medicine (COM) in Swiss ambulatory care. A cross-sectional investigation of claims data of mandatory health insurance was made for the years 2002 and 2003. Practice costs of 562 primary care physicians with and without a certificate for CAM were analyzed and compared with patient-reported outcomes. Linear models were used to obtain estimates of practice costs controlling for different patient populations and structural characteristics of practices across CAM and COM.	Statistical procedures show similar total practice costs for CAM and COM, with the exception of homoeopathy with 15.4% lower costs than COM. Patients reported better quality of the patient-physician relationship and fewer adverse side effects in CAM. Higher cost-effectiveness for CAM can be deduced from this perspective.
Torres et al. (2001)	30 children with asthma were treated with homoeopathy and 30 with conventional medicine.	All 60 had a satisfactory clinical course, but the conventional treatment was 10 times more expensive.

Author	Study description	Findings
Trichard et al. (2004)	Researchers compared the effectiveness, the quality of life of the parents, and the direct and indirect costs associated with treatment from homeopathic and non-homeopathic GPs in this pragmatic, prospective observational study.	This study produced new findings that indicate that, in France, acute rhinopharyngitis is handled differently by homeopathic GPs and non-homeopathic GPs: homeopathic GPs prescribe fewer antibacterials than non-homeopathic GPs for the treatment of recurrent acute rhinopharyngitis in children aged between 18 months and 4 years. Moreover, homeopathic treatment gave better results in terms of pragmatic medical effectiveness (fewer episodes and fewer complications) and the parents' quality of life, with similar total medical costs to social security.
Trichard et al. (2005)	A pharmacoeconomic study to compare, in terms of: medical effectiveness, quality of life and costs two treatment strategies ('homeopathic strategy' vs 'antibiotic strategy') used in routine medical practice by allopathic and homeopathic GPs in the treatment of recurrent acute rhinopharyngitis in 18-month to 4-year-old children. Statistical analysis of data obtained from a population of 499 patients included in a previous 6-month prospective, pragmatic study. The patients were regrouped according to type of drug prescribed. Medical effectiveness was assessed in terms of (i) episodes of acute rhinopharyngitis, (ii) complications, (iii) adverse effects. Quality of life was assessed using the Par-Ent-Qol scale. Direct medical costs (medical consultations, drug prescriptions, prescriptions for further tests) and indirect medical costs (sick-leave) were evaluated from three viewpoints (society, patient, Social Security) using public prices and French Social Security tariffs.	The 'homeopathic strategy' yielded significantly better results than the 'antibiotic strategy' in terms of medical effectiveness (number of episodes of rhinopharyngitis: 2.71 vs 3.97, P<0.001; number of complications: 1.25 vs 1.95, P<0.001), and quality of life (global score: 21.38 vs 30.43, P<0.001), with lower direct medical costs covered by Social Security (88 Euros vs 99 Euros, P<0.05) and significantly less sick-leave (9.5% of parents vs 31.6% of parents, P<0.001). Conclusion: Homoeopathy may be a cost-effective alternative to antibiotics in the treatment of recurrent infantile rhinopharyngitis.
van Haselen (2000)	The practical implementation of a staged, multifaceted research agenda for the economic evaluation of complementary medicine (CM) at the Royal London Homeopathic Hospital (RLHH). The relative importance of economic evaluation as an evidence base of CM was assessed via a survey conducted with purchasers (n=481). The marginal costs of providing complementary care for patients with rheumatoid arthritis were calculated. The use, and changes in the use, of conventional medicines for patients' main complaints were established retrospectively (n=499) and prospectively (n=70). Health-related quality of life (patient utility) of newly referred patients was assessed with the EQ-5D (EuroQol) instrument (n = 70) on a 100 mm (0 = worst, 100 = best) scale.	Economic evaluation was rated 'important' as an evidence base, after safety and RCT data ('very important'). Consultation time (doctors and dietician) contributed 29% of the total costs of treating rheumatoid arthritis. The retrospective survey showed that many patients on conventional medication were able to stop (29%) or reduce (32%) intake in the course of treatment. The median (quartiles) health state of newly referred patients was 70 mm (50,78) in men and 60 mm (36,73) in women. Some results of an interim analysis of 6 months follow-up data are reported. Economic evaluation of CM is becoming increasingly important and should take place by using a multifaceted, staged approach. Before embarking on randomised trials, observational data on cost, effectiveness and utility should be collected. The cost-effectiveness of CM appears to be most sensitive to the duration of the consultation.

Author	Study description	Findings
van Wassenhoven and Ives (2004)	An observational study of eighty general medical practices in Belgium where physicians were members of the Unio Homoeopathica Belgica. A total of 782 patients presented with diseases of all major organ systems which were of sufficient severity to interfere with daily living in 78% of cases.	Compared to previous conventional treatment, patients reported that consultations were much longer but cost less. One or more conventional drug treatments were discontinued in over half (52%) of the patients: CNS (including psychotropic) drugs (21%), drugs for respiratory conditions (16%) and antibiotics (16%). Conventional drugs were prescribed to about a quarter of patients (27%), mostly antibiotics and cardiovascular medication. The antibiotics were almost exclusively (95%) used to treat respiratory infections. Prescription costs (including conventional medicines) were one third of the general practice average. Patients' satisfaction with their homeopathic treatment was very high (95% fairly or very satisfied), and ratings of their previous treatment was much lower (20%). The great majority (89%) said that homoeopathy had improved their physical condition; 8.5% said that it had made no difference, 2.4% said that homoeopathy had worsened their condition. Physicians' ratings of improvement were similar. Previous conventional treatment had improved 13% of patients, made no difference to 32%, and had worsened the condition of over half (55%). A similar pattern was seen for psychological symptoms. The study concludes that patients were very satisfied with their homeopathic treatment, both they and their physician's recorded significant improvement. Costs of homeopathic treatment were significantly lower than conventional treatment, and many previously prescribed drugs were discontinued.
Vincent et al. (2012)	Study to determine characteristics and management of patients visiting allopathic GPs (AGPs) and homeopathic GPs (HGPs) with influenza-like illness (ILI). 65 HGPs & 124 AGPs recruited a total of 461 patients. Patients & GPs completed questionnaires re demographic characteristics and patient symptoms, with report of treatments occurring on day 4.	In France, homoeopathy is widely accepted for the treatment of ILI and does not preclude the use of allopathic medicines. Patient satisfaction with treatment did not differ between the AGPs and the HGPs, but was highest for those treated only with homeopathic medicine.
Witt et al. (2005)	To evaluate the effectiveness of homoeopathy versus conventional treatment in routine care. Analyses of 493 patients (315 adults, 178 children) were undertaken.	The results indicated greater improvement in patients' assessments after homoeopathic versus conventional treatment (adults: homoeopathy from 5.7 to 3.2; conventional, 5.9-4.4; $p = 0.002$; children from 5.1 to 2.6 and from 4.5 to 3.2). Physician assessments were also more favourable for children who had received homoeopathic treatment (4.6-2.0 and 3.9-2.7; $p < 0.001$). Overall costs however showed no significant differences between both treatment groups.

Author	Study description	Findings
Witt et al. (2009b)	129 adults (mean age 43.6 +/- 12.7 y) were treated by 48 physicians. The patients mainly had chronic low back pain (average duration 9.6 +/- 9.0 y) and other chronic diseases. 91.3% had been pre-treated. Consultation time cumulated to 204.5 +/- 184.6 minutes. The patients received an average of 6.8 +/- 6.3 homeopathic prescriptions.	The severity of the diagnoses and complaints showed marked and sustained improvements with large effect sizes (Cohen's d from 1.67 to 2.55) and QOL improved accordingly (SF-36 physical component scale d = 0.33; mental component scale d = 0.54). The use of conventional treatment and health services decreased markedly: the number of patients using low back pain-related drugs was half of the baseline.
Zuzak et al. (2010)	The purpose of this study was to find out what experiences adults are having while treating children with complementary and alternative medicine (CAM) therapies in German-speaking Switzerland. Homoeopathy was the most frequently used form of CAM (77% of all CAM users), followed by herbal medicine (64%), anthroposophic medicine (24%), Traditional Chinese Medicine (13%), Ayurveda (5%), and others (34%).	From the respondents' point of view, the most marked difference between CAM- and Conventional Medicine therapies concerns the frequency and intensity of side-effects, which were markedly higher in the latter case.

5.2. Cost-effectiveness and clinical effectiveness

The cost-effectiveness of health interventions is relevant only if the health intervention achieves positive clinical outcomes. A sustained theme in the studies of the economics of homoeopathic care in Table3 is the concomitance of reduced costs with good clinical results. Only one study reported here finds no statistically significant difference between the costs of conventional care compared with homoeopathic care (Witt et al., 2005), and this study reported better clinical effectiveness for the same costs as conventional care. This study was commissioned by a German health insurance company to inform decisions about their continuance of rebates for homoeopathy. Using data provided by the health insurer, the study inquired into the treatment of common chronic conditions such as: lower back pain; headache; insomnia; depression and sinusitis in adults; and dermatitis, allergic rhinitis and asthma in children. Information was collected on symptom severity as rated by patients and doctors, quality of life and costs of consultations, medication, physiotherapy, hospitalisation, sick pay and medical devices at 6 and 12 months. The effectiveness of homoeopathic treatment was compared with conventional treatment in 493 patients with chronic conditions (315 adults and 178 children). While cost-neutral, patient assessments in the Witt et al. (2005) study showed greater improvement in the homoeopathically treated group and physician assessments were statistically significantly more positive for child patients in the homoeopathic treatment group.

In a study by Kneis and Gandjour (2009), a higher rate of cure (59% vs. 11%) was achieved in the treatment of acute maxillary sinusitis using a homoeopathic complex medicine, Sinfrontal, compared with a placebo, along with cost savings due to reduced time away from work for those treated homoeopathically (7.8 days compared with 12.9 days).

A French study of children treated for acute rhinopharyngitis compared homoeopathic treatment with antibiotic therapy (Trichard et al., 2005) and found positive outcomes across a range of variables in the homoeopathically treated children. Homoeopathically treated patients had better medical effectiveness (fewer episodes and fewer complications), higher quality of life measures and lower direct medical costs. Parents' sick-leave requirements were reduced for the homoeopathically treated children, resulting in further indirect cost savings.

In a study of 499 children aged between 18 months and four years by Trichard et al. (2005), homoeopathic and conventional treatment of acute recurrent rhinopharyngitis was compared. Homoeopathic treatment gave better results than antibiotics in terms of general medical effectiveness (the number of episodes of illness) with lower direct costs (88 Euros compared with 99 Euros), along with the need for significantly less sick leave (9.5% of parents of homoeopathically treated children took leave, compared with 31.6% of parents taking of children in the antibiotic group). In 2003, the same research group compared homoeopathic and allopathic treatments for anxiety disorder and both strategies were found to be equally effective, with the homoeopathic treatments offering potential cost savings (Trichard & Chaufferin, 2003).

Pomposelli et al. (2009) found similar positive outcomes from the homoeopathic treatment of diabetic neuropathy. This study showed that while both groups achieved symptom improvements, only the homoeopathy patients had improvements that were significantly better than their baseline symptoms. In the homoeopathically treated group, quality of life measures showed improvement and the cost of conventional drugs decreased by 20%.

5.3. Reductions in expenditure on conventional drug treatments

Cost savings due to effective substitution of homoeopathic medicine for pharmaceutical drugs emerge in several studies. A homoeopathic GP compared the costs for 100 patients treated homoeopathically, with the costs for pharmaceuticals they would otherwise have required and demonstrated savings of sixty pounds sterling per patient (Jain, 2003). Patients were assessed using the Glasgow Homoeopathic Hospital Outcomes Measure, and 92

patients improved without any side-effects, demonstrating both clinical effectiveness and cost-effectiveness, along with the safety of homoeopathic medicine.

In a retrospective observational study in Tuscany, costs for two groups of patients with similar chronic respiratory complaints were surveyed over a four and a half year period (Rossi et al., 2009a). Chronic asthmatics in the homoeopathically treated group reduced their conventional drug expenses by 71.1% after the first year of follow-up, compared with a 12.3% increase in drug expenses for the conventionally treated group. The second year of treatment continued to produce cost savings for the homoeopathy patients: their costs were reduced by 54%, while the control group had a 45% increase in their costs of medicines. Similar patterns of significant reductions in drug costs were reflected in patients treated with homoeopathy for recurrent respiratory infections at the same hospital.

In a pilot project at the Royal London Homoeopathic Hospital, van Haselen (2000) evaluated the cost effectiveness of homoeopathic treatments and identified cost-savings through reductions in expenditure on conventional medicines. Here, 29% per cent of patients were able to cease conventional medicines, 33% reduced their reliance on conventional treatments and 32% per cent reported no change in other medications whilst on homoeopathic medicine.

UK economist Christopher Smallwood (2005) estimated that dramatic reductions in drug costs were possible if homoeopathic health care was to be offered as frontline treatment. Smallwood referenced the findings of a 1992 study by Swayne (1992) which compared the National Health Service prescribing costs of 22 GPs using homoeopathy with those using conventional drug therapies. The 12% reduction in prescription items under homoeopathic treatment identified by Swayne was extrapolated to national levels by Smallwood, who estimated that the number of prescription items would be reduced by 41.5 million if homoeopathic treatment was more widely available.

Similarly, another UK study by Sharples et al. (2003) found that cost savings are achieved through reduced reliance on pharmaceutical medicines. Questionnaires from 499 patients who had CAM treatment within the National Health Service were analysed. Of the 262 patients who had been taking prescription medicines at the commencement of treatment, 76 (29%) had stopped and 84 (32%) had reduced their intake as a result of that treatment. Sixty-three per cent of patients in this study had had their main complaint for more than five years and a 90% patient satisfaction rating of their clinical care was achieved. Improvements were rated very much improved, moderately improved or slightly improved in 380 (81%) of the 499 patients surveyed. The authors concluded that orthodox treatment

fails to meet the needs of some patients, and that CAM may wholly or partly substitute for conventional medicines.

5.4. Patient satisfaction measures high in homoeopathic care

Lowered costs and high ratings of patient satisfaction (95% fairly or very satisfied) characterised the outcomes of a large observational study of 80 homoeopathic practices in Belgium (van Wassenhoven & Ives, 2004). Seven hundred and eighty-two patients were surveyed, 78% of whom had ailments of sufficient severity to interfere with activities of daily life. More than half of these patients were able to discontinue one or more conventional drugs, and 89% reported that homoeopathy had improved their physical condition, assessments that were matched by similar physician ratings of patient improvement. Psychological symptoms mirrored the extent of physical symptom relief in this group of patients, and this simultaneous improvement in the physical and psychological state of homoeopathic patients is a characteristic of this form of medicine. These responses reflect the nature of holism in health care: a well-prescribed homoeopathic medicine addresses the whole state of the patient and achieves a response at that level. In the study by van Wassenhoven and Ives (2004), only 13% had improved under previous conventional treatment, compared with 89% who improved when treated homoeopathically. For 55%of these patients, their condition had worsened under previous conventional care.

Rodrigues-Neto et al. (2009) found that the main reason that patients sought homoeopathic care was the failure of conventional care. Seventy-three per cent of homoeopathic patients in this study were satisfied or very satisfied with their treatment, and for 70.2% of those treated homoeopathically, the cost of treatment was considered reasonable or cheap. Patient satisfaction was also rated as high in homoeopathy patients in the study by Marian et al. (2008), where 3,126 patients were surveyed in a primary care setting comparing homoeopathy with conventional care.

Studer and Busato (2011) reported that CAM therapies resulted in a better quality of the patient–physician relationship, lower costs and fewer adverse effects. In a 2011 study to identify the characteristics of a good doctor, by Kliems and Witt (2011) found that patient-centeredness, a holistic approach and the competence of the practitioner were all important factors for both patients and physicians, while the availability of time was important as a prerequisite for other physician qualities.

5.5. Reduced general practitioner consultations following homoeopathic care

A 45% reduction in GP consultations for homoeopathically treated patients was found in a review of complementary and integrative care at the Glasgow Homoeopathic Hospital. This research was conducted by the International Data Collection Centres for Integrative Medicine (1998), an evidence-based action research program for assessing and improving patient care. In this review of the care of very ill patients, 85% had health problems severe enough to cause major disruptions to activities of daily life: the study generated a range of very positive findings for the use of complementary and integrative health care for these patients whose problems had resisted orthodox treatment. These patients received a range of therapies, with 95% receiving homoeopathic treatment. The researchers concluded that an integrative approach to patient care "interrupts the cycle of escalating Health Service costs associated with these patients. In addition to [this] cost containment there is striking evidence of long term reductions in iatrogenesis and economic costs for a large proportion of these patients" (International Data Collection Centres for Integrative Medicine, 1998, p.2).

A 70% reduction in the need for GP consultations was a feature of findings by Sharples et al. (2003). While the costs of homoeopathic medications were not addressed in this study, preventing a direct cost comparison of each model of care, the study indicated the potential for very significant reductions in the demand for medical resources, both personnel and drugs, from the provision of homoeopathic care in general practice.

Reduced morbidity may reduce related health costs resulting from repeated demand for medical consultations, drug prescriptions, and time away from work or families. A study comparing the treatment of ear infections by either homoeopathy or conventional methods (Friese et al., 1997) found that only 5 (5%) of the 103 in the homoeopathically treated group required antibiotics. This group also had faster pain relief and fewer re-infections over the following year: 70% of the homoeopathic group had no recurrence over the following year, compared with a 56.5% recurrence rate in the conventionally treated group. The duration of pain in otitis media in the homoeopathic group was two days, compared with three days in the conventional group. This study, published in the *International Journal of Clinical Pharmacology*, concluded that homoeopathy should be the front line treatment in cases of childhood middle ear infections.

5.6. Lower costs of homoeopathic care across a range of measures

The findings of studies initiated by French health insurers suggest that homoeopathic treatment costs less than conventional approaches (Chaufferin, 2000; Trichard & Chaufferin, 2003). While some problems in evaluation of data were encountered in the Chaufferin (2000) study, it identified a range of cost benefits of homoeopathic medical care: homoeopathic medicines were found to be one-fifth to one-quarter of the cost of conventional drugs; health expenses from consultations with homoeopathic physicians were 42% below those of conventional practitioners; homoeopathic physicians claimed 38% less compensation for medical provisions and 45% less for medications; and homoeopathic physicians gave 68% fewer days off work to their patients.

In epidemiological studies of the use of homoeopathic prophylactic medicines in potential epidemic settings (Bracho et al., 2010; Marino, 2008), the response to homoeopathic interventions was markedly positive, suggesting that, at a population level, greater economic benefits are possible through homoeopathic treatments compared with usual vaccination programs. In San Paolo, Brazil, a protective effect was established from the use of a single dose Eupatorium perfoliatum 30c when given to 40% of a neighbourhood that is usually severely affected by dengue fever (Marino, 2008). Dengue fever incidence was reduced by 81.5% in the area treated with Eupatorium compared with neighbourhoods who did not receive the remedy.

Due to an insufficient supply of conventional vaccine, 2.5 million people in a region of Cuba prone to Leptospirosis infection were given the homoeopathic prophylactic against the disease (Bracho et al., 2010). This annually occurring epidemic has a high morbidity rate, even when conventional vaccines are given. While tens of thousands are usually infected each year, only 10 people in the treated area developed the infection after homoeopathic dosing in the 2007 season. The protective effect continued without re-dosing into the following season, with another reduction in disease incidence of 84% in 2008 amongst the population treated homoeopathically. The Cuban study noted the highly cost-effective nature of this intervention compared with conventional vaccine. The health benefits from homoeopathic preparations at a population level suggest marked economic benefit. In a randomised controlled trial evaluating the treatment of malaria with individualised homoeopathy, van Erp and Brands (1996) found a response rate of 83% in the homoeopathically treated group compared with a response rate of 72% in the Chloroquine treated control group. It is likely that wide scale use of homoeopathy at population level would deliver substantial savings in public health provision.

In routine clinical care, physicians using homoeopathic medicine spend more time with their patients, resulting in higher consultation costs. This extra expense may be defrayed by the range of potential savings generated by homoeopathic health care provision. These include: reduced costs due to fewer pharmaceutical products; lower levels of diagnostic testing; reduced calls on the homoeopathic doctor and medical care in general over time due to the patient's improved health following treatment; and reductions due to the negligible incidence of side-effects of homoeopathic care. All of these factors may contribute to considerable potential savings using the homoeopathic model of health care.

6. Safety

6.1 Safety of homoeopathic medicines

Concern about toxicity led to the practice of diluting and the vigorous shaking of the medicinal substance referred to as succussion. This radical innovation by the founder of homoeopathy, Dr Samuel Hahnemann (1755–1843), continues as the principal modus operandi of homoeopathic pharmacology, which was controversial at the time of its inception and remains so today. Advocates and detractors of homoeopathy alike, however, concur that the repeated dilution of medicinal substances greatly reduces the likelihood of adverse reactions. This minimisation of potential toxicity is achieved through the careful preparation of homoeopathic medicines by specialist homoeopathic pharmacies worldwide.

Homoeopathic pharmacies are governed by local regulatory mechanisms that ensure appropriate conditions for the safe manufacture homoeopathic medicines. The world-wide homoeopathic manufacturing industry adheres to internationally accepted homoeopathic pharmacopeia that provide protocols for the standardised preparation of these medicines (European Council for Classical Homeopathy, 2009). In Australia, the Therapeutic Goods Administration of the Federal Government has oversight of the conditions governing the manufacture of homoeopathic products (Therapeutic Goods Administration, 2012).

As demonstrated in the research evidence documented in section 4 above, homoeopathic medicines have biological effects, and therefore there is the potential for adverse effects. The relative safety of homoeopathic medicines is, however, frequently cited as a distinguishing feature of homoeopathy (Adler, 1999; Bornhöft et al., 2006; Dantas & Rampes, 2000; Grabia & Ernst, 2003; Thompson et al., 2004). The European Council for Classical Homeopathy (2009) undertook research into the safety of homoeopathic medicinal products and homoeopathic prescribing and concluded that, "current evidence seems to confirm the claim that [homoeopathic medicinal products] are safe to use and homoeopathic treatment provided by statutorily regulated or self-regulated homoeopaths is safe" (p.3).

When homoeopathic medicines are prescribed in a professional clinical setting, guided by the principles of similarity, potentisation and minimum dosing, adverse drug effects are generally avoided. The careful selection of a homoeopathic, most-similar, medicine targets the established response of the patient's manifest symptoms and represents a complex form of personalised medicine that was developed well before contemporary innovations in genetic medicine (National Health and Medical Research Council, 2011). Based on the principle of similarity, homoeopathy is thought to act through a process of reinforcing the

body's inherent response: the most similar medicine in potentised form may therefore act to optimise the body's response to its pathology and so facilitates resolution of that pathology.

6.2. Homoeopathic remedy responses

A detailed knowledge of the therapeutic action of remedies derives from homoeopathic drug trials or *provings* (Dean, 2004) of medicines on healthy human subjects. This accumulation of medicinal information means that, in a given clinical situation, the action of a carefully prescribed medicine may be able to be predicted. While negative responses to homoeopathic medicines are not common (Posadzki et al., 2012), patients are informed of the typically short duration of any medicinally related effects should they occur and of management of symptoms, if required. These reactions are not the same as the side effects that are common in conventional medicine, but are the result of a particular interaction of the patient's whole state with the medicine most similar to that state. In the professional setting, potential responses to prescribed medicines are discussed with patients before treatment. Possible homoeopathic remedy reactions can be categorised as: an initial aggravation, a proving response or a return of old symptoms (Bell, 2008; Dhawale, 1967).

Whilst it is emphasised that these responses are not typical of everyday homoeopathic practice with remedy reactions which could be regarded as negative, it will be of interest to the reader that over 200 years of application, observation and empirical record of homoeopathic practice has provided an extensive knowledge base of the range of action of homoeopathic medicines. The theory derived from these observations is presented in the following sections – 6.2.2, 6.2.2, 6.2.3.

6.2.1. Initial aggravation

It is within the ambit of homoeopathic laws that, in certain circumstances, a remedy response can provoke a temporary exacerbation of the presenting symptoms; referred to as an 'initial aggravation'. This phenomenon is most commonly mild and short-lived. These reactions may indicate systemic eliminatory responses to the prescribed medicine, and may be regarded as signs of a positive response to the medicine, are rarely troublesome to the patient and are well-managed within the professional homoeopathic setting.

6.2.2. Proving response

The Homoeopathic Materia Medica has evolved from the accumulated knowledge of the capacity of homoeopathic potencies to elicit symptom responses from healthy individuals

when medicines are repeatedly applied as part of a homoeopathic drug proving or homoeopathic drug trial (Dean, 2004). The capacity for a proving response to occur in a sensitive patient is clearly understood on the rare occasions that it may occur.

Highly sensitive patients from whom a marked drug reaction such as a proving response may be anticipated, and therefore usually avoided, are identified from the data derived from homoeopathy's very detailed case-taking. High sensitivity in a patient guides the choice of potency of the medicine and its frequency of use, and both of these therapeutic strategies are employed to minimise potential reactions.

Despite these typical cautions, some highly sensitive patients may react by proving or displaying a range of remedy effects, similar to those emerging in a formal proving or homoeopathic drug trial of the medicine being used. These effects are typically of very short duration and only rarely require a homoeopathic antidote or the recourse to other treatments. Similarly, if a prescribed medicine is taken very frequently over an extended period of time, a proving response may result. Repetitive prescriptions are rare in single-remedy or holistic homoeopathic practice. In the treatment of chronic conditions, remedy dosing is typically infrequent, and in the treatment of acute conditions, repeat dosing usually occurs over a limited period of three to four days, usually with instructions that the remedy be reduced or ceased as improvement in symptoms is established.

6.2.3. Return of prior symptoms

A return of prior symptoms after the application of a simillimum is a process originally described by Dr Constantine Hering (1800–1880) and is known as Hering's Law. This retracing response is regarded as a positive indication of remedy action and represents a usually very brief and typically mild reprisal of symptoms that the patient has experienced in earlier episodes of illness (Endrizzi et al., 2005; Swayne, 2002; Thompson et al., 2004). This process is understood as the effect of the homoeopathic remedy activating a response, and observational evidence suggests that it signals an end to any further recurrence of these symptoms and heralds an improvement in health.

6.3. Adverse events in homoeopathy

The potential remedy reactions described above are recognised as a potential feature of professional homoeopathic practice, but their occurrence is relatively rare. A limited number of studies have explored the incidence of adverse events in homoeopathy. A review of reports of adverse events conducted by Dantas and Rampes (2000) identified 19 clinical

trials, 19 case reports and 15 homoeopathic pathogenic trials or provings published from 1970–1995. In the clinical trials, the mean incidence of adverse events was 9.4 for homoeopathy groups, compared with 6.1 in the placebo groups. The authors concluded that adverse events in homoeopathy were comparable to placebo-induced adverse events, and were rare and transient in homoeopathic treatment.

A meta-analysis of 3,437 patients from 24 placebo-controlled RCTs from 1966–2002 showed only 63 (1.5%) adverse events for patients treated with homoeopathic medicines and 50 (1.5%) for the placebo group (Grabia & Ernst, 2003). The conclusion reached was that there was insufficient evidence to establish predictable homoeopathic aggravations.

Elsewhere, Cardinali et al. (2004) found that the repetition of low potencies of toxic substances may provoke systemic toxic effects. Prescriptions of low potency toxic substances are uncommon in professional homoeopathic care so that toxicity effects are extremely rare. The majority of medicines used in homoeopathic practice are in potencies beyond Avogadro's number, that is, where no molecules of the original substance remain.

A more recent study of adverse events was undertaken by Posadzki et al. (2012) who searched 378 articles published from 1978–2010. They identified 35 reports of possible adverse events in 1,142 patients, and in a further 17 cases, the withdrawal of conventional medicines may have resulted in indirect adverse events. In a case series involving the majority of these patients (1,070 patients), a causal relationship could not be clearly established. In 27 patients, a causal relationship "was almost certain" or "certainly" due to the medicines taken. Of these, the majority were allergic or toxicity effects; in three of these patients, however, the mode of causation of an adverse event was unclear.

In nine patients cited by Posadzki et al. (2012), substitution or neglect of conventional care was "almost certain" or "certainly" the cause of adverse events. In 46 patients, a causal relationship was considered "likely", but in 12 of these, there was no explanation of potential reasons which could establish a causal relationship. In 94.7% of cases, the dilutions involved were in the molecular finite range, which is unavailable for sale in Australia under the Therapeutic Goods Administration regulations. In Posadzski, et al (2012) the authors concluded:

> Our review … is thus not comprehensive. Crucially, it does not tell us anything about the incidence of adverse events. Considering the widespread use of homoeopathy worldwide and the relative paucity of the reported adverse events, it might be very low (p.1187).

Posadzki's team surveyed the global homoeopathic literature over a 32 year period, during which in excess of a billion homoeopathic treatments may have occurred. While it is likely

that many more adverse events occur in both conventional and homoeopathic medicine than are reported, the incidence of homoeopathic adverse events identified by Posadzski was low. In contrast, it was reported that 20% of the UK National Health Service drug bill is spent treating adverse events resulting from the prescription of conventional medicines (Bruck, 2012).

Observational studies by the European Council for Classical Homoeopathy to examine the incidence of adverse events found that, while adverse events can occur, no serious adverse events were found (European Council for Classical Homeopathy, 2009). Tables summarising the literature review of adverse events and homoeopathic aggravations by the European Council for Classical Homoeopathy provide the reader with a comprehensive overview of research in this field. The tables are reproduced here with permission.

Table 4. Observational studies published after 1995 considering possible adverse events and homoeopathic aggravation (studies older than 10 years are highlighted)

Author	Study design	Sample size	Indication	Homeopathic treatment	Adverse events	Homeopathic aggravation
Anelli et al. (2002)	Prospective multi-centre observational	1025 6 countries	All complaints	Individualised	2.7%	33.2%
Endrizzi et al. (2005)	Prospective observational	335	All complaints	Individualised	2.68%	26.3%
Everett et al. (2005)	Prospective observational	31	Postoperative complications	Unclear	None	Not specified
Güthlin et al. (2004)	Prospective observational	900	All complaints	Unclear	7.4%	(incl. in AE)
Haidvogl et al. (2007)	Prospective parallel group comparative	857	Acute respiratory and ear complaints	Individualised	3.1% 2.0%[1]	Not specified
Jain (2003)	Prospective observational	109	All complaints	Individualised	1 case	Not specified
Keil et al. (2008)	Prospective parallel group comparative	118	Eczema	Individualised	None	Not specified
Lacroix et al. (2005)	Prospective comparative	18	Effects on newborn children receiving breast milk	Unclear	None	Not specified
Li et al. (2003)	Prospective observational	13	Asthma	Isopathy	None	
Molassiotis et al. (2005a)	Descriptive cross-sectional survey on CAM therapies in general (incl. homoeopathy)	126	Colorectal cancer	Unclear	None for homoeopathy 1 patient for other CAM	

Author	Study design	Sample size	Indication	Homeopathic treatment	Adverse events	Homeopathic aggravation
Molassiotis et al. (2005b)	Descriptive cross-sectional survey on CAM therapies in general (incl. homoeopathy)	956	Cancer	Unclear	None for homoeopathy 4.4% for other CAM	
Pomposelli et al. (2003)	Prospective	55	Arthritis/rheumatism osteoporosis	Unclear	None	30.8%
Reilly (2005)	Unclear	1000	Acute complaints	Unclear	2%	Not specified
Riley et al. (2001)	Prospective parallel group comparative	281	RTI, allergies and ear complaints	Individualised	7.8%	Not specified
Schmiedel and Klein (2006)	Prospective parallel group comparative	397	Common cold	Complex HMP	None	Not specified
Sevar (2005)	Prospective observational	455	All complaints	Individualised[2]	2 patients	Not specified
Thompson and Reilly (2002)	Prospective observational	100	Cancer	Individualised	None	17%
Thompson et al. (2004)	Prospective observational	116	All complaints	Individualised	11%	24%
Trichard et al. (2004)	Prospective parallel group comparative	268	Acute rhinopharyngitis	Individualised	4.9%	Not specified
Trichard et al. (2005)	Prospective parallel group comparative	241	Recurrent acute rhinopharyngitis	Individualised	4.6%	Not specified

[1] Results were separated out for adults/children

[2] Presumed individualised based in description of results

Table 5. Experimental studies published after 2003 considering possible adverse events from homoeopathic treatment

Author	Study design	Sample size	Indication	Homoeopathic treatment	Adverse events
Brinkhaus et al. (2006)	Randomised, double-blind placebo-controlled	227	Recovery after knee surgery	Single remedy	Low No difference to placebo
Frass et al. (2005b)	Randomised, double-blind placebo-controlled	70	Severe sepsis knee surgery	Individualised	None No interference with conventional treatment
Furuta et al. (2003)	Randomised, double-blind placebo-controlled	40	Obstructive adenoid knee surgery	Three remedies	None
Jacobs et al. (2005a)	Randomised, double-blind placebo-controlled	83	Hot flashes after conventional cancer treatment	Individualised	None Transitory
Jacobs et al. (2005b)	Randomised, double-blind placebo-controlled	43	ADHD knee surgery	Individualised	None
Katz et al. (2005)	Randomised, double-blind placebo-controlled (homoeopathy , Fluoxetine, placebo)	6	Depression	Individualised (max. 30 remedies)	None
Kim et al. (2005)	Randomised, double-blind placebo-controlled	40	Seasonal allergic rhinitis	Potentised pollen	None
Stevinson et al. (2003)	Randomised, double-blind placebo-controlled	62	Prevention of pain and bruising in hand surgery	Single remedy	Similar to placebo[1]
Thompson et al. (2005)	Randomised, double-blind placebo-controlled	53	Symptoms of oestrogen withdrawal in breast-cancer survivors	Individualised	No difference to placebo
White et al. (2003)	Randomised, double-blind placebo-controlled	96	Childhood asthma oestrogen withdrawal in breast-cancer survivors	Individualised	Similar to placebo[2]

[1] Placebo (3): heartburn, sore throat, flu-like symptoms, faintness, headache. Arnica 30C (4): feeling unhappy/low, dry mouth, headache, feeling throbbing in head/neck. Arnica 6C (2): drowsiness, sore tongue

[2] Cases of AE: homoeopathy 13, placebo 10

6.4. Professional education of homoeopaths in Australia

Members of AROH must satisfy the Register's requirement regarding minimum levels of education, which is currently an Advanced Diploma of Homoeopathy, continued professional education and adherence to the professional ethics and standards of the organisation (see www.aroh.com.au). AROH stipulates that reasonable duty of care demands medical referral of patients with clinical indicators. Homoeopathic education in

Australia contains educational components designed to minimise the potential risks which might otherwise arise through substitution or neglect of conventional care. University-based education for professional homoeopaths would further improve the delivery of quality care for patients, and it is regrettable that bodies such as the Friends of Science in Medicine (MacLennan & Morrison, 2012) deride the homoeopathic profession and express concern about patient safety, whilst simultaneously lobbying to limit the access of this profession to university-based higher education.

6.4.1. The homoeopathic profession: support for improved education and training

The Australian homoeopathic profession has been actively improving the standards of education and training in homoeopathy during the past twenty years, and was the first of the CAM therapies to self-fund the development of nationally formulated and accepted competency standards (Homoeopathic Industry Reference Group, 1999). While homoeopathic practice across the globe is most commonly undertaken by medical practitioners, the majority of homoeopaths in Australia are professional homoeopathic practitioners. The safest and most effective use of homoeopathic medicine depends upon the depth and rigor of practitioner education and training.

During the 1990s, the Australian homoeopathic profession began a lengthy process of consultation and development in the area of education and training, towards the goal of producing Australian homoeopaths capable of the highest practitioner standards. In 1994, the profession united under the banner of the Homoeopathic Industry Reference Group. With the support of the Australian National Training Authority and the National Community Services and Health Industry Training Advisory Board, the Homoeopathic Industry Reference Group developed the National Competency Standards for homoeopathic education in Australia (Homoeopathic Industry Reference Group, 1999).

A four-year full time Advanced Diploma of Health Science (Homoeopathy) (CNF82) was being delivered in a number of the Vocational Education and Training organisations in 1994. The National Competency Standards published in 1999 incorporated and expanded the content of CNF82. This was integrated into the first Health Training Package HLT02 in 2002, as the unendorsed component of the training package. HLT60602, the Advanced Diploma of Homoeopathy superseded CNF82. The current training package is HLT07 containing the Advanced Diploma of Homoeopathy: HLT606012. The introduction of training packages has seen a regrettable erosion in course delivery time, developments that AROH vigorously resisted as the course can now be delivered in 2.5 years full-time study.

AROH accredited courses deliver the current training package in three years and comply with the unendorsed component of the training package. AROH participates in regular reviews of the National Training Package. These reviews are conducted by the Community Service and Health Industry Skills Council.

AROH assesses the qualifications and training of overseas trained homoeopaths through VETASSESS. For a graduate or overseas trained homoeopath to become an AROH registrant, the following is required:

- satisfy minimum levels of education (currently an Advanced Diploma in Homoeopathy)
- comply with the triennium continued professional development requirements
- adhere to the professional ethics and standards of practice outlined by AROH
- maintain appropriate levels of professional indemnity insurance
- hold current qualifications in Senior First Aid

Registered Training Organisations within the Vocational Education and Training and Higher Educational sectors delivering courses which AROH assesses for course accreditation must include components of the current training package designed to minimise risks, which might otherwise arise through substitution or neglect of conventional care. Neglect of conventional care is a common risk factor for patients using CAM therapies (Harvey, 2012a). Anecdotal experience of homoeopathic practice in Australia informs the profession that patients seeking homoeopathic care do so to complement conventional medical care, rather than as substitute care. The Swiss study undertaken by (Bornhoft & Matthiesen, 2012) found that fewer than 6% of patients were likely to rely solely on homoeopathic care.

Undergraduate degrees in homoeopathy are currently offered by private providers. University-based education for professional homoeopaths is a goal towards which the profession aspires, and which the community appropriately expects of health-care professionals. Access to university-based education for homoeopaths would further enhance patient care and provide important pathways for graduate research in the field of homoeopathy. Many Australian homoeopaths currently pursue higher degrees and research opportunities within mainstream institutions, improving the human resources of the homoeopathic community and furthering the standards of patient care.

7. Ethical Considerations

7.1. Friends of Science in Medicine

The debate around the science of CAM, or indeed, what comprises science and good medicine, frequently provokes passionate argument. Towards the end of 2011, a group of doctors, medical researchers and scientists united to form a lobby group, Friends of Science in Medicine. An early task of the FSM was an open letter to the private health funds. This letter demanded that the insurers confirm "… that you will withdraw insurance support for all modalities which the CMO determines to lack an evidence base". This letter then added that the health insurer's response will be posted on the Friends of Science in Medicine website.

This very directive letter demands an intrusion into the contractual relationship between the private health funds and their members. Democracy affords its citizens the right to choose their particular health insurance: they should also expect to have the right to choose health cover for the treatment modalities of their choice.

The lobby group FSM states that the health insurers support for CAM , "… frequently delay[s] correct diagnosis and effective treatment, resulting in unnecessary morbidity and expenditure, something insurers would wish to avoid". This statement, made without any supporting evidence, is extremely concerning to AROH and we expect that those conducting this inquiry will share this concern. The Friends of Science in Medicine lobby group asserts that people choosing CAM therapies are at increased risk of ill-health because of the choice they make, when available evidence – some of which is detailed in this submission – suggests that the opposite is the case.

The findings of a review conducted in New Zealand are of interest in this context. In 2006, the New Zealand Government asked Dr William Bain, pharmacist and coroner, to research and review Coronial records to identify whether complementary medicines, natural and traditional products, supplements and vitamins together with prescription and other drugs, had been involved in Coronial Inquests and deaths.

Dr Bain reported on an Australian study which showed that 10% of patients presenting to a GP had an adverse drug event in the preceding six months with 50% being in the moderate to severe range and 8% hospitalised as a result. A 2006 New Zealand study showed that one-third of hospital admissions were avoidable. The associated costs at just one Christchurch hospital were estimated at $96.6 million (Bain, 2006). Other studies showed that prescription drug errors double a person's risk of dying in hospital with costs

estimated at 2 billion a year. After an exhaustive investigation of the records, Bain concluded:

> What is ironic here is that what is being held out as a justification for high regulation and compliance in the area of Complementary Medicines, Natural Products, Traditional Products, Supplements, Vitamins etc, is public safety and risk. Despite a diligent search of Coronial records and the literature, no instances have been found to demonstrate that in fact with these products in NZ there is any serious public health issue or risk to the public. The problem is clearly with prescription and other drugs and no demonstrable risk at all with these natural products … The Coronial and literature searches in so far as natural products etc are concerned and linkages to public safety and risk can be described legally as De minimis non curat lex. That is-- of minimal risk importance. The law (regulations etc) does not and should not concern itself with trifles (Bain, 2006).

Lobby groups such as Friends of Science in Medicine argue that CAM therapies should demonstrate an evidence base for their practices, while simultaneously arguing that they have no place in public educational institutions. Such educational opportunities are pre-requisite to building a research-skilled workforce in the CAM sector. Myers et al. (2012, pp.69-70) argue in favour of the legitimacy of the inclusion of complementary medicine in the curricula of universities. They suggest that if these courses were removed from a tertiary setting it would not result in a reduced demand for complementary health practices but could well diminish the educational rigour of these courses, thus affecting the quality of the services offered to the consumer.

The following statement appears on the Friends of Science in Medicine website:

> [Friends of Science in Medicine] is hoping to influence universities (at least the reputable ones) to declare their support for science courses that are in fact evidence-based and adhere to accepted scientific methodology. It will then have a go at trying to influence the government, which helps fund these courses and uses taxpayers' money to allow health fund rebates for "treatments" with these demonstrably ineffective pseudoscientific therapies.

A declared conflict of interest is acknowledged by one member of Homoeopathy Working Committee, who was until recently a member of Friends of Science in Medicine. AROH has raised the question of what measures are to be taken to deal with this acknowledged conflict of interest in relation to the Review.

It can be argued that a key purpose of universities is to offer a range of ideas which reflect of diversity of the community in which they are situated, and that this breadth of ideas is as necessary for the survival of knowledge as genetic diversity is to the survival of a

species. If universities are charged with finding creative new ways to apply knowledge, then authoritarianism, corporatism and political correctness may be principal enemies of this endeavour (Bowen & Schwartz, 2005).

Friends of Science in Medicine wrote an open letter to those universities offering chiropractic degrees questioning, "… whether or not modern chiropractic concepts and techniques taught at your institution are, in fact, evidence-based and could meet the government's requirements" (Friends of Science in Medicine, 2012). The wisdom of the push to exclude chiropractic and other CAM therapies from universities and the lobbying by Friends of Science in Medicine to remove tax rebates for these therapies has been questioned by some.

Acknowledging that science by its very nature is often a battleground of contentious views vying for possession of the truth, some doctors point out the precarious connection between knowledge and power and note that, "… the risk is always present that those who command the dominant theories or ideologies will rely on their positions of influence to overcome those who oppose them". Physician and health care ethicist, Professor Paul Komesaroff urges caution in relation the actions of pressure groups, "what concerns us is a politicised process to apply pressure on governments and educational institutions to act in accordance with the views or convictions of one particular group"(Komesaroff et al., 2012). This perspective was reflected in a recent lecture by Sir Paul Nurse (2013) who offered his prescription for appropriate protocols for the provision of scientific advice to policy-makers. Nurse, current President of the Royal Society of London, stated that such advice should be as free as possible from political and ideologically motivated concerns and that "bombastic" views may arise from those who already perceive that they have lost the scientific argument.

Lobbying by the Friends of Science in Medicine group about the legitimacy of including CAM therapies in the curricula of universities provoked an initial flurry of support for this view. It is apparent that some of the original supporters have re-considered their membership and, like the president of the Australian Medical Association, Dr Steve Hambleton, have withdrawn their support (Schwager, 2012). Dr Hambleton believes the issue has become "much fuzzier and less clear", and that rather than a complete shutdown, these courses should be judged on their individual merit. He said, "It's too big a sledgehammer", and while caution should be used to guide giving a scientific imprimatur to such courses, he stresses the need for an open-minded approach (Moynihan, 2012).

Good science is dependent on both historical and cultural mores and has always developed from these bases and not necessarily incrementally (Myers et al., 2012). Myers et

al. remind us that science does not occur in isolation, but is a social phenomenon that reflects both the society in which it develops and the power and control of those funding scientific endeavour.

The motivations of the doctors and scientists orchestrating the campaign against CAM demand some examination. It is reasonable to enquire why this cohort of medical and other scientists who generally occupy positions of power and prestige bother to attack the relatively small and underfunded cluster of natural medicine courses (Schwager, 2012) and similarly why they pursue the miniscule amount of Government expenditure on health insurance tax rebates for CAM therapies (0.08% of all tax rebates for those privately insured).

It has been shown in this Submission that the numbers of homoeopathic professionals and homoeopathic medical doctors has grown considerably in many countries of the world over the past 30 years, and that there has been considerable growth in the sales of homoeopathic and other health care products (Banerjee et al., 2010b; Bhattacharjee et al., 2009; Biswas & Khuda-Bukhsh, 2004; Biswas et al., 2005; Bracho et al., 2010; Datta et al., 1999; Datta et al., 2001; de Souza Nunes, 2008; Frenkel et al., 2010; Guimarães et al., 2009; Khuda-Bukhsh et al., 2011b; Kumar et al., 2007; Marino, 2008; Mroninski et al., 2001; Pathak et al., 2003; Pathak et al., 2006; Sunila et al., 2007). Research work in mainstream science and medicine relies substantially on investment by the pharmaceutical industry. It is possible that the growth and development of the economic base of the CAM sector raises concern in some quarters in the medical and scientific community, perhaps particularly those whose interests may be served by protecting the market share of powerful financial supporters.

The pharmaceutical industry may feel the need to protect its interests from viable alternatives, including homoeopathy. Surveys of patients who consult with homoeopathic practitioners have established that the majority are satisfied with their choice (Adler, 1999; Cairo et al., 2001; Goldstein & Glik, 1998; Marian et al., 2008; Rodrigues-Neto et al., 2009; van Wassenhoven & Ives, 2004; Vincent et al., 2012). A number of investigations have also revealed that patients choose to use homoeopathy after conventional medicine has failed to meet their needs, and for some of these patients, homoeopathy succeeds (Goldstein & Glik, 1998; Marian et al., 2008; Rodrigues-Neto et al., 2009; Sevar, 2005; van Wassenhoven & Ives, 2004). The patients who seek homoeopathic services are not a broad sample of the ill population: demographic analyses show the majority are likely to be well educated and from higher income groups. These patients have either learned from anecdotal evidence provide of family and friends to trust non-mainstream health care options or they may have

actively sought complementary treatment following dissatisfaction with treatment received in conventional medical care.

7.2. The NHMRC, the Natural Therapies Review Advisory Committee and the process of the inquiries into homoeopathy

It appears the NHMRC had not conducted an investigation of its own into homoeopathy before declaring that the practice of homoeopathy was unethical (Medew, 2012). This announcement detailed the intention of the NHMRC to develop a position statement on homoeopathy. The influence of the dubious research of Shang et al. (2005) and of the much-criticised work of the UK House of Commons Science and Technology Committee was clear in the NHMRC pronouncement. Problems with these reports have been recorded in Submissions by the Australian homoeopathic profession to the NHMRC during 2011 (see Appendices 1 and 3). The NHMRC website states that "examining alternative therapy claims" has been part of its 2010–2012 strategic plan, and the NHMRC had an allocated amount of "almost $69 million provision of funds for complementary medicine research." None of these funds were directed at research in homoeopathy, and it was clear that the NHMRC, Australia's leading medical science research body, had allowed itself to be informed by research of dubious quality and by recommendations arising from that research which failed to gain the support of the UK Parliament.

Best scientific practice would have demanded consultation with experts in the field under investigation (Nurse, 2013), yet no such experts were engaged before these declarations, and none have been engaged since to assist the work of the current review into natural therapies. Neither the NHMRC Homoeopathy Working Committee nor the Natural Therapies Review Advisory Committee for the Department of Health and Ageing has homoeopathic researchers or any expert practitioners as a sitting member. It is of interest that, in the absence of any publically funded research into homoeopathy in Australia, a specific Working Committee has been established for homoeopathy. AROH is unaware of the creation of committees for other natural therapies modalities under investigation. The homoeopathic community is concerned that homoeopathy has been singled out for particular attention.

The review into private health insurance rebates currently underway was initiated at the time of the May 2012 budget, although AROH was formally notified of this inquiry only at the end of November 2012. AROH as the peak body in Australia for homoeopathy was then given one month to prepare a submission for this Review. This was clearly an

inadequate timeframe in which to respond to a review which has major ramifications for the profession, a time-frame made more difficult because it coincided with the pre-Christmas period; the extensions subsequently given by the office of CMO were essential.

Submissions to the Natural Therapies Review Advisory Committee have been assigned a protracted and unwieldy process through the various structures which have now been instigated. AROH has been advised that the homoeopathic Submission to the Review will not be given to the members of Natural Therapies Review Advisory Committee, but will be directed to the NHMRC's Homoeopathy Working Committee. The Homoeopathy Working Committee will define the nature of a literature review of homoeopathy to be carried out by a contractor who will report to the Homoeopathy Working Committee. The Homoeopathy Working Committee will, in turn, report to the NHMRC which will then report to the Natural Therapies Review Advisory Committee. Members of the Natural Therapies Review Advisory Committee will not be in a position to be informed directly by the AROH Submission, but only by the opinion which emerges from the three processes the Submission will pass through before the NHMRC report reaches the Natural Therapies Review Advisory Committee.

AROH has emphasised the importance of expert advice in the conduct of scientific inquiries, and the particular importance of such advice in the highly specialised field of homoeopathy. Although one member of the Homoeopathy Working Committee is a pharmacist with some knowledge of acute homoeopathic prescribing, AROH is unaware whether she has clinical or research experience with homoeopathy. This Submission has described the nature of homoeopathic practice which demands research protocols sensitive to its patient-centred (not disease-centred) focus. Because of these characteristics, particular to homoeopathy, a review of homoeopathic research involves matters that an experienced homoeopathic clinician or researcher would be able to clarify, and which would readily escape the attention of non-homoeopathic specialists. As noted in the discussion of the methodology of systematic reviews (Charlton, 1996), specific knowledge of the area under investigation is essential. No member of the Natural Therapies Review Advisory Committee has a detailed understanding and experience in the practice of homoeopathy, which would properly equip informed comment on the NHMRC report. Compounding this, the Natural therapy association representatives on the Natural Therapies Review Advisory Committee are likely to lack any extensive knowledge of homoeopathy and may have no clinical experience in this specialised area of practice. The absence of specialist personnel on both the Homoeopathy Working Group and the Natural Therapies Review Advisory Committee

is a matter of a failure of appropriate process in the conduct of a scientific inquiry (Nurse, 2013) and raises concerns about its basis in terms of ethics, as well as foundation of the inquiry's capacity to fulfil its task.

8. Conclusions

The role of the Natural Therapies Review Advisory Committee is to consider the report from the NHMRC and assess the information contained in the report of the Submissions in the context of the wider community, taking into account not only the scientific perspective summarised by the NHMRC, but also other scientific, ethical, economic, social, industrial and political realities, so that they are in a position to provide sound advice to the Government.

When seen in context, this review is concerned with the relatively small amount of money provided by the federal Government through rebates for homoeopathic consultations. This modest outlay, which can now be seen in the light of the evidence provided in this Submission as a highly cost-effective and sound method of health care providing a wise investment of public monies, and a positive contribution to community health care. These modest outlays may be compared with the massive expenditures made through Medicare Australia, the Pharmaceutical Benefits Scheme and other publically funded allied health provisions, the demand for all of which are potentially considerably reduced in relation to those patients receiving homoeopathic treatment.

This Submission has provided evidence of efficacy across a range of applications of homoeopathy, and shown has that homoeopathy can be effective for over 70 pathologies. In pharmaceutical research, well over 90% of trials fail to bring a product to market: compared with these outcomes, the number of positive results in homoeopathic trials is impressive. If it is claimed that homoeopathy is ineffective because a number of trials fail to prove efficacy or cost utility, one would similarly be required to claim that pharmaceutical medicine also lacks both efficacy and cost effectiveness. Homoeopathy, especially in its individualised application, exemplifies the paradigm of person-centred medicine as discussed by di Sarsina et al. (2012). The person-centred nature of homoeopathic practice, along with its clinical effectiveness, are two core qualities at the heart of the resurgence of homoeopathy over the past 40 years. While a highly skilled practice, homoeopathy provides a relatively low-cost avenue to assist patients who want to enter into a therapeutic relationship of this type as they towards improved levels of health. Homoeopathy is both therapeutically effective for presenting complaints, as well as having preventative potential, as evidenced in the material provided in this Submission. Patients have a right to choose their own therapeutic care and are themselves best placed to make such decisions.

If the Government decides to withdraw the tax rebate for CAM therapies, they may expect a considerable backlash from the users of these therapies. Homoeopathic patients, when told of this inquiry, express disbelief then outrage about this possible restriction to their right to choose. Patients are puzzled that a modality which helps to keep them well and is preventative in nature is not be seen as a positive, healthful choice, and as an essentially cost-saving in both individual and community terms.

Although the Federal Government may achieve minor short-term savings from the removal of the rebate for homoeopathy services, this Submission has shown that this decision may result in net losses to government through increased health expenditures and loss of revenue. Expenditure increases would arise from a range of sources including increased use of Medicare funded services and Pharmaceutical Benefits Scheme listed drugs, from increased work leave and related costs and from a likely reduction in taxation revenue from the homoeopathic sector.

Homoeopathy is an art and a science – one which privileges its practitioners to share in patient's healing journeys. This Submission ends therefore, not with more trials, facts or figures, but with the words of a homoeopath describing the therapeutic relationship:

> The action of the homeopathic medicine was intimately woven with the relationship that I had with her as a therapist. It is impossible to separate these two influences. That is what makes it very difficult to evaluate homeopathic medicines along the lines of pharmacotherapy, where this separation between the therapist and medicine is seen as essential (van Hootegem, 2007).

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