Submission to the Therapeutic Goods Administration (TGA)

Consultation: Options for the future regulation of "low risk" products.

Prepared by the

Australian Register of Homœopaths Ltd.
PO Box 1614 Wollongong DC NSW 2500
[redacted]

and

Australian Homœopathic Association Inc.
PO Box 7108 Toowoomba South QLD 4350
[redacted]

To:
Regulatory Reforms Team
Therapeutic Goods Administration (TGA)
tgaregreforms@health.gov.au
PO Box 100
WODEN ACT 2606

12 May 2017

Table of Contents

Background

The Australian Register of Homoeopaths (AROH) and the Australian Homoeopathic Association (AHA) welcome the opportunity to contribute a submission on the Therapeutic Goods Administration's consultation on 'Options for the future regulation of low risk products'.

AROH is the chief registration body for professional homoeopaths in Australia; its role is to maintain accredited standards of practice that meet government and community standards. The AHA is the main practitioner organisation representing professional homoeopaths in Australia. TGA's proposed changes to the regulation of homoeopathic products potentially directly impacts on the homoeopathy sector, of which AROH and AHA are key stakeholders.

Executive Summary

AROH/AHA strongly supports Option 1 ('maintain regulatory status quo'). The current regulatory framework strikes an appropriate balance that meets the requirements of all stakeholders - the public, government, manufacturers and health practitioners. TGA would thereby continue to fulfill its obligation of safeguarding the public by ensuring adherence to Good Manufacturing Practice (GMP) standards, monitor adverse reactions and enforce advertising and labeling standards.

It would also continue to allow homoeopathic products to make appropriate therapeutic claims, commensurate with their risk profile and level of evidence, according to whether the indication is based on traditional evidence or published research (as per low risk herbal products) and a system that has successfully operated since the inception of therapeutic goods legislation.

AROH/AHA also supports Option 2, requiring that serious therapeutic claims must be supported by scientific evidence. This would bring the regulatory framework for homoeopathic products into line with that applied to other complementary medicines. This Option can be adopted alongside Option 1.

AROH/AHA strongly rejects deregulation of homoeopathic products proposed under Options 3 and 4.

The consultation paper provides inadequate information how deregulation of homoeopathic products (including change to the definition) would affect the wide range of health practitioners that clinically prescribe homoeopathic preparations the under extemporaneous compounding provisions in therapeutic goods legislation.

Default Australian Competition and Consumer Commission (ACCC) oversight under Australian Consumer Law does not provide a viable, alternative specialty regulatory framework for homoeopathic products, which are solely supplied for a therapeutic end use and are thus not 'consumer goods'. By contrast, alternative specialty regulatory frameworks exist for the other complementary medicine product categories included in the consultation paper (but not for homoeopathic products).

Any change to the definition of 'homoeopathic preparation' in therapeutic goods legislation under Option 4 would be unique and not acceptable to industry or transferrable to other jurisdictions; it would also be contrary to a guiding principle of the MMDR review.

Of particular concern, the TGA consultation paper provides incorrect, misleading and/or selective information regarding the evidence base of homoeopathic products, overseas reports and international regulatory status. For example, the UK report referenced is not the position of the UK Government or Health Department (yet presented in this light), while a positive Swiss HTA report is not mentioned.

The TGA paper also publishes a value judgement that homoeopathic products are inherently 'not evidence based', directly referenced against a 2015 report published by the National Health and Medical Research Council (NHMRC) that has been referred to the Commonwealth Ombudsman for investigation.

By accepting the findings of the NHMRC report as a basis for regulatory change, TGA is failing to critically evaluate its flaws (while in full knowledge of them) and is holding homoeopathic research evidence to a far higher standard than it applies to any other product category (even registered prescription medicines). It is thereby accepting arbitrary criteria that are not recognised in TGA evidence guidelines.

The provision of imbalanced, selective and inaccurate information in the TGA consultation paper indicates a partial approach is being taken influenced by ideological factors beyond TGA's core role as a medicines regulator. Should TGA seek to adopt Options 3 and/or 4, it will be expected to demonstrate equity in its decision making processes when subjected to judicial and/or administrative review.

Introduction

The scope of the AROH/AHA submission paper is restricted to homoeopathic products/preparations/ medicines (pp.46-49 of the TGA consultation paper).

The TGA consultation paper identifies homoeopathic products amongst a range of other product types that represent 'low' or 'very low' risk for the purpose of Recommendation 48 of the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR), which was accepted by the Government:

> ***Recommendation Forty-Eight****: The Panel recommends that the Australian Government undertakes a review of the range of complementary medicinal products, currently listed in the ARTG and subject to regulation under the medicines framework, with a view to ensuring that products that might best be regulated under other regulatory frameworks, without undermining public health and safety, are removed from the auspices of the Act.*

Homoeopathic products - current regulatory framework safeguards 'low risk' status

In making its recommendations, the expert panel expressed the concern that *"there are a range of products listed in the ARTG that are subject to a level of regulation which is not commensurate with the risk posed by these products to Australian consumers".*

While this may be appropriate to classes of goods such as nappy rash creams, antiperspirants, sunscreens and hard surface disinfectants, products such as homoeopathic preparations **belong to a different risk category, since they are ingestive products that are manufactured and supplied solely for a therapeutic purpose**. Thus they are specialty therapeutic goods, not 'consumer goods', and should be regulated as such.

Removing current regulatory safeguards would elevate the 'low risk status of homoeopathic products (by virtue of the safeguards afforded by the current regulatory framework) to a higher risk category. In this regard, the "wisdom of crowds" framework presented in the TGA consultation paper in relation to the current regulatory environment no longer applies.

The potential consequence of relaxing the requirements for GMP has been recently demonstrated by safety concerns around Hylands teething products, linked to deaths associated with poor manufacturing standards, resulting in uncertainty regarding levels of the Scheduled poison *Atropa belladonna*.

In this case, a 'low risk' product was transformed into a 'high risk' product by virtue of GMP standards not commensurate with Australian standards. A greater risk is inherent to ingestive medicines, since the route of administration renders them more toxic under circumstances of contamination.

The intent of MMDR Recommendation 48 is to examine whether the product categories identified in the consultation paper *"might best be regulated under other regulatory frameworks, without undermining public health and safety"*. **The above represents a recent, real-world example where deregulation of homoeopathic products directly undermines public health and safety**.

Australian Consumer Law - Non-specialist regulatory framework

TGA needs to demonstrate that a **viable alternative specialty regulatory framework** exists for the regulation of homoeopathic products should it adopt Options 3 and/or 4, within the context of ensuring that public health and safety is not undermined.

All other complementary medicine product categories subject to the current consultation have specialist alternative regulatory pathways available to them: **this is not the case with homoeopathic products**. For example:

- Regulatory oversight of aromatherapy products could occur via the Australian Inventory of Chemical Substances (AICS);
- Vitamins and minerals could be regulated as food and dietary supplements under the Food Standards Australia New Zealand (FSANZ) as a viable alternative framework.

Default Australian Competition and Consumer Commission (ACCC) oversight under Australian Consumer Law (ACL) does not provide a viable, alternative specialty regulatory framework for homoeopathic products, **which are solely supplied and used for a therapeutic purpose and are thus medicines**, not 'consumer goods'.

Moreover, homoeopathic products are predominantly for use as ingestive medicines, therefore any down-scaling of regulatory requirements has a greater potential to impact on public health and safety.

The public continues to require that a **specialist** medicines regulator oversee the safety and quality of these complementary medicine products as therapeutic goods; also to ensure that appropriate levels of claims can be made against them (based on traditional use and/or higher level research evidence).

Perceived bias in TGA consultation paper

Of concern, the TGA consultation paper **communicates inaccurate and imbalanced information** regarding recent reports on the evidence on homoeopathy. It is also highly selectively in its provision of information on the regulatory status of homoeopathic products in other jurisdictions, suggestive of a partial approach aligned to ideological factors.

For example, the TGA consultation paper adopts a definitive, prejudiced stance that homoeopathic products are 'not evidence based' in raising 'issue' with maintaining regulatory status quo (Option 1):

> *"An issue of maintaining the current regulation of homoeopathic products under the same framework as evidence based medicines is that it may imply government endorsement of these products"*

This is both inaccurate and incompatible with TGA's statutory responsibility to apply principles of equity in its role as an impartial regulator of the wide variety of therapeutic goods used by **all** Australians, not just those of particular ideological predilections.

The inequity in TGA's approach to proposed changes to the regulation of homoeopathic products is evidenced in a number of ways in the consultation paper, as detailed below:

1. NHMRC Homoeopathy Review

AROH/AHA expresses concern at bias apparent in TGA's framing of Option 1, **by adopting the value judgement that homoeopathic products 'are not evidence based' directly aligned to the National Health & Medical Research Council (NHMRC) Homoeopathy Review's finding of 'no reliable evidence'**.

TGA is thereby endorsing the unique, unusually high thresholds for trial 'reliability' NHMRC developed especially for the Review, which are not recognised by TGA evidence guidelines, not accepted by any scientific standards internationally and not used before or since by any other research group internationally or in Australia (including NHMRC).

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

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

By accepting the findings of the NHMRC report, **TGA is accepting these scientifically unjustifiable criteria and holding homoeopathic evidence to a much higher evaluation standard than any other class of product (**even registered prescription medicines), as a measure of whether they are 'evidence based'.

By accepting the NHMRC's findings on 'no reliable evidence', TGA is by default endorsing this unique evidence assessment framework to the assessment of health evidence. This would represent **a double standard,** since TGA is not applying the same criteria to other medicine categories.

TGA needs to demonstrate to all stakeholders that it is applying principles of equity and is following due process.

NHMRC Homoeopathy Review - Commonwealth Ombudsman Complaint:

TGA had been notified that a major multi-stakeholder Submission of Complaint was lodged with the Commonwealth Ombudsman on behalf of the complementary medicines sector, detailing methodological and procedural flaws, conflicts of interest, bias and inaccurate reporting.

Further, **TGA had been notified of details of these issues prior to release of its consultation paper, yet proceeded with citing the NHMRC report's findings as credible without providing any critical evaluation of these facts for balance or transparency.**

Following is a précis of information presented to TGA by stakeholders prior to the consultation period:

- **NHMRC did the review twice**. They rejected the first report, despite it being undertaken by a reputable scientist and author of NHMRC's own guidelines on reviewing health evidence.
- The **existence of the first report has never been disclosed to the public** – it was only discovered by the AHA through Freedom of Information (FOI) requests.
- FOI documents indicate the first review **was of high methodological quality**.
- NHMRC informed the public and decision-makers that it conducted *"a rigorous assessment of over 1800 papers"*. In fact the Overview **only included 176 studies**, the rest were ignored.

- Of the 176 studies, **no original papers were retrieved or assessed** - unprecedented in NHMRC review processes. NHMRC also rejected the positive conclusions of the secondary sources (systematic reviews) that were solely relied upon in the Review.
- NHMRC **used a method that has never been used in any other review, before or since. NHMRC decided that for trials to be 'reliable' they had to have at least 150 participants and reach an unusually high (100%) threshold for quality**. This is despite the fact that NHMRC itself routinely conducts studies with less than 150 participants.
- These unprecedented and arbitrary rules meant **the results of 171 of the trials (97%) were completely disregarded as being 'unreliable' leaving only 5 trials NHMRC considered to be 'reliable'**. This explains how NHMRC could conclude that there was no 'reliable' evidence.
- FOI documents reveal that **all these rules were created and applied retrospectively**, months after the initial research protocol had been 'finalised' and after the second contractor (Optum) had already completed the evidence assessment.
- **None of the post hoc changes to the research protocol were reported or disclosed,** despite their forming the basis of NHMRC published findings.
- One of the 5 remaining 'reliable' trials was positive, meeting NHMRC's own definition for 'reliability'. The NHMRC information Paper that presented the findings of the Overview to the public **substituted this positive trial with a negative** one not considered in the Overview.
- NHMRC's methods and findings **did not pass (hidden) expert peer review** (see below).
- Professor Peter Brooks, initial Chair of the NHMRC committee that conducted the 2015 review, initially failed to declare that he was a member of the anti-homoeopathy lobby group 'Friends of Science in Medicine' (FSM). **NHMRC failed to disclose or formally manage the conflict for the duration of the review**.
- In 2014, during the public consultation phase of the review, NHMRC appointed a contractor with no expertise in CM/ homoeopathy research analysis, yet who was a **FSM Supporter**, to review additional evidence submitted (40 papers, 37 of which were positive for homoeopathy). **No conflicts of interest were declared or managed**.
- **All public consultation evidence was dismissed on grounds of 'self selection bias'** (despite NHMRC prescribing this mechanism of data collection); yet the extra evidence could not have influenced the findings **since the number that entered the Overview was 0** - making a sham of NHMRC's attempt at transparency and external cooperation.
- In violation of NHMRC's own mandatory guidelines there was **not one homoeopathy research or subject expert on the committee**.
- **Explicitly bias anti-homoeopathy comments by senior NHMRC staff** in the public domain, including the CEO who declared the sector to be *"charlatans"* and *"snake oil merchants"* and Chair of Council, who prior to the Review declared: *"Let me assure you that I am no supporter of homoeopathy. As Chairman of NHMRC I can also assure you that NHMRC does not support homoeopathy."*

The publically available Executive Summary of the Ombudsman Complaint can be accessed at: https://www.hri-research.org/wp-content/uploads/2017/04/Executive-Summary-to-Ombudsman-Complaint-re-NHMRC-Homoeopathy-Review-FINAL.pdf

TGA was also informed prior to the consultation period that the NHMRC Review's findings did not pass external expert peer reviewer feedback, as revealed through FOI documents:

In August 2013, the highly respected Australasian Cochrane Centre (ACC) advised NHMRC that the definitive nature of its findings **did not accurately reflect the research** (NHMRC FOI 2015/16 008-13):

> *"If the intent is to provide general statements about the effectiveness of homoeopathy, then 'no reliable evidence' may not adequately reflect the research. For example, when a substantial proportion of small (but good quality) studies show significant differences, […] 'no reliable evidence' does not seem an accurate reflection of the body of evidence."*

In other words Cochrane, regarded internationally as the 'gold standard' in scientific research methodology, informed NHMRC that its findings:

1. **Did not accurately reflect the research**; and that
2. **A substantial proportion of good quality homoeopathic research studies are positive.**

In 2014, one of NHMRC's expert reviewers extensively critiqued NHMRC methods and findings and reiterated the ACC's earlier conclusion (NHMRC FOI 2014/15 004-62):

> *"The dismissal of positive SRs compounded with the lack of an independent systematic review of high quality RCTs leaves me uncertain of the definitive nature of the Report's conclusions. […]*
>
> *If I were to dispassionately consider the evidence of efficacy, I am still left with niggling doubts that there are unanswered questions around the evidence. Contributing to those doubts is the absence of non-clinical in vivo and in vitro studies that examine the effects of homoeopathy, where placebo effects are not relevant."*

This and extensive other feedback was excluded from NHMRC's dedicated 'Expert review comments' document, published alongside NHMRC's report in 2015.

TGA has an obligation to dispassionately take regard of the information presented above and critically evaluate its merits in any proposed regulatory reforms to homoeopathic products.

2. Inaccurate and selective reference to overseas reports, ignoring positive reports:

The TGA consultation paper additionally aligns a preformed view that homoeopathic products are 'not evidence based' to two international reports:

1. A 2009 UK House of Commons Science and Technology Committee report
2. A 2016 US Federal Trade Commission.

UK House of Commons Report:

TGA has provided **incorrect and misleading information** to the community and other stakeholders in its reference to the UK report, implying it is the position of the UK Government when it is not. This report was generated as part of a political (not scientific) process considered by politicians, not scientists.

The UK report itself relied exclusively on only one meta-analysis that had already been shown to be methodologically flawed in the scientific literature[1]. The report ignored all other research evidence to

[1] https://www.hri-research.org/resources/homeopathy-the-debate/the-lancet-paper-by-shang-et-al/

the contrary; for example, the positive findings of several systematic reviews and placebo-controlled RCTs (62 out of 75 at the time showing efficacy for homoeopathy).

TGA conflates the report with the position of the UK Government, which rejected the report's recommendations in July 2010 and recommended that homoeopathy be retained on the National Health Service (NHS). The UK Department of Health also dismissed the report.

Thus **the UK report does not represent the view of UK Government or Health Department, which the TGA paper falsely implies**. The UK report is not a scientific document and therefore cannot be used as evidence by decision-makers. TGA needs to correct this error of public communication.

US Federal Trade Commission:

The TGA's mention of a US Federal Trade Commission workshop that *"concluded similar findings"* is a circular argument, as this document **predominantly cites the NHMRC report**, without independent or impartial assessment of any research evidence (which the NHMRC excluded by virtue of extensive exclusion criteria). The US FTC document thereby perpetuates the flaws of the NHMRC report.

TGA has a responsibility to independently assess such reports, now that it has been informed of serious issues relating to research misconduct inherent to the NHMRC report.

Failure to mention positive reports and broader research findings:

The TGA consultation **selectively excludes mention of reports from other overseas jurisdictions or the wider research evidence base** that includes a substantial amount of positive research on homoeopathy (excluded from scope of the NHMRC Review).

For example, no mention is made of a comprehensive Swiss Health Technology Assessment (HTA) report published into English in 2011[2] - a copy of which is undoubtedly in TGA's library, given that SwissMedic is one of TGA's close regulatory partners[3].

The Swiss report included a full assessment of published research entirely excluded by the NHMRC (e.g. observational studies, the findings of systematic reviews and meta analyses, laboratory research, non-human intervention studies, cost-effectiveness studies).

According to the authors, their report:

> *"confirms homoeopathy as a valuable addition to the conventional medical landscape – a status it has been holding for a long time in practical health care."*

The report's official conclusion was:

> *"There is sufficient evidence for the preclinical effectiveness and the clinical efficacy of homoeopathy and for its safety and economy compared with conventional treatment."*

It is unclear why TGA did not attempt to balance the consultation paper with **any** other major, scientific (as opposed to political) reports reaching opposing conclusions.

- More information on the Swiss report can be accessed at https://www.hri-research.org/resources/homoeopathy-the-debate/the-swiss-hta-report-on-homoeopathy/

[2] *Homoeopathy in Healthcare: Effectiveness, Appropriateness, Safety, Costs* by Gudrun Bornhöft and Peter F. Matthiessen (Editors). 2011. ISBN 978-3-642-20637-5 Full text

[3] https://www.tga.gov.au/australia-canada-singapore-switzerland-acss-consortium

- **Attachment A** to this submission provides a high level summary of published research evidence on homoeopathy to date.

3. Selective representation of international regulation of homoeopathic products:

Appendix 2 of the TGA consultation paper also **selectively omits mention of a broad range of other government regulatory frameworks internationally**. In many jurisdictions homoeopathy/products are well integrated and highly regulated (e.g. France, Germany, India, Brazil, Mexico etc).

For example, no mention is made of the full integration of homoeopathy into the Swiss healthcare system from May 2017, a highly relevant and contemporary development that TGA should have included.

This is also particularly surprising, since Switzerland is one of TGA's close regulatory partners, part of the Australia-Canada-Singapore-Switzerland Consortium, the goal of which is *"to maximise international cooperation, reduce duplication, and increase each agency's capacity to ensure consumers have timely access to high quality, safe and effective therapeutic products."*

By contrast, Appendix 2 to the TGA consultation paper *does* refer to the regulatory status of homoeopathic products in TGA's other ACSS partners, including Singapore (otherwise a small Asian jurisdiction). No mention is made of the regulatory status of homoeopathic products in India (Singapore's Asian neighbor), where homoeopathy is fully integrated into the healthcare system, including hundreds of training institutions and over 200,000 homoeopathic medical practitioners.

The imbalance in the information the TGA consultation paper provides is suggestive of a partial approach.

Commentary:

Like the NHMRC, TGA has a statutory responsibility to demonstrate the highest standards of ethical and impartial conduct when considering major regulatory changes, which would have such significant commercial implications for both the manufacturing and practitioner sector (impacting its viability), with commensurate impact on the risk profile of homoeopathic products affecting public safety.

We express deep concern that the TGA consultation paper appears to align itself with the ideological stance of a minority skeptics lobby, while selectively failing to inform the public of the broader international regulatory framework, including positive reports and broader research evidence excluded from scope of the NHMRC report.

TGA's role is to regulate the wide range of therapeutic goods used by **all** Australians to ensure safety and quality. Those who do not wish to use certain categories of therapeutic goods are free to choose not to.

It is not TGA's role to align itself with the ideological position of minority groups and skew its consultation in that direction. Such influences have no place in an objective, balanced consideration by the TGA as a publicly funded government regulator that must demonstrate impartiality in considering the wishes and interests of **all** stakeholders.

The subsequent sections to this submission provides specific comments against each of the Options presented in the TGA consultation paper on low risk products.

Option 1

AROH/AHA strongly supports maintenance of the current regulatory framework for homoeopathic products under Option 1.

Under this Option, TGA would continue to fulfill its statutory obligation to safeguard the public by continuing to:

- Set mandatory Good Manufacturing Practice (GMP) standards
- Provide a framework for advertising (*Therapeutic Goods Advertising Code*) and labeling standards (*Labeling Code*)
- Monitor adverse reactions and
- Provide homoeopathic practitioners with extemporaneous compounding exemptions for homoeopathic preparations as 'exempt goods' (*Therapeutic Goods Regulations*)

Maintaining the current framework strikes the appropriate balance that satisfies the needs of all stakeholders: the public that chooses to use these products for therapeutic use, government, manufacturers, pharmacists and the wide range of complementary and orthodox practitioners (including GPs) that prescribe homoeopathic products/medicines in clinical practice.

Maintaining the regulatory status quo is also consistent with the guiding principles of the MMDR review, specifically:

- Not to fundamentally change the definition of a medicine or medical device under the *Therapeutic Goods Act 1989* (the *Act*)
- Consideration of the purpose of regulation of therapeutic goods in relation to safety, quality and efficacy.

Option 1 continues to allow homoeopathic products to make appropriate therapeutic claims, commensurate with their risk profile and level of evidence, according to whether the indication is based on traditional evidence or published research (according to a graded scale).

This pathway is being preserved for herbal products and there is no reason why homoeopathic preparations, which are analogous traditional medicines, should not be afforded the same status.

- As outlined earlier in the AROH/AHA submission, the phrasing of the TGA consultation paper raises concerns of a partial approach being taken to the consultation on homoeopathic products aligned to ideological factors, which exceeds the bounds of impartial governance.

Maintaining regulatory status quo **meets TGA's statutory obligation to ensure public safety for goods that are used for a therapeutic purpose**. Homoeopathic products have a sole purpose of use as therapeutic agents via a predominantly ingestive pathway; thus they are therapeutic goods, not 'consumer goods'.

- As outlined earlier in the AROH/AHA submission, the current **medicines-specific** regulatory framework is therefore the most appropriate scheme for the regulation of homoeopathic products; the Australian Consumer Law framework is entirely inappropriate to this product category.

The TGA consultation paper infers that the main reason for TGA not to continue regulating homoeopathic products as therapeutic goods are 'issues' concerning lack of evidence of efficacy, which the paper directly links to the recent NHMRC Homoeopathy Review. The paper also makes the

inaccurate value judgement that homoeopathic products are inherently 'not evidence based' without any reference to the broader published evidence on homoeopathic preparations - **indicating a partial stance**.

- Flaws associated with the NHMRC report and bias in the TGA consultation paper have been outlined earlier in the ARH/AHA consultation paper.

In light of such factors, TGA would need to justify its stance under circumstances of an administrative/ judicial review should it recommend changes to the current regulatory framework that are not compatible with the intent of the MMDR and contrary to stakeholders' stated concerns.

The TGA consultation paper states that the **only** advantage of retaining Option 1 is that, *"sponsors and manufacturers who are already familiar with the regulatory framework would not need to understand or implement any regulatory changes"* - without balancing this with the broader advantages outlined above (aligned to the guiding principles of the MMDR and TGA's statutory role of ensuring pubic health and safety). Balanced information for the purpose of a meaningful public consultation **has therefore not been sufficiently identified/provided**.

As outlined earlier in the AROH/AHA submission, no other specialty regulatory framework(s) exists as a viable alternative for the regulation of homoeopathic products should they be removed from the auspices of therapeutic goods legislation. All other categories of complementary medicine products included in the TGA consultation paper subject to regulatory reform proposals have alternative specialty regulatory frameworks that they could be administered under. This is not the case for homoeopathic products. The current therapeutic goods legislative framework administered by the TGA is the only viable, alternative specialty framework that could adequately apply to homoeopathic products.

TGA 'endorsement' of homoeopathic products:

TGA's prejudicial stance that homoeopathic products are 'not evidence based' is discussed earlier in the AROH/AHA submission.

The TGA consultation paper infers that continuing to regulate homoeopathic products would constitute Government 'endorsement' of these products: a bizarre statement, incompatible with the approach TGA takes to the regulation of other categories of CM products.

This is contrary to the intent of the current regulatory framework for listed medicines and strongly suggestive of bias towards this product category by the regulator. Homoeopathic products are no different to other listed complementary medicines on the ARTG, which due to their low risk profile are eligible to enter the market prior to an evaluation of the evidence (whether traditional or otherwise) linked to an appropriate level of claim.

As part of the current reforms to complementary medicines, the Government has accepted MMDR Recommendation 39, to establish a new pathway for the listing of a complementary medicine where the sponsor can elect to have the regulator assess the evidence related to a higher level indications prior to its release on the market.

Recommendation 38 has also been accepted which will establish a list of permitted indications, from which sponsors must exclusively draw, for listed medicinal products in the ARTG. This will include the ability to specify an indication(s) where there is supporting evidence for its use within a traditional paradigm, such as traditional Chinese medicine, Western herbal medicine and homoeopathy etc.

Regulating therapeutic goods to ensure they are supplied according to appropriate manufacturing standards and that they can only make therapeutic claims according to prescribed level of evidence

(noting traditional evidence indications are accepted by TGA evidence guidelines) does not equate to 'Government endorsement'.

What TGA is essentially communicating by its statement is that it does not consider that there is any evidence (traditional or otherwise) for homoeopathic products that it regards as legitimate.

The TGA paper therefore is not openly/impartially seeking public or expert feedback on Option 1, it is presenting a definitive, preformed ideological position, in lieu of independent assessment of the broader research evidence or the serious flaws associated with the reports referenced in the consultation paper as outlined above.

Attachment A to the AROH/AHA submission provides a high level summary of published research evidence that neither the NHMRC or TGA has considered.

It is not TGA's role to take an ideological stance on the products it regulates, that are freely chosen by a significant proportion of the Australian community for use as therapeutic goods. TGA's responsibility is to maintain GMP, monitor adverse reactions and enforce advertising standards as part of its responsibility to monitor and evaluate the safety of therapeutic goods and manage risk associated with products.

Option 2

AROH/AHA supports Option 2.

We agree that serious therapeutic claims made against homoeopathic products should be supported by scientific evidence. This would bring homoeopathic products into line with the requirements for other medicines, fixing a current inconsistency in the *Regulations*.

It also brings the regulation of homoeopathic products into line with proposed reforms to the regulatory framework for complementary medicines, recommending new assessment pathways for low, intermediate and higher level claims commensurate with level of evidence.

- AROH/AHA lodged a submission to the TGA consultation 'Reforms to the regulatory framework for complementary medicines: Assessment pathways', supporting the proposals offered subject to homoeopathic products being included (since homoeopathic medicines are a long established traditional CM therapy used by around a million Australians).

Option 2 would also create greater consistency with other international regulatory frameworks.

Option 2 can be seen as a complementary reform that could be adopted alongside Option 1.

Option 3

AROH/AHA strongly rejects Option 3 that proposes to exempt homoeopathic products from listing in the ARTG and/or GMP.

Allowing a lower barrier to market for those homoeopathic products that were not previously exempt is not an outcome that AROH/AHA approves of. It would have a number of **unintended negative consequences, impacting on public safety and industry that runs contrary to the intent of the MMDR review and TGA's responsibility to ensure public health and safety**.

Public safety:

Option 3 **would result in a deregulated environment that would promote a proliferation of poor-quality goods from overseas jurisdictions**, without appropriate GMP standards in place. Thus allowing "a greater range of products for consumers" of potentially poorer quality than those produced within Australia currently is clearly not an advantage of this Option and inconsistent with both the guiding principles of the MMDR and TGA's statutory responsibility to ensure public health and safety.

Rogue products released on the market that are not manufactured according to GMP would breach the current definition of 'homoeopathic preparation' under the *Act*, but this safeguard would be removed in a deregulated environment.

It would inevitably result in an increase in adverse reaction events resulting from poor quality products flooding the market. In overseas jurisdictions, lack of regulation has resulted in the uncontrolled supply of products of unknown safety and quality profiles, creating problems for regulators and the public.

This would likely result in increased complaints from the public, generating entirely avoidable increased regulatory burden for government. This is not in the interests of any stakeholders involved.

Recent safety issues associated with Hylands teething products, due to uncertainty regarding levels of the Scheduled poison *Atropa belladonna*, highlights the kinds of issues that could proliferate should TGA GMP standards be relaxed. **It is in the interest of public safety that TGA continues to maintain a regulatory environment where such risks are mitigated** (Options 1/ 2).

Such factors would alter the status of homoeopathic products from 'low risk' to a higher risk category, running contrary to the intent and guiding principles of the MMDR. Such risk would be entirely mitigated by maintenance of the regulatory status quo (Options 1/ and 2).

TGA has a responsibility to ensure that therapeutic claims made by products intended for therapeutic use are appropriate to the level of evidence. The current framework under the *Therapeutic Goods Advertising Code* provides this coverage.

Impact on health care practitioners:

Option 3 also has significant implications for homoeopathic practitioners that the TGA consultation paper does not identify and therefore does not address.

As stated above, exempting homoeopathic products from Parts 3-2 and 3-3 of the *Act* would impact on the ability of sponsors and practitioners to make therapeutic claims against them under the Advertising Code.

The TGA consultation paper aligns proposed changes under Options 3 and 4 (deregulation) to the definitive, partial stance that homoeopathic products are 'not evidence based'. Issues associated with TGA's stated position and the NHMRC report TGA cites to substantiate this claim have been outlined earlier in this AROH/AHA submission.

The *Regulations* currently exempts homoeopathic practitioners with regards to using homoeopathic products for extemporaneous compounding in clinical practice. The consequences of proposed changes under Options 3 and 4 are uncertain and not adequately addressed in the TGA consultation paper.

For example, if homoeopathic products were no longer regarded as 'therapeutic goods', there is ambiguity surrounding what purpose the extemporaneous exemption provisions would serve - by exempting homoeopathic practitioners from using products as therapeutic goods that the legislation no longer regards to be 'therapeutic goods' (relevant to Option 4).

Impact on industry - anti-competitive:

Option 3 is also **anti-competitive** by disallowing homoeopathic products the opportunity to be included on the ARTG, an avenue that is afforded to other ingestive complementary medicine products.

Removing homoeopathic products from legislative requirements that apply to other traditional therapeutic goods is discriminatory; it takes away the right of manufacturers of homoeopathic products to make appropriate claims, placing them at commercial disadvantage.

By contrast, herbal ingredients are also used in low risk ingestive products listed on the ARTG and are able to continue to make therapeutic claims, commensurate with level of evidence (according to a graded scale from traditional to published clinical research). Homoeopathic preparations are no different - yet are targeted in the current consultation whereas herbal products are not.

By being 'exempt goods' under Option 3, the ability of homoeopathic products to make therapeutic claims against therapeutic products under the Advertising Code would be unfairly curtailed.

For equity and consistency, it is important that homoeopathic products continue to be afforded the same opportunity to be included on the ARTG as other CM products, unless these are exempt goods. They should maintain the ability to be subject to GMP under Part 3-3 of the *Act* and be subject to other legislative requirements as appropriate (Option 1).

The current regulatory framework only allows homoeopathic products/preparations to contain ingredients specified in the Permissible Ingredients list under s.26BB of the *Act*. It is unclear whether in a deregulated environment under Option 3 this requirement would be relaxed, resulting in a 'free for all'.

The consequences of this would be to allow currently non-permitted ingredients to included in preparations sourced from overseas, including poisons, drugs (illicit and prescription) and diseased materials. Without the GMP guidelines and legislation, these potentially expose homoeopathic preparations, and the public, to high risk circumstances.

Option 4

AROH/AHA strongly rejects Option 4. The current regulatory framework has worked well since the inception of therapeutic goods legislation and the reasons provided for making such substantial changes are not compelling and would result in significant commercial damage to an entire healthcare sector.

Under this option, it is proposed to:

1. Exclude all homoeopathic products from the regulatory framework, using an instrument under s7AA of the Act and redefine homoeopathic products as consumer goods subject to Australian Consumer Law enforced by the ACCC
2. Prevent homoeopathic products making therapeutic claims
3. Continue to regulate products with therapeutically significant quantities of restricted ingredients
4. Requiring them to be clearly labelled as homoeopathic products with a direction for use statement such as "as directed by your healthcare practitioner"
5. Require development of a new definition for what a 'homoeopathic' product represents.

The complexity of this Option is inherent in the proposed changes described; it would result in a unique and more complex regulatory framework than currently provided.

At its core, the basis for proposing such extensive and convoluted changes to the current (functional) regulatory framework **is TGA's partial position that homoeopathic products are 'not evidence based', cited against the NHMRC report and a political (not scientific) UK report - as stated in the TGA consultation paper.**

- This is entirely unacceptable and has been discussed in earlier sections to the AROH/AHA submission.

The only stakeholder group set to gain out of deregulating homoeopathic products under Options 3 and 4 is the skeptics lobby, an ideologically driven movement that TGA is **inappropriately aligning itself with** in the presentation of its consultation paper. Members of such groups are free not to use homoeopathic products, **however TGA's role is to regulate medicines in the interests of the entire Australian community**. Estimates are that around a million Australians regularly use homoeopathic products.

It is important that the regulatory framework for homoeopathic products supports the Australian public's right to access medicines of their choosing, without unfair impediment. TGA's role is to ensure that these medicines are of sufficient quality (in all respects) to be safe for public use.

TGA must take note that the NHMRC unduly involved active members of anti-homoeopathy advocacy groups in its review of the evidence without any declaration or management of these conflicts, in open breaching its own and Australian Pubic Service conflicts of interest policies (a serious research integrity issue).

Adoption of Options 3 and 4 would have a **major adverse impact on manufacturers of homoeopathic products, affecting their commercial viability**. It is anti-competitive, suppresses innovation and would cause commercial harm to a number of Australian businesses that employ staff.

In extension, it would also impact on healthcare professionals who source their medicines from manufacturers for extemporaneous compounding, if it became commercially non viable for these manufacturers to supply medicines.

By deregulating homoeopathic products under Options 3 and/or 4, **TGA sets to lose revenue from sponsors that list/register goods on the ARTG**. Therefore the claim that this would *"allow the TGA to focus more resources on the regulation of higher risk"* is not valid. AROH/AHA notes that TGA does not deploy any staff with specific homoeopathic expertise and that regulating the homoeopathic products on the ARTG is not resource intensive commensurate with their low risk. **Therefore maintaining regulatory status quo would be (at worst) cost neutral**.

1. Regulate homoeopathic products as consumer goods under the ACCC

The intent of MMDR Recommendation 48 is that any changes to the regulation of complementary medicine products ensures that they are best regulated under other regulatory frameworks without undermining public health and safety.

The inappropriateness of this option has already been discussed earlier in this AROH/AHA submission. In summary, regulating homoeopathic products under the auspices of the ACCC does not provide a viable alternative regulatory framework, as it lacks therapeutic goods specificity. By contrast, the other CM products under consultation do have alternative regulatory frameworks specific to the product type.

It is unclear how substituting the current specialty medicines regulatory framework with a non-specialty consumer goods framework protects public health and safety and upholds the guiding principles of the MMDR or meets TGA's statutory responsibility to ensure public health and safety. This makes little sense.

2. Prevent homoeopathic products making therapeutic claims

As discussed under Option 3, this directly damages the commercial viability of an entire healthcare sector - both manufacturers supplying homoeopathic products to the open market and the wide range of practitioners (including homoeopaths, naturopaths, herbalists, GPs, chiropractors etc) that prescribe them in clinical practice.

It prevents appropriate regulatory oversight of therapeutic claims that can be made commensurate with level of evidence, as is currently the case. This proposal is also **anti-competitive: in the interests of equity and consistency, it is important that homoeopathic products continue to be afforded the same opportunity to make therapeutic claims as per other ingestive CM products**.

TGA's current evidence guideline framework allows for low risk ingestive complementary medicine products (such as homoeopathic and herbal) to make low level claims against traditional evidence.

Other than TGA's adoption of an ideological position on research evidence that it has made no attempt to independently access or evaluate (see Attachment A), no credible reason has been provided why published homoeopathic research evidence should be treated differently and discriminated against:

- For example, around 41% of placebo-controlled, randomised controlled trials assessing homoeopathic interventions published in peer-reviewed journals are positive, with only around 5% negative (the rest inconclusive)[4]. This is the same proportion observed in conventional research findings (44%, 7% and 49% respectively)[5]
- In 2013, the Australasian Cochrane Centre (ACC) advised NHMRC that its findings 'did not accurately reflect the research, [especially] when a substantial proportion of small but good

[4] http://www.facultyofhomeopathy.org/research/
[5] El Dib RP, Atallah AN, Andriolo RB. Mapping the Cochrane evidence for decision making in health care. J Eval Clin Pract., 2007;13(4):689-92

quality studies show positive results' (feedback that NHMRC ignored and obfuscated; available at NHMRC FOI 2015/16 008-13)

- In 2012, NHMRC prematurely terminated a reviewer (principal author of NHMRC's own evidence review guidelines) who delivered on their contract to review the evidence A formal stakeholder investigation has revealed that the reviewer's work was of high quality and likely reported the good quality, positive research evidence known to exist in several medical conditions (as confirmed in the ACC feedback).

TGA has an ethical and administrative obligation to take full note of such information, applying principles of equity upheld by the APS Values. TGA's reference to the NHMRC report with prior knowledge of its flaws and a political (not scientific) UK report, whose recommendations were rejected by the UK Parliament in 2010, **is of particular concern**.

TGA would be taking the risk of aligning its processes with research fraud, in full knowledge of the facts.

As further outlined earlier in the submission, by claiming homoeopathic products 'are not evidence based' in reference to the NHMRC report, TGA is also holding homoeopathic evidence to a far higher standard than any other product category (i.e. N=150 trial participants AND 100% quality threshold). This is inequitable and scientifically unjustifiable.

3. Continue to regulate products with therapeutically significant quantities of restricted ingredients

This makes little sense. On the one hand TGA is proposing to exclude all homoeopathic products from the regulatory framework, while then proposing an alternative definition be created so that a sub-set of homoeopathic products can continue to be regulated.

This is particularly inconsistent in light of Schedules 4 and 5 to the *Regulations,* which already cover this subsection by specifying a one-thousandth (3X potency) concentration threshold for whether homoeopathic preparations are to be regulated or regarded as exempt goods - for the purpose of regulating products with therapeutically significant quantities of restricted ingredients (see point 5. below).

This only confirms that the current regulatory framework provides a good working model and should be retained (Option 1).

4. Requiring labelling 'as homoeopathic products' with a direction for use statement such as "as directed by your healthcare practitioner"

AROH/AHA strongly rejects this proposal. The same requirements should apply to **all** complementary medicines product categories; there is no justifiable reason why homoeopathic products should be singled out (other than issues related to the partial approach being adopted by the consultation paper, as discussed elsewhere in the AROH/AHA submission).

Further, the consultation paper provides no explanation of what "healthcare provider" refers to and thus provides inadequate information for meaningful public consultation.

5. Development of a new definition for 'homoeopathic' product

Option 4 would also require a fundamentally new and unique definition of 'homoeopathic preparation' to be created. **This is contrary to one of the core guiding principles of the MMDR reform agenda** (p.5, TGA consultation paper) that stipulates:

- *"It was not our intention to fundamentally change the definition of a medicine or medical device under the Therapeutic Goods Act 1989 (the Act), although it would be possible to change the regulatory approach taken for particular groups of products regulated under the Act."*

Option 4 requires a fundamental change to the definition of 'homoeopathic preparation'.

In 2010, the definition of 'homoeopathic preparation' in the *Act* was appropriately changed to reflect method of manufacture according to internationally recognised homoeopathic pharmacopoeial standards. TGA's intention to proceed with updating the definition in the *Regulations* was then suspended, pending the outcome of the NHMRC Homoeopathy Review. **This provides further evidence of the alignment of TGA's agenda for homoeopathic product regulation with the NHMRC review process**.

Any new definition of 'homoeopathic preparation' w**ould not accurately reflect what a 'homoeopathic product/preparation' actually is** and further, **would not be transferrable to/recognised by other international jurisdictions**. The definition would be unique on the sole basis of an ideological agenda to remove these products from legislation - which is unacceptable.

Any 'new definition' **would not align with homoeopathic pharmacopoeias**, which provide the internationally accepted standards for the manufacture of homoeopathic preparations. By reflecting homoeopathic pharmacopoeia standards, the current definition in the *Act* is both pragmatic for the purpose of therapeutic goods regulation and is also internationally recognised.

Retaining the current definition is also **consistent with TGA's agenda to enhance international harmonization** in the regulation of medicines.

Changing an accurate, extant international standard for one that is unique and not characteristic of the product category is illogical.

Concluding comment

As the peak bodies representing the interests of the homoeopathic profession, AROH/AHA strongly support maintenance of the current legislative framework. This is the only option that meets the needs of all stakeholders - the public, government, manufacturers and health practitioners.

Yours sincerely,

[redacted]

[redacted]

Australian Register of Homoeopaths (AROH)

[redacted]

[redacted]

Australian Homoeopathic Association (AHA)

Attachment A

Overview of homoeopathy research:

1. Homoeopathy research, although in its infancy when compared with conventional biomedicine, is an active and growing field of research worldwide (for further details on information presented in this document, visit the Homoeopathy Research Institute website).

2. Universities and academic institutes are currently supporting not only clinical research, but also fundamental and basic laboratory research into homoeopathy.

3. Over 1,000 clinical trials on homoeopathy have been published – ranging from randomised controlled trials to observational studies. The more recent published clinical trials demonstrate the increasingly high quality of work done in the field.

Meta-analyses:

4. 5 out of 6 published meta-analyses (which combine the results from multiple studies) conclude effects for homoeopathy beyond placebo.

5. Only 1 has been negative; for more details about this study, go to: https://www.hri-research.org/resources/homoeopathy-the-debate/the-lancet-paper-by-shang-et-al/

6. The most recent meta-analysis, a robust study by Mathie et al. (2014), found that homoeopathic medicines, when prescribed during individualised treatment, are 1.5- to 2.0-times more likely to have a beneficial effect than placebo[6] (p=0.013).

   This was the first meta-analysis to look solely at individualised homoeopathic treatment i.e. as delivered by homoeopaths in 'real world' practice. The findings of this meta-analysis passed a rigorous 'sensitivity analysis' to check the results were robust - i.e. no matter how the trials' analyses were changed, the result remained highly statistically significant (p<0.001).

   There was also no evidence that lower-quality trials had larger treatment effects.

Randomised Controlled Trials (clinical 'efficacy' studies in humans):

7. Around half of all clinical research trials into homoeopathy report statistically positive outcomes, with only 5% being negative - the same proportion as seen in conventional research[7].

8. Of 104 placebo-controlled RCTs published in peer-reviewed journals by the end of 2014, 41% were positive, 54% inconclusive and only 5% negative[8] - a strikingly similar proportion to that observed in published conventional medical research[9].

---

[6] Mathie, R. T. *et al.* (2014) Randomised placebo-controlled trials of individualised homoeopathic treatment: systematic review and meta-analysis, *Syst Rev*, **3**:142

[7] Australian Register of Homoeopaths submission to NHMRC, 2013.

[8] Faculty of Homoeopathy (UK), http://facultyofhomoeopathy.org/research/

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

9. There is evidence from several good quality, prospective controlled studies demonstrating effectiveness for homoeopathic treatments in several conditions (eg. diarrhoea in children, sinusitis, allergic rhinitis, upper respiratory tract infections, post operative ileus), for example (but not limited to):

    - Individualised homoeopathic treatment for diarrhoea in children[10]
    - Individualised homoeopathic treatment of otitis media in children [11,12]
    - Two different non-individualised treatments for allergic rhinitis – the homoeopathic medicine *Galphimia glauca*[13] and the isopathic medicine *Pollen 30C*[14]
    - The non-individualised complex homoeopathic medicine Vertigoheel for vertigo[15].

Laboratory research:

10. Around 75% of *in vitro* experiments on ultra-high dilutions (where there is no 'placebo effect') show the substance having an effect, and nearly 75% of replications have been positive[16].

    Reproducibility is increasing as scientists gain more experience and gradually understand what factors are influencing the results[17].

11. Many laboratory studies have shown ultra-high dilution homoeopathic medicines having biological effects, for example basophil (white blood cell) degranulation experiments:

    - 28 scientific papers have been published on this topic, 23 of which reported positive results. 11 publications were judged to be of high quality, of which 8 report positive results[18].

Observational ('effectiveness') studies:

---

[10] Jacobs et al, Homoeopathy for childhood diarrhea: combined results and meta analysis from three randomized, controlled clinical trials, Pediatr Infect Dis J, 2003; 22:229–34

[11] Jacobs, J., Springer, D.A., et al.(2001). "Homoeopathic treatment of acute otitis media in children: a preliminary randomized placebo-controlled trial." The Pediatric infectious disease journal 20(2): 177-183.

[12] Sinha et al. Randomised controlled pilot study to compare Homoeopathy and conventional therapy in Acute Otitis Media. Homoeopathy 2012, 101: 5-12.

[13] Wiesenauer and Lüdtke. A meta analysis of the homoeopathic treatment of pollinosis with Galphimia glauca. Forsch. Komplementärmed. 1996; 3: 230-234

[14] Reilly, D.T., Taylor, M.A., et al. (1986)." Is homoeopathy a placebo response? Controlled trial of homoeopathic potency, with pollen in hayfever as model." Lancet 2(8512): 881-886.

[15] Schneider et al. Treatment of vertigo with a homoeopathic complex remedy compared with usual treatments – a meta-analysis of clinical trials, Arzneim.-Forschung 2005, 55(1) 23-29.

[16] Witt CM, Bluth M, Albrecht H, Weisshuhn TE, Baumgartner S, Willich SN. The in vitro evidence for an effect of high homoeopathic potencies–a systematic review of the literature. Complement Ther Med., 2007; 15(2): 128-38

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

[18] Witt CM, Bluth M, Albrecht H, Weisshuhn TE, Baumgartner S, Willich SN. The in vitro evidence for an effect of high homoeopathic potencies–a systematic review of the literature. Complement Ther Med., 2007; 15(2):128-38

12. Observational studies examining the 'effectiveness' of homoeopathic interventions in real-world clinical settings consistently report positive outcomes for patients[19]. For example:

13. A 500-patient survey at the Royal London Homoeopathic Hospital showed that many patients were able to reduce or stop conventional medication following homoeopathic treatment.[20]

14. A study in Germany looking at 493 patients treated by GPs for chronic conditions showed that homoeopathy produced better clinical outcomes than conventional medicine, for similar costs.[21]

15. A multi-centre, 8-year longitudinal cohort study that followed over 3,500 adults and children receiving routine homoeopathic care from GPs, found that *"patients who seek homoeopathic treatment are likely to improve considerably"* - experiencing steady, long-term health benefits[22].

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

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

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

17. A recent randomised controlled trial carried out in a public research hospital in Mexico City assessed two treatments for moderate to severe depression in 133 menopausal women[24]. This study, published in 2015, found that both individualised homoeopathic treatment and Fluoxetine (a.k.a. Prozac) were safe and more efficacious than placebo. However, homoeopathy resulted in greater clinical improvement in symptoms of depression than fluoxetine, and also improved the patients' menopausal symptoms, whereas fluoxetine did not.

---

[19] https://www.hri-research.org/resources/homoeopathy-the-debate/essentialevidence/observational-studies/

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

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

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

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

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

18. For further examples, go to: https://www.hri-research.org/resources/homoeopathy-the-debate/essentialevidence/observational-studies/

Animal & plant studies:

19. Placebo-controlled clinical trials in animals and plants show that homoeopathy is not just due to 'placebo'.

20. For example, a rigorous research study found that a homoeopathic medicine can prevent *E. coli* diarrhoea in piglets[25] – a major problem in commercial farming.

21. High quality experiments have demonstrated homoeopathic ultra high dilutions having biological effects.

    For example, In amphibians, the hormone thyroxine stimulates metamorphosis. Over almost 20 years, various teams have tested homoeopathic dilutions of thyroxine on frogs by adding it to the bathing water tadpoles are kept in.

    An independent meta-analysis of these trials identified 22 experiments – 15 carried out by the original team in Austria and 5 by independent researchers[26]. All 22 experiments found the same trend – that thyroxine 30X (diluted beyond Avogadro's limit using the homoeopathic manufacturing process) inhibits metamorphosis, though the exact results varied.

    This effect has now been observed by 7 researchers from Austria, Germany, Switzerland and the Netherlands.

22. There is also good quality evidence in plant models demonstrating the specific biological effects of highly diluted homoeopathic preparations. For further details, go to: https://www.hri-research.org/wp-content/uploads/2014/08/HRI_ResearchArticle_16_Baumgartner_PlantModels.pdf

Swiss Health Technology Assessment report:

23. A comprehensive Swiss Health Technology Assessment (HTA) report officially concluded that evidence from laboratory studies and clinical research shows that homoeopathy is clinically effective, cost effective and safe.

    > *"There is sufficient evidence for the preclinical effectiveness and the clinical efficacy of homoeopathy and for its safety and economy compared with conventional treatment."*

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

    The Swiss HTA report found that 20 out of 22 systematic reviews of clinical trials into homoeopathy showed a positive direction of evidence in favour of homoeopathy.

[25] Camerlink I, Ellinger L, Bakker EJ, Lantinga EA. Homoeopathy as replacement to antibiotics in the case of Escherichia coli diarrhoea in neonatal piglets. Homoeopathy, 2010;99: 57–62

[26] Harrer B. Replication of an experiment on extremely diluted thyroxine and highland amphibians. Homoeopathy, 2013;102(1):25-303

24. The findings of the Swiss HTA report were entirely ignored by the 2012-2015 National Health & Medical Research Council review of the evidence on homoeopathy, with the report not assessed in any detail as part of the Review.

French virologist Prof Luc Montagnier, who won a Nobel Prize in 2008 for his role in discovering HIV, says homoeopaths are right in using high dilutions. In an interview in *Science* magazine he states:

> *"What I can say now is that the high dilutions are right. High dilutions of something are not nothing. They are water structures which mimic the original substance."*

Further reading:

- Homoeopathy Research Institute (HRI) - https://www.hri-research.org
- Australian Homoeopathic Association (AHA) - http://www.homoeopathyoz.org
- British Homoeopathic Association (BHA) - http://www.britishhomoeopathic.org