Submission to the Department of Health Consultation:

Review of Pharmacy Remuneration and Regulation Interim Report

OPTION 3-4: HOMEOPATHIC PRODUCTS

I am writing to strongly oppose Option 3-4 of the Interim Report to ban the sale of homeopathic products from Pharmacy.

Introduction:

The Interim Report does not demonstrate a balanced approach to the evidence presented, referring only to hearsay not reflected or reported in its 'Commissioned Research' documents and the National Health & Medical Research Council (NHMRC) Homeopathy Review, in lieu of assessment of any other evidence or reports.

The NHMRC report is subject to a Commonwealth Ombudsman Complaint. Its findings were challenged by its own methodological expert peer reviewers (e.g. the Australasian Cochrane Centre), advice NHMRC ignored and withheld from public disclosure. In August 2013 the ACC advised NHMRC[i]:

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

Thus the ACC , an independent scientific institution with no connection to homeopathy, advised:

1. NHMRC's finding of 'no reliable evidence' does not accurately reflect the research evidence; and
2. A significant proportion of small but good quality studies assessing the efficacy of homeopathy show significant differences.

Another expert peer reviewer similarly advised NHMRC in May 2014 (in advice NHMRC also ignored and withheld from public disclosure)[ii]:

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

The Expert Panel has an ethical responsibility to the Australian public to take such expert reviewer advice into account and demonstrate it has considered the broader range of homeopathic evidence, which the NHMRC ignored as out of scope of its Review (outlined further below).

Consumer right of choice:

The PSA ethics guidelines (Care principle 2) stipulate and uphold the principle that a pharmacist must "respect patient choice".

Option 3-4 is not consistent with this and would represent an inappropriate breach of consumer/ civil rights.

There is also a question mark over whether such an extreme measure is constitutional. The Option is also not compatible with the Pharmacy Review's 'Strategic vision and Intent' (p.3). It is a retrograde measure that adversely impinges on consumer right of choice.

Homeopathic products have been sold in pharmacies for many years without any evidence of 'safety risk' to consumers. On the contrary, demand for homeopathic products has increased due to consumers finding them to be effective adjuncts in assisting to manage a range of everyday ailments.

The Expert Panel presents views in the Interim Report under Option 3-4 that it states were elicited during its consultation, that:

- Occurred in the absence of any consultation with any stakeholders in the complementary medicines and/or homeopathy sector
- Are not referenced anywhere in the 'Commissioned Research' documents (http://www.health.gov.au/internet/main/publishing.nsf/Content/review-pharmacy-remuneration-commissioned-research). A search of these documents does not make reference to any feedback on homeopathic products.

'Safety' of homeopathic products - speculation, not evidence-based:

Homeopathic medicines/ products have a proven track record of safety in Australia and internationally. This is supported by 'real-world' data, which is unrefuted by evidence to the contrary.

The Therapeutic Goods Administration (TGA) defines/ measures whether or not medicines pose a 'safety' risk according to recorded adverse reaction events, drug interactions and safety studies. Adverse reaction data is accessible on the TGA's Adverse Reactions database, accessible via the TGA website, demonstrating the excellent safety record of homeopathic products.

In Europe, homeopathic medicines are recognised as medicines and are only available in Pharmacy in the retail sector. Unacceptably, the Expert Panel has made no attempt to interrogate and present to the public any of the highly relevant research or analysis from such overseas jurisdictions where homeopathic products are widely available and used.

On what credible basis, then, does the Expert Panel offer the community its 'speculative' position that allowing the sale of homeopathic products in Pharmacy *"creates a risk of harm to the patient's health"* - a position that is not based on (and contrary to) real-world safety/ research data?

The Interim Report's "risk of harm" position on homeopathic products' is ill-informed, unscientific and based on opinion - not on any actual safety data assessment.

'Risk of harm' argument & the NHMRC Homeopathy Review:

The only basis offered by the Expert Panel for such speculation is the National Health & Medical Research Council (NHMRC) 2015 review of the evidence on homeopathy (the 'Homeopathy Review').

The Expert Panel offers the speculative argument that homeopathic products present a 'risk of harm because the NHMRC Review concluded there is no evidence of efficacy'.

1. NHMRC Homeopathy Review - no safety evidence assessed:

The Expert Panel should consider the following:

- The NHMRC Homeopathy Review did not include any assessment of the safety of homeopathy, nor any studies comparing the relative benefits/risks of using homeopathy versus conventional medicine; in fact all safety studies submitted to NHMRC during the Review were excluded as 'out of scope'.
- Yet the presence of this statement within a section called *"NHMRC's interpretation of the assessment of the evidence on the effectiveness of homeopathy"* in the NHMRC Information Paper (p.27) misleads the public into believing that it is based on the findings of their Overview, when it is not.
- This false impression is strengthened further by NHMRC repeatedly and inaccurately describing the Homeopathy Review to the public as a "Health Technology Assessment" (Information Paper, pp.5 & 38; FAQ document pp.4,9,11; Administrative Report, pp.5,6). HTAs *by definition* do assess safety, but conducted an 'Overview' not a HTA - and in doing so actively excluded from scope assessment of any safety data.
- The NHMRC also ignored the findings of other actual HTA reports, such a 2012 Swiss report that concluded[iii]:

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

The Expert Panel has an ethical duty to the community to take such actual, real-world safety/ research data (e.g. TGA and other international safety data, and the findings of other reports that have formally assessed safety) into consideration before developing such a drastic Option.

It is not acceptable that the Expert Panel has ignored such data and instead appears to be taking an ideological position on homeopathy, offering a policy position based on hypothesis - rather than objectively and impartially informing its position based on scientific/ technical data.

2. NHMRC Homeopathy Review - Over 90% of research evidence excluded from scope:

The Expert Panel should take note of the following facts:

- NHMRC misinformed the public, researchers and decision-makers that its findings were based on a *"rigorous assessment of over 1800 papers"*[iv] - whereas only 176 papers were included in scope, with the rest ignored altogether (e.g. of the '1800 papers' referred to, 374 were simply duplicate citations[v])
- Of the 176 papers included in scope, NHMRC did not retrieve or assess any of the original papers, instead relying solely on information in systematic reviews (SRs) - secondary sources that summarise the findings of the original studies.
- Despite conducting an 'Overview' - which by definition is supposed to summarise and present the findings of SRs - NHMRC ignored the conclusions of all the SRs (many of which are positive for homeopathy).

Thus, the findings of the NHMRC Homeopathy Review are based on less than 10% of the published research it told the public was assessed, and based its conclusions entirely on secondary sources, while dismissing the findings of those sources (even though those sources had already assessed the original studies). This hardly "rigorous".

A report that bases its conclusion on less than 10% of the evidence base and secondary sources cannot credibly be used as a *sole* data source to inform health policy, particularly when such an extreme measure is being proposed.

3. NHMRC Homeopathy Review - relevant evidence excluded:

The NHMRC Review excluded any assessment of the following evidence:

- 'Effectiveness' - observational/ cohort studies/ case series assessing the effectiveness of homeopathy in real-world clinical settings, nearly all of which consistently demonstrates positive effects for homeopathy[vi]
- Laboratory studies in animal/ plant/ cell models where the 'placebo effect' is annulled. Overall, 75% of *in vitro* laboratory studies show positive results, with around 75% of these studies having been replicated[vii].
- The findings of meta-analyses - 5 out of 6 of which report an effect for homeopathy that is not compatible with the 'placebo effect'. The only negative meta-analysis has been discredited in the scientific literature for being methodologically flawed[viii]
- 'Safety' - despite describing the Review as a 'HTA'
- 'Quality' - despite describing the Review as a 'HTA'
- Prevention studies - despite the existence of large population studies, where homeopathic interventions have been successfully applied (e.g. Cuba in the successful control of leptospirosis, involving millions of people[ix]).
- Other major reports, including a major Swiss HTA report[x], whose authors concluded 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 NHMRC did not disclose the Swiss report's findings).
- Around half of all clinical research trials into homeopathy report statistically positive outcomes, with only 5% being negative - the same proportion as seen in conventional research[1].
- Of 104 placebo-controlled RCTs published in peer-reviewed journals by the end of 2014, 41% were positive, 54% inconclusive and only 5% negative[2] - a strikingly similar proportion to that observed in published conventional medical research[3].

[1] Australian Register of Homeopaths submission to NHMRC, 2013.

[2] Faculty of Homeopathy (UK), http://facultyofhomeopathy.org/research/

[3] 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

4. NHMRC Homeopathy Review - evidence of maladministration & scientific misconduct:

The Expert Panel has an ethical duty to take account of a formal investigation into the NHMRC's conduct of the Homeopathy Review, details of which are now in the public domain[xi].

These details include the following revelations, that the NHMRC:

- **Fired a first reviewer** who assessed the evidence in 2012 - concealing the existence of this report, its findings and tax-payer expenditure (see http://www.nhmrchomeopathy.com/firstreview.html)

  Freedom of Information documents reveal:

  — The first reviewer was a principal author of NHMRC own seminal guidelines on how to review health evidence

  — The final Draft Report was of high methodological quality[xii].

- **Engineered the findings of the second (published) Review**, by creating and applying <u>all</u> of the criteria that underpinned its findings, as follows (see http://www.nhmrchomeopathy.com/incaccuratereporting.html):

  — The research protocol was agreed and finalised in December 2012 (but not disclosed)[xiii]

  — Optum completed the evidence assessment in March 2013 (not disclosed)[xiv]

  — In early May 2013, retrospectively adopting the "null hypothesis approach"[xv] (not disclosed)

  — In July 2013, adopting an arbitrary 'sample size exclusion threshold' of 150 trial participants (not disclosed)[xvi]

    - This (retrospectively) dismissed the findings of 146/ 176 of the studies from their results being considered as part of the Review's findings (not reported) [xvii].

  — In late July/ August 2013, adopting a further (unusually high) '100% quality rating' exclusion threshold (not disclosed)

    - This (retrospectively) dismissed the findings of 25/ 30 of the remaining studies from their results being considered as part of the Review's findings (not reported)[xviii].

- **Involved undisclosed, unmanaged anti-homeopathy conflicts of interest** at multiple levels of the Review, while concomitantly **excluding the involvement of any homeopathy subject/ clinical/ research experts** - in open breach of legislated conflicts of interest policy and mandatory NHMRC quality assurance standards (see http://www.nhmrchomeopathy.com/conflictsofinterest.html).

- **Ignored and did not disclose expert reviewer feedback** disagreeing with the Review's methodology and findings; for example, the following expert peer review advice was not disclosed (see http://www.nhmrchomeopathy.com/unreported.html):

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

- Aug 2013

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

- May 2014

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

- May 2014

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

- May 2014

In light of such damning evidence of maladministration and scientific misconduct, the Expert Panel cannot ethically or morally cite this flawed government report as a basis to inform health policy. Doing so would constitute a perpetuation of this misconduct on behalf of the Expert Panel, ignoring facts at its disposal.

The NHMRC's conduct of the Homeopathy Review is now subject to a Commonwealth Ombudsman Complaint and call for a Senate Inquiry to investigate this misconduct.

Further resources that the Expert Panel should take regard to include:

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

Perceived bias in Exert Panel's consultation:

Finally, I also note with considerable concern that Prof Stephen King has made pre-emptive, biased remarks towards homeopathy in the public domain prior to release of the Interim Report (e.g Four Corners, February 2017) and that another of the Expert Panel members is a member the Consumers Health Forum, a group that has an established history of providing a platform for anti-complementary medicine advocates.

For example, it is well known that the explicitly biased 2011 Draft NHMRC Position Statement on Homeopathy (which was abandoned on the basis of that perceived/ actual bias) was leaked to the media in 2011 via the CHF, when Dr Ken Harvey (Friends of Science in Medicine) was its 'complementary medicines spokesperson'[xix].

References:

[i] 2013.08.30 - Australasian Cochrane Centre follow-up methodological peer review advice. NHMRC Freedom of Information document 2015-16 007-05

[ii] Expert peer reviewer advice to NHMRC on Draft Homeopathy Review Information Paper. NHMRC Freedom of Information document 2014/15 004 Section 62

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

[iv] NHMRC media release, 11.03.2015 - uncritically reiterated by the media

[v] Optum Insight Overview Report, p.22

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

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

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

[ix] Bracho G et al. Large-scale application of highly-diluted bacteria for Leptospirosis epidemic control. Homeopathy, 2010; 99: 156-166

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

[xi] https://www.hri-research.org/wp-content/uploads/2017/04/Executive-Summary-to-Ombudsman-Complaint-re-NHMRC-Homeopathy-Review-FINAL.pdf

[xii] NHMRC Freedom of Information documents 2014/15 021-08 & 2016/17 016-13

[xiii] NHMRC Freedom of Information document 2014/15 004 Section 58

[xiv] NHMRC Freedom of Information document 2015/16 007-03

[xv] NHMRC Freedom of Information document 2014/15 021-11

[xvi] NHMRC Freedom of Information document 2015-16 008-06

[xvii] Independent expert analysis of NHMRC's methods, unpublished

[xviii] Independent expert analysis of NHMRC's methods, unpublished

[xix] NHMRC Freedom of Information document 2015-16 002-16