

## A review of the ethics of the National Health and Medical Research Council (NHMRC) focus on homœopathy, 2010-2015 - Part 1

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### Abstract

On 11 March 2015, the National Health and Medical Research Council (NHMRC) published its report on the review of the evidence on homœopathy, which concluded, 'there are no health conditions for which there is reliable evidence that homeopathy is effective'. This was the culmination of a process NHMRC initiated in 2010, when it decided to develop a position statement on homœopathy, in lieu of any evidence assessment or expert consultation. This process was abandoned in mid-2011 in favour of instigating a formal evidence review, due to perceptions of bias and lack of procedural or scientific rigour after the draft NHMRC statement was leaked to the media on 20 April 2011.

This paper is the first in a two-part series examining whether NHMRC fulfilled its obligation to fairly and objectively assess the evidence on homœopathy, according to accepted standards of ethical scientific inquiry and statutory Australian Public Service values and codes of conduct. It also examines how NHMRC approached reporting and managing anti-homœopathy conflicts of interest involved in the review process according to its policies. Part 1 predominantly focuses on the period 2010 to 2012 leading up to the commencement of the review of the evidence conducted under the contractor OptumInsight (the focus of Part 2).

This paper is part of a two-part series examining ethical issues associated with the National Health and Medical Research Council's (NHMRC's) focus on homœopathy between 2010 and 2015. Part 1 predominantly focuses on the period October 2010 to August 2012; Part 2 will focus on the period October 2012 to March 2015.

### Introduction:

Between October 2010 and March 2015 the National Health and Medical Research Council (NHMRC) conducted an investigation into homœopathy, to inform the Australian community on the "effectiveness of homeopathy." This included a formal review of the evidence on homœopathy (the 'Review') conducted between 2012 and 2015.

NHMRC's findings were that, for the 61 health conditions covered by the Review, *"...no good-quality, well-designed studies with enough participants for a meaningful result reported either that homeopathy caused greater health improvements than placebo, or caused health improvements equal to those of another treatment"*.

NHMRC's overall conclusion, based on this assessment of the evidence was, *"...there are no health conditions for which there is reliable evidence that homeopathy is effective."*

NHMRC's media release announcing publication of the Review claimed, *"The conclusion is based on the findings of a rigorous assessment of more than 1800 papers"* and recommended, *"Homeopathy should not be used to treat health conditions that are chronic, serious, or could become serious."*

The potential impacts of evidence review by a respected institution such as NHMRC is wide reaching – the general public, health practitioners, decision-makers and other researchers all rely on the findings. It is therefore essential that NHMRC reviews are free from bias, providing a fair and objective assessment of a given topic.

NHMRC's investigation was an example of its function to 'advise the community' under section 7(1)(a) of the *NHMRC Act 1992*<sup>1</sup>. It was instigated under the *NHMRC Strategic Plan*

*2010-2012 "to examine the evidence underlying the alternative medicines most highly used"*<sup>2</sup>. Yet homœopathy is one of the least used complementary medicines (CMs) in Australia, accounting for less than 5% of CM practitioner visits and only around 0.5% of CM over-the-counter medicine sales. Moreover, NHMRC did not examine any other CMs under the auspices of its *Strategic Plan*. Thus, from the start, there was a question mark over why NHMRC singled out homœopathy for review.

Before examining the question of whether NHMRC fairly and objectively approached its assessment of homœopathy, an understanding of NHMRC's roles and responsibilities as an Australian Public Service (APS) agency is required.

### Background to NHMRC's roles and functions

NHMRC's functions are to foster 'improved health and medical knowledge, including through funding research, translating research findings into evidence-based clinical practice, administering legislation governing research, issuing guidelines and advice for ethics in health and the promotion of public health'.<sup>3</sup> NHMRC's mission statement is 'Working to build a healthy Australia'<sup>4</sup> and it promotes itself as *'Australia's leading expert body promoting the development and maintenance of public and individual health standards'*<sup>5</sup>.

As an APS agency that conducts and funds scientific inquiry, NHMRC is bound by both scientific and administrative standards of conduct, embodied by:

1. Internationally accepted standards of conduct in scientific inquiry; and
2. Values and codes of conduct underpinned by legislation - the APS Values and Code of Conduct.<sup>6</sup>

In scientific inquiry, ethical principles and accepted research standards exist to safeguard the integrity of research processes. These principles are embodied by respect for the integrity of knowledge, collaboration, honesty, openness and objectivity. They are applied as basic elements of the scientific method and characterise ethical scientific inquiry.<sup>7</sup>

The *Public Service Act 1999* requires that APS employees and agency heads at all times behave in a way that upholds the APS Values and Code of Conduct, upholding the community's confidence in the APS to be impartial, committed to service (including working collaboratively), ethical, respectful and accountable. The Australian Public Service Commission (APSC) guidance document, 'APS Values and Code of Conduct in practice', states<sup>8</sup>:

*"Employees of the Australian Public Service (APS) occupy a position of trust. They are entrusted by the Government and the community to undertake important work on their behalf. With this trust comes a high level of responsibility which should be matched by the highest standards of ethical behaviour from each APS employee."*

*Together the APS Values, the APS Employment Principles and the APS Code of Conduct set out the standard of behaviour expected of agency heads and APS employees. They provide the public with confidence in the way public servants behave, including in their exercise of authority when meeting government objectives."*

The NHMRC *Service Charter*<sup>9</sup> upholds the APS Values and also identifies a number of 'NHMRC stakeholders'. These include 'clinicians and other health professionals and managers', 'the health and medical research sector' and 'industry'. Thus, the homœopathy sector formally qualifies as an 'NHMRC stakeholder'.

How did the NHMRC approach the homœopathic profession in its role as a stakeholder? Was it consistent with how NHMRC customarily approaches its other stakeholder sectors?

### **Ethical issues associated with NHMRC's obligation to inform the public on homœopathy**

A number of ethical issues and challenges were associated with NHMRC's focus on homœopathy. This relates to NHMRC predominantly drawing from and representing the orthodox medical research sector, a sector that is also the support base of anti-complementary medicine (CM) lobby groups, such as Friends of Science in Medicine (FSM) and the Australian Skeptics. Of note, FSM was formed in late 2011, during the planning stages of the NHMRC Homeopathy Review (see below).

Against this background, the question was whether NHMRC would be able to divorce itself from such influences and conduct an impartial investigation, in line with accepted research standards and statutory APS principles of conduct, designed to safeguard scientific and administrative processes against bias. Providing these principles were observed, there was no reason why NHMRC could not have fulfilled its obligation to fairly and objectively review the evidence on homœopathy.

Risk of bias is normally minimised by three key safeguards:

- 1. Use of standardised and accepted scientific methods**
- 2. Internal policies and procedures** - e.g. adherence to legislation, standards, guidelines and conflict of interest policy
- 3. Transparency and accountability** - e.g. public disclosure of processes followed, meaningful public consultation and accurate communications to the public.

The degree to which NHMRC upheld these safeguards in its 2010-2015 assessment of homœopathy is discussed below, principally focusing on the period 2010-2012.

### **Development of a Position Statement on Homœopathy, 2010-2011**

In October 2010, the former NHMRC Chief Executive Officer (CEO), Professor Warwick Anderson, directed NHMRC Council to develop a position statement on homœopathy for uploading to the NHMRC website<sup>10</sup>, on the sole basis of the UK House of Commons Science and Technology Committee (STC) Report, *Evidence Check 2: Homeopathy*<sup>11</sup>. The UK STC report was part of a political, not scientific process whose recommendations the UK Parliament had rejected in July 2010, in favour of supporting patients' rights to continue to access homœopathy and supporting further research into homœopathy<sup>12</sup>.

In adopting the findings of the UK STC Report, NHMRC did not:

- Acknowledge its political basis; which received two brief three-hour hearings before politicians (not scientists); was associated with bias in the choice of witnesses; excluded key evidence and was approved by only three of the original twelve committee members<sup>13</sup>;
- Critically evaluate the Report, which was based almost exclusively on a single study<sup>14</sup> that had already been discredited in the scientific literature for being methodologically flawed;
- Consult or collaborate with any homœopathy subject or research experts;
- Conduct any independent review of the evidence.

The same month that the CEO instigated this process via NHMRC Council, he submitted for publication an article to the *Medical Journal of Australia (MJA)* declaring his personal anti-homœopathy viewpoint (emphasis added):

*"I find it disturbing that now, in the 21st century, there is an apparent retreat from reason in many Western societies, and often a retreat from science. Many people seem to regard their own views and beliefs as being of equal value to any other, whether or not they are founded on any factual, scientific or logical base. There are many examples, such as the widespread use of such **alleged therapies as homœopathy**, or the belief that crystals have magic healing powers."*<sup>15</sup>

In addition to statutory APS principles of conduct outlined above, the *NHMRC Act 1992*, Section 42A(2), stipulates:

*'If the CEO has, or acquires, an interest that could conflict with the proper performance of the CEO's functions, the CEO must, as soon as possible after the relevant facts have come to his or her knowledge, disclose the nature of the interest to the Minister.'*

This did not occur.

In December 2010, NHMRC Council approved a draft Position Statement on homœopathy, subject only to administrative, not content checks<sup>16</sup>. NHMRC contracted the Consumers Health Forum (CHF) to conduct a 'health literacy' check, to ensure the Statement was 'readable' for dissemination to the Australian community. NHMRC correspondence to the CHF confirms:<sup>17</sup>

*"The aim of this project is to engage, inform and consult with Consumers Health Forum of Australia (CHF) members and other consumers about a draft public advisory statement developed by the NHMRC, to ensure that it can be read and understood by a consumer audience."*

The homœopathy sector, a 'NHMRC stakeholder', was not informed of the process and was not included in CHF's distribution list<sup>18</sup>. Communications between NHMRC/ CHF/ CHF memberships confirm that the content of the draft Statement had been prior-approved by NHMRC; i.e. that CHF had only been contracted to ensure that the Statement was 'readable'.

### **Draft NHMRC position statement leaked to the media**

On 20 April 2011, the Australian Homœopathic Association (AHA) accidentally learned of the existence of the NHMRC draft Position Statement process 'via a circuitous route'<sup>19</sup>. The AHA promptly contacted the CHF, requesting clarification and input into the process. CHF provided AHA with an embargoed copy of the draft Statement, stipulating<sup>20</sup>:

*"We are really trying to seek a consumer view on the readability of the statement, not the content, so you may not wish to comment."*

That same day, the draft Statement was leaked to the *Australian Doctor* and published<sup>21</sup>. At this time, the CHF's complementary medicine (CM) spokesperson was the anti-CM lobbyist and Australian Skeptic Dr Ken Harvey (currently an executive member of FSM). The leaked NHMRC draft Position Statement declared:

*"NHMRC's position is that it is unethical for health practitioners to treat patients using homeopathy, for the reason that homeopathy (as a medicine or procedure) has been shown not to be efficacious"*

It also asserted:

*"The prescription of placebos in this way is deceptive and raises ethical concerns."*

The leaked Statement also confirmed:

*"The findings of the [UK] Homeopathy Report are the basis of the NHMRC's public statement on homeopathy"*

NHMRC's stance on homœopathy, approved by NHMRC Council on the basis of a political report and developed in lieu of any evidence assessment or expert consultation, was clear.

From an ethical perspective, the development of the draft Statement was clearly not the result of an impartial, consultative, respectful or transparent evaluation of the research by Australia's 'leading expert body' responsible for providing the community with 'informed health advice'.

The anti-homœopathy bias NHMRC demonstrated in the development of the draft Statement was explicit.

### **Draft Position Statement abandoned, formal evidence review instigated**

After NHMRC's draft Statement was leaked to the media, NHMRC received multiple complaints from the homœopathy stakeholder sector, including the AHA, which also lodged a formal complaint on 28 April 2011<sup>22</sup>, alongside a formal letter of complaint addressed to the NHMRC CEO with attachments detailing research<sup>23</sup>. The letter informed NHMRC:

*"The AHA is the largest and only national association for homœopaths in Australia, and a major stakeholder in the profession. It would thus seem appropriate that we would be a part of any consultation process regarding homœopathy. ... There is a significant body of research that demonstrates its effectiveness, and you can find details and references to this on the AHA's website."*

The AHA also wrote to State and Federal Health Ministers to lodge formal complaints regarding the process undertaken by NHMRC, in particular the absence of any considered assessment of the evidence and NHMRC's lack of any consultation or desire to engage in a consultative approach with the homœopathic profession's subject and research experts<sup>24</sup>.

Controversy relating to bias and lack of scientific and procedural rigour resulted in NHMRC abandoning the draft Statement process, in favour of conducting a formal evidence review. NHMRC claimed the Statement 'was only a draft', despite NHMRC Council having previously approved its content.

Such an inauspicious start to NHMRC's focus on homœopathy raised significant concerns regarding NHMRC's ability to approach the subject with the required objectivity. The controversy created a window for NHMRC to acknowledge that it possessed an organisational bias towards homœopathy and to step away from the process.

Instead, NHMRC proceeded with instigating a formal evidence review, to substantiate a formal NHMRC position on homœopathy. In light of the preceding events, it was incumbent on NHMRC to demonstrate a high degree of objectivity and transparency in approaching this task, to dispel perceptions of questionable ethics and bias its conduct to date had created.

How did NHMRC approach the task?

### **NHMRC invites 'special interest groups' to submit evidence**

On 25 May 2011, NHMRC invited AHA to submit by 1 July 2011 (a 5-week deadline), any evidence it would like NHMRC to consider in the development of a formal position statement<sup>25</sup>. NHMRC also invited the Australian Medical Fellowship of Homeopathy (AMFH) to submit evidence, following a letter of complaint from the AMFH to NHMRC, which noted<sup>26</sup>:

*"I discussed the matter with a member of your staff, who said you had no intention of discussing it with representatives or experts in the homeopathic profession."*

On 1 July 2011, AHA and AMFH provided NHMRC with submissions detailing research evidence on the effectiveness of homœopathy, for NHMRC's consideration in the preparation of a position paper on homœopathy<sup>27</sup>.

Of 343 articles provided in these submissions, 334 (over 97%) were subsequently dismissed as out of scope, on the basis of extensive exclusion criteria that were retrospectively applied, without consultation with homœopathy topic experts. The findings of the nine remaining studies were later excluded from the findings published in the final report (see Part 2).

### Establishment of a homœopathy reference group, mid-2011

Around this time, NHMRC decided to form a 'homeopathy reference group' to oversee a formal evidence review. The reference group, which consisted of four members, later became the Homeopathy Working Committee (HWC) from 2 April 2012 upon the official commencement of the Review.

One of the major criticisms regarding NHMRC's draft Position Statement process was the lack of consultation with homœopathy subject and/or research experts. Accordingly, ensuring that the homœopathy reference group was balanced by the inclusion of suitably qualified homœopathy discipline/research experts (a cornerstone of ethical scientific review) would have corrected the imbalance. This was also pertinent in light of NHMRC having had no previous experience or expertise in homœopathy, even lacking a definition of homœopathy.

On 18 August 2011, the AHA wrote to the NHMRC nominating suitably qualified homœopathic experts as candidates for inclusion on the NHMRC reference group<sup>28</sup>. NHMRC did not respond and after several attempts by the AHA to engage the NHMRC on the issue, on 7 October the NHMRC belatedly replied:

*"The Chief Executive Officer of NHMRC, Professor Warwick Anderson, has indicated his preference for this reference group and he has selected another nomination who represents the complimentary [sic] and alternative medicines field."*

The CEO personally selected and appointed members of the reference group under section 39 of the *NHMRC Act 1992*, none of whom had any homœopathy subject and/or research expertise. The exclusion of topic experts was unprecedented in NHMRC review and guideline development processes, contravening accepted scientific research protocols as well as NHMRC guidelines on the composition of NHMRC committees and working groups (see below).

On 16 October 2011, the AHA wrote to the NHMRC protesting the exclusion of homœopathic experts, also querying the subject-specific credentials of the NHMRC's nominated 'CM expert'<sup>29</sup>:

*"We would appreciate background on the complementary and alternative medicines nominee as we are concerned that this field covers a wide range of modalities and it could not possibly be considered an "expert committee" without at least one expert in the field being present.*

*I would also like to suggest that having an expert who is qualified in homœopathy on the committee would save a lot of valuable time. Questions would be answered promptly and access to information would be more readily available and accurate.*

*Can you please provide appropriate detail on the background and qualifications of this nominee so that the AHA can*

*reassure its membership that the enquiry will be fair and scientifically objective."*

The NHMRC never responded to the AHA's correspondence on this issue from this point on, despite the AHA being the key expert 'NHMRC stakeholder' group. Although the NHMRC claimed that its evidence review process was 'separate and unrelated' to the previous one, it continued to exclude experts from the primary stakeholder sector.

### NHMRC Chair discloses a culture of ongoing anti-homœopathy bias

During this period, on 22 July 2011, the NHMRC Chairman, Professor Michael Good, disclosed the ongoing culture of organisational bias towards homœopathy when he publicly declared<sup>30</sup>:

*"Let me assure you that I am no supporter of homeopathy. As Chairman of NHMRC I can also assure you that NHMRC does not support homeopathy."*

This came at a time when NHMRC had purportedly abandoned its draft position statement in favour of initiating a more formal and impartial evidence review. This reinforced stakeholders' concerns that the subject of homœopathy was not in the hands of an objective entity.

### NHMRC expert committees

NHMRC quality assurance processes require that NHMRC expert committees contain experts relevant to the topic under inquiry, in line with accepted scientific standards. The inclusion of subject and research experts relevant to the topic under review on expert scientific review committees is also a foundational requirement of ethical scientific inquiry.

The NHMRC itself has stipulated that its expert committees are required to be comprised of members with both<sup>31</sup>:

- A "high level" of expertise relevant to the matter under investigation (subject expertise);
- Technical and scientific (methodological expertise).

According to the NHMRC, appointments of members to its expert committees for the purpose of developing health advice (which was the stated purpose of the Review<sup>32</sup>) is informed by the following instruments<sup>33</sup>:

1. Procedures and requirements to meet the 2011 NHMRC standard for clinical practice guidelines (the '2011 NHMRC Standard')
  - Requirement A.3 of the 2011 NHMRC Standard stipulates as a mandatory requirement that working committees must include "relevant disciplines and clinical experts";
2. NHMRC Guideline Development and Conflicts of Interest policy ('NHMRC COI policy'):
  - 1.2.1 - Guideline development, the provision of advice and peer review all require persons with expertise relevant to the topic under review;
  - 1.2.2 - Guidelines, advice and peer review would be of lesser quality without relevant experts.

By not appointing any homœopathic subject or research experts to the HWC, the NHMRC not only disregarded accepted

scientific protocols, but also breached the requirements of its own quality assurance policy. Why would the NHMRC disregard its own policy in this instance?

HWC meeting minutes obtained under Freedom of Information (FOI) confirm that the NHMRC appeared to regard the inclusion of homœopathy experts as representing “an unmanageable conflict of interest”<sup>34</sup>: a double standard not applied when members are appointed to any other NHMRC expert committees. NHMRC guidelines acknowledge that expert committees, by their very nature, “all require persons with expertise relevant to the topic under review”.

The NHMRC *Administrative Report* records, “One member of the HWC recorded a dissenting view regarding the absence of a homeopath on the committee”, which was “not supported by either NHMRC or the remaining committee membership”<sup>35</sup>. In 2014, one of NHMRC’s own independent expert reviewers also critiqued the omission of subject experts on the HWC<sup>36</sup>:

*“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.”*

The NHMRC did not disclose the second sentence of the reviewer’s feedback in its *Expert reviewer comments* document. In fact, around 80% (by word count) of the expert reviewer’s feedback was redacted, withholding from public view many other problems the expert reviewer identified with the Review methodology. By censoring these comments, the NHMRC withheld public-interest information and shielded itself from controversy. On what basis did the NHMRC selectively withhold public-interest information from inclusion in its dedicated *Expert reviewer comments* document?

The NHMRC claimed that methodological expertise was ‘all that was required’ on the HWC and promoted Professor Peter Brooks, a rheumatologist, as the committee’s ‘CM expert’<sup>37</sup>. Professor Brooks’ main research interest related to the treatment and epidemiology of rheumatic diseases, yet the NHMRC promoted him as a ‘CM expert’ as he was previously involved in establishing the Australian Centre for Complementary Medicine Education and Research at the University of Queensland, in association with Southern Cross University<sup>38</sup>. He had no discipline, clinical or research expertise in homœopathy.

Controversy relating to the appointment deepened when in early 2012, Professor Brooks joined the anti-CM political lobby group Friends of Science in Medicine (FSM), months after NHMRC had established the homœopathy reference group and well before the evidence review formally commenced.

Did Professor Brooks declare his conflict and how did the NHMRC manage and communicate it to the public?

## **NHMRC Homœopathy Review and conflicts of interest**

### ***Background – formation of FSM and the HWC:***

FSM was formed on 20 December 2011, with an agenda to oppose the teaching of alternative and complementary medicine in Australian universities and their practise in the community. From the outset, FSM’s extreme anti-CM agenda was widely reported in the media<sup>39</sup>. Since its inception, FSM has had an especially marked anti-homœopathy focus.

One of FSM’s first actions in building its support base included writing to all NHMRC reviewers, urging them to join FSM and use their positions of influence to further FSM’s anti-CM agenda<sup>40</sup>. FSM’s email to NHMRC reviewers placed homœopathy at the head of its list of ‘pseudosciences’.

On 22 January 2012, FSM published its list of Supporters. It included multiple members with NHMRC affiliations, including Professor Brooks<sup>41</sup>. This was months before the NHMRC CEO appointed members to the HWC. Was the CEO aware of FSM’s action of lobbying his agency’s reviewers before formalising membership of the HWC?

On 27 February 2012, the CEO was personally warned by letter of FSM’s attempt to lobby NHMRC reviewers<sup>42</sup>. The letter also attached a copy of the email from FSM’s co-founder Professor John Dwyer to the NHMRC reviewers. The letter to the CEO concluded:

*“The use of a published list of NH&MRC reviewers and the direct call to these reviewers to adopt a political position about complementary medicine, ushers in a dark day for Australian science. I believe that it is important for the NH&MRC to distance itself from these actions and to maintain the highest standards of objectivity by its reviewers.”*

NHMRC conflicts of interest policy:

During this period, on 2 March 2012, the CEO approved via the NHMRC Council updated the NHMRC *conflicts of interest* policy<sup>43</sup>, which included a provision (section 1.5.1(d)) requiring that the CEO:

*‘ensure the committee or working group is chaired by someone who has no conflicts of interest that could, or could be perceived to, erode the integrity of a group decision.’*

Regardless, the CEO proceeded with appointing Professor Brooks to the HWC and also as its Chair. This was despite Professor Brooks’ FSM membership having been in the public domain since 22 January 2012 and the CEO having been notified of FSM’s attempt to influence NHMRC reviewers.

The NHMRC *Administrative Report* (p.5) states, “A record of interests was managed by the Office of NHMRC and updates were made to the NHMRC website as required”. The website was never updated to disclose that it had appointed Professor Brooks, a FSM Supporter, as the first Chair of the HWC - only that he was a FSM Supporter until 16 April 2012. Why would NHMRC have withheld communicating such significant information to the public?

Before being appointed to a NHMRC expert committee, NHMRC conflicts of interest policy requires that prospective members declare any actual or perceived conflicts by completing and signing a Declaration of Interest (DOI) form; also stipulated in section 42A(3)(b) of the *NHMRC Act 1992* as:

*‘Before starting to hold office a member of a committee must give to the CEO a written statement of any interest the member has that may relate to any activity of the Council or committee.’*

On 16 March 2012, in accepting his position on the HWC, Professor Brooks signed a DOI form declaring that he was not<sup>44</sup>:

*"affiliated or associated with any organisation whose interests are either aligned with or opposed to homeopathy".*

### **NHMRC 'Complementary Medicine' webpage:**

The 16 March 2012 update to the NHMRC 'Complementary Medicine' webpage (live on 10 April 2012) presented the official announcement of the commencement of the Homeopathy Review under the heading, 'Evaluation of effectiveness'. Directly under this heading, NHMRC also published an excerpt of a transcript from an interview with the CEO, published in *Asian Scientist*<sup>45</sup>, specifically drawing attention to the anti-CM platform of FSM<sup>46</sup>:

#### ***Asian Scientist Chats With Prof. Warwick Anderson, CEO of Australia's NHMRC, 5 March 2012***

*A coalition that includes Australian professors called the Friends of Science in Medicine is advocating that complementary and alternative medicine (CAM) course be removed as vocational degrees in universities across Australia. What is your opinion on this controversy?*

... "We are not a high-education body, that is the university sector, but we do think that there is a particular responsibility for all health professionals to be honest and clear about this."

Was it ethical for NHMRC to have given a public platform to an extreme anti-homeopathy lobby group on their official website, let alone juxtapose this article right next to its announcement of the Review, noting that it was not balanced by any other opinion pieces, just FSM's? FSM's anti-CM views were entirely unrelated to the NHMRC's Homeopathy Review, yet their inclusion on the webpage presented the public perception of an alignment of views between the NHMRC and FSM. The excerpt was removed from the webpage by its next iteration on 1 September 2012.

Despite the NHMRC claiming that the Review was 'separate and unrelated to the previous process'<sup>47</sup>, the NHMRC 'Complementary Medicine' webpage reiterated the same themes and language in the leaked NHMRC draft Statement, that homeopathy is: 'implausible', 'placebo', 'inefficacious/not evidence-based' and that people may be 'misled' (cf. 'deceptive'). The NHMRC broadcast this pre-emptive message on its webpage prior to any evidence assessment commencing and retained it on the webpage until publishing its findings in March 2015 (after which the webpage was updated to include more neutral language).

The NHMRC 'Homeopathy Working Committee' webpage from 1 September 2012 only disclosed that Professor Brooks had been a Supporter of FSM until 16 April 2012; it did not disclose at any stage during the course of the Review that he was also the HWC's initial Chair. This was only disclosed after the final report was published in March 2015<sup>48</sup>. By selectively withholding such information during the Review, NHMRC shielded itself from the risk of controversy relating to the Review's procedural integrity.

In 2015, stakeholders wrote to the NHMRC requesting details regarding the FSM conflict, to which NHMRC provided the following responses:

*"Professor Peter Brooks was initially appointed as Chair of the HWC, however once NHMRC became aware of his affiliation with Friends of Science in Medicine (FoSiM), a management plan was implemented to manage any perceived conflict of interest. This included Professor Brooks resigning as Chair of the HWC. I would point out that Professor Brooks also resigned from FoSiM at that time."*<sup>49</sup>

*"an updated DoI which identified Professor Brook's association with this group was received in late March 2012, and a management plan subsequently initiated."*<sup>50</sup>

These imply that once Professor Brooks' conflict became known, a series of concurrent events took place, i.e.: NHMRC stepped him down as Chair, he resigned from FSM and NHMRC implemented a formal management plan to manage the conflict. This sounds entirely reasonable, until one learns that NHMRC did not disclose what really occurred (outlined below). The term 'perceived' also points to NHMRC's view that the Chair's FSM membership was not an 'actual' conflict.

### **NHMRC's management of the conflict and non-disclosure of information:**

Did the NHMRC uphold its ethical and statutory obligations to manage Professor Brooks' conflict in line with the requirements of its conflicts of interest policy and legislation? The answer to this question should be considered within the context of the following undisclosed facts:

On 27 March 2012, Professor Brooks updated his DOI form to declare his FSM conflict. Despite this, NHMRC took no action to manage the conflict. He remained as Chair of the HWC and chaired the inaugural meeting of the HWC on 12 April 2012 as an active FSM Supporter.

NHMRC legislation relating to disclosures of interest mandates that the following occur:

*'A member's disclosure at a Council or committee meeting must be recorded in the minutes of the meeting' (NHMRC Act 1992, section 42A(7));*

*'A member's disclosure, given otherwise than at a Council or committee meeting, must be recorded in the minutes of the first Council or committee meeting after the disclosure' (NHMRC Act 1992, section 42A(8)).*

In late 2014, the minutes of the first meeting of the HWC on 12 April 2012 were requested under FOI. The document that NHMRC released in October 2014 was extensively redacted, concealing the fact that Professor Brooks did not declare his conflict at the meeting and that the conflict was not recorded in the meeting minutes<sup>51</sup>, in breach of the *NHMRC Act*.

It also concealed that the minutes referenced the 2011 *NHMRC Standard* guidance document against the Review, which mandates that NHMRC expert committees contain subject experts (as outlined above). In discussion with stakeholders prior to the full release of this FOI document, NHMRC had stated that the *Standard* was not applicable to the Review. In fact, the 2011 *NHMRC Standard* applies to all NHMRC review and guideline development processes, as it defines the key administrative requirements of NHMRC's 'quality assurance' process (confirmed during a phone conversation with a NHMRC Director involved in the Review).

The unredacted minutes also reveal that a senior NHMRC Executive “reminded the Committee to be vigilant in any correspondence entered into pertaining to the homeopathy [sic] as it may be the subject of FOI request in the future”; suggestive of a culture where the expert stakeholder sector was regarded as an ‘out group’ (rather than a collaborative partner in line with the APS Values and NHMRC Service Charter); of a process where transparency was of potential concern.

The redacted minutes also concealed that NHMRC had started the Review process under a first contractor, a controversial fact that NHMRC never publically revealed (see below).

At this time in 2014, the Review was in its final stages of completion and had yet to undergo final Council approval or Ministerial consideration. Although finalisation of the Homeopathy Review was undergoing a deliberative process, the April 2012 HWC meeting minutes had no bearing or relevance to that deliberative process. The release of such public interest information would have generated controversy, jeopardising NHMRC’s agenda of finalising and publishing the report.

The redaction of such relevant information in the document highlights NHMRC’s sensitivity to this risk; NHMRC therefore appears to have withheld from the public for improper purpose under the *Freedom of Information Act 1982*. The minutes of the first HWC meeting were not released in full until July 2016<sup>52</sup> – when it no longer mattered.

Also at this time in 2014, the NHMRC CEO delivered a public oration<sup>53</sup> in which he used derogatory, rhetorical language implying homoeopathy/CM was, “useless”; not “ethical”; “implausible on the basis of known science”; “placebo”; expressing personal opinions such as, “annoys me that private health insurers offer rebates for unproven treatments”; would “save heaps” if CM was removed “from public or private reimbursement”. He also pre-empted the findings of the Review, prior to its completion and sign-off, in stating:

*“We will soon, before the end of the year, release our public statement on homeopathy. Already some pharmacists are urging their profession to stop stocking these remedies and others that don’t have an evidence base. Pharmacy, after all, is a profession based on and trained in science. So it comes as a shock to walk into some pharmacies to see them urging products on customers where there is no evidence base of effectiveness.”*

The use of such emotive, adversarial language in a public engagement in his role as CEO was not consistent with ethical standards of APS conduct<sup>54</sup>. Section 4.5 (‘Disclosure in the course of duties - Making public comment in an official capacity’) of the APSC guidance document ‘APS Values and Code of Conduct in practice’ stipulates:

*“Some APS employees, as part of their official duties, speak to, or write to, the media and others in the community. ... In doing so, employees should avoid partisan comment and ensure that their approach to speaking publicly about policies supports public confidence in the capacity of the APS to be impartial.”*

Section 6.2 (‘Making public comment, including online - Senior Executive Service’) stipulates:

*“Senior APS employees should consider the impact of any comments they might make particularly carefully. Senior Executive Service (SES) employees have a particular responsibility under section 35 of the Public Service Act to promote the APS Values, the Employment Principles and compliance with the Code, by personal example and other appropriate means.”*

SES employees within each agency are also part of a collective leadership group that extends across the APS. Because of the influence that they carry with stakeholders, and because they are likely to be required to advise on, or lead, the implementation of government policies and programs, SES employees should be particularly careful when making public comment. The role of SES employees provides more scope for conflict, real or apparent, between a personal view and the ability to fulfil current and potential duties in an apolitical, impartial and professional manner.”

Irrespective, in April 2015 the CEO again used highly rhetorical and derogatory language, reiterating biased views he had previously publically expressed between 2010 and 2014<sup>55</sup>:

*“I guess it’s one thing when people sell magic therapies to the worried well - that’s mostly just a waste of money or expensive urine. Perhaps a little placebo effect, as well. But it’s an entirely different matter when people who are ill with a treatable illness are pushed therapies that don’t work and, in fact, are often implausible, pushed by practitioners who we must assume either believe in magic or perhaps are just dishonest. Ill health has attracted charlatans since time immemorial. Snake oil merchants wanting to take your money by promising false hope. ... It’s distressing when unscrupulous people exploit the sick for their own personal gain, selling products that have no hope at all of helping the patient.”*

#### **Further non-disclosure of information:**

Despite resigning from FSM on 16 April 2012, Professor Brooks remained as Chair of the HWC until mid-May 2012, without any management of his conflict. This was not publically disclosed.

Furthermore, it appears the trigger for alerting NHMRC to the conflict came via external channels regarding the unconscionable conflict of having a FSM Supporter on the HWC. This brings into question how seriously the NHMRC regarded the conflict and whether it would have taken any action without such external pressure.

On 10 May 2012, the Office of NHMRC (ONHMRC) notified the CEO of the conflict, who then contacted Professor Brooks and asked him to step down as Chair, but not from the HWC. FOI returns confirm that Professor Brooks neither mentioned nor acknowledged his FSM conflict in his formal email to the CEO resigning as Chair of the HWC, stating as his official reason:

*“Dear Warwick - re the NHMRC Homeopathy review - because of other commitments I would like to resign as Chair but am happy to remain on the Committee. I hope this is acceptable.”*

In light of the circumstances, it appears Professor Brooks declared his conflict and resigned from FSM to avoid an on paper conflict. That such an *in vivo* conflict continued to

prevail appears likely. If the CEO deemed he was not fit to remain as Chair of the HWC due to his conflict, it is unclear on what basis he was then allowed to continue as a member of the committee.

On 15 May 2012, NHMRC expanded the membership of the HWC to include a consumer representative (Mr John Stubbs), the Chief Medical Officer (Professor Chris Baggoley) and a CM expert (Dr Evelin Tiralongo), none of whom had any homœopathic clinical or research experience or expertise. Thus, despite the expansion, the HWC continued to exclude any homœopathy subject and/or research experts. Professor Paul Glasziou replaced Professor Brooks as the new HWC Chair.

Despite the seriousness of the conflict, the CEO allowed Professor Brooks to remain as a member of the HWC without implementing a formal management plan. The NHMRC *Administrative Report* (p.5) confirmed:

*'No formal management plan implemented'.*

### **NHMRC's 'management plan':**

In 2015, stakeholders requested a copy of the 'management plan' NHMRC referred to in correspondence (above). In response, a brief email was provided between NHMRC and the new HWC Chair, Professor Paul Glasziou, dated 15 May 2012, which referred to the DOIs of Professor Brooks and Dr Tiralongo<sup>56</sup>. The email opened with the statement:

*"The DOIs seem to balance each other, so at least we don't have a stacked committee."*

Dr Tiralongo's DOI related to her expertise in CM education. It did not constitute a perceived or actual conflict, since she had no expertise in homœopathy and/or homœopathic research, nor any ideological, political or financial interests relating to homœopathy. By contrast, Professor Brooks was associated with a medico-political lobby group with an explicit agenda to eradicate homœopathy from Australian healthcare. This represented a conflict of an incomparable nature.

Professor Glasziou's statement that the DOIs 'balance each other', alongside the offhand remark that the committee therefore was not "stacked", not only demonstrated a lack of regard for the seriousness of the conflict, but also that prior to the appointment of Dr Tiralongo the committee possibly contained an anti-homœopathy bias.

Why did the NHMRC not formally manage such a significant conflict of interest and also allow the conflicted member to continue on the HWC, to the ongoing exclusion of any clinical and/or topic research experts?

### **NHMRC, conflicts of interest and FSM**

FSM's early membership drive not only recruited a member of the HWC: it also attracted a number of members of NHMRC's Principal Committees, as well as members of NHMRC Council itself.

One of NHMRC's five Principal Committees is the NHMRC Health Care Committee (HCC), under the auspices of which the 2012-2015 Homeopathy Review was conducted and the HWC reported to<sup>57</sup>. Both the HCC and NHMRC Council played

primary roles in overseeing the work of the HWC, including approving publication of the Review's findings.

The HCC was involved from the start of NHMRC's focus on homœopathy in October 2010, by advising the NHMRC Council to support the development of a position statement on homœopathy, on the sole basis of the UK House of Commons STC Report. The explicit anti-homœopathy bias associated with this process has been outlined above.

Thus between 2010 and 2015, the NHMRC Council, the HCC and the HWC collectively contained several FSM supporters, representing significant anti-homœopathy conflicts of interest at the highest levels of the NHMRC. In spite of statutory APS and NHMRC conflicts of interest policies, no conflicts were declared or reported by the NHMRC at any stage relating to HCC and/or Council deliberations pertaining to the Homeopathy Review. This is despite the *NHMRC Act 1992*, section 42A stipulating:

- (4) *A member of the Council or of a committee who has an interest in a matter being considered, or about to be considered, by the Council or committee must, as soon as possible after the relevant facts have come to his or her knowledge, disclose the nature of the interest*
- (5) *A member who has disclosed an interest in a matter under subsection (3) or (4) must not:*
  - (a) *be present when the Council or committee considers the matter; or*
  - (b) *take part in any decision of the Council or committee in relation to the matter.*
- (7) *A member's disclosure at a Council or committee meeting must be recorded in the minutes of the meeting.*

No declarations of interest are recorded in NHMRC Council Session minutes and HCC meeting minutes are not published. The NHMRC *Administrative Report* does not record any conflicts of interest declarations pertaining to HCC/ NHMRC Council oversight of the Review and Professor Brooks' FSM conflict was not formally managed and details not fully disclosed.

Part 2 details further FSM-affiliated conflicts of interest associated with the Review, which were also not disclosed or managed.

### **The first, undisclosed NHMRC homœopathy review**

Another significant fact that the NHMRC did not publically disclose was that the above-mentioned events occurred during a review of the evidence on homœopathy that was conducted between April and August 2012 under a first contractor.

The NHMRC prematurely terminated the first reviewer's contract in early August 2012, within days of the reviewer submitting the final Draft Report. The NHMRC has obfuscated the existence of this review and why it was terminated, also concealing its findings and methodology. The NHMRC Council, the HCC and HWC, which contained undeclared FSM and senior NHMRC officials who had publically expressed anti-homœopathy views (including the CEO and Chair of Council), had oversight over this process.



Viewed in the context of the aforementioned events, Professor Brooks chaired the HWC for 40% of the first contractor's review before standing down as Chair. Further details pertaining to the evidence review conducted under the first contractor is described in Part 2.

## Discussion

Australian Public Service agencies and employees are bound by legislated principles of conduct designed to protect the community from unethical conduct in public administration, thereby upholding the community's confidence in the ability of the APS to be impartial. The APS Values require that administrators perform their duties ethically, impartially, collaboratively, respectfully and accountably.

The events chronicled in this paper predominantly focus on the NHMRC's administrative conduct between 2010 and 2012, leading up to the commencement of the Optum Review. Did NHMRC's actions uphold the APS Values and Code of Conduct, providing the public and stakeholders' confidence that it approached the task in a fair and objective manner? The answer to this question is self-evident in the chronicled timeline of events.

Anti-homoeopathy comments expressed by senior NHMRC officials (including the CEO and Chair of Council) in the public domain between 2010 and 2015, before any evidence was reviewed and/or findings published, openly conveyed an organisational culture of ideological bias towards homoeopathy. Non-neutral language published on the NHMRC website throughout the process, which reiterated the same message of the abandoned 2011 draft NHMRC Statement on homoeopathy, continued to broadcast a predisposed negative stance towards the topic.

In relation to the conduct of senior APS officials and agency heads, the APSC guidance document 'In whose interests?: Preventing and managing conflicts of interest in the APS - Taking an ethical lead in the APS is everyone's business - Agency heads and SES employees', states:

*"Managers, and in particular senior managers, constitute the most influential community of practice in the public service. Their role impacts on every other community and every organisation. Their behaviour sets the values. Their ideas, words and actions in large measure shape the culture of the public service. (the Hon Jocelyne Bourgon PC OC, President Emeritus at the Canada School of Public Service, 19 June 2008)*

*In addition to the general requirement to comply with the APS Values and Code of Conduct, the Public Service Act 1999 places specific responsibilities on agency heads and SES employees to uphold and promote the Values and Code (sections 12 and 35). This obligation reflects the importance that senior managers have as role models in their agencies who set the tone for 'how things are done around here.'"*

In October 2010, the NHMRC CEO set the tone for 'how things were done' in his agency by directing NHMRC Council, on the advice of the HCC, to develop a formal Position Statement on homoeopathy, the content of which was approved by the NHMRC Council in December 2010. This occurred in the absence of any expert consultation or independent

evidence assessment. At the same time, the CEO submitted for publication an article in the *MJA* articulating his anti-homoeopathy stance, which he reiterated and strengthened throughout the Review process.

In its own right, the significance of bias expressed by the CEO of a government agency towards a topic under his agency's purview cannot be understated. This is further amplified by the central role the CEO played in the process: he was its prime instigator, personally selected and appointed members of the HWC under the *NHMRC Act* to the exclusion of topic experts (ignoring expert stakeholder protests) and officially signed off the Review for publication in 2015.

The CEO's refusal to appoint any homoeopathy subject and/or research experts to the HWC demonstrated lack of regard for a fundamental requirement of ethical scientific review. It was especially anomalous given that analogous lack of expert consultation was a core criticism of the previous 2010/11 draft Position Statement process, which was abandoned under controversial circumstances.

Such an exclusion was unprecedented in NHMRC review processes and contravened NHMRC's own quality assurance standards relating to the composition of its expert committees. It also represented a breach of the core APS Values 'committed to service (works collaboratively)' and 'impartial' - since the involvement of experts relevant to the topic under investigation is a core requirement of ethical scientific inquiry, safeguarding such processes from bias and upholding their intellectual rigour. This is why NHMRC conflicts of interest policy acknowledges: "*Guideline development, the provision of advice and peer review all require persons with expertise relevant to the topic under review.*" The exclusion was further criticised in expert peer review feedback, which NHMRC attenuated for the purpose of public disclosure, thereby shielding itself from undue controversy that may have risked derailing its agenda.

If the agency's most senior official openly expressed such strong antipathy towards a topic he had such close personal involvement in, this then influences the whole organisation, from the top down. At the very least, it influences the upper echelon close to the CEO, who it seems also shared his views. In correspondence to stakeholders in 2015, the NHMRC denied that the views of one individual could have influenced its assessment of homoeopathy due to broader oversight of the process, stating<sup>58</sup>:

*"The CEO approval/ release of documents is based on the recommendation of Council. Council's recommendation is based on the relevant Principal Committee (in this instance, the then Health Care Committee), and s39 committee (Homeopathy Working Committee (HWC))."*

This overlooks the fact that anti-homoeopathy conflicts were not limited to the administrative actions and public comments of the CEO. NHMRC Council, the HCC and the HWC all contained supporters of the anti-homoeopathy lobby group FSM, without any declarations of interest made in relation to their deliberations on homoeopathy at any stage during the Review. This was in open breach of conflicts of interest provisions in the *NHMRC Act 1992* pertaining to the operation of these committees.

It demonstrated that the NHMRC did not regard such conflicts to be of sufficient import to declare or manage, which was reflected in the casual manner it handled Professor Brooks' conflict in 2012, even allowing him to remain on the HWC. Other undeclared conflicts of interest associated with the 2012-2015 Optum Review will be outlined in Part 2.

The APSC website, under 'Preventing and managing conflicts of interest in the APS' notes:

*"Public confidence in the integrity of the APS is vital to the proper operation of government. That confidence may be jeopardised if the community perceives that public servants are working to serve other agendas. APS employees need to be aware that their private interests, both financial and personal, could conflict with their official duties, and need to know what to do when a conflict arises."*

According to training modules provided to new APS employees, administrative bias is regarded as fraud and is classed as a criminal offence. Fraud is defined as 'dishonestly obtaining a benefit, or causing a loss by deception or other means' and includes a breach of the APS Code of Conduct. Likewise, corruption can be defined as, 'the dishonest or biased exercise of a public official's duties', irrespective of whether this bias is actual or perceived. Different legislative instruments may be implicated, such as the *Public Interest Disclosure Act 2013*, the *Crimes Act 1914*, *Criminal Code Act 1995* and the *Public Service Act 1999*.

This article has examined ethical issues pertaining to the NHMRC's focus on homœopathy, mainly between 2010 and 2012. Part 2 will explore how ongoing bias and conflicts of interest impacted the NHMRC's administrative decision-making processes and the methodology adopted for the evidence Review conducted between 2012 and 2015.

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