Submission to the Therapeutic Goods Administration (TGA)

Consultation: Reforms to the regulatory framework for complementary medicines: Assessment pathways.

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27 March 2017

Consultation: Reforms to the regulatory framework for complementary medicines: Assessment pathways.

The TGA's role is to safeguard and enhance the health of the Australian community through effective regulation of therapeutic goods, including complementary medicines (CMs). The Australian Register of Homeopaths (AROH) is the chief registration body for homeopathy in Australia; its role is to protect the public by ensuring practitioners obtain and maintain an accredited standard of practice. The Australian Homoeopathic Association (AHA) is the chief practitioner organisation representing professional homeopaths in Australia.

As protectors of the public's interest with regard to homeopathic practice and subsequently homeopathic preparations and practitioners in the performance of that practice, AROH and the AHA are making a joint submission to the TGA on this reform consultation.

AROH/AHA notes that homeopathic products are to be assessed as part of a separate consultation process alongside other CMs such as low dose vitamins and minerals (Consultation document, pp.5-6).

We wish to express concern that no background or justification is provided in the Consultation document as to why homeopathic preparations have been singled out as a special category of CM products. Homeopathic preparations are currently appropriately classified as complementary medicines under the definition provided in Part 1(2)/ Schedule 14 to the *Therapeutic Goods Regulations 1990*, meeting all the criteria of the specified definition.

AROH/AHA informs TGA that it considers homeopathic products should remain under the coverage of therapeutic goods legislation. Recent concerns over alleged[1] adverse reaction events to Hylands Teething products in the US highlights the need to maintain Good Manufacturing (GMP) standards in Australia for such preparations, in the interests of protecting public safety (TGA's primary function).

Recommendation 48 of the Review of Medicines and Medical Devices Regulation (MMDR) informs:

> *"the review will involve consultation with consumers, industry, health professionals and other Commonwealth regulatory bodies."*

To our knowledge, the TGA has not invited homeopathic industry or health professionals to partake in the review of this recommendation and request that <u>all</u> parts of the homeopathy sector be involved in the discussion of changes to regulation concerning homeopathic preparations. **AROH/AHA hereby officially requests that TGA directly consult with the sector in regard to any regulatory reform agenda involving homeopathy**. The TGA has not consulted with the homeopathy health professional sector since 2010.

[1] Based on media reports, not confirmed by the US Federal Drug Administration. As TGA would be aware, adverse drug reaction (ADR) reports are often multi-factorial, with causality difficult to establish or due to other factors.

The exclusion of homeopathic preparations from this consultation is implying that there will be a different, limited or no assessment pathways applicable to homeopathic preparations. Currently there is positive research to show the proven safety record of homeopathic preparations and that they should continue to be included in the assessment pathways governed by the TGA.

AROH/AHA response to Reforms to the regulatory framework for complementary medicines consultation

Proposal One: A risk based approach for therapeutic indications:

Providing homeopathic preparations are included within these assessment pathways, we agree with the intent of the new pathway proposed.

Proposal Two: Products excluded from the new pathway:

We consider it is reasonable that products to be processed through the proposed new pathway should be supported by the provision of scientific evidence (e.g. efficacy trials), to accompany evidence of traditional use.

Proposal Three: Approaches to establishing efficacy:

AROH/AHA supports the proposed approaches to establishing efficacy for products to be eligible to be included on the ARTG via the new pathway, but noting the following:

It is unclear what criteria will be used to assess efficacy data, which are not specified in the Consultation document. To ensure fairness to all applicants, guidelines for the study quality must be published and applied to all applications equally.

Furthermore, due to homeopathic products being excluded from this Consultation, it is implied that they will not be eligible for consideration in the proposed assessment pathways.

Good quality efficacy (randomised controlled trial) data exists for homeopathic finished products in several medical conditions (e.g. hay fever, upper respiratory tract infections, sinusitis, cough etc), which would be eligible for assessment via the proposed new pathway. To date, around 50% of RCTs assessing homeopathic interventions have been statistically positive. Of 104 placebo-controlled RCTs published in peer-reviewed journals by the end of 2014, 41% were positive, 54% inconclusive and only 5% negative - a strikingly similar proportion as observed in published conventional medical research. Each year, increasingly good quality, positive research is being published on homeopathic healthcare interventions.

AROH/AHA expresses its concern that TGA has been misinformed about research evidence base of homeopathy by the findings of the National health and Medical Research Council (NHMRC) review of the evidence on homeopathy, which erroneously concluded there is 'no reliable evidence' that homeopathy is effective in treating health conditions.

NHMRC Homeopathy Review - For TGA's information:

TGA may be aware that a multi-stakeholder complaint revealing misfeasance in NHMRC's procedures and methods has been referred to the Commonwealth Ombudsman for review. The AHA is a co-complainant, alongside Complementary Medicines Australia (CMA) and the Australian Traditional Medicines Association (ATMS), collectively representing over ten thousand practitioners and the millions of Australians that utilise CM products and services. AROH/AHA highlight the following critical flaws associated with NHMRC's methods and procedures, including:

- The sacking of a first reviewer in 2012 that reported positive research evidence on homeopathy,

concealing its existence, findings and tax-payer funds expended on the process

- For the second (Optum) review, retrospectively creating and applying arbitrary criteria that have never been used before or since, which directly resulted in 171 out of the 176 included studies (97%) from being dismissed (outright) from any consideration in the review's findings
- All the criteria underpinning NHMRC's published findings and 'evidence statement framework' were developed entirely post-hoc, after Optum had completed its assessment
- None of these key post-hoc changes to the research protocol were disclosed or justified
- Not disclosing that the review's findings and key criteria did not pass expert peer review. For example, the Australasian Cochrane Centre advise NHMRC: "*when a substantial proportion of small (but good quality) studies show significant differences … 'no reliable evidence' does not accurately reflect the research"* (from FOI returns)
- Employing multiple undisclosed, unmanaged conflicts of interest (e.g. Friends of Science in Medicine) in the review process, in breach of APS conflicts of interest policies
- Excluding any homeopathy subject or research expertise, breaching accepted research protocols and mandatory NHMRC standards (e.g. the *2011 NHMRC Standard*, Requirement A.3)
- Exclusion of all observational studies (e.g. cohort, case control, clinic outpatient studies), which consistently demonstrate the real-world 'effectiveness' of homeopathic interventions.

The NHMRC Review involved the undue influence of several anti-homeopathy conflicts of interest, which were not disclosed or managed; the report did little to accurately inform the public and decision-makers on the evidence on homeopathy. Instead, it has fed misperceptions and led to the vilification of a healthcare sector used by hundreds of thousands of Australians.

Such conduct towards any other subject would never have been accepted or tolerated - and rightly so. NHMRC's conduct in executing the Review raises serious ethical issues relating to administrative and research integrity, which the Commonwealth Ombudsman has been asked to review.

AROH/AHA advises TGA that it considers it entirely inappropriate that such a patently flawed report be used to inform any regulatory reform agenda concerning homeopathic products. The NHMRC review appears to have unacceptably influenced the current TGA reform agenda, which is a matter of considerable concern to the homeopathy and broader CM sector, which stands united on this issue.

Homeopathy and homeopathic products are core elements of CM practice and use in Australia and should be retained under the auspices of therapeutic goods legislation. **Skeptic-aligned bias around homeopathy's poorly understood mechanism of action has no place in regulatory decision-making processes** - particularly when the balance of evidence from clinical and laboratory research is increasingly demonstrating the biological efficacy and effectiveness of homeopathy and homeopathic preparations (which the NHMRC review also failed to differentiate between).

Proposal Four: Evidence requirements

AROH/AHA supports maintaining the existing evidence requirements for listed and registered complementary medicines to establish efficacy for low and high level indications respectively and meet the minimum evidence requirements stipulated in Tables 2 and 3 - **providing homeopathic preparations are included within these assessment pathways**.

In relation to the minimum evidence requirements for the new pathway, certain homeopathic preparations/ products may currently be eligible for consideration, noting the rapidly growing body of high quality laboratory and clinical research evidence published each year.

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[2], a proportion that is increasing as the phenomenon is being better understood. This entire evidence base was excluded from consideration by NHMRC, therefore would be unknown to TGA.

The international charity, the Homeopathy Research Institute (HRI), was established in recent years to address the need for high quality scientific research in homeopathy, supporting fundamental and clinical research. Its third biennial conference will be held in Malta in June 2017, dedicated solely to high-end, robust scientific research involving homeopathy, including clinicians and academic researchers from outside of the world of homeopathy.

AHA/AROH notes TGA's role in the Australia-Canada-Singapore-Switzerland- (ACSS) Consortium. The TGA may be aware that Switzerland has decided to fully integrate homeopathy into its medical system, due to its widespread use and popularity; supported by evidence of efficacy, effectiveness, safety and cost-effectiveness in reports such as a comprehensive Health Technology Assessment published by Swiss experts in 2010 (published into English in 2012). This report was ignored by the NHMRC, dismissed on the grounds of 'wrong publication type' (see Optum Overview Report Appendices).

Homeopathy also has a strong traditional evidence base, with indications developed through a standardised method of defining the symptomatology of individual medicines ('provings'), confirmed by over 200 years of global clinical application. In many respects, this represents a stronger traditional evidence base than that of other CM modalities such as herbal medicine.

Proposal Five: Criteria for permitted indications

AROH/AHA supports in principle the preparation of a legislative instrument (LI) comprising a consolidated list of all permitted indications, with indications consistent with the relevant treatment paradigm (scientific or a tradition of use) - as per the criteria for low level indications (Tables 5 and 6).

As stated above, AROH/AHA considers that **homeopathic preparations should be included as treatment paradigm in the proposed LI**.

Homeopathic ingredients are currently included in the 26BB legislative instrument as active and/or excipient ingredients and should remain there; the new proposed LI should include permitted indications against these ingredients appropriate to their traditional uses in the homeopathic paradigm.

Proposal six: Implementation of permitted indications

AROH/AHA considers that sponsors of homeopathic products are best placed to comment on which option best meets their requirements.

The comprehensive list of traditional and scientific 'core' indications and specifying qualifiers for further consultation with stakeholders **should include homeopathic ingredients**. These should appropriately reflect the traditional use of homeopathic ingredients.

Proposal seven: Use of a claimer

AROH/AHA considers that sponsors of homeopathic products are best placed to comment on the use of a claimer.

Proposal eight: Protection for new ingredients

[2] 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

AROH/AHA considers that sponsors of homeopathic products are best placed to comment protection for new ingredients.

Proposal eight: Protection for efficacy data

AROH/AHA considers that sponsors of homeopathic products are best placed to comment on protection for efficacy data.

Concluding remarks:

Thank you for the opportunity to provide input into the consultation process for reforms to the regulatory framework for complementary medicines.

As stated, AROH/AHA expresses its concern that no background or justification has been provided in relation to why homeopathic preparations have been excluded from the current consultation round. We are aware that in 2010, the TGA suspended previous regulatory reform agenda concerning homeopathy pending completion of the NHMRC's assessment of the evidence on homeopathy. As outlined, AROH/AHA considers the NHMRC report and its findings to be so seriously flawed that it is not fit-for-purpose as a policy document able to inform official decision-making processes.

It would be unfortunate and wrong for the TGA to perpetuate the considerable harm already done to the homeopathy sector by the conduct of the NHMRC. AROH/AHA considers it is TGA's ethical responsibility to critically evaluate the rigour of the NHMRC report, rather than accept it at face value, particularly in light of the critical flaws the CM sector has disclosed to the TGA (as further detailed in the multi-stakeholder complaint to the Ombudsman).

As the peak bodies representing the interests of the homeopathic professional sector in Australia, AROH/AHA hereby requests that TGA directly consult with the sector as the consultation process progresses.

Yours sincerely,