Review of Pharmacy Remuneration and Regulation
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Interim Report - Review of Pharmacy Remuneration and Regulation

Brauer Natural Medicine (Brauer) welcomes the opportunity to provide comment in relation to the interim report from the *Review of Pharmacy Remuneration and Regulation,* published 22 June 2017.

Option 3-4 Sale of Homeopathic Products

Homeopathy and homeopathic products should not be sold in PBS-approved pharmacies. This requirement should be referenced and enforced through relevant polices, standards and guidelines issued by professional pharmacy bodies.

Brauer strongly opposes Option 3-4 of the Interim Report to prevent the sale of homeopathic products in PBS-approved pharmacies.

The recommendation for homeopathic products to be banned from sale in pharmacies receiving PBS funding is particularly concerning and one which Brauer strongly opposes for the following reasons.

1. This recommendation is not consistent with the Therapeutic Goods Act

The Therapeutic Goods Act 1989 defines homeopathic medicines as a type of medicine, specifically a complementary medicine. The panel would be aware that changes to the Act can only be made by an Act of Parliament. The King Review, being an economic review of Pharmacy Remuneration has no legal right to independently change Commonwealth legislation, nor does it have a legal right to redefine what constitutes an allowable medicine, or to attempt to force the Pharmaceutical Benefits Scheme to arbitrarily force Pharmacists to exclude anything that the TGA defines as medicine.

2. Option 3-4 relies on the NHMRC Homeopathy Review, a review which is deeply flawed, has been criticised by the NHMRCs own Independent Reviewers and which is currently the subject on a Commonwealth Ombudsman Complaint

The interim report justifies the banning of homeopathic products in pharmacies based upon a review conducted by the National Health and Medical Research Council (NHMRC), a review that has been called into question due to suspected bias, such as the influence of an anti-homeopathy lobby group while failing to include any homeopathic experts.

Consultation with experts in a field to be studied is recognised as an essential requirement of research, so it is reasonable for an investigation into the contribution that homeopathy makes to healthcare to include the input of suitably qualified experts in the field. As Kuhn (1970) memorably demonstrated, researchers are inclined to continue arguing in accordance with internalized beliefs.[i] Any homeopathy review that includes anti-homeopathy proponents, whilst excluding experts in the field, does not provide valid justification for outcomes in relation to homeopathic products.

A number of independent experts expressed strong concerns with the review methodology and a complaint has been lodged with the Commonwealth Ombudsman regarding manipulation of the NHMRC review. A publicly available copy of the Executive Summary of the Ombudsman Complaint can be found at: https://www.hri-research.org/wp-content/uploads/2017/04/Executive-Summary-to-Ombudsman-Complaint-re-NHMRC-Homoeopathy-Review-FINAL.pdf

On 30 August, 2013, the highly respected Australasian Cochrane Centre advised the NHMRC:

"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."

It would appear that the methodology chosen by the NHMRC was designed to exclude a large proportion of the existing evidence base of homeopathy, which ensured a 'no evidence' result. This is hardly consistent with an objective investigative process designed to produce an informed report into a system of healthcare that is estimated by the World Health Organisation to be used by over 550 million people worldwide.

The inclusion/exclusion criteria applied to the evidence base for homeopathy are not consistent with the guidelines used in the evaluation of scientific evidence used by the Federal Health portfolio and its agencies in evaluating scientific research. The NHMRC adopted a narrow review methodology that resulted in the exclusion of a very large percentage of high quality and relevant research data.

For example:

Foreign language studies were excluded from the scope: this is despite the fact that homeopathy's origins are German and it is predominantly practiced and researched in non-English speaking countries.

N < 150: Studies that otherwise met the NHMRC's inclusion criteria, but where the number of participants were less than 150 (irrespective of the quality of the study design), were deemed 'unreliable'. No justification was provided for this in the draft report. This is not consistent with methodology applied by the broader Health portfolio (eg. the TGA) in evaluating scientific evidence.

Animal, plant, cell studies: this is a crucial omission of relevant evidence, since core to the main criticism of homeopathy by its detractors is its apparent 'implausibility' and that any positive effects must be due to the 'placebo effect': the NHMRC has also directly stated this. Animal, plant and cell studies minimise and/or eliminate the placebo effect variable to the highest degree. Many large, high quality studies exist, yet their exclusion from scope prevented this crucial question from being investigated.

It is worth noting that the NHMRC Review of Homeopathy held Homeopathy to a higher evidence standard than is required by the TGA for all forms of Complementary Medicines and most Registered Medicines. In itself, the NHMRC Review should have no relationship with the King Review and the correct standard to judge homeopathy by is the Therapeutic Goods Act

Since its inception, the homeopathic profession has had its detractors, yet it has successfully co-existed as part of the international (and Australian) healthcare landscape on the basis of its clinical efficacy, consumer support base and governments' supporting the democratic principle of user-choice. For Australia to restrict the sale of homeopathic products in any capacity would please a small vocal minority. Groups with extreme negative views are entitled to those views; however, as much as possible, ingrained bias has no place in government process, where the highest standards of ethical and impartial administration should be demonstrated.

3. Evidence in Homeopathy

Brauer recognises that the Panel has adopted, from the beginning, an openly hostile position towards homeopathic products. However, the inference that homeopathic products are 'not evidence based' is incorrect.

Convergent evidence to support the use of homeopathic products include:

- Over 200 years of continual clinical practice, yielding a vast global literature base and numerous high quality documented cases (many published as case series).
- Successful application of homoeopathic treatment in government funded health systems (e.g. India, Germany, France, UK), with continued funding justified by evidence of clinical effectiveness.
- Randomised controlled trials (including placebo-controlled) published in peer-reviewed journals, around 50% of which (overall) report statistically significant results, with only around 5% negative - commensurate with the findings of conventional medicine research.
- Meta analyses, 5 out of 6, which support conclusions for homoeopathy that are not consistent with the 'placebo effect'.
- Systematic reviews, a good proportion of which report positive findings in a growing number of health conditions (the findings of which were dismissed by the NHMRC).
- Observational studies, many involving thousands of patients, which consistently show the effectiveness of homoeopathic interventions in real world clinical settings.

Such published evidence is not consistent with the profile of inert substances that lack therapeutic effects. Only substances that have therapeutic effects can be associated with an evidence base that shows such strong indications of efficacy and effectiveness, from both traditional and published evidence-based research models.

The proposed restriction of an entire product category is a serious issue that will adversely impact public health and cause significant commercial and reputational harm to a sector that has operated safely and responsibly in Australia since the 1840s.

4. The 'Risk of harm' argument against homeopathy – is based on opinion and is not evidence-based

"In particular, the Panel notes that the supply of homeopathic products through pharmacies is not benign but, rather, risks creating a perception of reliability and efficacy in the mind of the consumer based on the status of the pharmacy as a healthcare provider. This may encourage patients to choose a homeopathic product over a conventional medicine with robust evidence of efficacy, which creates a risk of harm to the patient's health."

These are safe, low risk products, and popular with consumers for the minor, self-limiting conditions for which they are indicated. Homeopathy is a traditional system of medicine that originated in Europe in the late 1700s. In the modern era, it is practiced in the majority of the world's nations and has been integrated into the healthcare systems of many developed and developing countries on the basis of its efficacy, safety and cost-effectiveness (eg. the UK, France, Germany, Portugal, Switzerland, India, Brazil).

For therapeutic goods, dangerous is typically defined by the TGA in terms of risk of adverse events, side effects, drug interactions, etc. Homeopathic medicines have one of the best safety records in Australia, when made in accordance with TGA Guidelines for listed medicines. In Australia, the largest manufacturers of homeopathic products comply with Good Manufacturing Practice (GMP) standards prescribed by the TGA, thereby also ensuring that their products sold in pharmacy comply with community expectations of quality and safety. For the King Review to suggest otherwise is ill informed, unscientific and not based on the data.

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 NHMRC Statement on Homeopathy claims, *"People who choose homeopathy may put their health at risk"*.

The presence of this statement within a section called "NHMRC's interpretation of the assessment of the evidence on the effectiveness of homeopathy" **misleads the public into believing that it is based on the findings of their Overview, when it is not**. **It is speculation, not evidence-based**.

This false impression is strengthened further by NHMRC repeatedly and inaccurately describing the Homeopathy Review to the public as a 'Health Technology Assessment' (HTA)[1]. HTAs by definition do assess safety, but NHMRC did not conduct a HTA, it conducted an 'Overview' and excluded all customary HTA parameters, with the exception of 'efficacy'.

In adopting the NHMRC's position, the Expert Panel is adopting (without critical evaluation) a position based on **opinion, not assessment of evidence**.

By contrast, the Swiss HTA report (referenced above) *did* assess 'safety' evidence in reaching its conclusion, *"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 critical flaws of the NHRMC Review, including its extensive exclusion criteria (preventing the results of 97% of the included efficacy studies from contributing to the Review's findings), are outlined below in the submission.

Further, in overseas jurisdictions where homeopathic medicines are available through pharmacy and are popular and widely used (such as in European Union countries), no evidence exists that they are associated with any 'safety' risks.

5. **This recommendation is a breach of consumer / civil rights with respect to a person's right of control and self-determination with respect to their medical treatment**

Such an extreme proposal to ban the sale of an entire class of medicines impinges on consumer right of access to medicines of their choice and is a civil liberties issue. *Singling out* a particular class of medicines for government prohibition that:

- Have been available in pharmacies for decades both in Australia and multiple overseas jurisdictions without any real-world evidence of 'safety risk' or harm (real or perceived)
- Are underpinned by a growing body of evidence showing efficacy, effectiveness, cost-effectiveness, safety and quality
- Are being increasingly used and demanded by consumers (including by around a million Australians)

represents an extraordinary and unprecedented imposition on behalf of government on consumer choice.

The Expert Panel would be aware that no precedent exists for an entire class of medicines to be targeted for selective prohibition of sale, particularly when underpinned by a long traditional history of use and growing research evidence base demonstrating efficacy and effectiveness.

Yet the Expert Panel is proposing such an extreme option on the *sole* basis of a deeply flawed (NHMRC) report that excluded for consideration the vast majority of this extant evidence base.

Brauer notes the Expert Panel's recognition that, *"regulation presents costs to the public, the government and the participants in the medicine supply chain. Regulation must be sufficient but not excessive and must underpin sustainable consumer access."*

Further, the PSA ethics guidelines (Care Principle 2) states that a pharmacist must *"respect patient choice".* The Interim Review Option 3-4 is not consistent with this guiding principle.

> "The principle was affirmed recently by the High Court of Australia in Secretary, Department of Health v. JWB and SMB. The High Court stated that the requirement that a legally valid consent be obtained before medical treatment can be administered originates in 'the right in an individual to choose what occurs with respect to his or her own person' and thereby 'protects the autonomy and dignity of the individual'. In discussing this need for consent, the High Court also variously referred to 'the principle of personal inviolability', 'the right to personal security', 'the right to physical integrity [that] protects a person's self-estimate', and'[a person's] rights of control and self-determination in respect of his or her body' and 'a person's right of bodily integrity'."
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> Source : Parliamentary Library
> http://www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Library/pubs/rp/RP9697/97rp3

Brauer's external legal advice is that Option 3-4 is in breach of a person's right of control and self -determination with respect to their medical treatment.

6. Positions of professional pharmacy bodies

The Interim Report's reference to the positions of 'professional pharmacy bodies' such Pharmaceutical Society of Australia (PSA), included to give 'weight of consensus' to its position, presents a circular argument, since such bodies have based their positions on the same flawed NHMRC report.

As the PSA 'Position Statement on Homeopathy' confirms[2]:

> *"PSA endorses the NHMRC report, released in March 2015…"*

Neither the PSA or the Guild are aware of the level of accusations raised in the NHRMC Homeopathy Review Ombudsman's Complaint. The Complementary Medicines Industries legal advice is that it is likely the NHRMC Report will be over turned.

7. Adoption of Option 3-4 in proposing to ban homeopathy, would put Australia at odds with all major overseas pharmacies and at odds with all of Australia's Regulatory partners

The Interim Report does not provide any contextual information or analysis relating to the sale of homeopathic products in international jurisdictions. The European Union (EU) provides a pertinent context relating to the sale of homeopathic products in pharmacy, given widespread prevalence and support from both pharmacy and community. In the EU, there is strong support amongst pharmacies to sell homeopathic products, given such a large proportion of the population use and benefit from them.

The EU is a highly regulated jurisdiction, where 29% of EU citizens regularly use homeopathic products to support their healthcare needs (representing over 100 million Europeans who use over-the-counter or prescribed homeopathic medicines)[3,4].

In the EU, almost all sales to the public of homeopathic medicinal products occur through retail pharmacies. In most EU countries, homeopathic medicinal products are exclusively sold in pharmacies, since they are classed as medicinal products (only in some Scandinavian countries, such as Sweden, are they sold out of pharmacies, due to regional low population density).

Strategic vision & WHO Traditional Medicines Strategy 2014-2023

The World Health Organisation (WHO) *Traditional Medicine Strategy 2014-2023*, to which Australia is a signatory, acknowledges that forms of complementary medicine (CM) such as anthroposophic medicine, chiropractic, homeopathy, naturopathy and osteopathy are in "extensive use".

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[2] http://www.psa.org.au/downloads/ent/uploads/filebase/policies/position-statement-complementary-medicines.pdf

[3] di Sarsina PR, Iseppato I, 2011, Looking for a person-centred medicine: non-conventional medicine in the conventional European and Italian setting, *Evidence-based Complementary and Alternative Medicine*, vol 2011, article id 382961

[4] European Commission, 2007. http://www.echamp.eu/eu-legislation-and-regulation-documents/Commission_Report_Dir_9273_and_9274_Homeo_July_1997.pdf

The WHO Strategy acknowledges the important role of traditional medicines (including homeopathy) to global community health into the future and *"aims to support Member States in developing proactive policies and implementing action plans that will strengthen the role traditional medicine plays in keeping populations healthy"*.

This aim, which encompasses ensuring community access to homeopathic medicine, directly aligns with the stated principles of the 'strategic vision' of the Pharmacy Review.

Any proposal to remove homeopathic medicines from pharmacy not only contravenes the principles of the Review's strategic vision, it is also out of step with international best practice and with Australia's obligations under the WHO's goal to improve global health by ensuring access to traditional forms of medicine, which includes homeopathy as an extensively used class of therapeutic goods.

Brauer would be please to discuss any points of this submission further as required

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