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Interim Report - Review of Pharmacy Remuneration and Regulation

Complementary Medicines Australia (CMA) welcomes the opportunity to provide comment in relation to the interim report from the *Review of Pharmacy Remuneration and Regulation*, published 22 June 2017.

We note that the Panel has acknowledged that consumers value access to complementary medicines in the community pharmacy setting and that 90 per cent of pharmacy owners see a role for complementary medicines in pharmacy. This is in line with global expectations and trends. The World Health Organization acknowledges that more countries are coming to accept the contribution that traditional and complementary medicines (T&CM) can make to the health and wellbeing of individuals and to the comprehensiveness of their healthcare systems. *“Many countries now recognize the need to develop a cohesive and integrative approach to health care that allows governments, health care practitioners, and, most importantly, those who use health care services, to access T&CM in a safe, respectful, cost-efficient and effective manner.”* (WHO traditional medicine strategy 2014-2023).

Benefits of Complementary Medicines to Australia’s Health System

A significant amount of scientific research has been conducted looking at the direct health benefits of using complementary medicines, and numerous studies demonstrate that many of these medicines have a positive effect on reducing the risk of a secondary disease event.¹ Clinical indications and claims made by complementary medicines are not always trivial and include conditions that are major Australian national health priority areas. Improved integration of evidence based complementary medicines may not only improve health outcomes, but impact significantly on national health costs as described below.

A 2014 Frost & Sullivan report *‘Targeted Use of Complementary Medicines: Potential Health Outcomes and Cost Savings in Australia’* shows robust links between several of the more well-known complementary medicines with reduced risk of a secondary disease event among high-risk groups, and with major potential healthcare cost savings. The report examined the use of six complementary medicines across four chronic disease conditions – cardiovascular disease (CVD), osteoporosis, age-related macular degeneration and depression – all of which contribute heavily

to the national burden of illness in Australia. Large cost savings were identified, especially for the use of calcium and vitamin D by women aged over 50 who had been diagnosed with osteoporosis or osteopenia. For these conditions alone, the report estimated that between 2015 and 2020 an average annual hospitalisation cost of A\$922 million could be potentially saved, along with gains in productivity of A\$900 million – a net gain of A\$1.8 billion.

A 2013 US study '*Smart Prevention – Health Care Cost Savings Resulting from the Targeted Use of Dietary Supplements*', found the use of key dietary supplements, including omega-3s, B6, B12 and folic acid, could reduce hospitalisation costs by \$US billions per year. In addition, a 2010 Access Economics report, '*Cost effectiveness of complementary medicines*', commissioned by the National Institute of Complementary Medicine, found that the use of omega-3 fish oils for secondary prevention of heart disease could provide significant cost savings to the Australian health budget.

These reports begin to demonstrate the potential savings offered by complementary medicines as a means to combat unsustainable health care costs, and as a means for high-risk individuals to reduce their chances of having to deal with potentially costly disease-related events.

Inclusion of Complementary Medicines in King Review

From the start, CMA has held grave concerns about the inclusion of complementary medicines in the King Review. The 6CPA did not mention complementary medicines being a part of the review, yet the initial discussion paper raised questions about whether keeping vitamins and dietary supplements (VDS) on pharmacy shelves compromised professional practice, customers' expectations of a healthcare service and if customers received any benefit from their provision within a pharmacy setting. Comments made by Professor King during public briefings suggested that the evidence behind complementary medicines was also being questioned, and that Professor King held entrenched negative views towards complementary medicines in general and homeopathic products in particular.

Despite acknowledging the overwhelming support for complementary medicines in community pharmacy, the interim report includes options to enforce restrictions upon pharmacists as to how and where complementary medicines are displayed and what may be sold.

CMA notes that the interim report discusses the sale of complementary medicines in community pharmacies in sections 3.3 to 3.5 and will specifically address the proposed options relating to these sections.

Option 3-2 Complementary Medicines – Supply from Pharmacies

Community pharmacists are encouraged to:

- a. Display complementary medicines for sale in a separate area where customers can easily access a pharmacist for appropriate advice on their selection and use
- b. Provide appropriate information to consumers on the extent of, or limitations to, the Therapeutic Goods Administration (TGA) role in the approval of complementary medicines. This could be achieved through the provision of appropriate signage (in the area in which these products are sold) that clearly references any limitations on the medical efficacy of these products noted by the TGA.

As an integral part of Australia's National Medicines Policy, the quality use of medicines (QUM) is defined as the judicious, appropriate, safe and effective use of medicines, with the term 'medicine' encompassing prescription and non-prescription medicines, including complementary healthcare products. In practice, the layout of products within a pharmacy environment tends to clearly segregate different classes of goods such as scheduled medicines, over-the-counter remedies and complementary medicines from those of other consumer goods – all with accessible access to the pharmacists for additional advice.

Complementary medicines are often recommended by health professionals, with the most recommended including vitamin D, iron with vitamin C, multivitamins, magnesium, calcium, iodine, vitamin B12 and folic acid and omega-3s. It should be noted that the 2011-12 Australian Health Survey identified that:

- Calcium intake across the population is largely inadequate; nearly three quarters of females (73%) and half of all males (51%) aged two years and over did not meet their calcium requirements based on their intakes from food.
- Females are more likely to have inadequate iron intakes than males, with one in four (23%) not meeting their requirements compared with one in thirty males (3%).

The term 'complementary medicines' refers to a range of products that have a wide spectrum of both scientific and traditional evidence supporting their use. Any shelving signage that states "limitations on the medical efficacy" of complementary medicines is likely to be wildly incorrect, complex and confusing for consumers, and create a disservice to both community pharmacists and to community health. Research has shown that a negatively-worded statement about the regulatory status of a product has the unsurprising result of decreasing market share for that product. Spinks & Mortimer (2015) found that consumers prefer positively worded statements to negative ones and that "if the intention of including negatively-worded statements is to decrease the likelihood of making poor quality decisions (as opposed to simply decreasing utilisation), it is not clear how such an effect would act in isolation and not 'spill-over' to decrease potentially good consumer choices."ⁱⁱ

The regulatory system in Australia has evolved around the acknowledgment of the inherent lower risk of complementary medicines, regulated as medicines only in Australia, and as such, strict quality and safety standards are the main pillars of focus for the TGA to invest its resources. Despite this, it is important to acknowledge that reforms to the regulatory framework for complementary medicines will see the development of a pathway that specifically allows medicine sponsors to apply for pre-market approval of the evidence associated with a product. The educational messaging to consumers should be around these positive set of reforms as opposed to any negative and conflicting messages within a pharmacy setting.

Positive Disclaimer

The Australian Government provided its response to the Review of Medicines and Medical Devices Regulation (MMDR) in September 2016, accepting the majority of the recommendations

proposed by the Panel led by Professor Lloyd Sansom AO. The regulation of complementary medicines is being reformed to provide a pathway that encourages greater investment in clinical research, and to strengthen compliance powers of the regulator, whilst recognising the low-risk nature of complementary medicines.

As part of the reforms to complementary medicines, the Government has accepted recommendation 39, to establish a new pathway for the listing of a complementary medicine, where the sponsor can elect to have the regulator assess the evidence related to a higher level indication(s) prior to its release on the market.ⁱⁱⁱ As consumers have been found to respond better to positively-worded statements, it is a sensible approach that where a medicinal product is listed on the ARTG following an assessment by the TGA under the proposed new pathway, the sponsor is able to indicate on the label and on promotional materials that the efficacy of the product has been independently assessed for the approved indication(s). It will provide accurate and useful information about complementary medicine products and will contribute to improved consumer choices.

The Government has also supported the intent of Recommendation 44, which is to assist in educating consumers. The TGA is to conduct further consultation on ways to better educate consumers about the listing system. The Government did not support the requirement that sponsors place a negative disclaimer on product labels.

Regulatory Reforms for Improved Consumer Information & Protection

The TGA has instigated labelling changes to make important information about medicines easier to find. The labelling requirements are being updated after many years of consultation with industry, health professionals and the wider community, and will align Australian medicines labels with international best practice. This will help consumers to make more informed choices about their medicines and to use them more safely.^{iv}

The Government accepted MMDR recommendation 46, where the TGA should develop, or adopt from comparable overseas regulators, efficacy monographs for commonly used active ingredients that have been approved for use in listed medicinal products. Such monographs would document the evidence supporting specific ingredients for specific indications, and allow the improvement of availability and accuracy of information for consumers.

Recommendation 38 has also been accepted, which will establish a list of permitted indications from which sponsors must exclusively draw for listed medicinal products in the ARTG. This will restrict sponsors to a pre-determined list of indications available for listed medicines, and will include the ability to specify indication(s) where there is supporting evidence for its use within a traditional paradigm, such as traditional Chinese medicine, Western herbal medicine and homeopathic paradigm etc. If a traditional paradigm is selected, this must be specified on the product label.

The TGA is already in the process of implementing a more comprehensive post-market monitoring scheme for listed medicinal products, which includes an increase in the number of products subject to random or targeted review by the regulator.

The King Review is occurring against a backdrop of implementation of the accepted recommendations made by the MMDR. Implementation of the recommendations will address concerns with regard to transparency in advertising, evidence to support indications and claims, greater information for consumers, and compliance powers for the regulator. Redundant restrictions as to how pharmacists are allowed to display, sell, or educate consumers about complementary medicines will not improve consumers' quality use of these products.

Traditional Evidence

Over the centuries, empirical knowledge has amassed to form a body of evidence commonly referred to as traditional evidence. This form of evidence is not simply 'anecdotal' as it is the accumulation of observations by generations of practitioners and is based on the basic tenets of good clinical practice: careful observation of people, their environment and the diseases they acquire.^v ^{vi} In 1985, it was noted by Professor Norman Farnsworth that of the 119 drugs of known structure that had been derived from plants, 75 per cent had the same use in conventional biomedicine as they did in traditional medicine.^{vii}

Option 3-3 Placement of Pharmacy Only and Pharmacist Only (Schedule 2 and Schedule 3) Medicines within a pharmacy

Access to Pharmacy Only (Schedule 2) and Pharmacist Only (Schedule 3) medicines should be clearly separated from complementary medicines within a pharmacy.

Options to achieve this might include:

- a. Ensuring that all Pharmacy Only (schedule 2) and Pharmacist Only (schedule 3) medicines only be accessible from 'behind the counter' in a community pharmacy so that a consumer must always seek assistance or advice in obtaining these medicines
- b. Requiring that complementary medicines are not displayed 'behind the counter' in a community pharmacy.

The option suggested by the Panel to require that complementary medicines not be displayed behind the counter in community pharmacy presumably stems from the misapprehension that this is done to create a pseudo-registration for such products. This is not the case.

Complementary medicines differ from other medicines in that the ingredients may have multiple actions, as they treat the person not the disease. Consequently, there are a number of medicines that health care professionals use on a case by case basis. Practitioner-only products evolved because sponsor companies wanted the option to leave off the indications for use on the label, thus giving the practitioner a responsible way to personalise their script to their patient's needs. At its simplest – a practitioner-only product is not suitable for public access without a practitioner in the loop for the practical reasons of determining the use, dosage and duration for the presenting individual. In the retail environment, practitioner-only products should not be accessible until after a consultation with a healthcare professional or upon presentation of a current script written by a healthcare professional.

Practitioner-only products are only to be supplied to and dispensed by a healthcare professional as described in section 42AA of the *Therapeutic Goods Act 1989*. From a regulatory perspective, the difference between 'For Practitioner Dispensing Only' complementary medicine products (or words to that effect), and other Listed or Registered complementary medicines, is that these products are for dispensing and are *not* required to include a statement of purpose on the label. This labelling exemption is provided by section 3(2) (m)(ii) of the *Therapeutic Goods Order No. 69*.

The TGO 69 states in section 3(2) (m), particulars to be included on a label are as follows:

- (m). a statement of the purpose or purposes for which it is intended that the goods be used, except:
 - i. where the goods are specified in Schedule 4 or Schedule 8 of the Poisons Standard; or
 - ii. where the goods are a dispensing pack supplied solely to a *complementary healthcare practitioner*, and include on the label the words 'For Practitioner Dispensing Only' ...

A dispensing pack, in relation to a complementary medicine, is defined in the Therapeutic Goods Order 69, Section 2, as 'a pack which is to be supplied solely to complementary healthcare practitioners for supply to a person after affixing an instruction label following a consultation with that person'.

Sponsors of 'Practitioner-only Products' (Listed or Registered complementary medicines) can opt to include a statement of purpose on their products if they wish. These statements must meet the same requirements as other complementary medicine products, Listed and Registered, with regard to evidence substantiation for indications and reflect only those therapeutic indications included on the ARTG for that product. However, if a statement of purpose is not included on a practitioner-only product, the dispensing pack must include the statement 'For Practitioner Dispensing Only' or words to that effect.

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.

The recommendation for homeopathic products to be banned from sale in pharmacies receiving PBS funding is particularly concerning. These are safe, low risk products, and popular with consumers for the minor, self-limiting conditions for which they are indicated.

In Australia, medicines containing homeopathic preparations, whilst considered to be low-risk medicines, are regulated under the *Therapeutic Goods Act 1989*. The definition of a complementary medicine is outlined in the *Therapeutic Goods Regulations 1990* and supported by the TGA's Regulatory Guidelines (ARGCM). That is, 'complementary medicine' means a therapeutic good consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and a traditional use. For a complementary medicine, a designated active ingredient means an active ingredient, or a kind of active

ingredient, mentioned in Schedule 14 (to the Regulations)... 6. **a homoeopathic preparation**. The decision as to what constitutes a medicine is clearly outside the scope of this review.

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).

A review conducted on behalf of the Swiss government included analysis of a range of studies that were relevant to the way that homeopathy is practiced in real world settings and found that homeopathy is an effective, safe and cost-effective modality. The Swiss Health Technology Assessment (HTA) report, published into English in 2011, concluded^{viii}:

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

As a result of this inquiry homeopathy was formally reintegrated into Switzerland's healthcare system earlier this year.

NHMRC Review

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.^{ix} 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 publically 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.

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.

Evidence in Homeopathy

CMA 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.

Role of Pharmacists – Education / Knowledge

Use of complementary medicines amongst Australian consumers, including those purchased in pharmacies, is significant. CMA agrees that it is vital for pharmacists to be knowledgeable about complementary medicine products and able to provide information about their safe and appropriate use. Customers expect pharmacists to be knowledgeable about these products, and in turn, the vast majority of pharmacists see it as a part of their professional responsibility and commitment to community health.

Increasingly, individuals have been seen to take a more proactive approach to healthcare, becoming more confident in self-selection and willing to take preventive measures to support their health. A recent systematic literature review found that it is no longer “ethically or professionally acceptable” for pharmacists to ignore patients’ use of complementary medicines. The reviewers argue that the evidence is in support of an expanding role for the pharmacist in the area of traditional and complementary medicines, and that there are seven identified responsibilities for pharmacists.^x These include to:

- acknowledge and ask about the use of traditional or complementary medicines;
- be knowledgeable and take steps to educate themselves about TM/CMs;
- ensure safe and appropriate use of TM/CMs – this goes beyond being diligent about potential adverse events to recommending the best possible products;

- document the use of TM/CM products by customers;
- report suspected adverse drug events involving TM/CM products;
- educate patients about the quality use of complementary medicines and encourage them to report their use to their doctors and other health professionals; and
- collaborate with other health professionals: one study found a high use of CM among cancer patients, with pharmacist playing a key role in updating the patients' doctors about this use.

The use of complementary medicines in Australia continues to grow, along with its supporting evidence base, so there is a need for policy makers and practitioners to respond meaningfully to this component of the Australian health care system. Australians are more likely be seeing a TM/CM practitioner than not. What should unite health professionals is the desire to do what is safest and most effective for their patients. To obtain good health outcomes, it is important for consumers to participate in decisions and choices about their care and health needs. This provides the basis for informed consent and informed decision making and includes respecting their choice of safe and effective complementary medicines.

We would be pleased to discuss any points of this submission further as required.



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Appendix

CMA is the peak industry body for the complementary medicines industry, representing members throughout the value chain: manufacturers, raw material suppliers, distributors, retailers, practitioners and educators. The Australian complementary medicines industry generates \$3.5 billion annually, which is expected to grow to \$4.6 billion in 2017-2018. CMA promotes appropriate industry regulation and advancement to ensure consumers have access to complementary medicines of the highest quality.

Regulated in Australia as medicines under the *Therapeutic Goods Act 1989*, complementary medicines include vitamins, mineral and nutritional supplements, homeopathic, aromatherapy products and herbal medicines (unless specifically exempt). The term 'complementary medicines' also comprises traditional medicines, including traditional Chinese medicines, Ayurvedic, Australian Indigenous and Western herbal medicines. Traditional and long-term use is taken into account in establishing safety as a medicine. Other natural healthcare products may be regulated as foods, such as functional foods and special purpose foods, or as cosmetics, such as natural cosmetics that use herbals and botanicals.

ⁱ Frost & Sullivan. (2014). Targeted Use of Complementary Medicines: Potential Health Outcomes & Cost Savings in Australia

ⁱⁱ Spinks, J., Mortimer, D. (2015). The effect of traffic lights and regulatory statements on the choice between complementary and conventional medicines in Australia: Results from a discrete choice experiment. *Social Science & Medicine* 124, 257-265

ⁱⁱⁱ Commonwealth of Australia (2016) Australian Government Response to the Review of Medicines and Medical Devices Regulation. Accessed from: <http://www.health.gov.au/internet/main/publishing.nsf/Content/CCB4916435683A5BCA257FA100839F95/%24File/govresp.pdf>

^{iv} TGA (2017) Australia's medicine labels are becoming clearer. Accessed from <https://www.tga.gov.au/australias-medicine-labels-are-becoming-clearer>

^v Phelps, K. Hassad, C. (2011). *General Practice: The Integrative Approach*. Churchill Livingstone, Melbourne.

^{vi} NICM (2014) Australian Government rebate on Private Health Insurance for Natural Therapies: Highlighting complementary medicines research

^{vii} Phelps, K. Hassad, C. (2011). *General Practice: The Integrative Approach*. Churchill Livingstone, Melbourne.

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

^{ix} Kuhn, T.s (1970). *The structure of scientific revolutions*. Chicago: The University of Chicago Press.

^x Ung, C, Harnett, J. (2017). *Community pharmacist's responsibilities with regards to traditional medicine/complementary medicine products: A systematic literature review*. *Research in Social and Administrative Pharmacy* 13 688-716