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National Health and Medical Research Council

RESEARCH
TRANSLATION
FACULTY

CASE FOR ACTION- PROPOSAL TO NHMRC

Lack of informed and appropriate use
of complementary medicines by the
community

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Submitted by the Research Translation Faculty Claiming Benefits for
Human Health Steering Group (October 2014)

CLAIMING BENEFITS FOR HUMAN HEALTH

The National Health and Medical Research Council (NHMRC) Research Translation Faculty (the Faculty) was established as a key advisory forum in 2012. The primary work of the Faculty for the 2013-15 Triennium has been to help NHMRC accelerate the translation of research by identifying the most significant gaps between research evidence and health policy and practice in each of the major health areas in the NHMRC Strategic Plan, and to propose to NHMRC possible action it could consider taking to address that gap – these are called Cases for Action. In April and May 2013, fourteen Faculty steering groups were established as NHMRC working committees to each oversee the development of a Case for Action.

The Faculty's Claiming Benefits for Human Health Steering Group is comprised of a range of experts and includes primary (1°) and secondary (2°) representatives of NHMRC Health Care Committee (HCC), Prevention and Community Health Committee (PCHC) and Research Committee (RC). Further information is available at: www.nhmrc.gov.au/research/research-translation/research-translation-faculty/research-translation-faculty-steering-groups.

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Declaration of interests

The declarations of interests of Steering Group members, authors and contributors are available at Appendix 1.

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NHMRC Research Translation Faculty

Claiming Benefits for Human Health Steering Group

Case for Action

Title: Lack of informed and appropriate use of complementary medicines by the community

Submitted to NHMRC for consideration: October 2014

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Summary

The need for more informed and appropriate use of complementary medicines

This Case for Action (CFA) focuses on the lack of informed and appropriate use of off the shelf complementary medicines which results from (a) unclear communication to consumers of the evidence base for complementary medicine products (CMs) and (b) inadequate incentives for manufacturers to undertake high quality research and development (R&D). Australians are among the world's highest consumers of CMs. It is estimated that two out of three Australians use CM¹, with rates as high as 87% among specific patient groups, such as those with breast cancer.² Yet, little guidance is provided to consumers on the evidence base for these CMs with few sponsors issuing either *Product Information* inserts or more general *Consumer Medicines Information*. Consumers who use CMs are unable to differentiate between medicines which have strong evidence to support them and those with weaker evidentiary support. No information is provided at the point of sale which enables consumers to differentiate even the *nature* of the evidence between products. It is difficult for consumers to make informed choices for CMs, particularly when surveys indicate that consumers do not understand the regulation of CMs nor their evidence base. In addition, the current regulatory system, in combination with the international intellectual property protection regime, does not encourage CM sponsors to undertake high quality, clinical research to substantiate the claims made by their products. Unlike pharmaceuticals, many CMs are unable to be patented, because their individual ingredients have related traditional medicinal uses and are already in the public domain. As a result, sponsors who undertake research to support their products are not provided with any form of protection for their products over a competitor's products, even if a new extended claim is justified. A competitor may be able to make similar claims about their product without incurring the expense of research. Sponsors thus usually rely on research conducted elsewhere, or a history of traditional use, in the sale and distribution of CMs in Australia. This results in very little Australian innovation in this area, despite extensive potential and opportunities for new product development and validation. No significant work has been undertaken to date with regard to improving communication of CM product evidence to consumers and health professionals. There is also a dearth of product specific clinical trials in Australia. These are required to improve evidence based practice.

We recommend the consideration, evaluation and implementation of appropriate models to address the two principal barriers contributing to this evidence-practice gap. In particular, we recommend the establishment of two Working Groups under the auspices of the NHMRC or the Department of Health and Ageing focused on addressing each of the key barriers to effective development and translation of CM evidence. The first Working Group would focus on developing a simple and broad mechanism to communicate (the nature of) the evidence of efficacy at the point of sale. The second Working Group would focus on improving incentives for industry to invest in R&D to strengthen and clarify evidence of efficacy.

RATIONALE

1. The significance of the gap to health and medical practice or policy in Australia (i.e. to patients and/or policy makers) and why there is a strong need in Australia to address it.

a. The evidence-practice gap

This Case for Action (CFA) focuses on the lack of informed and appropriate use of complementary medicines which results from (a) unclear communication to consumers of the evidence base for complementary medicines (CMs) and (b) inadequate incentives for manufacturers to undertake high quality research. The focus of this CFA is upon CM products that are obtained off the shelf by consumers and which includes all CM products on the Australian Register of Therapeutic Goods (ARTG). The program will not apply to specific CMs prepared by practitioners for patients.

According to the Therapeutic Goods Administration (TGA), medicinal products containing ingredients such as herbs, vitamins, minerals, nutritional supplements and other preparations are referred to as 'complementary medicines' in Australia and are regulated under the *Therapeutic Goods Act 1989*.³ The *Therapeutic Goods Regulations 1990* defines a complementary medicine as a therapeutic good consisting principally of one or more designated active ingredients mentioned in Schedule 14 of the Regulations, each of which has a clearly established identity and traditional use:

Designated active ingredients:

- An amino acid
- Charcoal
- A choline salt
- An essential oil
- Plant or herbal material (or a synthetically produced substitute for material of that kind), including plant fibres, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll
- A homeopathic preparation
- A microorganism, whole or extracted, except a vaccine
- A mineral including a mineral salt and a naturally occurring mineral
- A mucopolysaccharide
- Non human animal material (or a synthetically produced substitute for material of that kind) including dried material, bone and cartilage, fats and oils and other extracts or concentrates
- A lipid, including an essential fatty acid or phospholipid
- A substance produced by or obtained from bees, including royal jelly, bee pollen and propolis
- A sugar, polysaccharide or carbohydrate
- A vitamin or provitamin.

Within the regulatory framework, CMs are either *Listed* or *Registered* based on perceived risk. Most CMs are *Listed* and considered 'low risk' medicines. The *Listing* process allows for more rapid market access for low risk medicines. This includes pre-evaluation of quality (through TGA licensing of Good Manufacturing Practice facilities) and safety of *Listed* medicines. This is not the case in many overseas jurisdictions and hence the TGA label holds significant appeal overseas, signalling a quality product. However, unlike *Registered* medicines, the TGA does not undertake pre-market evaluation of the clinical indications and substantiating evidence of *Listed* medicines prior to their inclusion in the ARTG. Sponsors are required to hold this evidence, and are subject to random and targeted audits.

Evidence used to support indications for *Listed* medicines is usually sourced from the available open literature, rather than from clinical trials specifically conducted on a particular CM. Depending on the proposed indication, the evidence will be sourced from scientific literature or based on a history of traditional use. To claim evidence of traditional use, the CM or ingredient must be an established part of a tradition of medicinal use within a particular paradigm or culture for over three generations. While some CMs have high quality, scientific evidence to support their use, others may not.

Australians are among the world's highest consumers of CMs. It is estimated that two out of three Australians use CM¹, with rates as high as 87% among specific patient groups, such as those with breast cancer.² For example, a national census of medicine use by Australians aged 50 years and older reported that CMs were used by 46.3% of participants, representing just over half (53.2%) of all medicines users.⁴ In this study, 87.4% of people used both conventional medicine and CMs. Yet, little guidance is provided to consumers with few sponsors opting to issue either *Product Information* inserts or more general *Consumer Medicines Information*.

(i) Unclear communication to consumers of the evidence base for CMs

Consumers who use CMs are unable to differentiate between medicines on the basis of the evidence which supports their listing on the ARTG. No information is provided at the point of sale which enables consumers to differentiate even the *nature* of the evidence between products. For example, some products hold strong scientific evidence based on product specific clinical trials, other products rely on generic evidence linked to their component ingredients and others base their claims on traditional use (including many Chinese medicines). Consumers and clinicians express concern that CM product evidence is difficult to interpret; it is not immediately obvious what evidence sits behind any product claims and indications. This relates to both the nature and strength/quality of the evidence. Indeed, in some cases, the combination of absence of therapeutic rationale, and absence of demonstrable therapeutic effect make the likelihood of any benefit negligible. Better mechanisms need to be established to increase awareness amongst the public where there is little or no evidence to support an intervention or where the available evidence conclusively demonstrates that the intervention ought to be discontinued.

There are many CMs available to consumers. For example, it was estimated that there were 10,000 CMs on the ARTG in 2011.⁵ Not all products are equally efficacious nor do they hold the same levels of bioavailability. For instance, differences in the formulation of glucosamine products, a commonly used CM in Australia, either through differing manufacturing processes or different raw or constituent materials are identified as a factor contributing to the heterogeneity in clinical trial results for glucosamine.⁶ Moreover, evidence suggests glucosamine hydrochloride products are associated with more negative results than glucosamine sulphate products. However, Australian regulatory and health authorities have not traditionally made distinctions between specific formulations, and little is known about public preferences between formulations.

In the absence of information about efficacy, it is difficult for consumers to make informed choices for CMs, particularly when surveys indicate that consumers do not understand the regulation of CMs nor their evidence base.

In 2004, a survey of complementary medicine use in South Australia found that 'half the population thought that [complementary and alternative medicines] were independently tested by the TGA before being allowed to be sold.'⁷ An anonymous, self-administered survey completed by randomly selected pharmacy customers at 60 community pharmacy

locations between August 2008 and February 2009 showed that 88% of surveyed consumers had never noticed the term 'AUST L'.⁸ Among those in the survey who did notice the AUST L, 33% thought it meant the product was tested by a government agency for safety, 26% thought it was tested by a government agency for quality, and 24% thought it denoted an Australian made product, 15% thought it was tested by a government agency for effectiveness and 13% stated they did not know what it meant.⁸

The National Prescribing Service (NPS) MedicineWise has found similar results. When NPS MedicineWise researched the information use and needs of CM users it found that more than half of respondents (52%) thought that CMs were independently tested by a government agency such as the TGA. Of those who thought they were tested, 25% thought they were tested for quality, 75% thought they were tested for safety, and 33% thought they were tested for efficacy or for what they claim to do.⁹ While the survey found that only 12.1% of CM users were concerned about the lack of research and 10.5% were concerned about the lack of efficacy, these low figures may in fact reflect the erroneous belief that CMs are tested by government.⁹ Studies in Canada have found that scientific evidence is an important decision-making factor for the use of CMs in osteoarthritis¹⁰ and cancer.¹¹ Nonetheless, advice from health care providers, friends and family was considered equally, if not more important. This may reflect the absence of easily accessible and reliable sources of information about CMs and the need to identify trusted sources of information.

Community pharmacy is one of the main suppliers of CM products in Australia. Nonetheless, pharmacists are not always able to adequately advise consumers on the most appropriate choice of CM for their health condition. According to a recent survey of 484 pharmacists in New South Wales, most pharmacists (71%) reported offering CM products for sale; however, 27% of these practices did not have access to CM information for pharmacy staff or patients.¹² Ninety-one percent of respondents believed that it is necessary for pharmacists to have knowledge of both CM and conventional medicine to be able to inform patients about their treatment options.

(ii) Inadequate incentives for sponsors to undertake high quality research

The current regulatory system, in combination with the international intellectual property protection regime, does not provide CM sponsors with the same incentives as sponsors of pharmaceuticals to undertake high quality, clinical research to substantiate the claims made by their products. Unlike pharmaceuticals, many CMs are unable to be patented, because their individual ingredients have related traditional medicinal uses and are already in the public domain. As a result, sponsors who undertake research to support their products are not provided with any form of protection for their products over a competitor's products, even if a new extended indication/claim is justified. A competitor may be able to make similar claims about their product without incurring the expense of research. Sponsors thus usually rely on research conducted elsewhere, or a history of traditional use, in the sale and distribution of CMs in Australia. This results in very little Australian innovation in this area, despite extensive potential and opportunities for new product development and validation.

In 2014, the National Institute of Complementary Medicine established an industry Working Group to better understand the impacts upon innovation of the lack of marketplace protection for new research and development (R&D).ⁱ Four key areas of concern were identified by industry that they believe contribute to diminished R&D investment, diminished innovation and consequently poorer evidence development and communication. These include:

ⁱ This Working Group will include observers from the Therapeutic Goods Administration, the Department of Industry and the Advisory Council on Intellectual Property.

1. The approval of novel CM ingredients for use in *Listed* medicines in Australia where those ingredients are currently approved for use in countries with comparable regulatory standards. This approval process is unnecessarily complicated. New ingredients are less readily accessible and hence innovative products not readily developed. For example, one company reported spending \$32,000 on an 18 month project to prepare the data to have sceleitium tortuosum (Zembrin®) approved for use in Australia. Ingredients such as ribose, methylcobalamin and glutathione have been approved for use in Canadian CMs but not in Australian CMs.¹³
2. The R&D required to develop and validate novel ingredients for use in *Listed* CMs is a significant cost. However, competitors can equally access these ingredients once the approval has been provided to the original sponsor. This acts as a disincentive to R&D to develop new products. For example, one company reported spending \$30,000 for a 2 year TGA evaluation of squid oil, after which competitors began making similar products and distributing them in the market on the basis of the first company's research.¹³
3. The R&D required for new claims from existing *Listed* CMs is not readily protected from being copied, or a very similar claim being communicated at point of sale, by a generic product. Industry identified developing a new *Registered* claim, and developing a new *Listed* claim or indication (both based on new research) as areas of concern.
4. The R&D required to develop new *Registered* CMs, where these formulations may be easily copied by a *Listed* medicine using the same ingredients.
5. The R&D required to further support product claims and indications where multiple sponsors are making similar products with relatively weak supportive evidence.

In combination, these two problems (a and b) contribute to a significant evidence-practice gap: the evidence that does exist is poorly communicated to consumers/patients and clinicians (specific claims limitations, dosage, etc); and there is little sector motivation (poor signals) to support the R&D effort to provide greater guidance and clarity around indications and claims.

b. Why is this important?

Australians are among the world's highest consumers of CMs. It is estimated that two out of three Australians use CM.¹ Research undertaken by the NPS in 2007 showed about 90% of general practitioners had recommended at least one CM in the last 12 months and almost all surveyed community pharmacists had recommended some kind of CM over that period.¹⁴

It is difficult, however, for health professionals and consumers to discriminate between CMs at the product level on the basis of efficacy without readily available information. It is not surprising that NPS MedicineWise research has identified a number of gaps in the quality use of CMs among consumers and health professionals.^{9,14} These included a lack of knowledge about the safety and effectiveness of CMs and a lack of awareness of accurate and reliable sources of information on CMs. In particular, there is an absence of information provided for off-the-shelf products at the point of sale.

Moreover, much of CM use occurs in combination with conventional treatment and without the advice of health professionals. A survey performed in 2010 indicates that up to 65% of Australian cancer patients use at least one form of CM,¹⁵ with over half of these patients using CM in conjunction with conventional therapy.¹⁶ A study of Australian radiotherapy patients found that only 40% discussed their use of CM with their oncologist.¹⁷ Similarly, a 2004 survey reported that half (50%) of the respondents who had used CM had taken them on the same day as conventional medicines⁷ and other surveys have indicated that consumers think that this is safe.¹⁸

While research suggests that scientific evidence is not the only important factor affecting CM use, scientific evidence is still material to consumer's decision making process.¹⁰ Australian

surveys indicate that 56.4% of CM users indicated are taking CMs for their benefits.⁹ It would appear that the reliance of consumers upon health professionals, family and friends is suggestive of a need to find evidence of the benefits of CMs particularly in circumstances where scientific evidence of efficacy is not readily available.

IBIS World estimates that Australians spent \$3.8 billion on all alternative health therapies in 2013-14.¹⁹ Within this sector, expenditure on dietary supplements and herbal medicines in supermarkets and pharmacies was approximately \$1.4 billion in 2012.²⁰ There is potential for substantial health benefit, and a reduced burden of private health expenditure, if such expenditure were principally directed to health products with strong evidence to support their use. Some CMs have been demonstrated to be as efficacious as conventional treatment, including the following examples:

- St John's wort for mild to moderate depression²¹
- Omega 3 fatty acids to prevent secondary cardiovascular events in Australia²²
- Calcium and vitamin D supplementation to reduce the incidence and severity of osteoporosis²³
- Chinese herbal medicine for reducing the incidence of diabetes in impaired glucose tolerance.²⁴

Better communication (and hence understanding) of the research evidence and mechanisms of action for CMs would enable clinicians and consumers to monitor the interactions between CMs and pharmaceuticals. While NPS MedicineWise and the TGA currently provide information on the potential interactions between some CMs and prescription medicines such as St John's wort and warfarin, little information is provided more broadly on the range of possible interactions that may occur.

c. Why has this particular gap been chosen?

This CFA seeks to address the systemic challenges with CM use, rather than just one single evidence-practice gap (be that overuse of an intervention without scientific evidence, or underuse of a well evidenced intervention). Addressing this evidence-practice gap will provide greater impact on the quality use of CMs, improving informed and integrated use of CMs, where justified, within conventional healthcare.

In reviewing the TGA's role in the regulation of CMs, the National Auditors' Office (2011) signalled the need to specifically adapt the *Quality Use in Medicines* framework to meet the unique challenges posed by CM.⁵

At present there is no systematic framework for providing consumers and healthcare professionals with access to the information and guidelines they need to make informed decisions about the use of CM. These challenges are also echoed internationally.^{25,26,27,28}

Effectively addressing this evidence-practice gap will assist industry to grow and innovate responsibly, to ensure more relevant and evidence guided use of CMs, and significantly reduce confusion in the community.

2. Any current activity already aimed at addressing the gap, and its efficacy.

There are two principal contributors to the gap in the evidence-based use of CMs:

- The poor level of communication of the research behind each CM product.
- The lack of high quality clinical studies of CM products.

No significant work has been undertaken to date with regard to improving communication of CM product evidence to consumers and health professionals. The authors are not aware of

any existing scheme internationally in the medicines industry to communicate the evidence base of products.

With the support of key industry members, NICM has established an informal industry Working Group that has been undertaking preliminary evaluation and consideration of approaches adopted by other industries to communicate information to consumers about the quality of goods and services. These include the Australian Government supported Health Star System, the Choices Program in the Netherlands and the University of Sydney's Glycemic Index. Although there is a dearth of studies showing the impact of these schemes on purchasing, some research has indicated that the front of package labels may have a positive impact. For example, European research on the Choices Program has shown that people who are health conscious purchase more products bearing the Choices logo and that there is increasing recognition and appreciation of the Choices logo by consumers.²⁹ In the USA, a survey by the Federal Drug Administration indicated that consumers self-reported use of front of package labels; 67% of respondents indicated that they used front of package labels sometimes or often when making food purchasing decisions.³⁰ Sales data has shown significant but small changes in food purchasing data over a period of 2 years following the implementation of the Guiding Stars system of the US retailer Hannaford. In 2006, 24.5% of the items purchased earned a star rating, increasing to 24.98% and 25.89% in the following first and second years.³¹

The potential for initiatives such as these to be applied to CMs has been mooted since the establishment of the 2003 Expert Committee on Complementary Medicines in the Health System after the Pan Pharmaceutical recall.³² However, no firm initiative has progressed.

Some organisations such as NPS MedicineWise provide some consumer information about CMs, which is available on their website. However, this information is ingredient specific, rather than product or formulation specific, which means that consumers are not able to choose between differing products with similar ingredients, possibly different dosages, formulations and extractions. Moreover, this information is not provided at the point of sale. Pharmacists (and consumers) also have access to various computer databases that again provide information on individual CM ingredients, but this depends on consumers requesting this information from pharmacists or accessing these databases (which are not always obvious) at a separate time point to that of purchase.

In its report, the *Expert Committee on Complementary Medicines in the Health System* (2003) noted that none of the 136 indicators being used to measure the implementation and effect of the *Quality Use of Medicines* (QUM) explicitly incorporates CMs.³² The Committee concluded that CMs merit greater attention than they currently receive under the strategy. In addition, the Committee found that there is a particular need to fund consumer and practitioner education initiatives relating to CMs. This role falls within the ambit of the QUM strategy, and should not be left by default to the TGA, with resultant pressure on cost recovery from industry. As a result, the Committee recommended that the Australian Pharmaceutical Advisory Council should facilitate a consultation process with the complementary medicines sector and other stakeholders to clarify the position of complementary medicines in the National Medicines Policy and the QUM. The current *National Strategy for Quality Use in Medicines* (2002) defines a medicine to include complementary medicines. Nonetheless, the principles of the QUM framework are not particularly well applied to CMs. For example, the Australian National Medicines Policy states that consumers and health practitioners should have timely access to accurate information and education about medicines and their use. As noted above, consumers are often purchasing CMs in the absence of such information.

The Australian Government is currently seeking to reduce regulation in the health portfolio and industry has identified the potential for some deregulatory initiatives (access to novel ingredients and facilitating approvals that leverage new R&D) to address the disincentives for R&D investment in CM. Further, on 18 March 2014, the Senate referred an inquiry into Australia's innovation system to the Senate Economics References Committee for inquiry and report. CM industry associations have made submissions to the Senate Economics References Committee. These initiatives may be progressed separately by the Australian Government, NICM or industry associations however, would need to be re-visited within the context of this CFA proposal and their capacity to contribute to minimising the evidence-practice gap.

Overall, while organisations such as NICM undertake a variety of publicly focused research on CM, there is an absence of product specific clinical trials in Australia. These are required to improve evidence based practice and their translation into easily accessible information for health professionals and consumers is vital. This shortfall may be able to be addressed through a range of policy and regulatory adjustments.

3. Any barriers that are currently preventing the translation of the research evidence into policy and practice in Australia, including whether barriers are modifiable and what is feasible for NHMRC to effect change.

The primary barrier is likely to be the inertia on behalf of the industry or government agencies to effect change. Change which results in improved communication of the nature and/or strength of evidence may be met with resistance by the industry sector, unless it is well devised and trialled to ensure more positive than negative impact on the industry and community. There is clearly unsatisfactory evidence communication at point of sale, and this will need to be addressed by a simple and broad mechanism that may be supported by more fulsome data, such as CMI or PI. An additional barrier may be the lack of understanding among consumers about the regulation of CMs and how evidence is generated to support their research.

The barriers are not insurmountable and appear to be modifiable, principally by creating a relatively easily understood system that improves communication of evidence. It is recommended this be developed in collaboration with the TGA, industry associations and appropriate consumer representation. The first step in effecting changes would be for the NHMRC to establish a Working Group to consider options for the model development and testing of a simple approach to communicating the nature of evidence in support of clinical indications and claims. More comprehensive translation of evidence into easily accessible information for clinicians, pharmacists, consumers and other health professionals may follow in a second stage of work (for example, through CMIs, PIs, barcode access to electronic databases by mobile phone, etc) if funding permitted.

The current regulatory system does not provide data protection for research into the efficacy, new uses, new dosage or delivery forms for CMs. In other countries, data protection is provided as a reward for R&D in CMs, preventing companies from copying the formulation and research claims made by the company that has conducted the R&D. Data protection is a means by which a sponsor's data (new R&D) is protected for a period of time from competitors and this includes a subsequent sponsor seeking similar approval for an equivalent therapeutic good. In this context, data refers to the information that a sponsor provides in relation to a therapeutic good when seeking some form of approval for that good under the *Therapeutic Goods Act 1989*. Other jurisdictions, particularly the European Union and the United States, China, have data protection regimes that are quite favourable to sponsors and make Australia's look rather restrictive by comparison.³³

Through some form of data protection, commensurate with the level of R&D invested to support the therapeutic claim, sponsors will be encouraged to invest in R&D if they have the opportunity to gain a return on their investment before competing products enter the market. This is consistent with the recommendations of the 2003 *Expert Committee on Complementary Medicines in the Health System* which recommended that the TGA convene a stakeholder group to identify incentives to encourage innovation and research in CMs including data protection and market exclusivity.³²

4. The health-related benefits that would result if the gap were closed.

This represents the most important initiative in CM that would significantly address the largest evidence-practice gap in this field

Specifically, it will enable more informed and appropriate use of CM, the major concern expressed by all sectors (proponents, sceptics, users, prescribers) in relation to CM. This action would potentially impact all existing and future users of CMs by ensuring greater visibility of more scientifically robust CMs whose evidence is communicated to consumers. This affects 2 in 3 Australians who are regular CM users. As a result, the action would have a broad application across the Australian population.

Clinical indications and claims made by CMs are not trivial and include osteoporosis and bone fractures, childhood bronchitis, secondary prevention of cardiovascular events, aspects related to metabolic disease, dementia and other major Australian national health priority areas.

Improved integration of evidence based CMs may not only improve health outcomes, but impact significantly on health costs national health costs as described below.

5. Cost-effectiveness and/or other economic considerations.

It is estimated that the current Australian expenditure on alternative health therapies is \$3.8 billion.¹⁹ Within this sector, expenditure on dietary supplements and herbal medicines in supermarkets and pharmacies was approximately \$1.4 billion in 2012.²⁰ This proposed action would provide consumers with sufficient evidence to choose appropriate, safe and efficacious products. As this scheme is to be funded from industry, there is minimal impact on government spending. It is unlikely that the scheme will result in a rise in the cost of CMs, given the availability of low cost CMs available via the internet from overseas suppliers that will keep prices low and the multiplicity of other factors that exist in pricing.

While it is difficult to demonstrate precise cost savings from a scheme that has not yet commenced, there are several studies which have demonstrated the potential cost savings presented by CM use for specific health issues. In 2010, NICM commissioned studies to examine the cost effectiveness of specific CM interventions.²² The interventions selected were:

- Acupuncture for chronic low back pain
- St John's wort for mild to moderate depression
- Omega 3 fish oils for the prevention of heart disease among those who have experienced myocardial infarction
- Omega 3 fish oils for rheumatoid arthritis
- Phytodolor®, a proprietary herbal medicine, for osteoarthritis.

While all interventions were considered to be effective, St John's wort for mild to moderate depression, fish oils for the prevention of heart disease among those who have experienced myocardial infarction and Phytodolor® for osteoarthritis were all considered to be cost effective.²²

If costs associated with switching treatments were taken into account in sensitivity analyses (including additional medical supervision and reduce quality of life for patients), St John's wort dominated standard anti-depressants for mild to moderate depression (i.e. St John's wort was both cost saving and also resulted in a reduced disease burden). Savings were calculated to be \$50 million plus 49 Disability Adjusted Life Years (DALYs) per annum.²²

Fish oils were found to be highly cost effective - consistent with other international cost effectiveness studies.³⁴ The incremental cost per person was \$128 per annum and the incremental effectiveness 0.06 DALYs. The cost per DALY avoided was \$2,041. Sensitivity analyses were conducted around treatment effect variables (MI, stroke, revascularisation, CHD mortality and other mortality). The results remained highly cost effective under all of the sensitivity scenarios, evaluated against all the cost effectiveness thresholds.²² Applying the unit cost difference to overall CHD prevalence – estimated as 309,726 people - provided an overall higher cost bound of the fish oil intervention of \$39.6 million per year. The estimated maximum wellbeing gain was 19,424 DALYs averted per annum.²²

The herbal preparation Phytodolor® was also compared with Diclofenac (a non-steroidal anti-inflammatory drug) in the treatment of osteoarthritis. The per person saving in cost was 0.28 per day, or \$102.20 per annum.²² With osteoarthritis estimated to affect 1.74 million Australians in 2009, if all these people used an NSAID such as Diclofenac, then there could be around \$178 million per annum in potential savings from switching to Phytodolor® compared to using Diclofenac.²²

In 2012, the Complementary Healthcare Council of Australia commissioned Deloitte Access Economics to undertake a cost benefit analysis (CBA) of fish oils and estimate the net benefit (or cost) of fish oils as adjunctive treatment for prevention of heart disease among those who have experienced myocardial infarction (MI), versus no fish oils, taking into account the cost per person of the treatment and the DALYs avoided.³⁵ The incremental cost per person was \$128 per annum and the incremental effectiveness was 0.06 DALYs. Incremental costs per person included the additional costs of fish oil supplementation as well as the expected costs per person of the health outcomes (MI, stroke, revascularisation and cardiovascular disease death). Applying a cost benefit analysis, the maximum value of the DALY benefits from the intervention was estimated as \$4.19 billion. The DALY value was monetised using a parameter estimate from the Australian Government Department of Finance and Deregulation (DOFD) for the value of a statistical life year (VSLY), of \$151,000 in 2007, also inflated to 2011-12.

6. Any specific patients or groups of patients particularly affected by the gap, and describe any health disparities, inequities, or impact on vulnerable populations, including Aboriginal and Torres Strait Islander people.

The groups most affected by this proposal are those who have chronic illness and those without health insurance. Research has indicated that the former group use CM extensively for a wide range of reasons while the latter would not be able to afford professional advice from CM practitioners.³⁶

7. Whether addressing the gap would help to advance other aspects of the NHMRC Strategic Plan.

Addressing this gap would assist in achieving the NHMRC Strategic Plan of tackling the lack of evidence around certain health practices where beneficial health claims are made (claiming benefits for human health not based on evidence) In addition, addressing this gap would advance other goals in the NHMRC Strategic Plan such as improving the care of patients with multiple and chronic diseases and focusing on national health priority areas. It is envisaged that the action would also lead to increased investment in R&D within the CM sector, encouraging product innovation and the development of new treatments for medical conditions. Many CMs show considerable promise in treating chronic diseases such as dementia, cardiovascular risk factors, diabetes, and more than 40% of complementary medicine use in Australia is for chronic diseases.

PROPOSED ACTION

8. What action can the NHMRC pursue?

We recommend the consideration, evaluation and implementation of appropriate models to address the two principal barriers contributing to this evidence-practice gap.

We recommend the establishment of two Working Groups under the auspices of the NHMRC or the Department of Health and Ageing focused on addressing each of the key barriers to effective development and translation of CM evidence. The first Working Group would focus on developing a simple and broad mechanism to communicate (the nature of) the evidence of efficacy at the point of sale. The second Working Group would focus on improving incentives for industry to invest in R&D to strengthen and clarify evidence of efficacy. These Working Groups should be broadly composed to include representatives of key stakeholder groups, including the TGA, IP Australia, Department of Industry, ASMI, CMA, NICM, NPS, ANZFA and consumer groups. It would be advantageous to engage with NICM, ASMI and CMA to capture the progress made in these areas since submission of this CFA.

Model development – evidence communication

Improvements in communication of the nature and/or strength of evidence of the product will need to be well devised and tested to ensure a new model delivers a positive impact on the community and industry. The model will facilitate the translation of CM evidence into easily accessible information for clinicians, pharmacists, consumers and other health professionals. The information will be provided for off-the-shelf CM products and be provided on a product, rather than ingredient, basis. Products will have already been approved by the TGA for safety and efficacy and so the model will help consumers distinguish what the evidentiary basis is between products.

In the first instance the most important element to communicate will be the *nature* of the evidence, that is, whether the indications and claims for the CM product are premised on product specific evidence, whether they are based on third party scientific evidence for the ingredients or whether they are based on a tradition of use. These three basic product categories combined with easily comprehensible explanations will provide considerable consumer and clinician guidance with minimal effort and complication.

It is proposed that the model of communication (signalling category of evidence) could be undertaken and delivered by an independent third party to be funded by a minimal 'opt-in' cost to industry, rather than falling to the TGA or another government agency.

More comprehensive translation of evidence into readily accessible information for clinicians, pharmacists, consumers and other health professionals may follow in a second stage of work, and be incorporated for example, through CMIs, PIs, barcode access to electronic databases by mobile phone, etc. However, this will take considerably greater effort and financial investment and require extensive industry support. Ultimately, however, it is expected that the model would employ a trademark logo with an easy to understand grading. Research in other areas (such as nutrition) has shown that simple front of package labels are most easily understood by consumers.³⁷

In consultation with key members of industry, NICM has undertaken preliminary work in this area and has proposed that the following be key features of the model for evidence communication:

- Voluntary
- Independent

- Transparent
- Consumer friendly
- Stakeholder engagement
- Equitable participation.

Voluntary. It is intended that companies would need to ‘opt-in’ to the model in order to provide their product for evaluation. While evaluation of all products in the market place would be ideal for consumers, product sponsors may not support this for various reasons (costs, branding, market segment). It is more appropriate that companies elect to participate in the model, which in itself enables consumers to distinguish between those products utilising the trademark logo and those which have not done so.

Independent. The model would need to operate independently from industry, assuring its credibility. The credibility of front of package labelling systems has been found to be critical to their success.³⁷ Mechanisms will be put in place to avoid and manage any conflicts of interest in decision-making about the model. Funding would be sourced from fees associated with products licensing the trademark logo for advertising and front of package labels as well as with associated databases.

Transparency. The following information would need to be publicly available:

- Logo standards/criteria
- How the model is funded
- Model board members and governance.

It is likely that the model would operate in parallel with the TGA guidelines to ensure that the systems support one another and to minimise the evidentiary burden to be placed upon companies. The model would also need to be protected from copying or gaming. Evidence in food front of label packaging schemes suggests that consumers desire uniform and credible schemes.³⁷

Consumer friendly. The model would be helpful and accessible to consumers who can:

- Easily access published information about which products are endorsed
- Call a local or free-call number for information and to give feedback.

Stakeholder engagement. Broad consultation would be required prior to developing standards and criteria for the model, as is required under international standards (ISO-17065) for bodies operating product certification systems. There would also be education programs for key groups of stakeholders to ensure that the scheme is understood and operated appropriately in practice.

Equitable participation. The fee structures should ensure any sponsor or manufacturer can participate in the model, regardless of size or profits. The fee schedules should be tiered, based on a percentage of sales or a similar structure that caters fairly for producers of different sizes.

Impact studies and implementation – evidence communication

Prior to implementation of any model of evidence communication, sufficient field testing will be required. Specifically, the willingness of industry to participate and the ease of comprehension by consumers and health professionals will be essential targets to meet. Pilot studies would also need to identify ways in which to make the information salient and meaningful to consumers and to correct current discrepancies in understanding about the way in which the regulatory system works. Careful assessment of any potentially negative

impact on either the industry or quality healthcare practice will need to be determined. A managing agency (preferably independent of government) for evidence communication will need to be identified and relevant processes and policy framework initiated, again with significant industry support. The NHMRC would then issue guidelines to industry, consumers and clinicians supporting a better understanding of the evidence-base for CMs which would be accompanied by an education program. The implementation program should be closely monitored and evaluated to ensure success of intervention.

Model development – R&D Incentives

The Working Group would identify the specific barriers to innovation faced by the CM industry in particular in as much as they lead to reduced R&D investment in scientific research, failing to meet evidentiary requirements expected by the community. For each perceived and quantified barrier, potential solutions need to be considered, which may in some instances include a form of marketplace exclusivity to CM products through a sui generis category of confidential data protection. These approaches have already been explored by the current NICM Working Group (2014) which is composed of leading industry associations and key industry members and has had attendance from the TGA, Department of Industry and the Advisory Council on Intellectual Property.

These regulatory modifications, which may in some instances result in deregulation and in others a simple adjustment within the current *Listing* pathways, would reward CM sponsors who develop strong evidentiary support for CMs.ⁱⁱ Some countries currently provide protection mechanisms for scientific data as a reward for successful research investment. China has established this type of protection for traditional Chinese medicines which are manufactured in China and have been included into the national drug standards. Protection terms are between 7 and 30 years. The USA has considerable encouragement for innovation in the self-care product industry. Public Law 98-417 was enacted in 1984 and requires a five-year period of data exclusivity for new molecular entities. Once approved for sale a copy cannot be approved for five years after the innovator. The Act also calls for a three-year data exclusivity period for other types of self-care products requiring clinical trials. The European Union has recognised the need for encouragement for innovation, and in March 2004 the European Parliament and the Council of Ministers signed revisions to pharmaceutical legislation, which include a provision for one year of exclusivity on data used for new indications. Models and regulatory reform initiatives will need to address as many perceived barriers as possible.

The Working Group will also need to examine the R&D tax incentive that was put in place to provide rewards to companies engaged in R&D as well as other schemes that operated in related industries such as the Factor F scheme. It will determine whether there are special circumstances in the CM industry that warrant specific initiatives to benefit both local industry and the health of consumers.

Impact studies and implementation – R&D incentives

Relevant regulatory options would be narrowed down and developed in detail with input from key Australian Government agencies and industry sectors. Impact studies would then be conducted to determine any economic, regulatory and clinical implications in the adoption of lead models. The proposed regulatory reform models could be examined for potential unintended effects which might include risk of anti-competitiveness and other factors. Finally, these regulatory changes would need to be implemented by the relevant agency (most likely TGA), and communicated to industry stakeholders with a view to promoting adoption and adequate transitioning requirements. Once again, the implementation program should be closely monitored and evaluated to ensure success of intervention.

ⁱⁱ Several of these options have already been proposed and are under development with the NICM Working Group.

9. What specific activities and engagements should be advanced by the NHMRC?

As noted above, the NHMRC should work closely with other agencies, including the TGA, NICM and industry associations, to support the process of review that leads to improved evidence communication to patients and health professionals and stronger ongoing development of scientific evidence in the CM sector.

The NHMRC should have an oversight role in addressing the two barriers presented in this CFA, but work closely with the TGA, NICM, ASMI and the CMA. Once the recommendations and models have been piloted more broadly in the community and tested for any unintended effects, NHMRC should ensure adequate community engagement and education, either directly or with partners, to promote sufficient awareness by the community and uptake by industry. It may be appropriate to develop NHMRC guidelines on evidence interpretation relevant to CMs. In addition, the NHMRC may take a direct interest in monitoring outcomes, contributing to potential IT solutions to evidence communication (more detailed product evidence summaries via smart phones and bar codes). The NHMRC may also be interested in health service improvement by encouraging appropriate evidence based integrative care in the growing number of public healthcare facilities which have an interest in supporting appropriate CM use by patients.

10. What are the principal barriers and enablers to implementing the proposed actions and how will each proposed action will address these?

Evidence communication

The principal anticipated challenge to improving accurate communication of evidence of CM product efficacy will be resistance to change within industry. Industry is a key partner in this process. Historically, key members of industry have demonstrated their support for greater research in the sector by committing \$75m in cash and in-kind to a NICM application for a Cooperative Research Centre for Complementary Medicines in 2010. For this reason especially it is strongly recommended that the NHMRC work with industry associations and NICM in the development of potential models, rather than devising and imposing models by a government agency or other party, which may have minimal experience and history of engagement with the CM industry.

An additional challenge will be to determine the most appropriate (and adequate) means of evidence communication to consumers and health professionals to ensure that this evidence forms part of their decision-making criteria. It is strongly recommended that this is relatively simple for industry to adopt and consumers to understand in the first instance. A categorical system that communicates the nature of the evidence supporting the therapeutic indication or claim will be a much easier system to adopt and implement than a complex system that attempts to grade the quality and strength of evidence and this is supported from research in other industries.³⁷ The relevance and strength of scientific evidence that supports therapeutic claims can be explained more fully in accompanying PIs which should also be encouraged through various mechanisms. Most importantly, if the first stage of evidence communication is successful (good industry uptake and community understanding) then the sector will be encouraged to participate in further improvements. It is likely that a rigorous program of education will be needed to both explain the regulation of CMs to health professionals and consumers and the importance of evidence of efficacy in decision-making about CMs.

R&D incentives

The principal anticipated challenges here lie in firstly clearly identifying major real (not only perceived) barriers to research investment, and clearly identifying the easiest routes to resolution of these barriers. Preliminary work by the NICM Working Group has identified five or six potential barriers that are currently being quantified. It appears that some easy deregulatory processes would readily address some of the research disincentives, whilst on or two other barriers would require administrative management by the TGA electronic *Listing* system, but this also appears relatively straightforward. One final barrier may require a stronger form of data protection through minor regulatory reform by the TGA to prevent copying of products with similar claims made by competitors. Testing and implementation of these proposed changes are likely to represent minimal cost to the TGA and industry.

However, in addressing both barriers there will be the need to provide central funding to refine model development or potential regulatory reforms via pilot testing of these schemes. It is envisaged that implementation costs to address both barriers will be minimal. The regulatory changes should be able to be readily adopted by the TGA and the evidence communication model will function best as an 'opt in' approach funded by industry, hence ensuring its acceptance by industry will be critical to its success. Notwithstanding the minimal cost of these improvements, it should be noted that the Australian Government currently collects at least \$140 million per annum in GST from the industry and to date has provided negligible return investment or support to the sector.

It is noted that there is no data on the impact of providing greater incentives for research-based CMs. Nonetheless, anecdotal evidence from industry suggests that partners are interested in investing in CM research including the commitment of a \$75m Cooperative Research Centre bid in 2010. In addition, evidence from related industries such as pharmaceuticals has shown an increase in research impact as a result of programs designed to remove barriers to research and development.³⁸ Moreover, many CMs show significant potential for the treatment of chronic and other diseases such as dementia where current treatments are unavailable, expensive or have significant side effects. Clinical indications and claims made by CMs are not trivial and include osteoporosis and bone fractures, childhood bronchitis, secondary prevention of cardiovascular events, aspects related to metabolic disease and other major Australian national health priority areas.

11. Identify the target for the action and other responsible agencies/organisations that the NHMRC would have to work with to implement the proposal.

The target for the action would be the CM industry, the TGA, NICM, Department of Industry, IP Australia, consumers and health professionals. Key participants on evidence communication would include NICM, ASMI, CMA, as well as some consultation directly with individual CM sponsors. NICM, industry, consumers and health professional bodies would need to be consulted in order to provide information on the differing levels of evidence that support CMs and how to communicate these to consumers. Groups that may be consulted include the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, the Royal Australian College of General Practitioners and the Australian Medical Association. Consumer consultation would also be required. The TGA, Department of Industry, IP Australia and industry associations would need to be engaged in order to ensure the appropriateness or otherwise of regulatory proposals and the capacity to facilitate those changes.

12. Describe the timeframe for implementing each proposal, identifying which are short-term (up to 12 months); medium term (1-3 years); and long-term (over 3 years).

Some preliminary work for these proposed changes has commenced under the auspices of two NICM Working Groups. This preliminary work can be transferred directly to any new responsible agency. It is anticipated development of clear proposals to deal with the two identified barriers can be completed within 12 months and pilot tested within a further six months. Implementation and roll out could be completed in the following 12 months.

13. Outline appropriate evaluation measures and monitoring strategies for the proposed actions.

Evidence communication

The evaluation and monitoring strategies that would need to be adopted include:

- (a) The number (and proportion) of CM products and industry participants that engage in the 'opt-in' model for evidence communication and provide their data for evaluation by the independent agency
- (b) A survey of consumers, pharmacists and clinicians on their understanding of the new model CM evidence communication, and its assistance in guiding informed decisions; and
- (c) Sales figures for CM products in the model when compared to similar products that were not endorsed by the model.

R & D incentives

It is envisaged that the action would also lead to increased investment in R&D within the CM sector, encouraging product innovation and the development of new treatments for medical conditions. The evaluation and monitoring strategies that would need to be adopted include:

- (a) The number of CM product innovations and industry participants that utilise the regulatory changes (e.g. access to new ingredients, TGA IT data protection mechanisms, etc);
- (b) Monitoring of total industry R&D investment (NICM has already completed two national audits); and
- (c) A survey of industry participants with regards to the awareness of regulatory changes, adoption of these processes, and new investment in R&D.

14. Describe any ethical issues that NHMRC's Australian Health Ethics Committee could be asked to address in relation to the proposed actions.

None anticipated.

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Claiming Benefits for Human Health Case for Action - Declarations of Interests

The declarations of interests of Steering Group members, authors and contributors to this Case for Action are listed below.

Name and Role(s)	Interests declared
Prof Alan Bensoussan <ul style="list-style-type: none"> • Steering Group member • Author 	<p>Consultancy fees/honorarium</p> <ul style="list-style-type: none"> • Limited consultancy (5 days per year) to complementary medicine company providing advice on Chinese medicine formulations. <p>Speeches/lectures</p> <ul style="list-style-type: none"> • Frequent presentations on evidence based practice in complementary medicine (CM), the nature of evidence and research methods specific to CM. <p>Expert testimony</p> <ul style="list-style-type: none"> • Recent National Institute of Complementary Medicine submission to Review Committee for Private Health Insurance for Natural Therapies. <p>Other</p> <ul style="list-style-type: none"> • Advocate for better funding of CM research and recognition of relevant evidence. <p>Relationships</p> <ul style="list-style-type: none"> • Director of the National Institute of Complementary Medicine at University of Western Sydney. <p>Activities</p> <ul style="list-style-type: none"> • Advocate for better funding of CM research and recognition of relevant evidence.
Prof Vivian Lin <ul style="list-style-type: none"> • Steering Group member 	<p>Employment</p> <ul style="list-style-type: none"> • LaTrobe University. <p>Board Membership</p> <ul style="list-style-type: none"> • Chinese Medicine Board of Australia. <p>Grants</p> <ul style="list-style-type: none"> • CAMELOT project funded by NHMRC. <p>Speeches/lectures</p> <ul style="list-style-type: none"> • Edited book on evidence-based healthy policy, published by Oxford University Press, and various articles and lectures on the topic. <p>Activities</p> <ul style="list-style-type: none"> • Boards: International Union for Health Promotion and Education, Parenting Research Centre, Centre for Health Economics-Monash University. <p>Employment</p> <ul style="list-style-type: none"> • Taking leave from La Trobe University from late July 2013 and has accepted position with the World Health Organisation in Manila.
Prof Simon Foote <ul style="list-style-type: none"> • Steering Group member • Research Committee contact 	<p>Employment</p> <ul style="list-style-type: none"> • Director, John Curtin School of Medical Research (JCSMR), Australian National University (ANU). <p>Board membership</p> <ul style="list-style-type: none"> • European Molecular Biology Laboratory (EMBL) Australia Council • Scientific Advisory Board, Ramaciotti Foundation(philanthropic organisation) • Chief Scientific Officer, Australian Phenomics Network – National Collaborative Research Infrastructure Strategy (NCRIS) funded organisation • Chief Scientific Facility, Australian Phenomics Facility – part of JCSMR, ANU • Advisory Board member, National Centre for Indigenous Genomics, ANU. <p>Relationships</p> <ul style="list-style-type: none"> • Macquarie University – Adjunct Professor. <p>Ownership</p> <ul style="list-style-type: none"> • Founder and shareholder, Genera Biosystems Pty Ltd- DNA detection biotech company. <p>Direct or indirect pecuniary interest</p> <ul style="list-style-type: none"> • Founder, Murigen Pty Ltd – private biotechnology company. Mouse genetics.

Name and Role(s)	Interests declared
<p>Prof Graham Mann</p> <ul style="list-style-type: none"> Steering Group member Health Care Committee (HCC) primary contact 	<p>Employment</p> <ul style="list-style-type: none"> An employee and a senior academic of the University of Sydney in Sydney Medical school Receives occasional honoraria for lectures, examination of theses and ad hoc committee work. <p>Activities</p> <ul style="list-style-type: none"> Holds unremunerated appointments as a researcher at Westmead Millennium Institute for Medical Research (WMIMR) and Melanoma Institute Australia (MIA), where his laboratories facilities of his research program are located, and where some staff that he supervises are employed. He is a member of the Faculty of WMIMR and is co-director of research at MIA. <p>Grants</p> <ul style="list-style-type: none"> Holds research grants as Chief Investigator from NHMRC, Cancer Institute NSW, NSW Health, the Cancer Council NSW and Bioplatfroms Australia. <p>Direct or indirect pecuniary interest</p> <ul style="list-style-type: none"> Other than as part of managed superannuation funds, has no investments in shares.
<p>Prof Graeme Hankey</p> <ul style="list-style-type: none"> Steering Group member HCC secondary contact 	<p>Relationships</p> <ul style="list-style-type: none"> The University of Western Australia, School of Medicine and Pharmacology Department of Neurology, Sir Charles Gairdner Hospital. <p>NHMRC Grants</p> <ul style="list-style-type: none"> Program: Improving Stroke outcomes; attenuating progression and recurrence Project: Assessment of Fluoxetine In stroke recovery (AFFINITY) National Centre of Research Excellence to improve management of peripheral arterial disease, James Cook University. <p>Honoraria</p> <ul style="list-style-type: none"> Received for serving on: the executive committees of the AMADEUS trial (Sanofi-Aventis), ROCKET-AF trial (Johnson & Johnson) and BOREALIS trial (Sanofi Aventis); the steering committee of the TRA 2 P-TIMI 50 trial; the stroke outcome adjudication committee of the ACTIVE-W, ACTIVE-A, RE-LY and AVERROES trials, and for speaking at sponsored scientific symposia and consulting on advisory boards for Bristol-Myers Squibb, Boehringer Ingelham, Bayer and Pfizer Australia.
<p>A/Prof Matthew Cook</p> <ul style="list-style-type: none"> Steering Group member 	<p>Grants</p> <ul style="list-style-type: none"> NHMRC Program and Project grants. <p>Speeches/Lectures</p> <ul style="list-style-type: none"> Novartis Annual Neuroscience Meeting in September 2011. <p>Other</p> <ul style="list-style-type: none"> Advice provided to the clinical governance framework for intravenous immunoglobulin use conducted by Ernst and Young (for the NBA). <p>Relationships</p> <ul style="list-style-type: none"> Wife works at the National Blood Authority.
<p>Prof Henry Krum</p> <ul style="list-style-type: none"> Steering Group member 	<ul style="list-style-type: none"> Nil interests to declare.
<p>Mr Anthony McBride</p> <ul style="list-style-type: none"> Steering Group member Prevention and Community Health Committee (PCHC) primary contact 	<p>Board membership</p> <ul style="list-style-type: none"> Chair, Australian Health Care Reform Alliance (AHCRA). <p>Direct or indirect pecuniary interest</p> <ul style="list-style-type: none"> Co-owner/Director of 'Community Owned Primary Health Enterprises' (COPHE), assisting NGOs to develop primary health care services. Co-owner/Director of Tanjable PL, providing strategic planning, program review, consultation and facilitation services to NGO sector. <p>Consultancy fees – honorarium</p> <ul style="list-style-type: none"> Consultancy fees from Tanjable and COPHE \$500 p.a. honorarium from AHCRA.

Name and Role(s)	Interests declared
<p>Prof Mark Harris</p> <ul style="list-style-type: none"> • Steering Group member • PCHC secondary contact 	<p>Employment</p> <ul style="list-style-type: none"> • Professor of General Practice, Scientia Professor, Executive Director Centre for Primary Health and Equity, University of NSW. <p>Board membership</p> <ul style="list-style-type: none"> • Member of the Board of Directors of Inner West Sydney Medicare Local. <p>Grants</p> <ul style="list-style-type: none"> • Chief Investigator (CIA) on NHMRC Partnership Project with National Heart Foundation, Royal Australian College of General Practitioners, BUPA Foundation • NHMRC Senior Principle Research Fellowship on prevention and management of chronic disease in primary health care • Centre for Research Excellence (CRE) Obesity prevention and management in PHC (COMPaRE-PHC) - funded by Australian Primary Care Research Institute in collaboration with University of Technology Sydney, University of Sydney, University of Adelaide, University of Queensland and Deakin University • Investigator on CRE on Access to Primary Health Care for Vulnerable Population Groups. Grant funded by Australian Primary Care Research Institute and Canadian Institutes of Health. <p>Consultancy fees – honorarium</p> <ul style="list-style-type: none"> • Consultant on BUPA self management guides - Provide review of patient self management guides prepared Healthwize for BUPA. Reimbursed for time. Funds paid to UNSW.
<p>Ms Syvilla Boon</p> <ul style="list-style-type: none"> • Author 	<ul style="list-style-type: none"> • Nil interests to declare.