AIMA's Response to TGA Draft Evidence Guidelines for CM Products

AIMA believe it is vitally important that they, as well as other practitioner associations, are involved in the consultative document on the new proposal on TGA guidelines for CM products. We further believe that the proposal is likely to generate various legislative, academic and industry opinions and arguments, however, in the instance of professional CM/IM (Complementary Medicine/ Integrative Medicine) prescription it is the practitioner, doctor or otherwise, who is at the coal face of guiding genuine CM/ IM (as opposed to self-prescriptive) usage amongst the public (as our patients).

Issues we wish to raise in reference to the proposed guidelines are as follows:

1. Of most significance, the proposed CM guidelines represent significant changes to CM/IM practice in Australia **without any staged approach to implementation.** As shall be highlighted by further comment, this is of critical significance if we are to encourage a fluid transition towards the vital professionalization of the industry.

2. **AIMA sees the proposed CM guideline as an ideal position to be worked towards. However, we do not see it as a workable model over the short and intermediate period.** Such a model, if implemented in a single phase, would risk major disruption of CM/IM supplies that may critically injure the industry and detract from, rather than assist, the professional usage of CM/IM prescription.

3. It is acknowledged that many CM products may not meet the present level of evidence required by the proposed guidelines, however, these same products are often used safely and successfully by clinicians who have vast experience with such products accumulated over time in primary care.

   Contrary to the arguments of many present academics, this gap in evidence does not indicate improper prescription, rather that the pace of accumulated biochemical and physiological evidence as applied to pathophysiology infers clinical usage of nutrients and herbs at a rate that far exceeds the scientific communities ability to conduct research.

   Similarly, the vast compendium of traditional medicines that require scientific evaluation also need to be considered, although it is understood that a level of acceptance may be achieved within the current proposal according to the Traditional Evidence (Level 5) category.

   The question that needs to be asked is, will these proposed guidelines negate the vast clinical experience that is available on the use of products that have not as yet, been able to be fully researched?

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It is emphasised that absence of evidence DOES NOT imply absence of benefit and that there is a limit to the applicability of available research to present clinical applications of CM/IM.

We therefore need to respect this evidentiary gap in research and build this into any model proposed for CM/
IM product regulation. Science rarely outpaces clinical insight in CM/IM due to the limited research grants available, even if biochemical and physiological research usually drives the hypothesis applied successfully in clinical care.

4. AIMA proposes, therefore, that an **interim guideline position** needs to be developed to accommodate for the lag between clinical hypothesis backed by experience of safe and efficacious results at the practitioner-patient level and the evidentiary level proposed by the guidelines.

   One means to achieve this may be via a secondary level of regulatory clearance, that being a **Clinician's Evaluation Panel**, somewhat like the current CMEC or QUM. The role of such a panel would be to valuate the clinical usage of products that presently lack clinical evidence but have been found to be safe and effective by experienced non-industry aligned health-care professionals.

5. Such a regulatory approach may also clarify the usage of 'Practitioner Only' titles for CM/IM. It is suggested that such an evidentiary approach would only apply to products that are formally registered with a 'Practitioner Only' title or that have been independently recommended by a suitable qualified non-aligned professional. This would empower the use of 'Practitioner Only' with a list of criteria to increase the professionalism of CM/IM prescription. This is an issue dealt with in the 'Protection of Prescription Rights' Position Statement which is available from our AIMA Office.

In effect, this would apply two levels of acceptance of product according to TGA listing:

- **Full evidentiary support according to an expert panel.**
- **Clinical evidentiary support pending progression to full evidentiary support.**

  It would further be proposed that the second tier of TGA acceptance be instituted on the condition that such a product would be expected to evolved to a an evidentiary level within an appropriate time frame that allows appropriate research to be undertaken and results to be finalised.

6. Such a two phased approach would have numerous advantages in transiting the current low evidence requirements towards the ideal position recommended by the current proposal:

   1) Prevent the possibility of a sudden reduction in the availability of all CM/IM products, a concern raised by industry and already cynically welcomed by some anti-CM campaigners.

   2) Ensure a professional transition in CM/IM regulation guided not only by legislators and academics, but clinicians with a vast experience in the individual application of CM/IM. Respected healthcare practitioners with an emphasis on clinical experience should be sort to take on the evaluation role.

3) Encourage a situation in which clinical hypothesis can be driven by practitioners rather than solely academics /industry with the ultimate aim to pass all CM/IM through adequate evidentiary research evaluation.

4) Allow high quality practitioner providers to spread their cost of regulation over an extended period while encouraging research to progress product to a full compliance category.

5) Inform the public as to the level of evidence, fully researched, clinical or otherwise of a supplemental product.

6) Allows for meaning to be placed on the 'Practitioner Only' label that empowers the practitioner. This is critical in the instance of CM/IM use within an integrated framework in which CM/IM products are used simultaneous with alterations in pharmaceutical medicine usage. The full implications of this are beyond the scope of this proposal but vital to the safety of the public who use CM/IM.

7. The length of any transition phase between current guidelines and what is eventually proposed must account for the lengthy period required to not only evaluate present available evidence, but to undertake comprehensive clinical trials to demonstrate safety and efficacy where an absence of the same presently exists. This phase should furthermore take into consideration that many corporations have multiple products and cannot be expected to develop evidence for all existent products simultaneously. Efficacious medicine should not be limited by the financial limitations of corporation. New CM/IM guidelines should in no way bottleneck the availability of high quality existent CM/IM products in such a way that it will impact on the current care provided by practitioners to the public.

8. Irrespective of the guidelines ultimately legislated, such guidelines must not lead to a market in CM/IM that distorts the public's use of CM/IM towards:

1) Unregulated internet access for parallel products removed from the market or made disproportionately cost effective in comparison to products authorised through TGA processes.

2) Poorly regulated products shifted onto 'Food labels' to avoid legislative processes.

3) Individually compounded herbal formulations (liquid extracts, dry herbs etc) that cannot be regulated at the site of practice.

4) Industry providers that choose to circumvent industry standards via pragmatic ploys such as frequent re-titling of product. Each of the above CM/IM access methods to the public impose obvious dangers to the purchasers such as:
1) No claim regulation
2) No assessment of product quality
3) No education of client at the point of sale to risk and side effect profiles.

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9. This implies that there should also be:

1) An undertaking to regulate internet access to CM/IM parallel to these guidelines otherwise the guidelines will be practically counterproductive. In the current global environment the implications are obvious; if professional CM/IM products are restricted or heavily priced due to the cost of high evidentiary standards, the public will logically turn to the above 4 methods of bypassing guidelines in order to access their desired CM/IM product.

2) Means of sanction for each of the above methods of bypassing TGA guidelines.

In the absence of a meaningful means of regulation and sanction of CM/IM, AIMA believe there is genuine risk of danger rather than benefit in instituting any overly rapid approach to CM/IM regulation.

10. AIMA requests an appropriate acknowledgement of all contributors to the proposed document with a full declaration of conflict of interest in order to establish transparency in the TGA process regardless of the outcome. This not only includes industry, academic and legis**lative affiliations, but in the present medicopolitical environment, associations with any societies that may have a positive or negative position on CM/IM in general.**

In summary, AIMA fully acknowledges that the present guidelines of CM/IM remain less than adequate and, furthermore, that the proposed guidelines are an ideal to be worked towards in the future. However, as demonstrated, we would also like to see a fluid transition in the manner in which TGA regulation of CM/IM evolves. Integrative practitioners work in a clinical environment dependent upon CM/IM prescription to benefit the specific needs of our patients. This is a position that has independent challenges to that of regulation, academia and, indeed, industry preferences that we strongly believe needs to be taken into account by any proposed TGA regulation.
Any proposed alterations in TGA guidelines must take into consideration the need not to fracture the current CM/ IM environment in the pursuit of an optimal and idealistic position, that, on the contrary may be not only highly disruptive to patient care, but, indeed, dangerous and counter-productive. The vision of the proposed document is respected, however, the manner of implementation and time frame, we believe, needs to be carefully re-assessed.

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Attachments

1. **AIMA Position Paper - AIMA and the Complementary Medicines Industry**

2. **2013 AIMA Sponsorship and Advertising packages**

3. **AIMA's Response to TGA Draft Evidence Guidelines for CM Products**

4. **AIMA Position Paper - The Protection of Prescription Rights in Integrative Medicine**

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AIMA

AIMA and the Complementary Medicines Industry

The Australasian Integrative Medicine Association (AIMA)

The Australasian Integrative Medicine Association (AIMA) is an independent not for profit organisation of individual medical practitioners seeking to provide whole person medical care by integrating evidence-based complementary medicine into mainstream practice. AIMA is supported by its membership and governed by a Board of voluntary doctors and academic leaders in the field of integrative medicine.

Since its inception in 1992, AIMA has grown to be the leading voice for integrative practitioners. AIMA's membership and successful events, including the International Holistic Health Conference, have helped promote the growing body of research and provide education about complementary medicines and therapies.

AIMA and the Complementary Medicines Industry

As the peak body representing medical doctors and other complementary medicine (CM) professionals, AIMA believes it has a vital and evolving role in liaising with the Complementary Medicines Industry, particularly in assisting with the continued availability and, indeed, growth in use and quality of safe and efficacious evidence based products specific to the needs of clinical groups.

We believe that it is vital, if Integrative Medicine is to truly integrate into the mainstream, that a standardised industry regulation is adopted for the use of complementary medicines, particularly when prescribed in conjunction with pharmaceutical medicines and other allopathic interventions in order to ensure ongoing safety and efficacy.

It is therefore vitally important that increasing communication and development occurs between industry and professional bodies within IM/CM to ensure this professionalism evolves and, where it already exists, is made transparent through appropriate networking and media liason to the political, medical and wider community. AIMA sees that this is critical if the current divide between mainstream and IM/CM is to be overcome such that CM usage continues to expand as appropriate to evidence for its usage.

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AIMA and Complementary Medicine Supplementation

Nutritional and Herbal Supplementation is a core interest of most IM doctors and other CM practitioners and, most obviously, the Complementary Medicines community. However, the use of nutritional and herbal supplementation when used by professionals for specific clinical groups has, of itself, unique issues that are most important not only to IM/CM practitioners, but the view of IM/CM by wider bodies of interest.

As is now well documented, drug-herb-nutrient interactions can occur when pharmaceutical and CM prescription are administered simultaneously. While accepting the reality of this, AIMA is also well aware of the disproportionate media coverage of such risks compared to pharmaceutical medicines and the danger such media presents to the image of IM/CM in the environment.

For the medical doctor (and the CM practitioner who has an established relationship with a medical doctor) in particular, simultaneous usage of pharmaceutical and CM is a fine tuned and diligent process as it is provided on a professional rather than ad hoc basis. The medical doctor needs to know at all times how a patient is using CM and its relative influence on both the patient's condition and level of pharmaceutical usage. The Complementary Medicines Industry must be aware of the critical importance of professional prescription of specific CM therapies in combination with specific pharmaceutical medications.

AIMA therefore believes that it is essential that codes of contact in the use of CM supplementation in conjunction with pharmaceutical medicines are established to address this vital issue. Unfortunately, unlike pharmaceutical prescriptions, there is no ability to manage quality prescription, product substitution and/or change of patient's condition in the current environment which both endangers the patient and the wider viewer of the professionalism of CM. For a broader discussion of the issues see AIMA's Position Statement, The Protection of Prescription Rights, attached.

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'Practitioner Only' Supplementation

To address this situation AIMA strongly believes in a consistent regulated use of the 'Practitioner Only' title when administered by IM/CM practitioners such that it is more than an arbitrary catch phrase. The sub-set of products called 'Practitioner Only' should therefore adhere to a regulated single standard across the industry otherwise a continued degradation in the meaning of the term will make it meaningless and potentially dangerous in the future.

This categorisation should entitle a broad range of definitions that include:

- Product only to be prescribed by a qualified healthcare practitioner
- Prescribed only after a thorough assessment with a defined minimum of retained documentation
- Documentation of prescribed pharmaceutical medication(s) and potential risks of interactions with any new CM products prescribed – both being identified and communicated to the patient at the time of consultation
- Minimum reassessment of the patient regarding change of medical condition and pharmaceutical prescription accompanied by appropriate documentation when supplement is re-supplied.
- That the prescribing/providing healthcare practitioner shall take on the full extent of medico-legal responsibility regarding any CM product supplied to a patient.

AIMA, Retail Supplementation and IM Education

AIMA is fully supportive of the retail community as the main product interface with the CM consuming public. We believe in the continued increase in the standards of the community in supplying high quality scientific and standardised CM products to the public for preventative healthcare needs, and, where applicable, the treatment of simple health conditions as paralleled by the use of readily available over the counter pharmaceutical medications.

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Furthermore, we are fully supportive and, indeed, willing to assist in any educative programmes that increase the knowledge and qualification of retail providers of CM therapies. Such education should emphasise not only the efficacy and safety, but also the limitations and risks in the use of CM, particularly in consumers with complex medical conditions for which they are consulting medical doctors or CM practitioners and especially in the instance of the integrated use of pharmaceutical medicines.

AIMA and the Therapeutics Goods Administration (TGA)

AIMA believes it has a key role as an interface between the medical profession, the Complementary Medicines Industry and the TGA. AIMA has recently provided submissions to the TGA in regards to proposed industry changes and several of our members are currently associated with aspects of the TGA governance process.

AIMA believes it is vital for both the IM community and Complementary Medicines Industry that we continue to advocate to the TGA that a reasonable and graduated progression of the industry towards quality regulated products based on evidence and risk is undertaken.

However, we are also aware that this needs to be a graduated evolution that respects the specific and pragmatic medical, social, financial etc. factors unique to the Complementary Medicines Industry. In fact, it is vital in our view that a key and often missing position in the continued debate of CM availability to the public is the medical doctor/other healthcare practitioner voice as a practical interface between the roles of policy makers, academia and industry.

AIMA is fully supportive of communications and networking with the Complementary Medicines Industry in order to progress the professionalism and policy position of the IM/CM industry and look forward to ongoing communication in this regard.

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AIMA and Clinical Research Trials

Many AIMA members work in multidisciplinary practices conducive to undertaking pilot trials in IM/CM. An interest has been voiced by many AIMA members in undertaking such pilot trials to assist with providing evidence of CM within the clinical environment. Furthermore, AIMA is in the process of developing a relationship with a consortium of University level clinical researchers to progress the evidence behind IM usage including CM products. Indeed, this is one of the reasons behind AIMA's development of the Consortium of Academic Health Centres in Integrative Medicine-Australasia.

AIMA and its members are excited with the possibility of increased participation in clinical research in the future. We also believe that we have an important role in highlighting to policy makers/other important bodies, such as the NHMRC, the importance of increased funding for research in conjunction with the CM industry to clarify the often controversial view of CM perceived by mainstream medical, policy and media bodies.

AIMA also believes that we play an important role in guiding relevant CM research due to the experiential knowledge of its members in the practical application/ integration of CM products.

The Future of AIMA and the CHC Industry

AIMA looks forward to the continued growth and evolution in the IM/CM industry. We consider it vitally important if IM/CM is to continue to evolve, adapt and ultimately integrate into the mainstream that our professionalism, evidence of efficacy and safety also comply to the reasonable expectations of policy makers and the public.

We therefore look forward to developing close relationships with the Complementary Medicines bodies (eg. CHC, ASMI etc) and individual members of these bodies that share our vision.

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In particular, we believe that AIMA can assist with:

- The continued development of standards, regulation and codes of conduct within the Complementary Medicines Community
- Policy and position statements in favour of CM usage
- Communication with the TGA regarding the support of CM usage within a framework of reasonable graduated progress towards increased TGA regulation upon evidence based standards
- Assistance with advocating clinical efficacy in the use of CM within an IM framework where an absence of current high quality scientific evidence exists in regards to particular CM products.
- Networking to establish pilot projects within the clinical settings of our member's IM practices
- Providing key opinion leaders to assist with product development and/or staff education as appropriate

Attached :

TGA Submission June 2012

AIMA Position Paper 2012 : The Protection of Prescription Rights

Corporate Sponsorship Package

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AIMA POSITION PAPER: THE PROTECTION OF PRESCRIPTION RIGHTS IN INTEGRATIVE MEDICINE

The interest in Integrative Medicine in Australia continues to grow, both amongst patients and doctors alike. Supportive evidence for the use of such supplementation has also developed as indicated by evidence based texts such as *General Practice: The Integrative Approach* (Kerryn Phelps and Craid Hassad) and *A Guide to Evidence-based Integrative and Complementary Medicine* (Vicki Kotsirolos, Luis Vitetta, Avni Sali).

With the development of such evidence and usage it has become increasingly important to establish the nature of the prescription of complementary medicines when made upon evidence based lines by doctors. Given that complementary medicines may be used simultaneously with pharmaceutical medicines, guidelines for prescription protection by the treating doctor need to be developed, given the retail availability of many nutritional and herbal supplements to the public.

While it would be ideal that any supplement prescription made by a doctor would meet the same level of content protection as pharmaceutical prescription (given the concern for mutual drug-herb-nutrient interactions), various differences in the provision of supplements in compare to pharmaceutical medication makes this far less likely at present.

Issues include:

- The common availability of many competing complementary products that may or may not meet the standards of nutrient/herb formulation/compounding/extraction required by the doctor. In a far less standardised environment in complementary medicine the integrative doctor is often required to make an intensive review of product formulation in order to establish which supplement best serves the unique needs of the patient, both in content and quality. Thus it would appear critical for both the efficacy and safety of supplementation that the product supplied to the patient is exactly that which has been prescribed, rather than simply an apparently similar product.
- There unfortunately is at present no specific regulation to assert that any provider of prescribed supplementation need necessarily provide the specific prescription recommended by the doctor. It is a common experience of integrative doctors that when a product is accessed without direct supervision or a process of regulation, that variations in prescription regularly occur, often risking both potential gains and, on occasion, side effects to the patient's health.
- It is difficult for the doctor to substantiate the training level of a nutrient/herb provider, outside of any direct professional relationship that has been established. Furthermore, unfortunately there is no standardised requirement for training in complementary medicines as applied to either retail or chemist based sales.

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- The dangers present when an initial prescription by an integrative doctor is carried on past the time frame in which the doctor intended, without further follow up. In the instance of pharmaceutical medicines, the limited number of repeats and ultimate time frame in which a prescription is valid limits the patient's risk of continued usage after a change in condition might suggest an alternative approach may apply. However the common availability of nutritional supplements and herbs prevents a limit from being set on the time frame supplementation may be used for prior to any necessary review. This endangers the patient from using supplements when they are no longer appropriate, or, more importantly, after a change in condition or treatment in which previous nutrient/herb recommendations are no longer appropriate or even contraindicated by present condition or treatment (for example, in which a patient's depression has persisted after an initial trial of St John's Wort, and medical treatment is altered to an anti-depressant, contraindicating the ongoing use of this herb).

These points highlight the necessity that a formal and consistent policy towards prescriptive protection as applied to doctors providing complementary medicines needs to be formulated to avoid the aforementioned risks. While the current standards for pharmaceutical dispensing provide some guide to the establishment of prescription standards, the different environment that presently exists between the sale of pharmaceutical and non-pharmaceutical complementary medicine suggest other means of monitoring safe use of complimentary medicines need to be established.

These may include;

- Integrative prescriptions should be provided to all clients with clear indication of product usage, no different to that provided for chemist supplied pharmaceuticals. Importantly such issues as exact product prescribed, dosage, daily usage and the time frame for which the prescription applies should be clearly indicated.
- It should be clearly noted on any prescription pad that the prescription is invalidated in the circumstance of a change of medication or condition, unless further consultation is made with the prescribing doctor.

- Understanding with both retailers and chemists must be sort to establish that integrative medical prescription by a professional, in the case that they supply the supplement provided, must be to the exact letter of the prescription. This includes all issues of product, dosage, daily usage and prescription validity date. In all instances the provider would need to establish that no change in medical condition or medication has occurred to warrant an immediate review of the prescription by the prescribing doctor.

- Any professional, chemist or retailer who provides products independent of that prescribed by the doctor must also establish that the nutrient or herb is appropriate for the patient and communicate that decision to the doctor in question. The choice to retail or prescribe also comes with the responsibility of ensuring safety to the patient. Responsibility cannot simply be assumed by an integrative doctor because they are simultaneously supplying integrative medicines.
- Any retailer/chemists providing a prescribed nutritional/herbal supplement for a specific medical condition (rather than for lifestyle benefits) should keep records of provision to the standards kept by medical professionals. In the absence of such records it would appear a risk to integrative doctors that they would assume all responsibility for the patient's complimentary health choices, irrespective of whether or not the information was provided by themselves, a retailer, chemist or otherwise.
- Retailers/chemists choosing to supply complementary medicines to people with any specific medical condition should have an appropriate level of indemnity insurance to provide protection for any injury, illness or otherwise to that person as a result of their provision.

- Practitioner Only Supplementation is an industry term which implies the restriction of particular nutrient/herb formulations to the usage of qualified integrative practitioners. However this would appear a loosely used term that needs to be further clarified as to what is required for a practitioner/professional to qualify to prescribe to a customer/patient.

  Examples of clarification required include such questions as:

  1. Does walking into a shop manned by a naturopathic practitioner or otherwise qualify a customer to access Practitioner Only Supplements simply by fact of the retailer being a naturopath?
  2. What training constitutes a practitioner in nutritional/herbal/complementary therapies [should massage therapists, chiropractors, physiotherapists/ nurses etc have access to supply]?
  3. What standard of care constitutes a practitioner assessment in terms of assessment and follow up?
  4. What are the documentation requirements in supplying Practitioner Only products?

- Without clarity on this issues it would not appear that the term 'Practitioner Only' lends any weight to protecting the prescription of a practitioner. This is an area in which national standards, whether under the guidance of the CHC, ASMI, TGA, AIMA, ACNEM or otherwise, should be developed in order to sustain and improve upon the provision of effective complementary medicines.

- The presence of an onsite dispensary at integrative medical practices at the location in which a prescription is made would appear to be advantageous to prescription protection, allowing ongoing monitoring of prescription compliance. Communication of side effects, problems, condition changes etc are far more likely to be professionally managed onsite than relying on communication at a distance to identify and rectify any patient-doctors concerns. Furthermore the ethics of sale of any product would suggest that the safest point of sale is at the point of most knowledge, which would certainly appear the medical practice.
- The Position Statement on the Sale of Complementary Medicines by Integrative Doctors can be found at the AIMA website. This, certainly, would need to be balanced to ensure that the patient is not coerced into purchase at the site, allowing any undue profit to be procured from vested interests. The patient must always feel free to purchase elsewhere according to their presently valid prescription, yet this would appear no different to any other medical practice in which full financial disclosure is required, patients are billed for equipment used during a service or, for that matter, pathology, testing or surgical needs.

Much of the professionalism, efficacy and safety of nutritional/herbal medicine supplementation is dependent upon the protection of prescription made by the integrative doctor/professional. With this is mind it is therefore essential that high standards of prescriptive administration are established to ensure this is evident. The sale of complementary medicines, as highlighted in this statement, occurs within a different set of parameters to that of pharmaceutical medicines.

Most pertinently it is the practitioner (in particular, the doctor, if pharmaceuticals are co-administered) who holds both the expertise and evidence to administer any supplement, and ultimately the responsibility, come what may, unlike pharmaceutical medication in which under our current structure the doctor delineates much of this role to the pharmacist (few of which have any training in evidence based integrative medicine). This logically implies that the more closely linked prescription and provision of supplementation, the greater the safety and efficacy of the use of complimentary medicines will be, protecting both the public and medical professionals of all kinds, alike.