AIMA

To: Dr Jenny Doolan
TGA Medicine Labelling and Packaging Review
labellingreview@tga.gov.au
TGA Labelling and Packaging Review
PO Box 100,
Woden ACT 2606

21TH August 2012

Dear Jenny

RE: TGA Medicine Labelling and Packaging Review Consultation Paper

Version 1.0 May 2012

Thank you for the opportunity to comment on the proposed regulatory changes in relation to Medicine Labelling and Packaging.

ABOUT THE AIMA

The AIMA is an independent not for profit organisation of individual medical practitioners and allied health practitioners seeking to provide whole person medical care by integrating evidence-based complementary medicine (CM) 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 (IM). Since its inception in 1992, AIMA has grown to be the leading voice for integrative practitioners.

AIMA has forged relationships with key organisations such as the Royal Australian College of General Practitioners (RACGP) and the Australian Medical Association (AMA), as well as other professional bodies with an interest in integrative therapies. Currently AIMA is recognised as a specific interest group and works closely with the RACGP via a Joint Working Party and through the Integrative Medicine Network. AIMA hopes to improve the understanding, evidence and risks associated with the use of CMs by health practitioners.

AIMA seeks to ensure both practitioners and consumers have access to the best available knowledge about the benefits and risks associated with these modalities so that optimal patient care and good health can be achieved and maintained, and to ensure proper informed consent for use of these therapies.

AIMAs objectives include to:

- Promote the practice of evidence based integrative medicine
- Act as a peak peer body for medical practitioners
- Maintain the role of the medical practitioner as the primary care provider whilst working in a multidisciplinary team of other health providers
- Collect and circulate research and other information relating to the mainstream and complementary medicine profession to members
- Encourage the practice of ethical non-pharmaceutical approaches when appropriate
- Act as an advisory body to government and medical bodies in the formation of policies relating to IM
- Promote improvements or changes in the law relating to medical practice where appropriate
- Develop position papers and contribute to policy development on various issues related to CM

TGA Medicine Labelling and Packaging Review Consultation Paper

Thank you for the thoughtful work by the TGA in re-evaluating Medicine Labelling and Packaging. We wholeheartedly agree with all the proposed changes as outline in the document (Appendix A). We believe the proposed changes will help reduce risks, adverse events and confusion that consumers may experience.

We also believe that the Review is an opportunity for the TGA to consider a secondary level of regulatory assessment of AUST L Complementary Medicine products that have not been as yet been assessed for efficacy but have been found to be safe. Assessment of efficacy for these products can be done by a Clinician's Evaluation Panel, somewhat like the current Advisory Committee on Complementary Medicine (ACCM) or a Quality Use of Medicine panel, to

identify those products that have an evidence base (but are still Listed) and those that would be suitable for 'Practitioner Only' use to increase the professionalism of CM/IM prescription. This has been raised and discussed in AIMAs submission to the TGA DRAFT EVIDENCE GUIDELINES FOR CM PRODUCTS (attached Appendix B). Review of packaging can consider this information on labels to help consumers identify those that are evidence based supported by some level of scientific evidence, and to improve safety of some of the products when prescribed and dispensed by registered health practitioners.

We hope our suggestions and comments are of help to the TGA.

With kindness

Dr Vicki Kotsirilos	**Professor Kerryn Phelps**	**Dr Lily Tomas**
GP, Past President AIMA	GP, President AIMA	Vice President, AIMA

Attachments:

Appendix A : TGA Medicine Labelling and Packaging Review Consultation Paper - AIMA response to questions

Appendix B : TGA EVIDENCE GUIDELINES FOR CM PRODUCTS

Appendix A

TGA Medicine Labelling and Packaging Review Consultation Paper AIMA response to questions

Prominence of active ingredients on medicine labels

General questions on the proposed regulatory changes for the prominence of the active ingredients on medicine labels

What do you think will be the impact of increasing the prominence and standardising the location of the active ingredient on the medicine label? POSITIVE

What do you think about the proposed warnings for paracetamol and ibuprofen containing products? Yes agree with TGA proposed changes.

Are there any other concerns you have with the size or position of brand names and active ingredient? NO

If the active ingredient name is clear, directly below the brand name and in a large font, what are the additional benefits that you see by making it the same size as the brand name? AGREE with TGA listed benefits.

What is the smallest size font that you consider readable? 3mm

Look-alike and sound-alike medicine brand names and look-alike packaging and branding

General question on the proposed regulatory changes for look-alike sound-alike names and look-alike packaging

Do you think the proposed changes to address LASA names and LA packaging will improve medicine safety? Yes agree with TGA proposed changes.

A good example is Cold and Flu tablets. There are multiple brands of Cold and Flu tablets, some containing pharmaceuticals and others containing Complementary

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Medicines. It is not uncommon for consumers to confuse one brand over another posing great risk to the person.

Why/why not? Need clearer labels to differentiate brands with different ingredients. TGA should ensure no same brand names.

General questions on the proposed regulatory changes for look-alike medicine branding

What benefits, if any, do you think the proposed changes to address look-alike medicine branding will have for consumer safety? Avoids purchasing of wrong brands and reducing risks eg taking wrong medication, interactions and adverse events.

Do you understand the proposed changes? Yes agree with TGA proposed changes.

If you can read the labels and warnings clearly, will these changes reduce the potential for harm? YES

Standardised Information Format: the Medicine Information Box

General question on the proposed regulatory changes for Standardised Information Format: Medicine Information Box
To what extent do you think a standardised format for information on the labels of over-the-counter and complementary medicines will improve access to information for these medicines? Empowers consumers and

raises awareness especially if labelling can indicate which AUST L products are evidence based.

Are there other ways that the presentation of information could be improved? Include excipients such as propylene glycol, lactose and gluten on product labels.

Do you think the proposed requirements for products with more than three active ingredients (directions and warnings and allergy information), is sufficient for these

products? No, many Complementary Medicine products have more than 3 active ingredients, so these would also need to be listed.

Please propose an alternative if you don't agree with current recommendation. A pack insert flyer may be necessary to include extra information.

Dispensing label space

General question on the proposed regulatory changes for dispensing label space
Do you support a designated space for the dispensing label on prescription medicines? Yes agree with TGA proposed changes.

Blister strip labelling

General question on the proposed regulatory changes for blister strip labelling
Do you think the proposed information for blister strips is sufficient? NO when a product contains more than 3 ingredients eg Complementary Medicines

Small containers
General question on the proposed regulatory changes for small container labelling
To what extent do you support the proposed changes for small container labels? Please provide details. We agree with TGA proposed changes.

Pack inserts

General question on the proposed regulatory changes for pack insert requirements
Do you support the proposed changes for pack inserts? Yes agree with TGA proposed changes.
Do you have any further suggestions regarding pack inserts? Pack inserts may assist for more information to be included, especially Complementary Medicine containing multiple ingredients.

Labels and packaging advisory committee

General question on the proposed establishment of a labels and packaging advisory committee
To what extent do you think that a Labels and Packaging Advisory Committee will assist the TGA to manage consumer health risks associated with medicine labels and packaging? Enormous benefit to help assess labelling on current products and any new products before they reach the market. A committee can help assess product information to ensure they meet TGA guidelines.

AIMA

Appendix B

TGA DRAFT EVIDENCE GUIDELINES FOR CM PRODUCTS:

PRESENT POSITION OF THE AUSTRALASIAN INTEGRATIVE MEDICINE ASSOCIATION

The new proposal on TGA guidelines for CM products has recently been released with a short time frame for assessment. The Australasian Integrative Medical Association (AIMA) wishes to make additional comment on this proposal, and in the instance that written consultation is closed, would like to request immediate face to face meetings regarding our input on this issue.

AIMA believe it is vitally important that they, as well as other practitioner associations, are involved in the consultative document. 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**.

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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?

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 Advisory Committee on Complementary Medicine (ACCM), or Quality Use of Medicine. The role of such a panel would be to evaluate the clinical usage of CM AUST L 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:

1) **Full evidentiary support according to an expert panel.**
2) **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.

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 legislative affiliations, but in the present medico-political 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.

Thanking you,

Yours sincerely,

Professor Kerryn Phelps

AIMA President

Dr Lily Tomas

AIMA Vice-President

21st August, 2012