Consultation submission cover sheet

This form accompanies a submission on:

The document 'Evidence Required to Support Indications for Listed Medicines (excluding sunscreens and disinfectants)'			
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Phone	(02) 9922 5111	Email	steve@asmi.com.au
☒ Yes ☐ No	I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)* All documents except the ASMI cover letter are to be treated as confidential and must not be published. Due to the unreasonably short timeframe for consultation none of our submitted documents have been properly screened for errors or sensitive materials. The preliminary RIS responses do contain sensitive information.		
☐ Yes ☒ No	I would like my name to be removed from all documents prior to publication and not be included within the list of submissions on the TGA website. *(Please strikethrough whichever is not applicable)*		

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, a: (*tick all that apply*)

Business in the therapeutics industry (please tick sector):

☐	Prescription Medicines	☒	OTC Medicines
☒	Complementary Medicines	☐	Medical Devices
☐	Blood/Tissues	☐	Other

☐	Sole trader	☐	Business with employee(s)				
☐	Importer	☐	Manufacturer	☐	Supplier	☒	Industry organisation
☐	Government			☐	Researcher	☐	Professional body
☐	Consumer Organisation			☐	Institution *(e.g. University, hospital)*		

☐ Healthcare Practitioner - please indicate type of practice

☐ Other (please specify):

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The Project Officer
Office of Complementary Medicines
Therapeutic Goods Administration

By email to: ocm@tga.gov.au

25 May 2012.

Dear Sir/Madam

Invitation to comment – Evidence required to support indications for listed medicines

The Australian Self Medication Industry (ASMI) thanks you for the opportunity to provide comment on the Therapeutic Goods Administration's approach to updating the 'Guidelines for levels and kinds of evidence to support indications and claims'.

About ASMI

The Australian Self-Medication Industry (ASMI) is the industry body for the Australian self care industry representing consumer healthcare products including over-the-counter medicines and complementary medicines. ASMI represents companies involved in the manufacture, distribution, import and export of non-prescription consumer healthcare products. We estimate that our members' combined turnover is about $3bn per year.

ASMI's mission is to promote better health through responsible self-care. This means ensuring that safe and effective self-care products are readily available to all Australians at a reasonable cost. ASMI works to encourage responsible use by consumers and an increasing role for cost-effective self-medication products as part of the broad national health strategy.

Overview of ASMI's Response

ASMI is fully supportive of reforms that would enhance the regulatory framework for complementary medicines to maintain credibility and public confidence in these products.

However, we must inform you that ASMI cannot accept the proposed guideline in its current form as it fails in several respects which we outline below. We also put forward the outlines of an alternative model. It was not possible to fully develop this model but we would be keen to meet with you to discuss it in more detail.

ASMI's key issues:

1. Consultation process

We must state at the outset that our response is of a preliminary nature.

The consultation document was released on 23 April and the consultation period closed on 25 May (i.e. a review period of only 23 working days).

This is wholly inadequate to prepare a meaningful response to the 61 page consultation document. A meaningful response requires a thorough review of the proposal, an accurate identification of all the issues, consultation with our members, the collation of industry feedback and the synthesis of a response which accurately reflects the views of industry.

On this point we note that the consultation document is extremely detailed, deals with a complex topic and proposes significant changes.

Not only does ASMI strongly object to the inadequate timeframe allowed, we wish to register our disappointment that the ASMI request to (reasonably) extend the deadline to 8 June was rejected by the TGA.

Consequently, our response is incomplete and cannot be said to accurately identify all the issues or to accurately reflect the views of industry.

2. Guiding principles to address regulatory failure

ASMI endorses the COAG Principles of Best Practice Regulation and is disappointed that the principles have not been applied to this proposal.

In our assessment of this consultation we have concerns in relation to the following COAG principles:

- A range of policy options have not been considered and costed (principle 2)
- The proposed changes have not been shown to provide the greatest net benefit for the community (principle 3)
- Competition will be restricted without the benefits of the proposed change having been shown to outweigh the costs and without the proposed change being shown to be the only option available (principle 4)
- Effective guidance has not been provided (principle 5)
- Mechanisms have not been proposed to monitor the proposals for relevance and effectiveness (principle 6)
- Effective consultation has not been incorporated (principle 7)
- Actions have not been shown to be effective and are not proportional to the issue (principle 8).

We encourage the TGA to adopt a risk-based approach to this issue. Listable complementary medicines are at the lower end of the risk continuum and any regulatory intervention should be consistent with that level of risk.

ASMI encourages the TGA to consider all options before making such important changes. If a regulatory intervention is warranted then it should be the minimum effective regulation commensurate with the risk.

Additionally, the TGA should not seek to develop requirements specific to Australia and should instead seek to harmonise with appropriate international jurisdictions and standards.

Disproportionate response: The requirements laid out in this proposal are excessively onerous, overly complex and impractical, and appear to be equivalent to or higher than those for registered over-the-counter medicines. We consider them inappropriate for listed medicines which are low-risk by definition and which are permitted to carry only low-risk indications.

Ineffective response: Without increased and effective enforcement activity, the proposal will have little or no effect on non-compliant sponsors. In contrast it will have a major adverse impact on those sponsors who do comply with the requirements. In response to this excessive regulatory burden, smaller Australian sponsors may be forced to close down because of increased costs, other sponsors may be tempted to move products offshore, for online purchase, or de-list products and present them as foods.

Any new guidelines should be accompanied by increased and effective monitoring, enforcement and sanctions.

Harmonisation: The requirements of the proposed guideline appear to be at variance with those of comparable regulators such as Health Canada. The Baume report (1991) recommended that Australia reflect global practices rather than set up a distinctly different set of Australian regulations.

If respected authorities such as governments, WHO and the Cochrane collaboration have already produced well-constructed and robust assessments and systematic reviews, it would seem unnecessary for sponsors or TGA to repeat the process over and over again. This is of particular concern in the absence of any compelling argument that an Australian system needs to be more demanding than other comparable systems.

Any new guidelines should align more closely with other comparable jurisdictions and standards.

Principles-based guidance: the legislated standard should be principles-based, concise and straightforward. Additional guidance and reference material should be adopted by reference.

Please see *Attachments 3A, 3B and 3C* for examples prepared by industry for inclusion within the Australian Regulatory Guidelines for Complementary Medicines (ARGCM).

Guidance material on the application of the guideline should be adopted by reference. Industry recommends that this guidance material be incorporated into the ARGCM.

3. Aims of reforms

The stated aims of this proposal are to improve compliance with regulatory requirements by providing greater clarity and certainty for sponsors. Any guidance document should also be user-friendly and practical. However, instead of improving the clarity of existing requirements, the proposal is overly complex and prescribes inappropriate and much more onerous requirements.

Lack of clarity - Inappropriate and ineffective response: The overall readability of the document is not user friendly and is overly complex.

4. Context within the broader TGA Blueprint for reforms

Lack of context: Industry is aware that the TGA is working on a number of reforms affecting complementary medicines, including the Coded Indications project, labelling, transparency and advertising. As these have yet to be circulated for consultation, industry has been forced to consider the draft evidence guideline in isolation from these critical components of the full reform package. This renders it impossible for industry to assess the real-world impact of the full package and to deliver to the TGA a fully informed response.

The current regulatory reform projects, including labelling, coded indications and evidence requirements need to be coordinated so that sponsors can incorporate all necessary changes at the same time.

5. Specific concerns about the proposed guidance document

Please refer to a detailed analysis of the draft guideline prepared by ASMI and CHC at *Attachment 1.*

Inappropriate expert requirement: We believe that the summary of evidence should be judged on whether it meets the stated requirements, not on whether it has been prepared by a prescribed 'expert'. In this regard, the TGA has proposed an overly prescriptive qualifications profile that is out of step with available credentials across the industry. It is the sponsor's responsibility to appoint a suitably qualified person to perform this role.

ASMI encourages the TGA to consider the ramifications of such a prescription. By specifying the qualifications necessary to perform a particular role within a sponsor's organisation, the TGA will be in effect regulating employment within the industry, an area which is well outside the TGA's jurisdiction.

Inappropriate reporting requirements: The proposal appears to require the preparation of a full systematic review of every ingredient and/or every indication for every product. Sponsors of multi-ingredient products would be severely affected by the cost burden of preparing such reviews, without apparent benefit to the regulator, the industry or importantly the Australian consumer. The requirement of full and systematic review for every indication is excessively onerous and should be deleted.

Complex algorithms: the requirements to prepare complex algorithms, and to calculate clinical significance based on theoretical and untested methodologies, are inappropriate for low-risk medicines. Requirements for algorithms and clinical significance calculations should be removed.

Not straightforward: Requirements should be clearly spelt out and not added in as examples only.

Advisory Statements: There is no place for advisory statements in a guideline for evidence. Rather, these should be included in RASML.

Indications vs claims: The proposal fails to clarify the distinction between an indication and a therapeutic claim. If these are to be treated differently, they should be clearly explained.

Structure and function statements: the proposal fails to consider the use of widely accepted evidence, such as pharmacopoeias and government publications, to support generally recognised claims, such as structure / function statements. The use of acceptable scientific reference works to support these claims should be clearly laid out.

RDIs: the proposal fails to clarify the dose, ie the percentage of RDI, required to permit a vitamin or mineral to carry claims. As the majority of claims for these ingredients are based on accepted reference works rather than clinical trials, there is no direct relationship between the evidence and a supplementary dose. We request the reinstatement of the 10% and 25% levels to support structure-and-function and supplementation claims, respectively.

References: The proposed list of reference sources (Appendix 1) has not been updated or expanded to include currently available authoritative works. The list of references should be updated and expanded. Provision for the use of acceptable reference works and systematic reviews should be added. We have provided an expanded list of references for consideration in *Attachments 4A and 4B.*

6. Impact on industry

We have provided preliminary information on the effects on industry, to be considered in the Regulatory Impact Statement at *Attachment 5.* Due to the unreasonably short timeframe for response, we stress that this data is far from complete.

7. Transitional arrangements

Appropriate transitional arrangements are critical for industry to ensure minimum disruption to business. While it is premature to consider the details of transition arrangements in the absence of an agreed reform package we anticipate that, given the magnitude and complexity of reforms in this area, that a minimum of 5 years would be an appropriate transition period.

Once agreement has been reached on the details of the reform package industry would be in a better position to assess the impact of changes and the time required to transition to new arrangements.

8. Alternative model

Within the limited time available ASMI and CHC have developed the outline of an alternative model for the requirements for evidence held by sponsors, including templates. (Refer to *Attachments 2 -4)*. Please note that this draft is incomplete due to the inappropriate time provided for full and proper consultation with our members; and so requires further work.

Our alternative approach is for a simple, clear and concise legislative entry to underpin the requirement that the sponsor hold appropriate evidence to support all indications and therapeutic claims for a medicine.

The legislative entry would deal with the guidance documents by reference only: that is, that the evidence held must meet the standards specified, and be provided in an acceptable format, as laid out in the current version of the ARGCM. This approach would give legislative underpinning to the evidence requirements while allowing the guidance document to be amended and updated as necessary, in consultation with stakeholders.

We have provided draft models of the standards of evidence appropriate to different types of claims and indications; model templates; and a model guidance section for incorporation into the ARGCM. Due to the time constraints, it must be again stressed that these are incomplete, preliminary and untested drafts.

9. Suggested way forward

ASMI remains committed to work with the TGA to develop solutions which will achieve the stated aims of the reforms. We seek an urgent meeting with the TGA to discuss how we could work together to develop a practical proposal which satisfies the requirements of the regulator, improves compliance and meets consumer expectations.

Please note that members and staff of ASMI and CHC have invested approximately 150 person-days into this response, demonstrating our willingness to engage fully in the development of an effective and appropriate standard.

We thank you again for the opportunity to make comments on this draft guideline and look forward to further discussions in the near future.

Yours sincerely,

Steve Scarff
Regulatory and Scientific Affairs Director

Attachments

Attachment 1: Detailed Comments from Industry on the Draft Guideline.

Attachment 2: Industry's alternative model for the guideline.

Attachment 2A:	Proposed guidance to support scientific evidence
Attachment 2B:	Proposed guidance to support traditional evidence

Attachment 3: Industry's model for the guidance materials for the ARGCM.

Attachment 3A:	Proposed model for the guidance material in the ARGCM
Attachment 3B:	Proposed Product Summary Template
Attachment 3C:	Proposed Evidence Summary Template

Attachment 4: Associated Appendices.

Attachment 4A:	Proposed list of scientific evidence reference sources
Attachment 4B:	proposed list of traditional evidence reference sources

Attachment 5: Anonymised preliminary RIS data.

Attachment 5A:	Anonymised preliminary RIS data (ASMI Member 1)
Attachment 5A:	Anonymised preliminary RIS data (ASMI Member 2)
Attachment 5A:	Anonymised preliminary RIS data (ASMI Member 3)