Consultation submission cover sheet

This form accompanies a submission on:

The document 'Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants)'	
Name and designation	Dr Wendy Morrow, Executive Director
Company/organisation name and address	Complementary Healthcare Council of Australia
Contact phone number	02 6260 4022

I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)* The cover letter to the submission can be made a public document. XXXXXXXXXXXXXXXX	☒ 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.	☐ Yes ☒ No

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 ☒ Complementary medicines ☐ OTC medicines

☐ Medical devices ☐ Blood, tissues, biological ☐ Other

☐ Sole trader ☐ Business with employees

☐ Importer ☐ Manufacturer ☐ Supplier ☒ Industry organisation

☐ Government ☐ Researcher ☐ Professional body

☐ Consumer organisation ☐ Institution (e.g. university, hospital)

☐ Regulatory affairs consultant ☐ Laboratory professional

☐ Health professional – *please indicate type of practice*:

☐ Other - *please specify*:

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

Comments

An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
Please see attachment 6 to this submission.
Whether or not you support the revised Evidence Requirements. If not supported, please provide reasons why.
Please see industry submission for areas of continued concern.
Any additional information on issues not asked in the above questions. If your comments relate to specific parts of the document please provide the page number and reference.
Please see attachment 2 for a track changed version of the consultation document.

If you would like to be kept informed about TGA activities, please subscribe to one of the TGA's email lists <http://www.tga.gov.au/newsroom/subscribe.htm>.

Submission on the draft guideline: Evidence required to support indications for Listed medicines (excluding sunscreens and disinfectants).

To:

Office of Complementary Medicines

Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

ocm@tga.gov.au

From:

Dr Wendy Morrow

Executive Director

Complementary Healthcare Council of Australia

PO Box 450

MAWSON ACT 2607

Date:

Monday, 22 October 2012

Introduction

Thank you for the opportunity for the complementary medicines industry, through the Complementary Healthcare Council of Australia (the CHC), to provide comment on the revised consultation document *'Evidence Required to Support Indications for Listed Medicines (excluding sunscreens and disinfectants)*', version 2.0 August 2012.

The Australian Complementary Medicines Industry is proud of the benchmarks it sets in global regulatory standards and sees consumer safety as a key priority. Therefore, whilst we remain fully supportive of reform that strengthens the regulatory framework to maintain consumer confidence in these products, we will not support increased regulation without proper basis.

Regulation without an appropriate risk framework that is cognisant of the COAG Principles is unlikely to achieve its objectives and will simply result in impediment to market and excessive bureaucratic burden on an already highly regulated industry.

In particular, whole market segments will be decimated without the benefits of the proposed change having been shown to outweigh the costs.

There is no evidence that shows that the proposal presented is the only option available; in fact, to the contrary, simply providing better guidance to industry (as recommended by the ANAO), plus appropriate penalties and sanctions (as recommended by the ANAO) would provide the greatest net benefit for the consumer and would be a response proportional to the issue seeking to be resolved.

Additionally, there is no evidence that any COAG Principles of Best Practice Regulation have been considered as the basis for addressing the specific, perceived 'regulatory failure' that initiated this review.

Whilst the CHC acknowledges the removal of the requirement for an Expert, as outlined in the original consultation document; most other requirements outlined in the first draft remain virtually unchanged.

The CHC reiterates its previous calls for appropriate review and updating of the Guidelines for the Levels and Kinds of Evidence for Complementary Medicines.

Specific Concerns

1. Inclusion of the Evidence Requirements in Regulation

The CHC recommends the requirements for evidence held by sponsors to support indications for Listed medicines be principles based and as concise as possible.

The Blueprint Reports Informal Working Group on Complementary Medicines (CM IWG) Rec 3 was to Update '*Guidelines for levels and kinds of evidence'* and include '*Guidelines for levels and kinds of evidence*' in regulation. This recommendation received In-principle agreement from government with further consultation to be undertaken.

The CM Industry believes that a simple, clear and concise legislative entry to underpin the requirement to hold appropriate evidence to support indications for Listed medicines is appropriate. The legislative entry should refer to the principles of the evidence requirements (Part A) and these should be as clear and concise as possible. The CM Industry proposes rewording of Part A as per attachment 1 to this submission. This legislative entry should require that the evidence held meet the standards specified, and be provided in a form described in the Australian Regulatory Guidelines for Complementary Medicines (ARGCM), (currently under review), or equivalent mechanism to provide the same standard of outcome.

Guidance regarding the fulfilment of the requirements should be included in the revision of and related appendixes to the ARGCM. This approach would give legislative underpinning to the evidence requirements and the guidance document would provide an interpretation on listing compliance. This would also allow guidance to be readily amended and updated, in consultation with industry, as necessary.

2. Sources of Established Evidence List

The CHC recommends the SEE List at Attachment 3

The list of Sources of Established Evidence (SEE) is not adequate to support the current proposal. The sources outlined in the SEE have differed in both revisions, with no explanation of the methodology used for the selection or rejection of sources. There has been a lack of transparency regarding the publication and subsequent withdrawal of the July

2012 version (V 1.0b TRIM R12/940495), where SEE differed considerably from the current proposal. The CHC proposes the expanded list of sources of evidence, which updates that previously provided in May 2012 (see attachment 3) and provides consideration for homoeopathic references at attachment 4.

3. Mechanism for Additional SEE

The CHC recommends a clear and efficient mechanism for the addition to the SEE List

The list of SEE should be included as an appendix to the ARGCM, to allow for efficient review and addition. Rather than restricting sponsors to texts only on the list, the CHC recommends that there be a reference appendix that includes a "quality" check list, this would provide transparency and guidance on what the TGA deems to be required in a reference to allow it to be considered an acceptable SEE reference.

A clear process for the addition of SEE to the list is essential for industry. The CHC recommend that a sponsor should be able to propose an SEE text and gain provisional acceptance. Justification of inclusion should be required to take into account the principle requirements outlined in part A (industry version) and any guiding points outlined in the ARGCM.

Increased Bureaucratic Burden

Current TGA reforms will increase the bureaucratic burden on compliant sponsors. The CHC continues to have strong concerns that without increased and effective enforcement activity, the proposed changes will have little to no effect on non-compliant sponsors.

Robust, Ethical Industry

Regulatory reforms that prevent compliant sponsors from placing product in the market will:

- **drive consumers toward on line off-shore purchases;**
- **distort consumer use of CMs;**
- **increase prices and therefore decrease cost effectiveness; and**
- **drive sponsors to (1) move products off-shore for on-line purchase (2) delist product ranges and re-present as (non-compliant) foods.**

Without effective deterrents non-compliant sponsors will enjoy even greater market advantage and objectives of the Blueprint will not be accomplished.

Context

The CHC recommends the evidence requirements finalised before progressing the Coded Indications Project

The industry has expressed concern around progressing the evidence guidance in isolation to parallel reforms such as the Coded Indications project and Labelling consultation. In particular, the CHC notes that the progression of the Coded Indications project is running concurrently but separately from the consultation on *'Evidence required to support indications for listed medicines*'. It is important to bear in mind that the regulatory processes in relation to these projects are interrelated. This is acknowledged in the TGA reforms: A Blueprint for TGA's future (the 'Blueprint') where the IWG Rec. 4 states that the review of the current coded indications project will be based on the revised '*Guidelines for levels and kinds of evidence*.' It is therefore critical for industry to be able to consider all proposals for change in context of the whole reform package.

Evidence Report

The CHC recommends that the format and content of the evidence report is the key factor

The removal of the independent expert requirement is underpinned by the fact that the format and content of the evidence report is the key factor, not who writes the report. Therefore, the CHC does not support the requirement of listing the designation, relevant qualifications and experience of the report's author. The importance here is that the indications, labelling and claims are all consistent with the evidence and that the evidence may be from either an SEE or from an appropriately conducted review. The CHC strongly supports that where evidence is obtained via a review, that evidence should be robust and representative of the body of evidence.

Nutrients and Nutrient Supplementation

The CHC recommends that the requirements of the current guideline are maintained to assist consistency and transparency

The draft guideline includes a substantial increase to the percentage of RDI, adequate intake or nutrient reference value for that vitamins/minerals/ nutrients, from 25% to at least 50%, in relation to statements supporting supplementation. This proposed change would have an

unsubstantiated and unjustified impact on existing products in Industry. The CHC recommend that requirements of the current guideline are maintained to assist consistency and transparency. Please see suggested wording at attachment 2.

Weight loss

The CHC recommends that the comments in Attachment 4 be adopted

While the consultation document acknowledges the benefits of weight loss, the draft sets the criteria for scientific assessment at unattainable levels and no existing research on Listable complementary medicines would be acceptable to the TGA as supporting evidence for a weight loss indication.

The CHC can not support the parameters proposed by the TGA in relation to weight loss and stress that it should be the responsibility of the person reviewing the evidence that the evidence for a product supports the specific weight claim for the product. Additional comments at attachment 4.

Studies involving specific cohorts

The CHC recommends that the requirements allowing the use of clinical trial evidence be broadened

This section is detailed under the heading general factors – health status and outlines characteristics of biomarker ranges (healthy reference range) for relevant study populations. The table on page 37 can not be supported by industry in its current form. The ranges specified, as a percentage beyond the normal range, are so restrictive that they can not allow for the generation of evidence to support indications for listed medicines. Even considering the continuum between health and disease, researchers are unwilling to invest time and money in research on healthy populations.

Alternate approaches should be considered in this regard that taken into account the proposed Food Health Claims reforms and the increasing un-level playing field the CM industry faces. The CHC is keen to continue exploring options around this area to ensure the sustainability of the CM industry.

Coordinated approach – Transition

The CHC recommends that a transition period of a minimum 5 years is required

A transition period of a minimum 5 years is required for reform of this type of magnitude, and impact on industry. This period will allow all of industry to review and re-list their product ranges. The current regulatory reform projects, including Labelling and Coded Indications, need to be coordinated with that of the evidence requirements so that Sponsors can incorporate all necessary changes at the same time.

Conclusion

The Attachments listed below are provided as a component of this submission and provide more detailed comment on specific areas. The CHC strongly recommends that consideration be given to and action be taken on:

- **Attachment 1**
  Revision of Section A;
- **Attachment 2**
  Detailed analysis of the guidance, as prepared by the peak industry associations;
  Further review of the guidance in consultation with industry as part of the phased ARGCM review;
- **Attachment 3**
  Revised SEE list;
- **Attachment 4**
  Deficiencies in relation to weight loss;
- **Attachment 5**
  Deficiencies in relation to homoeopathic references;
- **Attachment 6**
  Preliminary information on the effects on industry to be considered in the Regulation Impact Statement (RIS).

The CHC thanks you again for the opportunity to make this submission. The CHC will continue to work proactively in providing feedback to the TGA on key guidance documents, including the priority update of the ARGCM and appropriate Evidence Guidelines for Listed Medicines. The CHC encourages a closer examination of the intersection between evidence based-industry focused research and robust policy development to achieve lasting outcomes that will provide for improved population health.

Yours sincerely,

Dr Wendy Morrow
Executive Director
Complementary Healthcare Council of Australia