



## **CMA Submission to TGA on Consultation Draft TGO 79 Standards for the Labelling of Medicines**

Submission to:  
TGA Medicine Labelling Consultation  
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Complementary Medicines Australia (CMA) welcomes the opportunity to provide a response to the Therapeutic Goods Administration on its consultation draft TGO 79 - general requirements for medicine labels, dated August 2014.

CMA represents all stakeholder groups in the complementary medicines industry. Our members include importers, exporters, manufacturers, raw material suppliers, wholesalers, distributors, retailers, practitioners, consultants, direct marketers, multi level marketers and consumers.

CMA supports that the purpose of the medicine label, for complementary medicines, is for the information on the label to continue to be presented in such a way that a consumer can:

- a) choose an appropriate medicine on their own**
- b) use the medicine safely and effectively**
- c) readily find the information they need, understand it and act on it appropriately**
- d) access further information, if they want to know more about the medicines**

CMA provides the following comments in relation to the TGA consultation document:  
*Regulatory Impact Statement - general requirements for labels of medicines.*

1. The RIS document outlines that in order to prevent confusion and accidents such as overdosing, under medicating or medicating with the incorrect medicines that are associated with unclear labelling of medicines, the requirements for a change to labelling aims to ensure that labels of medicines supplied in Australia provide healthcare professionals and consumers access to information on the medicine including active ingredient name and in the case of over-the-counter medicines, proper and safe usage.

CMA supports the above aims of the review to the Labelling Order and reiterates that the promotion of medicines should be done in a manner that supports proper and safe usage.

However, CMA's overall impression of the proposed changes to the labelling of medicines is that it is largely based on the risk profile associated with prescription and registered over the counter medicines. The extra regulatory requirements for labelling and packaging of complementary medicines are considered to be out of proportion to the risk classifications of these medicines.

The consultation paper aims to highlight that due to 'lower risk' medicines being available for self selection, this factor alone poses a risk as the consumer receives no additional information except the instructions on the label. Indeed, while this highlights the importance of the information on the medicine label, no evidence has been provided that the proposed changes will contribute to provision of better consumer information and safety. A change to the amount of active ingredients that can be included on the front of the medicine label and an increase in font size for homeopathic medicines, for example, will have little affect on consumers self-selection.

Sponsors of listed medicines are already required to certify that the medicines meet a range of requirements. In particular, they must certify that:

- **the medicine is eligible for Listing;**
- **the presentation is not unacceptable;**
- **the medicine is safe for the purposes for which it is to be used; and**
- **evidence is held to support any claim made in relation to the medicine.**

Listed medicines may only make limited therapeutic claims and are not permitted to include substances that are scheduled in the Poison Standard. Consumers can identify these lower risk medicines by the presence of an 'AUST L' number on the medicine label.

We reiterate that during the consultation process no evidence of harm has been presented to indicate a change required to the way in which low risk listed complementary medicines (including homeopathic medicines) are labelled. We therefore do not support imposing [subsection 9(6)(b)] and maintain that for listed complementary medicines the current TGO 69 requirement should be retained, which states for particulars to be included on the main label except:

3(3) b - where there are *two or more* active ingredients that are vitamins or minerals or that are required to be quantified as the equivalent fresh or dry weight or volume under sub clauses 4(11)(b) or 4(11)(c) – it shall be sufficient compliance with this sub clause if the names and quantities or portions of these active ingredients together with the names and quantities of every active ingredient in the goods are included on the side panel or side label or on a rear panel or rear label.

By imposing [subsection 9(6)(b)] would mean a requirement to go from two or more active ingredients to four or more active ingredients that may be declared on a side panel/label or rear panel/label. This would increase the regulatory cost for these low risk listed medicines without any evidence of consumer benefit being presented.

- 2. The Labelling Order, as a legislative instrument, will be legally enforceable by the TGA under powers provided by the *Therapeutic Goods Act 1989*. The labelling Order is supported by best practice principles outlined in the *Australian Regulatory Guidelines for Complementary Medicines (ARGCM)*.**

Aspects of the proposed Order could arguably be seen to be open to a level of interpretation. For example, that the name of the medicine on the main label must be presented in a continuous, uninterrupted manner and not be broken up by additional information, logos, background texts, or graphics.

The CMA considers any requirements that could be open to interpretation should not be included in a legislative instrument that is legally enforceable, rather it should be articulated clearly in best practice guidelines.

CMA supports that the current mechanisms in place for the labelling and packaging of complementary medicines are sufficient to promote the quality use of these medicines by

consumers. CMA supports that the current labelling requirements of TGO 69 be maintained for listed low risk medicines, including homeopathic medicines.

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CMA provides the following comments in relation to the TGA consultation document: *Therapeutic Goods Order Standard for the labelling of medicines*.

#### **Transition arrangements (4) 1**

The possible transition options proposed to stakeholders includes a two, three or four year transition period. The RIS document details that the new labelling Order would be a one-off cost for those business that would not be changing their labels during the transition period.

CMA highlights that there are many small owner-operator complementary medicine business that would not generally be in the practice of changing their medicine labels every few years as indicated in the RIS document. The 2014 industry survey participants included larger CM company representatives and is only indicative of that sector of the industry. Specifically, the RIS did not look at the fact that smaller companies would employ the skills of professional consultants to carry out the work required to ensure compliance with the new labelling Order. This cost factor alone, for changes proposed to low risk listed medicines is considered an unnecessary additional regulatory burden that would not necessarily equate to any consumer self-medication benefit.

CMA submits that based on the governments announcement for an independent expert review into the regulation of medicines, including complementary medicines, which is due to commence the second quarter of 2015, that the focus of the TGA be one of reducing the regulatory burden, enhancing efficiencies in existing process whilst upholding the safety and quality of complementary medicines available to consumers. For these reasons CMA submit that we may seek an extension over and above the proposed 3-4 year transition period for any changes that proceed outside of the independent review.

#### **General requirements, including label presentation [7 (2)(d)]**

CMA supports that for listed medicines there has been no change in font size from the current requirement of not less than 1.5 millimetres (equivalent to a font size of 6 point Arial)<sup>1</sup> and that the font size for the AUST L number is maintained at 1mm height.

The current print requirement of not less than 1.5 millimetres letter height is to be replaced with a general requirement that label text must be displayed in a size not less than the equivalent of 6 point Arial (unless otherwise specified). This requirement addresses both the height and width of the characters. The TGA are to interpret the acceptability of fonts by superimposing the labelling text in the font chosen by the sponsors onto the text in Arial.

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<sup>1</sup> Font size detailed on page 15 of *Regulation impact statement: General requirements for labels for medicines*

- **That the name of the medicine be on three non-opposing sides of the carton – [8 (r)].**

It is proposed that where the medicine is packaged in a primary pack that is a carton, the name of the medicine, as defined, must appear on at least three non-opposing sides of the carton. CMA does not support that the label of a complementary medicine be on three non-opposing sides of the carton. This proposal is intended so that medicines can always be stacked so that the name is visible and as such is addressing an error that can occur in prescription medicine dispensing and should not apply to listed or registered complementary medicines as they are not displayed in a dispensing setting.

#### **Information to be included on the main label Section 9**

- **The name of the medicine on the main label must be presented in a continuous, uninterrupted manner and not be broken up by additional information, logos, background text or graphics – [9(2)].**

The CMA does not support such a requirement for complementary medicines and considers that it is open to a degree of interpretation and as such should not be included in a legislative instrument that is legally enforceable. Rather it could be included in best practice guidelines.

CMA provides an example at the attached appendices (page 1 & 2) that demonstrates a current registered complementary medicine that *may* have an interrupted name and as such may be required to change labelling, though with a common sense approach may continue to be considered perfectly acceptable.

- **Subject to sub section (7), the active ingredient(s) and the quantity or proportion of active ingredients must be identifiable in relation to the other material on the label (whether required under the Order to be included or otherwise). Including through the choice in type size, font type or colour of the name of the active ingredient(s) and the quantity or proportion of the active ingredient(s) and of the other material – [9(5)]**

Due to the lack of applicability and number of active ingredients in complementary medicines, CMA does not support such a requirement be imposed. To include a requirement in relation to ingredients being 'identifiable' in relation to other material on the label through the use of font size, type or colour, is open to a level of interpretation and as such should not be included in a legislative instrument that is legally enforceable, rather for lower risk medicines it could be included in best practice guidelines.

- **If the medicine is intended to be, or is, listed goods:  
b) If there are four or more active ingredients in the medicine – the name of every active ingredient, together with the quantity or proportion of every active ingredient, may appear on a side panel or side label or an rear panel or rear label – [9(6)(b)]**

CMA does not support imposing [subsection 9(6)(b)] and maintain that for listed complementary medicines the current TGO 69 requirement should be retained, which states for particulars to be included on the main label except:

3(3) b - where there are *two or more* active ingredients that are vitamins or minerals or that are required to be quantified as the equivalent fresh or dry weight or volume under sub clauses 4(11)(b) or 4(11)(c) – it shall be sufficient compliance with this sub clause if the names and quantities or portions of these active ingredients together with the names and quantities of every active ingredient in the goods are included on the side panel or side label or on a rear panel or rear label.

By imposing [subsection 9(6)(b)] would mean a requirement to go from two or more active ingredients to four or more active ingredients that may be declared on a side panel/label or rear panel/label. This would increase the regulatory cost for these low risk listed medicines without any evidence of consumer benefit being presented.

- **Subject to (8), if the medicine is intended to be, or is, registered goods:**
  - a) **the name of the active ingredient(s) and the quantity or proportion of active ingredient(s) must be displayed in a text size of not less than the equivalent of 15 point Arial in any sans serif font [9 (7)(a)]**

CMA provides at the appendices mock up sample labels of a current registered complementary medicine that has the new proposed requirements applied. This label also provides an example of how the proposed font size requirements and medicine information panel format would not work for certain sized medicines.

- **If the medicine is intended to be, or is, registered goods and there are four or more active ingredients and:**
  - b) **10 (20) applies – the names of every active ingredient(s), together with the quantity or proportion of every active ingredient, need not be displayed on the main label.**

Based on the guidance provided at section 6.2 for registered non-prescription medicines, CMA understands that registered complementary medicines would come under this category and would therefore be required to include a medicine information panel. CMA provides at the appendices a mock up label of a registered complementary medicine that includes three active ingredients in a 60ml container. Based on the increase to font size and a requirement for a medicine information panel the label would not fit on the existing package size of the medicine.

## **Section 10 - Qualifications and special requirements**

### **(9) Homoeopathic medicines**

- Where all the active ingredients in a medicine are homoeopathic preparations, the main label on the container and the main label on the primary pack (if any) must, in addition to the requirements referred to in sections 8 and 9, include a statement to the effect that the medicine is a homeopathic medicine in text size that is **not less than 50% of the text size of the name of the medicine and (in any event) not less than the equivalent of 8 point Arial.**

(10) Formulations containing both homeopathic preparations and non-homeopathic ingredients

Where a medicine contains active ingredients that are homeopathic preparations, and other active ingredients that are not homeopathic preparations, then, in addition to the requirements referred to in sections 8 and 9 above:

- (a) the main label on the container and the main label on the primary pack (if any) must include a statement to the effect that the medicine contains homeopathic preparations in text size that is not less than **50% of the text size of the name of the medicine and (in any event) not less than the equivalent of 8 point Arial**; and
- (b) the label on the container and the label on the primary pack (if any) must differentiate ingredients that are homeopathic preparations from those that are not, such as by including the statement 'contains homeopathic preparations of' adjacent to the list of homeopathic ingredients, or by prefacing the name of the homeopathic active ingredient with the term 'homeopathic'.

The consultation labelling Order proposes three different font sizes across the medicines category. What it highlights is an inconsistency in the font sizes proposed for registered complementary medicines (15/12 point Arial), listed complementary medicines (6 point Arial) and homeopathic listed medicines (statement required in 8 point Arial), which if based on a system of risk classification is perplexing. No real explanation has been provided as to why there is a new mandatory requirement to include a statement on the main label that the medicine is a homeopathic medicine or contains homeopathic preparations in an increased font size to that of a general listed complementary medicine. No real explanation has been provided as to why an increase to the font size for the homeopathic medicines statement was considered a requirement based on a safety perspective. The guidance document details that the statement is intended to assist consumers with an appropriate selection for a medicine and minimise confusion that may arise with self-selection.

CMA strongly believes in Australia's National Medicine Policy that states everyone has a part to play in the Quality Use of Medicines (QUM). The current labelling Order requires there to be a declaration that clearly states the product is homeopathic and contains homeopathic ingredients on the front of the pack and the additional detail of this information on the back of the pack in the ingredients and indications section would clearly justify the medicine as being based in the homeopathic paradigm. This change in requirement to homeopathic medicines has not been consulted in previous 2012 public consultations and appears to have been added in as an after thought. CMA does not support any additional change to this low risk category of medicine.

Section 3(15) of the current labelling Order (TGO 69) already stipulates that a statement indicating that the active ingredients in the goods are homeopathic preparations, such as, 'homeopathic product' or 'homeopathic preparation'.

## **(12) Medicine Kits**

The label on the package that, together with medicines, constitutes a medicine kit must include the following information:

- a) the name given to the kit; and
- b) the name and contact details of the sponsor of the kit; and

- c) the name of each of the medicines within the kit and its dosage form; and
- d) the name, and quantity or proportion, of all active ingredients in each of the medicines within the kit; and
- e) the quantity of each medicine within the kit; and
- f) **a statement of purpose for each medicine within the kit** except where a medicine contains a substance that is included in schedule 4 or Schedule 8 of the Poisons Standard; and
- g) **directions for use for each medicine within the kit or a statement directing consumers to the directions for use on the label of each medicine within the kit**, except where the medicine contains a substance that is included in Schedule 4 or Schedule 8 of the Poisons Standard; and
- h) the batch number of the kit is preceded by the batch number prefix; and
- i) an expiry date for the kit, being the earliest expiry date of the medicines within the kit, preceded by the expiry date prefix; and
- j) any warning statements that relate to the any of the medicines within the kit; and
- k) storage conditions applicable to the kit, being the most restrictive of the storage conditions for any of the medicines within the kit; and
- l) the listing number given to the kit, set out on the label consistent with the requirements specified in the Regulations.

Based on the requirement in subsection 12(f), complementary medicine kits would be required to state the functionality of each of the medicines within a kit. Being multi-ingredient based with ingredients that often overlap in their therapeutic approach, it would be very repetitive to list the functionality of each medicine and take up considerable space on the label.

## **Section 11 - How information is to be expressed**

### **(2) Expression of quantity or proportion of active ingredient**

(2)(j) It is proposed that herbal ingredients include the actual amount of herbal extract in addition to the equivalent amount of starting herbal material from which the preparation was derived. This is proposed as it “enables the consumer to gain meaningful information from the label in relation to the ‘strength’, ‘concentration’ or quantified levels in general of the herbal ingredients in the medicine”<sup>2</sup>.

To implement this would require at least two lines for each herbal material ingredient on the medicine label, to express both quantities. CMA considers this requirement increases the regulatory burden of low risk listed medicines by increasing the amount of information required on a label and hence label size. The addition of this extra information, for the average consumer, would most likely create confusion as to which line of expression to draw a meaningful conclusion from. Additionally the detail of the herbal extract can already be obtained from the public ARTG so the consumer already has access to this information if they wanted to specifically compare product information.

CMA provides at the appendices numerous mock-up label examples of listed complementary medicine labels (small container size, multi herbal ingredient products etc.) where this requirement has been implemented and results in the current information no

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<sup>2</sup> Page 29 of Guideline for the labelling of medicines & Page 14 of document: Comparing TGO79 with TGO 69 V1.0 August 2014

longer being able to fit on the label. One of the examples would require four lines to detail the information for a common standardised herbal ingredient, *Panax ginseng*.

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CMA provides the following comments in relation to the TGA consultation document:  
*Consultation: Guideline on medicine labelling*

### **Name of the medicine (3)**

The name of the medicine is now defined for the purpose of labelling requirements. It is defined as the name on the Certificate of Listing, without inclusion of active ingredient name, strength, dosage form, container details, pack size, flavour description, new formulation or similar representations or name or logo of the sponsor (unless intended to be part of the name). It includes a proposed requirement that the name of the medicine on the main label must be presented in a continuous, uninterrupted manner and not be broken up by additional information, logos, background text or graphics. Fonts of similar size and style are recommended for all words in product names.

The guideline indicates that for registered medicines containing two or three active ingredients where it is impractical to fit the names and quantities of all active ingredients on a single line on the main label, to display the names and quantities of the active ingredients on more than one line.

CMA provides at the appendices an example of a registered complementary medicine containing 3 active ingredients where the name and quantity of the active ingredients have been displayed on more than one line. Based on the example container size, the proposed changes do not fit onto the front of the label.

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## **Schedule 1 to TGO 79 – Substances or groups of substances required to be declared on the label**

### **Ethanol/alcohol**

This group of substances to be declared on the label is not consistent with the ARTG generated warning for ethanol/alcohol.

Ethanol, as one of the substances required to be declared on the label can carry the declaration 'contains alcohol'. However, the same ingredient warning that is generated on the ARTG for use if this ingredient is in the formula as a listed excipient is: ETHAN contains ethanol (or words to that effect).

### **Recommendations:**

- Streamline the ARTG warning and TGO 79 declaration, so that the wording is consistent.
- Need to clarify if both the ARTG warning and the TGO 79 declaration are both required on the label, if the situation arises where there is already an ARTG generated 'ethanol' warning.

Other ARTG/TGO 79 inconsistencies:

Other ingredients such as potassium sorbate already generate ARTG warnings if listed as excipients, and is also in the group of substances required to be declared on the label.

Again, the wording used is inconsistent:

ARTG warning: SORB8, (If the medicine contains one sorbate) Contains [insert name of sorbate] OR (if medicine contains two or more sorbates) Contains sorbates [or words to that effect].

#### **Recommendations:**

- Streamline the ARTG warning and TGO 79 declaration, so that the wording is consistent. If the product contains one sorbate eg potassium sorbate, ARTG warning is 'Contains potassium sorbate' but TGO 79 declaration is 'Contains sorbates'.
- Need to clarify if both the ARTG warning and the TGO 79 declaration are both required on the label, in these situations.

#### **Gluten**

The two provisions for the declaration of gluten on the label from an ARTG generated label statement and TGO 79 appears contradictory.

- TGO 79 – requires declaration 'Contains gluten' where gluten or an ingredient derived from gluten-containing grain is present. (No provision for gluten being below certain ppm)
- ARTG – Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats and must be declared when the route of administration is other than topical and mucosal. Medicines containing more than 0.3% gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. (This represents 3000 ppm of the medicine, and is way above food labelling standards which are 'Must contain no detectable gluten' (currently can be detected at 3ppm or 0.0003%).

If there is gluten derived maltodextrin sourced from wheat, at 3ppm (0.0003%), according to ARTG, there should be no need to make a warning declaration.

Recommendation:

- To streamline the gluten label statements.

#### **Phenylalanine**

Many mineral amino acid chelates contain phenylalanine as part of the amino acid portion of the mineral and ingredients such as Spirulina whole cell powder would contain phenylalanine, as part of its protein profile. CMA proposes that the schedule 1 list include additional information as to what ingredients the phenylalanine warning applies to.

**CMA Resources in reference to the Labelling of Complementary Medicines :**

- CMA submission on the [Medicine Labelling and Packaging Review](#) (24 August 2012).
- CMA submission to Head of Market Authorisation, Labelling and packaging of Complementary Medicines (12 April 2013).