CMA Submission to TGA on Consultation Draft TGO 92
Standards for the Labels of non-prescription medicines

Submission to:
TGA Medicine Labelling Consultation
Management and Coordination Section
Office of Scientific Evaluation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
labellingreview@tga.gov.au

From:
Complementary Medicines Australia
PO Box 450
MAWSON ACT 2607

23 December 2015
Contents

PART 1 – CMA RESPONSE ON THE DRAFT TGO 92 ................................................................. 5
Standard for the Labels of Non-Prescription Medicines......................................................... 5
EXECUTIVE SUMMARY ........................................................................................................... 6
General overview of comments on TGO 92 ........................................................................... 7
Section 7 General requirements, including label presentation.............................................. 7
Section 8 Information to be included on the label ................................................................. 8
Section 9 Information to be included on the main label ......................................................... 9
Section 10 Qualifications and special requirements ............................................................. 11
International harmonisation considerations – homeopathic naming conventions .............. 13
Section 11 - How Information is to be expressed................................................................. 15
Use of appropriate metric units ......................................................................................... 15
Expression of quantity or proportion of active ingredients ................................................. 15
Regulatory Impact Statement (RIS)- general requirements for labels of medicines, version 1.0
August 2014 ......................................................................................................................... 16
Transition arrangements ........................................................................................................ 17
Schedule 1 - Substances or groups of substances present in medicines that are required to be
declared on the label of medicines ...................................................................................... 18
Schedule 2 - Specified Units for Enzymes ........................................................................... 20
CMA comment on the Guideline for medicine labels, draft version 1.0, October 2015 ...... 20
CMA resources in reference to the labelling of complementary medicines.......................... 21
CMA detailed table of reform recommendations and impact of TGO 92 ......................... 22
Appendix 1 – mock up labels to TGO 92 requirements ....................................................... 23
PART 1 – CMA RESPONSE ON THE DRAFT TGO 92

Standard for the Labels of Non-Prescription Medicines
EXECUTIVE SUMMARY

Complementary Medicines Australia (CMA) welcomes the opportunity to provide a response to the Therapeutic Goods Administration on its targeted consultation draft TGO 92 – *Standard for the labels of non-prescription medicines* and related guidance document, dated October 2015. This submission follows from CMA’s response to the Therapeutic Goods Order for medicine labels (TGO 79), 2014 and the Medicine Labelling and Packaging Review, 2012.

In general, complementary medicines (CMs) are lower-risk medicines. As such the majority of complementary medicines are self-selected by consumers, necessitating the medicine label as a vital information source, allowing consumers to make informed purchasing decisions and to use the medicine safely. It is therefore in the interest of the community that complementary medicine labelling be well designed and effective for its intended purpose.

Overall CMA supports the revision of the labelling Order into two separate Orders, for prescription medicines and non-prescription medicines, including complementary medicines. This approach was supported in recognition that different types of medicines present different levels of risk. Following from this, CMA also supports that these different levels of risk are relevant *within* the registered non prescription type, for example, lower risk registered complementary medicines.

We support that the guidance document details a tiered approach in the recognition of levels of risk within the registered medicine category and we have provided additional comment around how this could be further clarified in the Order itself.

CMA supports the aims of the review to the Labelling Order, as outlined in the 2014 Regulatory Impact Statement¹, are to address and prevent confusion and accidents, such as overdosing, under medicating or medicating with the incorrect medicines that are associated with unclear labelling on medicines. It is important that label requirements aim to ensure medicines supplied in Australia provide healthcare professionals and consumers with access to information on the medicine including the active ingredient name and in the case of over-the-counter medicines, proper and safe usage.

However, our sector continues to outline that the increased regulatory requirements required to implement TGO 92 outweigh the perceived benefit to the community in the absence of any usage testing or extensive RIS calculations.

CMA believes the cost to the complementary sector is disproportionate to the risk arising from the sector, particularly when weighing the likely benefit arising from the proposed changes. One of CMA’s members estimates these changes will cost their business alone in excess of $2 million for their complementary medicine range over the granted transition period. Overall CMA supports further improvements to processes be made within the context of the existing framework.

General overview of comments on TGO 92

We reiterate that the labelling of complementary medicines should be well designed and effective for its intended purpose. This has been explored during a number of labelling consultations undertaken over the years, however, no evidence of consumer misuse due to labelling of complementary medicines has been presented to CMA to indicate a change required to the way in which these lower risk medicines (including homeopathic medicines) should be labelled.

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.

As such there remains a number of requirements proposed in the redrafted Order that appear unjustified and result in an unnecessary increase to the regulatory burden for this sector.

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

CMA supports that the current mechanisms in place for the labelling of complementary medicines are sufficient to promote the quality use of these medicines by consumers. CMA supports, where not further indicated in this submission, that the current labelling requirements of TGO 69 be maintained for listed low risk medicines, including homeopathic medicines.

Section 7 General requirements, including label presentation

- Labels must be in a colour or colours contrasting strongly with the background

As stated in the CMA 2014 submission, ambiguous and subjective requirements should, on principle, not be included in a legislative instrument.
Considering the guidance document elaborates on the proposed requirement, CMA reiterates that we are not aware of there being consumer safety issues of this nature reported for CM products, which are of a lower risk and hence consider the mandatory requirement unjustified for this sector of goods.

TGO 92 should be amended to include this as a best practice principle only in the guideline for registered non prescriptions medicines, excluding listed medicines and registered complementary medicines.

Section 8 Information to be included on the label

- Section 8(2) - Labels of registered medicines must provide information in a consistent order and manner in a medicine information panel (MIP)

While CMA agrees that directions, warnings and allergen information are all important information, access to other information is also necessary for consumers to make an informed purchasing decision.

CMA is of the position that for lower risk registered medicines, such as registered complementary medicines, there should be flexibility to present mandatory information in a clear and concise manner without the constraint of a medicine information panel (MIP). This will minimise unnecessary costs to the CM industry associated with resizing labels or providing goods in larger container sizes with increased headspace.

Section 1.5.5 of the Guidance document outlines that “a medicine information panel is not required for certain lower risk registered medicines – these are detailed in subsection 8(2) of TGO 92”. Subsection 8(2) however, does not appear to detail specifically what types of lower risk registered medicines would not require a MIP. CMA suggests that this part of the Order and guidance is expanded to include specifically that registered complementary medicines are not required to include a MIP.

Based on the proposed requirement for a medicine information panel, should the amendment impact registered complementary medicines, mock up labels have been provided to demonstrate that the requirement would necessitate a change to label sizes for complementary medicines, which is considered unjustified.

CMA provides at the appendix, example 1, a mock up of a registered complementary medicine to demonstrate how the inclusion of a MIP would not work and necessitate labelling complications and medicine container size considerations.
Section 9 Information to be included on the main label

- Section 9(2) The name of medicine on the main label must be presented in a continuous, uninterrupted manner and not be broken up by additional information or background text
- Section 9(5) All text required by this Order to appear on the main label must be orientated in the same direction

CMA submits that the proposed requirements to orientate all text in the same direction on the main label, and for medicine names to be presented in a continuous and uninterrupted manner, would not, for lower risk medicines, have any meaningful impact upon consumer safety and as such the change is considered unjustified for lower risk medicines.

Feedback from our members indicates that medicine labels are often developed as a result of consumer testing. In addition, CMA has not been presented with information that consumers have any usability difficulties with the presentation of information on complementary medicine labels.

It is well documented that consumers generally select complementary medicines and non-prescription medicines by brand and category and seek out brands that they know. Branding is important for complementary medicines and consumers are familiar with many well-known brands of medicines for general wellbeing, cough and cold, joint health, bone health and many other categories. Limited label space is therefore an important issue, particularly for certain products and label types.

Such a change would impact upon brand recognition for many companies. As such, CMA considers this an unjustified change to requirements adding to unnecessary regulatory burden.

Industry requires the revised labelling Order to be implemented in a way that avoids impact on branding and does not require consequential changes to dimensions of packs or labels or changes to the packaging details of a medicine.

- Sec 9 (3) Proximity of active ingredient name in relation to the trade name and requirement for separate lines
- Sec 9 (7)(a) The names of the active ingredient(s) in registered medicines with less than four active ingredients must be in a text size of no less than 3.0 millimeters on the front panel directly under the trade name.

Given consumers use complementary medicines as part of self-care, the label of these medicines is the primary source of information for consumers. This requirement would mean that a large portion of the main label would be used to display the active ingredients, which are detailed on the label elsewhere.
Information on active ingredients is not always the most meaningful aspect in consumer self selection of these goods, rather information sought by consumers tends to be focused around what the product can be used for.

Due to the increase in font size, active ingredients will take up a larger portion of label space and there will be reduced space to indicate the intended purpose of the product on the front of pack. If the container and label size are increased as a result of this, without increasing the number of tablets or capsules in the bottle, this could give the consumer a negative perception due to the increased head space of the container. Ultimately this would also impact on rework to shelf space and environmental impact to carbon footprint.

CMA provides at the appendix, example 1, a mock up of a registered complementary medicine to demonstrate how the inclusion of 9 (7)(a) would not work and necessitate labelling complications and medicine container size considerations.

- Sec 9 (6) 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

As outlined in our 2014 submission, subsection 9(6)(b) is not supported for inclusion in the labelling Order. The requirement for change to listed and registered complementary medicines was not adequately justified from a risk perspective, rather the requirements appear to be a hangover from the risks perceived from the prescription and registered non-prescription medicine sector.

CMA’s position on the number of active ingredients that may appear on the front of a label for listed goods is that TGO 69 requirements be maintained.

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 lower risk listed medicines without any evidence of consumer benefit being presented.

CMA suggests the following amendment to TGO 92.

If the medicine is intended to be, or is, listed goods:

6 b) if the medicine is a listed complementary 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 on a rear panel or rear label.

CMA provides this suggested amendment based on previous requirements outlined in TGO 69 and on a risk appropriate basis. To elaborate further on mock up labels provided in 2014,
CMA includes specific examples at appendix 1, example 2, impact on label size for listed complementary medicines containing three active ingredients to be displayed on the front of the label (currently they may be detailed at the side or rear).

- **Sec 9 (7)** If the medicine is intended to be, or is, registered goods, then:

(a) where the medicine contains three or four active ingredients, the name of the active ingredient(s) and the quantity or proportion of active ingredient(s) must be displayed on the main label in a text size of not less than 3 millimetres

(b) where the medicine contains four or more active ingredients and the requirements of subsection 8(2) do not apply, then the names and the quantities or proportion of the active ingredients may be included on a side panel/label or rear panel/label, when displayed in a text size of not less than 2.5mm.

CMA’s position on this section is that TGO 69 requirements be maintained.

By imposing subsection 9(7)(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 costs for registered complementary medicines without any specific evidence of consumer benefit relating to this lower risk class of good being presented.

Within the complementary medicine category, listed and registered complementary medicines will be presented (depending on the number of active ingredients present) in a different manner. That is, some will detail active ingredients at the front of the pack while others (with 4 or more active ingredients) will detail the ingredients at the side or rear of the pack. CMA submits that for the purposes of standardisation and consistency on where to find information, for lower risk goods, consumers should be encouraged to refer to the back/side of the pack for ingredient information.

CMA provides a mock up of a registered CM provided to demonstrate how the inclusion of 9 (7)(a) would not work and necessitate labelling complications and medicine container size considerations.

**Section 10 Qualifications and special requirements**

**Sec 10(3)** & **Sec 10 (4)(a)** 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 above, include a statement to the effect that the medicine is a homoeopathic 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 2millimeters.
CMA does not support any additional change to this lower risk category of medicine.

No explanation or justification has been provided during the course of labelling consultations 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 statement “homeopathic medicine” was considered a requirement based on a consumer safety perspective.

Previous explanations for this addition has centred on factors that the statement is intended to assist consumers with “an appropriate selection for a medicine” and “minimise confusion that may arise with self-selection”. However, 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 homoeopathic paradigm. As such CMA proposes that this section be removed from the Order.

- Section 6 Interpretation in the Order Homeopathic medicines – naming conventions

(line 305) Name of the active ingredient (b) where the ingredient is a homoeopathic preparation: (i) either the name of the active ingredient, or the substance from which the dilution was prepared, that is accepted for inclusion in the Australian Approved Names (AAN) List, together with a statement of the homeopathic potency; or (ii) until such time as a name is accepted for inclusion in the Australian Approved Names List, a traditional homoeopathic name in full or as traditionally abbreviated with a statement of homeopathic potency

Given the recent redraft of the labelling Order, it is an opportune time to explore potential amendments that aim to increase the clarity for requirements around homeopathic medicines for both industry and the regulator.

CMA submitted in May 2013 via the International Harmonisation of Ingredient Names consultation that there appeared to be no mention of the naming of homoeopathic ingredients. That is the use of Homoeopathic Pharmacopoeia (HPUS)/ traditional naming or the application of new/ AAN homoeopathic names. As such we resubmit information for consideration here.

It is suggested that an amendment be made to allow for homeopathic medicines:

1. The traditional homeopathic pharmacopeia name as the primary name with the Australian Approved Name (AAN) in brackets; together with a statement of the homeopathic potency
   a. E.g. Sinapis nigra (Brassica nigra) 6X
2. For small containers, the traditional homeopathic pharmacopeia name only; together with the a statement of the homeopathic potency

   a. E.g Sinapis nigra 6X

That is, the traditional homeopathic name is to be used as the primary name including the AAN unless on “small containers”. Both the traditional names and AANs could be included on full website information, which would allow additional space to elaborate on the naming of traditional homeopathic ingredients (where required).

To implement this, CMA proposes the following amendment to the definition of the name of the active ingredient:

(b) where the ingredient is a homoeopathic preparation:

   (i) the name of the active ingredient expressed as the traditional homoeopathic name (in full or as traditionally abbreviated) with a statement of homoeopathic potency; and, the name that is also accepted for inclusion in the Australian Approved Names List (if available) in brackets;

   (ii) for small containers, the name of the active ingredient expressed as the traditional homoeopathic name (in full or as traditionally abbreviated) with a statement of homoeopathic potency.

It is in the consumers’ interest that traditional pharmacopeial names be amended so as to be the primary name. The concern here is that by enforcing the current definition and taking the AAN name alone, outside of the traditional context, the consumer may only get the name in its full chemical/non homeopathic form causing potential confusion and or safety concerns. Additionally, the AAN name alone (due to small label space requirements) may appear as a different active ingredient all together causing consumer alarm.

For example: False Unicorn Root

<table>
<thead>
<tr>
<th>Traditional homeopathic name</th>
<th>AAN name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Helonia dioica</td>
<td>Chamaelirium luteum</td>
</tr>
</tbody>
</table>

If a consumer wishes to know more about a homeopathic medicine ingredient, many sources of information (pharmacopoeias, texts, materia medica) refer to the traditional name as the primary point of reference. To elaborate, further examples have been provided (Appendix 1, example 5) with this submission.

**International harmonisation considerations – homeopathic naming conventions**

**ACSS Consortium**
The TGA is part of the ACSS Consortium along with Health Canada, Health Sciences Authority of Singapore and Swissmedic. According to the TGA website, the ACSS Consortium was formed in 2007 by 'like-minded' regulatory authorities to promote greater regulatory collaboration and alignment of regulatory requirements, with the goal of maximising international cooperation, reduce duplication, and increase each agency's capacity to ensure consumers have timely access to high quality, safe and effective therapeutic products.

**Heath Canada**

The Health Canada website (http://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq.do?atid=homeopathy) provides guidance to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization for homeopathic products (updated July 2015). It states:

- "The proper name(s), common name(s) and source material(s) must be as per the homeopathic monograph referenced as the Standard or Grade (please refer to the specifications).
- The medicinal ingredient(s) must be a permitted substance with a homeopathic monograph in one of the Natural and Non-Prescription Health Products Directorate (NNHPD) accepted homeopathic pharmacopoeia.”

The Standards or Grades refers to a list of homeopathic pharmacopoeias containing the traditional homeopathic names.

Health Canada also includes guidance for the labelling of homeopathic medicines on its website (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/ehmg-nprh-eng.php#a5). It includes the following guidance for labelling for small packages:

5.3 Labels for Small Packages
The NNHPD recognizes that small packages, such as those used by some homeopathic medicine manufacturers, may not have an area large enough for the inner labelling requirements. Therefore, separate small package labelling requirements have been developed. Please see the Labelling guidance document for information specific to small package labelling.

**SwissMedic**

In Switzerland, homeopathy has been fully integrated into the Swiss medical system. SwissMedic’s HAS (Homeopathic and Anthroposophical medicines) list includes both Latin/chemical names and their homeopathic synonyms. It appears that homeopathic products in Switzerland also allow for the use of homeopathic names on products labels (noting the strong tradition of use of homeopathy in the region).

**FDA**

The FDA also recognises the traditional homeopathic names, with HPUS as the standard. The HPUS has labelling guidelines for homeopathic medicines\(^2\) that links in with the labelling


Section 11 - How Information is to be expressed

Use of appropriate metric units

- Sec 11 (1)(b) The abbreviations to ‘mg’ and ‘g’ can be used on all labels but microgram should be used in full unless the medicine is in a small container. Then abbreviation ‘μg’ may be used.

Where several ingredients are presented on a label statement in microgram, microliter quantities, the repetition of expressing the unit in full greatly expands the length of the text and hence label space becomes an important issue.

Further, CMA questions if the requirement is mandatory, given it is expressed as ‘should’ in the standard compared to ‘must’ in the guideline.

This proposed requirement, if mandatory does not allow for consistency on the label and increased label space is required. CMA submits that an abbreviated form of microgram should be permitted in the standard.

Expression of quantity or proportion of active ingredients

Sec 11 (2) Expression of quantity or proportion of active ingredients

11(2)(i) states that in addition to the requirements of paragraphs 11(2)(a)-11(2)(h), and therefore includes 11(2)(a) …the quantity of the active ingredient”.

11(i)(ii) where the active ingredient is a herbal preparation as the dry or fresh weight of the herbal material from which the preparation was derived except”…

This amendment appears to propose 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.

As detailed in our 2014 submission, we do not support the increased information requirements for the expression of herbal medicines to be expanded on the medicine label (section 11(2)).

The 2014 consultation suggested the reasoning for the additional requirement to include the input amount of the herbal material on the label was that it “enables the consumer to
gain meaningful information in relation to the ‘strength’, ‘concentration’ or quantified levels in general of the herbal ingredients in the medicine”.

To implement this requirement however, it would require the addition of an extra line of information for each herbal material ingredient, to express both quantities on the medicine label. The majority of complementary medicines are multi ingredient formulations, sometimes with as many as 25 ingredients in a product. The addition of at least two lines to express each herbal ingredient, would for the average consumer, most likely only create confusion as to which line of expression to draw a meaningful conclusion from.

The main concern is that this would lead to two quantification values for the same inputted ingredient, which would be open to misunderstanding, and if other than the native extract amount potentially no more helpful to the consumer. Additionally, this requirement does not appear to impact upon the safe or proper usage of the medicine, if used within the context outlined on the label.

CMA considers that this requirement would significantly increase the regulatory burden of lower risk medicines by increasing the amount of information required on a label and hence label size. Label space will become an issue and an impracticality, pushed to some degree and with an obscure label this could lead to other potentially misleading packaging issues. We again provide mock up labels at the appendix to demonstrate this significant increase in requirement.

Clear concise labelling of ingredients with one quantity, the extract equivalent of the herb, provides consumers with satisfactory information that allows comparison with other products.

CMA requests that TGA provides a detailed reasoning behind the proposed amendment including evidence that the current requirement is impacting on the safe and proper usage of listed medicines, if that is the case. In the absence of this information, CMA does not support implementing this section of the labelling Order and that it be drafted without this specific requirement.

CMA provides a mock up label at the appendix 1, example 3, to demonstrate the increased requirements to listed low risk medicines.

**Regulatory Impact Statement (RIS)- general requirements for labels of medicines, version 1.0 August 2014.**

The TGA provided a regulatory impact statement and other supporting documents\(^3\) as evidence in support of a change to the labelling of medicines, the proposed changes were however largely based on the risk profile associated with prescription and registered over the counter medicines with no direct reference to misuse of complementary medicines in

---

\(^3\) Labelling and packaging practices, version 1.0 January 2013. file:///C:/Users/technical/Downloads/consult-labelling-packaging-review-120524-analysis-evidence.pdf
the context of self-selection being outlined. 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 2014 consultation highlighted 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 would contribute to the provision of better consumer information or safety. A change to the amount of active ingredients that can be included on the front of the medicine label and additional information around the expression of herbal ingredients for example, are proposals for change that are not supported by CMA as they have not been evidenced to be a safety issue nor undergone consumer use testing to demonstrate any improvement on the status quo would be gained. In summary they will have little affect on consumers self-selection.

The 2014 labelling consultation included a regulatory impact statement, which from an industry point of view grossly underestimated the cost of changes.

Copy from the RIS:

The labour burden for businesses who need to change a label would be approximately 20 hours (includes reading the current guidance and applying it to their design work and the small amount of labour involved in providing new label information as part of the application to vary the entry) at a labour rate of $42 per hour.

The additional requirements proposed in the Order and schedule 1 will result in all companies conducting a review of each medicine formulation, checking for compliance to these revised requirements. It is estimated that the $42 per hour labour rate above would increase to approximately $60 per hour for the time required to carry out the review. One member estimates that the labour hours would increase from 20 to 30 hours and takes into account that different sections within an organisation and external organisations are involved in obtaining documentation for example, suppliers, distributors, manufacturers. Testing may also be required to confirm if any allergen residue remains in the raw material.

**Transition arrangements**

CMA notes that the proposed transition arrangement includes a four year period where by compliance with the current labelling Order (TGO 69) or the revised TGO 92 would be permitted. By 2020, full compliance with TGO 92 would be required. While this is an improvement from the 2014 proposal, CMA highlights, that further refinements to TGO 92 is required to reduce the regulatory burden for complementary medicines.
Should the Order be implemented as currently drafted, there will be many complementary medicine businesses that would be negatively impacted. Not in the least, many small owner-operator complementary medicine businesses would not generally be in the practice of changing their medicine labels every few years, as indicated in the TGA RIS document.

The transition period will also be particularly problematic where the labelled information will differ despite no change in formulation e.g. change in apparent quantification, ingredient name, or ingredient placement.

The RIS document also detailed that the new labelling Order would be a one-off cost for those businesses that would not be changing their labels during the transition period. The 2014 participants in the TGA industry survey included larger CM company representatives and therefore 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 lower risk listed medicines is considered an unnecessary additional regulatory burden that would not necessarily equate to any consumer self-medication benefit.

CMA submits 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 submits that further refinements to TGO 92 be made to accommodate lower risk medicines.

**Schedule 1 - Substances or groups of substances present in medicines that are required to be declared on the label of medicines**

It appears that some inconsistencies remain in the declaration statement of certain substances in Schedule 1 of TGO 92 compared to warning statements generated on the ARTG.

**Ethanol/alcohol**

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

- Contains alcohol vs contains ethanol (%v/v)

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 TG0 92 declaration, so that the wording is consistent.

Need to clarify if both the ARTG warning and the TGO 92 declaration are both required on the label, if the situation arises where there is already an ARTG generated ‘ethanol’ warning.

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].

Contains sorbates vs contains [insert name of sorbate] (if the medicine contains one sorbate) or contains sorbates (if the medicine contains two or more sorbates) in the event that the medicine contains only potassium sorbate, according to the warning statement required on the ARTG, the label would have ‘Contains potassium sorbate’, whilst it would read “Contains sorbates’ to comply with schedule 1 of TG0 92.

Recommendations:
- Streamline the ARTG warning and TG0 92 declaration, so that the wording is consistent. If the product contains one sorbate eg potassium sorbate, ARTG warning is ‘Contains potassium sorbate’ however, TGO 92 declaration is ‘Contains sorbates’.
- Need to clarify if both the ARTG warning and the TGO 92 declaration are both required on the label, in these situations.

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 or outline the ingredients, such as those mentioned above, that are exempt from the requirement.

Imposing such requirements to all ingredients may cause unnecessary concern to the consumer.
Schedule 2 - Specified Units for Enzymes

- CMA recommends the addition of Bromelain to Schedule 2

<table>
<thead>
<tr>
<th>Unit</th>
<th>Unit description</th>
<th>Permitted ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>PU</td>
<td>Papain Units</td>
<td>Bromelain</td>
</tr>
</tbody>
</table>

Currently, the TBS only allows the quantity of the ingredient to be expressed in milligrams (mg). Previous considerations of this issue has identified that the "per mg" expression is not the most appropriate for the material. Whilst GDU (gelatine digesting unit) is acknowledged to be the unit most commonly used for the material, papain unit is proposed as this is the specified unit from bromelain by the joint FAO/WHO expert committee on Food Additives (JECFA), the Food Chemical Codex, and the unit adopted by Health Canada in its monographs for 'Stem bromelian' and 'fruit' bromelian. We note also that there is a simple conversion factor that can be applied to quantities expressed as GDU.

CMA comment on the Guideline for medicine labels, draft version 1.0, October 2015

- 3.3.3.3 Where standardisation of a herbal material or preparation is claimed

In the given example of Camellia sinensis leaf standardised to cetechins, CMA proposes the removal “(of Camellia sinensis)” after the standardised component name.

[standardised to contain cetechins (of Camellia sinensis) 30mg]

This is proposed as all the information of the herbal active ingredient (weight of preparation and herbal material, and quantity of standardised constituent) would be expressed together. This reiteration appears to be redundant and would take up more space on the label.

- Previous TGO 79 guidance 6.2.7 Order of information

Detailed information within the panel must be presented under the specified headings in the following order [section 10(20)(e)]: Ingredients, ‘Uses’ or ‘What this medicine is used for’, Warnings, Directions for use and Other information.

CMA understands that a MIP is not required for listed medicines, however, it is not clear from the revised order or the guidance whether the later requirement (presented in a specified order) needs to be followed for listed medicines.
CMA interprets the revised TGO 92 update to mean that this would no longer be a requirement. However, we have provided a mock up label at appendix 1, example 4 to demonstrate how this requirement, if relevant, would impact multi ingredient herbal medicines.

CMA resources in reference to the labelling of complementary medicines

- CMA submission, Consultation Draft TGO 79 Standards for the Labelling of Medicines (November 2014)
- CMA submission, Labelling and packaging of Complementary Medicines (12 April 2013).
- CMA submission on the Medicine Labelling and Packaging Review (24 August 2012).
CMA detailed table of reform recommendations and impact of TGO 92
Appendix 1 – mock up labels to TGO 92 requirements