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KEEPING YOU WELL.
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To Whom It May Concern:

Re: "TGA Medicine Labelling and Packaging Review" Consultation Paper

Comvita New Zealand would like to thank you for the opportunity to submit this response to the government's consultation paper "*TGA Medicine Label and Packaging Review*".

Comvita New Zealand acknowledge that this consultation is in response to the analysis of previous consultations with key stakeholders on proposed updates to *TGO 69*. We also understand that the review was conducted with consumer safety in mind and with particular regard to pharmacy and over the counter medicines. Therefore many aspects of this review are not suitable or easily applied to complementary medicines.

In its present form Comvita do not support the proposed document. Comvita believe it imposes high pharmaceutical standards that are not proportionate to complementary medicines, which TGA has considered to be low risk based on assessment of ingredient safety and manufacturing quality. Given the low risk and safety profile of complementary medicines, we believe that the standardisation of ingredients on the medicine label will be impractical and unworkable for the complementary medicine industry. The proposed label and packaging requirements will limit the space available for indications that allow consumers to make informed decisions when purchasing complementary medicines. The consultation paper should be re-drafted to include a specific focus on the applicability of the proposed changes to complementary medicines.

Further, Comvita are aware that TGA is working on a number of related reforms, as set out in the *TGA reforms: A blueprint for TGA's future* and it is noted that recommendations 6 and 7 fall outside the scope of this review. As we have not yet been consulted on all the proposed changes in these reforms for complementary medicines it is difficult to judge the full impact of this review and hence provide a fully informed response.

Comvita acknowledge that clear labelling of medicine packaging assists consumers to use medicines in a safe manner and is in line with the principles of the National Medicine Policy. However, the majority of complementary medicines generally have a wide range of active ingredients present in the finished product and to list all of the ingredients on the front of the medicine label would not be feasible. A number of the regulatory proposals outlined in this consultation document will not be achievable for those products such as multivitamins, as well as those with active ingredients which are of herbal origin where genus and species names are lengthy. Comvita considers

that more time is need in consultation with industry to derive workable and alternative solutions to the labelling and packaging issues.

The aims of the current review are quoted as (Pg.8):

> "to reduce the risk of errors by healthcare professionals and facilitate consumer access to the information they need to:
> - make informed choices where they are self-managing minor conditions, such as a headache or a cold
> - safely use a medicine that they are have been prescribed by a health care practitioner for the treatment of a more serious condition"

Complementary medicines are listed products, and as such the second aim (i.e. have been prescribed) cannot be applied. We would therefore expect the regulation to reflect 'low-risk' complementary medicines as well as 'high-risk' prescription medicines. TGA has said it applies risk-based regulatory processes to therapeutic goods[1]. Comvita fail to understand how this consultation document takes into account requirements for different types of therapeutic goods (e.g. AUST R vs. AUST L), especially given that the background document to the consultation,[2] excluded complementary medicines from the scope of their discussion. ***Comvita therefore question whether this approach to labelling is really risk based. And would like to propose that "TGO 69 General requirements for labels for medicines", be amended to include alternative labeling and packaging requirements for registered (AUST R) and listed (AUST L) therapeutic goods, in particular complementary medicines.***

In addition to this consultation, we have recently been consulted on the *Evidence required to support indications for listed medicines*[3]. It is anticipated in the event this proposal is successful that listable indications on pack will be required to meet the structure requirements set out in Section 1.1 of that consultation. This will mean more space is required on the label to meet these requirements in clarifying the indication of the product. The proposed labelling requirements set down in the *TGA Medicine Labelling and Packaging Review* consultation document will reduce the space available to meet the structured indication requirements.

Comvita are disappointed that so many requirements are being put onto the complementary medicines sector. The largest impact will be a reduction in the amount of space on labels that allows sponsors to clearly communicate the product benefits to the consumer – particularly on the front of the pack where consumers get their first glance of product indications. This is deemed unacceptable for complementary medicines where products need to be advertised to create sales, compared to prescription only and pharmacist only medicines for which advertising to the general public is prohibited. According to the ANAO Complementary Medicines audit report[4] the complementary medicines sector in Australia was estimated to be worth $1.2 billion a year in 2010, and globally $US 83 billion annually. If products are unable to communicate indications on the front of pack due to the restricted space generated by this proposal, it is likely that consumer confidence will be reduced by

[1] Australian Government. (2001). TGA reforms: A blueprint for TGA's future.
[2] Australian Commission on Safety and Quality in Health Care. (2011). Report of the National Round Table on Safer Naming, Labelling and Packaging of Medicines.
[3] Australian Government, Department of Health and Ageing. (2012). Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants). Retrieved on 23 July 2012 from: http://www.tga.gov.au/industry/cm-evidence-claims.htm
[4] The Australian National Audit Office, Performance Audit Report No.3 (2011-2012). Therapeutic Goods Regulation: Complementary Medicines

the lack of information available on pack. Studies have shown that consumers relate to health claims (indications) and that they help the consumer establish the perceived benefit[5], if they cannot establish the perceived benefit it is likely that loss of sales will result.

If the proposed regulation goes ahead as is, it is anticipated that it will impact all products Comvita sell in Australia under the listed medicines regulation. Not only does it have the potential to reduce sales as discussed above through reducing the available space for indications, but it also has significant immediate costs in meeting the new compliance requirements. This imposes huge costs, both in the terms of new packaging design, origination costs for new printing plates etc. We have estimated that these costs will amount to approximately $80,000 and we would require the proposed 3 year transition period. In addition, many product labels are currently shared across multiple markets (e.g. Australia and New Zealand share the same packaging), if this proposal goes through there will be further additional costs added as we will have to generate Australia only packaging and this means higher print costs for lower volumes of printing for Australia specific packaging.

These additional costs will invariably be passed onto the consumer, increasing the cost of public health. This increase in consumer costs goes against the World Health Organization charter[6] which states "Access – Increase the availability and affordability of TM/CAM, as appropriate, with an emphasis on access for poor populations."

In addition to the general comments mentioned above, Comvita would like to respond to some of the questions asked in the review, and comment more specifically on certain aspects of the review document.

Prominence of active ingredients on medicine labels

Re: Page 15 Consumer health risks associated with not knowing the active ingredient – first paragraph discusses the risk where it is specific to pharmaceuticals, while the second paragraph is specific to OTC.
Comment: Complementary medicines are not discussed in terms of risk to the consumer. It is our opinion that this risk is mitigated in complementary medicines. Since many complementary medicines are based on herbal preparations, herbal names are specified in the ARTG by approved names (AAN, AHN, ABN) that must be present on the label. TGO 69 3(2) presently states that the active ingredient(s) must be on the label and that this statement must include the approved name – this current standard is commensurate with the level of risk associated with complementary medicines.

Re: Page 18, 1.1 The active ingredient(s) must be listed immediately below the brand name.
Comment: Comvita understand how this may be appropriate for pharmaceutical prescription medications, however believe it is not workable for complementary medicines. It might also be argued that this recommendation could compromise a company's legal position in relation to the *Consumer and Competition Act 2010*, as this might be considered as "misleading and deceptive". TGO 69 3(3) presently

[5] Verbeke, W., Scholderer, J. & Lahteenmaki, L. (2009). Consumer appeal of nutrition and health claims in three existing product concepts. *Appetite*, **52(3):**684-692. Retrieved on 12 July 2012 from: http://www.sciencedirect.com/science/article/pii/S0195666309000531
[6] World Health Organisation. (2002). *WHO Traditional Medicine Strategy 2002-2005*; page 5. Retrieved from: http://www.who.int/medicines/publications/traditionalpolicy/en/index.html

states that the active ingredient(s) must appear on the main label, except where there are >2 active ingredients (3(3)(b)) in which case they can be listed on the side or rear panel of the packaging, Comvita believe this position should be maintained.

Re: Page 18, 1.2 The active ingredient must have equal prominence with the brand name. And regarding (1.2.2, 1.2.3) font size and differentiation of the active ingredient from the medicine brand name on the main/front label.
Comment: We ask you to consider if displaying the active ingredient in this manner is commensurate with the risk of complementary medicines. Comvita do not this is workable for complementary medicines, especially since many complementary medicines contain botanicals which requires a lot space to give the botanical name (genus and species) of the ingredient. Unlike pharmaceutical products, complementary medicines make claims on the front of pack to help consumers identify products that might help with their issue (e.g. Traditionally used by native Americans to support digestion), if these requirements are enforced there is likely to be limited space for other information that helps the consumer select a product. As discussed earlier, consumers use health claims to help establish the perceived benefit, if these are not easily visible, decreased sales are likely to result. This is especially important considering the complementary medicines industry is in consultation with the TGA on the appropriate evidence required to support indications for listed medicines.

Re: Page 18, 1.3 >3 active ingredients, the most abundant ingredients must appear on the main label....
Comment: How do TGA define "most abundant"? This is an ambiguous statement and clarification is required around how many ingredients sponsors would be expected to list on the front of pack under this requirement? For example, how would this work with a product like a multivitamin, where you have many vitamins added in similar amounts? Or a herbal preparation with 5 ingredients, each present in similar amounts? – In these situations it is not reasonable to list all active ingredients on the front of pack or list according to the most abundant. Comvita would like to question, if this really benefits the consumer?

Given the complexity and diversity of complementary medicine ingredients this proposal is unworkable and will cause more confusion and be misleading for consumers giving the impression that the product contains solely those active ingredients mentioned on the front portion of the label. This proposal will be extremely misleading to consumers, and poses the potential for them to believe the 3 ingredients on the main label are the only ingredients in the product.

An addition the primary ingredients contributing to the effectiveness of the complementary medicine formula may not be the most abundant ingredients by quantity. **Overall this proposal is unworkable across all therapeutic goods and could lead to consumers being mislead about the benefits of the product.**

The current review was centered on consumer safety, and to avoid multiple doses of the same active, then the disclosure of only 'the most abundant' ingredients on the main label, would not provide added insurance. For example, a multi containing zinc, a 6x ingredient cold and flu product containing zinc, and a 4x ingredient Vitamin C product containing zinc, may all have zinc listed on a part of the label other than the main label. In this case, one product out of the three may have zinc listed on the main label. This is a very likely scenario for complementary medicine products, as the majority contain multiple actives.

Re: Page 19, 1.4 For day and night products, the composition of each tablet must be provided immediately below the brand name.
Comment: We ask you to consider if displaying the active ingredient in this manner is commensurate with the risk of complementary medicines. Unlike pharmaceutical products (e.g. acetaminophen), complementary medicines (e.g. Echinacea) make claims on the front of pack to help consumers identify products that might help with their issue (e.g. May assist in reducing symptoms of the common cold), if these requirements are enforced there is likely to be limited space for other information that helps the consumer select a product.

Re: Page 19, 1.5 The active ingredient(s) must be included with, and of equal prominence as, the brand name on at least 3 non-opposing faces of a carton.
Comment: We ask you to consider if displaying the active ingredient in this manner is commensurate with the risk of complementary medicines, and if this is practical for labels to fit in larger font given all the other label requirements? Comvita believe that the Medicine Information Box or similar is sufficient in communicating information in regards to product formulation in a direct and concise manner. There should be sufficient space left on the main panel to highlight claims and benefits of the product to the consumer.

Look at your example box (Figure 4), is it realistic to duplicate this information on a minimum of 3 sides, given all the information expected from Figure 2 – I note that this has been achieved in Figure 2, but thought needs to be given on how to handle this if there are >3 active ingredients as is the case in many complementary medicines.

What do you think will be the impact of increasing the prominence and standardizing the location of the active ingredient on the medicine label?
While appropriate for registered pharmaceutical products, Comvita believe this requirement is not based on the standard of risk associated with complementary medicines. The major impact will be on the amount of available space for indications on the front of pack that helps consumer confidence during purchasing.

Are there any other concerns you have with the size or position of brand names and active ingredients?
Comvita are concerned that no many requirements are being put on the placement and size of active ingredients. Further information needs to be provided to industry on the exact number of actives TGA deem necessary to put on the front of pack, "most abundant" is too ambiguous for comment.

If the active ingredient name is clear, directly below the brand name and in large font, what are the additional benefits that you see by making it the same size as the brand name?
Comvita see no benefit in this requirement, rather we see that this may negatively affect the complementary medicines industry due to a potential reduction in the space available to communicate product indications to the consumer on the front of pack. Further, it will likely cause confusion for consumers as to what 'actives' are in multi-ingredient complementary medicines.

What is the smallest size font that consider readable?
This is entirely dependent on the font selected, as you can appreciate some fonts (such as Arial and Calibri) are easily read at font sizes as small as 1mm, compared with *script* type fonts which would not be easily read at this size.

Look-alike packaging and branding

Re: Page 23, 3.4 Products that are listed on the ARTG cannot be marketed under the same name as a registered medicine.
Comment: Comvita disagree with this proposal. Generally, consumers are motivated by their individual health concerns and may be unaware of the particular product/ingredient that may be well known for one use is also beneficial for another. Sponsors can simplify this by highlighting the benefits as packaging through sub branding and as the claim or benefit is required to be substantiated at the time of listing, this communication pathway should be retained.

What benefits, if any, do you think the proposed changes to address look-alike medicine branding will have for consumer safety?
The safety issues raised on page 22 indicate the biggest risk associated with look-alike branding is the risk of overdose or the perceived benefit, usually as a result of a consumer selecting their own intervention. The proposed changes should negate the risk of misrepresenting the perceived benefit, however Comvita feel that the risk of overdose might not be so improved. This is because, while a consumer may realize the active ingredient of the product they may not assume mixing this with another product with the same active ingredient will cause overdose – this is where consumer education needs to clarify the risks for the consumer and we suggest this needs to take place at the time of purchase, whereby the pharmacist or sales person should provide advice.

Do you understand the proposed changes?
Yes, the proposed changes are clear and sufficiently descriptive that they could be followed.

If you read the labels and warnings clearly, will these changes reduce the potential for harm?
This is difficult to say, it comes down to consumer interpretation and perception of what they have read.

Standardized Information Format: the Medicine Information Box

Re: Page 28, 4.1 Mandatory information on labels and packaging of non-prescription medicines and complementary medicines is presented in a standardized medicine information box.
Comment: Please consider if this is not an over the top requirement for low risk medicines, especially complementary medicines. Especially given the lack of evidence that content and format effect safety (discussed below). In addition, with regards to global harmonization, the use of the term 'Medicine Information Box' would have implications for products also sold in New Zealand where they are regulated as Dietary Supplements. It would be confusing for example to have a medicine information box on a dietary supplement.

To what extent do you think a standardized format for information on the labels of over-the-counter and complementary medicines will improve access to information for these medicines?
Comvita do not support this recommendation, it is not commensurate with the level of risk for complementary medicines. All this information is presently required on labels under *TGO 69* and we are not convinced that displaying it in a medicine information box like those use on pharmacy only medicines will improve consumer safety. In the

research the review mentions by Shrank[7] it is clearly stated that the authors conclusion that the content and format of prescription drug labels facilitates communication and comprehension by patients:

> "is limited by their assumption of a significant relationship between readability, comprehension, and appropriate medication-taking behavior." (page 797)

And that:

> "Many of the studies cited here were performed in a non-clinical setting.... They may not capture the true complexity of medication-taking in a real world setting in which patients may be taking multiple medications and have numerous competing demands." (Page 797)

The authors then go onto to summarize that there is:

> "little evidence to link label design or contents to measurable health outcomes, adherence or safety." (page 798)

Based on the reference provided, we feel that while you have proven that content and format may have an effect it has yet to proven in a real world setting on health outcomes such as patient safety which is the primary objective in this consultation.

Are there other ways that the presentation of information could be improved?
If TGA are adamant about wanting to mandate the use of medicines information box, we would like to propose an alterative. Instead of the strict requirements around the box you have set out in sections 4.1-4.6 we would like to suggest a grouping rule, rather than the specified box format. So it could be mandated that the information proposed for the medicine information panel has to be 'grouped' together on the panel, such that it must all appear in the same field of vision. This will provide companies with enough design freedom to set out their labels (to fit their brand) but also by having information grouped in a specific area will still allow for easy comparison of different brands of therapeutic goods.

Do you think the proposed requirements for products with more than three active ingredients (directions and warnings and allergy information), is sufficient for these products? Please propose and alternative if you don't agree with current recommendation.
For listed medicines, this requirement is not appropriate. Listed medicines are not always packed into a box which would provide a place for the insert to be placed, and since they are not dispensed by a pharmacist there is no opportunity for the insert to be handed out. There should always be space for this information on the label, where it not possible for the information to fit we would like to propose that a smaller font size is allowable in these situations, we would like to propose that a not less than 1 millimeter letter height is allowed in these cases.

In addition, if TGA wish to make this a requirement Comvita would be required to box some of our products and print these inserts. This will add additional costs for packaging, which will invariably be passed onto the consumer.

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[7] Shrank, W., Avorn, J., Rolon, C. & Shekelle, P. (2007). Effect of content and format of prescription drug labels on readability, understanding, and medication use: A systematic review. *Annals of Pharmacotherapy*, **14:**783-801.

Blister Packs

Do you think the proposed information for blister strips is sufficient?
Comvita do not support the proposal to include the batch and expiry data more frequently on the blister strip than what is currently required. The TGO 69 currently requires the above information to appear once on each blister strip, when each dosage unit cannot be readily detached.

Batch numbering is usually applied to blister strips as a stamp at the time of manufacturer at one end of the blister strip so that packaging artwork does not have to be amended for every batch. It is not practical to implement printing of the batch number on the foil of the blister packaging.

This would also pose technical considerations, in particular the repetition of the expiry date, where the embossing of this information once every two units would not be practical once it is sealed with tablets/capsules. Such recommendations would mean that production would be slowed significantly to facilitate the online printing, resulting in significant capital expenditure and increased operating expenditure, costs that are ultimately passed onto the consumer. Comvita would like to highlight that printing more information on the foils encourages consumers to remove the blister from the cartons where all of the dosage instructions and warnings are located and this is not in the interest of public health and safety.

What other changes would you like to see for this type of packaging?
No comment.

Small Containers

Re: Page 36, 7.1 These containers must be enclosed in a primary pack that fully complies with all labeling requirements and that includes a pack insert that provides detailed instructions for use.
Comment: The pack insert should not be required if the primary pack is fully compliant. Comvita fail to see the added benefit of the pack insert, this will add additional costs that will ultimately be passed onto the consumer. Further, if instructions for use are detailed on the primary pack, the insert is not going to provide any additional information to that on the primary pack. The discussion on page 35 states that the "additional information in only effective if the primary packaging and package insert is not discarded and always carried with the medicine." Given that any pack insert is likely to be discarded along with the primary packaging, and the most important information is on the small container label then there is no reason to support the need for a pack insert.

Re: Page 36, 7.2 The label on the container must include the following details in a letter height of not less than 1.5 millimeters; brand name, active ingredients, batch number, expiry date.
Comment: We would ask that TGA consider decreasing the font size for small packaging requirements, this would allow companies to include more information on pack, and meet labeling requirements more easily. We would recommend not less than 1 millimeter as this might allow for the inclusion of warnings on the container packaging which is considered a requirement for consumer safety, especially when primary packaging (including pack inserts) is discarded.

To what extent do you support the proposed changes for small container labels? Please provide details.
We do not support the proposed changes to small container labels. We believe the requirement for a pack insert adds an unnecessary component to the packaging of listed complementary medicines that adds little value to the consumer given all this information can be contained on primary packaging (box).

Further, The requirement for small container labels on page 36-37 appears to state both that the container label must include the names of all actives and also that only the three most abundant must appear on the label and all of them on a primary pack and an insert. Hence there would then be a disagreement between label and primary pack and presumably more words required to explain that the full list of ingredients is to be found elsewhere. This may be difficult if carton and insert have been thrown away, for example.

Do you have any further suggestions for how labeling for small containers could be improved?
Please see comments above.

Pack Inserts

Do you support the proposed changes for pack inserts? Why/why not?
It is unclear as to why this regulatory change has been proposed and how this change will improve the safe and effective use of medicines. Pack inserts offer sponsors of complementary medicines an opportunity to provide consumers with suggestions for other products which are related to the medicine which they have purchased and may benefit from. It is acceptable to prohibit the advertisement of prescription medicines on pack inserts because advertisements of these medicines are prohibited under the Therapeutic Goods Advertising Code (TGAC) however such restrictions do not apply to complementary medicines and as such this regulatory proposal should exclude complementary medicines. Pack inserts should only be required if all the necessary information cannot be included on the product label.

The purpose of these requirements is to protect public health by promoting the safe use of therapeutic goods, ensuring that they are honestly promoted as to their benefits, uses and effects. Through a series of co regulatory and self regulatory arrangements advertising of therapeutic goods is to be conducted in a manner that promotes the quality use of the product, is socially responsible and does not mislead or deceive the consumer. The sponsor therefore, should have the ability to communicate how the product works (in addition to technical jargon that are usually used in indications) via product packaging to consumers, this is especially the case for listed complementary medicines, which are available for self selection by consumers.

Comvita agree that the pack insert needs to be in a form separate to the packaging. If it were to be printed on the inside of the carton it is not going to be easily accessible to the consumer to read and this does not help with consumer education about the medicine.

Do you have any further suggestions regarding pack inserts?
No further suggestions.

Summary of Recommendations:

- Propose separate labeling and packaging requirements for AUST R and AUST L therapeutic goods (particularly complementary medicines) that is commensurate with their level of risk.
- Maintain current labeling requirements for complementary medicines.
- Do not make the medicines information box mandatory – consider a grouping rule.
- Do now enforce pack inserts for products with >3 ingredients. Suggest you adjust the font size to allow the information on pack to not be less than 1.0 millimeter.
- Small packs should have the font size adjusted to not less than 1.0 millimeter.

Overall, Comvita do not support the proposed consultation as it imposes high level pharmaceutical standards on low-risk complementary products.

Thank you,

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