TGA Medicine Labelling and Packaging Review – Consultation paper

In principle, we agree with these changes in relation to prescription medications, however there are several issues with applying these changes broadly across all medicines. Therapeutic goods regulation within Australia is a tiered risk-based model, and while the presented regulatory changes appear appropriate when referring to high-risk (prescription products), the question of whether these changes are advantageous, appropriate or reasonable for medium-risk (OTC products) or low-risk (complementary medicines) needs to be considered. The impact of these proposed changes, for the complementary medicine industry, are largely negative, and based on a risk model, unnecessary. Aside from the feasibility issues of presenting the required information on the label, in the required format, the financial cost of these changes would present an unreasonable burden to the majority of Sponsors. The plate costs of implementing these changes would be excessive, even if a three year phase-in period is allowed.

Operating within the complementary medicines sector, our comments will obviously retain that focus; however there are concerns regarding the application of these changes to OTC medicines as well. It seems appropriate that a risk model is applied to these changes and this consultation, and that labelling is regulated relative to the tier/risk associated with the medicine. It would be prudent given the long history surrounding these changes and the apparent risks to prescription consumers that a separate labelling code is developed for prescription medications. Based on experience, I would support a separate standard pertaining to prescription medicines; frequently when either consumers or pharmacy assistants request information on supplement/medication interactions, often the information provided is in relation to a product name, with no information on either the class of medication or active ingredient available. I do agree that increasing the prominence of the one or two active ingredients in a prescription medicine would help remedy this issue.

The suggested amendments to labelling are also running the risk, in the long term, of being to the detriment of consumer safety and essentially increasing the exposure of industry and brands to litigation. It is impossible to warn against every possible contingency, and the pitfall of removing consumer responsibility for their healthcare is the increased assumption that the consumer is not responsible. Although in no way does this advocate creating undue exposure or reducing industry regulation, it does support the suggestion that instead of spending the effort bringing into play potentially unnecessary regulations and additional monetary and temporal burdens, in the long term increased public education about reading labels and understanding what they are consuming is going to lead to a healthier and more self-sufficient population.

Prominence of active ingredients on medicine labels: Complementary medicines are not usually associated with simple, single or dual active formulations, and although the proposal seeks to address this by providing a contingency (only the first three ingredients to be displayed on the front panel); it is only functioning as a contingency to an inappropriate labelling system for the style of product. For instance, considering the number of multivitamin products on the market, the proposed format for multivitamin/mineral products is to state on the front panel the three most prominent actives; however we believe this style of labelling will create a greater degree of confusion with consumers as each multivitamin/mineral product may end up featuring a different three ingredients.

Look-alike and sound-alike medicine brand names and look-alike packaging and branding: Primarily, our concerns here lie with the application of the term "branding" and whether this may end up encompassing a wider net of products than initially intended. It seems that the application of "brand" being used in the proposed amendments is quite specific to prescription and certain consumer healthcare products, rather than complementary medicines. There is a disparity in the application of a brand between these markets. Predominantly, in the complementary medicines sector, a "brand" is less likely to be linked to a single product, and hence to position the branding as per the recommendations has more potential to confuse the consumer than to provide the sought clarification.

The suggested warning for paracetamol and ibuprofen should ideally include a maximum daily consumption of these substances; this way the consumer is better informed to take responsibility for their own health care without the need to see their doctor unnecessarily.

Standardised information format: the medicine information box: From a feasibility perspective, the current labelling requirements are already suitably challenging to fit without reducing the font size below the current minimum. To revise this information to include borders, sections and mandatory heights for the headings of 2 mm (instead of the standard 1.5 mm) will not fit on the majority of products without compromising the current minimum font size requirements. If the intention is to increase readability of information, then this approach will most likely be counterproductive. As an alternative, for complementary medicines, including headings for each of the key sections (potentially as per those specified) at the same minimum font size as the text, but in bold, without a requirement to have the heading on a separate line would help increase readability and the consumer's ability to locate specific information for product comparison.

The medicine box, as proposed, with its headings (proposed 2 mm height) and additional space constraints are not going to contribute to the readability of product information for most complementary medicines as the labels do not have adequate space to include this information at a reasonable font size.

- The inclusion of "Medicine Information Box" is unnecessary, and simply takes up space. The product, by the inclusion of an AUST L or AUST R is identified as a medicine. The information pertaining to the ingredients and warnings is obviously "information". To include this all in a box, which takes up space, is counterproductive to maintaining a minimum font size.
- Although it would be of benefit to consumer comparison to provide the information in a set order, when preparing smaller packaging, and even some cartons, this becomes unfeasible. Specifying that information must appear in a particular order removes the flexibility that is sometimes required to rearrange information to optimise available space; this may lead to a reduction in font size that could compromise the readability of the information, which is contrary to the objective of the proposal.

- Including additional information on a pack insert is frequently not a viable option for complementary medicines, as they are often presented as a bottled product without an outer carton. The only other recommendation provided by the proposal is that an alternative label format or font size is provided for approval, however given that pre-market review is in not applied to listed medicines, this suggestion is obviously not geared at the complementary medicines sector in any way and potentially an alternative should be provided that is more appropriate to the risk assessment and claims level associated with these products.

Dispensing label space: Although this is outside of the professional scope of this company, this section of the proposal is supported.

Blister strip labelling: The proposed information for blister strips is excessive. The current proposal appears to suggest that products, even without perforated or removable sections, contains the batch code and expiry every two dosage units. Although I can see advantages of this being applied when there are perforated sections, if this is not the case then this proposal is unreasonable and will cause undue difficulty to both Flexibles printers and the packaging production lines for a large number of manufacturers. In many cases this would require new equipment to be purchased and validated to allow in-process printing of this information. This is both expensive for packaging facilities and jeopardises the business of Flexibles printers without providing a significant benefit to consumers.

Pack inserts: The proposal states that "Advertising material will not be permitted to be included as a separate pack insert or incorporated into an approved pack insert". Although there could be potential issues including advertising material on a pack insert that also contains product information, it seems excessive to eliminate the inclusion of any advertising or marketing material as a separate pack insert, if the sponsor chooses to use this. Secondly, this statement pertains to an "approved pack insert" as once again complementary medicines appear to be bundled up with products subjected to a pre-market review.

Labels and packaging advisory committee: There is potential for an advisory committee to assist the TGA in managing consumer health risks, however from the information provided the scope of this advisory committee it is not clear, or how this would interact with the already very useful Advisory Committee on Complementary Medicine (ACCM).