PART A - SUMMARY OF ISSUES AND ALTERNATIVE PROPOSALS

1. Issues with the consultation process

In Ego's view the principal deficiencies with the consultation process are that:

- There has not been compliance with the COAG Principles of Best Practice Regulation.
- Critical views of an External Reference Group specifically set up to advise the TGA on this consultation were not taken into account.
- Insufficient time has been allowed to prepare a comprehensive industry response with tested alternative proposals.

See Part B for a detailed discussion.

2. Issues with the consultation paper

In Ego's view the principal deficiencies with the consultation paper are as follows:

Content: inconsistencies & errors

- The paper contains errors and inconsistencies which resulted in a lack of clarity and which made interpretation difficult.
- The figures include material which is not explained in the text, which do not comply with current labelling requirements, demonstrate a lack of internal consistency within the paper and imply additional proposals.

Insufficient evidence supporting problem identification and proposed solutions

- No attempt was made to appropriately segregate the evidence of risk in relation to prescription and non-prescription medicines.
- No evidence was provided that the proposed reforms will achieve the stated objectives of the review.

See Part B for a detailed discussion.

3. Impact of proposals on pack size

- The proposed changes involve both increased font sizes and increased levels of content. The inevitable consequence of this will be an increase in the physical dimensions of the product packaging. The ramifications of this will be far-reaching and extremely costly.
- In our response we have made no attempt to address this complication in detail. Indeed, any attempt to address this issue in the absence of finalised proposals would be premature.

See Part B for a detailed discussion.

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4. Response to specific proposals

The alternatives put forward below all come with an important caveat. None of the proposals have been tested as the consultation timeframe was insufficient to undertake that task. The need to subject the proposals to rigorous testing prior to implementation cannot be overemphasised.

In relation to the TGA's stated "risk-based approach to regulation", the TGA states that:

> *"One of the roles of the TGA is to regulate therapeutic products based on an assessment of the evidence of the risks compared to the benefits of the therapeutic products. The TGA does this by applying scientific and clinical expertise."*[1]

Despite this, the Consultation paper proposes uniform solutions across medicines categories. We do not support such a blanket approach.

4.1 Prominence of active ingredients on medicine labels

The objective of the Review in relation to this issue:

- To develop appropriate regulatory solutions that effectively address the consumer safety risks posed by information about the active ingredient(s) contained in the medicine which is not always easy to find.

Ego's position on the proposals

- Ego acknowledges the importance of consumers being able to readily identify product ingredients on the label and the risks associated with taking more than one product containing the same ingredient(s).
- Ego believes that this could be achieved by giving due prominence to ingredient names.
- Only one option was put forward, that of "equal prominence". Ego does not support this proposal as there are alternative options possible which could effectively address the issue, ranging between "equal size" and the current situation. Our chief concern is the potential detrimental impact on brand recognition, which is a vital element in consumer product selection.
- Ego does not support the proposal that active ingredients be displayed on 3 non-opposing panels. Ingredient identification could be enhanced through alternative mechanisms.

Alternative options

- Consistent with a risk-based approach a distinction should be drawn between the different non-prescription medicines categories. We do not support a blanket approach to be applied to all non-prescription medicines.

[1] http://www.tga.gov.au/about/tga-regulatory-framework.htm

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- The proposal that in the case of multi-ingredient products the 3 most abundant ingredients should be displayed on the front-of-pack would be nonsensical and potentially misleading for the vast majority of complementary medicines, e.g. multivitamins. We suggest instead that a 'referral' statement, e.g. "See back of pack for the active ingredients", could be considered.
- Sunscreens are arguably at the lowest end of the risk continuum and Ego is not aware of any risks in relation to this category of products. Without evidence of risk, we contend that current requirements applicable to sunscreens are still appropriate and should be retained.
- The impact on the labelling of small containers should be assessed and allowances considered.
- For other non-prescription medicines, alternative options for achieving due prominence of ingredient names should be investigated. These include:
    - Use of colour, graphics, positioning in relation to brand name and different font types and sizes.
    - A standard band at bottom of the front panel of the label for inclusion of the actives could facilitate recognition through consistent placement and presentation which is supported by available evidence.
    - A "scaling approach" to the size of the actives (e.g. similar to the approach taken for signal headings) and making these proportional to available label space (height/area) to make this practicable in the case of smaller packs.
- It seems likely that a standardised back-of-pack format for information ("Medicine Information Box") will facilitate consumer's ability to locate and identify the active ingredient and this should be taken into account when considering any changes to the front-of-pack.
- Non-regulatory approaches to mitigate risks must also be considered. Consumer education is a critical element in enhancing QUM.

See Part C for a detailed discussion.

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4.2 Look-alike and sound-alike medicine brand names and look-alike packaging and branding

The objective of the Review in relation to this issue:

- To develop appropriate regulatory solutions that effectively address the consumer safety risks posed by:
    - Use of the same brand name for a range of products with different active ingredients resulting in look-alike medicines branding (also called brand extensions, umbrella branding or trade name extension);
    - Medicine names that look-alike and sound-alike (LASA) that can lead to use of the incorrect medicine
    - Medicine containers and packaging that looks like that of another medicine.
- Stated alternatively:
    - To reduce the risk of accidental overdose that could result from consumers being given the wrong medicine or selecting the wrong medicine because of similarities in the names or packaging of the medicines.

Ego's position on the proposals

- While Ego fully endorses the objective of avoiding possible harm which may result from confusing different medicines, we do not support the blanket and simplistic approach to both prescription and non-prescription medicines advocated in the consultation paper.
- Distinction should be drawn between proposals in relation to prescription and non-prescription medicines. The paper confusingly amalgamates four interrelated issues into a single topic applicable to both prescription and non-prescription products. The four issues (look-alike sound-alike products; different strengths within a prescription medicine brand; umbrella branding; indication specific branding) all apply differently to prescription and non-prescription medicines.
- This is a complex and multi-faceted area for non-prescription medicines in particular. Branding and brand recognition through brand extensions ("umbrella branding") are key issues for non-prescription medicines, both from an industry viability perspective but equally importantly from the consumer self-selection perspective. The costs associated with establishing a novel non-prescription medicine brand (as well as developing consumer awareness and trust) are considerable. These costs will be a key determinant in the decision to launch a new product. Inappropriate restrictions on umbrella branding will have a detrimental impact on access to new products.
- Consistent with a risk-based approach, proposals should be reflective of the risks posed by the different categories of products. For example, the potential risks associated with ingesting a medicine are different from those associated with topical application of product.

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Alternative options

- Given the complexity of these issues (and in view of the above) Ego feels strongly that this area requires more in depth exploration and consultation with all stakeholders to generate confidence that reforms will achieve the stated objectives and not result in unintended consequences.
- The TGA in collaboration with consumers, industry and other stakeholders should pursue the development of guidelines for LASA and brand extensions ("umbrella branding"). Clear guidelines and protocols would assist both sponsors and the TGA to objectively assess the risks associated with product brands, names and packaging.
- Additionally, Ego believes that evidence-based and objective decision-making would be greatly enhanced by the development of a broadly acceptable label testing methodology. The aim of such a methodology would be to generate test results that would provide confidence that any risks in relation to product identification and other issues impacting on safe use have been effectively addressed.
- Ego proposes that the TGA commissions a paper on international best practices for label comprehension testing.

See Part C for a detailed discussion.

4.3 Standardised information format: the Medicine Information Box

The objective of the review in relation to this issue:

- To develop appropriate regulatory solutions that effectively address the consumer safety risks posed by the following issues:
    - There is a lack of standardised format for information included on medicines labels and packaging
    - Information about the active ingredient(s) contained in the medicine is not always easy to find;
    - Inconsistent placement of information such as dosage and usage instructions, precautions (including potential allergens) and storage instructions increases the risk that a medicine may be taken or stored inappropriately.
    - Consistent formatting and presentation of information will assist consumers to identify and interpret the information they need.

Ego's position on the proposals

- Ego agrees that a standardised back-of-pack format for medicine information has merit.

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Alternative options and considerations

- Any proposed back-of-pack format should be tested prior to adoption.
- Provision should be made for alternative formats to accommodate different product categories or types, subject to consumer testing.
- The relevance/need for the title "Medicine Information Box" should be consumer tested – it may not be relevant to all product categories.
- The impact on the labelling of small containers should be assessed and allowances considered.
- A "matrix" approach to headings - outlining which ones are required for which categories- should be considered
- Cues on the front-of-pack drawing attention to the panel should be explored and tested

See Part C for a detailed discussion.

4.4 Dispensing label space

This item has been identified as applying to prescription medicines only.

Ego offers no comment in relation to this part of the Consultation paper.

4.5 Blister strip labelling

Blister strips are not used for the packaging of Ego products.

Ego therefore has no comment to make in relation to this part of the Consultation paper.

4.6 Small containers

Ego's position on this issue

- The consultation paper appears to re-state existing requirements for non-prescription medicines and it should be clarified how the "proposed changes" differ from the current arrangements.
- Ego agrees with the comments about the practical considerations and challenges in relation to small containers.

Options proposed by Ego

- Given the practical limitations of small containers, the impact of the proposed changes in their entirety need to be examined in detail (for example the inclusion for the "Medicines Information Box" headings alone will have a significant impact).

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4.7 Pack Inserts

Ego's Position

- It appears that the proposed changes simply re-state the current arrangements. It is not clear how the "proposed changes" differ from the current arrangements.

Options proposed by Ego

- That pack inserts should only be required if all the necessary information cannot be included on the product's label.
- Ego suggests that the ARGOM already provides appropriate guidelines in relation to cross-referencing of other products and these should remain in place.

See Part C for a detailed discussion.

4.8 Labels and packaging advisory committee

Ego's position in relation to this proposal

- Ego appreciates the value of an appropriately constituted Committee in objectively applying clear guidelines and protocols to expedite evidence-based decision making in relation to medicines labelling and packaging.

See Part C for a detailed discussion.

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