PART C – DISCUSSION OF THE SPECIFIC PROPOSALS

Prominence of active ingredients on medicine labels

Summary of Ego's Position

The stated intention of these proposals is to reduce the risk of accidental overdose.

The TGA has not provided any evidence to demonstrate the size or the nature of the risks posed by the current labelling requirements.

The TGA has not provided any evidence that current labelling requirements for non-prescription medicines pose a risk to consumers.

Prescription and non-prescription issues and proposals need to be separated.

Consumer risk(s) identified in the consultation paper

In relation to prescription medicines, the consultation paper indicates that: "it is important to know the active ingredient so that the consumer avoids taking multiple doses of the same active ingredient".

In relation to over-the-counter medicines, the consultation paper indicates that: "it is common for several products with different brand names to include the same active ingredient" and that "a consumer who takes several of these products at the same time may receive an overdose of the active ingredient".

Notes on the Evidence Provided by the TGA

In support of the general statements about the risks to consumers of not knowing the active ingredient in a non-prescription medicine, the TGA has provided no evidence.

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Proposed regulatory change(s) and Ego's concerns with the proposals

Proposed Regulatory Change	Concerns
1.1 The active ingredient(s) must be listed immediately below the brand name, with the first letter of the active ingredient directly below the first letter of the brand name. 1.2 On the front/main panel of the label, the active ingredient must have equal prominence with the brand name. 1.2.1 The intention of 'equal prominence' is for the active ingredient to be as easy to locate and identify on the label as the brand name. 1.2.2 The font size of the active ingredient must be at least 100% of the font size of the medicine brand name on the main/front label. 1.2.3 For improved differentiation between the brand name and the active ingredient there should be a difference in font style or letter spacing or font colour. 1.2.4 The active ingredient should begin with an uppercase letter but the remainder should be in lower case.	Generally: • The stated intention of the proposals is to reduce the risk of accidental overdose. • The TGA has not provided any evidence to demonstrate the size or the nature of the risks posed by the current labelling requirements. • The TGA has not provided any evidence that current labelling requirements for non-prescription medicines pose a risk to consumers. • Prescription and non-prescription issues need to be separated, as the active ingredient problem appears to relate only to prescription medicines. • All changes need to be based on risk. • The TGA has not demonstrated that equivalence in font size for active(s) and brand names is the only, or most effective, way to resolve this issue for non-prescription medicines. • For self-selection, consumers need the link between active ingredients, dosage and usage. • Equal prominence of active ingredients and brand name is more likely to create consumer confusion by increasing clutter and reducing legibility of label, and reduces brand recognition. The size of active is disproportionate and overwhelms the other information the consumer needs in order to make appropriate self-selection decisions. • There is already limited space on packs and this proposal will limit space even further. • Non-prescription shoppers generally select by category/symptoms, then brand (not active). (See further discussion on purchase hierarchies later) • Legibility – bigger does not necessarily mean easier to read.

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	• Other ingredients are of relevance in the purchase/use decisions, e.g. excipients. • Any increase in pack size to accommodate larger active prominence will have flow-on cost implications to the entire supply chain. • Based on the graphics in TGA's consultation paper, we request clarification on company name, brand name and product name. • Note that several other jurisdictions have prominence requirements, such as 50% of brand name height and immediately underneath the brand name with no intervening text.
	<u>Low risk topical OTC products</u> (e.g. sunscreens and toothpastes) • The stated intent is to reduce the risk of accidental overdose. No such risk exists with these products. • These products pose a limited safety risk (excluding hypersensitivity). • The prominence of the SPF for sunscreens will be overwhelmed by prominence of active. • Sunscreen active ingredient names are long and could potentially scare consumers into not using a sunscreen (this could have a negative public health outcome). • These products are regulated as cosmetics overseas. This limits the relevance of overseas data and raises the possibility that the proposed changes will have an impact on competition. • In Australia, primary and secondary sunscreens are regulated differently as therapeutics and cosmetics respectively • Harmonisation options for sunscreens need to be aligned with appropriate cosmetic overseas labelling requirements.

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	Complementary medicines: • These products are regulated as dietary supplements overseas, not therapeutics. This limits the relevance of overseas data and raises the possibility that the proposed changes will have an impact on competition. • Minerals have to be presented as elemental or compound quantity. • There will be issues with the length of names for herbals ingredients (e.g. length of the name itself, together with presentation as an extract/dry/fresh equivalent and the identification of the plant part). • The Consultation paper is unclear about the distinction between company name and brand name (i.e. are Swisse, Nature's Own or Cenovis the company or brand names?). This is confused by the TGA's examples of label graphics which allow different sizes for the company name, brand name and sub-brand. The prominence of active appears to be equivalent to the sub-brand.
1.3 Where there are more than 3 active ingredients, the most abundant ingredients must appear on the main label immediately below the brand name and the names, together with the quantities of every active ingredient, are to be included on a side panel/label or on a rear panel/label for the product. (This does not apply to day and night preparations.)	• It is unclear from the proposed change how many of the most abundant ingredients are to be included. Ego has assumed that the intention is to include the three most abundant active ingredients. • It is unclear how this proposal fits with proposal 1.5. • The TGA has not provided any evidence that current labelling requirements for non-prescription medicines pose a risk to consumers. • For multi-ingredient products, just having 3 ingredients on the front panel is misleading and will confuse consumers about the contents and intended use of the product. • Having 3 active ingredients on the front panel may be misleading by ignoring the hypersensitivity issues of other ingredients (e.g. topical products).

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	• The requirement for the 3 most abundant active ingredients on the front label will mislead (e.g. in the Elevit pregnancy supplement, folate would not be listed on the front panel, and the 3 most abundant actives are calcium, magnesium and phosphorus).
1.5 The active ingredient must be included with, and of equal prominence as, the brand name on at least 3 non-opposing faces of a carton.	• The TGA has not provided any evidence that current labelling requirements for non-prescription medicines pose a risk to consumers. • This requirement appears to be an attempt to address issues with the prescribing and dispensing of prescription medicines. • Such a requirement has no place in relation to non-prescription medicines. • This is more of a pharmacist selection and dispensing issue, and is not relevant to the way consumers shop. They will already be placed in a category on shelves and will be selected by brand. • For non-prescription medicines, this will mean that the active ingredients will have to appear on the front, the back, and two other non-opposing faces. Repeating all this information on four of the six carton faces is unnecessary and wastes the limited space available.
See artwork mock-up labels below which show the impact that the proposed changes will have on brand recognition, pack clutter and pack size for non-prescription products.	

Alternative options

The alternatives put forward below are meant as a starting point only. None of these suggestions has been tested and no regulatory change should be introduced without consultation and not until rigorous and objective consumer testing has been undertaken.

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]

Proposals:

- The TGA should take a risk-based approach to the proposed changes. Changes must be evidence-based (both in terms of the risks posed by the current requirements and the benefits to be obtained by the proposed change). The TGA should not modify the current labelling requirements until such evidence has been put forward and consulted on.
- As the risks are different for the different medicines categories, the requirements should also be different.
- The TGA should retain the current differences in requirements (per TGO 69, ARGOM etc) for complimentary medicines and sunscreens.
- The TGA should consider non-regulatory approaches to mitigate risks (e.g. consumer education).
- The TGA should consider the impact of a standardised back-of-pack on the consumer's ability to locate and identify the active ingredient and factor this into any proposals affecting front-of-pack.
- The TGA should abandon the requirement to include the 3 most abundant ingredients on the front-of-pack and instead consider a requirement to include some sort of referral statement (e.g. "see back of pack for the active ingredients") if the actives cannot fit on the front-of-pack.
- The TGA should abandon the requirement to include the actives on 3 non-opposing panels (and should consider active ingredient disclosure on front and back of pack only for non-prescription medicines).
- The TGA could consider achieving prominence through other means (e.g. colour, graphics, position, size and difference of font, etc).
- The TGA could consider a band at bottom of front-of-pack with (or without) a contrasting background for inclusion of the actives.
- The TGA could consider some sort of scaling approach to the size of the actives (e.g. similar to the approach taken for signal headings).
- The TGA could consider making the requirements proportional to available label height/area to accommodate smaller packs.
- The TGA should consider non-regulatory approaches to mitigate risks, e.g. consumer education.

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

Caveats

The figures in the Consultation paper are flawed and have hampered the consultation process. Where stakeholders have mis-interpreted the proposed changes we suggest that a further round of consultations will be necessary.

No change should be made until a clear evidence-based justification for the change has been put forward.

No regulatory change should be made unless it has been subjected to rigorous and objective consumer testing.

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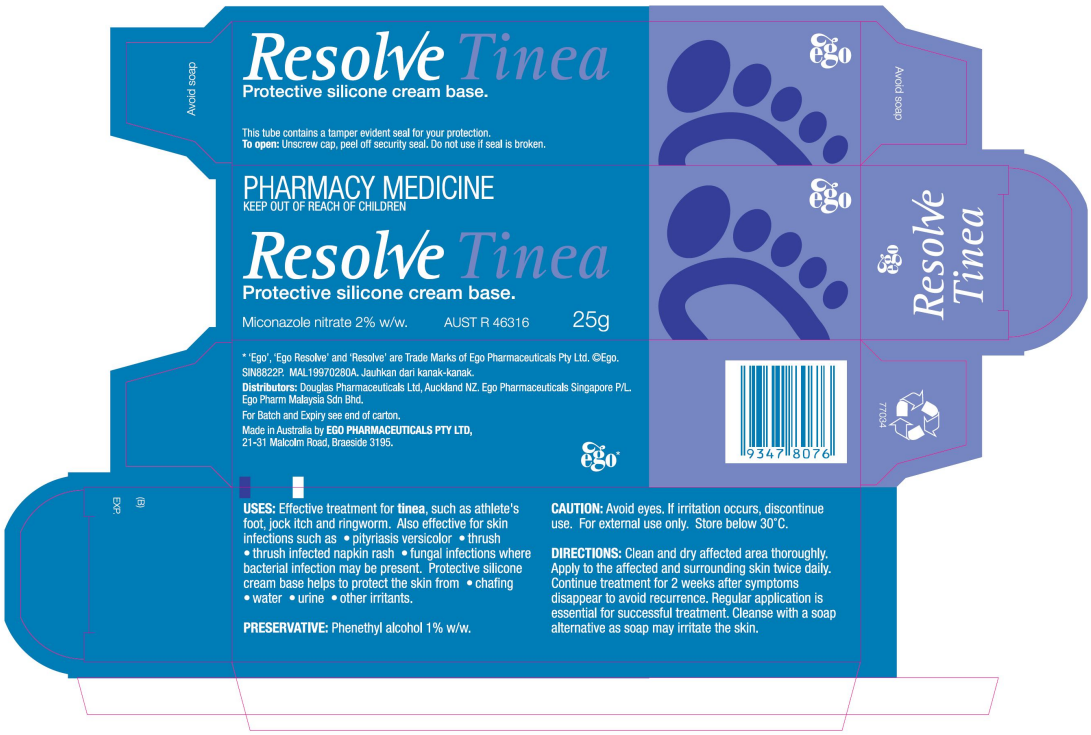
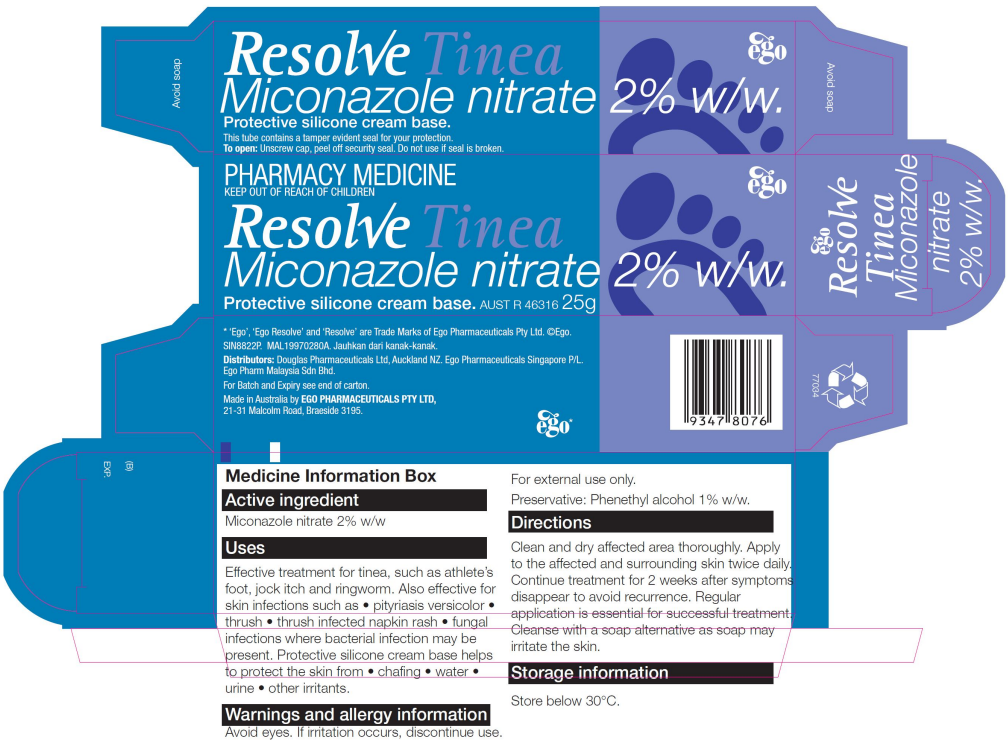
Artwork labels - Current Labels versus Mock-up Labels

A. Resolve Tinea (Current)



B. Resolve Tinea (Mock-up)



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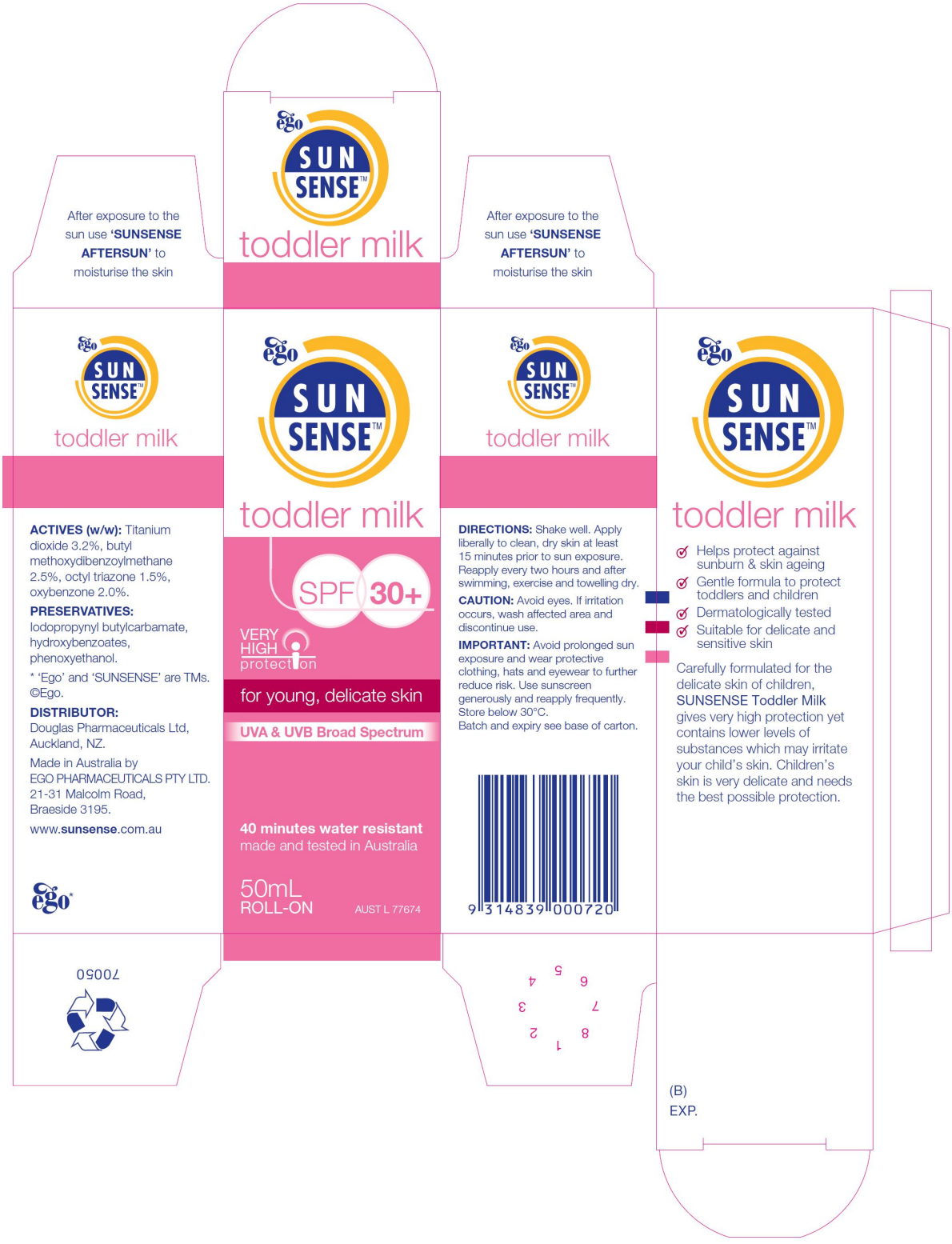
C. SUNSENSE Toddler Milk (Current)



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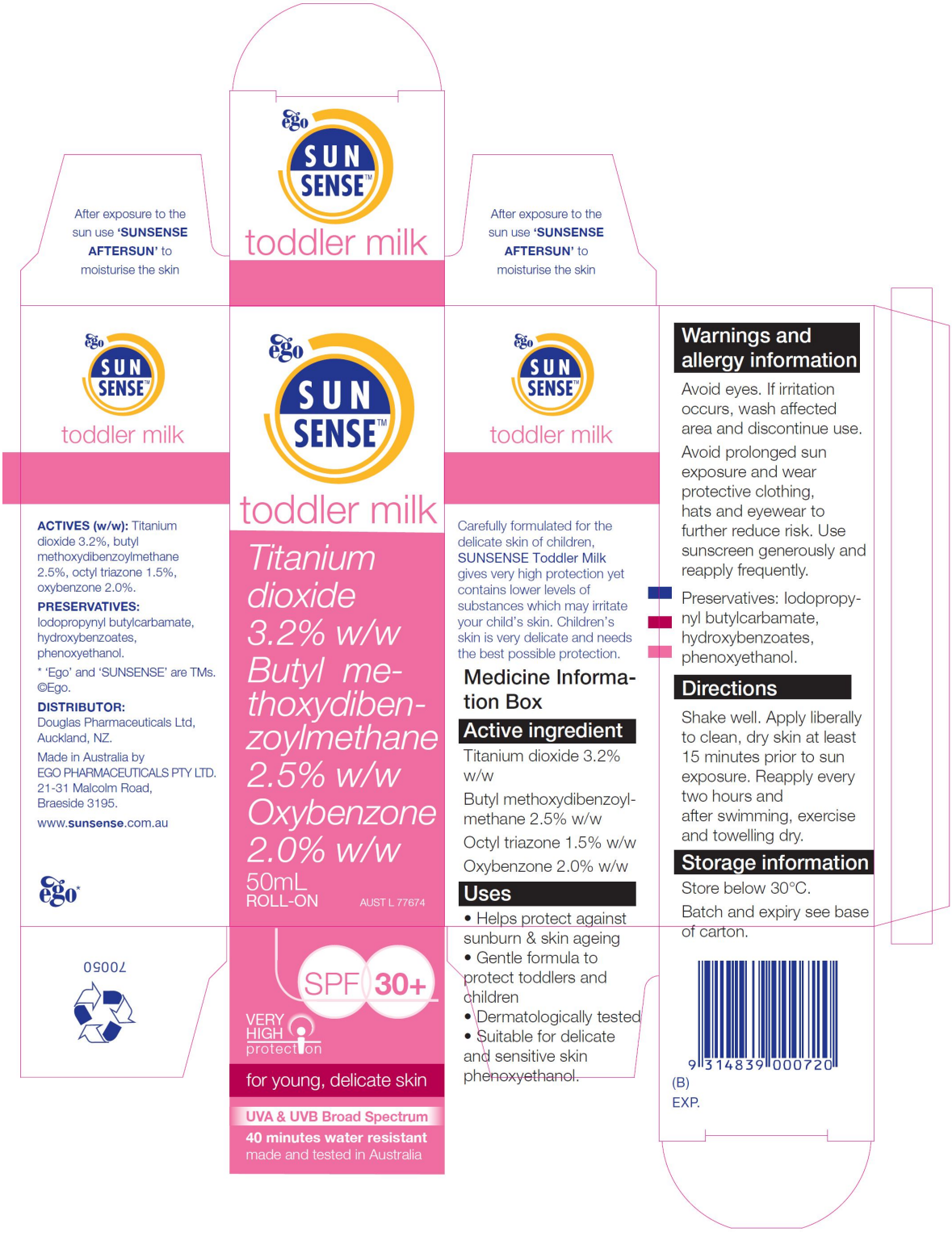
D. SUNSENSE Toddler Milk (Mock-up)



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

Summary of Ego's Position

The stated intentions of these proposals are to:

- Reduce the risk of consumers being given the wrong medicine or selecting the wrong medicine because of similarities in the names or packaging of the medicines.
- Reduce the risk of accidental overdose.

The TGA has not provided any evidence to demonstrate the size or the nature of the risks posed by the current labelling requirements.

The TGA has not provided any evidence that current labelling requirements for non-prescription medicines pose a risk to consumers.

Prescription and non-prescription issues and proposals need to be separated. On this point, it appears that in applying prescription issues to non-prescription products, there has been a complete disregard for the fact that non-prescription medicine labels already include detailed information about the product on the label.

The proposals are unacceptable to Ego.

Consumer risk(s) identified in the consultation paper

The Consultation paper indicates that: "*Key risks to consumers from LASA brand names result when they are accidentally given the wrong medicine by a pharmacist or health care professional or they select the wrong medicine themselves due to the similarity of the name or packaging of a medicine.*"

The Consultation paper also states that: "*there is also a risk of overdose if the consumer takes a product containing the same active ingredient but is marketed under a different name."*

Notes on the Evidence Provided by the TGA

In support of the general statements about the risks to consumers of the look-alike and sound-alike names, packaging and branding of non-prescription medicines, the TGA has provided no evidence.

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In support of this entire section of the consultation paper, the TGA has identified a single reference. Ego's comments in relation this reference is as follows:

Reference	Comments
Australian Council for Safety and Quality in Health Care (2002) Second national report on patient safety. Improving medicine safety.	• This report focuses almost entirely on incidents that relate to prescribing, dispensing and administration by healthcare professionals. • The strategies identified as having been shown to reduce medication incidents deal with systems and processes to be employed in hospitals, surgeries and pharmacies. • The examples given of look-alike and sound-alike issues are of prescription products. • An example is given (page 37) of the potential confusion between "Panadol" and "Herron" paracetamol products. However, this example is presented in the context of a pharmacist dispensing a generic medicine and at this point the authors state: "While this has the potential to lead to adverse drug events that result in patient harm, no data are available on the extent to which this occurs." • This paper is therefore of limited relevance to the risks associated with the labelling of non-prescription products in Australia.

The TGA has provided no other evidence to support the claims made in the Consultation paper.

The TGA has provided no evidence to support the need for reforms to non-prescription product labelling.

Proposed regulatory change(s) and Ego's concerns with the proposals

Proposed Regulatory Change	Concerns
3.1 Sponsors of new medicines will be required to submit evidence of risk assessment of the proposed labelling and packaging. The TGA will work with industry to develop guidance for this assessment, which may include consumer testing or risk assessment checklists similar to those used in other countries. The TGA is investigating methods to electronically screen proposed brand names against already existing brand names to identify potential LASA names. 3.2 In relation to applications to include a new medicine in the Australian Register of Therapeutic Goods (ARTG), if the proposed	**Look-alike and sound-alike medicine names** **Look-alike medicine packaging** • The stated intention of the proposals is to reduce the risk of consumer being given the wrong medicine or selecting the wrong medicine because of similarities in the names or packaging of the medicines. • The TGA has not provided any evidence to demonstrate the size or the nature of the risks posed by the current labelling requirements. • The TGA has not provided any evidence that current

medicine brand name differs from another product included in the ARTG by three letters or fewer, the presentation of the proposed medicine label and packaging must use colours and designs that contrast with the medicine label and packaging of the existing product. During the implementation of this change, the TGA will work with the medicines industry to develop guidelines to provide clarity about these proposed requirements. 3.3 In relation to applications to change the labelling and packaging of existing medicines, if the brand name of the medicine differs from another medicine included in the ARTG by less than three letters, the proposed changes must use colours and designs that contrast with the medicine label and packaging of the other medicine. A well known combination product that contains paracetamol under a particular umbrella brand name would not be able to use this same umbrella brand name for another combination product that also contains ibuprofen.	labelling requirements for non-prescription medicines pose a risk to consumers. • Prescription and non-prescription issues need to be separated, as this issue appears to relate only to prescription medicines. • All changes need to be based on risk. • The proposed changes are arbitrary. • Proposal 3.1 arbitrarily assumes that all products carry the potential for confusion based on look-alike sound-alike (LASA) issues. • Proposals 3.2 and 3.3 arbitrarily assume that "three letters or fewer" is the cut-off for acceptable risk. • The proposed changes ignore the higher risks (and different safety profiles) of prescription medicines in comparison to non-prescription medicines by failing to recognise that: o Dispensing errors relate to prescription medicines o Consumers can be confused between the branded and generic prescription medicines - this is also a prominence of active issue o Non-prescription medicines have detailed information on the labelling (prescription medicines do not). o Prescription medicines do not include information about the product purpose on their labels. o Non-prescription medicines are placed in therapeutic categories in pharmacies and grocery, e.g. Zyrtec and Zantac would be stored separately. o Non-prescription products with similar sounding active ingredients, e.g. loratadine and loperamide would be stored with other allergy and anti-diarrhoeal products respectively. There would be minimal risk of confusion. o Consumers buy their non-prescription medicines by brand and indication, not according to active ingredients.

	o Pharmacists select and dispense prescription medicines, whereas the consumer often self-selects non-prescription medicines. o With Pharmacist-Only medicines, the pharmacist provides the product either based on specific request from the consumer or on recommendation for symptoms. • Global companies try to establish globally recognised brands to assist consumers find their product anywhere in the world. Where a specific brand name is required for Australia it undermines this objective • Requiring a specific brand name for Australia will have Trademark implications. • Non-prescription medicines use brand names, designs and colours to differentiate form other products. • Evidence provided on LASA in the consultation document relates to prescription medicines only. • The proposed method to electronically screen brand names is based on US software. Evidence is required; firstly that the software works in the US and, secondly, that the software will work for Australian names and pronunciations. • LASA issues extend beyond medicines to cosmetics, devices and foods.
3.4 Products that are listed on the ARTG cannot be marketed under the same name as a registered medicine.	**Look-alike medicine branding, also known as brand extension or trade name extension** **[AUST R/AUST L]** • This requirement is arbitrary and makes no more sense that applying a similar restriction based on scheduling (i.e. preventing S2 and unscheduled products having the same name). The TGA has not provided any rationale for this requirement. • Clarification is required as to whether export only products (which are AUST L) are included in this proposal (i.e. will sponsors require different names for the export only and the domestic products).

	• Some complementary brands already have products that range across the AUST R and AUST L classifications based on scheduling or indication (e.g. Centrum). There is no evidence that this practice causes harm. • Some other non-complementary brands have products that range across the AUST R and AUST L classifications based on indication or active ingredient (e.g. Dencorub, Neutrogena, Blistex). There is no evidence that this practice causes harm. • Another example is MOOV headlice range, which includes products classified as cosmetic (defence spray), AUST L (helps detect headlice and remove eggs), AUST R (kills lice and eggs) and a device (treatment by suffocation). All these products are for head lice but have different claims. This helps consumers identify, within a brand range, what treatment options are available for each stage of infestation. There is no evidence that this practice causes harm. • Clarification is required as to whether kits that include AUST R products will be impacted by being listed under the same brand name. • The proposal is that listed medicines cannot be marketed under registered product brand names. How will the ELF system prevent this? • Furthermore the brand names and packaging design of AUST L products are not assessed by the TGA prior to entry on the ARTG. How will this be managed?
3.5 Medicines that contain the same quantity of active ingredient(s) cannot be selectively differentiated or marketed for a subset of symptoms or uses, unless the medicine has specific characteristics that make it more suitable for a particular symptom. For example: Products cannot be marketed as "BRAND headache", "BRAND backache", "BRAND joint pain" if they include the same active ingredients in the same quantity. 3.6 The same brand name cannot be	**Look-alike medicine branding, also known as brand extension or trade name extension** **[Different actives and indications]** • It is unclear as to what is meant by 'brand name'. Does this include the corporate name (e.g. Chemists Own, Terry White Chemists, Herron, Swisse)? Does it include different formats of the same products (e.g. slow-release)? The TGA should clarify this. • Sunscreens and toothpastes have multiple actives, often more than 3, and the need to change the brand name for each variation is not justified from a safety perspective.

applied to products that have different active ingredients or combinations of active ingredients unless all of the following conditions are met: a. The active ingredients are closely related (e.g. different salts of the same pharmaceutical chemical), and b. The safety profile, efficacy and dosage regimen are similar. Examples of the application of the above requirements include: A brand name that has historically been strongly associated with a particular anti-histamine would not be permitted to be used for a new product with a different type of active ingredient, such as a corticosteroid or a different anti-histamine.	These products are at the therapeutic/cosmetic interface and they would be at a commercial disadvantage. This proposal could therefore restrict competition. • No evidence is provided in the consultation document to demonstrate consumer confusion. • Umbrella branding issues are very situational and depend on the category, brand, packaging, graphic area/space and brand history (heritage). Blanket restrictions such as this are likely to stifle innovation. • Non-prescription products include different cues to help consumers differentiate between products: o packaging and labelling ▪ brand, sub-brand and indication, including strengths of active ingredients, e.g. hydrocortisone 0.5% and 1.0%, and directions for use ▪ structural, such as size, orientation, shape ▪ differentiation in graphics, colour, font, flags, etc ▪ there may be difficulties due to global sourcing and manufacturing limitations o form and dose differentiation ▪ colour of dose ▪ embossing/printing on dose ▪ shape ▪ coating • Any decision making process needs to be objective, not subjective and based on published guidelines. • The resulting proliferation of brand names will be associated with increased costs to register and maintain brands (in terms of the trademarks themselves and the development of brand awareness). On this point the cost of innovation equals the cost of new product development plus the cost of brand development.

	• Testing of labels with consumers is expensive, any such requirements should be risk based. • Non-prescription shoppers generally select by category/symptoms, then brand (not active). See Attachment 1 – Confidential data on Consumer Decision Hierarchy (For Aqium Gel). • Most complementary medicines are effectively umbrella branded (e.g. Swisse, Blackmores, Cenovis, Nature's Own). Consumers shop by brand and indication, rather than ingredient. Even if they are looking for a specific ingredient (e.g. calcium, folic acid, vitamin D) consumers seek out brands they know. • Complementary medicines are recognised as having low risk. RASML requires label warning statements where necessary. The proposal for a standardised format on the back label will help ensure that these are seen by consumers.
	Look-alike medicine branding, also known as brand extension or trade name extension **[Indication specific branding]** • The stated intention of this proposal is to reduce the risk of accidental overdose. • The TGA has not provided any evidence to demonstrate the size or the nature of the risks posed by the current labelling requirements. • The TGA has not provided any evidence that current labelling requirements for non-prescription medicines pose a risk to consumers. • Prescription and non-prescription issues need to be separated. • All changes need to be based on risk. • Whether or not there is a risk of accidental overdose, there are good examples of when indication-specific branding is useful and helps the consumer identify the

	appropriate product. • If the purpose of the product speaks to the consumer's need (e.g. miconazole 2% for tinea, jock itch and thrush) then sub-branding by indication is justified as men do not want to use a female hygiene product or a tinea product for jock itch. These are embarrassing conditions and consumers would often prefer to be able to find a suitable product without having to read through all the possible indications. • Having the indication on front of pack as part of the brand name assists consumers in selecting the right product. • The TGA has not made clear what 'specific characteristics' might mean (in proposal 3.5) in relation to making a product more suitable for a particular symptom. Does this mean: o A faster acting formulation or salt o Extended release formulation o Products for different population age groups, e.g. children's medicines o Flavour variations within a range o Dose formats, e.g. tablets, capsules, liquids, effervescent dose forms, patches, gums, etc o Different packaging delivery system, e.g. nasal drops vs nasal spray; liquid preps with a spoon vs syringe dosing device • It appears that one of the inevitable consequences of these requirements will be that sponsors have to declare all the indications on the label. For complementary medicines in particular this will be confusing for consumers.
Importantly, blanket prohibitions are not appropriate here. Guidelines and protocols are needed to assist both sponsors and the TGA to objectively assess the risks associated with product brands, names and packaging.	

Alternative options

The alternatives put forward below are meant as a starting point only. None of these suggestions has been tested and no regulatory change should be introduced without consultation and not until rigorous and objective consumer testing has been undertaken.

Proposals:

- The TGA should take a risk-based approach to the proposed changes. Changes must be evidence-based (both in terms of the risks posed by the current requirements and the benefits to be obtained by the proposed change). The TGA should not modify the current labelling requirements until such evidence has been put forward and consulted on.
- As the risks are different for the different medicines categories, the requirements should also be different.
- The TGA should consider non-regulatory approaches to mitigate risks (e.g. consumer education).
- The TGA should separate out the prescription and non-prescription issues.
- The TGA should consider exempting non-prescription medicines from the LASA requirements as the risk has only been demonstrated for prescription products.
- The TGA should consider exempting sunscreens and toothpastes from any umbrella branding requirements.
- The TGA should acknowledge that non-prescription packs are already differentiated with colour, graphics, font type and size to help consumers find brands. This, in part, relates to trademark issues but there are more differentiating features on non-prescription packs than on prescription packs due to the nature of the information that needs to be conveyed to the consumer.
- If TGA establishes brand name screening software, they should consider linking to the ELF system so that AUST L brand names are also screened.
- The TGA should consider exempting existing brands from changing the colour of their packaging.
- The TGA should abandon any blanket prohibitions and instead base decisions on objective measures of risk.
- The TGA (in conjunction with industry and other relevant stakeholders) should develop clear and objective guidelines for LASA and Umbrella Branding to be developed in association with industry and other relevant stakeholders. These guidelines and protocols would assist both sponsors and the TGA to objectively assess the risks associated with product brands, names and packaging.
- The TGA should consider addressing the following items in the guidelines:
  - The role of prefixes and suffixes
  - The use of sub-branding
  - The use of colours and graphics and different fonts
  - The use of icons

  - The relevance of different dosage formats
  - Flagging actives, indications in a standard format
  - The prominence of the active ingredient
  - The standardised Medicine Information Box
  - A flow chart as to when umbrella branding issues apply and are relevant
  - A Labelling Code of Practice
  - Agreed protocols for testing labels with consumers,
- Testing protocols should address the following:
  - when testing is required (i.e. should not be required for all non-prescription products)
  - any category specific requirements
  - sample sizes
  - pass/fail criteria
  - benchmarking
  - comprehension testing
  - product selection and product use (at the point of sale, in the home)

- The TGA should consider the merits of making these guidelines to be as accessible as possible.
- The TGA should work with industry and relevant stakeholders in the development and introduction of any brand recognition software. Any developed brand recognition software should also be accessible to industry for planning purposes
- The TGA should only apply revised requirements to new medicines, not retrospectively.
- The TGA should consider the merits of testing methodologies used in other comparable jurisdictions.
- The TGA should consider indication-based umbrella branding for combination products in some categories, taking into account brand history (e.g. cough/cold, sunscreens).

Caveats

As mentioned earlier (and in ASMI's correspondence to the TGA dated 12 July – see Part B - Appendix 1), this section of the Consultation paper co-mingles prescription and non-prescription requirements, issues and proposals. Furthermore the related figures are flawed and have hampered the consultation process. It has therefore been difficult to clearly identify the scope of the consultation paper. Where stakeholders have mis-interpreted the proposed changes we suggest that a further round of consultations will be necessary.

No change should be made until a clear evidence-based justification for the change has been put forward.

No regulatory change should be made unless it has been subjected to rigorous and objective consumer testing.

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Standardised information format: the Medicine Information Box

Summary of Ego's Position

Ego agrees that a standardised back-of-pack has some merit, however the details need to be properly developed. Some flexibility needs to be incorporated and the designs must be based on the outcomes of consumer testing.

Consumer risk(s) identified in the consultation paper

The consultation paper indicates that: "*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*."

Notes on the Evidence Provided by the TGA

In support of this entire section of the consultation paper, the TGA has identified a single reference. Ego's comments in relation this reference is as follows:

Reference	Comments
Shrank (2007)	• This paper is a review of studies into the content and format of prescription labels. • The relevance of this paper to the risks associated with the labelling of OTC products in Australia (and the changes proposed by the TGA) is questionable. • The authors summarised their findings as follows: "We performed a systematic review of the published literature to evaluate the evidence regarding the optimal content and format of prescription labels that might improve readability, understanding, and medication use. The evidence suggests that patients request information about a medication's indication, expected benefits, duration of therapy, and a thorough list of potential adverse effects. The evidence about label format supports the use of larger fonts, lists, headers, and white space, using simple language and logical organization to improve readability and comprehension. Evidence was not sufficient to support the use of pictographic icons. There was little evidence to link label design or contents to measurable health outcomes, adherence, or safety."

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Proposed regulatory change(s) and Ego's concerns with the proposals

Proposed Regulatory Change	Concerns
4.1 Mandated information on labels and packaging of non-prescription medicines and complementary medicines is presented in a standardised Medicine Information box, based on the US FDA Drug Facts box. The mandatory headings are: • Active ingredient, including the amount in each dosage unit • Uses (indications) • Warnings and Allergy Information (including when the product should not be used and when to consult with a doctor or pharmacist. This section also includes information about possible side effects and substances or activities to avoid. The final lines of this section should include information about preservatives in the product.) • Directions/Dosage instructions • Storage information. 4.2 The font height for information must be no smaller than 1.5mm, with heading height at least 2mm. 4.3 The Medicine Information Box must have a white background with black text. Headings must be highlighted or bolded so they are sufficiently emphasised. 4.4 Where there is insufficient room on a single face of a package, the box may be split over more than one face. However, the overall format of the information is to remain the same. In these instances a pack insert may also be included containing the Medicine Information Box as a continuous table. 4.5 Information about the presence in the medicine of an allergen listed in Schedule 1 of TGO 69, which may be amended, must be included under the heading Warnings and Allergy Information. 4.6 For products containing more than 3 active ingredients, or products in small containers, there may be insufficient space on the medicine	• The TGA acknowledges that the proposed change is based on the US FDA requirements, however, no evidence has been provided as to the success of the US model. • Many Australian non-prescription labels have been developed as a result of consumer testing. Such testing provides evidence that the labels perform well from a consumer usability perspective. • The TGA does not appear to have drawn upon the work already done in relation to Australian labels. • While a standardised back-of-pack may appear acceptable in principle there are many issues with the details. • Many labels already need to include a lot of information on their label. This proposal adds the requirement to include the active ingredient again, as well as 2mm height for each heading and a title of 'Medicine Information Box'. This is particularly relevant for bottle labels • The proposed format will result in the wrapping of warning statements, which will reduce legibility. • All language used should be consumer friendly. • The title 'Medicine Information Box' is too restrictive for complementary products and AUST L topical products such as sunscreens and toothpastes, which are regulated as dietary supplements and cosmetics respectively in overseas jurisdictions. • Some of the headings may not be appropriate for all product categories. • There will be an impact on exports of Australian labelled product. • The proposal is not practical for small containers. It is unclear whether the proposal applies to small

container or primary packaging for a complete Medicine Information Box. In these cases a complete Medicine Information Box should be included as a pack insert. The minimum information to be included on the label will include information under the following headings: • Directions • Warnings and Allergy Information. Where space restrictions do not allow for the required information to be provided in the Medicine Information Box, an alternative arrangement or formatting of information should be provided to the TGA for assessment and approval, together with a justification for non-standardised presentation. This may include breaking the information over more than one panel, or reduction in font size.	containers or whether there will be exemptions for these. • Industry is not in favour of mandated black and white for the information panel. We understand that the FDA allows contrasting colours. For ease of comparison of 2 products, it would be better to have some colour cues or brand naming that allows differentiation. • For scan-ability of barcode, the barcode needs to be at 100% magnification and cannot be truncated. This cannot be achieved on side panels of cartons. This requirement appears to have been ignored in the consultation paper

Alternative options

The alternatives put forward below are meant as a starting point only. None of these suggestions has been tested and no regulatory change should be introduced without consultation and not until rigorous and objective consumer testing has been undertaken.

Proposals:

- The TGA should test the back of pack information panel with consumers using the Code of Practice for labelling of non-prescription medicines and the guidelines developed by the Communication Research Institute (CRI).
- Ego agrees with proposal in principle, but format, layout, titles and order of information MUST be consumer tested. The TGA should, however, consider introducing some flexibility into the standard to accommodate different product types and categories and ought to leave open the possibility to use a different back-of-pack altogether if that can be justified.
- The TGA could remove the requirement to include the title “Medicine Information Box” (the title does not appear to add anything as the groping of the information appears to be self-explanatory).
- The TGA could consider the use of bullet points and visual cues for warnings and precautions (e.g. ticks, crosses and question marks).
- The TGA should consider deleting the “Storage Information” title.

- The TGA should consider using more consumer friendly titles, such as 'When not to use', and allow bolding or boxing of headings.
- The TGA could allow branding or the use of colour on the panel to improve contrast and readability.
- The TGA could consider a matrixing approach to headings (outlining which ones are required for which categories) so that there will be a graded approach for toothpastes, sunscreens, complementary medicines and OTC medicines (this could also allow tailoring for different dosage forms).
- The TGA could consider cues on the front-of-pack drawing attention to the panel.

Caveats

The figures in throughout the Consultation paper are flawed and have hampered the consultation process. Where stakeholders have mis-interpreted the proposed changes we suggest that a further round of consultations will be necessary.

No change should be made until a clear evidence-based justification for the change has been put forward.

No regulatory change should be made unless it has been subjected to rigorous and objective consumer testing.

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Dispensing label space

Summary of Ego's Position

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

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

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Blister strip labelling

Summary of Ego's Position

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.

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Small containers

Summary of Ego's Position

It appears that the proposed changes simply re-state the current arrangements.

The TGA should clarify exactly how the proposed changes differ from the current arrangements.

The TGA should consider exempting small containers from the "Medicine Information Box" requirements.

In the absence of evidence demonstrating that current labelling requirements for non-prescription medicines pose a risk to consumers, the current labelling requirements should remain.

Consumer risk(s) identified in the consultation paper

The Consultation paper acknowledges the limitations imposed on amount of information that can be included on the label of a small container and concludes that: "*It is therefore critical that the small container contains the most important information that a consumer or health care practitioner needs*".

Notes on the Evidence Provided by the TGA

In support of the statements made about consumer risks and in support of the proposed regulatory changes, the TGA has provided no references.

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Proposed regulatory change(s) and Ego's concerns with the proposals

Proposed Regulatory Change	Concerns
[for medicine containers with a nominal capacity of 20 millilitres or less]: 7.1 These containers must be enclosed in a primary pack that fully complies with all labelling requirements and that includes a pack insert that provides detailed instructions for use. 7.2 The label on the container must include the following details in a letter height of not less than 1.5 millimetres: • The brand name of the medicine • The name(s) of all active ingredients in the medicine • For ophthalmic preparations the name of any antimicrobial preservatives in the medicine • Where there are more than three active ingredients, the three most abundant ingredients are to be included on the label of the container and the complete list of ingredients on the primary packaging and the pack insert • The batch number of the medicine • The expiry date of the medicine • If an injection, the approved route of administration • If an ophthalmic preparation for multidose use, a statement to the effect that the medicine should not be used later than four weeks after the container is first opened • If a solid ophthalmic medicine for preparing eye drops for multidose use, a statement to the effect that the medicine should not be used later than four weeks after the container is first opened 7.3 A clear space should also be provided to allow a pharmacist to affix a dispensing sticker. This space need not be the size of a standard dispensing sticker (80 x 40 mm), but should allow a folded sticker to be attached like a flag without obscuring information.	• It is unclear what the intent of the proposal actually is as what is proposed for the label is not significantly different to TGO 69 requirements. However, when taken in context of the Medicine Information Box proposal, the impact on small containers is significant. Proposal 7.1 also requires a primary pack that fully complies with all labelling requirements AND a pack insert with detailed instructions for use. • It is unnecessary and wasteful to require a pack insert as well as a fully compliant primary pack • The Medicine Information Box format is difficult, if not impossible for small containers. • The alternative to achieving a Medicine Information Box on small packs is to abandon the boxed formatting or to increase the size of the container. The second option is costly requiring not only larger packaging but new stability testing and increased costs through the whole supply chain. It may also raise deceptive packaging concerns and consumer complaints. • Inclusion of a pack insert will increase costs. • Concertina/peel back/roll out labels are costly. There are likely to be issues as consumers do not always recognise the feature. Also, if opened in store, they may be assumed to have been tampered with or damaged. • Provide clarification that space for dispensing sticker is for prescription medicines only. • Individually wrapped goods have not been addressed in the consultation, i.e. is it out of scope or has it been omitted?

Alternative options

The alternatives put forward below are meant as a starting point only. None of these suggestions has been tested and no regulatory change should be introduced without consultation and not until rigorous and objective consumer testing has been undertaken.

Proposals:

- Changes must be evidence-based (both in terms of the risks posed by the current requirements and the benefits to be obtained by the proposed change). The TGA should not modify the current labelling requirements until such evidence has been put forward and consulted on.
- The TGA should consider treating individually wrapped goods as per blister packs.
- The TGA should consider exempting small packs from the requirements for a Medicine Information Box (as part of a tailored approach to the Medicine Information Box for different categories, pack formats and dosage forms).
- The TGA should consider the impact on other formats such as roll wraps (where a cut-off based on container volume is not appropriate).

Caveats

It appears that the proposed regulatory changes simply re-state the current arrangements. To the extent that this is not the case, the TGA need to provide clarity as to what, exactly is changing. Where stakeholders have mis-interpreted the proposed changes we suggest that a further round of consultations will be necessary.

No change should be made until a clear evidence-based justification for the change has been put forward.

No regulatory change should be made unless it has been subjected to rigorous and objective consumer testing.

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Pack Inserts

Summary of Ego's Position

It appears that the proposed changes simply re-state the current arrangements.

The TGA should clarify exactly how the proposed changes differ from the current arrangements.

Consumer risk(s) identified in the consultation paper

The Consultation paper suggests that "*If pack inserts are used to compensate for information restrictions on small containers, it is important that the insert is concise and does not include extraneous information, such as advertising material*".

Notes on the Evidence Provided by the TGA

In support of the statements made about consumer risks and in support of the proposed regulatory changes, the TGA has provided no references.

Proposed regulatory change(s) and Ego's concerns with the proposals

Proposed Regulatory Change	Concerns
8.1 Advertising material will not be permitted to be included as a separate pack insert or incorporated into an approved pack insert.	• The TGA needs to clarify what is meant by "advertising material", as advertising and promotional material per se are currently not allowed in labelling. • It should be noted that ARGOM does allow cross-referencing to: o more suitable dosage forms within the same range for different age groups, e.g. liquids instead of a solid dose form for children o another product that can be used in conjunction with the current product as part of the treatment regimen o a sponsor's other products within the same product range that have the same trade name as the current product, e.g. nicotine replacement therapy dose forms

	• Ego supports the continuing ability for sponsors to appropriately cross-reference other (possibly more suitable) products. • Ego questions whether this proposal is designed to restrict referral to patient support programs which aim to aid consumer compliance. Ego requests that the TGA provide clarity on this point.
8.2 A pack insert must be in a form separate to the packaging; i.e. it cannot be printed on the inside of a carton.	• Ego understands that this represents the current requirements. However, the TGA should clarify why such an arrangement is entirely unsuitable (for example including this information on the inside of the carton of a single use product may be acceptable and would minimise the amount of materials used).

Alternative options

Ego suggests 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.

Caveats

It appears that the proposed regulatory changes simply re-state the current arrangements. To the extent that this is not the case, the TGA need to provide clarity as to what, exactly is changing. Where stakeholders have mis-interpreted the proposed changes we suggest that a further round of consultations will be necessary.

No change should be made until a clear evidence-based justification for the change has been put forward.

No regulatory change should be made unless it has been subjected to rigorous and objective consumer testing.

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Labels and packaging advisory committee

Summary of Ego's Position

Ego does not support the establishment of such a Committee.

Clear guidelines and protocols need to be developed first, and the Committee should only be established if those guidelines and protocols fail to deliver predictable outcomes.

Consumer risk(s) identified in the consultation paper

None identified.

Notes on the Evidence Provided by the TGA

In support of the proposed regulatory changes, the TGA has provided no references.

Proposed regulatory change(s) and Ego's concerns with the proposals

Proposed Regulatory Change	Concerns
The TGA proposes to establish a panel to provide advice on the acceptability of proposed names, labels and packaging, particularly for products involving potential umbrella branding or look-alike sound-alike issues. It is proposed that this expert advisory body will provide advice to the TGA on product-specific as well as general matters relating to medicine labels and packaging.	• Industry would like clear guidelines and protocols developed as a starting point. The guidelines and protocols should allow objective assessment of the risks, benefits and merits of labelling and packaging. • A Committee such as the one proposed should only be established if stakeholders agree that the proper functioning of the guidelines and protocols would be enhanced by the Committee. • Labelling decisions (whether made by the Committee or by the TGA) need to be objective and consistently applied. • The composition of the committee should include acknowledged experts in the field of manufacturing, packaging and printing, and communication. • Uncertainty exists as to how the Committee decisions would fit into the evaluation process and what effect such decisions would have on predictable timeframes.

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	• Sponsors want to be confident of the success of a product name at the start of the product development phase and this is why clear guidelines and protocols will be essential. To find out at the end of an evaluation process that a branding proposition is unsuccessful is a costly exercise. • Sponsors need to be confident that investment in developing and testing labelling to an agreed set of guidelines and protocols will result in an application that will be accepted by the TGA. • Clarity is required as to the exact composition of the proposed Committee, its role, the nature of its decisions, whether those decisions are binding or contestable.

Alternative options

Ego suggest that clear guidelines and protocols in relation to medicines labelling be developed as a starting point and that the Committee only be established if stakeholders agree that the guidelines and protocols require such additional support.

Caveats

Without knowing the precise role and composition of the proposed Committee, Ego is unable to appropriately assess the merits of the proposed Committee.

Questions Raised in the Consultation Paper

Ego would like to register our disappointment at the questions included in the Consultation paper. The leading nature of the questions appears designed to provoke a pre-determined response. The questions presume that the proposed changes will achieve the stated objectives of the review. Some of the questions are misplaced and/or difficult to understand. It is unclear how these questions will reliably inform the review.

See Attachment 2 for the Answers to the Questions Raised in the Consultation Paper.

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