



## ***General Comments About the Consultation Document***

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As [REDACTED] is a member of [REDACTED] the comments in relation to the consultation are fully endorsed by [REDACTED]. For the sake of brevity, the particular issues will not be repeated in the [REDACTED] submission.

Additionally, there are a number of discrepancies within the consultation document that may have resulted in the misinterpretation of the intent of the consultation document. As it was the development of the images that significantly delayed the release of the consultation document, it is somewhat disappointing that there are a number of issues with the images that could result in sponsor confusion and misinterpretation of the consultation document.

### **Figure 2 p14**

The TGA website is stated under the AUSTR number. This labelling review has made no reference to this being a formal requirement. Furthermore, the inclusion of the TGA website address would contravene Medsafe's guidelines, and thus is counter-productive with respect to Trans-Tasman labelling harmonisation.

This labelling review has made no reference to the country of origin requirement. This is a requirement under the Customs Act, and should arguably be outside of the scope of the current consultation.

### **Figure 3 p17**

The TGA's recommendation for the placement of the warning on Paracetamol is not aligned with the requirements of the SUSMP, in that no text can be placed on same lines as the required signal headings.

The barcode information is on the same line as the signal headings (back of pack)

### **Figure 4 p18**

The TGA's recommendation for the placement of the warning on Ibuprofen is not aligned with the requirements of the SUSMP, in that no text can be placed on same lines as the required signal headings.

### **Figure 10, p 33**

The perforation shown in this figure splits the blister platform into 2 equal sections rather than 2 dosage units. This would result in the batch number and expiry date across the 2 dosage units to be split, which defeats the purpose of the recommendation.

## ***Prominence of Active Ingredients on Medicine Labels***

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### **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.**

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The concern that [REDACTED] has with this proposal is that there has been no data or evidence provided to the effect that there are performance issues with the labels as they currently exist. Of greater concern is that there is a distinct lack of evidence that demonstrates that this proposal will result in less consumer confusion and safer use of medicines. Whilst [REDACTED] has no objections for a proposal that will definitively improve readability of a medicine label and potentially improve patient safety, we cannot support a change that might make the current situation worse.

**It is absolutely critical to have consumer testing of the proposed changes** in relation to the positioning of the active, in addition to alternative options, to ensure that the change improves the current situation and does not make the perceived label performance issues worse.

Other options may include, but are not limited to:

- The actives being listed in a band at the bottom of the label (Appendix 1)
- The active being listed in a box, but separate section of the label, as seen with labelling of products with multiple actives as approved for consumer use in Canada (Appendix 2).

Introduction of such a drastic change without adequate consumer testing could result in the implementation of a label that is potentially more confusing for the consumer and might increase the risk of medication errors by consumers.

**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.**

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Further clarification should be provided for the definition of “equal prominence” as it could be confused with equal size, which in this case is not correct.

If the intent is that equal prominence of active ingredients means same font size as the brand name, it is believed that this is more likely to create consumer confusion by increasing clutter and reducing legibility of label, and reduces brand recognition. Brand is an important factor in the self selection process. In the absence of the guidance of a healthcare professional, it allows the consumer to recognise and select a product/brand they know and trust. In fact, if the size of active is disproportionate it will overwhelm the other information that the consumer needs to make appropriate self-selection decisions, and is likely to result in incorrect product selection and potentially medication errors.

If it is determined that equal prominence is required, the likelihood of further consumer confusion is significantly increased. Having the actives as large as a brand would be no different to brand names that are deemed to be look alike, sound alike. If we consider antibiotics of the same class - Benzathine penicillin & Benethamine penicillin (hypothetical situation, marketing status is not considered). Similar in name, but arguably have different antimicrobial and resistance profiles, however there is similarity in the generic names. This example lends itself to the fact that simply increasing the size of the active may not provide the outcome that is being sought.

## 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.

In addition to the points made in 1.2.1, there are a number of practical implications that will result, should this proposal be implemented. Assuming that the pack size cannot change, the impact of having the actives the same size as the brand, the following must be considered:

- the length of AANs such as:
  - Pseudoephedrine hydrochloride,
  - Dextromethorphan hydrobromide or
  - *Eleutherococcus senticosus* (Siberian ginseng) extract equiv. to dry root
 will dictate the size of the brand on the pack
- The SUSMP outlines the requirements for the position, lay out, font type and size of the signal heading (Pharmacy Medicine, etc) and KEEP OUT OF REACH OF CHILDREN. This is relative to the height of the Brand name.

█████ believes that it is not the intent of this proposal to impact the size of the required SUSMP signal headings, as this is clearly not in the best interest of public health. This is one of the outcomes that will result from an increase to the font size of the active i.e. the size of the brand will have to be reduced to accommodate the size increase of the active, consequently reducing the size of the SUSMP signal headings. An example of artwork prepared using the proposed guidelines have been provided in Appendix 3 as a demonstration to the impact to the SUSMP headings.

As mentioned above in point 1.2.1, the increase in the size of actives does overwhelm all of the other key information on the principal panel and may actually make the label comprehension worse. For this reason, █████ cannot support the proposed recommendation of having the actives at 100% the size of the brand.

**It is vital to have independent consumer testing of the proposed changes**, along with alternative options, to ensure that the changes proposed do improve the current situation and does not compromise consumer label comprehension or readability.

Alternatives to the proposed 100% font size might include (these alternatives should also be the subject of consumer testing), but is not limited to:

- The font size of the active should be no less than 25% the height of the brand
- Using a similar approach to size of active ingredients to that taken for determination of signal heading (SUSMP) – half the height to a maximum of 6 mm
- Options include having text type to be proportional to available label height, or set agreed height – to accommodate smaller packs.

Another point for consideration is the appearance of the actives on sunscreen labels. It is most unfortunate that the active ingredients for sunscreens appear “industrial” and to the average consumer “scary”. Highlighting these actives by making the actives 100% size of the brand is likely to result in consumers not using sunscreens. Longer term, this could result in other health issues. Consideration should be given to the fact that these requirements should not apply to sunscreens or other low risk products.

**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.**

█ has no objections to this recommendation if it has been **demonstrated** to improve consumer comprehension of medicine labels and there is a reduced risk of potential medication errors.

Arguments that this proposal definitively improves medicine label comprehension by consumers are purely academic until the concepts have been subjected to rigorous and validated consumer testing.

**1.2.4 The active ingredients should begin with an uppercase letter but the remainder should be in lower case.**

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To further differentiate between brand names and active ingredients, [REDACTED] recommends all characters of the active ingredient be in lower case, including the first letter. Brand names tend to always start with upper case lettering. This recommendation is consistent with current best practice guidelines.

**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.)**

Further clarification needs to be provided on the definition of “most abundant ingredient” as an ingredient may not have the most quantitative amount in the product, but due to its potency, may be the “most abundant”. Clarification on how Sponsor’s will reconcile the relative abundance of ingredients whose contents are listed as IU as opposed to mg quantities is required.

If the consumer’s safety is genuinely at the heart of this recommendation, **consideration must be given to maintaining the status quo (i.e. as per current version of TGO 69)**. In the realm of complementary medicines, there is a large number of consumers that are supplement *cocktailers*, meaning that they will take a vast array of different vitamins, minerals and other supplements based on their need state. There is potential for a consumer to consider that only the three actives listed on the front of pack are contained within a particular supplement. For substances that are known to be safe in microgram quantities (and hence are unlikely to be placed on front of pack as per current proposal), there is potential for these *cocktailers* to unknowingly consume large quantities of this ingredient. This proposal would discourage consumer from looking elsewhere on the pack, and hence is not in the best interest of public health.

Additionally the main benefit of a product may not be called as a result of this recommendation. By way of example, if we consider [REDACTED], the 3 most abundant active ingredients on the front label would be calcium, magnesium and phosphorus. Folate would not appear on the front label. The benefit of folate in helping to prevent spinal tube defects during the first trimester of pregnancy has been well established and is well understood by the average consumer. When purchasing a pregnancy supplement the presence of folate is one of the key factors contributing to its purchase.

In addition to the potential safety implications that this recommendation will result in label congestion and cluttering of the main panel and potentially poorer label comprehension by the consumer.

It must be pointed out that section 18 of the Australian Consumer Law states:

*‘A person must not, in trade or commerce, engage in conduct that is misleading or deceptive or is likely to mislead or deceive.’*

Should this recommendation be implemented, it is likely that sponsors will potentially breach this law, as conduct, which includes using packaging and/or labels on product, creating the impression in the mind of the consumer that is not accurate. The concern, would be that, as by definition multivitamins contain a large number of active ingredients, to merely highlight three of these in the manner proposed has the potential to mislead the consumer as to the number and identity of all active ingredients contained, as well as the nature of the product, which is to provide a spectrum of vitamin and minerals supplements to the consumer and not merely 3 such supplements.

Finally the purchase decision hierarchy for a number of categories does not rely upon the actives. Multivitamins and mineral supplements are classic examples of where consumers look for benefits

as opposed to actives (there are of course exceptions, such as fish oil and glucosamine), in addition to looking for a brand that they trust.

**1.4 For products containing day and night preparations that have different formulations, the composition of each tablet must be provided immediately below the brand name and the font size must be no less than 2 mm in height on the main/front panel.**

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As per point 1.1, the concern that [REDACTED] has with this proposal is that there has been no data or evidence provided to the effect that there are performance issues with the labels as they currently exist.

Of greater concern is that there is a distinct lack of evidence that demonstrates that this proposal will result in less consumer confusion and safer use of medicines.

Whilst [REDACTED] has no objections for a proposal that will definitively improve readability of a medicine label and potentially improved patient safety, [REDACTED] cannot support change that might make the current situation worse.

**Consequently, it is absolutely critical to have consumer testing of the proposed changes to positioning of the active**, in addition to alternative options to ensure that the change does improve the current situation and does not make it any worse.

The example provided by the TGA in the consultation document shows only 6 active ingredients which overwhelm any other information on the label and will most likely confuse a consumer. There are a number of Day and Night composite packs that have more than 3 actives for each tablet type. The packaging for these products under the current proposal will be cluttered and difficult to read.

Current labels of Day & Night products do include all these actives but as the font is smaller they are more easily read and do not dominate the label. Consumer readability and label comprehension rely on more than just font size – layout and clear space also contribute significantly to the reader's ability to easily find the information they seek and understand what they are reading.

**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.**

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██████ believes that this recommendation is excessive and cannot see any perceived benefit for the consumer, especially for complementary medicines where there might be anywhere from one through to fifty different actives present in a particular product.

This also becomes a significant issue for small containers and where the actives may be extremely long (such as herbal preparations).

It appears that this proposal is an attempt to address issues with the prescribing and dispensing of prescription medicine and would aid a pharmacist more in selection and dispensing, and is not relevant to the way consumers purchase non-prescription medicines. Typically non-prescription medicines are sorted by category and the consumer makes a choice based on brand and benefits as opposed to the active ingredients.

**1.6 Non-prescription medicines that contain paracetamol must include the following information on the front of the packaging. The information must be presented in bold text in letters of at least 1.5 mm high and on a background that contrasts with the rest of the packaging:**

***"Contains paracetamol. X mg. Consult your doctor or pharmacist before taking other paracetamol products."***

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As pointed out in the consultation document, this proposal is similar to the action that has previously been taken by other countries such as the UK, Ireland and the USA. It is disappointing that the TGA has not provided any evidence or an assessment to their success at reducing unintentional misuse.

Currently, there is a mandatory statement that is required on all packs warning against the concomitant use of other paracetamol products. This proposal would make this current warning redundant.

Additionally, should this recommendation be implemented, [REDACTED] has concerns that by isolating these statements to front of pack, the consumer may miss the other important information (or assume that this is the only important information).

Further, the question must be asked as to why this recommendation is only restricted to non-prescription medicines. There are prescription medicines that contain paracetamol. The risk of paracetamol overdose in prescription medicines is no less than that seen in OTC medicines. Whilst it is acknowledged that ancillary label 19 as described in the Australian Pharmaceutical Formulary, is to be placed on the primary pack of all prescription medicines containing paracetamol at the time of dispensing, the pharmacist may use their discretion in deciding whether to omit this label.

**1.7 Non-prescription medicines that contain ibuprofen must include the following information on the front of the packaging. The information must be presented in bold text in letters of at least 1.5 mm high and on a background that contrasts with the rest of the packaging:**  
*"Contains ibuprofen. X mg. Consult your doctor or pharmacist before taking other medicines for pain or inflammation."*

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The TGA has provided limited evidence of concerns surrounding paracetamol, but have provided no evidence in relation to any other active. It is unclear why ibuprofen has been included in this requirement.

It is apparent that this proposal is being made largely due to the apparent paracetamol challenge. Ibuprofen does not have the same risk profile as paracetamol and poses less risk than paracetamol in overdose.

Unlike paracetamol, [REDACTED] has not been able to find evidence of similar statements being used in other countries. The TGA has not provided any evidence that this is a requirement elsewhere in the world, let alone a report on its success.

These are not the only risks with taking these products, and there is concern that by isolating these statements to front of pack, the consumer may miss the other important information that is located on the back of pack.

Further, isolating this warning to the front of pack is inconsistent with the grouping of information evident in the Medicine Information Box proposal.

## ***Look-alike sound-alike names and look-alike packaging***

**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.**

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 proposal arbitrarily assumes that all products carry the potential for confusion based on look-alike sound-alike (LASA) issues; however this is not always the case, especially with OTC medicines. The examples cited by the TGA in the consultation document are examples of prescription medicines. No example of non-prescription medicines are provided, and no data as to the cause of the dispensing errors were provided i.e. were these a result of difficulties in deciphering a hand written prescription?

In considering this proposal, retail presentation must be considered. Non-prescription medicines are typically placed in therapeutic categories in pharmacies and grocery, e.g. [REDACTED] and [REDACTED] although contain similar letters and letter order, they are stored separately in the retail environment i.e. Allergy and gastro-intestinal products are displayed in separate and distinct areas of the pharmacy.

The current label requirements for non-prescription medicines ensure that the intended uses are included on the packaging. This serves as another check for the consumer.

The proposal of actives being 100% the size of the brand may actually add to consumer confusion in respect of LASA, e.g. loratadine and loperamide (albeit these would be stored with other allergy and other anti-diarrhoeal products, respectively). Arguably, if it perceived that brands that are LASA are a safety concern, then with the equal prominence of the active as proposed by the TGA, the potential for confusion amongst actives in generic medicines is equally, if not more, likely. This only emphasises the importance of the brand when trying to minimise confusion.

The proposed method to electronically screen brand names is based on US software. Evidence is required; firstly, evidence to demonstrate that the software works in the US and, secondly, that the software will work for Australian names and pronunciations. Neither has been provided to industry to date.

The requirement to submit the risk assessment will cause an onerous, additional expense to the sponsors of new medicines and should be taken into account. It is not unreasonable to expect that this added expense will be passed onto the consumer.

Finally, the LASA issue extend beyond medicines to devices, cosmetics and foods. Regulating brands across these sectors poses to be a difficult challenge to the TGA.

**3.2 In relation to applications to include a new medicine in the Australian Register of Therapeutic Goods (ARTG), if the proposed 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.**

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Sponsors currently do not have access to any electronic screening tool that would enable detection of proposed brand names with such letter similarity and therefore Sponsors would not be able to detect brand names for applications which are currently under evaluation with TGA and not yet approved.

In principle, there are no objections that new medicine brands use contrasting colour and design to differentiate from the brands. However greater clarity and robust guidelines will be required.

Consideration must be given to the many ways to differentiate products using colour or design, defining look-alike sound-alike product names or medicine brands based on three letters or fewer is too simplistic an approach.

For generic medicines, the active ingredient typically is part of the product name. This being the case, how will this issue be addressed for names actives that are genuinely look alike and sound alike, but may have very different therapeutic uses and safety profiles?

**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.**

As discussed for recommendation 3.2, the accessibility of packaging for existing products on the ARTG will need to be addressed for this measure to be effective (which would need to include all levels of medicines – complementary medicines through to prescription medicines). This suggestion is likely to require a significant investment in IT infrastructure at the TGA.

As this TGA operates on a full cost recovery model, industry will be paying for this upgrade. Therefore it is **critical** that the desired outcome is a guaranteed deliverable.

For two or more existing products whose brand names differ by three letters or fewer and whose packaging does not contrast, how would the TGA determine which existing product should change its packaging colour and design?

**To reduce the risk of consumer confusion and medication errors caused by look-alike medicine branding, the TGA proposes the following regulatory options:**  
**3.4 Products that are listed on the ARTG cannot be marketed under the same name as a registered medicine.**

The TGA has provided absolutely no basis or valid argument for this recommendation. This requirement is arbitrary and makes no more sense than applying a similar restriction based on scheduling (i.e. preventing S2 and unscheduled products having the same name).

It would appear that export only medicines have not been considered when this recommendation was put forward. An export only medicine is an AUST L product. Based on this recommendation, export only medicine will need to have a different brand name to registered medicines marketed locally.

No consideration has been given to registered complementary medicines. By way of example, [REDACTED] has products that are both listed and registered. Under this proposal, registered complementary medicine will have to be separate from the brand. There is absolutely 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. [REDACTED]). Again there is no evidence that this practice causes harm.

Another example is [REDACTED] which includes products classified as cosmetic ([REDACTED]), AUST L ([REDACTED]), AUST R ([REDACTED]) and a device ([REDACTED]). All these products are for [REDACTED] but have different claims. This helps consumers identify, within a brand range, what treatment options are available [REDACTED]. There is no evidence that this practice causes harm.

No consideration has been given to medicine kits. A medicine kit is an AUST L; however these kits may contain AUST R Products. Clarification is required as to whether kits that include AUST R products will be impacted by being listed under the same brand name. The question that must be asked is what safety benefit is there for a consumer with this proposal [REDACTED]

[REDACTED] There appears to be no logic to this recommendation and no evidence to show that this current practice has resulted in consumer confusion or has resulted in an increased risk to public health.

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) can not 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 can not be marketed as " BRAND headache", " BRAND backache", "BRAND joint pain" if they include the same active ingredients in the same quantity.**

Brand extensions and “*umbrella branding*” issues are very situational and depend on the category, brand, packaging, graphic area/space and brand history (heritage). Blanket restrictions will prevent innovation. As such any decision making process needs to be objective, not subjective and based on robust and published guidelines.

There is no justification for this proposal for Sunscreens. The need to change the brand name for each sunscreen variant within a particular brand is not justified from a safety perspective. These products are at the therapeutic/cosmetic interface and sponsors would be commercially disadvantaged. This proposal could therefore restrict competition. The loser here would be the Australian consumer.

Further, symptom/indication specific labelling helps the consumer as it speaks directly to the consumer’s needs. As indicated in the images provided in the consultation, that TGA has concerns of this practice with Ibuprofen ( and presumably paracetamol). But it would appear a strong consideration has not been given to other categories. For example the 2% preparation of [REDACTED] indicated for [REDACTED]. Sub branding by indication is completely justified [REDACTED]

[REDACTED] 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.

The TGA must give further consideration to the ramifications of this proposal (beyond ibuprofen and paracetamol), and should this recommendation be adopted, clarification will be required - Will this be applied retrospectively to existing medicines? If this is applied prospectively only, it will be perceived that the TGA is commercially favouring sponsors that have previously registered indication/symptom specific products that are otherwise undifferentiated.

**3.6 The same brand name cannot be 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.**

This proposal has no regard for current convention for ingredients within a particular category. Brands that belong to the cough, cold and flu category are not restricted to a particular active, rather a range of appropriate actives that may be used to treat symptoms of cough and colds and flu. Brands in this category are not known to consumers for a particular active.

It is believed that the TGA’s intent of this is to reduce consumer confusion when self selecting medicines. If this is the case, it is difficult to understand:

- Why branded products are treated differently to products branded with a corporate name (which is arguably a substitute for a conventional brand) such as [redacted] or [redacted]?
- Why about non-corporate names e.g. [redacted] ([redacted]) - are these treated any different to conventional branded medicines?
- Why is it that an ex or non-corporate brands ([redacted]) can have both paracetamol and ibuprofen under the 1 brand umbrella, yet this is not allowed for conventional brands?
- Why does the TGA consider that this does not cause confusion yet if it were to occur under a different brand it would be a safety concern?

The TGA should provide evidence to demonstrate that different actives under corporate banners result in less confusion and pose a lower risk to the consumer than the same active under a conventional brand. If there is no evidence, then the TGA should apply the same principles in relation to umbrella brandings to all products/brands/sponsors thereby ensuring a “level playing field”

This issue needs to be addressed to ensure that these guidelines do not give one sponsor a particular commercial advantage over another sponsor.

### ***General Comments about Section 3 of the Consultation and Branding***

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■ is concerned that the value of a brand has not really been considered as part of this consultation.

Brands provide reliability to consumers. Through experience, the products of a Brand raise a consumer's expectations of quality, reliability, performance and safety. Consumers become comfortable with a Brand and its reliability and a "trust relationship" is developed between the consumer and their chosen Brands.

Global Branding allows for "*economies of scale*" increasing the ability to fund innovation and improve quality and safety. Without branded products, there would be no innovation in non-prescription medicines. Brands drive innovation in terms of delivery systems, packaging improvements, new combinations and alternate ingredients and new claims to meet unmet medical needs. ■ is concerned that some of the recommendations in this section of the consultation, if implemented, this will result in a lack of innovation and new products for the Australian consumer.

## ***Standardised Information Format: the Medicine Information Box***

### **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.**

In principle, [REDACTED] agrees that a standardised back-of-pack has some merit, however the details need to be properly developed in consultation with Industry and some flexibility will need to be built into any guidelines developed for the standardised back-of-pack. The actual layout and final design features should only be applied only after consumer testing has been conducted to ensure that the proposed allows for good consumer comprehension.

The concern with this proposal is that 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.

[REDACTED] strongly opposes the use of the term “Medicine Information Box” and would prefer to see the term “Consumer Information Box” on the basis that there are a number of products that are regulated as listable complementary medicines in Australia, yet these are dietary supplements in New Zealand. There is a high degree of Australia-New Zealand packaging harmonisation in this area. It puts companies in a difficult position if they were to market these products in New Zealand with the product labelled as a medicine.

Additionally, Sunscreens are deemed to be cosmetics in New Zealand, not medicines. Again if a product was to be marketed in both Australia and New Zealand, it would put the sponsor in difficult position having a cosmetic with the term “medicine” on back of pack.

Other areas for consideration:–

- [REDACTED] is not in favour of mandated black and white for the information panel. It is our understanding 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.
- The proposal is not practical for small containers. It is unclear whether the proposal applies to small containers or whether there will be exemptions for these. Further clarification is requested

**4.2 The font height for information must be no smaller than 1.5 mm, with heading height at least 2 mm.**

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Again, in principle, there are no objections the font height for the information. Whether having an increased font height for the heading as opposed to having some other method of differentiating the headings (e.g. different colours etc.) should really be addressed in consumer testing of this proposal.

**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.**

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█ is not in favour of mandated black and white for the information panel. It is our understanding that the FDA allows contrasting colours. For ease of comparison of 2 products, it would be ideal to permit the use of different colours or brand naming that allows differentiation of products within a particular brand, in addition to differentiating between brands.

**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.**

The practicality of this proposal needs to be considered. There are a number of small bottles, tubes and sticks (e.g. sunscreens) that are not packaged in a carton or on a backing card. In these instances, consideration must be given for an exemption to these requirements.

**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.**

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█ has no objections to this proposal.

**4.6 For products containing more than 3 active ingredients, or products in small containers, there may be insufficient space on the medicine 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.**

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To have these packaged in cartons or backing cards, with the addition of a pack insert will result in a significant increase in the cost of goods. This increase in cost would, in all likelihood, be passed onto the consumer. Consideration for exemptions may need to be considered.

## *Dispensing label space*

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**5.1 A designated space of 70 x 30 mm, consistent with international best practice, must be provided to accommodate the dispensing label.**

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This proposal is not relevant to [REDACTED] products, therefore, no comment is offered.

**5.2 Where a clear space is not practical due to constraints from packaging size and shape, the information should be arranged so that information that is likely to be obscured is the same as the information repeated on the label. The area for placement of the sticker should be illustrated by corner placement marks on the packaging.**

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This proposal is not relevant to [REDACTED] products, therefore, no comment is offered.

**5.3 For small containers, for example eye drops and ointments, where a designated space of 70 x 30 mm is impractical, a clear space should be provided to affix the edges of a folded dispensing label.**

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This proposal is not relevant to [REDACTED] products, therefore, no comment is offered.

## ***Blister strip labelling***

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The TGA Consultation document states “*Often blister strips are stored away from their outer wrapping or packaging that contains the information about how to use the medicine safely. For example, it is not uncommon for people to carry a blister strip in their handbag, purse or travel bags without the primary container.*”

A lot of effort goes into preparing packaging to ensure all relevant warnings and directions are on the back of pack for consumers. These are there for the benefit and safety of the consumer.

By including this additional information on the blister foils, it is only going to encourage the storage of blisters away from the carton. This is a practice that should not be encouraged as it potentially compromises the safety of the consumer.

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.

## **6.1 The brand name of the medicine, the active ingredient and a amount of active ingredient, batch number and expiry date must be repeated at least once every two units.**

There is no benefit for consumers of non-prescription medicines. It is unlikely to result in a better safety profile for any non-prescription product. If there is benefit for the consumer, shouldn't this be a requirement on Webster packs?

This proposal may impact specialist low-volume medicines with small order quantities, where Australian-specific foil would be unable to be pre-printed with batch numbers due to minimum order quantities constraints. Responsiveness to unexpected surge in demand e.g. due to competitor manufacturing issues, out of stock, disease outbreak, would also be significantly impaired as batches may be unable to be reallocated to Australia from another market to meet increased need. Given the size of the Australian market in terms of global supply (estimate 1%) it would not be feasible to introduce dedicated packaging lines for Australia into global manufacturing plants due to both cost and space constraints. It would, therefore, be expected that these circumstances could result in the TGA being inundated with Section 14 labelling exemption applications to ensure continuity of supply in our market.

This proposal is not practical or not possible and for many local manufacturers as it requires the printing of the foils during manufacture. In most cases foils are pre-printed and delivered in a finished state for the production lines. B/Exp information is printed or embossed onto the finished blister platform after the dosage units have been blistered, not during the process. In our view this recommendation is not in line with international best practice. The current practice of once per strip would be acceptable.

The major concerns with this proposal are:

- Implementation
- readability of the text

Each of these concerns are specifically addressed below.

### **Implementation**

None of the manufacturers utilised by [REDACTED] currently have the tooling (such as online printers) required for the implementation of this proposal. The current practice is for the batch and expiry date to be embossed at the end of the blister platform.

To introduce the level of detail onto the blisters the following options may be considered:

- Third party supplier pre-printed foil.
- On-line printing of foil
- Off-line (in house) printing of foil

### Third party printing

From an inventory management (ensuring sufficient stock is available for a batch without excessive reject material) and a GMP perspective (management of foil printed with specific batch information) this would present to be an extremely difficult prospect.

The management of batch specific foil would not only impact the site, it would also involve management of printing plates from the supplier to ensure no additional foil would be printed without prior approval.

### In-House options

The option of on-line and offline printing options would require significant capital investment. From the purchase of capital equipment (on-line printers – costing approx \$350 – 400 K AUD), commissioning, qualification and validation of the equipment.

For an off-line set up there would be the additional costs for space, maintenance, and operation. In many cases, manufactures are at capacity, so infrastructure investment may need to be built.

The in-house option will require significant capital and operating expenditure. This additional expense is likely to an increase in the cost of goods, and will be passed on to the consumer. In the global market, it is difficult for local manufacturers to stay competitive. This additional expense may be enough to cripple the manufacturing industry in Australia.

### **Readability of Text**

The readability of text is a major concern. The current minimum lettering height as determined by TGO 69 is 1.5mm (equivalent to 6pt Helvetica font). The readability of the small size of the print will be further compounded by the knurl pattern produced during the sealing process, whereby the interference of the knurl would render some characters unreadable. The knurl is used to distribute load during the sealing process and is therefore an important attribute. Should the pitch of the knurl decrease (which *may* facilitate better readability of print on the blister) the potential for sealing issues to arise. This will compromise the quality and stability of the tablet/capsule in the blisters. This is not in the best interest of the consumer.

In the instance of small tablets/capsules, there may be insufficient space between the blisters to accommodate the extra information as proposed.

Often multi-coloured foils are used to differentiate products in a composite pack (e.g. day/night combinations). Printing expiry date and batch numbers on foils would prove to be difficult due to the opposing colours often used in these foils (e.g. yellow and blue for day and night). To achieve adequate contrast between the foils will require (most likely) 2 online printers.

**6.2 Where strips can be segmented, the brand name, the active ingredient and amount of active ingredient, batch number and expiry date is to appear on each segment.**

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In principle, this recommendation does appear logical; however there are concerns as raised above. Including this additional on the blister foils, is only going to encourage the storage of blisters away from the carton. This is a practice that should not be encouraged as it potentially compromises the safety of the consumer.

A lot of effort goes into preparing packaging to ensure all relevant warnings and directions are on the back of pack for consumers. These are there for the benefit and safety of the consumer. Storage of blisters away from this information should be discouraged.

**6.3 A maximum of 3 active ingredients should be listed on each segment/each 2 units of a blister strip for registered medicines.**

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This recommendation is only workable if space is permitting. However, as the recommendation is for registered medicines only consideration should be given to the case of registered complementary medicines, where there are typically more than 3 active ingredients. In this instance it would be more appropriate to simply have the brand name and product name rather than listing 3 of the actives, especially when multivitamins may have up to 50 actives. Questions should be asked as to whether this requirement might compromise a sponsor's legal position in relation to section 18 of Australian Consumer Law and the engagement in misleading and/or deceptive behaviour.

**6.4 Where there are more than 3 ingredients, for example multi-vitamins packaged this way, it may be sufficient to include a single list of active ingredients printed on the foil of each blister strip. Alternatively, the brand name, together with batch number and expiry date, should be repeated on the foil.**

There is no opposition to including a complete single list of actives across an entire blister platform where there are multiple actives. The caveat for this proposal would be that the blister platform is not perforated, and effort would be required by the consumer to cut up the blister (which as mentioned previously, this behaviour should be discouraged).

As for having the batch number and expiry date repeated on the foil, please refer to point 6.1 for [REDACTED] comment on this proposal.

**For oral contraceptives and other medicines that have a "race track" format to support their safe use, the TGA proposes the following requirement:**

**6.5 Blister strips that have a "race track format" must include the trade name, the active ingredient(s) and their amount(s), batch number and expiry date in a single location.**

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In principle, there is no objection to this proposal.

## *Small containers*

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**The following requirements are proposed 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.**

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The TGA has not provided evidence demonstrating that current labelling requirements for non-prescription medicines pose a risk to consumers. Consequently, the current labelling requirements should remain, until evidence is provided.

There are a number of small containers that do not come in a carton. This proposal would require these small containers to be packaged in cartons, in addition to the inclusion of a product insert. In many instances, the products in small containers are produced for the global market; there would be significant capital investment from manufacturers to start to package these small containers in cartons. This would also result in an increase in the cost of goods, which is likely to be passed on to the consumer. It would be unfair to the Australian consumer to pay more for a medicine as a result of manufacturers trying to fix a problem for which there is no evidence to support its existence.

From an environmental perspective, it is unnecessary and wasteful to require a pack insert as well as a fully compliant primary pack.

Alternatives to a pack insert such as Concertina/peel back/roll out labels are costly and come with the added issue that consumers do not always recognise the feature. Additionally, if opened in store, they may be assumed to have been tampered with or damaged.

**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 a non-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.

Generally, the bulk of information proposed would make it impossible for the average Consumer to read the text. There has been no evidence provided that the current arrangements under TGO 69 are inadequate.

Reference is made to the previous comment for Section 1.3 on defining the “most abundant” ingredient.

**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.**

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Please note that the standard dispensing sticker is now to be 70 x 30 mm as per earlier recommendations. Whilst not relevant to [REDACTED] there is no objection to this proposal providing that consistency is achieved (the consultation document references 2 different sizes for dispensing stickers i.e. 70 x 30 mm and 80 x 40 mm).

## **8.1 Advertising material will not be permitted to be included as a separate pack insert or incorporated into an approved pack insert.**

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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:

- more suitable dosage forms within the same range for different age groups, e.g. liquids instead of a solid dose form for children
- another product that can be used in conjunction with the current product as part of the treatment regimen
- 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

█ supports the continuing ability for sponsors to appropriately cross-reference other (possibly more suitable) products.

█ does have concerns that this proposal will result in a restriction on referring patients to patient support programs which aim to aid consumer compliance (e.g. stop smoking support programs).

**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.**

In principle, [REDACTED] has no objections to this proposal.

## *Labels and packaging advisory committee*

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### **9. 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.**

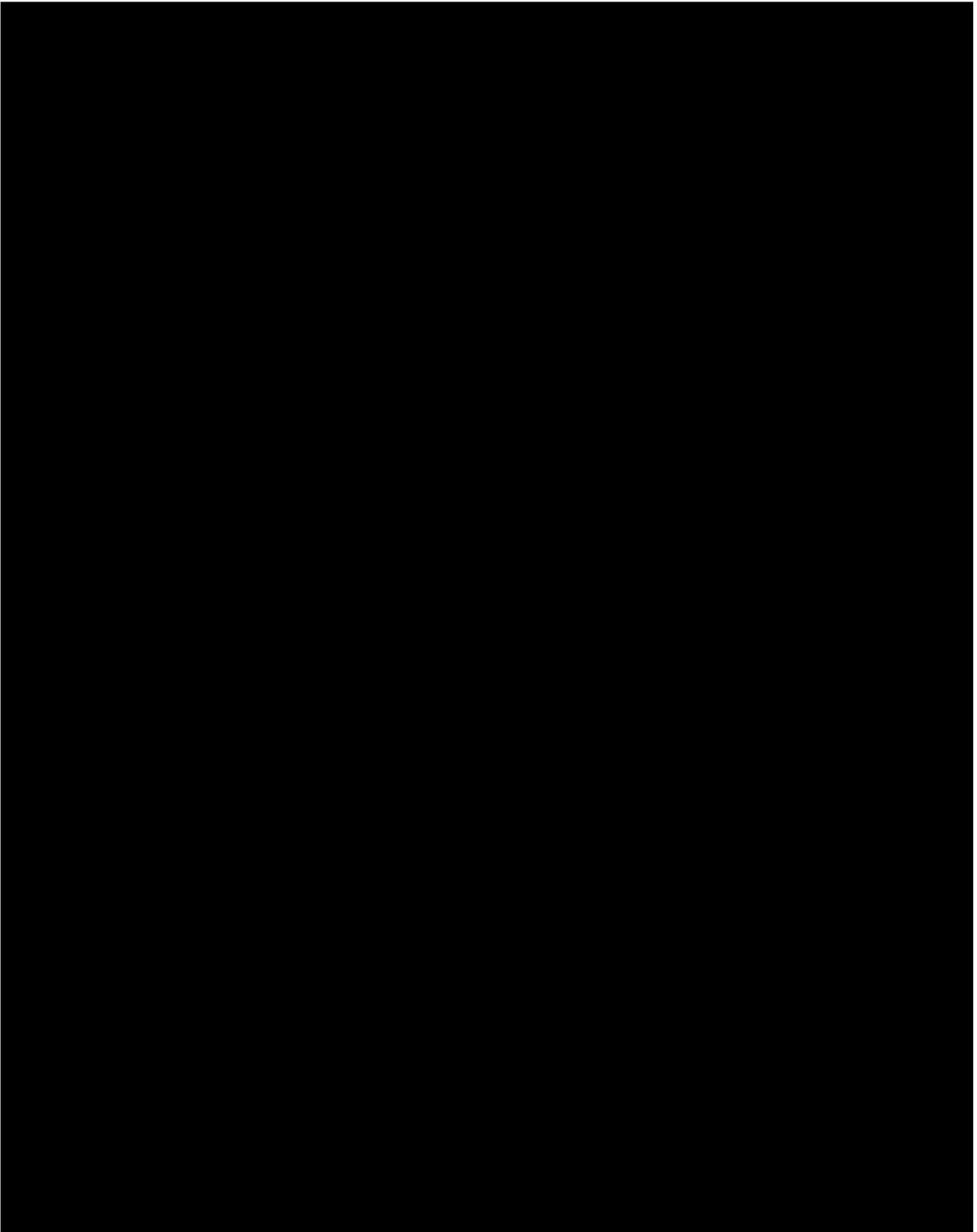
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If clear guidelines and protocols are developed then arguably an expert advisory body would not be necessary. There may be merit for the TGA to have the scope to convene an independent advisory body (on an ad-hoc basis), in instance where the TGA and sponsor cannot come to a mutually agreeable outcome.

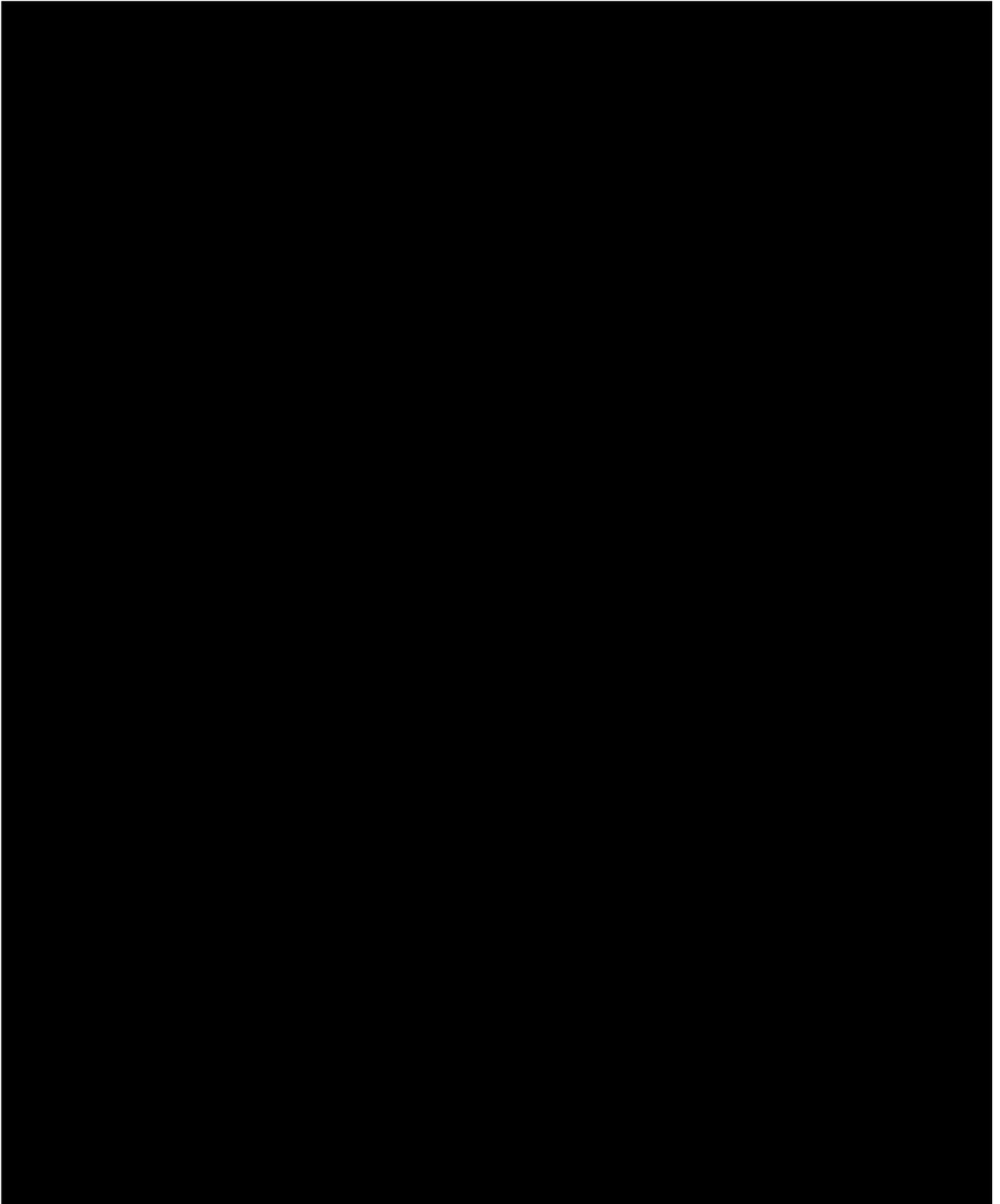
Should the decision be to adopt this recommendation, the composition of the committee should include acknowledged experts in the field of manufacturing, packaging and printing, and communication.

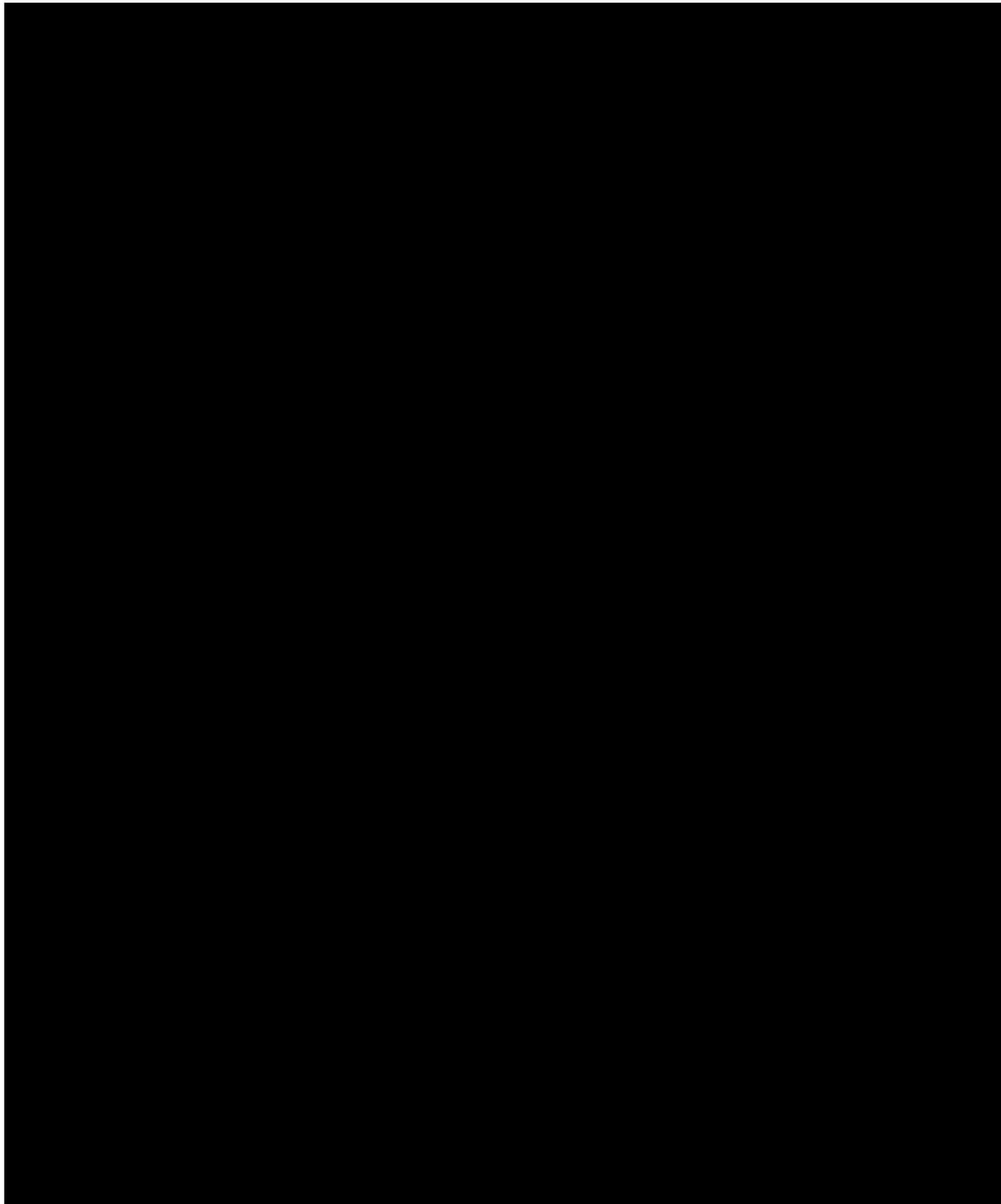


## **Appendix 1 – Alternative option for Positioning of Actives**



## **Appendix 2 – Examples of Medicine Labels from Canada**





## **Appendix 3 – Examples of Artwork Prepared in accordance to the TGA Consultation Document**

