14 August 2012

The TGA Labelling & Packaging Review
PO Box 100
Woden ACT 2606
AUSTRALIA

Dear Sir / Madam

RE: TGA MEDICINE LABELLING & PACKAGING REVIEW – CONSULTATION PAPER – VERSION 1.0, MAY 2012

Please find attached to this letter the submission from the New Zealand Self Medication Industry Association.

We are pleased to have been able to contribute to this consultation paper and look forward to reading the summary document at the conclusion of the consultation process.

If further information is required, please do not hesitate to contact the writer.

Yours faithfully

Tim Roper
Executive Director
New Zealand Self Medication Industry Association

CONSULTATION RESPONSE
TGA Medicine Labelling & Packaging Review Consultation Paper
Version 1.0, May 2012

INTRODUCTION

The New Zealand Self Medication Industry Association Inc (NZSMI) is the national trade association representing manufacturers, marketers and distributors of a wide range of products generally available "over the counter" (OTC) and mainly for use as self-medication by New Zealand consumers. NZSMI is recognised as the premier body for non-prescription medicine products in New Zealand and works to encourage responsible use by consumers and actively promote self-medication as part of a wider national health strategy.

Following the announcement in June 2011 by the prime ministers of both Australia and New Zealand that ANZTPA had been reborn – i.e. the formation of a Trans-Tasman Joint Regulatory Agency – we believe all consultation workstreams from either the TGA or Medsafe need to recognise and consider the implications of ANZTPA despite the fact that full integration doesn't occur until 2016.

The TGA Labelling and Packaging Review appears to ignore any reference to ANZTPA, and this is of grave concern to NZSMI. We do not believe it is acceptable to introduce a major piece of legislative reform that does not consider the need for harmonisation under ANZTPA.

EXECUTIVE SUMMARY

- Since the recommencement of the ANZTPA joint agency was announced by the Australian and New Zealand Prime Ministers in June 2011 and the agency will be operational by July 2016, it is imperative that any consultation on medicine labelling and packaging be considered as a trans-Tasman project, rather than simply a TGA review. NZSMI would not like to see changes implemented through this process which then require further adjustment when ANZTPA comes into full effect.

- The design, colour and graphics of the label should not be used as a primary determinant for differentiating between medicines. The major focus should always be on reading the label – in particular, reading the name and active ingredients, and reading the purpose and instructions for use as a key advice to consumers.

- The consultation document seems very prescription driven, with OTC's being considered under the same document almost as an afterthought. We are unaware of existing data that suggests the current labelling requirements are inadequate for OTC medicines and represent a risk to the consumer. Industry has worked hard to develop consumer focussed labelling, as required by the TGA, over recent years and believes the standards of OTC labelling to now be very high and comparable to overseas markets. Over the last 10 years, industry has moved substantially towards the use of the performance-based labelling format, which is supported by well-designed research as improving legibility and understanding, and it does not appear logical to move to another format that is not equally proven.

- NZSMI believes consumers need to be encouraged to read the label and to understand their medicines. Making the actives more prominent does nothing to aid education and could be likened to shouting more loudly at someone who does not understand something; it does not improve their understanding.

- The consultation document is silent on why the existing regulatory controls are insufficient. International companies have invested significantly in brands and their IP. Changes proposed would have a substantial impact on the ability to market globally.

- The cost for companies to abide by the changes proposed are significant. Inevitably a cost/benefit analysis could lead to the viability of some products becoming unsustainable with the resultant negative impact on the consumer. A move away from international harmonisation of labelling as best practice towards a localised focus is a retrospective step in NZSMI's view.

CONSIDERING VARIOUS POINTS IN THE DOCUMENT

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Figure 2: The components of a medicine label

- The TGA appears to be proposing that the Brand name is prefixed with a company name. We disagree with this entirely as a company name on the front label will only serve to add to the clutter of information demanding the consumer's attention.

- The website of the TGA will make any harmonised labelling with New Zealand extremely difficult. What is the purpose of having this information on the label? Would a consumer be able to navigate the TGA website to locate information of value to them? Traditionally, the regulator has not acted as a primary source of information for the consumer and we question the appropriateness of every label directing the consumer to the regulator. This potentially will result in a considerable workload for the regulator that is not currently undertaken.

- Barcodes have many requirements to be acceptable. Placement on a side panel will not be acceptable to grocery outlets. The proposed barcode is also too small and does not have enough clear space around it. Consideration of the requirements of GS1 must be taken into account regarding the location and size of barcodes. Note that products will not be accepted by many distribution outlets if the barcodes do not have GS1 approval.

- The proposals seem to be very focussed on requirements for prescription labelling. The same rules applied to an OTC label may add to consumer confusion by focussing so heavily on the active. The focus in our view should be on the purpose of the medicine, the dose and warnings. There is a distinct difference in the safety profiles and method of use between prescription and OTC medicines, and labelling requirements should reflect the different needs of these different types of users of medicines.
- NZSMI would contend that the focus should be on educating the consumer and providing both the benefits and risks of OTC products clearly through labelling, which is the consumers' primary source of information.

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What are the consumer health risks associated with not knowing the active ingredient?

NZSMI would like to raise the following 2 issues with this section of the consultation paper:

1. Co-mingling of prescription and non-prescription requirements, issues and proposals

The consumer health risks described in this section of the consultation paper are greater for prescription compared to non-prescription products based on:

- the inherent difference in the safety profiles of prescription & non-prescription products

- the difference in the number of brands for prescription and non-prescription medicines.

To be consistent with the TGA's risk-based approach, we request that The Review take into account the above differences and consider issues relating to prescription and non-prescription medicines separately.

2. Extrapolation of paracetamol risks to other OTC medicines

Published data showing that a significant number of accidental paracetamol overdoses occur annually in Australia has been referenced in the consultation paper. While this is a serious issue, the proposed regulatory changes should not apply to other OTC products that do not carry the same degree of risk.

We request that a more targeted approach be used, with regulatory changes directed at problem areas or products and not indiscriminately applied to all medicines. A blanket rule for all medicines is at odds with what is accepted by other Health Agencies. For example, in Ireland, the UK and USA, an additional warning statement has been included on paracetamol-containing products to reduce the risk of paracetamol duplication.

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Identification of non-prescription medicines containing Paracetamol or Ibuprofen

- NZSMI notes the uniqueness of Paracetamol and the potential for adverse events when dose instructions are not adhered to. The consultation notes that an additional warning statement has been added to the labelling of paracetamol by Ireland, UK and the USA but then goes onto to link Ibuprofen as if it had the same risk profile. Therefore linking it specifically with Ibuprofen in our view is inappropriate as ibuprofen poses much less risk even in overdose.

- Acknowledging the dangers of Paracetamol when taken inadvertently through both analgesia and cough/cold products is to be noted. We feel that this labelling protocol is being imposed largely due to the Paracetamol challenge.

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Figure 3

- NZSMI believes the Paracetamol warning is inappropriate in this form and may be interpreted by a consumer as permissive. We would prefer *"Contains Paracetamol. Do not take other Paracetamol products at the same time."* (or words of similar impact)

- NZSMI accepts the front face is suitable for Paracetamol due to the unusual circumstances which relate to this active.

- The active name placement and size is too prescriptive and will add to consumer confusion for OTC medicines. Some flexibility is required for OTC manufacturers to fit all required information on the front label.

- The active ingredient should not be mandated to appear on 3 or more opposing sides as in the case of small labels this could force critical information onto a leaflet. We would prefer more flexibility in repeating the active name as often as space allows. Our recommendation is that the active ingredient be on the main panel and ONE end for OTC products.

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- The size of the active ingredient in our view is unacceptable and we believe duplication is unnecessary. Bold facing for single ingredients may be appropriate but not for multiple ingredients. The functionality of the label is critical.

- The example given in Figure 4 demonstrates this very well. The label is very cluttered and would be very difficult to interpret if the consumer had no knowledge of active ingredients. We reiterate that research has been done to show that Performance Based Labelling, as in place, is achieving successful outcomes. Consumer testing on the proposed requirements, demonstrating their superiority in terms of legibility and comprehension, over current requirements, would be required before any changes are implemented to the current requirements

Para 1.1

- NZSMI does not agree with this statement and believes it will not improve safety and appropriate taking of OTC medicines.

- NZSMI believes OTC companies should be allowed greater flexibility and the present format in its uniformity would cause confusion rather than clarity. We do not believe the requirements for prescription medicines are necessary for OTC medicines. A size of lettering up to 5mm would overcome this issue of identification with exception given to small containers.

Para 1.2.1

- Acceptable for prescription medicines but not for OTC.

Para 1.2.2

- We do not agree with this requirement for OTC medicines; more flexibility is required. Functionality is the issue and this statement is too prescriptive. Again we query where is the evidence to suggest risk to the consumer has increased?

Para 1.2.3

- Agree with this statement.

Para 1.2.4

- Unnecessary in our view. This would exclude companies using “Tallman” lettering and does not comply with INN naming requirements.

Para 1.3

- NZSMI disagrees with this statement. Where there are more than three multi-active ingredients there may be issues with determining the three most <u>important</u> actives as they may not be the most abundant e.g. a multi vitamin for pregnant women - folic acid is probably the key active but will not appear as one of the 3 most abundant and so will not be listed on the front according to this proposal. The inference is that the only actives that are important are the three most abundant ones. Again this is not in a consumer’s best interests, they need to know the most important active(s). We

suggest that all the active ingredients be presented on another panel other than the front panel. A statement could be added to the front panel explaining this, i.e. “All active ingredients are listed on the back”.

Comments on Fig.4 – pge 18

- We would question why ‘USES’ is included on the front label. Is this a requirement or an anomaly in the examples? What evidence is there to suggest that this has any value?

- The presence of the TGA website, which is quoted on each label at the bottom right-hand corner, is questioned especially in the light of the forthcoming ANZTPA (see Executive Summary).

Para 1.4

- Labels for Day & Night preparations can be the most confusing of all labels. The example shows 6 active ingredients which overwhelm any other information on the label and will most likely confuse a consumer. 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. It is well-known that for good legibility, size is not the only consideration – layout and a certain amount of clear space contribute significantly to the reader’s ability to find the information they seek and understand what they are reading.

Para 1.5

- We believe is totally unnecessary and would suggest a maximum of two faces be used – on the main panel and one side. It becomes a major issue in small OTC containers.

Para 1.6

- We would reference our comments made earlier that this is a permissive statement and needs rewording- but agree with the 1.5mm lettering size.

Para 1.7

- We disagree with this requirement as the risks with Ibuprofen are less than with Paracetamol. Please refer to our earlier comments made in this document.

General questions on the proposed regulatory changes for the prominence of the active ingredients on medicine labels

1. Our view is the lack of clear space causes confusion. There is no evidence to support that this layout improves readability for the consumer and that the extra information required on the front panel is of any benefit to the consumer The active ingredient references clash for prominence with both the use and the warnings. We recommend customer testing to justify the necessary changes.

2. We would refer to our earlier comments.

3. We would refer to our earlier comments.

4. We see no benefits here, only problems. Please see earlier comments

5. 1.5mm but needs exemptions for some small containers, e.g. eye drops.

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Lookalike and sound-alike medicine brand names and lookalike packaging and branding

- We would note the last paragraph on page 20 refers to error statistics for prescription medicines, not to OTC. Therefore this brings into question the relevance of this whole section to OTC medicines.

- NZSMI contends that this is primarily an issue for prescription medicines, not OTC, and would like the TGA to consider the relative risks in the following settings:

  — In the pharmacy setting, there is risk of misreading the doctor's handwriting and dispensing the wrong prescription medicine due to LASA names. There is also risk of selecting the wrong prescription medicine due to LASA names and look-alike packaging as prescription medicines are often placed in the dispensary in alphabetical order. In the OTC setting, however, medicines are located in their relevant categories; hence there is less risk of consumers taking the wrong medicine due to LASA names.

  — If a consumer has been provided with or has self-selected the wrong medicine due to LASA names, the risk of the consumer actually taking the wrong medicine is less with OTC products as these are clearly labelled with indications, contraindications and precautions.

  — If a consumer accidentally takes the wrong medicine due to LASA names, the risk is higher with prescription than OTC due to the inherent difference in safety profiles.

- These are mistakes by Pharmacists not consumers. Consumers need to be educated to read the label and to understand their medicines. Making the actives more prominent does nothing to aid education and could be likened to shouting more loudly at someone who does not understand something; it does not help them understand any better. We therefore believe this is irrelevant in the OTC setting.

Para 3.1

- NZSMI believes that this is an unnecessary expense to sponsors. We would also question how it would be audited.

- We believe that the current guidelines are sufficient for OTC medicines.

Paras 3.2 & 3.3

- NZSMI disagrees with these statements. If the registration is for an entirely new medicine with a very similar name to an existing medicine then the name of the newer medicine should change. As mentioned in our Executive Summary there should not be a reliance solely on colour or design as a differentiator for OTC medicines. The focus needs to be on the name and reading the instructions carefully and noting the warning statements.

- Since there are many ways to differentiate products using colour or design, defining look-alike sound-alike product names based on three letters or fewer is too simplistic an approach. There is no evidence that we are aware of that would require this change to occur.

General questions

- We do not believe the proposed changes will improve OTC medicine safety.

Proposed regulatory changes – lookalike medicine branding

Para 3.4

- This is a change to ARTG. We do not agree with this change. For example, folic acid can have different strengths and can be listed or registered. It would add to consumer confusion if the same product containing folic acid from the same manufacturer could not be marketed under the same brand name. In this case differentiation could be by way of 'extra strength' or similar. We accept that different claims can be potentially made for listed and unlisted products.

- It begs the question as to how products already listed on the ARTG would be dealt with and whether or not sponsors would be forced to change the trade name of existing products?

Para 3.5

- NZSMI does not believe that this change will increase safety for the consumer. The change in our view could cause greater risk issues for the consumer. Currently consumers can choose a specific medicine for a sub-set of symptoms, this helps them select the correct medicine and actually reduces confusion. There is no evidence that this targeted marketing is causing a risk to the consumer (see Appendix 1).

Para 3.6

- This is what happens currently so we do not believe there is any need for change.

General questions

- NZSMI offers a more detailed response to these questions as Appendix 2 to this submission.

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What is a Medicine Information Box?

- NZSMI agrees with the overall intent in that more consistency would assist in readability. However we believe the current approach of "performance based labelling" to be well-proven, and we oppose the prescriptive nature of the Medicine Box concept. We do not believe that this suggested change will improve safety and would ask where is the evidence to suggest that this approach is warranted or an improvement? In our view it precludes the opportunity to **BOLD** / colour code for serious safety risks.

- Current labelling guidelines require that all of this information is already included on a label. The OTC industry has adopted performance based labelling and many labels are now already approved and marketed using this approach. The research for performance based labelling has proved it to be effective. The proposed approach is along the lines of the "Consumer Information panel" (CIP) which New Zealand has recently removed from legislation as it did not aid readability and was difficult to implement. Furthermore, it did not harmonise with current Australian requirements. In our view labels from the USA are difficult to read and are confusing for consumers.

- We believe consumers will be less likely to read the information as the back of every single pack will appear, at first glance, to be the same and so the assumption will be it is the same as they read last time.

- The reference provided to support the need for the medicine information box is for Prescription labelling (reference 10). This does not support it being required for OTC medicine labelling. Separate research would need to be provided to support a need for this prescriptive labelling for an OTC medicine.

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Figure 7

Illustration of how a Medicine Information box may be presented on carton with all the required headings

- The active ingredient is repetitive here. If we follow the consultation document the actives now appear on all but one face; this appears to be excessive. We restate that visibility on the main panel and one side would suffice.

- The Schedule statement, keep out of reach of children, trade name and actives are all repetitive information and can be found on the front label. The term 'Medicine Information Box' is not required as the information conveyed is obvious

- The example shown is for a 30g tube of hydrocortisone cream. As noted previously it would be difficult to fit this and all other the requirements in this document onto a 15g OTC pack for retail sale. Manufacturers successfully convey all this information on current packaging, as approved by the TGA. Any change to these prescriptive requirements would make this and many other labels almost unworkable and certainly more confusing.

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- We note the example stated in figure 8 does not meet the TGA's suggested guideline of being directly under the brand name, nor the instructions around font size being adhered to.
- This example serves to demonstrate how confused a label could become. The barcode, B/Exp and manufacturers address are on the front label, none of this is primary information for the consumer.

PROPOSED REGULATORY CHANGES

- 4.1 – Agree. Current OTC labelling already provides this information. It might also be useful to include "Other important information", where appropriate.

- 4.2 – Agree.

- 4.3 – We believe this is unnecessary, strongly contrasting and legible writing is all that is required. This precludes **bold**, UPPERCASE and colours as required for critical information.

- 4.4 – This is a practical impossibility to get all of the information on the box in some cases. The suggestion to add it to a leaflet is self-defeating as this is the information a consumer needs at the time of purchase. A leaflet cannot be accessed until after purchase. Current approved OTC labelling fits all the required information on the label, without needing a leaflet, in the vast majority of cases.

- 4.5 – Agree.

- 4.6 – We agree but note that the number of actives does not always relate to the size of the container or the number of warnings.

General question on the proposed regulatory changes for standardised information format: Medicine Information Box.

1. NZSMI is opposed to this proposal and contends that the required information is already provided on OTC labels.

2. The information required is currently provided on all OTC labelling.

3. See 4.6 above

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Dispensing label space

- We would request confirmation that this is not required for OTC medicines.

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Blister strip labelling

- 6.1 – NZSMI agrees with the brand name, active and quantity and notes that this is current practice. We strongly disagree with the batch number and expiry date being required at every 2 positions. This is not practical and for many manufacturers not possible as it requires 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 after the dose units have been blistered, not during the process. In our view this is not international best practice. The current practice of once per strip would be acceptable.

- 6.2 – NZSMI believes this is not practical for segmented blisters. NZSMI believes that the only requirement should be:

    (a) Brand name, Active, Amount on each segment.

    (b) Batch number, Expiry only once per blister strip.

Other options are impractical or impossible and would require all sponsors to upgrade their equipment at an unacceptable cost.

- 6.3 - Unlikely to be possible due to minimum font size requirements.
- 6.4 – Agreed.
- 6.5 – Agreed but a single location is impractical.

General question on the proposed regulatory changes for blister strip labelling we would reference our earlier comments.

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Small containers

- 7.1 – We are opposed to having both. We suggest can be *either or* but not both.
- 7.2, bulletpoint 4 – We refer to our earlier comments on this the most abundant ingredients not necessarily being the most relevant.
- 7.2, bulletpoint 8 – We would change the four weeks to *"open shelf life"* as more appropriate.
- 7.3 – NZSMI believes that this should only apply to prescription medicines and not OTC medicines.
- General question on the proposed regulatory changes for small container labelling – We only support this in the context of its practical application to OTC medicines.

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Pack inserts

- 8.1 – We would ask for clarification around what is meant by *"advertising"*. We suggest that "patient support information" should be permitted.
- 8.2 – We believe that there needs to be flexibility to allow for producing information to be attached inside the carton where appropriate. We also believe the use of technology should be encouraged with regard to website references or *"see your pharmacist"* statements.

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Labels and Packaging Advisory Committee

- NZSMI believes that this could be beneficial. However an appropriate mix of skills on the Expert Committee is required. Further we suggest that there needs to be:

    — A fair and transparent election of the committee.

- Clarity around the nature of recommendations and decisions, i.e. whether binding or not.
- Transparency in the process and protocols.
- Precedent law should apply.
- Decisions should be auditable and publishable.
- A rigorous appeal process in place.

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Most questions have been answered in detail above, the following are additional comments

Question 16 – When will the changes come into effect? Why cannot this occur sooner?

- We would ask for clarification as to how this relates to the ANZTPA changes. As stated at the beginning of this submission, it is imperative that any consultation on medicine labelling and packaging be considered as a trans-Tasman project, rather than simply a TGA review.
- We would also suggest that it ties in with other changes in RASML 6. Industry are already facing a number of labelling changes due to RASML and possibly due to ANZTPA. We ask for some rationalisation and coordination on the timing and implementation of all required changes so that industry can make one considered change to encompass all requirements, from whatever source.

Appendix 1

A major New Zealand sponsor has provided the following data:

Only 1 complaint has been received over indication specific labelling over a 3 year period.

In total 21 consumer contacts were made with the Call Centre (many for advice only). This for a period from January 2009 until March 2012.

The sales of SKU's for this company in 1 year approximate to 13 million units (i.e. 39 million over 3 years).

Appendix 2

In response to the General questions on look-alike medicine branding NZSMI would submit the following comments.

Over recent years there has been increasing interest and use of "umbrella branding" i.e. extension of the invented brand name across different medicinal products. The use of umbrella branding can provide many benefits to consumers; among them are easy identification, lower costs and above all quality and safety relating to the preservation of the brand reputation. An appropriate definition of an Umbrella trademark in the OTC setting would be:

"An umbrella trademark is a single brand name for a group of non-prescription products intended to increase the familiarity of the consumer with the product as a group. These products may differ in their composition with regard to active ingredients, their pharmaceutical form and their therapeutic indications".

When promoting a particular brand manufacturers take into account the fact that awareness of a branded medicine is not established by the name alone. A medicine invariably has distinctive features attaching to it in a number of respects, for example size, shape, formulation, marketing etc. Furthermore, the design of the packaging of the medicines can be used to differentiate products within a broader product range, for example by the use of different colour schemes, graphics etc

Use of features such as the following should suffice to avoid confusion:

- Pharmaceutical form.
- An appropriate use of suffixes or prefixes, as well as sub-brands and other qualifiers.
- Labelling, which should be prominently displayed e.g. "Brand name Z Cough remedy".
- And Brand name Z Cold Formula.
- Basic pack design.
- Colour to highlight key differences.
- Pictograms.

It has been suggested that confusion may arise when the proposed product name uses a brand name associated with another product containing different active ingredients which have already been licensed. The argument has been made that consumers could purchase the new product believing it to contain the same active ingredient as the established brand.

Evidence from markets which have permitted use of umbrella branding for products containing different active ingredients demonstrates that this risk can be adequately mitigated by other aspects of the product's presentation.

Three different situations can be identified:

A) The proposed product contains additional ingredient(s) but is for use in the same therapeutic area as the existing product.

It would be normal for the proposed product name to be different from the name of the existing product in this situation. This can be achieved by adding an appropriate qualifier or suffix/prefix to the brand name. The name of the product must be given prominence as part of the pack labelling. The active ingredient should also be displayed prominently

B) The proposed product contains additional active ingredient and is for use in a related therapeutic area to the existing product

If the existing product name is associated with a particular therapeutic area it is essential for the product name to be clearly different from existing products. This can be done for example by the addition of the appropriate suffix or prefix to the brand name. In addition the therapeutic area should be given prominence as a part of the pack labelling or included as part of the product name. The active ingredients should always be displayed prominently. Basic pack design (graphics etc)and highlighting key differences in colour could differentiate between products.

C) The proposed product contains different active ingredient(s) but is for use in the same or a related therapeutic area to existing products.

If the existing product name is associated with a particular active ingredient whether it is for the same or a related area the challenge can be overcome by ensuring the proposed product name is clearly different from the existing product. Again the use of an appropriate qualifier or suffix/prefix to the brand name should be used. Different active ingredient(s) and and/or therapeutic area must be given prominence as part of the product name. Basic pack design (graphics etc) and highlighting key differences in colour could differentiate between products.

CONCLUSION

Umbrella branding can provide considerable benefits both to consumers and manufacturers. Umbrella brands facilitate efficiency in the market by ensuring that a wide variety of products are available to consumers at lower prices than would otherwise be the case.

There is no evidence to suggest that umbrella branding “per se” misleads consumers. Industry practice is to provide labels and in advertising. clear direction to consumers regarding the product information. Evidence from readability tests demonstrates that consumers can read and comprehend labelling instructions.

NZSMI and its members are committed to ensuring that only products of proven efficacy, safety and high quality reach our consumers. The use of brands and umbrella branding has been and will be pursued by industry in a responsible and beneficial way.

NZSMI takes all the required measures to ensure that the benefits of umbrella brands are taken advantage of, whilst avoiding risks that may be associated with their use. Imposing additional requirements would simply constitute an unnecessary restriction on our citizens to practice responsible self-medication.

Tim Roper
Executive Director
On behalf of the New Zealand Self Medication Industry Association