TGA Medicine Labelling and Packaging Review
(Consultation paper version 1.0, May 2012)

Submission by Medicines New Zealand

Preamble

Medicines New Zealand (MNZ) is the industry association representing companies engaged in the research, development, manufacture and marketing of prescription medicines. A central objective of Medicines New Zealand is to promote the benefits of a strong research based medicines industry in New Zealand.

Although the Medicine Labelling and Packaging Review has been initiated by the TGA and relates to the regulatory system in Australia, the outcome of the review is very likely to be carried forward into the Australia New Zealand Therapeutic Products Agency (ANZTPA), hence Medicines New Zealand is making this submission on behalf of its member companies.

Since the activities of Medicines New Zealand members are primarily focused on prescription medicines, this submission concentrates on the TGA proposals that relate to prescription medicines, rather than non-prescription and complementary medicines.

In June 2011, the New Zealand and Australian governments announced the re-activation of work on ANZTPA; the trans-Tasman agency is intended to be fully operational by July 2016. Medicines New Zealand notes that on page 53 of the consultation document it states that the changes in the proposed revised Therapeutic Goods Order will not be fully operational until three years after the TGO is registered as a legislative instrument, i.e. approximately mid-2016.

With these time frames in mind, it is of significant concern that the TGA Medicine Labelling and Packaging Review makes no reference whatsoever to ANZTPA and the possible labelling and packaging requirements that may be implemented in a joint agency environment. Similarly, the Australian Government *TGA reforms: A blueprint for TGA's future* (December 2011) document also omits any reference to ANZTPA.

Medicines New Zealand considers that it is no longer acceptable for either TGA or Medsafe to commence any significant review of regulatory policy or procedures with a view to only local implementation of changes. Instead, any such review should henceforth be conducted as an ANZTPA project.

MNZ recommendation 1:

The Medicine Labelling and Packaging Review should immediately be assigned as an ANZTPA project. The implementation of any changes to labelling and packaging requirements should coincide with the commencement of ANZTPA.

MNZ recommendation 2:

Any other significant review of therapeutic products regulation should be handled as an ANZTPA project and consultation routinely extended to the relevant stakeholders on both sides of the Tasman.

Executive summary

While Medicines New Zealand supports some of the proposals in the consultation document, it considers that many of the proposals are unduly prescriptive and would not necessarily improve patient information and the safe use of medicines. The consultation document does not demonstrate that the existing labelling and packaging requirements are not adequately ensuring patient safety, hence MNZ considers that the requirements specified in TGO 69, combined with a suitable risk assessment by the regulator, generally remain satisfactory.

The consultation document applies to both prescription and over-the-counter medicines. Because of the quite different consumer requirements and risk profiles for these products, quite separate labelling & packaging requirements need to be developed for Rx and OTC medicines.

Many of the proposals involve mandatory word placement and text size to differentiate between medicines. However, it is important to note that there are many different elements that can be utilised to effectively communicate the particular information required by the pharmacist and patient, e.g. font, colour, bold, italics and overall design.

Many of the proposals would lead to unnecessary clutter, which could reduce the readability of medicine labels and the ability of patients to easily locate important information. Although the proposals would lead to greater uniformity of product labels, this would reduce the differentiation between products and could actually create safety issues.

Companies have a considerable investment in the branding and intellectual property of their products and many companies utilise corporate and brand designs on an international basis. On page 11 of the consultation document it states that the TGA will draft a new Therapeutic Goods Order and will conduct a consultation to determine the economic impact of the proposed changes on the medicines industry. MNZ considers that the intellectual property of its members would be severely curtailed by the proposals and this issue not been satisfactorily addressed during preparation of the consultation document. MNZ would welcome the opportunity to provide input into a Regulatory Impact Statement.

The proposals would lead to significantly increased costs for new equipment, packaging lines, stability studies, submission of variations, etc. The proposals would likely lead to companies having to implement Australian-specific labelling, which would reduce moves towards international harmonisation and would further increase costs. This could affect the viability of some products.

Prominence of active ingredients on medicine labels

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.

MNZ does not support this proposal.

While the active ingredient may be relevant to the dispensing pharmacist, it may not be important to the patient. With a prescription medicine, it is unlikely that a patient would be provided with different brands containing the same active ingredient, so the risk of confusion is minimal. For most medicines, the name of the active ingredient is already placed below or close to the brand name; in any case it can readily be found on the main label. The existing requirements, combined with a suitable risk assessment by the regulator, remain satisfactory.

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.

MNZ does not support this proposal.

The name of the active ingredient should be *prominent* but need not be the same prominence and size as the brand name. It is worth noting that in the UK and Canada, the active ingredient is required to be only 50% of the size of the brand name. However, it is important to note that mandatory word placement and size is not the only way to differentiate between products – there are many different elements that can be utilised to effectively communicate the information required by the pharmacist and patient, e.g. font, colour, bold, italics and overall label design. The existing requirements, combined with a suitable risk assessment by the regulator, remain satisfactory.

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.)

MNZ does not support this proposal.

As stated above, the positioning of the active ingredient does not need to be mandated. While it may be relevant to list the three most abundant active ingredients on the main label, these may not be the three most *important* ingredients, so some flexibility should be allowed. In this type of situation, it would be best to list all the active ingredients together on another panel, as is the status quo.

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 2mm in height on the main/front panel.

MNZ does not support this proposal.

These mandatory requirements may be unsuitable in certain circumstances and could lead to unnecessary clutter on the main label. In the interests of patient safety, some flexibility should be allowed, e.g. listing all the active ingredients together on another panel.

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.

MNZ does not support this proposal.

While this could be achieved with some products, it would create major difficulties for others, e.g. products with multiple active ingredients, small containers, etc. It could lead to unnecessary clutter on labels and is unlikely to increase patient safety.

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 1.5mm 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."

MNZ considers that this proposal is not applicable to its members, as the wording on page 16 of the consultation document and proposal 1.6 refers to identification of *non-prescription* medicines containing paracetamol [and ibuprofen]. However, Figure 3 includes the proposed paracetamol warning statement on a mock-up label for a prescription only medicine, so MNZ seeks clarification on this point.

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 1.5mm 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."

No comment – not applicable to MNZ members.

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

What do you think will be the impact of increasing the prominence and standardising the location of the active ingredient on the medicine label?

MNZ does not support these proposals – see comments above.

What do you think about the proposed warnings for paracetamol and ibuprofen containing products?

No comment – not applicable to MNZ members.

Are there any other concerns you have with the size or position of brand names and active ingredient?

See comments above.

If the active ingredient name is clear, directly below the brand name and in a large font, what are the additional benefits that you see by making it the same size as the brand name?

MNZ does not support this proposal – see comments above.

What is the smallest size font that you consider readable?

MNZ considers that a minimum text size of 1.5 mm (height of capital letters, or lower case letters with an ascender or descender) is generally appropriate for medicines labelling. However, in cases where the container too small to use letters of that size (e.g. ampoules, eye drops), a minimum type size of 0.75 mm should apply.

MNZ additional comments on Figure 2 (The components of a medicine label):

- **The example includes the company name before the brand name. MNZ would not support this as a requirement, as this would detract from the trade name and add unnecessary clutter to the label.**
- **The example also appears to require inclusion of the TGA website address. MNZ would not support this requirement, as this would necessitate Australia-specific labelling. Where the same product is marketed in Australia and New Zealand, it may be appropriate to include both the TGA and Medsafe websites, although this could increase clutter on the label. It would be difficult for a consumer to quickly access information from the website; if patients have queries about their medicines, they should in the first instance ask their doctor or pharmacist. The most relevant information would be the Consumer Medicine Information, though the URL for the CMI would be subject to change and too long to include on the label.**
- **The barcode included on the example would probably be unacceptable for routine use, as it is too small and placed on the side panel rather than a main panel. The GS1 standard requirements should be followed.**

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.

MNZ does not support this proposal.

MNZ is keen to work with the regulator to develop general guidelines and risk assessment checklists but does not support mandatory requirements for consumer testing of prescription medicine labelling, as this would impose undue compliance costs. LASA names are already reviewed by the regulator as part of the risk assessment evaluation. As part of the trademarking process, companies already have to ensure that brand names are unique and significantly different to other products.

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.

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.

MNZ does not support proposals 3.2 and 3.3 as mandatory requirements, although it does support the effective use of colour, design, etc. to differentiate between medicines.

Defining look-alike sound-alike product names based on just three letters is too simplistic an approach. Companies often utilise the same brand name across many international markets, so this proposal could impact on international harmonisation and increase costs. It is worth noting that some of the potentially confusing product names in the table on page 21 of the consultation paper differ by more than three letters, so would not be covered by these proposals.

General question on the proposed regulatory changes for look-alike sound-alike names and look-alike packaging:

Do you think the proposed changes to address LASA names and LA packaging will improve medicine safety? Why/why not?

MNZ sees some potential for the proposed changes to improve medicine safety; however it considers that the existing risk assessment during the evaluation process is sufficient to mitigate risks in the majority of cases.

Look-alike medicine branding

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.

MNZ does not support this proposal.

Where the same active ingredient may be presented in both a Listed medicine and a Registered medicine, if the products have the same brand name the patient would more likely to realise that they are similar, hence would actually be *less* likely to take an excess amount of that ingredient. In most cases, the scheduling of an active ingredient will determine how it may be distributed, and the appropriate level of information to be included on the labelling. Rather than implementing a blanket prescriptive approach, MNZ favours a specific risk assessment by the regulator on a case-by-case basis.

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.

No comment – not applicable to MNZ members.

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.

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.

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.

No comment – not applicable to MNZ members.

General questions on the proposed regulatory changes for look-alike medicine branding:

What benefits, if any, do you think the proposed changes to address look-alike medicine branding will have for consumer safety?

Do you understand the proposed changes?

If you can read the labels and warnings clearly, will these changes reduce the potential for harm?

Look-alike medicine branding is primarily an OTC medicine issue. However, MNZ does not support these proposals, as it considers that the existing risk assessment during the evaluation process is sufficient to mitigate risks in the majority of cases.

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 of 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 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.

General questions on the proposed regulatory changes for Standardised Information Format: Medicine Information Box:

To what extent do you think a standardised format for information on the labels of over-the-counter and complementary medicines will improve access to information for these medicines? Are there other ways that the presentation of information could be improved?

Do you think the proposed requirements for products with more than three active ingredients (directions and warnings and allergy information), is sufficient for these products? Please propose an alternative if you don't agree with current recommendation.

No comment – the Medicine Information Box proposals are not applicable to MNZ members.

Dispensing label space

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

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.

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.

General question on the proposed regulatory changes for dispensing label space:

Do you support a designated space for the dispensing label on prescription medicines? Why/why not?

MNZ does not support the dispensing label proposals being mandatory requirements.

Companies try to maintain labels free of clutter wherever possible, and the labels of most prescription medicines already have space where a dispensing label can be affixed. While a designated space for a dispensing label could prevent important information from being covered up, the proposals could necessitate Australia-specific labelling, which would reduce moves towards international harmonisation and increase production costs. Original pack dispensing is now international best practice.

MNZ notes that there are inconsistencies in the discussion document about the size of the proposed space for the dispensing label – it is variously stated as 70 x 30 mm (proposal 5.1 and Figure 9) and 80 x 40 mm (page 30, second paragraph and proposal 7.3).

Blister Strip Labelling

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

MNZ notes that it is current practice for blister strips to be labelled with the trade name, active ingredient and amount of active ingredient at least once for every two units. However, MNZ does not support the repeating of the batch number and expiry date at least once every two units, as this is not international practice and would be unduly expensive to implement. In some case, it would require larger blister strips and completely new tooling.

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.

For the same reasons specified under 6.1, MNZ does not support this proposal.

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

For the same reasons specified under 6.1, MNZ does not support this proposal.

It is not clear whether the proposal is to list the three most *abundant* or the most *important* active ingredients (see also MNZ response to proposal 1.3).

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.

MNZ supports 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.

MNZ notes that this is current practice for blister strips in 'race track format'; however it does not support this proposal being a mandatory labelling requirement.

General questions on the proposed regulatory changes for blister strip labelling:

Do you think the proposed information for blister strips is sufficient?

What other changes would you like to see for this type of packaging?

No further comments.

Small containers

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.

MNZ does not support this proposal.

MNZ considers that <u>either</u> the container should be enclosed in a primary pack that fully complies with all labelling requirements, <u>or</u> should include a pack insert.

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.*

MNZ supports this proposal, but again it is not clear whether the proposal is to list the three most *abundant* or the most *important* active ingredients (see also MNZ response to proposal 1.3 & 6.3).

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.

MNZ does not support this proposal being a mandatory requirement.

Instead, MNZ considers that <u>*where possible*</u> clear space should be provided to allow a pharmacist to affix a dispensing sticker.

MNZ notes that there are inconsistencies in the discussion document about the size of the proposed space for the dispensing label – it is variously stated as 70 x 30 mm (proposal 5.1 and Figure 9) and 80 x 40 mm (page 30, second paragraph and proposal 7.3).

General questions on the proposed regulatory changes for small container labelling:

To what extent do you support the proposed changes for small container labels? Please provide details.

Do you have any further suggestions for how labelling of small containers could be improved?

No further comments.

Pack inserts

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

8.2 A pack insert must be in a form separate to the packaging; ie it cannot be printed on the inside of a carton.

General questions on the proposed regulatory changes for pack insert requirements:

Do you support the proposed changes for pack inserts? Why/why not?

Do you have any further suggestions regarding pack inserts?

MNZ supports the proposals for pack inserts.

Labels and Packaging Advisory Committee

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.

General question on the proposed establishment of a labels and packaging advisory committee:

To what extent do you think that a Labels and Packaging Advisory Committee will assist the TGA to manage consumer health risks associated with medicine labels and packaging?

MNZ supports the proposal to establish a Labels and Packaging Advisory Committee.

MNZ considers there should be further consultation with relevant stakeholders concerning the appropriate representation on the committee, selection of members, processes and procedures adopted by the committee, etc.