Generic Medicines Industry Association Pty Ltd

ABN 19 096 009 540
PO Box 222
Pymble BC
NSW 2073

24 August 2012

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Dear Sir / Madam,

Re: GMiA Submission on TGA Labelling and Packaging Review Consultation Paper (Version 1.0; May 2012)

Please find attached the GMiA submission to the Therapeutic Goods Administration on the current Labelling and Packaging Review Discussion Paper Version 1.0, May 2012.

Members of GMiA look forward to the opportunity to further discuss the matters raised in this submission before the TGA makes any further reviews.

Kind regards,

Kate Lynch
Chief Executive Officer
Generic Medicines Industry Association Pty Ltd

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Generic Medicines Industry Association

Submission to Therapeutic Goods Administration on Labelling and Packaging Review.

August 2012

For further details

Please contact

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GMiA Generic Medicines Industry Association Pty Ltd

Objectives of the Labelling and Packaging Review

The GMiA acknowledges and confirms that the TGA has initiated a review in relation to Therapeutic Goods Order 69 (TGO 69) *General requirements for labels for medicines* and has committed to reviewing *the Best Practice Guideline on prescription medicine labelling*, and the *Code of practice for tamper evident packaging*.

As part of the TGA's commitment to the National Medicines Policy and the quality use of medicines in the community, the GMiA acknowledges that the outcomes from this review will shape new comprehensive guidelines for how medicines can be labelled and packaged. Furthermore, principles will be developed for assessing labels and packaging in the context of clinical safety as part of the authorisation process.

The GMiA has gone through the TGA Labelling and Packaging Review Discussion Paper Version 1.0, May 2012 and has put forward the recommendations contained in this paper with a focus on improving consumer safety and ensuring the quality use of medicines. The GMiA concurs that these are the key objectives underpinning this review.

The format of this submission replicates the key points outlined in the TGA discussion paper with the GMiA response and position identified after each point. The general questions outlined in the boxes found towards the end of each sub-section have also been answered as part of this response, wherever relevant.

The GMiA confirms that in addition to the TGA's contribution to the National Medicines Policy, a number of consumer health risks related to medicine labelling and packaging issues have been identified, including medicine labels that look alike, product names that sound alike, umbrella branding of medicines and lack of visibility of the active ingredient of medicines. These issues may undermine the quality use of medicines and have the potential to put consumer safety at risk.

The identification of these consumer health risks has highlighted to the GMiA the need for a comprehensive and vast-reaching medicine awareness campaign that is carried out within the context of the three main pillars that are underpinning the labelling and packaging review. Namely:

- Quality use of medicines;
- Consumer safety; and

International harmonisation.

OVER-ARCHING COMMENTS

Members of GMiA are concerned about the following:

- Repeated regulatory changes flowing from sequential reviews, namely the current review and the ANZPTA review;
- The absence of evidence supporting the proposed changes recommended in the draft TGA paper;
- The absence of consideration of the **significant cost** associated with the proposed changes to labelling & packaging;
- The limited time allocated to the sponsors to provide comments to TGA
- The review should be separate for Prescriptions Medicines, OTC Medicines and Complementary Medicines as the requirements for each of these segments are different.

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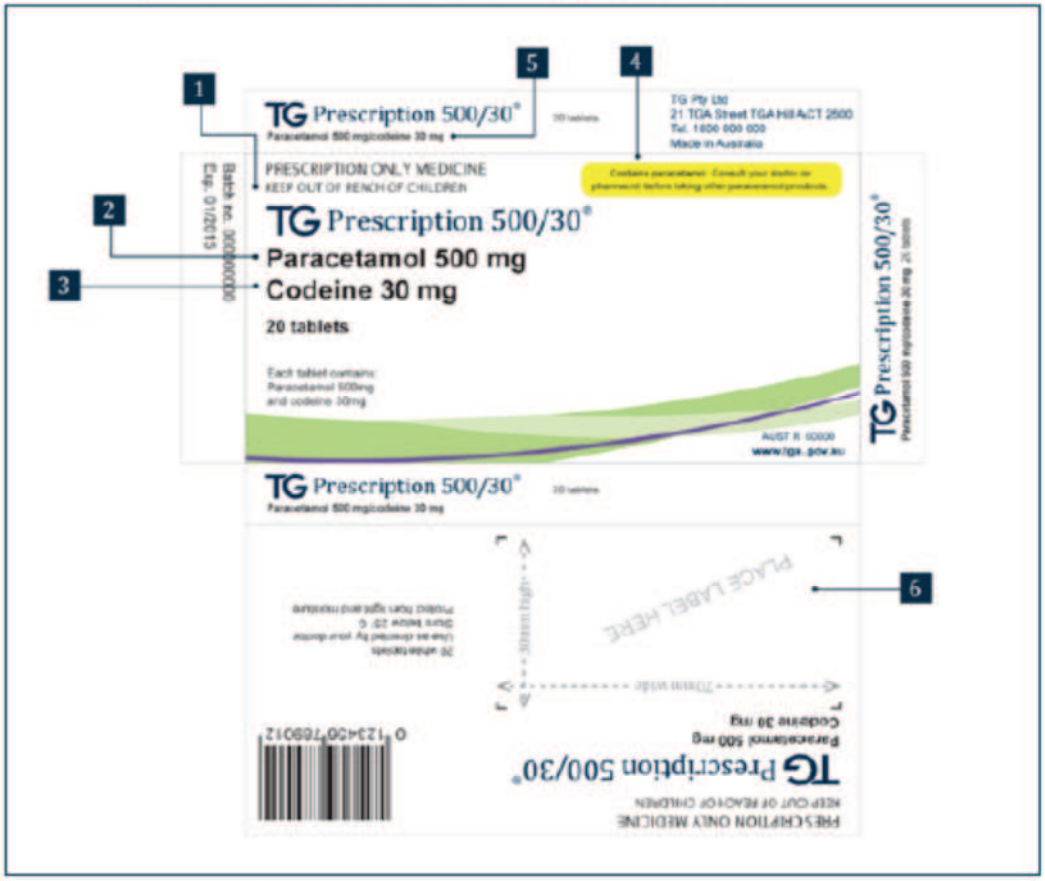
Recommended Regulatory Changes

PROMINENCE OF ACTIVE INGREDIENTS ON MEDICINE LABELS

Proposed Regulatory Changes and GMiA Comments

On page 17 of 55, the TGA has provided an illustration of a proposed blister pack carton which incorporates the recommendations set out in the discussion paper in terms of active pharmaceutical ingredient (API) prominence (as well as the proposed warning statement for products containing paracetamol) (i.e. Figure 3):

Figure 3: Illustration of the recommendations for active ingredient prominence and the warning statement for products containing paracetamol.



1. Mandatory warning included on the label
2. Active ingredient directly below brand name. The first letter of the brand name is directly above the first letter of the active ingredient.
3. Active ingredient of 'registered medicines' (AUST R) has equal prominence with the brand name.
4. Paracetamol warning, see recommendation 1.6
5. Active ingredient on 3 non-opposing sides.
6. Designated space for dispensing sticker.

GMiA wishes to provide some comments in response to this proposed mock-up:

- We do not see any added benefit in repeating the active ingredient names on the main/front panel of the carton. The mock-up provided above repeats the active ingredient names directly below the trade name at a scale of 100% relative to the brand name **and** within the bottom statement beginning with 'Each tablet contains…'. This generates unnecessary clutter of information. Sponsors should be allowed to choose how to present this information; so long as prominence is maintained (e.g. font size of the active ingredient (API) is to be a minimum of 40% of the brand name on the front panel; refer to GMiA response to recommendation 1.2 below).

- We do not agree to the fixed positioning of the active ingredient statement being left aligned with the brand name. In the absence of evidence demonstrating that this will improve the safe use of medicines or decrease dispensing errors, GMiA does not agree with fixed positioning of the active ingredient as increased prominence of the API should be sufficient in improving on such aspects. Depending on the number of actives, the length of the statement for salts, etc, this will all have a profound impact on how such information is presented.

- We note that the proposed mock-up carton contains the TGA website on the front panel. There was a proposal in the October 2011 version of the discussion paper whereby the TGA website would be included on the container label as a way for consumers to access the PI and CMI. GMiA wants to confirm that the TGA is no longer pursuing this option, and the website on Figure 3 is representative of the sponsor of the medicine, if opted to be included by the Sponsor.

- We note that the equal prominence of the API and the brand name is only shown on the front/main panel. All other panels show that the API is at the minimum font size

of 1.5 mm. GMiA is in agreement with the font size requirements for the API for all other panels other than the main/front panel.

- We note that there is text on the same lines as the signal headings and were wondering if there had been a relaxation of the rules that no text is allowed on the same lines as the signal headings.

GMiA Response to Proposed Regulatory Changes

1.1 The active ingredients(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.

The GMiA supports the recommendation for the active ingredient to be located directly underneath the trade name. We do not agree with the necessity for the first letter of the active ingredient to be left aligned directly below the first letter of the brand name. The position of the active ingredient name should be left up to the individual companies as long as they ensure they incorporate the elements of TGO69, TGO80 and Best Practice Guidelines in the design.

1.2 On the front/main panel of the label, the active ingredient must have equal prominence with the brand name.

The GMiA supports the proposal in principle that that active ingredient name is easy to find on the front panel; they do not agree that this means it must be equally prominent to the brand name. Please see 1.2.2 below for further information.

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.

Please see 1.2.2 below for the reasons the GMiA agree in principle, but do not agree with the proposal.

1.2.2 The font size of the active ingredients must be at least 100% of the font size of the medicine brand name on the main/front label.

The GMiA believes the proposal of 100% equal font size for the brand name and the active ingredient on the front panel is impractical and should explicitly be excluded on those labels with limited space. In some instances where the container size is small, it is not feasible, especially in light of the TGA's requirement to now add the salt within the active ingredient description. GMiA considers that a relative font size of not less than 40% compared to the brand name is sufficient in displaying increased prominence for the pharmacist/consumer/health professional to clearly identify the active molecule.

Thus the GMiA is not convinced that increasing the font size to 100% relative to the brand name will improve safety and decrease dispensing errors.

Further, the GMiA would like to draw the TGA's attention to UK MHRA guidelines section 4.2[1] whereby it stipulates that if a molecule is part of brand name it is not necessary to repeat the active ingredient. The naming convention adopted by many generic suppliers in Australia uses the active ingredient name with a prefix or suffix. The GMiA is of the opinion that in these instances, the TGA should adopt the MHRA guideline. Further, GMiA considers making the separate line for the active ingredient at least of equal prominence as the brand name (especially when positioned left aligned directly underneath the brand name as recommended in 1.1 above) would provide no added benefit and may cause confusion to the consumer. Therefore, GMiA considers there should be an exemption to this requirement in cases where the active ingredient name is already part of the brand name/trade name.

[1] Best practice guidance on labelling and packaging of medicines: MHRA Guidance Note No. 25. Published June 2003.

For other forms of packaging (e.g. vial and carton), GMiA is in agreement with adopting the current minimum font size of 1.5 mm AND proposing a requirement of not less than 40% of the size of the brand name for the active ingredient.

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.

The GMiA agrees that there needs to be differentiation between the brand name and the active ingredient name.

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

The GMiA does not agree that the active ingredient name should begin with an uppercase letter and the remainder should be in lower case. They consider that ensuring there is improved differentiation by using a different font, letter spacing or font colour is adequate to provide differentiation between the brand name and the active ingredient name.

1.3 Where there are more than 3 active ingredients, the most abundant ingredients must appear on the main label immediately below the brand name and the names together with the quantities of every active ingredient are to be included on a side panel/label or on a rear panel/label for the product. (This does not apply to day and night preparations.)

It is not clear from this proposal how many active ingredients are required to be on the main panel versus a side or rear panel. Detailing only one of the APIs on one panel, and the other API's on other panels (side/back panel) has the potential to create confusion as to what exactly is contained within the medicine and could lead to medication errors.

Consumers are used to finding this information on a side or rear panel and splitting it up would be more confusing than having it together in one location. It should be at the

manufacturer's decision, but ensuring ease of finding the information may be accorded by placing it inside a table or box. Thus the GMiA considers this could lead to consumer confusion and a better approach to this is to include all active ingredients on a single panel, but decrease the font size to accommodate all information in one location on the label.

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.

The GMiA has concerns that requiring the composition of each tablet to be placed immediately below the brand name, rather than as is currently accepted practice, has the potential to make the front panel too "busy". This will increase the busyness of the label making it harder to read, and/or lead to an increase in pack size so that there is potential to infringe the deceptive packaging elements of the Trade Practices Act. Finally, it will increase the shelf space requirements with a concomitant increase in costs to the manufacturer with the potential to drive up costs to the consumer.

1.5 The active ingredient must be included with, and of equal prominence as, the brand name on at least 3 non-opposing faces of a carton.

The GMiA notes that this contradicts the illustration provided in Figure 3 which shows that only the front panel has equal prominence of the active with the brand name (the other panels show the active ingredient only complying with the minimum 1.5mm height requirement). Having said that, the GMiA is in agreement that mandating the requirement that the active ingredient is prominent only for the front panel is appropriate (at not less than 40% of the brand name as per 1.2.2), and on the other panels should be at least 1.5mm in height. The term "equal" from Comment 1.5 should be deleted and the statement modified to remove the requirement for prominence of the active ingredient on at least 3 non-opposing faces of a carton.

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 letter of at least 1.5mm high and on a background that contrast with the rest of the packaging:

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

The GMiA has no issues with including such a statement on the front of the packaging. Please see further comments in 1.7 below.

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 letter of at least 1.5mm high and on a background that contrast with the rest of the packaging:

"Contains ibuprofen. X mg. Consult your doctor or pharmacist before taking other medicines for pain or inflammation."

The GMiA has no issues with including such a statement on the front of the packaging. Please note however, that the example provided by the TGA includes the statement on the same line as the signal headings. In future, will the TGA allow text on the same line as the signal headings?

GMiA Response to 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?***

  In principle, an increase in prominence will provide better clarity and method of identification of the active ingredient within the medicine. This is especially important considering that the generics market is increasing in size, and it becomes more important for both patients and health professionals to be capable of differentiating between medicines by looking at the labelling.

However, increasing it to 100% or greater has the potential to create confusion for the consumer, particularly if it is aligned to the first letter of the brand name, and there is no added benefit in standardizing the location of the active ingredient. It should be sufficient that the active ingredient be more prominent for the purposes of identification.

As stated in 1.2.2, the GMiA would like to draw the TGA's attention to UK MHRA guidelines section 4.2[2] whereby it stipulates that if a molecule is part of brand name it is not necessary to repeat the active ingredient. The naming convention adopted by many generic suppliers in Australia uses the active ingredient name with a prefix or suffix. The GMiA is of the opinion that in these instances, the TGA should adopt the MHRA guideline.

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

  Please refer to GMiA's comments above. We can see the benefit in increasing prominence of the active ingredient name by changing the font, its colour or lettering but not in terms of size or positioning of the brand name or the active ingredient, especially in light of the fact that this information is repeated on at least 3 panels.

- ***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?***

  GMiA does not see any benefit in 100% prominence of the active ingredient name compared to the brand name on the front panel. For generic medicines, where many generic suppliers use the active ingredient name with a prefix of suffix, the GMiA

[2] Best practice guidance on labelling and packaging of medicines: MHRA Guidance Note No. 25. Published June 2003.

consider equal or greater prominence than with the brand name can be confusing to patients.

- ***What is the smallest size font that you consider readable?***

  Whilst this question is relative depending on the target audience for which this question is being aimed, GMiA believes that the current requirement of a minimum of 1.5mm is sufficient to be legible and clearly read.

Supporting Attachments

In **Appendices 1** and **2** are some label mock ups for the molecule "*Generisartan".*

Two options are presented as follows:

Appendix 1: One trade name using the API name + suffix

Appendix 2: One trade name using a brand name

Within each of these two trade names are four options:

1. Where the API name is 100% of the trade name
   a. Option 1 shows how big the API name is
   b. Option 2 shows how small the trade name would have to be to fit the API name (with 100% prominence with the brand name)
2. Where the API name is 50% of the trade name (Option 3)
3. Where the API name is 40% of the trade name (Option 4)

The purposes of these concepts are to show the impracticality of having the API name being 100% equal in prominence to the brand name. The provided cartons are only representative of medicines which only have one API. It would be impractical for obvious reasons to show concepts whereby the 100% equal prominence requirement is shown on medicines where there are two or more APIs.

LOOK-ALIKE AND SOUND-ALIKE MEDICINE BRAND NAMES AND LOOK-ALIKE PACKAGING AND BRANDING

GMiA Response to Proposed Regulatory Changes

LOOK-ALIKE SOUND-ALIKE NAMES AND LOOK-ALIKE PACKAGING

3.1 Sponsors of new medicine 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.

Clarity is sought by the GMiA as to what sort of information would be required by TGA as 'evidence' for risk assessment, why it is considered necessary, and why such an action is needed in the first instance, rather than just discussing the suitability of the proposed trade name with the TGA.

Executing consumer testing is costly and time consuming and is considered to not add any value to the process. Before a risk assessment checklist could be implemented, it would need to be agreed to by all key stakeholders, including industry bodies. Additionally, the way pharmacists currently stock their shelves in their pharmacy should be taken into consideration (e.g. storage by brand name or molecule name).

It appears that the evidence presented in the discussion paper where examples of incorrect medicine being dispensed is unsolicited reports to the TGA. The GMiA requests further information on the analysis of the sources of information, the frequency of occurrence, and if evaluation per market segment of prescription, over the counter and complementary medicines has highlighted any one segment as being more

affected by LASA than the others. The GMiA would like to identify what corrective actions have been made in the past to fix these matters.

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 letter 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.

The branding of products is the intellectual property of the sponsor of the medicines and as such, could realistically be expected to be trademarked. For TGA to regulate these aspects of packaging and labelling, they would need to develop a standardised and unbiased way of reviewing it such that there is a common agreement as to what is and is not acceptable for the packaging of products with similar brand and molecule names.

In addition, in order for Sponsors to generate artwork for submission to TGA for new products that would meet the proposed requirement to be different to the labelling of other products in these instances, the artwork for these existing products would need to be readily available to allow comparison. Although this may be possible for marketed products, it would be difficult for products that are registered but not marketed and thus the TGA would have to do the final evaluation of the suitability of said labelling. Clarity on the TGA's stance is requested for such situations.

It is the GMiA's considered opinion that this is not the best use of the TGA's time.

3.3 In relation to application 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.

Please refer to GMiA's response to Point 3.2. Further discussions required around how Sponsors would be able to execute such searches for comparative purposes, especially for non-marketed medicines.

LOOK-ALIKE MEDICINE BRANDING

3.4 Products that are listed on the ARTG cannot be marketed under the same name as a registered medicine.

The GMiA consider more consultation is required around this proposal. They do not agree for instances where the medicines have the same active ingredient, the same strength, the same manufacturer and Sponsor and the difference is only the number of dosage units, as is currently the case with for example, proton pump inhibitors and antiviral medicines.

3.5 Medicines that contain the same quantity of API 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.

The GMiA are equivocal about this proposal; they consider that, as long as the medicine is approved for the symptom, the active ingredient name is displayed prominently directly below the brand name, and all other mandatory statements are included on the packaging or in the advertising material, there should be no impediment to the use of selective differentiation based on a subset of symptoms or uses.

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 APIs are closely related (e.g. different salts of the same pharmaceutical chemical), and***

b. ***The safety profile, efficacy and dosage regime are similar.***

This proposal appears to contradict the proposal in point 3.5. Please refer to our response in 3.5.

GMiA Response to General questions on the proposed regulatory changes for look-alike sound-alike names and look-alike packaging

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

  In the absence of any evidence, it is difficult to determine whether the proposed changes will have any substantial impact on improving medicine safety. The focus of this issue needs further discussion, and evidence to support such proposals needs to be analysed. GMiA need to understand how frequently this issue arises before determining whether safety would be improved by implementing the proposals. The GMiA considers that increasing the prominence of the API statement is a progressive step and should be complemented by the implementation of an awareness program on Quality Use of Medicines addressing the importance of prescribing a product by its active ingredient for both Health Care Professionals and pharmacists.

GMiA Response to 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?***

  Please refer to the comments above. There needs to be a heavier emphasis placed on the need for greater public education.

- ***Do you understand the proposed changes?***

  Whilst most changes are self-explanatory, there is a conflicting emphasis on either increased prominence of the API or a need to improve how the brand name is presented (especially in light of umbrella branding). Tools and guidelines need to be compiled and made available to Sponsors for use when generating labels to ensure that LASA are adequately contrasting to reduce the potential for medication errors and consumer confusion.

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

  The proposal to completely change the labelling of all medicines has an enormous cost & time burden for all Sponsors and will most likely see some smaller product lines and Sponsors/ manufacturers withdrawing from the market place. It will also impose a large time burden on the TGA when they evaluate these changes,

  The consultation review does not differentiate between prescription, over the counter (OTC), and complementary medicines. They each subsist in a separate market segment which has different information requirements. The GMiA members consider that an education campaign detailing how to read the labels of medicines and what sort of information needs to be drawn from them, particularly for OTC and self-selection medicines, would be more cost effective.

STANDARDISED INFORMATION FORMAT: THE MEDICINE INFORMATION BOX

GMiA Response to Proposed Regulatory Changes

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 Ingredients, incl. the amount in each dosage unit***

**** Uses (indications)***

**** Warnings and Allergy Information***

**** Directions/Dosage instructions***

**** Storage information***

The GMiA considers that so long as the information is included on the label, this should be sufficient. It does not agree to a standardized format. Space for such a format whilst complying with the 1.5mm/2mm requirement will be an issue. It will lead to an increase in the size of packaging, with concomitant issues around deceptive packaging concerns of the Trade Practices Act. The text may become illegible, thus reducing patient safety. This is especially problematic for Day/Night and Combination products. Further evidence is required to support the use of a Medicine Information Box. Furthermore, heavier emphasis should be placed on the pharmacist to distribute the CMI at the time of dispensing.

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

The GMiA accept 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.

The GMiA has concerns that if a consumer is comparing two medicines by turning the pack over to read the information, they may get confused, as the information would appear alike. This goes against the LASA proposals for differentiation of the labelling.

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 GMiA considers this alternative approach can potentially distort the information being provided in the box. Splitting the Medicine Information Box into a pack insert can also cause confusion for the patient, and is unlikely to improve patient safety. There should be flexibility on the type and extent of information on such Medicine Information Boxes for smaller boxes and bottles.

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.

GMiA considers the current regulations are sufficient to address these types of matters. Adding additional lines of text, when there are other proposals' to increase the information on the label is contradictory to improving the readability of it. .

4.6 For products containing more than 3 active ingredients, or products in small containers, there may not be sufficient 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***

**** Warning 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.

The cost implications need to be taken into account when considering the proposal of having a leaflet included in the carton where it's impractical to include a Medicine Information Box on the container itself. The TGA should allow sponsors to shorten the text and reduce font size to accommodate the necessary information to be printed on the carton to satisfy these requirements.

GMiA Response to 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?***

  The GMiA considers that the inclusion of a standardised format for information on the labels for OTC and complementary medicines will make little difference in terms of improving access to information. We agree that the headings proposed (such as listing potential allergens) are important and is currently practiced by Sponsors any way. So long as the information is present, the need for a standardised format serves little purpose and will be costly.

- ***Are there other ways that the presentation of information could be improved?***

  The GMiA considers that information currently regulated on the artwork for such medicines is adequate.

- ***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 provide an alternative if you do not agree with the current recommendation.***

  The GMiA is of the opinion that the proposed requirements for products with more than three active ingredients will not add any further value and that the current requirements are adequate. They consider that current regulations are adequate in providing directions, warnings and allergy information for such products, and do not see a need for further change.

DISPENSING LABEL SPACE

GMiA Response to Proposed Regulatory Changes

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

The GMiA notes that this requirement is recommended for primary packs for solid dose forms in the TGA Labelling and Packaging Review Discussion Paper Version 1.0, October 2011. The recommended space of 70 x 30mm is in line with UK guidelines. The GMiA would like the TGA to clarify that this recommendation is only required for oral solid dose forms.

The size of Australian dispensing labels should be taken into consideration. Whilst it appears that the majority of blister pack cartons may be able to accommodate this requirement, the folded dispensing label as described in the above-mentioned TGA discussion paper (referred to as flagged label in the UK guidelines[3]) would be required for bottle presentations, where the dispensing label would be applied to the flagged portion of the label and the clear portion would be applied to the original packaging to ensure lack of obstruction of the labelling information underneath. Whilst good in theory, it will be difficult to get pharmacists to carry this out in practice.

The GMiA propose that the suggested 70 x 30mm space be left clear on one panel of the carton if size permits, but when this is not feasible because of the space required to fit the other mandatory information, this requirement should be exempted and the clear dispensing sticker label should be applied.

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

[3] Design for Patient safety. A guide to the design of dispensed medicines Edition 1, 2007 (pg 49) NHS, National Patient Safety Agency

the same as information repeated on the label. The area for placement of the sticker should be illustrated by corner placement marks on the packaging.

The use of corner placement marks or space can be impractical considering sponsors need to accommodate mandatory text and comply with minimum font size requirements. The GMiA would like to seek clarification on whether the TGA is referring to the need to repeat information on the container label or to the information printed on the dispensing label.

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

The GMiA do not consider the inclusion of a clear space for small containers to be practical. The GMiA proposes a better solution would be for the TGA to mandate that the pharmacist uses a clear dispensing sticker to ensure label information is not obscured. Please also see further comments provided below.

GMiA Response to General questions 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?***

  The GMiA do not believe a designated space for the dispensing label is required for ALL medication packaging. We consider this requirement is more applicable to those dosage forms where patients are required to follow dosage instructions as prescribed by their doctor (e.g. oral solid dose forms, Schedules 4 or 8 Medicines taken by patients in the home setting).

  In particular, injectables (vials and ampoules) should be exempted from this requirement. In the vast majority of cases they are administered to the patients by Healthcare Professionals in a clinical setting. The injectables are dispensed by the

Pharmacists in the hospitals where an internal dispensing label (e.g. the edges of a folded dispensing label) is often applied to the immediate packaging instead of the secondary packaging, which is generally discarded during the dispensing process.

In addition, it is impractical to allow a clear space or corner placement marks on the container labels of injectables, due to size constraints. The GMiA consider the onus should be placed on the pharmacists to follow their internal practice guidelines as outlined by the Society of Hospital Pharmacy Association (SHPA) Standards of Professional Practice. When applying an internal dispensing label onto the packaging (may it be primary or secondary packaging) the information obscured is to be repeated on the dispensing label itself (e.g. product name, strength, active ingredient, batch no. and expiry).

The primary purpose of a dispensing label is to instruct the patient when self-medicating. A dispensing label on injectables has limited value as patients don't generally self-medicate using vials or ampoules except for certain therapeutic groups such as insulin. Furthermore, we consider pharmacists should be encouraged to use the clear dispensing sticker where the container size is small, such that the use of a dispensing label is impracticable as described in the TGA October Discussion paper (also referred to as flagged label in the UK guidelines). This dispensing label will be applied to the flagged portion of the label and the clear portion will be applied to the original packaging.

The use of clear dispensing sticker will always ensure lack of obstruction of the labelling information underneath, therefore GMiA would like to propose stronger wording in the communication to the pharmacy bodies regarding the use of clear dispensing stickers.

The GMiA proposes that industry members should be encouraged to leave the suggested 70x30mm space clear on one panel of the carton of prescription medicines (Schedule 4 and 8) and injectables for a specified therapeutic group, such as insulin where self-medication is common practice. When this is not practical due to constraints from packaging size and shape, this requirement should be exempted and the clear dispensing label used by the Pharmacist to ensure lack of obstruction of critical information.

BLISTER STRIP LABELLING

GMiA Response to Proposed Regulatory Changes

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

The GMiA agrees with part of the proposal, namely that the brand name, active ingredient and strength be repeated at least once every two units. The GMiA do not agree with the proposal that the batch number and expiry date be repeated at least once every two units. In addition, further discussion is required for smaller blisters where the pockets may be positioned very close to each other. It will be difficult to comply with this proposal whilst still maintaining a minimum font size of 1.5 mm.

The GMiA members consider the proposal to repeat the batch number and expiry date every two units for non-perforated blisters, to be impractical. Currently, most Contract Packers in Australia do not have the capability to do it. Packaging machinery that will print on-line require a large capital expenditure running into hundreds of thousands of dollars. This proposal requires the information to be printed onto the foils online during the blistering stage. This will mean the ongoing costs of packaging will increase sharply; foils will need to be printed in small quantities since they're batch specific, all tooling will have to be updated, increased write-off and rejects costs for start-up and clean-down between batches, the increased amount of text to be printed on-line is likely to decrease the legibility of the text and may potentially result in tearing of the foil during packaging. Accommodating the increased print requirements would be especially problematic for small blisters, such as oral contraceptives.

This information is already provided on the edge of the blister foil as a single entry, and on the outer carton. There is therefore no added value to the consumer by

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.

Please refer to point 6.1 above for practical issues relating to printing on-line during the packaging process. The GMiA considers an education program to be more effective in the use of foils with segmentation.

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

Please refer to point 6.1 above. For those medicines that contain 3 or more active ingredients, the GMiA considers the proposal to list these ingredients on each segment (across two units), to be impractical due to the font size constraints. The GMiA do not support this proposal.

6.4 Where there are more and 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.

Please refer to point 6.1 and 6.3 above. The GMiA do not support the proposal to provide a list of active ingredients on the foil.

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.

The GMiA accepts this proposal.

GMiA Response to General questions on the proposed regulatory changes for blister strip labelling

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

  The GMiA agrees with part of the proposal, namely that the brand name, active ingredient and strength be repeated at least once every two units. The GMiA do not

agree with the proposal that the batch number and expiry date be repeated at least once every two units.

SMALL CONTAINERS

GMiA Response to Proposed Regulatory Changes

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.

The GMiA submits that this can only be done if there is an increase in PBS pricing. With the current plethora of PBS reforms affecting the economic viability of this industry sector further costs incurred via packaging should be avoided. The GMiA believes that TGO69 is adequate; furthermore, it is not practical from a production perspective to include primary (outer) packaging for all small containers (e.g. bottles) due to significant increased production costs. The addition of outer packaging will also lead to the need for additional shelf space in pharmacies to accommodate the increase in the pack dimensions.

These increased costs will lead to increases in cost to the government and the consumer. Finally, it is most likely that the outer carton packaging would be discarded by patients, thereby negating any benefit of this proposal.

More importantly, the additional information that proposed for the additional primary packaging would be in the existing CMI document. The GMiA strongly suggests that there should be an increased education to inform patients that pharmacy should provide a CMI at the point of dispensing, ensuring more current, relevant information is provided to the patient.

7.2 The label on the container must include the following details in a letter height of not less than 1.5mm:

**** 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 3 active ingredients, the 3 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***

**** The expiry Date***

**** 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 4 wks 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 4 wks after the container is first opened.***

The GMiA supports the intent of this proposal, however, noting that where the active ingredient is part of the brand name the repeat ingredient name can be dropped.

7.3 A clear space should also be provided to allow a pharmacist to affix a dispensing sticker. The space need not be the size of a standard dispensing sticker (80 x 40mm), but should allow a folded sticker to be attached like a flag without obscuring information.

It is noted that this proposal specifies 80 x 40mm, in contrast with previous proposals which specify 70 x 30mm. Regardless, for small containers, such space is not always available. The GMiA propose that if the space to affix a dispensing sticker is smaller than 70 x 30mm, then an exemption be granted.

GMiA Response to General questions on the proposed regulatory changes for small container labelling

- ***To what extent do you support the proposed changes to small container labels. Please provide details.***

  The GMiA does not support the proposal of leaving a clear space on the container to accommodate the dispensing sticker as it is impractical on small containers due to size constraints. It would be more practical to mandate that pharmacists use the clear dispensing sticker and hand out the appropriate information (e.g. CMI, if available) at the point of dispensing.

PACK INSERTS

GMiA Response to Proposed Regulatory Changes

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

The GMiA supports this proposal.

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.

The GMiA supports this proposal.

GMiA Response to General questions on the proposed regulatory changes for pack insert requirements

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

  The GMiA supports the changes.

- ***Do you have any further suggestions regarding pack inserts?***

  No.

LABELS AND PACKAGING ADVISORY COMMITTEE

GMiA Response to General questions on the proposed establishment of a labels and packaging advisory committee

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

  It is assumed that the Labels and Packaging Advisory Committee would assist with the risk assessment of the similarity of the product name and labels. The proposed committee should include expertise relating to the reading capability and knowledge of the general public and should assess this periodically.

  With opinions to be sourced from varying bodies, there needs to be controls put in place to ensure that all comments are streamlined in such a way that an agreement can be easily reached between all respective stakeholders. The TGA needs to be prepared that there may be conflicting interests.

  Expertise on current overseas practices should be taken into consideration.

CONCLUSION

Members of GMiA place a high emphasis on ensuring that labelling of medicines supports the principles of quality use of medicines. Members of GMiA adhere to legislation and regulation and as providers of follow-on medicines, will adopt any further labelling requirements. Members respectfully request that implementation of any change to labelling requirements recognise the substantial costs and timelines associated with producing changed labelling and that sufficient transitional arrangements and periods are taken into account in the potential adoption of changed requirements.

APPENDIX 1

APPENDIX 2