TGA Medicine Labelling and Packaging Review

Note: WATAG comments shown below by blue text

Proposed regulatory changes - Prominence of active ingredients on medicine labels

The following regulatory changes are proposed.

1.1 The active ingredient(s) must be listed immediately below the brand name, with the first letter of the active ingredient directly below the first letter of the brand name.

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

1.2.1 The intention of 'equal prominence' is for the active ingredient to be as easy to locate and identify on the label as the brand name.

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

1.2.3 For improved differentiation between the brand name and the active ingredient there should be a difference in font style or letter spacing or font colour.

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

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.)

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.

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.

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."

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."

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? This should improve the ability to correctly and safely identify the product. The active ingredient should be given greater prominence (size and colour) than any branding.

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

Are there any other concerns you have with the size or position of brand names and active ingredient? Yes: generally concerned about the proposed regulatory changes and would prefer that a brand name not be included on the packaging except on the packaging of the innovator brand (i.e. first of kind) product. All subsequent generic versions of an active ingredient should display only the company name and the active ingredient (generic) name. That is, a generic version of an active ingredient should not introduce

a new brand name. Branding of every version of an active ingredient is a major source of confusion and creates an excessive and unnecessary array of brand names. Company name branding on all products is acceptable as an aid for product differentiation. Similar standards apply in other countries and it is unsafe for Australia not to also apply this standard.

The active ingredient name should be more prominent in size, font and colour than the company name or the brand name (for innovator products) i.e. at least 100% the size of the company name.

The active ingredient name should be all lower case (including the first letter). This avoids confusion with brand names and correctly informs the consumer of the product's active ingredient/generic name. It is incorrect to capitalise the active ingredient name and this should not be accepted in the regulatory framework or elsewhere.

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? Proper use of active ingredient labelling will enable consumers to more accurately identify and compare products. Use of company name labelling allows consumers to differentiate products, removing the need for generic brand naming. A simplified naming system should reduce confusion and improve patient safety.

What is the smallest size font that you consider readable? Readability depends on factors other than font size, such as font type (eg. whether it is regular or narrow, serif or sans-serif etc), font colour, background colour and contrast. Font size also needs to consider the needs of the visually impaired. A 10 point font was suggested as a minimum readable size.

Proposed regulatory changes - 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.

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.

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? The proposed changes are generally supported. As discussed above, the removal of brand naming for generic drugs will minimise the number of brand names in the market without significantly effecting product identification. A simpler regulatory environment for product naming and labelling will also minimise LASA issues and have a greater impact on medicine safety.

Notwithstanding this recommendation, if a proposed new brand name differs from an existing name by 3 letters or less, the company should be asked to consider revising the name.

The proposed pre-marketing review process for LA products is accepted.

A guide to assist consumers and health professionals with the correct pronunciation of the active ingredient name would be of great educational value in improving communication and reducing LASA errors (eg *EYE-bew-PROH-fən* for ibuprophen etc). This guide could be located on the packaging or inserts.

Proposed regulatory changes - 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.

3.5 Medicines that contain the same quantity of active ingredient(s) cannot be selectively differentiated or marketed for a subset of symptoms or uses, unless the medicine has specific characteristics that make it more suitable for a particular symptom.

For example: Products cannot be marketed as “BRAND headache”, “BRAND backache”, “BRAND joint pain” if they include the same active ingredients in the same quantity.

3.6 The same brand name cannot be 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.

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? The proposed changes are strongly supported as they will produce a simpler regulatory framework and minimise the potential for consumer confusion.

Do you understand the proposed changes? Yes, the regulatory framework should in no way support medicine branding that has the potential to lead to look-alike confusion.

If you can read the labels and warnings clearly, will these changes reduce the potential for harm? It cannot be assumed that consumers will read labels and warnings in every instance. The potential for product confusion needs to be eliminated wherever possible and addressed in a systematic way. Labelling should be clear and simple.

Proposed regulatory changes - Standardised Information Format: the Medicine Information Box

4.1 Mandated information on labels and packaging of non-prescription medicines and complementary medicines is presented in a standardised Medicine Information box, based on the US FDA Drug Facts box. The mandatory headings are:

· Active ingredient, including the amount in each dosage unit

· Uses (indications)

· Warnings and Allergy Information (including when the product should not be used and when to consult with a doctor or pharmacist. This section also includes information about possible side effects and substances or activities to avoid. The final lines of this section should include information about preservatives in the product.)

· Directions/Dosage instructions

· Storage information.

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 question 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 proposed Medicine Information Box appears to provide the necessary consumer-level information that is most important. The standardised format is also likely to improve the ability of consumers to readily find the information they need.

However, we are concerned about the amount of information that may be crammed onto a Medicine Information Box and the space this occupies on the packaging. The extra Medicine Information Box labelling, the dispensing box, bar coding and the warning box is likely to be too much printed information competing for limited package space. This will probably lead to use of small fonts, loss of clarity and confusion. While sounding sensible, the proposed changes may not significantly affect safety, and could have a negative effect. In essence, the Medicines Information Box will not be a substitute or even a complimentary action to the provision of a CMI. For complementary medicines without a CMI or other information supplied with the product, the information in the Medicines Information Box (however presented) should be considered a minimum requirement.

Are there other ways that the presentation of information could be improved? Consideration should be given to including a 2-D bar coding or Quick Response (QR) Code on the packaging or insert for online lookup of the information through a mobile device such as smartphone or tablet.

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. Appears sufficient; no further suggestions.

Proposed regulatory changes - Dispensing label space

5.1 A designated space of 70 x 30 mm, consistent with international best practice11, 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? Yes, this proposal is strongly supported.

Proposed regulatory changes - Blister strip labelling

For blister strips, other than those that have a “race track” blister strip format to facilitate the quality use of the medicine (such as oral contraceptives), the following requirements are proposed:

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.

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.

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

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.

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.

General question on the proposed regulatory changes for blister strip labelling

Do you think the proposed information for blister strips is sufficient? No. To facilitate product identification and safety, information should be repeated on each unit, where possible. However, there is a need to balance desirability of labelling every unit with need for adequately sized font as legibility of information on blister strips is often a problem for patients with visual impairment, especially when the surface is light reflective. Brand name and/or company name need not be on each unit if space is an issue.

What other changes would you like to see for this type of packaging? Suggest use of company name for product identification rather than use of a brand names (except for innovator products). It may be possible to label the blister strip once with the company name, increasing the space available to label each unit with other essential information.

Proposed regulatory changes - 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.

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

· The brand name of the medicine

· The name(s) of all active ingredients in the medicine

· For ophthalmic preparations the name of any antimicrobial preservatives in the medicine

· Where there are more than three active ingredients, the three most abundant ingredients are to be included on the label of the container and the complete list of ingredients on the primary packaging and the pack insert

· The batch number of the medicine

· The expiry date of the medicine

· If an injection, the approved route of administration

· If an ophthalmic preparation for multidose use, a statement to the effect that the medicine should not be used later than four weeks after the container is first opened

· If a solid ophthalmic medicine for preparing eye drops for multidose use, a statement to the effect that the medicine should not be used later than four weeks after the container is first opened

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

General question 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. Proposals supported. Prefer use of package insert rather than Medicines Information Box and other information on external packaging as space is limited and small print reduces readability.

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

All packaging and labels (small and large containers) should be required to show the route of administration.

In particular, under 7.2 “Small Containers”, the 7th dot point: the words “If an injection” should be removed and the route of administration always shown irrespective of route of administration.

Proposed regulatory changes - 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; i.e. it cannot be printed on the inside of a carton.

General question on the proposed regulatory changes for pack insert requirements

Do you support the proposed changes for pack inserts? Why/why not? Yes, proposals supported.

Do you have any further suggestions regarding pack inserts? Consider the Medicines Information Box as a standard insert or CMI header rather than printing on external packaging because of concerns about the available space on packaging and the need to provide information in a readable font size.

Labels and packaging advisory committee

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? This proposal is supported as it is considered important that appropriate expertise and representation is harnessed and developed to address ongoing labelling and packaging requirements, and to achieve best practice in Australia. Consumer representation on the committee is important.

Advocate a simple mechanism for reporting labelling and packing issues to the Labels and Packaging Advisory Committee before these issues cause adverse incidents. Requires priority consideration.

Additional comment

Combination products

For common combination medicines, the TGA should consider formally providing a naming convention of the generic names. For example amoxycillin / clavulanic acid could be given the standard name "coamoxyclav", or similar. This would be an important initiative in view of the increasing number of combination products and to facilitate ease of use in both manual and electronic systems. This convention exists in other countries and should be introduced to Australia.

Bar coding

The proposed changes do not address the issue of bar coding. Bar coding will be essential as electronic medication management and closed loop medication management systems are introduced. These systems are being introduced specifically to improve medication safety and it is critical that labelling and packaging standards support contemporary practice. Bar coding should include information about the drug name, strength, batch and expiry as a minimum. 2-D bar coding has the potential to provide additional information such as in the Medicine Information Box. The need for bar coding standards cannot be over emphasised.

Route of administration

All packaging and labels should be required to show the route of administration. This information should be clear and prominent.

Concentration of liquid solutions

All liquid solution labels should show the concentration of active ingredient as weight per volume (recent example where "5 mL contains methadone hydrochloride 25 mg" rather than 25 mg in 5 mL caused confusion)

All liquid solution labels, including oral liquids, should show the concentration as weight per 1 mL (5 mg/ mL rather than 25 mg/ 5 mL).

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