Proposed regulatory changes

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.

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."

What do you think will be the impact of increasing the prominence and standardising the location of the active ingredient on the medicine label?
Increasing the prominence and standardising the location of the active ingredient on the medicine label will enhance the ability of consumers to locate and be alerted to the active ingredient/s of medicines, leading to the improved safe and quality use of medicines. The proposed changes will complement the NPS: Better choices, Better health's *Be Medicinewise* campaign, launched in 2011, which encourages consumers to understand their medicines (including understanding what the active ingredient is and where to locate it on the medicine packaging) and make informed decisions about their health.

A heightened awareness of the active ingredient can assist consumers to recognise when two different brands have the same active ingredients (thereby avoiding accidental double dosing), identify when two medicines are not the same, avoid taking a medicine that they are allergic to or shouldn't be taking with other medicines and identify suitable alternatives to their usual medicines when travelling.

What do you think about the proposed warnings for paracetamol and ibuprofen containing products?
The proposed warnings for paracetamol and ibuprofen containing products will improve the safe and effective use of medicine and help reduce the risk of accidental overdose. It is noted that the proposed warning is consistent with Cautionary Advisory Label 19a of the Australian Pharmaceutical Formulary and handbook (APF22). PBD suggests that there could be potential benefits in extending the warning to apply to other over the counter products where there are high risks of medicine misadventure (eg potassium supplements).

Are there any other concerns you have with the size or position of brand names and active ingredient?
With regard to recommendation 1.3 (if there are more than 3 active ingredients the most abundant ingredients must appear on the main label), it should be noted that there may be instances where it could be more important to list the most toxic ingredient on the label first (which may be in a smaller quantity/ strength) rather than an ingredient with a larger quantity but lower toxicity level. In emergency situations it is important to be able to quickly identify the quantity of the most toxic ingredient.

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?
PBD is supportive of the proposed regulatory changes with respect to equal prominence of the active ingredient, particularly noting that the font size of the active ingredient must be at least 100% of the font size of the brand name on the front label. Increasing the prominence of the active ingredient will improve identification of the active ingredient and contribute to the facilitation of safe and effective brand substitution.
What is the smallest size font that you consider readable?
Not less than 1.5mm.

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?
Yes. PBD is supportive of a pre-marketing assessment process to determine the risk associated with proposed medicine names and their associated packaging and labelling, leading to the safer naming, labelling and packaging of medicines. Restricting the registration of products with confusable names will reduce the opportunity for error in the future. PBD is very supportive of a method to electronically screen proposed brand names to determine their similarity to existing brand names.

A set of principles for the safe design of medicines labelling and packaging would also be highly desirable (including guidance for industry on the use of font type, font size, use of bolding and colour to ensure that packaging is easily readable and products can be clearly distinguished from one another).

Look alike and sound alike names and packaging pose a significant safety risk for consumers, particularly given the potential for incorrect selection of medicines at the point of prescribing, self-selection and dispensing of medicines. A recent example of sound-alike names that created confusion amongst health practitioners has been brought to the attention of the Paediatric Medicines Advisory Group (PMAG). A group of paediatricians reported that the name Fluvax created confusion among general practitioners who use the word 'fluvax' as shorthand for "flu vaccine" or 'flu vaccination". The confusion of the proprietary name with the influenza vaccine creates a potential safety issue in vaccinating children less than five years of age, as Fluvax is not registered for use in children less than five years in Australia. Data entry errors were also evident where "fluvax" was recorded as the doctor's order whereas a different brand of the influenza vaccine (appropriate for children less than 5 years) was given.

In summary, the proposed regulatory changes have the potential to significantly reduce the risk of harm to consumers from LASA errors, including those relating to prescribing (such as incorrect selection of a look-alike name in electronic prescribing software) and dispensing (such as misreading of a look-alike name from a prescription or incorrect selection).

Has consideration been given to some form of incentive/requirement for manufactures to change the labelling and packaging of existing medicines where LASA brand names or packaging exist which pose a significant risk to consumers?

Whilst it is noted that the Tall Man lettering standard developed by the Australian Commission on Safety and Quality in Health Care (ACSQHC) falls outside the scope of this review, we believe the standard could be used by the medicines industry to help make similar looking drug names more easily differentiable and reduce the risk of medicine name selection errors during prescribing or dispensing. In addition, pharmacists can generate shelf labels with Tall Man lettering for use in pharmacies and hospital wards to reduce the risk of the wrong medicine product being selected. The ACSQHC has developed a National Tall Man Lettering List which contains a list of 250 pairs of confusable Australian drug names.

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?
PBD supports the proposed regulatory changes to look-alike medicine branding, particularly relating to the proposal to prohibit the marketing of products as "BRAND headache", "BRAND backache", "BRAND joint pain" if they include the same active ingredients in the same quantity. The changes will reduce the potential for confusion associated with the selection of medicines by consumers, reduce the risk of accidental overdose based on selection of one or more products to treat different conditions which contain the same active ingredient. Additionally, the proposed changes will improve the quality use of medicine and improve product differentiation by restricting umbrella brands.

Do you understand the proposed changes? Yes.

If you can read the labels and warnings clearly, will these changes reduce the potential for harm?
Yes. For most non-prescription medicines, labels are the primary source of information for consumers, and therefore it is important that they are able to clearly read, understand the warnings and act on the information presented on the label. This will benefit self-medicating consumers.

Better informed consumers, increased consumer participation, and improved consumer awareness and health literacy, will assist consumers make better decisions, and take more responsibility, in relation to their healthcare, and result in improved adherence/compliance, a reduction in adverse events and improved health outcomes.

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 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?

PBD is supportive of the proposed regulatory changes for a standardised information format (the medicine information box). For consumers, the label is the most important source of information for non-prescription medicines, and the information should help consumers to select and use medicines safely and appropriately. The consistent placement and presentation of key medicine information, grouped under mandatory headings, will allow consumers to easily identify the most important information about a medicine, enhance their ability to compare different brands of medicine, and to identify whether a medicine is suitable for them based on readily available warnings. This will help consumers to make informed decisions about the medicines they take and how to use them safely.

PBD is aware that the Australian Self Medication Industry (ASMI) has undertaken research to identify the best way to present information on medicine labels and packaging to maximise readability. We hope that the learnings from this work have been incorporated into the proposed design of the Medicine Information Box.

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

- The presentation of the text in the Medicine Information Box example on page 22 appears cramped and may reduce readability and fail to engage consumers. Consideration may need to be given to font size, use of bullets/bullet size and colour.
- If the directions for use (dose) are specific for three or more age groups, it is recommended that a tabulated format is used under the 'Directions' heading to make this information easier to read/distinguish.

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. Yes.

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?
PBD is supportive of a designated space for the dispensing label on prescription medicines. This will ensure that important information included on the primary packaging produced by the manufacturer is not covered up by the label, such as dosage instructions, warnings or storage instructions (eg keep refrigerated). Without access to this information, there is a risk that consumers will not use the medicine appropriately or the efficacy of the medicine will be compromised if it is not stored correctly.

This change will also assist pharmacists who often encounter difficulty affixing the dispensing label without covering up important information, due to inadequate dedicated space provided on the primary packaging by the manufacturer, especially in small containers for prescription medicines.

In terms of pharmacist dispensing labels, PBD would welcome consideration being given to measures to support improved dispensing labels, in line with quality use of medicine (QUM) principles. QUM improvements in this area could be guided by the responses to the current labelling and packaging review. PBD would welcome the opportunity to work with the TGA, as well as the Pharmacy Board of Australia, to develop proposals for change s to Appendix L (requirements for dispensing labels for human and veterinary medicines) of the Poisons Standard.

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.

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?
PBD supports the standardised printing of the brand name of the medicine, the active ingredient and amount of active ingredient, batch number and expiry date on the blister strip. However, we believe that this information should be repeated across *every* unit to support quality use of medicines and reduce the risk of harm from administration of the wrong medicine or risk of overdose if the active ingredient is not easily identifiable. This would help reduced medication errors in circumstances where a blister is perforated or cut into individual doses, or where a medicine is packaged in a dose administration aid, but due to stability considerations can not be removed from the blister packaging until directly prior to administration (resulting in a single pocket being perforated from the strip and placed in the DAA).

What other changes would you like to see for this type of packaging?
PBD would like to suggest that the inclusion of the website address for the TGA PI/CMI search facility on the top or bottom of the blister strip could be beneficial, to enable consumers to access CMI information about the medicine.

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.
The proposed changes for small container labels will improve access to important medicine information such as active ingredient/s and antimicrobial preservatives which are the key information that consumers and pharmacists first look for in ophthalmic preparations and injections.

PBD provides specific comments in relation to the proposal that an ophthalmic medicine for multidose use should include a statement that the medicine should not be used later than four weeks after the container is opened. Consideration should be given to the fact that there are some ophthalmic preparations where the product information indicates that 'in use' stability is greater than four weeks. This has occurred in the last 2-3 years due to the development of new preservative agents. For example the PI for Optive lubricant eye drops (Allergan) indicates that the product should be discarded six months after opening.

Do you have any further suggestions for how labelling of small containers could be improved? PBD suggests that the use of wrap-around or concertina labels could provide additional space for important information on small containers.

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 question on the proposed regulatory changes for pack insert requirements

Do you support the proposed changes for pack inserts? Why/why not?
Yes. The proposed changes for pack inserts will allow consumers to access other important information about the medicine not included on the medicine label.

Do you have any further suggestions regarding pack inserts?
Will there be a standard format/template for the pack insert? It is noted that proposal 4.6 indicates that for products containing more than 3 active ingredients, or products in small containers, where there is insufficient space on the primary packaging, a complete Medicine Information Box should be included as a pack insert. As a result, will the pack insert assume the same layout as the Medicine Information Box in some circumstances or is it based on the validated Product Information or Consumer Medicine Information for prescription medicines?

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?

PBD considers that a Labels and Packaging Advisory Committee could have an important role in providing independent, expert advice on the quality use of medicines for labelling and packaging. This could include reviewing and providing recommendations relating to the acceptability of new medicine names, and associated labelling and packaging. The Committee could also have a role in developing appropriate guidance/checklists for industry in relation to safe naming, labelling and packaging of medicines.