



24 August 2012

## Comments by the Pharmacy Guild of Australia on TGA Medicine Labelling and Packaging Review – Consultation Paper Version 1.0, May 2012

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### Introduction

The Pharmacy Guild of Australia (Guild) welcomes the opportunity to comment on the May 2012 Medicine Labelling and Packaging Review Consultation Paper (Consultation Paper) prepared by the Therapeutic Goods Administration (TGA).

The Guild is an employers' organisation servicing the needs of independent community pharmacies. It strives to promote, maintain and support community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of medicines, medicines management and related services.

### Comments

The Guild acknowledges that the TGA has initiated a review in relation to Therapeutic Goods Order 69 (TGO69) *General requirements for labels for medicines* to develop appropriate regulatory solutions that effectively address consumer safety risks posed by a number of medicine labelling and packing issues and ensure that TGO69 continues to be relevant to the objectives of the National Medicines Policy.

The Guild has considered the proposed regulatory changes (blue italics) and responded to the general questions posed in the Consultation Paper, with particular reference to pharmacy practice within Australia and the Quality Use of Medicines (QUM).

#### ***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.*

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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."*

#### **Guild Response:**

The Guild supports moves that improve consumer awareness of active ingredients as a means of reducing the risk of misadventure from accidentally doubling up or taking different brands. In addition, arrangements that improve the safe and effective use of generics should have a positive impact on the Pharmaceutical Benefits Scheme (PBS) by making it more affordable in the long term for Government and consumers.

#### **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?

The Guild supports the intention to increase the prominence of the active ingredient. This will not only assist consumers in better identifying their medicines, but assist pharmacists with product selection as part of the dispensing process. The Guild also approves of specifying relevant details in a clear and precise manner to minimise misinterpretation of intent.

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

The Guild fully supports this recommendation although we would suggest a re-wording of recommendation 1.6 to say 'Consult your doctor or pharmacist before taking other products containing paracetamol'. Paracetamol is included in products indicated for a range of symptoms or conditions, including pain, fever, colds and flu and sinusitis. Consumers may not identify a particular medicine as a 'paracetamol product', but understand that the medicine contains paracetamol.

We have long been concerned about the ready availability of a wide range of paracetamol products from within both the pharmacy and grocery sectors and the associated risks with patients intentionally or inadvertently doubling up on paracetamol medicine. This risk is even greater now with the availability of more products containing different unit strengths of paracetamol.

Whereas consumers were once advised of the importance of not exceeding eight 500mg paracetamol units per day, they are now advised of the importance of not exceeding 4g per day of paracetamol. The Guild is concerned that consumers with poor health and numeracy literacy may not understand the warning or that they may be unknowingly taking multiple medicines containing paracetamol.

While there is a known risk of people taking overdoses of paracetamol products in suicide attempts, there is a greater risk of either accidental or intentional overdose by people seeking better pain relief. A recent report indicates that staggered overdose patients were more likely to have liver and brain problems, require kidney dialysis or help with breathing and were at a greater risk of dying than people who had taken single overdoses<sup>i</sup>.

The US FDA has been concerned about the public health problem of liver injury related to the use of both non-prescription and prescription paracetamol (acetaminophen) products and coordinated a meeting<sup>ii</sup> of an advisory committee in June 2009 to consider the matter. Background information for this meeting advised that nearly half of the paracetamol overdose cases in the USA are due to accidental overdose and identified the following as contributing factors:

- consumers attempting to treat different conditions or symptoms with multiple choices among products containing paracetamol, not realising that paracetamol was an ingredient common to each
- the association between paracetamol and liver injury is not common knowledge
- extensive retail availability may contribute to the perception that the ingredient is unlikely to be harmful.

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

- We would support greater prominence for active ingredient for prescription products or non-prescription products listed on the PBS. We also believe that the proposed changes for prescription medicines should have complementary requirements that the active ingredient should also feature on computer-generated prescriptions, dispensing labels and computer-generated repeat forms.
- We note recommendation 1.3 proposes use of subjective terms such as ‘most abundant’ which is unclear and subject to misinterpretation. We suggest that subjective terminology be avoided wherever possible. Given that it is the complementary medicine sector which is most affected by this recommendation, we would support consultation specifically with this sector.
- The Guild is concerned that having two different lists of active ingredients on the label in which one may be incomplete would be confusing for consumers and providers. Particularly with non-prescription medicines, there is a risk that consumers may refer to the incomplete list and not realise the medicine contains a potentially harmful ingredient, such as one they are allergic or intolerant to or which may interact with other medicines.

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?

Promoting greater consumer awareness of the active ingredients of medicines would encourage the safer use of generics. This in turn should have a positive impact on the affordability of the PBS.

Consideration should also be given to how salts of active ingredients should be listed. This is particularly relevant, but not exclusive, to small containers. As an example, listing Pilocarpine as the active rather than Pilocarpine Hydrochloride or Pilocarpine HCl may be more suitable. If salts are of little or no consequence, the Guild suggests these should be omitted from the label and included in the Consumer Medicines Information (CMI) and Product Information (PI). This may also address some of the issues identified with brand extension.

What is the smallest size font that you consider readable?

The Guild has no specific comment but would support the TGA conducting consumer focus testing to determine a recommendation. Such focus testing should include consumers from more vulnerable population groups such as the elderly.

### ***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.*

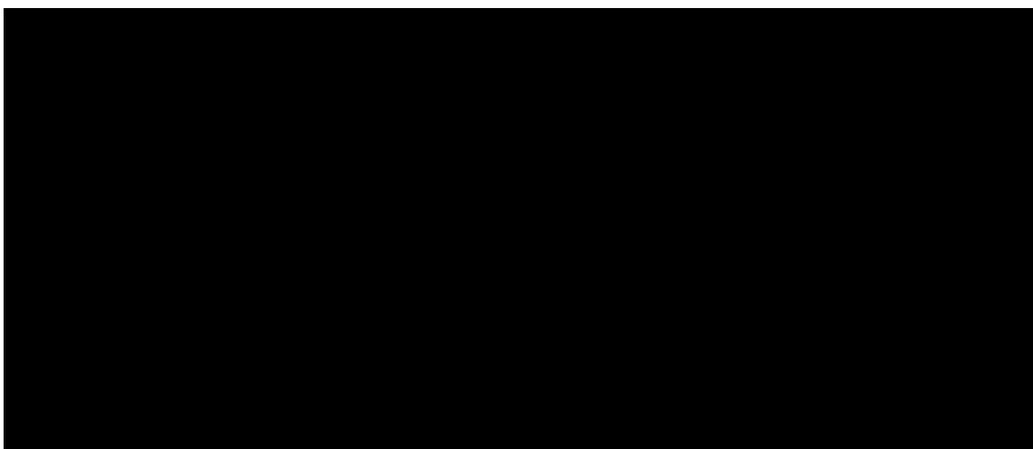
*3.3 In relation to applications to change the labelling and packaging of existing medicines, if the brand name of the medicine differs from another medicine included in the ARTG by less than three letters, the proposed changes must use colours and designs that contrast with the medicine label and packaging of the other medicine.*

### **Guild Response:**

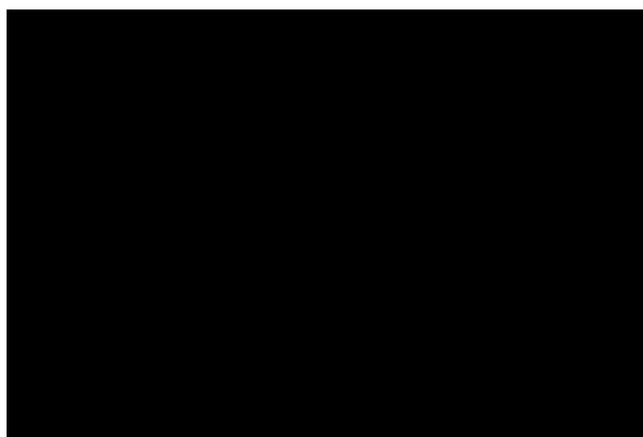
The Guild agrees with this recommendation in principle, but believe it must go further. This is a critical issue to assist pharmacists with product selection as part of the dispensing process to minimise dispensing errors. While measures such as barcode scanning have been introduced to minimise dispensing errors, it is imperative that other elements such as labelling and packaging are as effective as possible to also minimise errors that can arise following incorrect product selection.

- Colours must be significantly different – some products use colour difference for only small parts of the label or use only very slight colour differences.
- Consideration should also be given to the packaging – having bottles with similar colour caps and similar labels can be confusing and significantly increase the risk of incorrect product selection and dispensing errors.

Some examples are provided below to demonstrate how poor colour differentiation can increase the risk of incorrect product selection and subsequent dispensing errors. In the instances of [REDACTED] and [REDACTED] it can be seen that there is little label (and cap in the latter instance) differentiation between the different strengths.



On the other hand, the example below demonstrates how within one product range, coloured labels can effectively differentiate between different strengths to minimise incorrect product selection. Coupled with barcode scanning as part of the dispensing checking process, this assists in mitigating risks within the dispensing process.

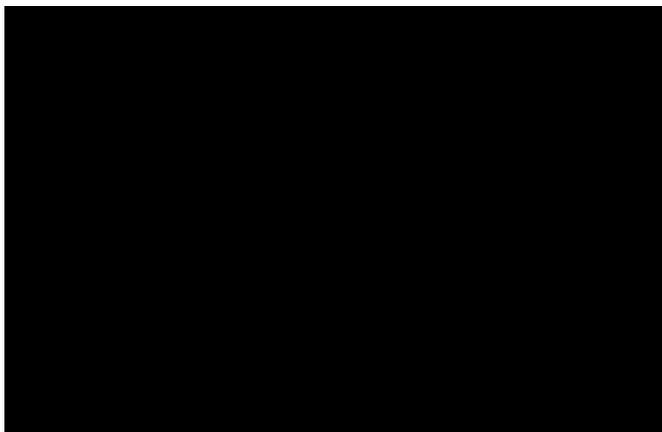


- Consideration should be given also to how products are to be stored on dispensary shelves. While some pharmacies store medicines alphabetically according to active ingredient, the majority of community pharmacies store medicines alphabetically according to brand name as the former becomes problematic for medicines containing multiple ingredients (which are becoming more common).

Given that space is at a premium and pharmacists often have to make room for storing new products that come onto the market, medicines in packs are often stored on their side. Including identification on the side panels and end panels give pharmacists greater flexibility to safely store medicines within often restricted spaces.

The following example highlights how colour has been positively used to distinguish products within the same range, but how consideration has not been given to how the product is stored on the dispensary shelf. In order to highlight the colour

differentiation of a single yellow, green or blue stripe for the different medicine forms, the product must be stored so that the end panel is read upside down. If stored for the end panel to be easily read the right way up, there is no colour differentiation to distinguish the packs for easy selection.

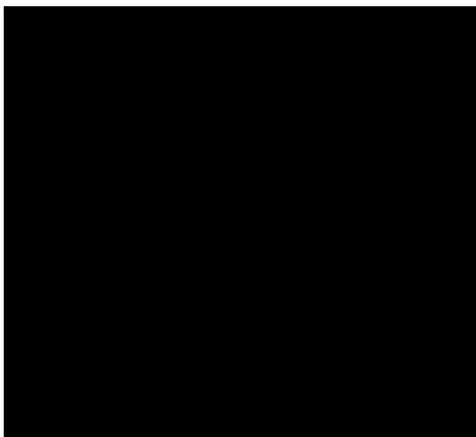


As previously mentioned, changes for prescription medicines should be supported by requirements for the active ingredient to also feature on prescriptions, medicine orders, dispensing labels and repeat forms as it is unlikely that problematic products will have look-alike and/or sound-alike brand names and actives.

#### **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?

A pre-marketing risk-assessment review that includes community pharmacist representation will be invaluable in minimising risks associated with look-alike and sound-alike products being marketed. As an example, in 2010, a community pharmacist would have immediately recognised the risk with having the updated packaging for [redacted] almost identical to that of [redacted]



Not only did these products look very similar, but if stored alphabetically according to brand (the most common practice for community pharmacy), they would be next to each

other on the dispensary shelf or in very close proximity. To further complicate the risk, both tablets were green. In the event of a dispensing error, consumers may have difficulty recognising that the pack or the medicine was different.

The Guild also believes there would be value in standardising the use of abbreviations within prescription medicine nomenclature, such as the use of 'EC' for 'Enteric Coated' versus a number of acronyms to imply extended or sustained release e.g. 'XR', 'ER' or 'SR'.

### ***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.*

### **Guild Response:**

The Guild agrees with this recommendation in principle.

### **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 main benefit with these proposed changes is reducing the risk of medicine misadventure from accidental overdose due to consumers inadvertently doubling up by taking the same medicine from different products. This should reduce clinical presentations of accidental overdose to doctors or hospitals.

In addition, these measures should provide cost-savings to consumers by minimising the purchase of duplicate medicines.

### Do you understand the proposed changes?

The Guild acknowledges responsible brand extension as not only being an effective marketing tool for medicine companies but being useful for consumers and health care professionals in recognising a product range for specific health conditions e.g. [REDACTED]. However, the Guild does not support irresponsible brand extension, including umbrella branding, that is designed to encourage purchase of medicines in excess of a person's needs.

- We support brand extension to distinguish between forms e.g. 'Brand X' adult tablets, 'Brand X' adult mixture, 'Brand X' children's suppositories.
- We support brand extension to distinguish between products with similar ingredient bases e.g. 'Brand X' non-drowsy cold tablets and 'Brand X' night-and day cold tablets.
- We do not support brand extension across several medical conditions in which each product has the same active ingredient (irrespective of whether different salts are used) e.g. 'Brand X Headache' tablets containing the same active ingredient as 'Brand X Backache' tablets or 'Brand X other ache' tablets.

We are concerned that recommendations 3.5 and 3.6 are ambiguous. The example provided indicates that 'Brand headache' cannot be marketed alongside 'Brand backache' if containing the same active in the same quantity. We suggest that quantity should not be a factor, 'Brand headache' in a pack of 20 should not be marketed alongside 'Brand Backache' with the same active ingredient in a pack of 24. Similarly, using different salts with different molecular weights and claiming different active ingredient quantity should not be permitted.

- The Guild does not support umbrella branding in which the same brand name is used for different products in which there are no active ingredients in common e.g. 'Brand X Pain' tablets containing paracetamol and 'Brand X Anti-inflammatory' tablets containing ibuprofen.

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

While the availability of clear and concise warnings may assist to some extent in reducing consumer harm from medicines misadventure, it is not sufficient as a stand-alone approach.

The Guild believes that QUM is best supported by the supply of medicines through a pharmacy where there is access to professional support and advice from a pharmacist, with assistance provided from trained pharmacy assistants. When medicines are exempt from scheduling, they can be accessed from numerous non-health related outlets such as supermarkets, corner stores or service stations. There is no requirement to include CMI within the pack of these medicines, or even online, and consumers must rely entirely on the information included on the pack label in order to understand what the medicine is used for, how to use it and any additional cautions to be aware of. However, there can be significant risks with this.

A 2002 survey in the US<sup>iii</sup> identified that while 95% of Americans using non-prescription medicines read some portion of the product label, they do so selectively when they first buy the product and when they first use the product:

- When they first buy a non-prescription medicine, only 34% read the label for the active ingredient, 19% for usage directions, 16% for dosage level, 10% for side-effects and only 7% reads the label for usage warnings.
- When taking a non-prescription medicine for the first time, only 25% read the label for dosage instructions, 22% for usage directions, 20% for active ingredient, 9% for side-effects and again, only 7% reads the label for usage warnings.

The same report indicates a third of Americans would take more than the recommended dose, believing it to be more effective, and 36% are likely to take multiple non-prescription medicines when they have multiple symptoms.

If a similar pattern is demonstrated by Australian consumers, there is a significant risk that Australians will be largely unaware of safety warnings and directions, irrespective of the inclusion of such information on the label. In addition, considering the premium of shelf space within supermarkets, it is unlikely that manufacturers will be increasing pack size to accommodate these requirements. The end result is likely to be highlighted brand and condition and very difficult to read health and safety information. Plus, some of the warning statements require good literacy and a significant understanding of English. The Guild is concerned that more vulnerable population groups such as the elderly, the culturally and linguistically diverse (CALD), those with poor sight or poor literacy may be at particular risk when they do not have access to healthcare professional advice from a pharmacy.

### ***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.*

#### **Guild Response:**

The Guild agrees with this recommendation in principle.

#### **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?

Setting minimum requirements for what information is to be included in the Medicine Information Box will not only be useful for consumers, but very useful for pharmacists and pharmacy assistants in providing advice about non-prescription and complementary medicines. It will also assist in training pharmacists and pharmacy assistants in how to effectively respond to consumer enquiries for these products. While some existing products have already got very effective information panels in place that are clear and easy to read, there are many other products in which it is difficult to quickly locate the relevant information in response to a query (if it is included at all). In addition, having a standardised format would assist any public education campaigns to assist consumers with reading medicine labels.

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

- Many consumers are interested in knowing if products contain lactose, gluten or sugar. Noting it is proposed to have a section for 'active ingredient', it would also be useful for products to advise on the presence of at least these three excipients under the 'Warnings and allergy information'. This would provide a useful and quick reference source for consumers and pharmacy personnel for commonly sought information.
- While improving the effectiveness of the information for consumers on non-prescription medicines, this will not replace advice provided by a health care professional to an individual based on their personal health background. While the proposed standardised format improves the opportunity to include a greater amount of important product information that can be easily followed, we are concerned that sections such as the 'warnings and allergy information' section may be used in such a way that it has the opposite effect to its intent. If there is too much information, or the information is too small, too condensed or too complex, consumers may misread or ignore the safety warnings which could have a detrimental health impact. Groups with poor health literacy such as the elderly, CALD or poorer socio-economic are particularly vulnerable.

While pharmacy personnel can assist consumers with reading and interpreting the information included on scheduled medicines, this is not the case with products that are exempt from scheduling. There should be strict requirements for the presentation of information on non-scheduled medicines, and limitations to the extent that non-scheduled medicines can address safety issues solely by warning labels.

As an example, the Guild has been concerned with the recent scheduling exemption for loperamide with a subsequent proposal to address safety risks by increasing the number of advisory statements from two to seven, some of which are complex.

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.

In addition to directions, warnings and allergy information, storage and batch/expiry information should also be readily available.

The Guild's main concern with using pack inserts as an alternative means of conveying the Medicines Information Box for products containing more than 3 active ingredients or in small containers is ensuring pharmacy staff have ready access to the information in order to assist in counselling or responding to consumer enquiries. This is problematic in packs with security seals. There is also a cost impost for manufacturers associated with pack inserts.

A possible alternative for allowing a manufacturer not to include a Medicine Information Box as recommended is if the information is available from standard reference sources. In the case of pharmacy, this may be texts that are a source of current product information such as MIMS Annual, eMIMS or AusDI Advanced<sup>iv</sup> or publicly accessible hosts of product information such as medicines.org.au.

We would also like to reiterate that the Guild does not support the outer labelling of a medicine to list a limited number of active ingredients as this can lead to confusion for consumers and suppliers. We believe that complete lists should be included on the outer pack label.

### ***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.*

### **Guild Response:**

The Guild agrees with this recommendation in principle.

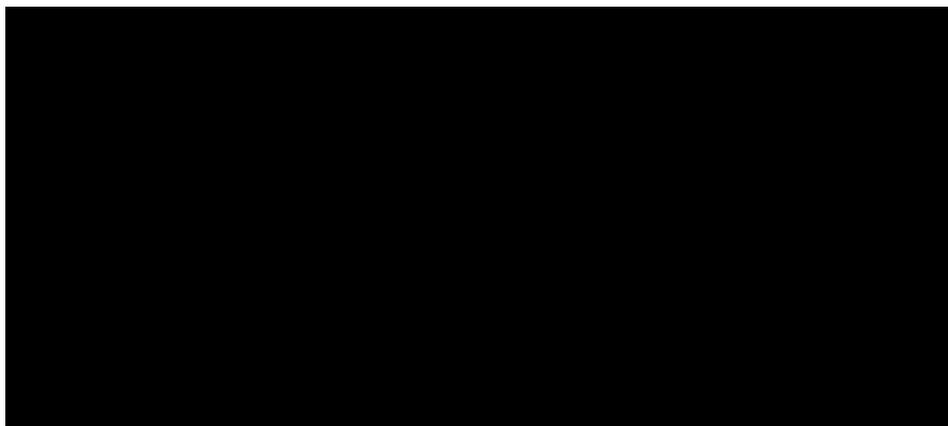
### **General question on the proposed regulatory changes for dispensing label space**

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

The Guild very much supports a requirement to include a designated space on prescription and PBS-listed medicines to allow pharmacists to effectively attach a dispensing label. We acknowledge the intent of these recommendations but we feel there are still some issues which have not been adequately addressed:

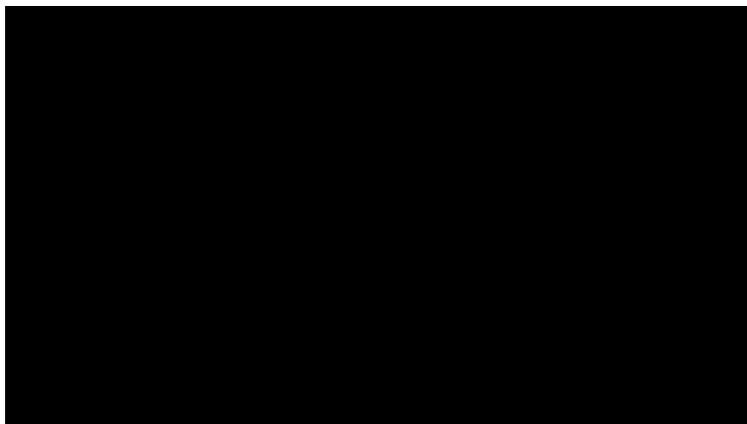
- We note that the recommended size of 70 x 30mm is smaller than standard dispensing label size of 80 x 40 mm which is also reflected in the current version of the 'Best practice guideline on prescription medicine labelling 0 17 November 2008'.

- As including a designated space for a label is more practical for medicines available in cartons (as compared to plastic bottles), the Guild believes there should be incentives to encourage industry to package medicines in cartons.
- Regarding recommendation 5.2, the only information that would be routinely duplicated on the dispensing label is the name of medicine (brand name and/or active ingredients), strength and form. If the suggestion is for pharmacists to enter other details (e.g. storage, batch number or expiry), this is not routine and would have a significant impact on the dispensary workflow and would not be supported by the Guild.
- While the EAN-13 barcode has been the standard barcode used with Australian medicines to assist in a scanning identification process, barcodes such as the Data Matrix barcode are being used to a greater extent overseas. Data Matrix barcodes are smaller and contain data over and above item identification, such as batch numbers and expiry dates. These newer forms of barcodes are also useful to verify medicine authenticity to ensure medicines are not counterfeit. Consideration should be given to incentivising all sectors to commence switching to more advanced barcode technology.
- The Guild is concerned with effectively managing the labelling of small medicine bottles in such a way to enable pharmacists to effectively label the medicine so that consumers can easily read the dispensing label. Examples of small bottled medicines include [redacted] or [redacted] and [redacted] (pictured below).



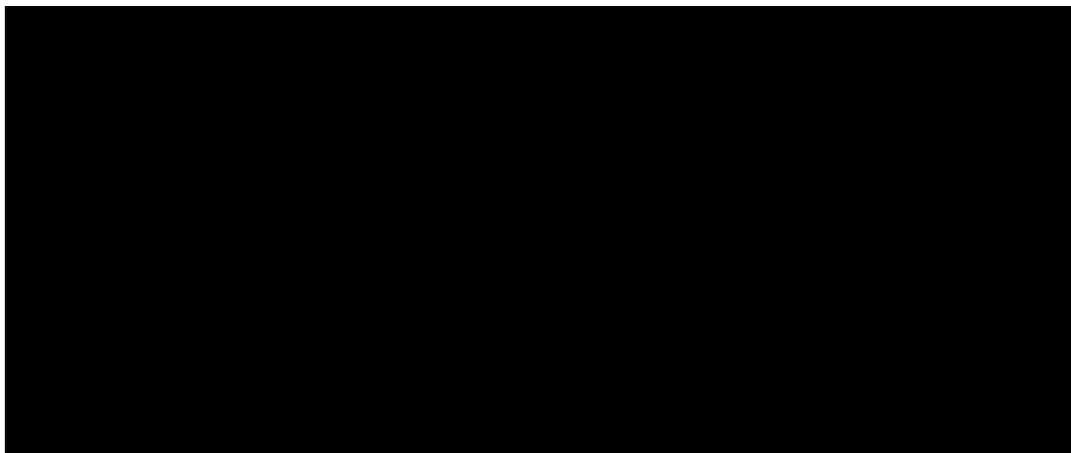
Factors that should be considered include:

- the use of flagged labelling to avoid covering important information (e.g. batch, expiry, storage)
- managing flagged labelling to meet jurisdictional regulatory labelling requirements [e.g. in order to maximise the readability of the directions, the pharmacist may need to flag and fold the primary dispensing label (the larger top label in the image below) so that pharmacy details are obscured or alternatively attached a flagged secondary dispensing label (the smaller bottom label in the image below)]
- assessing consumer attitude to flagged labelling and ascertaining how much more difficult it is for consumers to read and understand folded labels

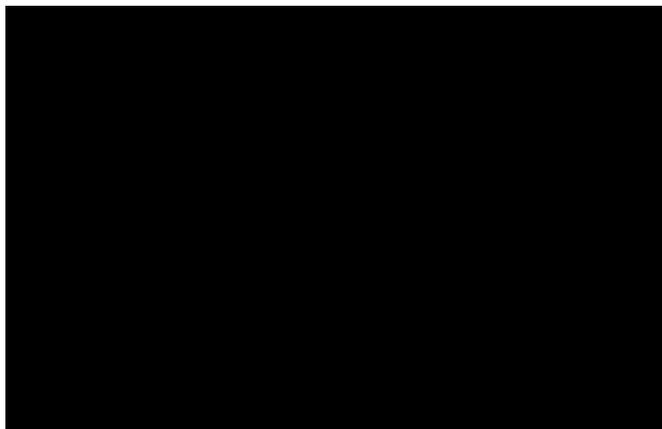


- providing sufficient room for labelling to minimise the use of flagged labelling
- positioning barcodes so that the application of a dispensing label does not cover barcode (ideally barcodes should be on a side panel)
  - allows pharmacists to scan a labelled medicine prepared by technicians as part of a final checking process
  - allows greater use of matrix bar codes in the future to enable consumer access to other information by scanning the medicine after having it dispensed
- Not only do pharmacists prefer labelling packs with foil strips over bottles or packs with smaller bottles inside, but it is easier for consumers to read the dosage instructions for their medicines. Pharmacists are more likely to attach flagged secondary dispensing labels to small bottles in particular so that they meet jurisdictional regulatory requirements. Labelling these medicines can be particularly problematic when there are complex instructions to convey, such as with hormone or steroid medicines.

An example of a product which has changed its packaging for the better is [REDACTED]. Compare the photos below in which [REDACTED] used to be supplied in a small bottle within a larger cardboard pack to the updated packing in which the medicine is supplied as foil strips within a cardboard pack. With the old packaging, the pharmacist would usually attach the larger primary dispensing label to the outer cardboard box (running the risk that the consumer may discard the pack with the dosage instructions attached) and attach a flagged version of the smaller, secondary label to the small inner glass bottle containing the tablets. The added complication with this product was that instructions would often be complicated with incremental dose adjustments. Only labelling the outer carton risked the consumer discarding the pack with the detailed dosage instructions and the smaller flagged labels were more difficult to read. The new pack design allows the pharmacist to easily use the larger dispensing label which is more easily read by consumers.



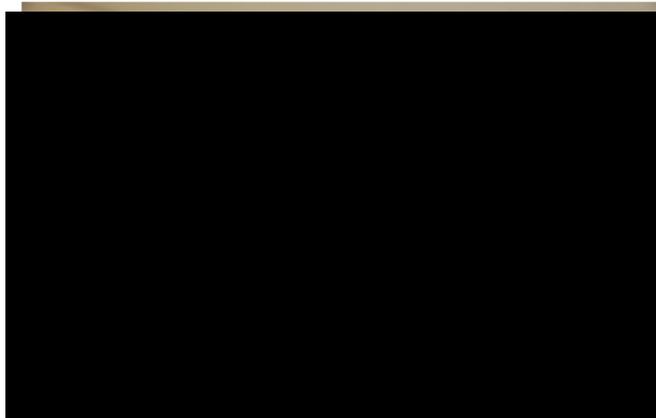
- The Guild is also concerned with products with several layers of packaging. Pharmacists have a professional responsibility to label the direct pack from which consumers access their medicine. There are many instances in which medicines have an outer pack and an inner pack in which the outer pack meets regulatory requirements, but is not used by the pharmacist for attaching a dispensing label, or if used, is likely to be discarded by the consumer. An example of this is the old [redacted] packs (see above) or [redacted] (see below).



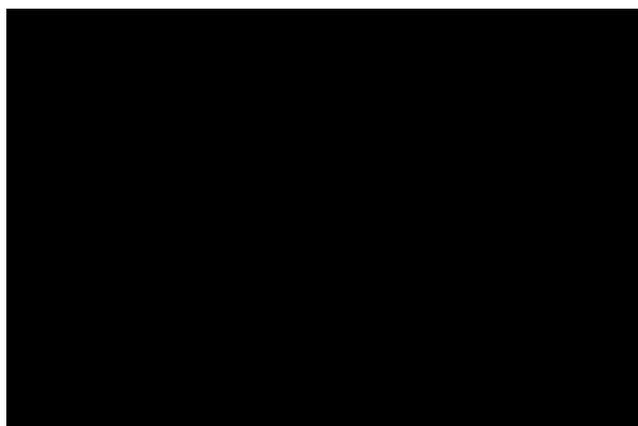
This issue can be particularly problematic for medicines such as asthma inhalers in which children need to take a labelled medicine to school (therefore the inhaler mouthpiece should be labelled), or where different members of a family or household may use the same asthma medicine and need each individual's inhaler identified.

- Another issue which pharmacists have is with medicines that are supplied with security seals on an outer pack but which require pharmacists to attach a dispensing label to the inner pack. Again, inhalers are an example of this type of issue. While some inhalers have an outer cardboard pack that is unsealed to allow easy access to label the inhaler, others have security seals which must be broken by the pharmacist to attach a dispensing label to the inhaler inside. [Note – professional guidelines advise that a dispensing label should be attached to the immediate container (including each component of multiple-therapy packs) unless the immediate container is so small or is so constructed that the label would compromise the patient's ability to use the medicine].<sup>v</sup>

This then requires explanation to the consumer about why the seal is broken, taking up counselling time and consumer focus which may be better applied to other counselling advice. The example below shows the blue inhaler which has a pack that can be easily opened to enable a pharmacist to label the blue mouth piece. The other pack has a security seal which must be broken before accessing the mouthpiece to label.



- The packaging of combination packs should also be considered. As with the example of the inhalers, combination packs should ideally not have any security seals, allowing pharmacists to open the outer container and attach dispensing labels to the inner packs. In such instances, the inner packs should also be designed to allow pharmacists to effectively attach dispensing labels. Examples of such packs include [redacted] and [redacted]



### ***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.

#### **Guild Response:**

The Guild agrees with this recommendation in principle.

#### **General question on the proposed regulatory changes for blister strip labelling**

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

While the ideal would be to have relevant information on each blister, the Guild acknowledges that this can be burdensome for industry. We are however pleased to see the more stringent requirement for perforated strips where blisters are segmented. Anecdotal experience from pharmacy practice suggests some consumers routinely detach individual blisters from blister strips which can create medicine identification issues, particularly if the consumer is doing this with a number of medicines.

We have mentioned earlier our concern for products with multiple ingredients having sections with only a limited number of ingredients identified. We believe this would apply primarily to complementary medicines and as such, we do not have any significant concerns with identifying the brand name on the blisters and having a full list of ingredients referenced on the pack. We are unaware of any current application to prescription medicines and would need to consider this further in such instances.

The Guild has no strong views on the recommendation to include batch and expiry date on every two units (or every unit for segmented strips). While this recommendation would be an ideal, so long as the batch and expiry date is easily readable (in ink) on the main strip, we believe this would suffice. In this instance, we suggest consideration be given to the impact on industry and how easily it can be accommodated.

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

With racetrack format with days of week, consideration should be given to the prescribing of smaller quantities than a standard pack. In such instances, the pharmacist must cut the strip and disrupt the 'racetrack'. This can potentially lead to patient confusion, particularly with more vulnerable patient groups such as the elderly or CALD. Ideally racetrack strips should be aligned in a design to allow greater opportunity for pharmacist to cut the strip so as to maintain an effective 'racetrack' flow if smaller quantities are prescribed.

#### **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.*

#### **Guild Response:**

The Guild agrees with this recommendation in principle, although we have issues with some of the specific recommendations.

#### **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.

We note with recommendation 7.1 that there is a risk that outer packages may be discarded by the consumer. Some manufacturers also seal outer packages, encouraging pharmacists to only attach a dispensing label outside. Of prime importance is the design and labelling of the small container itself which contains the medicine, as such, the Guild sees no reason to mandate an outer package. Likewise, we do not see a need to mandate the inclusion of a pack insert which has a risk of being obsolete at the time of dispensing. At the consumer's discretion, pharmacists can provide a CMI containing all the relevant information.

The Guild believes all levels of packaging should include the strength of the active ingredients. We are pleased to see the need to accommodate a pharmacist's dispensing label, but once again we oppose the recommendation for products with multi actives to list only a limited number. Where active ingredients are to be listed, the Guild believes it should always be a full list. Again it would seem that this has application mainly to the complementary medicine sector, however, in this instance there is also application to the prescription medicine sector. In considering the example of [REDACTED] and [REDACTED] we believe that listing only the three most abundant active ingredients on the container label is contradictory to patient safety and QUM principles.

### **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.*

#### **Guild Response:**

The Guild agrees with this recommendation in principle.

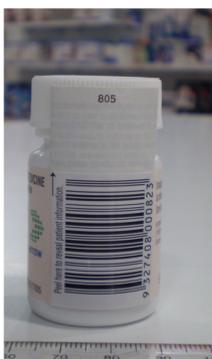
#### **General question on the proposed regulatory changes for pack insert requirements**

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

The Guild believes pack inserts should only provide information specifically about the product. Including promotional material for other products could be confusing for consumers, particularly if promoting brand extensions. The people who are most at risk of confusion are the more vulnerable population groups such as the elderly of CALD.

Do you have any further suggestions regarding pack inserts?

Some inserts for prescription medicines are attached as part of main label for unfolding by patient. The example below shows a small bottle in which the CMI is attached behind the barcode. Such practices make it difficult for pharmacists to appropriately label the container in a manner to leave access to the CMI, not cover other important information and include a dispensing label that can be easily read and meets all regulatory requirements.



#### **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?

The Guild supports establishing and utilising a Labels and Packaging Advisory Committee that requires the inclusion of a practising community pharmacist. We believe that had a review process that included a community pharmacist been in effect in 2010, the [REDACTED] packaging issue would have been identified and rectified prior to marketing and distribution. However, such a committee must be managed so that their functions are performed effectively and expediently. Depending on the workload of the committee, to minimise intrusion on a clinician's practice, specific

professions could be represented by a number of practising clinicians who participate on the committee on a rotational basis.

To facilitate the progress of new or amended packaging and/or labelling changes, an alternative arrangement could have the sponsor conducting a review by an independent panel that consisted of consumer, community pharmacist and other relevant representatives. If the review can demonstrate its independence, it could be recognised as part of the application process. This could by-pass the requirement for review by a Labels and Packaging Advisory Committee. Safeguards could be introduced to avoid any abuse of such arrangements.

### **Additional Comments (may be included in responses to specific questions or may be kept as addendum)**

The Guild would also like to draw attention to the following issues as part of the review into packaging and labelling:

1. Incentives should be in place to encourage manufacturers to package and label medicines effectively and responsibly.
2. Final recommendations should be codified into regulations rather than progressed as guidelines which may be ignored. Exemptions should be the exception, and granted only after review by an independent panel that included consumers and relevant health care professional representation (this may be a role for the proposed Labels and Packaging Advisory Committee).
3. Consideration should be given to the issues that arise for community pharmacy when there is a schedule change in which medicines may be available that do not comply with the labelling requirements. Examples often happen when a medicine is down-scheduled, particularly from Schedule 4 (Prescription Only Medicine) to Schedule 3 (Pharmacist Only Medicine), but can also happen if there is an up-scheduling.

Changes in 2010 to the scheduling of combination analgesics containing codeine are a recent example in which medicine packs were available with the old labelling but had to be stored and supplied in line with updated arrangements. Professional organisations such as the Guild provide pharmacists with information and support relating to these changes, however there is no transparency for any special arrangements that may be in place, such as labelling or packaging exemptions.

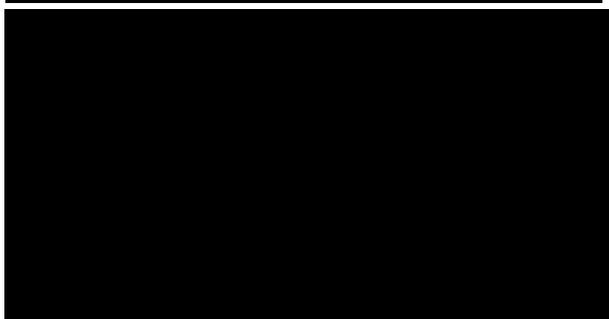
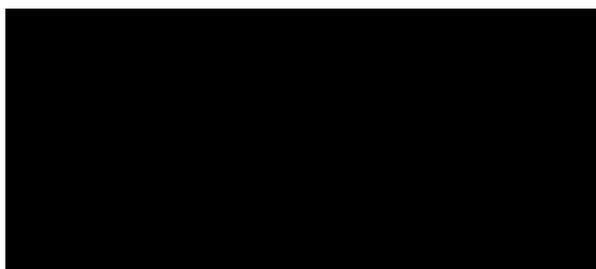
Acknowledging that exemptions are usually provided at a jurisdictional level, the Guild believes there should still be a publicly accessible register of labelling and/or packaging exemptions at a national level providing the following details:

- duration of exemption
  - jurisdictional application (i.e. confirmation that exemption applies to all jurisdictions)
  - information about special requirements (e.g. pharmacist to attach dispensing label)
4. For oral medicines in particular, consideration should be given to mandating, or at least incentivising, the inclusion of an image of the tablet/capsule on the pack for easy reference by consumers and health care professionals. Not only can this be of use to consumers and their carers to recognise the medicine they take, but it can also be useful for pharmacists to assist in counselling or when preparing adherence aids such as Dose Administration Aids.

5. Consideration should also be given to the labelling and supply of ‘starter-packs’. The Guild is concerned with anecdotal reports of prescribers issuing starter-packs without including information such as patient name, directions, prescriber/supplier details or date of supply. Given that prescriber practices are unlikely to have dispensing stations for the supply of starter-packs, it would be sensible to mandate that starter-packs must be labelled to enable the prescriber to easily annotate the necessary information. A rudimentary example is provided below:

<p><b>Brand X Tablets xx mg Starter Pack</b> Take ..... tablet/s ..... times a day. Patient Name: Date of supply: Prescriber details:</p>
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6. The clear communication of batch numbers and expiry dates on medicine labels is essential for the safe operation of pharmacy practice and to facilitate QUM for consumers. Embossing of batch numbers and expiry dates without ink is difficult to read. It should be a mandatory requirement through regulation that all batch numbers and expiry dates are inked. Compare the two examples below to note the difference between inked and un-inked embossing.



7. Consideration should also be given to naming products that do not overstate product efficacy. This is especially problematic for listed weight loss products. As part of the registration process, proposed product naming should be reviewed by an appropriate panel with representation that includes consumers and community pharmacists.

## Conclusion

Ensuring consumer safety requires a concerted effort from all elements of the medicine supply chain. Effective packaging and labelling, particularly for prescription medicines, is necessary in order for pharmacists to effectively meet their professional requirements.

Given the increasing reliance on information about non-prescription and complementary medicines being provided to consumers as part of the product label, it is essential that this information is provided in a format to facilitate easy reading and understanding.

The Guild acknowledges the consideration given to both pharmacy practice and medicine accessibility through pharmacy in preparing this review.

### Reference Sources:

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<sup>i</sup> Laurie Barclay; Repeated use of acetaminophen can be fatal; Medscape Dec 2011

<sup>ii</sup> June 29-30, 2009; Joint meeting of the Drug Safety and Risk management Advisory Committee with the Anesthetic and Life Support Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee; [www.fda.gov](http://www.fda.gov)

<sup>iii</sup> Attitudes and beliefs about the use of over-the-counter medicines: a dose of reality; A national survey of consumers and health professionals; Prepared for the National Council on Patient Information and Education; Jan 2002; [http://www.bemedwise.org/survey/final\\_survey.pdf](http://www.bemedwise.org/survey/final_survey.pdf)

<sup>iv</sup> Pharmacy Board of Australia; Pharmacy Guidelines on practice-specific issues – Guideline 1 (List of References); <http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx>

<sup>v</sup> Pharmacy Board of Australia; Guidelines for dispensing of medicines; 7.1 Labels